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Cover photograph of rural laboratory, Ganiyari. Courtesy: Biswaroop Chatterjee

EDITORIALS

Can ethics committees address society's concerns about standards in research?

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Two years ago in an editorial (1) we discussed the importance of bringing the spotlight onto the functioning of ethics committees (ECs) in India. Since the first ethical guidelines for biomedical research were formulated by the Indian Council of Medical Research (ICMR) in 1980 (and their subsequent versions in 2000 and 2006), India has officially adopted a decentralised system of ethics review and monitoring of biomedical research by institution-based ECs. We expressed serious concern on the lack of any oversight over these institutional ECs by the Drugs Controller General of India (DCGI), the legal regulator of drug research, and the ICMR (which is also the department of health research of the Government of India), the original proponent of this system. We had opined that "the present decentralisation of clinical trial governance is a highly irresponsible decentralisation of governance, exposing the legal regulator to the criticism of effectively abandoning its obligations to regulate" (1). We had also pointed out that ECs have become enigmas, with very little known about their functioning and their competence to discharge their duties. We had given a call to all those involved in the ethics review of biomedical research to make ECs more transparent, to conduct research on them and to critically assess the system. Since not enough research on them was coming out, we had exhorted members of ECs to break their silence by sharing their experiences.

We are happy to learn that in last two years there has been increasing discussion and sharing of experiences and views on the pages of *IJME*. We were able to publish a special section titled "Ethics in Ethics Committees" twice, each time with three contributions. Besides, our sections on commentaries and discussion have covered some major controversies in ethics in biomedical and public health research; the Gadchiroli trial and the HPV vaccine demonstration project are two major examples of this.

Special issue on ethics committees

We are happy to take the discussion forward in this issue by publishing a collection of five papers on the subject, making it a special issue on ethics committees. All credit for bringing together this collection goes to Prof Silke Schicktanz and Prof Michael Dusche who have guest edited this collection and also written a thought provoking introduction to it. Our readers will be immensely benefitted by this collection in two ways. First, it provides a history, situation analysis and reflections on ECs in Israel, Bulgaria and India and also on the international situation in the report on the 8th Global Summit of National Ethics Committees in Singapore in July 2010. Clearly, the EC as a system for rigorous and appropriate ethics review is facing serious challenges (and perhaps a crisis) not only in India but globally as well. The historical and empirical information provided by these papers should make all of us reflect on whether the weaknesses of the EC system lie only in "not doing it right" and in the paucity of trained ethics experts. Are the weaknesses more in the fundamental assumptions, both theoretical and systemic, on which the system is established?

The second strength of the collection is that it also provides some deep philosophical and political reflections on the fundamental assumptions on which the EC system for ethics review of research is established. Are ECs meant to simply regulate research? Surely, legal experts and human rights activists would like to look at it that way. But then, on whose behalf is this regulation of research being done? The first objective of most ethics guidelines would say that it is for the protection of research participants. To put it in plain, political terms, participants are citizens, diseased or not diseased. And thus, ECs are actually there to work for these citizens, for their protection and welfare. In that case, by getting citizens and their representatives to work on their behalf, ECs ought to effect or create a process of democratisation of science or research; and empower citizens. Interestingly, at the ground level, ECs are anything but representatives of citizens. While the guidelines talk about the independence of ECs from their appointing bodies, the institutions, they hardly ever mention their "dependence" on citizens and give them fair, if not dominant representation. Our experience of work in ECs suggests that the ECs are, in fact, most dependent on the institutions from which they are supposed to be independent; we still have to see an EC that regularly goes to research participants to get their views, let alone being open to inviting some of them into their midst. This situation exposes ECs to the criticism of being bodies of experts, reviewing scientific protocols of experts for the furtherance of the work of experts. Indeed, the ECs are more complex entities than has hitherto been understood in our country. For us the challenge is to understand whether they have the potential to be vehicles of democratisation, or at least to make science and research transparent and accountable to the people.

Another point for reflection is provided in a paper that proposes a four-stage deliberative democratic process for formulation of ethical standards and, thus, ethics guidelines. The paper emphasises the process of deliberation, not just with scientists and the health professionals (the “experts”), but also with the people, particularly the marginalised and vulnerable communities, who are used the most in research. This does beg a few questions for India. Indian society has multiple languages, religions, ethnic groups and so on. What would be the best process and method to elicit the views of these different groups on various ethics standards? Would people be more interested in having elaborate rules on informed consent and privacy, or would they like more practical and achievable rules for, say, post-trial access of the drugs that are tested on them? Interestingly, our guidelines pay lip service to ethical standards using more rhetoric when it comes to post trial access. We are sure that ethics committee members would agree that there is very little available in these guidelines to operationalise post-trial access at the micro-level of the institution where research is conducted. In essence, would such a deliberative process, if made workable and adopted with all sincerity, turn the priority we accord to the ethics standards upside down?

Changing scenario

The period since 2000 when the ICMR released ethics guidelines is marked by two, relatively separate developments. One, occurring among scientists and ECs, is moving slowly, while another, involving people and civil society, is gaining momentum. Scientists as a community (there are many individuals who are honorable exceptions, but are in a minority) are taking their own sweet time to acknowledge, let alone be strict about implementing, ethics standards in their work. They often find it difficult to incorporate ethics into their research process as they have got used to the old way of functioning. Yet there is a perceptible change, and that is in terms of moving away from the denial that ethics is important in research, though this on its own may not translate into a change in behaviour. On the other hand, some ECs have started taking their work seriously, and there is an increase in their knowledge about procedures and guidelines, as shown in the study on ethics committees in India in this issue.

But all of them are still very slow processes. What is overtaking them very fast is another process reflected in the increasing activism on biomedical research in civil society, media and sections of people. Unlike the ECs that are entrusted with the job of contributing through a positive approach in the improvement of observance of ethics, this process is driven more by “negative happenings” or ethical violations. This is very natural. Like human rights, ethics becomes publicly more visible because of ethical violations. Interestingly, as ethical violations are publicly more debated, the demand for more and stricter regulations grows, and ECs which were so far spared in public campaigns may increasingly find themselves in the eye of public controversies.

We hope that the arguments and empirical material presented in this special issue, combined with the consciousness that there is increasing public pressure for accountability and participation, will motivate many among us to reflect on the system and governance of research ethics.

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Inclusion of ethics matters in the undergraduate medical curriculum

ANSHU

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Ethics is now at the centre stage of medical education and calls to intensify its formal teaching in the curriculum are getting louder (1, 2).

In the past, ethics was often given short shrift in the Indian MBBS curriculum, and consigned to a few forgotten pages in textbooks of forensic medicine. These mostly dealt with legal ethics; clinical and research ethics hardly ever found their way into classroom teaching. Students were expected to imbibe lessons in ethics from their seniors and learn to solve medical ethical dilemmas on their own. Unfortunately, all too often, their role models fell short of their expectations and there was a chasm between what was preached and what was practised (3).

Nevertheless, there have been glimmers of hope with formal ethics teaching being introduced in institutions like the St John's Medical College in Bengaluru (4) and universities like the Rajiv Gandhi University of Health Sciences (RGUHS) and the Maharashtra University of Health Sciences (MUHS). As I write, a mammoth churning exercise is being carried out on the directive of the Board

of Governors at the Medical Council of India (MCI), with several structural modifications being envisioned in the undergraduate and postgraduate curricula. Against this background, this paper takes a look at the place accorded to ethics and professionalism in the Indian medical education scenario. Further, it outlines the various steps involved in developing an ethics curriculum and tries to identify the key points which need to be borne in mind while doing so.

What does MCI's Vision 2015 document propose?

The Vision 2015 document (5) which proposes reforms in the undergraduate and postgraduate curriculum was released by the Medical Council of India on March 29, 2011. Among the many changes recommended to restructure the existing curriculum are plans to "integrate ethics, attitudes and professionalism into all phases of learning" to "enable the Indian Medical Graduate to function professionally and ethically".

For the first time, a Foundation Course is being planned right at the beginning of the course. This two-month long course will include elements of ethics, professionalism and communication skills besides giving students an orientation to national health policies, health economics, computer skills and an overview of anatomy, physiology and biochemistry. The document also outlines plans to introduce early clinical exposure at the primary care level with a focus on communication, clinical skills and professionalism.

Further in an attempt to introduce flexible learning options in the curriculum, students will be allowed to pursue electives for two months. The areas for elective postings include areas that students are not normally exposed to as part of their regular curriculum, and students are expected to do a project and enhance self-directed learning, critical thinking and research abilities. The options enumerated for electives include bioinformatics, tissue engineering, ethics, genetics, sports medicine, assisted reproductive technology, and ethics and medical education. Details of how the MCI plans to integrate ethics and professionalism into all years of the MBBS curriculum have still not been revealed.

In this context of curricular reform, let us take a look at the process of designing and implementing an ethics curriculum using Kern's model (6).

Designing and implementing an ethics curriculum

Kern proposed a six-step model of curriculum development. These six steps are: problem identification and general needs assessment; targeted needs assessment of learners; goals and specific measurable outcomes; educational strategies; implementation, and evaluation and feedback.

Problem identification and general needs assessment

Several reports have highlighted the problem of malpractice and unethical behaviour by medical practitioners in society (7, 8). Inclusion of formal ethics training in medical schools has been identified as one step by which the need for ethical behaviour can be reinforced and faith in the medical profession can be revived (1, 2, 4).

Needs assessment will include reviewing the substantial information which already exists, consultation with experts in the field and obtaining new information from all stakeholders. Several brainstorming exercises have been carried out in the past, which have succeeded in identifying our contemporary needs (9-11). In September 2008, a WHO/SEARO expert group identified the lack of suitable learning resources and the paucity of trained faculty to teach medical ethics as some of the constraints to implementing ethics modules. The group developed a module on medical ethics for medical students (9) in the South-East Asia region and went on to develop an excellent Handbook and a Facilitator's guide (10) to achieve this aim. More resource material in the form of books and CDs was also prepared as one of the main outcomes of the South-East Asia Health Ethics Network (SEAHEN) project (11). The Rajiv Gandhi University of Health Sciences (RGUHS) prepared its own ethics curriculum involving experts from the Indian Council of Medical Research, National Law University, Bengaluru, ethicists from St John's Medical College, Bengaluru, transplant surgeons, faculty from Ayurveda, medical colleges, non-governmental organisations and practising consultants.

The Medical Council of India also got together experts to brainstorm on how ethics and professionalism could be incorporated into the Foundation Course. Extending this process to individual subjects, using formal and informal consultations and techniques like the Delphi process overseen by a central coordinating team, could help refine this approach further. The experiences of institutes and universities which have previously tried ethics training can also be good learning grounds.

The needs assessment exercise also includes identification of resources required to put the curriculum into practice. A cursory analysis will reveal that we lack indigenous books and trained faculty with an ethics background to deliver this curriculum. The MCI has identified a curriculum implementation support committee whose job is to ease the process of introducing innovations through a tiered system of faculty development initiatives.

Targeted needs assessment of learners

Targeted needs assessment is a process by which knowledge learned from general needs assessment is applied to learners and the learning environment (6). While there is an urgent need to introduce ethics and professionalism into the curriculum, it is clear that a transplanted western model of ethics teaching will not work for the Indian medical graduate. Indian values, philosophy, cultural diversity and social complexities will have to find their way into our curricula.

Further, each university and institution will need to make specific modifications to the proposed national curriculum depending on the specific needs of the learners and institution. Let us, for example, look at the St John's, JIPMER and RGUHS models. At St John's Medical College, Bengaluru, a college run by the Catholic Bishops' Council of India, a structured ethics training programme (4) with 40 hours of teaching includes elements of medical ethics, professional ethics, research ethics and Christian bioethics. The Jawaharlal Nehru Institute of Postgraduate Medical Education and Research in Puducherry uses a different approach. Their ethics curriculum, introduces research ethics, including informed consent for research, ethics of drug promotion and animal ethics in Pharmacology. During the internship, the focus shifts to the Consumer Protection Act and how to deal with drug representatives. When students pursue their post-graduation and work on their dissertations, issues such publication ethics and plagiarism are included. At the Rajiv Gandhi University of Health Sciences, the 40-hour programme is spread out from the first year of MBBS to the final year and there are also criteria for assessment. The entire ethics curriculum is included as Section V in the "Regulations and Curriculum for MBBS course".

The Medical Council of India will therefore need to issue broad guidelines and allow flexibility to individual institutions, to align their resources and content with their learners' needs.

Goals and specific measurable outcomes

It is critical to explicitly define broad goals and specific measurable objectives as they help to determine the curricular content, prioritise resource allocation and plan educational strategies (6). One of the five goals of the MBBS training course enlisted in the Vision 2015 document (5) is to "produce a doctor who is able to function as a professional, who is committed to excellence, is ethical, responsive, and accountable to patients, community and profession". The competencies expected of an MBBS doctor as a professional have also been defined in the document.

In the same manner, it is an essential prerequisite to define specific measurable objectives too, as this will help define the instructional and assessment methods to be used to deliver this curriculum. At the moment, this process of writing specific objectives is being done by the working groups. Here it will be important to adopt a multi-disciplinary approach and involve as many trained faculty across departments as necessary. The WHO/SEARO facilitators' guide (10) advocates a multidisciplinary approach in teaching ethics involving faculty from several departments including forensic medicine, community medicine, internal medicine, obstetrics and gynaecology, surgery, anatomy, clinical pharmacology, psychiatry, paediatrics, the medical education unit and any other clinical departments, as considered necessary.

Educational strategies

Choosing educational methods which are congruent with our objectives is perhaps the key to teaching ethics effectively. That medical ethics can be taught and learnt like any other basic science course is a flawed conjecture. A medley of methods is advocated -- lectures must be supplemented by role plays, demonstrations, case studies and group discussions. Active learning must be encouraged using facilitation skills that promote reflection, introspection and openness.

David Kolb's experiential learning cycle (12) talks of four stages of learning: *immediate or concrete experiences*, which provide a basis for *observations and reflections*. These observations and reflections are assimilated by the learner and distilled into *abstract concepts* which can be *actively experimented with* to create new experiences. Using this cycle, we need to first provide our students with experiences, either using cases or real situations, to acquaint them with complex issues of ethics, upon which they can reflect. Reflection is an art which the faculty must first learn themselves and then teach students. As these students reach their clinical years, they need to be given opportunities to develop and then test their concepts in practice.

What must not be forgotten is the "hidden curriculum". Hafferty and Franks (13) argued that the most critical determinants of physician identity operate not within the formal curriculum, but in a more subtle hidden curriculum. The authors bemoaned that what students learn is not from formal content in the lectures, but between the blackboard and the bedside, in the "evil corridors". Students learn from what teachers do, rather than what they are told. And when the gap between what is preached and what is practised is huge, the message that goes out to the students is diluted or distorted. Each teacher is a role model for students, and teachers must be conscious of the profound impact they make as they subconsciously mould the personalities of their students with their everyday behaviour.

Ethics issues are not merely individual concerns, but also institutional concerns. Each institute needs to develop its ethical culture

and milieu which rubs off on the student's personality. Institutional systems and practices (like for example, taking informed consent, functioning of institutional review boards, ethics matters related to clinical research and dissertations) must be in place, which reinforces the seriousness with which ethics issues are viewed. Callousness and disrespect towards patients should not be tolerated as a policy matter and strict guidelines must exist.

Implementation

While the process of curriculum design usually progresses well on paper, implementation has always been the bottleneck for most innovations in India. A closer look at the objectives and educational strategies will reveal that the key to implementation lies in strong administrative and leadership skills. In India, departmental hierarchies and divides are rather difficult to penetrate. So, deciding who will do what, how much and how, are probably the most crucial decisions to be taken by each institution. Leaving the whole burden of teaching ethics on the shoulders of one department like forensic medicine or community medicine will probably spell disaster even before the efforts begin. The ethics curriculum will have to be longitudinally spread throughout the MBBS course, starting with the Foundation Course, followed by inputs from anatomy when the students first reach the dissection hall, till the time they acquire their degrees. A central team will have to use its abilities to coordinate between departments to ensure the successful launch of this endeavour. Needless to add, any change will encounter resistance and how each institution convinces its stakeholders and manages its people, time, funds and facilities will determine how effectively the curriculum is delivered.

Evaluation and feedback

It is known that what is not assessed is not learnt. Students need to be assessed using formative and summative methods on the issues of ethics and professionalism. There is need for supervised, monitored experiences to be provided to students so that directly observed feedback can be given. The impact of periodic formative feedback from faculty at each stage cannot be overemphasised.

Curriculum development is an iterative dynamic process. Program evaluation has to be built in as it gives an impetus to the faculty, curriculum designers and other stakeholders. It is important to continuously check whether the curriculum is achieving its planned objectives and if the products of the medical school are actually practising ethical behaviour. A continuous process of data gathering, monitoring and check needs to be in place to ensure that quality is maintained and changes are made according to the need.

To conclude, the Vision 2015 document proposes certain long-needed and laudable changes to introduce ethics into the MBBS curriculum. But it is crucial that these documents do not merely gather dust and are actually put into practice. Eventually ethics must be seamlessly integrated into the MBBS curriculum in a longitudinal manner and any effort to enshrine it in a separate department will perhaps not yield the desired benefits. There might be no dearth of a sense of what is right and wrong in our medical practitioners, but we need to nurture the right attitudes in our medical students by moulding them early, when they are malleable like wet clay.

Conflict of interest: *The author was part of the faculty team working on designing the Second MBBS pathology curriculum and the curriculum implementation support programme of the Medical Council of India. She was not directly part of the team which designed the ethics curriculum.*

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FROM THE PRESS

Mass caesareans in Kerala: unseemly haste

Twenty one caesarean sections were performed at the state-run Cherthala Taluka Hospital in Kerala over a period of two days (April 16 to 18). This was reportedly done in total disregard of whether the women patients in question were in a position to deliver normally and whether the hospital had the facilities, such as bed strength, for the post-delivery care of mothers and infants. Consequently, the women and infants had to lie on the floor post surgery, according to reports. The Cherthala hospital is mainly used by fisher folk and coir workers, and has the capacity to conduct a total of just six surgeries a day.

The District Medical officer, Dr KM Sirabuddeen, who carried out a probe, recommended suspension of three gynaecologists and the hospital superintendent. The reason for their scandalous haste was, apparently, that the concerned doctors had holiday plans for the long Easter weekend. They were exposed by relatives of the patients who complained that some of the women could have waited for a normal delivery, but were not allowed to do so.

A similar incident was reported from the Kadakal government hospital, Kollam District, where 16 C-sections were performed over three days, from April 16 to 19, apparently because the anaesthetist wished to go on leave. An inquiry has been ordered there too by the District Collector.

Besides this incident, experts say, Kerala's figures for caesarean sections regularly exceed the WHO norm of 15 per 100 deliveries, and have, on occasion, touched 45 per 100 deliveries. The state government has now announced the setting up of a team of experts to inquire into this alleged mass malpractice.

The youth and women's wings of all the major parties have demanded strict action against the offenders. The state human rights commission has asked the health ministry for a report on the matter.

PTI. 21 caesarians in 2 days in Kerala Govt Hospital. Outlookindia.com April 23, 2011. Available from: <http://news.outlookindia.com/item.aspx?719725> PTI. More 'mass caesarians' in Kerala. *The Asian Age* April 25, 2011. Available from: <http://www.asianage.com/india/more-mass-caesarians-kerala-976> HT Correspondent. Mass C-sections: 4 docs suspended. *Hindustan Times*. April 23, 2011. Available from: <http://www.hindustantimes.com/Mass-C-sections-4-docs-suspended/Article1-688878.aspx>

Ethical to show reality?

A cancer awareness campaign jointly organised by the Ministry of Health and Family Welfare (MoHFW) and several organisations, including the Tata Memorial Hospital, the World Lung Foundation, and the Indian Dental Association, has culminated in ChewOnThis.in, a website that reveals vividly the terrible effects of using tobacco, whether in cigarettes or the smokeless variety.

Initially, a short video was made, showing horrifying images of sufferers from oral cancer at the Tata Memorial Hospital, Mumbai, but the ministry rejected it as "too gory for general viewing". The focus was then shifted to an individual patient, a young man aged 24, who was shown being interviewed and discussing his condition in the first video; while the second video was shot after his death in October 2009. The idea was to bring home to viewers the impact of the death of a young person they had identified with. These were both aired on television.

The group of organisations later convinced the authorities to use the censored footage, which would have a more forceful impact, on the internet. "ChewOnThis.in exposes the images the tobacco industry doesn't want Indians to see," said Sandra Mullin, Senior Vice President, Policy and Communications, World Lung Foundation. "Sometimes reality is too graphic for TV but new media allows us to appeal and interface directly with citizens. The campaign shows how young men and women suffer with gruesome oral cancers, some with windpipes or tongues removed." The year-long public health campaign plans to SMS more than 2 million Indians as well as place picture ads on social networking sites leading to the two-minute web video with these images. The site is said to have received 4,000 hits on day one.

BK Prasad, Joint Secretary, MoHFW, Government of India, said; "Chewing tobacco is a major health challenge to the country as it causes 80-90% of the oral cancers. We are more concerned because India shares the highest burden of oral cancer in the world. We have already launched an intensive prevention campaign against the use of tobacco, especially chewing tobacco."

According to Dr PC Gupta of the Healix-Sekhsaria Institute for Public Health, "The shocking reality is that smokeless tobacco is highly addictive and contains many cancer-causing agents. Its effect on the soft tissue in the mouth and throat is so virulent that people can suffer cancerous lesions after only one or two years of chewing." Dr Gupta adds, "We know that the images are unpleasant but the increasing figures of oral cancer are equally disturbing. Also, they are not photo-shopped images, they are real pictures,"

Jyoti Shelar. Graphic oral cancer video that the govt didn't want you to see. *Mumbai Mirror*, April 23, 2011.

Furore over Fukushima risk levels

The Japanese are battling for survival in the continuing combined disaster of earthquake, tsunami and nuclear radiation. Meanwhile, there seems little consensus on medical norms regarding what can be called safe levels of radiation and groups of experts have been slugging it out on this issue.

The US advocacy group Physicians for Social Responsibility (PSR) has recently criticised press reports which said a safe

threshold is 100mSv for ionizing radiation exposure. It said that there are no safe doses of radiation and any dose can increase an individual's risk for the development of cancer. Tilman Ruff, of the University of Melbourne, states that there may be a threshold for some effects of radiation, but not for cancer. Ruff, who is also a member of the International Physicians for the Prevention of Nuclear War, dismissed as "self-interested" those parties implying "a threshold for radiation exposure below which there are no adverse consequences," Peter Burns, of Australia's nuclear safety agency ARPANSA says the media have tended to overplay the health effects of small amounts of radiation. However, both experts agree that "There is no level below which we believe radiation effects can't occur." Most importantly, the impact of radiation is greater on the unborn, infants and children, especially girls, as compared to adults.

All the while, the most vulnerable segment, the workers at the Fukushima Daiichi nuclear plant, has been working round the clock to prevent a nuclear meltdown and endless radiation leaks. They have had some success, but the ever-present fear of radiation and continuing stress are endangering the physical and mental health of workers in Fukushima. These workers have to depend chiefly on themselves and their co-workers in order to keep on working. They suffer from insomnia, dehydration and high blood pressure and are at risk of developing depression or heart trouble, according to Dr Takeshi Tanigawa, an epidemiologist who examined them.

Dr Tanigawa said the workers get little rest, no baths or fresh food, and are under constant threat of exposure to radiation, which is so high in many areas, that robots are being used to take measurements. He feels the work conditions don't meet the basic rights guaranteed to workers by Japan's constitution. According to him, although emergency conditions may have justified harsh working hours in the early days of the crisis, the situation has now "become chronic." "TEPCO (Tokyo Electric Power Company) and the government don't think about them. The workers must do a good job, but they do not have any support," he said.

"They feel a deep sense of responsibility to be there," he said. "I asked many if they wanted to stop, but they responded, 'Who would do this if I didn't?'" Meanwhile, the ethical dilemmas of how to safeguard these workers who have already been exposed to radiation; of whom to send in if they are relieved; and of how to complete those essential tasks necessary to protect the general population without injustice to the workers, still have to be tackled.

As a first step, the UN Scientific Committee on the effects of Atomic Radiation (UNSCEAR) said it will study the radiation impact of Japan's nuclear disaster on people and the environment, but it did not expect to detect any major health effects. The study is expected to take two years to complete.

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China revamps organ transplant law

After a longstanding scandal about organs being removed from executed prisoners for use in transplants, China has made substantial efforts to prevent such crimes, including cracking down on transplants performed by medical institutions without transplant qualifications, and punishments ranging from fines and jail terms to dismissal and cancellation of licences of doctors.

The *China Daily* newspaper, in the first public acknowledgement, in 2009, of the reliance on prisoners for body parts, had said that 65 per cent of donations came from Death Row. Huang Jiefu, the country's Deputy Health Minister, stated that condemned prisoners were "definitely not a proper source for organ transplants".

Despite a 2007 regulation barring trading in human tissue, the demand for new organs far exceeds legitimate supply. About one million Chinese need organ transplants each year but only one per cent receive them. To meet the demand, an illegal trade in organs has boomed in a country that puts to death more convicted criminals than the rest of the world combined.

There has also been a surge in living donors. About 40% of transplants were carried out with organs from living donors in 2009, up from 15% in 2006, according to Professor Chen of the institute of Organ Transplantation, Tongji Hospital. China's newly revised criminal law, which the top legislature adopted in February of this year, is the first to enumerate crimes related to transactions in human organs.

Criminals convicted of "forced organ removal, forced organ donation or organ removal from juveniles" could face punishment for homicide. Those convicted of organising people to sell human organs could receive a prison term of a maximum of five years and a fine, while those involved in serious cases could serve a term of more than five years.

Launching a new service to encourage more legitimate donations, Mr Huang stressed the rights of prisoners and said: "Transplants should not be a privilege for the rich." The new donation system, piloting in 10 provinces and cities, will encourage post-death donations and start a fund to provide financial aid to the needy and to donors' families.

J Macartney. Death row organ donor scandal exposed in

China. *The Sunday Times*. August 26, 2009. Xinhua. China to launch nationwide crackdown on illegal organ transplants. CNTV, April 19, 2011. Xinhua. China to crackdown on illegal organ transplants. *China Daily*, April 19, 2011.

Negligence in sex selection investigations benefits the culprits

Union health ministry reports reveal that only 55 convictions have been achieved out of 805 cases filed in 17 states, under the revised Pre-conception and Pre-natal Diagnostic Techniques Act (PC and PNDT Act). Most of the other cases have been shelved due to "poor investigation and insufficient evidence against the accused." While the highest number, 161 cases, were filed in Rajasthan, not one of these has resulted in a conviction.

The other states have not fared much better. 23 out of 54 cases filed in Haryana, 22 out of 112 in Punjab, four out of 82 in Gujarat, three out of 139 cases filed in Maharashtra, two out of 61 in Delhi, and one out of two in Chandigarh resulted in convictions. The figures are slightly better in the sealing of ultrasound machines, with Gujarat first, with the sealing of 168 machines, Haryana second, with 133, Maharashtra third, with 82, Rajasthan fourth, with 76, and Orissa fifth, with 68 machines.

With India's child sex ratio dropping to 914 girls per 1000 boys in the provisional Census figures for 2011, as against 927 girls in the Census of 2001; this has been the worst showing since 1947. The union health secretary met with health officials of 17 states to decide how to better implement the PC and PNDT Act. The plan of action places more emphasis on follow up of cases, strengthening legal assistance and training the judiciary and public prosecutors.

State officials have been told to monitor blocks under their jurisdiction with a higher density of ultrasound machines, stationary or portable; register every operational machine, strictly enforce filling up of the necessary Form 'F'; and ensure that doctors convicted under the Act permanently lose their licences to practise.

K Sinha, Only 6% of doctors held for sex-selection practices convicted, *The Times of India*, April 20, 2011 Available from: http://articles.timesofindia.indiatimes.com/2011-04-20/india/29450665_1_ultrasound-machines-court-cases-convictions K Sinha. Sex selection to cost doctors licence. *The Times of India*, April 21, 2011. Available from: http://articles.timesofindia.indiatimes.com/2011-04-21/india/29458945_1_ultrasound-doctors-selection

Something rotten in the state of India?

The Supreme Court recently ordered the Central government to release one million additional tonnes of cereals to prevent starvation deaths and reduce malnutrition in the country. The court was incensed that the states had lifted only 40% of their allotment during the year 2010-11 for distribution under the public distribution system, Antyodaya Anna Yojana, for the poorest of the poor. While hearing a petition by the People's Union of Civil Liberties on the issue, the apex court criticised

the Planning Commission for fixing a rate of Rs 15 to 20 per capita per day as the norm for classifying people as being below the poverty line (BPL), and asked the Commission to revise its benchmark in line with the Tendulkar Committee's recommendations on consumption per day in urban and rural areas.

While the government had offered to release only 50 lakh tonnes, the Court questioned its rationale in a situation where inadequate storage was resulting in grains either rotting or being burnt. It asked the PUCL, the Justice Wadhwa committee, and government representatives to jointly work out the modalities of the distribution.

Dhananjay Mahapatra. Release 1 mn tonnes of cereals: SC. *The Times of India*, May 15, 2011.

Indian firm to stop exporting 'execution drug' to US

Sodium thiopental is a sedative so far used, in combination with two other drugs, in executions by 34 US states that carry out capital punishment by lethal injection. As the sole American manufacturer stopped producing the drug last year, the authorities have been facing a shortage. Most of the concerned states now import the drug from overseas, with Indian firms being key suppliers.

Kayem Pharmaceuticals, an Indian supplier of sodium thiopental, which distributed the drug to Nebraska and some other states, has announced, under pressure from Reprieve, a United Kingdom-based provider of legal assistance to prisoners, that it will no longer sell the drug to American prison departments. According to Kayem's website, the company decided to stop selling the drug as the clients' purpose is purely for lethal injection. However, it continues to sell the drug to Angola and other markets. Several other Indian firms are reported to be exporting the drug, but they do not do so directly to the US.

Meanwhile, four US states, including Texas, Mississippi and Arizona, have begun using pentobarbital, a stronger sedative often used to euthanise animals, in executions.

India halts lethal drug export to US, Press TV, April 8, 2011. Available from: <http://www.presstv.ir/detail/173706.html> AFP. Alabama switches execution drug. *Google.com*, April 27, 2011. Available from: http://www.google.com/hostednews/afp/article/ALeqM5iNX36VDYLemW_r27_2IRZ3YDm3Hg?docId=CNG.8c02dc1f70911ad531053577b7a01385.2d1 Ullekh NP. Once bitten, Kayem Pharmaceuticals not shy about new pastures. *Economic Times*, April 12, 2011. http://articles.economictimes.indiatimes.com/2011-04-12/news/29410000_1_lethal-injection-prisons-navneet-verma Indian firms not to sell sodium thiopental to US jails. *Rediff.com*, April 6, 2011.

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DISCUSSION: ETHICS OF ETHICS COMMITTEES

The ethics of ethical expertise in science, medicine and healthcare policies

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With the global spread of medical and scientific developments such as genetically modified crops, stem cell research and assisted reproductive technologies (ART), many countries have seen another trend, namely the implementation of institutionalised expert advice and expert committees. Ethics committees are becoming a widely used tool in policy making concerning science and healthcare, and expert advice is as common nowadays as it is diverse. The spectrum of experts ranges from physicians, scientists and lawyers to philosophers and social scientists. They act as advisers in local, national, or even transnational ethics committees such as at the World Health Organization (WHO), or at the United Nations Educational, Scientific and Cultural Organization (UNESCO).

However, as recently discussed in the case of the Indian moratorium on genetically modified food plants (such as BT brinjal, a transgenic eggplant resistant to some plant specific pests) (1), the role of these ethics-experts is often far from clear. The question of their practical relevance and democratic legitimacy arises particularly when their democratic role is compared to the role played by media, non-governmental organisations, and direct public consultations. The Indian magazine *Frontline* (2) critically questioned the legitimacy of ethics committees with respect to their relationship with democratically elected policy makers. Thus one may ask about the legitimacy of such ethics committees as they have sprung up of late in the political arenas of both India and Germany.

Democratic science policy between “scientification” and “ethicisation”

In this special collection of articles in the *Indian Journal of Medical Ethics*, therefore, we would like to address the complex relationship between science and democracy, an issue that has been widely discussed in political theory (3-7) but less so in bioethics. The relationship between science and democracy is problematic for the following reasons:

1. On the one hand, democratic politics has to rely on scientific findings as facts, as they are believed to stand aloof from biases and vested interests. On the other hand, theorists of science in the vein of Max Weber, Thomas Kuhn and Paul Feyerabend have cautioned against scientific experts, as they are not always able to steer clear of, or make explicit, the normative presuppositions that may colour their work from the production of facts to the level of theories and conclusions.

If ethical expertise is to be effective and morally and ethically justified, it seems important to better understand the role given to experts in the complex interface of science and democratic politics.

2. Ethical inquiry as a reflective approach to common practices in science requires a critical questioning of the appropriateness of scientific methods, aims and even points of departure. This critical reflection also encompasses the increasing number, globally, of ethical guidelines generated by ethics committees with the participation of ethicists and various other experts. In the context of this “scientification” of political discourse, the question arises: under what circumstances can the liberal democratic state be allowed, on the basis of scientific ethics advice, to interfere with the liberty of citizens to make use of the opportunities offered to them by modern science and medicine? Also, when may the state legitimately interfere with the academic freedom of researchers to chart out their own research agendas?

As Ernesto Laclau has pointed out, there is a general trend towards “ethicisation” of politics. Several scholars have suggested this term to describe the phenomenon of the institutionalisation of ethics advice in science governance. In science, as well as in medicine, we can observe a number of such institutions growing at different levels: at the local level (ethics committees in hospitals or universities), at the meso level (ethics committees in research associations), at the macro level (national ethics councils), and even at the supra-national level (ethics boards hosted by agencies such as WHO or UNESCO). The collection of articles in this issue of *IJME* will problematise this phenomenon of “ethicisation” of politics in connection with the discussion of ethics review boards on all four levels.

The role of scientific experts in modern society

From a very broad perspective it seems that the domain of science and that of society (and politics) belong to two clearly distinct spheres. Whereas science is preoccupied with the unchangeable laws of nature, society in general and politics in particular mark the domain of human agency. Science thus limits the domain of politics by delineating the sphere of things that politics has to accept as a given fact. Science thus defines the domain of those things over which there can be no rational (political) disagreement. Having said this, a possible source of misuse of science in politics becomes apparent, and it is here

that the problem of ethical expertise in liberal democratic societies arises. A scholarly or political discourse can obscure from view a possible domain of collective responsibility and political agency simply by declaring something as a scientific fact, i.e. as universally true, natural and unchanging. This has been a common discursive trick ever since the Enlightenment period where rules legitimising the polity were represented by scholars as if they were laws of nature. Familiar terms such as "natural law," the "state of nature" (from where to derive the legal-ethical principles that govern society) and "natural rights" come to mind. If the rules governing society are based on natural laws then politics is bound by them. Thus, by way of representing certain legal, social, economic or historical phenomena as governed by "laws of nature," the world of science assumes precedence over the world of politics. Policies can be represented as necessary if they can be portrayed as in congruence with some alleged natural law. In this way, modernity has been represented as a process driven by "natural laws." The same is true for "secularisation," "progress" and "globalisation." In actual fact, however, there is nothing necessary or law-bound about these historical processes. They may continue in the perceived direction but they may also stall, or reverse, depending on contingent factors. But if they are represented as if they were natural processes, they can no longer be the object of human agency and have therefore to be taken into account by state and politics, no matter what. After all, politics as human agency cannot change the laws of nature. Medicine and healthcare as policy fields are particularly pertinent here.

Thus, it turns out that what is presented as natural, universal and unchanging is often cultural, contingent and subject to historical change. The latter would normally be the domain of history or social sciences. However, even the social sciences have at times fallen prey to a positivist (Comptean) attitude that treats the domain of the social on a par with the domain of nature. Here again the Enlightenment acted as a "godfather." Notably, Immanuel Kant distinguished between the domain of human agency and free will on one hand and the domain of natural law on the other. He did not take into account the domain of the cultural or the social as a separate category. In this category, rules do obtain but these rules are not hard and fast, like natural laws, but open to change by collective actors. It is this domain of collective agency that is the province of ethics. Norms govern society by way of generic rules. But in contrast to natural laws, these generic rules allow for exceptions. They have to be interpreted and applied by individual human beings, which leads to variation and change over time. Norms that govern society are part of a socially shared convention that transcends the individual human being. Thus they cannot be changed at will by individual actors alone. They are represented as rules that society imposes on the individual. From the perspective of the collective, however, and from a political point of view, these rules are open to change.

Keeping this in mind, science and scientific experts (with science we hereby refer to all disciplines, not only natural sciences) have a particular responsibility not to lend themselves

too easily to the legitimising role that science can play in political discourse.

As institutionalised sources of legitimacy, experts play a central role in modern society. As sociologist John W. Meyer (8) has pointed out, their authority derives not from their strength as actors but from their ability to assimilate and develop the rationalised and universalistic knowledge that makes action and actor-hood possible. This authority is organised in academic institutions. As disciplines they are devoted to specific bodies of knowledge and their dissemination. Their rationalised knowledge structure constitutes the superego of modern society, replacing in good measure the older religious frameworks.

The advantages of scientific and ethical advisers to policy makers and law makers may not easily be dismissed. They may be in a position to detect social and ethical problems at an early stage and they may function as an internal self-control mechanism of society as they try to integrate expertise from different fields - not only ethics, but also the pure and applied sciences and the social sciences. However, one has to keep in mind that representing social rules as natural laws serves to limit the political debate over them. By doing so, scientists can play into the hands of those who do not like to be questioned about or held responsible for the social, legal and political norms that they generate or enact.

Thus misconceived, the role of experts runs the risk of becoming the equivalent of a new priestly caste from which statesmen, legislators and policy makers derive their legitimacy. The high priests of modernity, however, are also common citizens of their own respective polity and as such they have a share in the burden of collective responsibility. As various ethicists have argued, "ethical expertise" may not always be equated with "moral expertise." We have summarised and argued this elsewhere (6, 7). What is needed, however, is an ethics of expertise, or an ethics that takes into account the socio-political justification as well as the professional ethos of experts in ethics committees.

Practical function of ethics boards in science and healthcare policies

One way to analyse and understand these issues in the relationship between the social system of science and society at large is to analyse the changing role of the "authority" of experts over the leading paradigms, methods and practical consequences of their expertise. Their analysis of the role of expertise offers a model for a better understanding of the relationship between science, society, and politics. Expertise and scientific advice in policy making take very different shapes: At least seven functions can be observed:

1. Advice to legislators and executive organs;
2. Information or training of policy makers with regard to state-of-the-art science;
3. Facilitating compromise and consensus between conflicting interest groups;

4. Initiating and moderating public discourse;
5. Simulating public deliberation based on broad information;
6. Developing concrete guidelines and recommendations; and
7. Monitoring materials and arguments used by policy makers.

Each of these functions may be meaningful and justified. However, what is often missing when a board is set up is a systematic and transparent justification of the functions assigned to it. Therefore what is needed is a discussion of the benefits and burdens of the political-philosophical role of expertise in modern, democratic societies and a discussion of the processes of their legitimisation at the intersection between bioethics, political theory and social science.

To illustrate what could be meant by "ethicisation" of expert advice, Germany can serve as a case in point. In various respects, Germany offers a good example of an "expertocrat" model of science and healthcare politics. For several legislative periods two national ethics committees existed, one with Parliament (Bundestag), the other set up by the Federal Chancellor (Bundeskanzler) to advise the government. Both were in many ways competing with each other and struggling with regard to their legitimisation and political influence (Bogner and Menz have done an exemplary analysis of this [9]). Furthermore, there are several committees assigned to national bodies and societies (for stem cell research, for the allocation of public healthcare, for the ethics of organ transplantation, for end-of-life decisions, for bio-safety, for gene therapy, for genetic testing, etc.). In addition to these national level boards, more than 50 ethics research committees or institutional review boards were established at regional levels (about 10 for living organ donation in different parts of Germany). Clinical ethics committees that deliberate in local conflicts are quite rare compared with the US where about 90 per cent of all hospitals have such institutions. However, more interestingly, in contrast to neighbouring countries like Switzerland, the Netherlands, Great Britain, or Denmark, in Germany, the involvement of the broader public (through mechanisms such as citizens' conferences, focus groups and round tables) is still rare. In India, the above-mentioned case of public deliberation on BT brinjal points in the same direction.

With the papers included in this publication, we can identify four different, but related, topics in future bioethics that seem worth elaborating from different angles. These are: 1) the normative justification of expertise within the broader framework of democratic deliberation; 2) the epistemic justification of expertise; 3) the critical assessment of expertise within the global system of academic exchange; and 4) the existing power relations within society and the relationship between experts and non-experts. From these four perspectives the following questions arose and were addressed by the contributing authors:

1. A question pertaining to the normative justification of expertise within the broader framework of democratic deliberation is: what kind of ethical criteria do we have to attribute to expert work, and what consequences should experts face in the event that these criteria are not met? *Erica Blom and Raymond de Vries* show in their discussion of genetic research among Native American populations in the 1990s that lack of cultural sensitivity among researchers can lead to failure on ethical or even legal grounds. In their critical analysis of this case, Blom and de Vries show that neither the ethics committee's work nor existing ethical guidelines sufficiently reflected the cultural sensitivity of the research. Nor did they sufficiently address the issue of ethical misconduct by researchers. To increase cultural sensitivity as well as to detect ethically critical issues for researchers, the authors argue for a direct dialogue between the researchers, ethics committees and populations involved.
2. A question pertaining to the epistemic justification of expertise is: what makes expert knowledge superior to other forms of knowledge? As the paper by *Yordanka Krastev* illustrates, referring to the development of ethics committee work in Bulgaria, the political climate as well as international influences are important factors that determine what is regarded as "expert knowledge". Recent international developments have led to the insight that experts need specialised training in ethics in order to be able to fulfil their role. The paper of *Pratibha Nadig, Medha Joshi and Aradhana Uthappa* provides insights into current work and the background knowledge of Indian ethical review boards. The results of their quantitative survey show that sufficient knowledge of ethics and legal requirements by the experts cannot always be presupposed, but a third of the ethical review boards are conducting internal audits to ensure the quality of their procedures.
3. A question pertaining to the critical assessment of expertise within the global system of academic exchange is: how should we deal with "battles of expertise", with expert dilemmas and issues of uncertainty and ignorance? In their paper, *Marie-Charlotte Bouësseau, Andreas Reis and W Calvin Ho* advocate an intensified international exchange between national ethics committees to reach a broader consensus. They argue that international organisations such as the WHO should assume a leading role in moderating and consensus-building in this domain.
4. A question pertaining to the existing power relations within society and the relationship between experts and non-experts is: how will the process of expertise do justice to the perspectives of both patients and the broader public? Without this we could be running the risk of a polarisation along the lines of populism on one hand and "expertocracy" on the other. Using the case of Israel, *Carmel Shalev and Yael Hashiloni-Dolev* show in their paper that technocracy in bioethics leads to a decentralised governance system in which legal experts and medical professionals can decide over life and death without involving the patient

community or the broader public. This system sponsors a kind of paternalism that is at odds with liberal democratic precepts of individual autonomy and inclusive democratic deliberation.

The concept of the "autonomy of science from the social institutions that legitimated it" may have become (or may have always been) an illusion, as science historian Dhruv Raina has pointed out (10). However, even falling short of complete autonomy, there are many ways in which ethics advice can be kept independent of political and vested interests without depriving the state of its ultimate prerogative to decide on normative issues regulating its social life. This is what the contributions assembled in this special issue make very clear. Thus, the dialogue between researchers, ethics committees and populations should be increased, scientific experts should be awarded special training in ethics before joining ethics committees, inter- and supra-national organisations should be involved in procedures of international moderation and consensus-building, and, finally, decisions over life and death should always be conducted in close dialogue with the community of concerned patients and the broader public. Since social rules, unlike natural laws, involve individual and collective interpretation, adaptation to local contexts, and cultural sensitivity, their enactment and enforcement necessitate a maximum of democratic participation at all levels.

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Towards local participation in the creation of ethical research guidelines

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Abstract

Research ethics committees are entrusted with implementing guidelines to protect both scientists and human subjects of research from harm. These guidelines are often based on western contexts and may not resonate with the local moral traditions of the communities that they seek to protect. In this essay, we discuss how using principles of deliberative democracy with a "local derivation" approach may help in the drafting and implementation of ethical guidelines for research that better serve society.

The Havasupai Indians of the United States (US) struggle with phenomenally high rates of diabetes. The disease has ravaged

their community and left its members desperate for aid. In the early 1990s, help seemed to arrive when research scientists from the University of Arizona came to the Havasupais' home deep in the Grand Canyon. The researchers offered to provide genetic clues to the tribe's diabetes epidemic in exchange for individual blood samples. Formal ethical procedures related to the project appeared fulfilled: researchers received approval from a research ethics committee (REC), and the participating Havasupai gave their consent. At the time, the partnership between the researchers and the Havasupai seemed unproblematic.

Researchers then used information gained through an analysis of the Havasupais' blood to locate their ancestors far from

where the Havasupai believe their origins to be and to study links between illness and inbreeding. This challenged the tribe's cultural wisdom and embarrassed the Havasupai. Tribal members argued that this use of their blood violated their rights and filed a lawsuit against the participating researchers (1). The researchers argued in their defence that research on migration and inbreeding is an essential component of investigating the genetics of a disease among an isolated population. They held that any perceived wrongdoing was solely the result of miscommunication and misunderstanding (1,2).

The Havasupai case calls attention to longstanding ethical questions around scientific research involving scientists and subjects of research, particularly those from different backgrounds (3-5). Today, cross-cultural and cross-national collaborations are proliferating at a pace faster than most communities, particularly those in the global South, can react to them (6). Consequently, researchers and government agencies often have insufficient time, experience, and resources to generate local ethical guidelines to regulate these new research relationships and reduce any harm that may result from them. Instead, ethical guidelines from the US, Canada, and western Europe are often adopted wholesale or, at best, reshaped to fit local circumstances (7). Frequently, these guidelines are then applied by hastily assembled RECs with little sustained effort to ensure that implementation is equitable and ethical. As a result, it is often the case that neither the design nor the implementation of ethical guidelines for research resonates with the local moral traditions of the communities that they seek to protect (8).

In addition to reminding us of important ethical problems in research, the Havasupai case makes it clear that differences in moral reasoning can vary even within a single western nation. We must acknowledge that ethical guidelines based on western values may not fit even multicultural western societies. Accordingly, single countries may need to have multiple RECs to address alternative local needs while also complying with national standards.

Furthermore, the Havasupai case makes clear that sustained, respectful, and inclusive dialogue between researchers, the subjects of research, and other pertinent actors can reduce the potential harm arising from research that is cross-national and/or cross-cultural. Accordingly, a suggestion has been made to foster an inductive approach to creating more culturally sensitive and effective ethical guidelines for research (7). This approach - a strategy of "local derivation" - uses local moral concepts as the basis of guidelines. Knowledge of ethics developed in the West is used to illustrate how moral ideas are translated into regulatory guidelines. This approach begins a conversation among a diverse set of actors - ranging from policymakers and government actors to local community members and lay people - about how best to move from the moral ideas of a society to creating a system for ethics oversight. This conversation allows all involved parties to learn from each other. Key to this process is mutual respect and

continued communication with the goal of producing ethical guidelines that represent the beliefs, values, and needs of the populations that such guidelines serve.

The local derivation approach has not yet been put into practice. Nonetheless, deliberative democracy processes have promoted public participation in other areas where the creation of regulations must respond to the realities of research and local needs. Like the strategy of local derivation, deliberative democracy aims to foster mutual respect and open dialogue between actors with varied backgrounds. Deliberative democracy is lauded as a means for creating better informed, legitimate, and more broadly "owned" policies (9). The literature on deliberative democracy can inform the local derivation approach and advance the potential for RECs to be more attuned to a diversity of beliefs, values, and experiences (see, for example, 10-17).

Much of the literature on deliberative democracy describes how best to foster public participation in what may be characterised by four cyclical stages in the policy design and implementation process (18). We can apply insights from this literature to advance locally situated ethical guidelines for research.

The first stage consists of analytical or diagnostic work, when the information relevant to the design and implementation of guidelines is gathered. Public participation can and should be the broadest at this stage, so that the concerns and needs of actors from an array of cultural, socioeconomic, racial, religious, and ethnic backgrounds are included in any future decision-making. It has been suggested (7) that information gathering should take place through induction: the public must be solicited for their contribution no matter what values they hold. Public participation should accommodate all people, addressing physical, financial, and other challenges that could possibly prevent someone from contributing. And while a certain amount of public education is necessary to obtain constructive feedback, this education should use dominant western theories and practices sparingly and only as a model of how one uses moral tradition to inform policy. Surveys, deliberative polling, national discussions and public comment periods are some strategies that may facilitate public participation during this first stage (12).

The formation of a strategy for creating and implementing ethical guidelines occurs during Stage Two. While continued direct involvement of the public is ideal, at this stage it is likely that such involvement will lessen because of the resources needed to draft policies. Accordingly, the information gathered in the first stage must inform whatever draft guidelines emerge in this second one. Reliance on prior data collection demonstrates how vital it is that Stage One produces the most comprehensive and representative information possible. However, even with this prior input, direct representation that gives voice to a variety of viewpoints should still be present in the second stage. Consensus conferences, citizen juries and scenario workshops are examples of different methods to ensure that local populations continue to inform guidelines

(11-13). Empirical evidence about the risks and benefits of each of these deliberative methods will help determine how best to adopt these strategies in the creation of representative and effective ethical guidelines (see, for example 14-17).

Stage Three releases the guidelines for review, debate, and approval, rejection, or revision. Ideally, the guidelines will be equally endorsed by both scientists and groups at risk. Redrafting is necessary if there is strong opposition to the guidelines. This stage is essential for ensuring that any resulting guidelines meet the needs not only of specific local actors but also of the broader research and regulatory communities. Finding common ground among diverse opinions undoubtedly will be difficult, and repeating the prior two stages may be required.

Once ethical guidelines receive comprehensive approval, they are implemented in a fourth and final stage. Implementation includes continued dialogue with the public, especially marginalised communities and those most at risk during any scientific research. As society and science change, the nature and potential impact of research will be transformed. An REC must therefore be flexible to the evolving needs of the society that it serves, repeating any and all of the previous stages as necessary to ensure that ethical guidelines continue to best serve the intended populations.

If public participation in the four stages of ethical guideline design and implementation is to be effective, those leading these efforts must avoid what has been called the “expertise barrier”- the formal and informal rules of technical policymaking domains (including those relevant to ethical guidelines for scientific research) that make it difficult for actors without the dominant expertise to engage as equals (19). This barrier results from (often western) assumptions about the notion of public ignorance in matters of science and the regulation of research, the belief that scientific and empirical knowledge is value free, and the idea that if the public better understands quantitative facts it will agree with the ethical decisions of elites (20). For example, the lead scientist in the Havasupai study maintained that she “was doing good science,” and the University of Arizona defended this position for years (1). But the definition of “good science” is not value free. To the researchers involved, good science meant discovering scientific facts about illness, behaviour, and ancestry. But to the Havasupai, such science undermined the tribe’s cultural narratives while shaming its members in deeply personal ways. Had the type of inclusive dialogue that we call for taken place initially and throughout the study, all the parties involved could have better understood the social, cultural and scientific implications of the research

and addressed it accordingly. In confronting the expertise barrier head-on, local derivation is an inclusive approach that advances the design and implementation of ethical guidelines to the benefit of society, its members, and the work of science.

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Institutionalisation of Bulgarian ethics committees: history and current status

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Abstract

This paper provides an overview of the institutionalisation of the ethics review process in Bulgaria in accordance with the worldwide trend in establishment of ethics committees. Historical and current politico-legal changes influencing the work of ethics committees are analysed. The paper focuses on ethics committees which review biomedical research involving humans, with an emphasis on their composition, functions, training of members, and decision-making processes. Recent positive changes addressing insufficient training of ethics committees' members are highlighted. Recommendations are made for enhancement of the ethics review process and improved transparency.

Background

The formation of ethics committees (ECs) in healthcare started in the 1960s at almost the same time in the United States of America and Europe. Among the motivating forces for the institutionalisation of ECs were the brutal medical experiments on camp prisoners during the Second World War and the Tuskegee syphilis experiments on untreated Afro American men in Alabama, USA (1932-72) (1). Such practices inspired the creation of the Nuremberg Code, which introduced the concept of voluntary "informed consent" (2). This was followed by other international ethical guidelines and standards for conduct of biomedical research involving humans, such as the Declaration of Helsinki, the Belmont Report, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guidelines for Good Clinical Practice (ICH/GCP), and the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organisation (WHO) International Ethical Guidelines for Biomedical Research Involving Human Subjects (3-6). The common element of all of these documents was the requirement for ethics review and approval of clinical research by an independent review committee before the commencement of the research. These committees needed to demonstrate independence from political, institutional or professional influences, as well as competence, efficiency and timely review of research proposals (7).

Today, ethics committees across the world have different names: research ethics committee (REC), human research ethics committee (HREC), institutional review board (IRB), and local ethics committee (LEC). Their common main purpose however, is to ensure that the research is conducted in accordance with guiding ethical principles and that the rights and welfare of research participants are protected.

In the last two decades Bulgaria experienced a major transition in its healthcare from a centralised system to an open market,

similar to the other transitional countries in Central and Eastern Europe. The expansion of clinical research in these countries including Bulgaria, undertaken by large international pharmaceutical companies, has led to the establishment of ethics committees (8). Their purpose is to provide ethics review of submitted research protocols involving humans and to ensure the safety and wellbeing of participants.

Historical overview of the establishment of Bulgarian ethics committees

The ethics review of research involving humans in Bulgaria started in the mid-1980s, but there was no formal regulation until the early 1990s (9). In 1995, in response to the increased volume of clinical trial proposals from international companies, the Ministry of Health passed the Law of Drugs and Pharmacies in Human Medicine, which regulated all aspects of the conduct of clinical trials (10). A separate document, Regulation N 14 of the Ministry of Health (11), contained detailed guidelines for the establishment, composition and functions of the Local Ethics Committee (LEC). The regulatory body for registering all LECs across the country and monitoring compliance with the standard operating procedures (SOP) was the Bulgarian Drug Agency (BDA) (12). Ethics committees were established in all major Bulgarian hospitals. They were assigned the job of reviewing clinical trial protocols submitted to them and providing opinions about the ethical aspects of the research. This process was the first step towards institutionalisation of ethics committees in Bulgarian healthcare.

However, due to the top-down approach in the establishment of this new advisory body in hospitals, there was uncertainty among health personnel about the EC's role and decision-making power. Further, because ethics committee members did not have formal training in the ethics review process, they were often inadequately informed (9). Moreover, conflicts of interest existed in some ethics committees because the chair of the committee was the director of the hospital. In addition, hospitals selected as sites for a clinical trial and clinicians participating in the trial gained financially from taking part in the research. (They had, however, to show evidence of compliance with international ethical guidelines for conducting research involving humans.) Only a few members of the public had access to information about the existence and role of ethics committees.

Major developments in the regulation of research involving humans took place after 2004 when Bulgaria began harmonising its laws with European legislation in preparation for European Union (EU) membership. The new laws and regulations were introduced when Bulgaria joined the EU in

2007. The Rules of Good Clinical Practice were approved by Regulation 31 of the Ministry of Health (13). In April 2007 the Law on Medicinal Products for Human Use replaced the Law of Drugs and Pharmacies in Human Medicine (14). This new law is in compliance with Directive 2001/20/EC, Directive 2005/28/EC and the ICH/GCP Guidelines (5, 15-16). All clinical trials conducted in Bulgarian healthcare facilities must comply with the above-mentioned documents and the Declaration of Helsinki (3). Another important amendment is that a new ethics committee for multi-centre clinical trials was established by the Minister of Health. Existing local ethics committees now review only single-site clinical trial applications.

Current situation of Bulgarian research ethics committees

There are currently two types of ethics review of biomedical research involving humans in Bulgaria. One is for clinical trials of new medicines involving humans (predominantly internationally funded trials) and biomedical research including human use of medicines (conducted by MEC and LECs) and the other is for clinical and non-clinical biomedical research applications excluding clinical trials of medicines (conducted by university research ethics committees) (17).

The ethics review of *single-site clinical trials* is conducted by LECs established in all healthcare facilities by their director. Currently 150 LECs are registered with the BDA (12). The composition of LECs has not changed since the first legislation was introduced in 1995. They have seven to 12 members with different medical specialties, both males and females, at least two members with a non-medical degree and at least one person who is financially independent of the institution. Members are predominantly middle-aged physicians (49 years (± 1.4)) with a range of specialties and experience, lawyers, health administrators and few representatives from nursing, psychology, philosophy or ethics backgrounds (9). Since 2007, the operating procedures of LECs require preliminary ethics training and continuing education of all LEC members, overseen by the Chair of the LEC. Members of the LEC must attend a training course and obtain a certificate to fulfil this requirement. This is an essential step towards addressing the insufficient training of ethics committee members, an issue faced by ethics committees worldwide (9, 18). How this will influence the quality of the ethics review process is still not known, but it is a positive change in the work of Bulgarian ethics committees. The law also allows the involvement of external experts according to the needs of the LEC; however, there is limited information available about the extent of their involvement and the type of expertise required by the committees. The most commonly invited experts are medical specialists (60%) and lawyers (35%). The least likely to be invited are nurses (5%) and other non-health professionals (3%) (9).

The main function of LECs is to review ethical aspects of proposed clinical research, with particular attention to participants' rights, security and wellbeing, especially those of participants from vulnerable groups. Other functions include

monitoring of research, preparation of guidelines, and ethics education. Most LECs fulfil their main function very well, but at the expense of the other functions (9). Some LECs prove to be more efficient than others, depending on the size and location of the hospital. One explanation of the ethics committees' efficiency is that review of clinical trial protocols is important and also brings prestige and financial benefits to the hospital and investigators involved in research. Ethics committee meetings are held monthly and decisions are made by open vote. Despite the WHO recommendations, consensus is not accepted for decision making, because of the constraints of the SOP which require a final decision to be made by simple majority of the eligible to vote members of EC (19).

LEC approval is necessary for research to start, however it is not sufficient due to the advisory nature of the approval. Other bodies such as the BDA must also provide inputs. For example for phases I, II and III clinical trials approvals from the following two bodies should be obtained: the Department of Clinical Trials at BDA and the Specialised Committee for Approval of Clinical Trials based at the Ministry of Health (14). This adds another layer to the ethics review process and can delay the research. Second, decisions of the LEC are only advisory. In the future their role and authority could be enhanced by making their decisions binding, as is the case in other countries (e.g. Australian RECs). This would also reduce the time required for the ethics review and final approval by removing the unnecessary intermediate levels of approval.

Recently the workload of LECs has been reduced substantially because of the limited number of single-site clinical trial applications. The majority of clinical trials conducted in Bulgaria are international multi-centre trials and these applications are reviewed by the Multicentre Ethics Committee. The role of the LECs in multi-centre clinical trials is limited only to receiving copies of research-related documentation for record keeping purposes, site-specific approval allowing the hospital to take part in the study as a clinical site, monitoring, and notifications of adverse reactions (19).

Multi-centre clinical trials are reviewed by the Multicentre Ethics Committee (MEC) whose composition and functions are identical to those of LECs. Since the MEC's establishment in 2007 all applications for multi-centre clinical trials across the country are submitted to this committee located in the country's capital, Sofia. Members of the MEC must deal with a large volume of applications, and a workload that is beyond the current committee's capacity. This sometimes delays the approval process. If the workload continues to increase, it may necessitate the establishment of a second MEC located in another Bulgarian city.

Local ethics committees and the MEC are overseen by a central ethics committee reporting to the Council of Ministers. This committee has a predominantly advisory and arbitration role (to provide opinion when approached by LECs, the MEC or by contracting authorities) in the ethics review process of clinical trials (14).

The second type of ethics review is for clinical and non-clinical biomedical research involving humans, human tissue, animals and genetically modified animals or microorganisms, as well as research using personal biomedical information. It doesn't deal with applications for clinical trials of new medicines involving humans and biomedical research including human use of medicines (as mentioned above these are reviewed by LECs and MEC). This review is undertaken by ethics committees at universities or research institutes called University Research Ethics Committees. Their composition is similar to that of LECs; however they are monitored by a Central Committee on Research Ethics at the Ministry of Education and Science (17). Their work is guided by international and national guidelines such as the United Nations Universal Declaration of Human Rights, the Declaration of Helsinki, the Bulgarian Health Act, and the Regulation 31 of the Bulgarian Ministry of Health (3, 13, 20-21). Although there is currently no legal requirement for those conducting biomedical research at Bulgarian universities to seek ethics approval (except for clinical trials involving humans that need to be approved by an LEC or the MEC), many international funding organisations and academic journals require it. (A similar situation existed in Sweden before 2004, when there were only 10 ECs acting as advisory boards, and researchers were not required by law to obtain ethics approval. During the implementation of Directive 2001/20/EC, these committees were replaced by independent ethics committees and all research projects conducted on humans in universities had to be approved by them (22).

This raises the question of the necessity of a formal legal requirement for an ethics review process for biomedical research other than in clinical trials - such as qualitative studies or medico-social surveys. Currently, some of the university ethics committees in Bulgaria consider only a few research projects at each monthly meeting. Most of the applications require expert opinion on the ethical aspects of research with minimal ethical impact (e.g. laboratory experiments with animals (23). There is a positive move towards making the work of ethics committees more transparent and available to the public. Major university research ethics committees have their standard operating procedures published on their websites and include the contact details of the EC's secretariat.

Discussion and conclusions

The worldwide trend in the establishment of ethics committees in healthcare had an influence on Bulgaria, where biomedical research, especially in the form of international clinical trials, gained momentum in the mid-1990s. The establishment of ethics committees in large Bulgarian hospitals using a top-down approach was the first step towards the institutionalisation of the ethics review process. According to international guidelines, ethics committees must demonstrate independence from political, institutional or professional influences, and provide competent, efficient and timely review of research proposals (7). Not all these requirements were

met initially. In the first decade of the establishment of ethics committees, the training of their members was inadequate, and there was lack of clear guidance and consistency in their work. Some ethics committees performed their duties efficiently but others may have existed primarily to satisfy the legal requirement of the hospital conducting research.

During the preparation for EU membership there was a major change in the legislative basis underpinning the work of ethics committees. The composition of ECs remains the same; they are still dominated by physicians and lawyers, with minimal representation from other medical and non-medical professionals. The ethics review process would benefit from broader multidisciplinary representation and wider ethics expertise, which would enhance the decisions made by the committee.

A positive step towards increasing ethics committees' competencies and addressing the insufficient training of their members is the newly introduced compulsory preliminary ethics training and continuing education. In recent years, different certified training courses have been organised in the capital city.

Is this training sufficient? Has the quality of the ethics review process improved? The answers to such questions will come only from further research. The advisory character of ethics committees' decisions weakens their role, and the two layers of approval delay the start of the research. The situation could be improved by requiring only one approval, as is the case in other countries, and ensuring a timely ethics review process.

In 2007, LECs in existence at the time were assigned to review only single-site clinical trial applications and a new ethics committee for multi-centre clinical trials was established by the Minister of Health. This change left LECs without a specific role to play in the ethics review of clinical trials and led to an excessive workload for the new committee and delay in the approval process. Other EU countries such as Hungary and Portugal also experienced problems resulting from the centralisation of clinical trial assessment, evidenced by tensions between local ethics committees and the new central body (22). This too raises questions: Is centralisation of the ethics review processes the best solution for Bulgarian ethics committees? How will it affect the decision making process? Will this new system be effective?

To establish compliance with international ethical standards, the review of biomedical research other than clinical trials also needs to be made into a formal legal obligation.

Ethics committees play an important role, and they will continue to play an important role in the future. We need to look closely at their context and understand what they do. There have been a number of improvements in their work, making information about their role and functions available to the public. However, there is still need for further transparency of the ethics review process and the availability of this information in the public domain.

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Competence of ethics committees in patient protection in clinical research

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Abstract

Research Ethics Committees (RECs) are responsible for the protection of patients' rights and wellbeing. In this paper, we describe the findings of a survey of ethics committee members in a south Indian state. 29 members of 11 RECs responded to a questionnaire of 56 questions on their knowledge of and attitudes towards ethics review and the practices of the RECs to which they belonged.

Introduction

Research Ethics Committees (RECs) play a critical role in the conduct of good research. They are responsible for the

protection of patients' rights and wellbeing. The Declaration of Helsinki (1) and the Good Clinical Practice (GCP) guidelines of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use (2) have set international standards for ethics review of clinical research.

In India, clinical trials are governed by Schedule Y in the Drugs and Cosmetics Act (3). Schedule Y requires that the study protocol be reviewed and approved by an REC, following the Indian Council of Medical Research's (ICMR's) ethical guidelines for biomedical research (4). The ICMR guidelines lay down various requirements for RECs, including their composition and

the review and decision making process. The REC must include members from scientific as well as non-scientific backgrounds. It must conduct a thorough ethics review, be independent in taking decisions, and have written procedures for its functioning.

In 2003, the ICMR with the World Health Organization conducted a survey on 223 institutional ethics committees in India (5) which found that many committees did not meet regulatory requirements in terms of composition and function. Since then, no reports have been published on this subject. In this paper, we describe the findings of a survey of ethics committee members from three cities in a south Indian state.

Methods

A questionnaire was prepared based on the ICMR-WHO survey (5) with the addition of questions in order to address three domains: respondents’ knowledge of ethical guidelines, their attitude towards ethics review, and the practices followed by the REC to which they belonged. The survey was carried out from November 2008 to December 2009 after obtaining ethics committee approval.

The questionnaire was pre-tested on subject experts and members of RECs. The revised questionnaire had 56 questions: 12 addressed respondents’ knowledge of ethics review, 17 enquired about their attitudes to review, and 27 concerned the practices of the RECs to which they belonged. Knowledge and practice were assessed through a mix of open ended, multiple choice and true/false questions. Questions on attitudes used a 5-point Likert scale.

Those Research Ethics Committees involved in the review of sponsored clinical trial protocols and which had an experience of reviewing at least 10 protocols were identified and included. The names of the committees were obtained through our contacts with sponsors and investigators. Four cities were identified representing the North, South, East and West parts of the state.

The questionnaire was sent to members of 20 ethics committees after verbal permission was taken from the committees’ chairpersons. The authors met the chairpersons personally to brief them about the study, after which the questionnaires were sent by e-mail or courier, or hand delivered. An accompanying covering letter stated that participation was voluntary; the study was for academic purposes, and confidentiality of participants and committees would be strictly maintained.

In all the cases the questionnaire was routed through the chairpersons. If there was no response after 30 days, the chairpersons were sent a reminder. If there was no response 30 days after this reminder, the authors visited personally to collect the responses from individual members after fixing up an appointment. One response was received online. The remaining responses were either collected personally or, in the case of committees outside Bangalore, received by courier. Responses from one committee were received only after one

of the authors made a presentation to committee members on the study. The responses from other cities were received by courier.

Analysis

Descriptive statistics were used. For the practice- and knowledge-related questions, the frequency of correct (as defined by the ICMR guidelines) responses for each question was calculated and expressed as a percentage of the total and 95% confidence interval (CI). Likert ul analysis was carried out for the questions on attitudes.

Results

Of the 20 ethics committees contacted, responses were obtained from members of 11 committees (response rate 55%) representing three cities of the state. Nine committees were institutional RECs and two were independent committees. Of the nine institutional committees, two were private medical colleges. The remaining were from private hospitals and research institutions conducting clinical trials. The year of establishment of the committees ranged from 1999 to 2007. A total of 29 members from 11 committees completed the survey.

Profile of respondents

Out of 29 respondents, 15 were men and 14 were women. Their educational background is given in Figure 1.

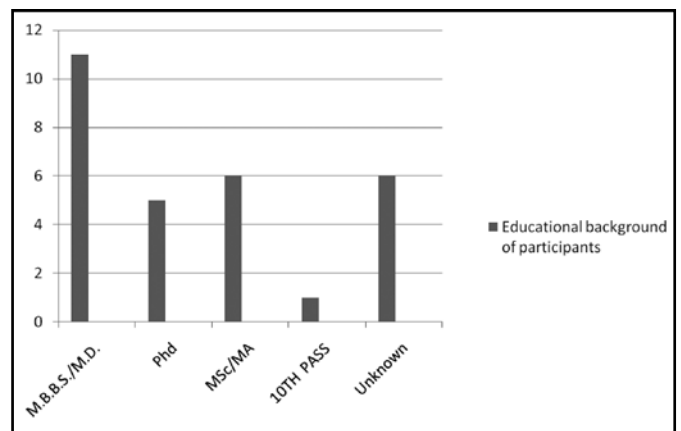


Figure-1

Seven respondents were the member secretaries of their REC and one was the chairperson. Two respondents were legal professionals, five were social workers or theologians, nine belonged to the layperson category, three were basic scientists, and one was a clinician. The background of one respondent is unknown.

REC composition and procedures

Membership and quorum: All the respondents reported that their committees contained a minimum of seven members and required a quorum for decisions. However, only 21% [6; 10-39] members were aware of how many people were necessary for a quorum.

Independence: All the respondents stated that their committees were independent in functioning and followed written standard operating procedures. 76% [22;58-88] reported that subject experts were invited when required. 24% [7; 12-42] stated that internal audits were conducted in their committees.

Honorarium: 97% [28; 83-99] respondents said they were paid some honorarium for participating in the REC. One person said their committee did not receive any honorarium.

Meetings: The frequency of meetings ranged from once a week to once in two months. 55% [16; 37-72] respondents said they met once a month, 28% [8; 15-46] met once a week, and 10% [3;4-27] met once in two months. 7% [2;2-22] respondents reported that the committee met as and when required.

Guidelines: All the respondents reported that their REC followed the ICMR guidelines (2006) while reviewing protocols. 52% [15; 34-69] members also referred to ICH-GCP; 31% [9; 17-50] followed WHO GCP guidelines in addition to those of the ICMR, 14% [4;6-31] also mentioned Schedule Y (2005). One member said they referred only to ICMR guidelines.

RECs' review procedures

The number of research proposals discussed per meeting ranged from 1 to 20. 83% [24; 65-92] respondents stated that proposals were sent to them two weeks prior to the REC meeting. 93% [27; 78-98] stated that the results of the discussion were communicated to the investigators within a week. All stated that the documents were archived for five years.

All the respondents stated that they reviewed the clinical trial protocol, informed consent form and case report forms. 28% [8; 15-46] stated that they also reviewed the translations of informed consent forms in various languages. 21% [6; 10-39] also reviewed the financial agreement between sponsor and researcher. All the respondents stated that they reviewed the study design in relation to its objectives and the informed consent process described in the protocols. 52% [15; 34-69] said they were provided with checklists for the review of clinical trial documents.

83% [24; 65-92] members said the decision to approve/reject the protocol was taken during the meeting with all members participating in the final decision making.

93% [27; 78-98] respondents said that periodic ethics review of ongoing trials was conducted. 28% [8; 15-46] respondents representing 3 RECs reported that on site monitoring was conducted. 72% [21; 54-85] respondents stated that the REC received a copy of the report at the end of the clinical trial. 52% [15;34-69] the respondents had received formal training in GCP.

There were 16 questions out of the total 27 practice questions pertaining to the elements of protocol reviewed. Each right answer was given a score of one. The mean score out of 16 was 12.96 [11-14].

Respondents' attitude towards their roles and responsibilities

Responses to 17 questions addressing attitudes were given on a Likert scale.

76% [22; 58-88] of the respondents strongly disagreed with the statement that trials may start before REC approval in order to save time. 69% [20; 51-83] agreed or strongly agreed that the key focus of ethics committee approval is patient protection. All also strongly disagreed with the statement that ongoing trials need not be monitored by the REC. 91% [27; 78-98] of respondents strongly disagreed that the honorarium might improve their performance. 41% [12; 32-51] felt the need for training of members, 34% [10; 25-44] for regulations for ECs, and to define a limit on the number of protocols reviewed per meeting 28% [8; 20-38].

Respondents' knowledge base

Knowledge of the respondents regarding regulatory guidelines, ethical principles, and clinical trial documents was assessed in 12 questions. More than 50% answered all the questions correctly. However, 69% [20; 51-83] were not aware of the different phases of clinical trials and 83% [24; 65 -92] could not name the regulatory body that approves the conduct of trials in India. The responses were also scored individually and the mean score out of 12 was 10.3[8-12].

Discussion

Based on the responses given by REC members in this survey, all the committees covered in this survey seem to function independently and with appropriate representation of persons with different qualifications as specified by the ICMR guidelines.

However, many members were unaware of the quorum requirement. Decisions taken by an ethics committee in the absence of quorum are not valid as per Schedule Y (3)

One third of committees reported conducting internal audits to ensure the quality of their procedures and function. This is an encouraging sign.

Onsite monitoring by RECs has been shown to prevent fraud and malpractice (6). In our survey, though many respondents reported that their RECs carried out periodic reviews of ongoing trials, only a few indicated that they carried out onsite monitoring.

The REC should examine the financial agreement between the investigator and the sponsor as any financial incentives can have ethical implications for the research. However, most committees did not review this document.

Though all respondents reported receiving the English version of the informed consent form, they did not review the back translations of the local language forms into English. In India, informed consent forms are prepared in many local languages and it is necessary to verify the translation of the informed

consent form into the local languages and its back translation into English to ensure that all participants get the same information. This is a requirement as per Schedule Y but the RECs surveyed are apparently unaware of this requirement.

Training in GCP is meant to equip REC members to conduct effective ethics review. The need for training was apparently felt by only 12(41%) of the respondents which implies that they are not completely aware of their responsibilities

4 (14%) respondents were unsure of the documents required to be provided to participants. Though the letter of approval from the Drugs Controller General of India is an essential document to be submitted to the ethics committee, 5(17%) members could not name the regulatory body for clinical trials in India.

Further, though the quality of ethics review can be affected by the workload, many members did not feel the need to restrict the number of protocols to be reviewed per meeting.

It is also a matter of concern that 41% felt that REC approval posed a hurdle in the process of clinical trials. This suggests that the critical role of RECs in the review process is not understood by all members.

The first survey on RECs was conducted by ICMR-WHO in 2003. 1,200 questionnaires were mailed to medical institutions out of which 223 responded (response rate: 18.58 %). It was observed that REC members were appointed by lobbying; many committees did not include legal experts; standard operating procedures were not followed, and records were poorly kept (5). The ICMR conducted a survey of RECs of institutions conducting clinical trials funded by the ICMR in 2006-2007 (7). The response rate was 42.5%. 64% of the committees had standard operating procedures for review, 39% had members trained in bioethics and almost all had a multidisciplinary composition as per ICMR norms. Our study had a response rate of 55 %. 52% reported training in good clinical practice. All

the RECs had written standard operating procedures and met requirements for the composition of the committee.

The findings of our survey suggest that there have been some improvements in the functioning of RECs in the past decade. However, our survey was based on a small sample, was restricted to a single state, and had a poor response rate. Our study should be viewed as the first step towards collecting more systematic information on the functioning of RECs in India.

We suggest that mandatory registration, accreditation and regular audits will provide such information, in addition to performing the function of regulating RECs.

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Global Summit of National Ethics Committees: an essential tool for international dialogue and consensus-building

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Abstract

Held for the first time in 1996, the Global Summit of National Ethics Committees (NECs) is a key platform for dialogue and fostering consensus on ethical issues at a global level. At the Eighth Global Summit meeting, which took place in Singapore in

July 2010, important decisions were taken to ensure the continuity of activities between the Summits. This article intends to briefly retrace the history and analyse the role and functioning of the Global Summit. It also discusses future challenges for international collaboration of NECs.

Historical background

The first national ethics committee (NEC) was established in France in 1983. Following this, an increasing number of nations have created official bodies to provide advice to their executive and legislative branches, and often to the general public, about bioethics. In 1996, the US National Bioethics Advisory Commission asked the French National Consultative Committee on Ethics to jointly invite the other NECs to attend an international summit meeting held in San Francisco in conjunction with the Third World Congress of Bioethics. Since then, eight Global Summits have taken place: San Francisco (1996), Tokyo (1998), London (2000), Brasilia (2002), Canberra (2004), Beijing (2006), Paris (2008) and Singapore (2010).

As the formal Permanent Secretariat of the Global Summit of NECs, the World Health Organization (WHO) maintains a close collaboration with NECs around the world.

Overview of the current situation of NECs

A recent web-based research (1) identified 93 countries (48.2% of WHO member states) with national ethics committees: 22 in the WHO African Region (47.8% of countries), 13 in the Region of the Americas (36.1% of countries), nine in the Eastern Mediterranean Region (42.8%), 38 in the European Region (71.7% of countries), four in the South-East Asian Region (36.4% of countries) and seven in the Western Pacific Region (25% of countries). Some of these committees are national ethics committees dealing with a broad range of ethical issues in health, while others are exclusively or predominantly research ethics committees. Sixty per cent (56) of these committees have some form of publicly accessible website, although not all of them have information in the English language. The differences in composition, goals and functions among NECs in the various regions arise from a variety of reasons that are historical, cultural and political. The diversity in mandates and missions of NECs is reflected in the range of organisational structures (2). Termed "National Commissions", "Advisory Committees", or the like, NECs can be appointed by chief executives, ministers of health, or legislatures, to analyse and offer recommendations about current issues in bioethics, or the ethics of health more generally, especially if legislative action or change in national policy is required.

International collaboration

Besides the WHO, several other international organisations have developed a wide range of activities in collaboration with NECs (3). These activities include:

- a) Setting up and training new NECs (see the project "Assisting Bioethics Committees" (4) of the United Nations Educational, Scientific and Cultural Organization, UNESCO). To date, several committees, mainly in Africa, have been established under this initiative (5);
- b) Facilitating dialogue on emerging issues relating to the development of science and technology (see, for instance, NEC Forum and International Dialogue (6) organised by

the European Commission, and the cooperation between NEC and the Council of Europe through the European Conference of NEC, COMETH); and

- c) Fostering global debate and consensus on issues of public health and research.

Using the platform of the UN Interagency Committee on Bioethics (UNIACB), WHO, UNESCO, the European Commission and the Council of Europe have over the last seven years increasingly striven to strengthen synergies and complementarities. UNESCO and WHO have also co-organised two regional summits of the NECs of the Eastern Mediterranean region, in 2007 and 2009.

In addition, the institutional development of NECs is fostered by the complementary activities and support offered by international organisations or institutions. Taking advantage of these opportunities, NECs can strengthen their national role through exchange of information and contribution to international debate.

Eighth Global Summit of National Bioethics Advisory Bodies

The Eighth Global Summit was hosted by the Bioethics Advisory Committee (BAC) and the Ministry of Health in Singapore from July 26 to 27, 2010. The meeting drew representatives from 33 countries and four regional and international organisations. The agenda was collaboratively developed by the BAC, the European Commission and the WHO.

The focus of the first day of the meeting was on ethical issues in organ, tissue and cell transplantation, research ethics committees and tuberculosis (TB) control. The WHO's three new guidance documents on these subjects were discussed. Also presented on the first day was an update on bioethical developments in Jamaica and Saudi Arabia. These developments make clear that there is considerable diversity in approaches to addressing bioethical concerns. In the light of this, a suggestion was made for an online repository to be established, with information on the NECs, their functions, work and approaches.

The session on organ, tissue and cell transplantation provided an opportunity for NECs to discuss the implementation of the guiding principles set out in the WHO's resolution (7) on the subject, which was adopted by the 63rd World Health Assembly in May 2010. In addition, NECs also discussed the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism* (8) that was prepared by the Transplantation Society and International Society of Nephrology, and adopted by participants at the International Summit on Transplant Tourism and Organ Trafficking in May 2008. Some of the more immediate practical concerns relating to the implementation of the guiding principles have been identified as: difficulties in recognising and removing inducement in various guises; providing longterm care for donors, and devising means of reducing reliance on living organ donors. In the long run, however, social and cultural factors (such as poverty and illiteracy) that

contribute to organ trafficking and related issues need to be better understood and addressed.

In the session on research ethics committees that followed, a standards document entitled "Standards and Guidance for Research Ethics Committees that Review Health Related Research with Human Beings" and prepared by the WHO secretariat was considered. This document served to outline key ethical requirements for the operations, functioning and governance of a research ethics committee that global stakeholders would regard as non-negotiable. These requirements include multi-disciplinary membership and clearly established terms of reference. The document was also intended to provide concrete guidance on how such committees could establish procedures to meet these international standards. While there was some consensus on operational procedures, many NECs felt that further clarification of roles and ethical expectations was required. While difficult to achieve, some level of harmonisation was generally felt to be important given the increasingly transnational nature of research.

The third WHO document that was considered and discussed by NECs was concerned with ethical guidance for programmes relating to care for and control of TB. The document, subsequently published in November 2010 (9), provides a comprehensive analysis of ethical issues and guidance to governments and other stakeholders in implementing TB care and control programmes in an ethical manner. Within the deliberative framework set out by the document, the discussion of the NECs was mainly focused on devising the appropriate balance between enabling research for public benefit and the autonomy of the patient or research subject. It was proposed that implementation issues and the role of ethics bodies be evaluated at the next Global Summit meeting.

The second day of the Eighth Global Summit comprised sessions on synthetic biology and biobanking, stem cell research and therapy, medical ethics and updates on bioethical activities of the European Commission, the Council of Europe and the WHO.

Several NECs have evaluated or are evaluating the ethical implications of synthetic biology. A document that was considered by NECs was an Opinion of the European Group on Ethics of Science and New Technologies on the ethical, legal and social implications raised by synthetic biology (10). As the Eighth Global Summit was the first occasion on which this field was discussed on a global level by NECs, it was felt that ethical concerns have to be better defined. Most immediately however, safety issues are most pressing and need to be addressed.

For biobanks to realise their full potential, international collaboration and exchange of samples and information are essential. There are numerous challenges entailed in operating and maintaining biobanks. One particular challenge is whether or not a more general form of informed consent can be ethically acceptable, given the fact that new research interest may emerge over time for which consent has not specifically

been given by sample donors. The experiences of NECs in France, Austria and Greece were considered in this session.

In the session on ethical issues in stem cell research and therapy, new policies in China and Japan were considered. It was felt in both countries that a regulatory framework would have to be developed for first-in-man trials involving human pluripotent cells, whether derived from an embryo or otherwise. Denmark presented its deliberations and discussions on the use of chimeras and hybrids in research. Finally, NECs considered the Australian experience with disclosing genetic information to a person's genetic relatives; the UK's Nuffield Council's ongoing deliberations on the ethics of medical profiling and online medicine; and current debates in Switzerland on end-of-life ethics. It was agreed that the next Global Summit meeting would follow up on these important medical ethics concerns.

A brief report on the Eighth Global Summit, as well as the final agreement of participating NECs, is available at the website of the BAC (11).

Outlook for the future

Over the last 14 years, the Summits have proven to be a valuable instrument to foster international debate on ethics and health and to facilitate collaboration between national ethics committees. They offer a critical forum for identifying pertinent issues of global importance, and in respect of which international agreements and cooperation are needed.

The international community needs local ethics committees to be committed to meeting global ethical challenges in a responsible and collectively accountable manner.

There are a number of challenges ahead. The first is to increase participation of low and middle income countries in future Global Summit meetings. To achieve this as a mid-term goal, the establishment of additional NECs, particularly in Africa and Asia, is necessary. The second is to build consensus on emerging international issues, such as ethics of global research, and to empower as well as encourage NECs to implement internationally-agreed guidance. Finally, as agreed in the Eighth Global Summit, continuing collaboration among NECs from different regions is necessary. For most of the NECs, the challenge is not so much to agree on general ethical principles, but to build a global consensus on modalities for implementation in health policies.

The next Global Summit is scheduled to be hosted by the Tunisian NEC in October 2012. In addition to the priority topics identified in Singapore, the focus will also be on protection of vulnerable populations and equity of globalisation. The Ninth Global Summit will be the first time that NECs will meet on the African continent.

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Bioethics governance in Israel: an expert regime

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Abstract

This paper provides an overview of bioethics governance in Israel through an analytical description of the legal framework for the interface between individuals and biomedical practices. There is no national agency with general oversight of bioethics policy and decision making, and the rules that apply to individual usage of biomedical technologies are laid down in a multitude of different statutes, regulations and administrative directives. Expert committees play a central role in this regulatory system in two capacities: as governmental advisory bodies that recommend policy; and as decision-making bodies that resolve conflicts around patients' rights or grant individual access to biomedical technologies. This decentralised system of governance through expert committees allows for adaptation to dynamic technological developments and flexibility in accommodating creative societal usage. At the same time the experts are the agents of the state's bio-power at the expense of personal autonomy and open public deliberation.

The paper is part of a larger study investigating Israel's bioethics governance and its regime of experts, which includes an examination of the normative level of regulation, and an analysis of the composition of the expert committees. Our findings suggest that Israel has a decentralised system of governance with piecemeal regulation that has established a bioethics technocracy, governed by the ministry of health and dominated by the medical profession. The present paper is confined to a description and discussion of the legal framework of Israel's expert bioethics regime. Here, our major conclusion is that Israel has established a technocracy of official expert ethics committees, which controls life and death decisions.

Introduction

Israel has a sophisticated healthcare system with generous public funding for universal access to advanced biomedical technologies from the beginning to the end of life. It is at the forefront of research in medically assisted reproduction (MAR), and has extraordinarily high rates of consumption of reproductive technologies (1-5). Also at the end of life the norm is rigorous medical treatment (6: 136).

Since the mid-1990s, there has been a flurry of legislation in Israel to address the ethical challenges of new biomedical technologies. Some of these laws are known for breaking ground in the legal regulation of biomedical technologies. In 1995 Israel was the first country in the world to legalise and regulate surrogacy (7). Likewise, in 2008 it enacted a unique organ transplantation law that regulates compensation for living donors and grants donor-card holders priority in organ allocation (8).

There is no national agency with statutory powers to exercise general oversight over bioethics policy and decision-making, or to gather information and report to the public on new biomedical practices and their socio-ethical implications, as opposed to the UK or France. Nor has any public authority been mandated by statute to engage or consult the general public in deliberations on bioethical dilemmas. Instead, Israel's governance of bioethics is characterised by piecemeal regulation, and the rules that apply at the interface between individuals and biomedical practices from the beginning to the end of life are laid down in a multitude of different statutes, regulations and administrative directives.

In this paper we examine the role played by expert committees

in this decentralised regulatory system. We find that the mechanism of an expert committee with the power to make decisions has become a key instrument in the regulatory system that evolved, and that expert committees act in two capacities: as governmental advisory bodies to recommend policy; and, as decision-making bodies with the authority to allow otherwise forbidden practices in individual cases.

Expert advisory bodies

While there is no central bioethics regulatory agency, expert committees play a central role as governmental advisory bodies to recommend policy in relation to the use of new biomedical technologies.

As in other countries, and in accordance with the World Medical Association's Declaration of Helsinki on ethical principles for research involving human subjects, medical experiments may not be conducted unless they have undergone review and approval by a research ethics committee (REC) under public health regulations (9). In Israel RECs are called 'Helsinki' committees, because the Helsinki Declaration provides the normative content for domestic law. Most medical research in Israel takes place under the purview of hospital committees, but where the subject of the proposed research goes to "artificial" reproduction or genetics it must come before a national committee. This national Helsinki committee (NHC) was vested with advisory statutory powers under two statutes enacted by the Knesset: that which sets a moratorium on reproductive cloning and genetic manipulation of eggs and sperm (10); and that which regulates genetic testing and research (11).

In addition, in 2004 the cabinet appointed a National Bioethics Council (NBC) (12), as an advisory body to all branches of government on bioethics policy. However, the relationship between the NBC and the NHC is not clear. Furthermore, in June 2010 the minister of health appointed an ad hoc committee, called the Fertility and Reproduction Committee (FRC), with the mandate to recommend legislation on a variety of matters related to MAR, including gamete donor anonymity, pre-implantation genetic diagnosis, and extra-territorial practices of reproductive tourism. The multiplicity of advisory committees creates some overlap and confusion. For example, the subject of fertility preservation (i.e. freezing of egg cells for future use without medical indication) was included in the mandate of the FRC, but the NCB had already issued guidelines on the matter in October 2009.

The FRC was appointed following a petition to the Supreme Court to allow gay couples access to surrogate mother arrangements (13). A similar petition in 2002 to allow single women access to surrogacy (14) also led to the appointment of an ad hoc committee at the ministry of health (MoH), which recommended no change in the law (15). Indeed, most advisory expert committees have been appointed ad hoc within the MoH. Sometimes these committees are appointed subsequent to court decisions on actions brought by individuals seeking relief against infringement of their autonomy to use a biomedical technology, as in the two cases of surrogacy

mentioned above. More often, committees are appointed independently to recommend legislation. For example, in 1991 a "public-professional commission" known as the Aloni Commission was appointed jointly by the minister of health and the minister of justice to recommend legislation on in vitro fertilisation, which ultimately led to enactment of Israel's surrogacy law. Likewise the Steinberg committee led to the Dying Patient Law (16). And other ad hoc committees prepared the ground for other legislation, such as the laws on organ transplantation and eggs donation.

Expert decision-making authorities

Expert committees also exercise actual decision-making powers in individual cases. Various statutes, regulations and administrative directives establish such committees and vest in their expert members the authority to allow otherwise forbidden biomedical practices, or the discretion to grant or deny individual access to a biomedical technology.

The first instance of a committee with decision-making authority in Israel's legal system is found in the law of abortion. In principle, abortion constitutes a criminal offence, but the medical profession took upon itself to self-regulate the provision of abortion as a 'therapeutic exception', by establishing hospital committees that would approve the interruption of a pregnancy on medical grounds. This practice was officially incorporated in Israel's law when the Knesset amended the Penal Law in 1977, concurrent with a worldwide trend to liberalise anti-abortion laws. The amendment allowed for legal abortion on certain statutory grounds, as an exception to the general criminal prohibition. The decision on whether or not there were grounds for legal termination of the pregnancy was vested in a hospital committee composed of two physicians and one social worker, and headed by a physician (17).

Research ethics committees might also be seen as authorised to permit an otherwise forbidden practice, since medical experiments may not take place without their approval. Of particular note is the authority of Israel's national Helsinki committee (NHC) under its anti-cloning law (section 5(a)) to permit certain exceptions to the prohibition of genetic manipulation of gametes. The NHC also acts as a decision-making body in relation to the approval of embryonic, stem cell and cloning research. Since Israel's anti-cloning law prohibits only reproductive cloning, all other matters of embryonic research are left to the discretion of the expert members of the national committee without guidance from the legislature and without public debate.

At the institutional level, besides the Helsinki committees, hospitals are supposed to establish committees under the Patient Rights Law, 1996 (18) and under the Dying Patient Law, 2005 (19). (In fact these committees are not always operative (20), but the present article analyses the policy as expressed in the law, rather than the practice.) The idea of including ethics committees in the Patient Rights Law was inspired by the voluntary practice in the USA of referring medical dilemmas to

an advisory ethics committee (21). However, the Israeli statutory committees are vested with actual authority to make decisions.

Ten years later, the Dying Patient Law also established a distinct system of institutional and national committees to resolve the special conflicts and ambiguities related to end-of-life medical care (22). These committees too have decision-making authority rather than an advisory mandate.

While these committees have statutory powers to resolve conflicts relating to doctor-patient relations, other statutes have established expert committees with the authority to grant or deny individuals access to biomedical technologies. These committees make decisions about many individual matters, including surrogacy, live organ donation, eggs donation and pre-implantation sex selection. As in the case of abortion, here too we find the model of 'forbidden but allowed', i.e., prohibiting a certain practice, but allowing it if approved by an expert committee. Thus the laws that regulate surrogate motherhood (23), organ donation (24) and eggs donation (25) all first ban the relevant practice as a matter of principle, except in accordance with the provisions of the law. Then they lay down the circumstances and conditions under which a statutory committee may approve the practice, despite the prohibition.

An outstanding example can be found in ministry of health (MoH) guidelines with respect to sex selection by means of pre-implantation genetic diagnosis (PGD) (26). The directive states that sex selection through PGD other than for medical purposes is prohibited. At the same time it may be performed "solely in extraordinary, exceptional, rare and special cases" with the approval of an expert committee, and under certain accumulative conditions. One of the conditions is that the applicants have at least four children of the same sex and do not have children of the other sex. And yet again, the expert committee has discretion to allow the procedure "in extremely rare exceptional cases" even if this condition is not fulfilled.

Discussion

Israel is often described as permissive in its approach to new biomedical technologies. But this permissiveness is not as liberal as it appears to be, because it comes hand in hand with intense regulation and control by the expert committees. We have seen that Israel has multiple committees of experts with either advisory capacity or actual decision-making authority in various matters that raise bioethical debate. At the national level the multiplicity of advisory committees creates overlap and confusion. At the hospital level too there will be no less than three committees - a research ethics committee, a patient rights ethics committee, and a dying patient committee. This means that all matters related to the protection of the rights of individuals, as either patients or participants in medical research, or to the resolution of conflicts in patient-doctor relations, are subject to the authority of expert bio-ethical fora rather than to the jurisdiction of the courts of law. This expert jurisdiction is in contrast with Germany, for example, where the power to make decisions, at least as regards end-of-life care is in the hands of legal experts. (27: 387-8).

Furthermore, a typical feature of the regulation of specific bioethics issues (abortion, surrogacy, organ donation, eggs donation and PGD sex selection) is that the practice is prohibited as a matter of principle, but allowed if approved by an expert committee. Hence individuals who wish to partake in such medical practices must receive the approval of an expert committee, which is vested with decision-making authority. The regulatory framework typically delineates what is forbidden and what is allowed in general terms, but leaves a large scope of discretion to the experts to depart from those terms. The pattern of deferring decisions to expert committees makes for a large degree of flexibility in individual cases, and is very much in line with the casuistic tradition of Jewish law. However, from the point of view of the individual, the experience may be of encountering bureaucratic barriers, which entail intrusion into privacy, humiliation, uncertainty, confusion, alienation and, above all, dependency on the appointed experts. This is at odds with the central value of personal autonomy in Israel's purportedly liberal bioethics discourse.

Different studies as well as data provided by the MoH itself indicate the power exercised by expert committees. Data from the MoH with respect to sex selection show that in the last five years less than 10% of the requests were approved by the expert committee and the vast majority of requests were dismissed (28), which amounts to restriction of personal choice and autonomy. On the other hand, despite the fact that most requests for abortion are approved, Amir (29) has argued convincingly that abortion committees are a mechanism which controls and regiments women's reproduction, and that women's experience of these committees is unnecessary intrusion into privacy and humiliation. Likewise, the surrogacy approvals committee imposes very strict screening criteria on candidates for surrogate mothers, which infringe on their privacy (30). The committee's guidelines list 15 conditions that are laid down in the law and must be met, as well as 16 additional conditions that the committee adopted in light of the experience it gained over the years. Fourteen of these additional conditions apply to the surrogate mother candidate, who must show among other things that she is able to maintain appropriate interpersonal relations; she is not in the heat of a crisis; she has a stable character, is responsible and has the ability to persevere; she has family and social support systems, and a sound parental relation with her children; and she has economic and social management capability.

While the expert regime restricts personal autonomy and privacy and comes in place of judicial review of biomedical practices, it is also worth noting the lack of any significant public engagement in making policy about bioethical issues that have broad social implications. Although the parliament provides a forum for public debate, and advisory committees typically invite comments from concerned parties, participatory practices for engaging and involving the public that are widespread in other countries are noticeably absent in Israel. This is in contrast to the United Kingdom, also a leading country in terms of new controversial medical technologies, where the Human Fertilization and Embryology Authority has conducted

multiple public consultations, since policy is based on social acceptability (31). In one exceptional case in Israel, where a public survey was conducted on the issue of sex selection, the finding was that public opinion was much more permissive than the policy (32).

Our major conclusion is that Israel has established a technocracy of official expert ethics committees, which controls life-and-death decisions. In other words, the governance of bioethics in Israel is characterised by a web of expert committees to which individuals are subjected either for approval of access to the technology or to resolve disputes with medical authorities. The experts have power not only to decide the fate of individuals but also, by so doing, to set moral boundaries demarcating good and evil, deviance and normality, insiders and outsiders (33, 34). Israel provides a clear example of the institutionalisation of expert advice in diverse official committees. In Israel experts are the legal and ethical gatekeepers (35) of new technologies which have the potential to manipulate individual life and death choices. In effect, Israel's expert bioethics committees act in the service of the state as the agents of what Foucault termed bio-power and governmentality, fabricating individuals and their bodies within a network of instruments of power (36-7)

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Endnotes

1. *The essence of the statutory function of these ethics committees is to permit exceptions from the general rules of patient rights at the request of a doctor. These exceptions pertain to the administration of non-consensual medical treatment, or the non-disclosure of personal medical information. (20)*
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ARTICLES

The role of basic laboratory services in strengthening primary health centres

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Abstract

Several proposals have been initiated under the National Rural Health Mission (NRHM) to strengthen public health services in the country. Primary health centres (PHCs) are the basic structure for implementing primary healthcare, and basic laboratory services are essential not only for strengthening PHCs but also for their sustainability. In order to accomplish these, possibilities within NRHM are discussed.

Introduction

As the National Rural Health Mission (NRHM) completes half a decade, it is important to examine the ways in which the mission has been able to strengthen primary healthcare in rural settings. This will help explore avenues for further improvement. Though evaluations were not part of the mission during the early phases, several such initiatives were carried out, most by civil society organisations (1) and some by academic institutions. The evaluations were largely concerned with the extent to which the programme could accomplish communitisation and decentralisation, through Accredited Social Health Activists (ASHAs), Rogi Kalyan Samitis (RKSs) and Village Health and Sanitation Committees (VHSCs). Another core area, the strengthening of public health services - especially primary health centres - was discussed primarily in the context of improving quality by attaining Indian Public Health Standards (IPHS). Here the final goal to be achieved is clearly stated but the focus of the processes involved in accomplishing it is not sufficiently clear.

Against this background, the present article examines the scope for strengthening primary health centres (PHCs) by introducing basic laboratory services, and the various options by which this end can be achieved through NRHM.

Strengthening PHCs through the NRHM

As per the commitment of the NRHM to improve public health services, one of the core strategies has been to strengthen PHCs and community health centres (CHCs) to meet the level of Indian Public Health Standards (2). The Mission envisages strengthening PHCs by allotting a second doctor to address the shortage of manpower, and by providing for adequate drug supply and equipment through the RKS or other resources. Further, a component in the NRHM on strengthening disease control programmes not only focuses on infectious diseases like malaria, tuberculosis, kala azar and filaria but also calls for

new initiatives for control of non-communicable diseases (2). The disease control programmes are presented as justifications for the need to improve functioning of PHCs in the country, though very little is mentioned about how to accomplish this.

The recent performance audit report by the Comptroller and Auditor General (CAG) on the implementation of the NRHM exposes the condition of PHCs, thereby reaffirming the need to strengthen them. As per the report, which is based on PHCs' performance during 2008, there are 8,613 PHCs fewer in the country than planned under NRHM with states like West Bengal, Jharkhand and Bihar having a shortfall of more than 1,000 PHCs. Further, of the total 687 PHCs selected for the audit, 120 (17.5%) were found to have inadequate water supply and 93 (13.5%) did not have electricity. Regarding support services within the PHC, 52% of them have a shortage of laboratory technicians (3). In comparison, there is a 11% shortage of medical doctors and 29% shortage of pharmacists. This highlights the need to examine, in detail, the role of laboratory services in PHCs.

The low priority given to improving support services like laboratory services can also be due to the perceived functions of PHCs. In some communities, PHCs are viewed only as centres to carry out preventive care activities with or without the support of national health programmes; sometimes they are seen as mere dispensaries. In the process, the core function of PHCs, namely medical care, has been sidelined. This is despite the fact that medical care was considered the primary function since the conception of the PHC in the Bhore committee report, as well as subsequently when PHCs were established for the first time in 1952 under the community development programme. Even six decades later, and even under the recent initiatives of the NRHM, the PHC's core function, medical care, is not adequately addressed.

Medical care as PHCs' major function

Any attempt to improve the functioning of PHCs should aim at improving their primary function of medical care. Medical care implies diagnosis, prognosis and treatment. Early diagnosis and treatment are essential not only as curative interventions but also for effective control of communicable diseases. This was demonstrated for TB (4), leprosy (5) and malaria (6). Thus, any initiative to strengthen medical care in PHCs will only add to their preventive component.

However, if one examines the history of various control programmes in our country, it becomes obvious that vertical approaches to disease control programmes have weakened, rather than strengthened, the medical care component of the PHC (7). Laboratory services in the PHC are the worst affected in this process. This is evident from the facilities in many PHCs; some can only examine for malaria parasites and others can test only for mycobacterium TB. This could also be due to inadequate training of lab technicians, the reasons for which can be traced back to the vertical approaches in disease control programmes.

In order to address the problem of inadequate laboratory facilities at PHCs, states like Bihar and West Bengal have entered into public private partnerships to provide laboratory services (8). However, any kind of public private partnership for core services like laboratory services defeats the very purpose of strengthening medical care in PHCs and thus strengthening public health services. One of the basic assumptions for entering into partnership is the explicit acknowledgement of the inability of the public sector to render those services.

The role of basic laboratory services in medical care

The debate about the role of technology and its utility in medical practice is an old one, whether it is the use of the stethoscope or the use of laboratory investigations. The role of any medical technology should be supplementary and contextual rather than a substitute for medical consultation. In the current situation, it has been found that patients also demand laboratory investigations as part of medical care. In other words, in the current age of 'laboratory medicine', medical care becomes comprehensive only with the support of basic laboratory facilities. Moreover, studies have also found that facilities like laboratory support along with other infrastructural facilities are an important determinant influencing the utilisation of health services (9).

One should be cautious while developing laboratory facilities at the PHC level. Here one of the basic principles of primary healthcare, namely, appropriate technology, becomes relevant. The kind of laboratory facilities to be developed should be 'basic', and not high-tech, and meant to equip the health facility to render effective medical care. Here, the reference point can be the IPHS which identifies facilities for routine blood and urine tests, basic tests for haemoglobin, TB, malaria and typhoid, along with those for reproductive tract infections, pregnancy, syphilis, faecal contamination of water and so on (10). Further, the increasing contribution of non-communicable diseases to total mortality, in some states, justifies the laboratory requirements for some of those diseases. These requirements include facilities for routine blood and urine tests for diabetes, and lipid profile and electrocardiogram for coronary heart disease.

Ensuring basic laboratory services at PHCs not only improves the quality of medical care but is also capable of creating a greater demand for essential drugs at the facility. This in turn can improve the potential of the PHC as a centre providing

primary healthcare. This was evident from the experiences of a rural laboratory in Chattisgarh, which has demonstrated that a trained technician with a microscope is able to support the efforts of the physician by systematically distinguishing between a range of diseases like TB, malaria, typhoid, upper respiratory tract infection, and pneumonia with better specificity. A proper diagnosis of these and other common acute illnesses can not only improve the treatment modalities but also can bring down the cost of treatment by minimising the use of the syndromic approach to treat minor ailments (11). Moreover, this can also be a starting point for setting standard treatment guidelines and protocols for medical care, again mentioned under strengthening of PHCs under the NRHM (2). Thus, we must devise specific strategies for strengthening PHCs by giving due consideration to the components of medical care. Improvement of medical care can influence the ambit of PHCs which in turn influences public opinion about PHCs.

Options within the NRHM for strengthening PHCs

Several evaluations of the NRHM have identified the strength of the Rogi Kalyan Samiti (RKS) as a means to empower PHCs; less has been said on its scope for operation. One of the major strengths of RKS is its ability to generate funds. Inevitably, this has led to the criticism that these funds are inadequate and sometimes used irrationally. It was found that during the initial years, the funds were not adequately utilised (12). In recent years, as well as earlier, the majority of funds were not used specifically to improve the care component in PHCs. The initial response also suggests that the utilisation of funds under the RKS was diverse, as is expected of any untied funds, but very little has gone into improving the quality of care in terms of providing drugs and so on. This led to a call for streamlining annual maintenance grants and untied funds through proper administrative mechanisms and procedures. When it comes to RKS funds and their utility, it is shocking to find that funds are not properly used as per the Accountant General's instructions; further, the amount spent under the RKS has contributed little to improve healthcare delivery in PHCs. Instead, most of the funds were used to 'beautify' the institution even when the physician is absent or drugs are inadequate (1, 11). Moreover, an analysis of fund utilisation between 2005 and 2008 found that almost 50% of the funds remained unutilised in many of the sample districts (11). The rate varied from 98 % in Bihar to 31 % in Karnataka (3). When the reasons for inadequate utilisation were examined, the initial responses were "fear to use the funds", "inadequate knowledge" and "delays" (1). On further inquiry, it was found that the diverse circumstances of PHCs also prevented policy makers from coming out with a common prescription for PHCs regarding areas in which one should spend RKS funds. This also comes from the fact there is inadequate knowledge on how exactly to strengthen PHC functioning.

Thus in order to strengthen the primary function of the PHC, namely medical care, the starting point is the development of a support system. To improve medical care in places where physicians and drugs are available, developing basic laboratory

facilities becomes a priority. This improvement could be procuring a microscope, training a lab technician, and so on. Here the issue is the diversity of situations in which PHCs operate in the country. In states where communicable diseases are predominant, laboratory facilities should be developed accordingly, whereas in states where non-communicable diseases take the greatest toll, facilities to address those needs should be given priority. In addition to the resources from the RKS, funds allocated under the NRHM for non-communicable diseases can also be used. As mentioned earlier, the current scenario is such that 13-17% of PHCs still lack adequate water supply and electricity facilities, drugs are inadequate in some, and there are no laboratory facilities in others. In this situation, members of RKS, viz. panchayat raj institutions members and medical officers, would benefit from a priority-based flowchart on how much to spend and for what purpose. Such a flowchart can be the tool to identify the needs of PHCs, giving due consideration to the prevalent scenario. For example, in those PHCs that lack water supply and electricity, priority should be given to address these lacunae first and not necessarily through the RKS but also through infrastructure building under the NRHM. Once these two facilities are established, priority should be given to providing for doctors, drugs and then laboratory facilities. This kind of priority list will not only improve RKS functioning but can also be used as a guideline for monitoring RKS fund utilisation.

Conclusion

The present article is an attempt to enquire into the possibilities of the NRHM to strengthen the core functions of PHCs, namely medical care. The need for strengthening the role of laboratory facilities in PHCs becomes important in the current context of medical care where basic laboratory services deserve an important place. This is because not only are laboratory services found to influence the preference for health services, they can also improve public opinion about PHCs, which in turn can affect the overall strengthening initiative. It must be noted that any strengthening of support services within PHCs should be in tune with the context of PHCs and their current state of affairs. This could be by focussing on the strengthening of laboratory services for communicable or non-communicable diseases, depending on their prevalence in the community. This is where

the need arises for appropriate prioritisation of the possibilities in resource mobilisation. The RKS in the context of the NRHM opens up possibilities for resource provisioning along with other sources within the NRHM. Thus, a proper prioritisation plan for strengthening medical care along with flexibility in the use of resources can be a starting point to strengthen the core public health services. This can also be a monitoring tool for both the strengthening initiative as well as for RKS fund utilisation.

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Medicare in the USA: a review of 45 years of health provision

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Introduction

Medicare, the federal health insurance in the United States of America for senior citizens 65 and older, and for disabled persons under 65, celebrated its 45th anniversary in 2010. 2010 also marked the introduction of major healthcare reform in the USA, the first significant overhaul since the 1960s. As part of the new healthcare reform, Medicare will serve as the laboratory for testing measures of efficiency and effectiveness in healthcare services, administration, and education. This paper reviews the policy, politics, and economics involved in the passage of Medicare legislation in 1965, and its proposed reformative role in healthcare in the coming years. Medicare serves not only as a provider of healthcare but also as a springboard for reform. Over the years, there have been successes and failures, based on the strengths and weaknesses of both the American healthcare system and the American political ethos. As an example of governance in the provision of healthcare, this paper discusses the Medicare model of incremental change as viable in American society. The discussion provides a historical and sociological review of a long-standing health programme designed to meet principles of equity and ethics, and to discuss how and if these goals are being met. As an expert on American education has written, "Large-scale, decentralized democratic societies are not very adept at generating neat, rational solutions to messy situations." (1) During the health reform legislative battle of 2010, heated exchanges among politicians, health providers and beneficiaries over every aspect of national healthcare goals were common (2).

The early years, 1965

"Medical care will free millions from their miseries. It will signal a deep and lasting change in the American way of life. It will take its place alongside Social Security and together they will form the twin pillars of protection upon which our people can safely build their lives and their hopes."

President Lyndon Baines Johnson, June 1966 (excerpt from speech prior to implementation of Medicare) (3).

Medicare legislation was passed in 1965, a period in US political and social history that witnessed the civil rights movement which had the objective of securing legal and civil rights for African-Americans, and the Great Society programmes, promoted by President Johnson, which had the goal of removing poverty in the US. At the time of passage, Medicare's beneficiary population was those aged over 65. Part of the impetus for Medicare's development and passage was research on poverty that found the aged were a significant segment of the population, impoverished largely by expenditures on

healthcare. As a population viewed with special concern in the US, the aged were among the first to benefit from universal health coverage. "The outpouring of civil rights activity in the early 1960s spurred politicians to support Medicare as part of Johnson's War on Poverty, and major civil rights groups all endorsed the legislation." (4: 77) Unions and retirees also supported Medicare (4: 77-78). Medicaid, passed in the same year, addressed the medical care needs of those under the US official poverty line for a family of four.

By July 1966, Medicare was an active programme for the 65 and over population, with an enrolment of 19.5 million (5: 471). Today, in the US, 12.9% of the population is over 65. There are 47 million enrolled in Medicare, and since the programme was expanded in the 1970s, this figure includes people with end stage renal disease, and the disabled of all ages who were added to the ranks of Medicare beneficiaries. It was believed in 1965 that Medicare would serve as a foundation for a national healthcare system; 45 years later, it remains as a health plan under federal auspices for the three categories identified here.

The federal government, often along with state governments, is involved in supporting several healthcare programmes in addition to Medicare. These are: Medicare covering 45 (now 47) million in 2008 (6); Medicaid covering 59 million in 2006 (7); the Children's Health Insurance Programme covering 4.9 million in June 2009 (8); Veterans Administration Health Affairs serving 5.5 million in 2008, with 3 million more, who did not use the system in that year, eligible for care (9); Tricare covering 9.4 million active and retired military and their families (10), and Indian (native American) Health Services covering 2 million (11).

Thus, approximately 127 million Americans are covered by government health programmes. Therefore, in a population of 310 million, 127 million are covered by federal health programmes, with Medicare accounting for 1/3 of these healthcare beneficiaries.

In 1965-1966, the goal was health coverage at 65, with a long term goal of universal coverage for the whole population. The objective of complete coverage was not realised by the 1960s legislation, but the 2010 reforms opened pathways to more extended coverage for much of the US population in the coming years. In 1966, the beneficiaries who were registered for Medicare numbered 19.5 million people, 65 and over. In 2010, 47 million people were enrolled in the three eligible categories (over 65, disabled, and kidney dialysis patients), with benefit payments totaling 509 billion dollars. Medicaid differs from Medicare in that it covers people in poverty, it is a combined federal and state programme and, in recent years,

states have introduced programmes designated for special groups, such as children in low income families, not at the official poverty level. As Stevens (5) shows, the 1960s and 1970s witnessed a proliferation of federal health agencies, causing the development of a healthcare industry (not systems) in which Medicare entered. Therefore, Medicare both pushed the development of many allied services, and attempted to control the growth and quality of these ever-multiplying health organisations and services. These tasks remain urgent ones for Medicare 45 years later because of ever exploding costs and expanding demand for medical services. As the healthcare debates of the post-2000 period show, the many players in healthcare (doctors, hospitals, pharmaceutical and medical technology companies) often see government as the adversary when it attempts to control costs, introduce efficiency, and rationalise services.

Developments in Medicare

Medicare legislation and implementation proceeded as it did for elders over 65 because this was a sympathetic group in the public and political view; the identification of poverty among the elderly, largely attributed to the high medical expenses they had to incur, clinched the passage of the bill. By twinning Medicare with Social Security old age pensions, politicians could declare they had ensured a package for old age security. However, the real hope was for a universal health coverage plan. Opposition came from the American Medical Association, a national organisation representing doctors. The AMA claimed that Medicare would “interfere with the doctor-patient relationship” and that doctors had already reduced or eliminated payments for elderly, poor patients. Therefore, the medical profession declared there was no need for this special insurance. This opposition led to the first provision of Medicare being for payment to hospitals, now known as Medicare Part A, thus bypassing doctor coverage although coverage for doctors’ services, known as Medicare Part B, was introduced soon after.

However, because of the wish of politicians and policy makers to ensure acceptance of Medicare by both hospitals and doctors, cost restraints were not part of the immediate provisions. Instead of just being paid for the cost of services to patients, hospitals were permitted to factor in their overall operating costs into the bills of patients; doctors were not constrained by the cost of their services—they were allowed to bill “customary, reasonable costs” in their geographical areas, and they were paid more for hospital visits to patients. As can be imagined, this failure to stipulate regulations, led to the expansion of services, hospitals, and clinics, leading to the rising cost of medical care in the 1970s. This problem, in turn, led to multiple attempts to control costs throughout the 1970s by introducing health maintenance organizations (HMOs) in which doctors’ groups provided services at fixed fees and to the development of DRGs (diagnostic related groups), now a standard method of categorising diseases in order to estimate the length of hospital stay and treatment. One particular service offered through Medicare for patients with ESRD is cited by Paul Starr (12) as an egregious example of a new technology,

kidney dialysis, achieving unique status. Reimbursement for dialysis led doctors, free-standing dialysis units and hospitals with these units to lobby for payment by Medicare for all patients with ESRD. Medicare used the hospitals/ health system in place as providers for ESRD. New hospitals were not created; however, the payment option for such specialised programmes pushed the development of for-profit hospitals, and a variety of free-standing speciality facilities which realised the revenue potential of dialysis and other specialised programmes.

By the 1980s, efforts to control costs became an incessant demand from health insurance companies, companies providing health insurance for employees, and government-sponsored plans such as Medicare, thus placing doctors and hospitals in the spotlight as the cause of runaway costs to the system.

“With a government program...public policy concerns such as cost and quality move front and center; in the case of Medicare, these concerns caused the programme to become a leader in the health insurance field.” (13: 70) Thus, as mentioned above, the introduction of DRGs by Medicare was imitated by health insurance companies, thereby becoming a standard for the health system overall. And, in terms of standards of care, standards for pharmaceuticals and for medical technology, Medicare has increasingly become the reference point for the health insurance industry.

Positive outcomes of Medicare included (in the early phases in the 1960s): rapid desegregation of hospitals in the South, since Medicare would not reimburse for services in segregated facilities; funds for medical training of physicians; payments to doctors for services rendered in and out of hospitals (previous health plans limited payments to in hospital services) (14). Later developments included standardisation of efficiency measures, the development of DRGs, and hospice services for terminal illness. Negative outcomes resulted as well, such as the proliferation of free-standing facilities for specialised services like dialysis; excesses in end-of-life care; focus on drug, surgical and technology services for the older population, rather than earlier intervention through preventive services. A regressive feature of Medicare funding is that low wage workers pay the same rate of Medicare tax out of their salaries as upper income wage earners. (Information on Medicare payments and services are provided in slide 1. The current population served by Medicare is described in slide 2.).

Medicare in the age of health reform: 2010 and onwards

By the 1990s and later, Medicare had assumed a larger role in establishing standards of care, use of evidence-based medicine, limits on hospital stays, and encouragement of outpatient services where and when feasible rather than more costly hospital stays. These standards also became those, by and large, of many health insurance schemes, as the way to control costs by ensuring efficiency and efficacy in the delivery of healthcare. Problems facing Medicare included the provision of drugs, which were not covered by Medicare until mid-2000. Middle-

income recipients solved the shortfalls in coverage through so-called Medigap plans-insurance provided by their employer-sponsored retirement health plan, or supplemental private insurance paid out of pocket. For lower income recipients, many states supported drug coverage programmes based on income eligibility. To solve the gap in drug coverage, Medicare introduced this coverage for some beneficiaries, under Medicare modernisation in mid-2000. Even with new payment mechanisms for drugs, these costs remain out of control throughout the healthcare system, not only in Medicare. An initiative to use generic drugs and new agreements with pharmaceutical companies under recent healthcare reforms, project expectations of reduced costs.

Throughout their history, Medicare and Medicaid have faced problems of fraud perpetuated by hospitals, free standing clinics, durable equipment providers, pharmacies, doctors, and even by patients themselves. Over the years, increased fraud detection measures have lowered fraudulent activities. Under the recent healthcare reform, Medicare is introducing more fraud detection measures, including reminding recipients to review their quarterly service statements to see that they reflect the services they received.

Additional new benefits in Medicare under the 2010 reforms include free preventive screenings for colorectal cancer and free mammography; free annual physical examinations; increased training of primary healthcare doctors and nurses; development of community health centers; coordinated care between hospital stay and home care; and improved long term care choices.

Medicare : payments and services	
Part A	Hospital coverage 37% - payroll taxes (employers / employees/self - employed). 13% - income tax paid on Social Security/trust fund investments interest/premium payments. 43% - general revenues
Part B	Doctors, lab services, durable equipment, etc.
Part D	Prescription drugs and administrative services.
Parts B and D	Paid by funds approved by Congress, premium paid by enrollees in B and D, interest on trust fund investments.
Part C	Medicare Advantage, allows enrollment in specified private health plans for Medicare beneficiaries

(Source: Kaiser Foundation September 2010)

Medicare : population characteristics
One half (47%) have incomes below 200% of the poverty line (\$21,660 for individuals \$ 29, 140 for couples in 2010)
More than one quarter of all beneficiaries have a cognitive/mental impairment
More than one quarter are in fair or poor health.
Eight million beneficiaries (17%) are nonelderly people with disabilities
Two million beneficiaries (4%) live in a long term care facility.

(Source: Kaiser Foundation September 2010)

Summary

From a review of the experience and history of Medicare in the US over these 45 years, politics and economics played a large role in its introduction, in the direction it took in its initial years, and more recently in the introduction of “donut hole” drug coverage. However, health planning and policy processes in federal and state agencies have grown, and by using data collected over the years on the Medicare programme specifically, and the health system more broadly, trial programmes to control costs and introduce efficiencies into healthcare have been and will continue to be undertaken. Those identified as workable and effective are then introduced as policy. For at least two generations now, in the US, the burden of health costs in old age, the period of greatest vulnerability to disease and chronic conditions, has been lifted, as foreseen by President Johnson in 1966.

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Content audit of drug advertisements in Pakistan

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Abstract

A sample of 120 drug advertisements was drawn by non-probability convenience sampling from among the stalls of 50 pharmaceutical companies participating in an exhibition in Karachi, Pakistan. 23 belonging to the NSAID drug group were selected and evaluated on whether they met guidelines for ethical advertisements as laid down in the Drugs Act, 1976. Only 5 out of the 23 advertisements met at least 14 out of 16 criteria for ethical advertisements as given in the Drugs Act, 1976.

Introduction

There is evidence that irrational pharmacotherapy is increasingly encountered in developing countries due to unethical pharmaceutical promotion (1, 2). Anecdotal evidence suggests that information provided to physicians in drug advertisements is inaccurate. It is important to study the contents of drug advertisements as they influence healthcare providers' prescribing behaviour (3)

Ethical criteria and legal framework for drug promotion

In Pakistan, the Drugs Act, 1976 (4), contains "criteria for medicinal drug promotion" in advertisements. The Act requires drug advertisements to meet 16 criteria comprising categories of information and the manner in which this information is presented.

The advertisements must mention the following: [1] the approved generic name(s) of the active ingredient(s); [2] the content of active ingredient(s) per dosage form or regimen; [3] the generic name(s) of other ingredient(s) known to cause problem(s); [4] approved therapeutic uses; [5] dosage form or regimen; [6] side-effects and major adverse drug reactions; [7] precautions, contraindications and warnings; [8] major interactions and [9] references where appropriate to authenticate claims. Further, they must contain [10] the retail price of the drug; [11] name and address of manufacturer or distributor; and [12] a statement that complete information would be provided on request.

Finally, the advertisements must [13] be legible; [14] avoid superlatives such as "the most potent" or "effective in all cases"; [15] avoid exaggerated claims and [16] make no direct or indirect comparison with any other drug.

However, drug advertisements do not always meet all these criteria, and there is no mechanism to enforce the law in this matter.

Methods

A sample of 120 promotional advertisements was drawn by non probability convenience sampling from among the stalls of 50 pharmaceutical companies that participated in an exhibition held in December 2008 in Karachi, Pakistan. Out of these 120 samples, 23 advertisements belonged to the NSAID drug group, and these were selected for analysis vis a vis the Drugs Act, 1976. NSAIDs were selected because they remain the most commonly prescribed over-the-counter drugs.

The advertisements were separated into two groups according to whether they were from local or from multinational companies (MNC). Nine of the 23 advertisements were of MNC drugs. All the advertisements were graded according to the number of criteria they fulfilled of the Drugs Act, 1976 (Table). The grading system was as follows: Grade A was awarded when at least 14 out of 16 criteria were fulfilled in the advertisements. Grade B was awarded when 12-13 criteria were met. Grade C was awarded when 10-11 criteria were met. Grade D was awarded when 9 or fewer criteria mentioned in the Drugs Act, 1976, were met.

Results

Summary

The writing in 19 advertisements was legible [i]; in 4 advertisements, the writing was too small to read easily. All 23 advertisements mentioned the approved generic name of the active ingredient [ii]. 16 of 23 mentioned the quantity of the active ingredient per dosage form or regimen [iii]. Only 1 of 23 advertisements mentioned the generic name of other ingredients known to cause problems [iv]. 20 of 23 advertisements mentioned the approved therapeutic uses [v]. 15 of 23 mentioned the dosage form or regimen [vi]. 11 of 23 advertisements mentioned the side-effects and major adverse drug reactions [vii]; precautions, contraindications and warnings [viii]; and major drug interactions [ix]. Information on the drug price was missing in all but three of 23 advertisements [x].

Only 10 of 23 advertisements refrained from using superlatives [xi], only 7 of 23 refrained from making comparisons with other drugs [xii], and 14 of 23 contained no exaggerated claims [xiii]. 19 of 23 advertisements provided references where appropriate [xiv]. 14 of 23 stated that complete information would be provided on request [xv]. 22 of 23 mentioned the name and address of the manufacturer or distributor [xvi].

Grades

Only 5 of 23 pharmaceutical advertisements met at least 14 of 15 criteria and fit in Grade A. 4 of these ads were from MNCs and 1 from a local company.

4 advertisements met 12 or 13 of the criteria and fit in Grade B. 1 of these ads was from an MNC and the other 3 were from local companies.

5 advertisements met 10 or 11 of the criteria and fit in Grade C. Of these, 1 was from an MNC and the other 4 from local companies.

9 of 23 advertisements fulfilled 9 or less out of the maximum 16 criteria of the Drugs Act, 1976, and fit in Grade D. 3 of these were from MNCs and 6 were from local companies.

Significant discrepancies were found in the advertisement contents. They did not contain essential information such as dosage, side-effects, precautions, scientific evidence and drug interactions. They did contain various inaccurate, misleading and unethical claims.

Examples

9 of 23 ads made exaggerated or unsubstantiated claims such as: *"As safe as placebo," "a record of worldwide experiences," rarely associated with side effects," "drug of choice," "the most economical in Pakistan,"* and *"is about 20 times more effective than aspirin and ibuprofen."* Such unscientific, false claims are known to influence the prescribing behaviour of physicians.

13 of 23 advertisements employed unjustified superlatives, specifically when comparing their drug with that of their competitors. To quote an example: *"Flubiprofen is the most potent inhibitor of PG synthesis than ibuprofen, indomethacin and aspirin."*

The most commonly noted violation - found in 16 out of 23 ads -- was comparing the company's drug with others. For example: *"The pain control was superior with NSAID as compared to diclofenac following third molar extraction."*

8 ads made exaggerated and unsubstantiated claims, and used unjustified superlatives while also comparing their drug with their competitors.

Discussion

This is the first study in Pakistan auditing the contents of promotional advertisements by pharmaceuticals to see if they conform to the framework laid down in the Drugs Act, 1976. A previous study (2) has looked at claims made by pharmaceutical companies in Pakistan but not specifically in relation to the law.

Studies have shown that drug advertisements are regarded by physicians in Pakistan as a means to keep up to date on the company's products, and they influence prescribing behaviour (5). Studies have also pointed to an unhealthy nexus between physicians and manufacturers here (2).

Currently there are 441 pharmaceutical manufacturers registered in Pakistan. Of these, 411 are local and 30 are MNCs (6). Our study suggests that MNCs are better in following the codes of advertisements as compared to local manufacturers. It may be that MNCs are required to follow the practices of their headquarters in western Europe and North America, where monitoring is strict and penalties for infraction are substantial. Local manufacturers operate in an environment which for all purposes is unregulated, and they exploit this deficiency in the state monitoring mechanism.

The majority of the advertisements that we analysed were found to be poorly organised and filled with irrelevant and misleading claims. The term "safety" was used in a number of places without supporting scientific evidence. Essential information was not presented, was inaccurate, or was printed in small, difficult-to-read fonts.

Information on the price of the medicine was left out in most of the advertisements in this study. In a country like Pakistan, where there is no health insurance and a substantial proportion of the population lives below the poverty line, the onus is on physicians to make choices for patients under their care, and highlighting the price of a drug would help them in ethical decision making.

Conclusion

Pharmaceutical advertisements subtly influence the prescribing behaviour of health providers and therefore affect the end user of these drugs, the patient. Prescription of irrational and/or harmful drugs is both unethical and dangerous.

We call for drug advertisements that are accurate, honest and informative; that present risks and benefits in an unbiased manner and are capable of withstanding scientific scrutiny. Advertisements should not contain misleading, unverifiable claims with the intention of subliminally conditioning the physicians' prescribing behaviour. Claims should be based on scientific evidence, and references should be provided for this scientific evidence supporting claims so that physicians can retrieve the publications for their independent evaluation.

The competent authorities must actively monitor advertisements to ensure that they comply with the law, and impose penalties in cases of non-compliance. It is also important to teach our physicians how to analyse the contents of advertisements to enable them to meet their moral and professional obligations to their patients.

Given the sampling method and the small sample in this study, the findings cannot be generalised. However, they can be used towards more systematic work in this subject in Pakistan and other countries in this region.

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Table: Promotional material audited as per the criteria of the Drugs Act, 1976

Drug information		Ethical criteria for drug advertisements																
Brand name	Generic name	i	ii	iii	iv	v	vi	vii	viii	ix	x	xi	xii	xiii	xiv	xv	xvi	Grade*
Anex	Naproxen sodium	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	A
Profenid	Ketoprofen	✓	✓	✓	×	✓	✓	✓	✓	✓	×	✓	×	✓	✓	✓	✓	A
Feldene	Piroxicam	×	✓	✓	×	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	A
Febrol	paracetamol	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	A
Ponstan	mefenamic acid	✓	✓	✓	×	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	A
Flubi	Flurbiprofen	×	✓	✓	×	✓	✓	✓	✓	✓	×	✓	×	✓	×	✓	✓	B
Ansaid	Flurbiprofen	✓	✓	✓	×	✓	✓	✓	✓	✓	×	×	×	✓	✓	✓	✓	B
Voren	Diclofenac sodium	✓	✓	✓	×	✓	✓	×	×	×	×	✓	✓	✓	✓	✓	✓	B
Tormax	Naproxen sodium	✓	✓	×	×	✓	✓	✓	✓	✓	×	×	✓	✓	✓	×	✓	B
Unix	Nimesulide	×	✓	✓	×	✓	✓	✓	✓	✓	×	×	×	×	✓	×	✓	C
Panslay	Diclofenac sodium	✓	✓	×	×	✓	✓	×	×	×	×	✓	✓	✓	✓	✓	×	C
Brufen	Ibuprofen	✓	✓	✓	×	✓	✓	×	×	×	✓	✓	×	✓	✓	✓	✓	C
Dorsiflex	Celecoxib	✓	✓	✓	×	✓	✓	✓	✓	✓	×	×	×	×	✓	×	✓	C
Cyclodex	Piroxicam	×	✓	✓	×	✓	✓	✓	✓	✓	×	×	×	×	✓	×	✓	C
Airtal	Aceclofenac	✓	✓	×	×	×	×	×	×	×	×	×	×	✓	✓	×	✓	D
Neurofenac	Diclofenac Sodium	✓	✓	×	×	✓	×	×	×	×	×	×	×	×	×	✓	✓	D
Naplur	Flurbiprofen	✓	✓	✓	×	✓	×	×	×	×	×	×	×	×	✓	×	✓	D
Modact-IR	Nimesulide	✓	✓	×	×	×	×	×	×	×	×	×	×	✓	×	✓	✓	D
Oragesic	Flurbiprofen	✓	✓	✓	×	✓	✓	×	×	×	×	×	×	✓	✓	×	✓	D
Froben	Flurbiprofen	✓	✓	✓	×	✓	×	×	×	×	✓	×	×	×	✓	✓	✓	D
Synalgo	Flurbiprofen	✓	✓	×	×	×	×	×	×	×	×	×	×	×	✓	×	✓	D
Altoron	Diclofenac Sodium	✓	✓	✓	×	✓	×	×	×	×	×	✓	✓	×	×	×	✓	D
Pcam	Piroxicam	✓	✓	×	×	✓	×	×	×	×	×	×	×	×	✓	✓	✓	D

Criteria

- i. Legibility;
- ii. Approved generic name(s) of the active ingredient(s);
- iii. Content of active ingredient(s) per dosage form or regimen;
- iv. Generic name(s) of other ingredient(s) known to cause problem(s);
- v. Approved therapeutic uses;
- vi. Dosage form or regimen;
- vii. Side-effects and major adverse drug reactions;
- viii. Precautions, contraindications and warnings;
- ix. Major interactions;
- x. Retail price of the drug;

- xi. Absolute characters, such as “the most potent”, “the most rapid”, “the most effective in all cases” or superlatives shall be avoided;
- xii. No direct or indirect comparison in any way with any other drug;
- xiii. Exaggerated claims should be avoided;
- xiv. References should be provided where appropriate to authenticate claims;
- xv. Provision of full information on request should be highlighted;
- xvi. Name and address of manufacturer or distributor.

* **Grading:** A: 14-16 criteria met; B: 12-13 criteria met; C: 10-11 criteria met; D: 9 or fewer criteria met.

Supported and unsupported claims in medicinal drug advertisements in Indian medical journals

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Abstract

The study assessed 292 supported and unsupported claims in 102 medicinal drug advertisements across 15 Indian medical journals published in 2009. WHO ethical criteria for medicinal drug promotion were applied. None of the advertisements satisfied all the WHO criteria. Safe prescribing information on major adverse drug reactions, contraindications and warnings was provided in only 19 advertisements. Of 292 drug claims, only 80 (27%) were supported with reference(s), of which only 7 (9%) claims were unambiguous, or well substantiated with references. 14 references quoted did not substantiate the claim and 15 constituted weak scientific evidence. Superlatives like "tested", "trusted", "guarantees success" and "matchless safety" were used without evidence to substantiate such claims. Stronger enforcement mechanisms are necessary to ensure reliable drug information in pharmaceutical advertisements.

Introduction

Advertisements are an important means of getting information on medicines to physicians. They are one of the techniques used by pharmaceutical companies to promote their products to physicians (1-3). Information provided in these advertisements should be of high quality to enable physicians to practise evidence-based medicine. However, it has been observed that the information provided in medicinal drug advertisements is often exaggerated, inaccurate and missing critical information on safe prescribing (4). Advertisements which exaggerate the benefits and downplay the risks of a drug, with poorly supported claims, failing to balance claims of efficacy with potential adverse effects, and promoting a drug for groups other than those for whom it is approved, are likely to adversely affect treatment (5-7). Physicians relying on such promotional information may prescribe irrational drugs that endanger their patients' lives (8).

There are three major codes which deal with the promotion of drugs: the International Federation of Pharmaceutical Manufacturers (IFPMA) code of pharmaceutical marketing practices (9); the World Health Organization's ethical criteria for medicinal drug promotion (10); and the code prepared by Health Action International (11). However, despite the availability of regulations worldwide, pharmaceutical advertising in medical journals has been criticised for being of poor quality. The mere existence of specific codes and regulations does not guarantee their enforcement and compliance, as demonstrated by a Brazilian study where 64.3% of prescription drug advertisements found in all sources of

drug advertisements in a Brazil city exhibited irregularities (12). Non-compliance with US Food and Drug Administration (US FDA) standards was also observed by Wilkes et al who reported 40% advertisements in US journals as having unbalanced drug information (5).

In India, at present the Magic Remedies (Objectionable Advertisement) Act 1954 deals with misleading promotion (13). The Act prohibits false or misleading advertisements related to drugs. However, there are no guidelines which deal with drug promotion.

Advertisements for promotion of pharmaceuticals are a regular feature of Indian medical journals. They form a major means of communicating drug-related information to the medical community.

The present study evaluated the supported and unsupported claims in 102 medicinal drug advertisements in 15 Indian medical journals.

Materials and methods

All Indian medical journals published in 2009 available in the library of a public teaching hospital were scanned for advertisements. Those journals which did not include any advertisement were excluded from the analysis. From the remaining 15 journals, the latest issue of each journal available in the library rack on the date of the library visit was selected for analysis. (Details of the journals are given in Table 1.) 102 medicinal drug advertisements were assessed. Advertisements referring to medical equipment, surgical appliances and nutritional supplements were excluded.

We assessed each advertisement according to WHO's ethical criteria for medicinal drug promotion to physicians and health-related professionals (10). The criteria include the following:

1. The text should be legible.
2. Advertisements that make a promotional claim should at least contain summary scientific information. (Some countries require an approved scientific data sheet or similar document, for a given period from the date of the first promotion or for the full product life.)
3. The name(s) of the active ingredient(s) using either international non-proprietary names (INN) or the approved generic name of the drug.

Advertisements should also include the following:

4. the brand name;
5. content of active ingredient(s) per dosage form or regimen;
6. name of other ingredients known to cause problems;
7. approved therapeutic uses;
8. dosage form or regimen;
9. side-effects and major adverse drug reactions;
10. precautions, contra-indications and warnings;
11. major interactions;
12. name and address of manufacturer or distributor; and
13. reference to scientific literature as appropriate.

Second, we determined the number of claims made in each advertisement and categorised them into five groups: those pertaining to effectiveness, safety, dosage or convenience and cost, and general or neutral claims. Claims were further classified as "supported" claims if references were supplied, and "unsupported claims" if a reference was not provided.

For all claims supported by references, we obtained original papers or their abstracts for all references available in the public domain and rated them in terms of the quality of evidence as relating to the study design, using a standard "hierarchy of evidence". We conducted internet searches for data held on file by pharmaceutical companies or presented solely at conferences, or in books, reports and newsletters, but were unable to obtain them.

A supported claim was rated as "unsubstantiated" by the cited study if one of the following criteria applied: it was a false statement; it was an exaggeration of efficacy; it selectively concealed information; it misquoted evidence; it exaggerated the drug's safety, or it made an unjustified generalisation. A supported claim was rated as "unambiguous" if the references cited substantiated the claim.

Results

Application of WHO criteria

None of the advertisements satisfied all the ethical criteria set by WHO. The number of advertisements satisfying WHO criteria is depicted in Table 2. Brand name 102 (100%), name of the active ingredient 92 (90%) and approved indications 87 (85%) were commonly mentioned. Safe prescribing information was given less importance. Only 19 of the 102 advertisements provided safe prescribing information such as on side effects, major adverse drug reactions, precautions, contraindications, and warnings. Only 16 gave information on major interactions. A summary of scientific information was provided in 18 of the 102 advertisements. 53 advertisements did not mention any reference to scientific literature.

Supported and unsupported claims

We identified 292 claims from 102 advertisements (Table 3). The claims were categorised into those regarding effectiveness

(170), safety (43), dosage or convenience (26), and cost (19), and other, neutral claims (34).

None of the 213 claims related to efficacy or safety was supported by data on absolute risk reduction and number needed to treat.

Of these 292 claims, 212 (73%) were unsupported claims (no references were given).

80 (27%) claims, in 49 advertisements, were supported with a total of 94 references.

These 94 references were two meta-analyses, one systematic review, 38 randomised controlled trials, 19 observational studies and narrative reviews, 3 animal studies and 31 other types of references (reports, newsletters, books, data on file). We were unable to trace references in the last category (31) on the internet or in the library where the journals were located. Therefore, a total of 63 references were examined.

Of 80 supported claims, only 7 (9%) claims were unambiguous claims. These claims were substantiated by 22 references.

Unsubstantiated supported claims

73 (91%) of supported claims were either unsubstantiated or poorly substantiated.

Of the 94 references given, 31 were not available for public searching. Of the 63 references in the public domain, 22 supported the 7 unambiguous claims which referred to them. Of the remaining 41 references, 12 could not be traced because they had incorrect or incomplete citation details. (This did not include incomplete or incorrect references which were traceable with considerable effort.) Of the remaining 29, 14 references were false or misleading and did not substantiate the claim made, and 15 references were of a low level of evidence or found to be scientifically weak on examination.

Table 4 contains examples of claims in medicinal drug advertisements which could not be substantiated through the references they cited. 14 of the bibliographical references did not substantiate the claims made. For example, Misoprost-600(r) (Misoprostol 600 mcg) is claimed to be used in pregnancy-induced hypertension. However, the study quoted in support of this claim excluded pregnancy-induced hypertensive patients (14). In another example, an ad for Capiibine(r) (Capecitabine) claimed "improved survival in colorectal cancer compared with 5-FU". However, the study population was of gastric cancer patients and did not claim improvement over 5-FU (15). Preclinical data for a drug was applied to humans. For example, the claim that Infen-25(r) (Dexketoprofen trometamol) was "gentle on GI tract" was supported by an animal study (16).

A total of eight claims cited 15 bibliographical references which appeared to be convincing but were found to be scientifically weak on examination. For example, it was claimed that Yasmin(r) (Drospirenone/ethinylestradiol) ensured "stable body weight" but the reference was an open label trial with an unacceptable drop-out rate of 29% (17). In another example

“predictable bioavailability” claimed for Dytor(r) (Torsemide) was based on an open label, non-blinded trial in patients with heart failure (18).

Some advertisements contained both supported and unsupported claims. Another claim for the same drug stated that it had been “tried, tested and proven in Indian patients,” but no reference was provided to substantiate this claim.

Such inconsistencies cast doubt over the validity of such claims.

Discussion

Advertisements are an important source of drug information for physicians and have been shown to influence prescribing patterns (3,8,19,20). Thus, misleading or incomplete information can lead to improper prescribing.

A well-substantiated claim is precise and based on relevant scientific evidence. Research cited in advertisements in medical journals should be evidence-based, meeting basic criteria for validity, significance of results and applicability to the readers' practice.

The majority of drug advertisements in Indian medical journals examined by us (53 out of 102) were unsupported by references to studies to support the claims made. Only 49 advertisements were supported by references. However, 31 of these 94 references were not in the public domain and 12 references were incomplete or inaccurate. Of the remaining, only two were meta-analyses, one was a systematic review and 38 were randomised controlled trials.

Only 7 out of 292 claims were substantiated by appropriate references traceable and accessible in the public domain. Not one of the 213 claims related to efficacy or safety was supported by data on absolute risk reduction and number needed to treat.

Our study found evidence of inappropriate use of references in pharmaceutical advertising in medical journals. A number of references did not support the claim made, and others constituted weak evidence for any claim. This suggests that the fact that references are given is no guarantee that the advertisement claims are valid. Prescription practices based on such claims - for example if promoted for categories of patients who have in fact been excluded from the study - can have adverse consequences for patients.

In a systematic review (21) of 24 studies evaluating the quality of drug advertisements in medical journals, studies of advertisements in developed countries found that the majority of all ads (median 65%, range 51-100%) provided references (except for a study in Spain which found that only 13% of ads provided references). The same review found that in developing countries, 23% of all ads (range 2-59%) provided references. An Australian study found that for 35% of the claims studied, the references were not searchable on Medline (22).

The level of scientific evidence used also assumes great importance. Gutknecht reported that in the US and Canada, references to randomisation and blinding were present in 37% and 47% advertisements respectively (8). In a study of advertisements in Australian medical publications, only 10% claims were supported by level 1 evidence (meta analyses) and 45% by at least one RCT (22).

Inappropriate drug advertisement is as common in India as in other developing countries (23,24). The poor quality of drug advertising is an important issue in India, where independent sources of information on medicines are limited and physicians rely on the drug industry to provide information on drugs.

Conclusion

This study has a number of limitations. The sample size is small and the advertisements were identified through convenience sampling. However, the study findings remain important and suggest the need for active monitoring to keep a check on the quality of pharmaceutical advertisements. Regulators may consider providing explicit requirements on the scientific evidence necessary to support claims in journal advertising. Strong enforcement mechanisms are necessary to ensure that pharmaceutical companies provide reliable information essential for rational prescribing. Physicians on their part should be cautious in accepting advertisement claims even when they are supported by bibliographical references.

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Table 1: Characteristics of journals reviewed

S. No	Journal name	Vol	Issue	Listed in Pubmed	Total pages	% Pages with ads
(1)	Indian Journal of Anaesthesia	53	1	Yes	134	7.46
(2)	Indian Journal of Cancer	46	3	Yes	92	4.34
(3)	Indian Journal of Chest Disease and Allied Sciences	51	3	Yes	72	1.38
(4)	Indian Journal of Gastroenterology	28	1	Yes	48	2.08
(5)	Indian Journal of Ophthalmology	57	4	Yes	140	40.71
(6)	Indian Journal of Orthopaedics	43	3	Yes	112	18.75
(7)	Indian Journal of Paediatrics	76	5	Yes	130	13.84
(8)	Indian journal of Plastic Surgery	42	1	Yes	152	0.66
(9)	Indian Journal Of Psychiatry	51	2	Yes	102	7.80
(10)	Indian Journal of Tuberculosis	56	2	Yes	64	1.56
(11)	Indian Journal of Urology	25	2	Yes	150	10.66
(12)	Indian Paediatrics	46	4	Yes	96	6.25
(13)	Journal of the Indian Medical Association	107	3	Yes	68	35.29
(14)	Journal of the Association of Physicians of India	57	3	Yes	100	14.00
(15)	The Journal of Obstetrics & Gynecology of India	59	3	Yes	95	14.73

Table 2: Number of advertisements satisfying WHO criteria for medicinal drug promotion

WHO criteria	Number of advertisements satisfying WHO criteria
Legible text	99 (97.1%)
Summary of scientific information	18 (17.6%)
Approved scientific data sheet	0 (0.0%)
Name of the active ingredient	92 (90.2%)
Brand name	102 (100.0%)
Content of active ingredient per dosage form or regimen	84 (82.4%)
Other ingredients known to cause problems	8 (7.8%)
Approved therapeutic uses	87 (85.3%)
Dosage form or regimen	50 (49.0%)
Side effects and major adverse drug reactions	19 (18.6%)
Precautions, contraindications and warnings	19 (18.6%)
Major interactions	16 (15.7%)
Name & address of manufacturer or distributor	87 (85.3%)
Reference to scientific literature as appropriate	49 (48.0%)

Table 3: Types of promotional claims in medicinal drug advertisements in Indian medical journals

Type of promotional claim	Claim present in number of advertisements N=102	Total number of claims in all advertisements N=292
Effectiveness	72	170
Safety	30	43
Neutral	25	34
Dosage form / convenience	18	26
Cost factors	18	19

Table 4: Examples of unsubstantiated claims in medicinal drug advertisements

S. No	Pharmaceutical product (active ingredient)	Claim	Reference	Type of reference and reasons for potential bias	Type of claim
(1)	Cipralext(r) (Escitalopram)	"Effectively prevents relapses"	Gorwood P et al. <i>Am J Geriatr Psychiatry</i> . 2007 Jul; 15;7: 581-93.	Single blind RCT Study population of trial consists of geriatrics (aged ≥ 65 yrs) only	Unjustified generalisation
(2)	Ecosprin(r) (Enteric coated aspirin)	"Optimal efficacy with increased safety"	Petroski D. <i>Clin Ther</i> 1993 Mar-Apr;15(2):314-20.	Single blind RCT Reference to duodenal mucosal injury omitted	Selective information Concealment
(3)	Glynase MF(r) (Glipizide + Metformin)	"Decreases FPG by 74 mg/dl; PPG by 83 mg/dl"	Simonson DC et al. <i>Diabetes Care</i> . 1997 Apr; 20(4): 597-606.	Double-blind multi-centred RCT Glipizide 5 and 20 mg doses decreased FPG by 42 (6 and 60 (6 mg/dl from baseline; and PPG by 60 (10 and 58 (10 mg/dl respectively. Further, study pertained to monotherapy	False claim
(4)	Infen-25(r) (Dexketoprofen Trometamol)	"Offers high potency and powerful analgesia as compared to oral morphine"	^a . Ighom G et al. <i>Br J Anaesth</i> . 2002 Apr; 88 (4): 520-6. ^b . Lopez-Munoz FJ. <i>J Clin Pharmacol</i> . 1998 Dec;38(12 Suppl):115-21S.	^a Double blind RCT No head to head trial of morphine with dexketoprofen ^b Animal study	Exaggeration of efficacy
(5)	Letroz(r) (Letrozole)	"Superior to CC in combined gonadotropin cycle"	Barosso G et al. <i>Fertil Steril</i> . 2006 Nov;86(5):1428-31.	Prospective, randomised, blinded trial Trial not designed to assess superiority of Letrozole over Clomiphene citrate (CC) but to study the efficacy of letrozole and CC as adjuvants to recombinant FSH (rFSH) in controlled ovarian hyperstimulation	Exaggeration of efficacy
(6)	Mefal Forte(r) (Mefenamic acid + Paracetamol)	"Least relative GI bleeding compared to ibuprofen and diclofenac."	García Rodríguez LA, Jick H. <i>Lancet</i> . 1994; 343 Mar 26; 343(8900):769-72.	Retrospective case control study The adjusted relative risk (95% CI) of GI bleed was similar for ibuprofen 2.9 (1.7-5.0) and mefenamic acid 2.9 (1.5-5.6)	False claim
(7)	Misoprost-600(r) (Misoprostol)	"Can be used in high risk patients of bronchial asthma, pregnancy-induced HTN, Rh -ve blood groups"	Rao SB et al. <i>Bombay Hospital Journal</i> .2002 Jan; 44(1): 30-5.	Single blind, non-randomised trial Patients with pregnancy-induced HTN were excluded in the study	False claim
(8)	Nipcare(r) (Lanolin USP Modified)	"For prevention of sore nipples, Lanolin should remain first-line therapy"	Hagen RL. <i>Arch Pediatr Adolesc Med</i> . 1999 Jun; 153(6):658.	Comment on RCT Comment does not state Lanolin as first line therapy. Moreover, original article corresponding to the comment advocates "In light of both the cost and the risk of infection, first-line treatment should remain breast shells and lanolin."	Misquoting of evidence
(9)	Orofer XT(r) (Ferrous ascorbate + Folic acid)	(A) "Helps to improve cognitive function, learning and memory"	Beard J. <i>J Nutr</i> . 2003 May;133(5 Suppl 1):1468S-72S.	Review article No independent study for improvement in learning and memory	Exaggeration of therapeutic benefit
		(B) "Negligible risk of anaphylaxis reactions"	Breyman C. <i>Blood Cells Mol Dis</i> . 2002 Nov-Dec; 29(3):506-16; discussion 517-21.	Review article Minimal (not 'negligible') risk of allergic accident	Exaggeration of safety
(10)	Rovamycin Forte(r) (Spiramycin)	(A) "Safety documented"	Nucera E et al. <i>Scand J Infect Dis</i> 2002; 34(7):550-1.	Case series of 2 pregnant patients Case series concludes further studies in a larger group of patients are needed in order to assess the safety.	False claim and unjustified generalisation
		(B) "Only antibiotic recommended in pregnancy"	Russo M, Carmellino S. <i>Infez Med</i> 1996;4(1):7-13.	Review article Reference does not state that spiramycin is the only antibiotic recommended in pregnancy. Moreover, Spiramycin is not approved by the US FDA and is considered as an experimental drug.	Exaggeration of safety

COMMENTS

Regulating (or not) reproductive medicine: an alternative to letting the market decide

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Abstract

Whilst India has been debating how to regulate 'surrogacy', the UK has undergone a major consultation on increasing the amount of 'expenses' paid to egg 'donors', while France has recently finished debating its entire package of bioethics regulation and the role of its Biomedicine Agency. Although it is often claimed that there is no alternative to the neo-liberal, market-based approach in regulating (or not) reproductive medicine - the ideology prevalent in both India and the UK - advocates of that position ignore the alternative model offered by France's tighter regulation, as well as its overarching concern with protecting the vulnerable and ensuring social justice. Whilst the concepts underpinning the French model of regulation also have their provenance in Western political philosophy and not in the developed world, they embody a very different attitude and suggest that there is indeed an alternative to letting the market decide. However, even in France that alternative is highly contested.

Introduction

Does India need a new independence struggle? If so, it would not be against British colonialism this time, but against the neo-liberal UK approach to regulating reproductive medicine. It is highly ironic that in its approach to encouraging commercial 'surrogate' motherhood and private IVF clinics, India seems to be following the same 19th-century liberal 'free market' arguments that have long prevailed in Britain and that are gaining further strength under the Conservative-Liberal Democrat coalition government (1,2). Despite the existence of a regulatory body, the Human Fertilisation and Embryology Authority (HFEA), 'let the market decide' often seems to be as much the order of the day in the UK today as in the time of the *Ragged-Trousered Philanthropists*. (3) But *laissez-faire* ideology is not the only available set of principles for regulating reproductive medicine-or, as *laissez-faire* would recommend, not regulating it.

Whilst India has been debating how to regulate 'surrogacy' and the UK has been undergoing an HFEA consultation on increasing the amount of 'expenses' paid to egg 'donors', France has recently finished debating its entire package of bioethics regulation and the role of its Biomedicine Agency. (I use inverted commas around commonly used key terms in the previous sentence because all three words are misleading:

the birth mother is the legal mother and not in any true sense a 'surrogate', the 'expenses' foreseen in the HFEA consultation border on 'wages', and paid egg 'donors' should more accurately be termed egg 'sellers'.) Although it is often claimed that there is no alternative to the neo-liberal, market-based approach in regulating (or not) reproductive medicine, which is the ideology prevalent in both India and the UK, advocates of that position ignore the alternative model offered by France's tighter regulation, as well as its overarching concern with protecting the vulnerable and ensuring social justice.

In this article I want to set out the underlying philosophical presuppositions of the British approach to regulating reproductive medicine and to contrast them with another set of attitudes: those embodied in the French debate on bioethics regulation in France's National Assembly and Senate. Whilst the concepts underpinning the French model of regulation also have their provenance in Western political philosophy and not in the developed world, they embody a very different attitude and suggest that there is indeed an alternative to letting the market decide. However, even in France that alternative is highly contested.

On June 23, 2011, the revised French bioethics bill was passed, resolving disagreement between the National Assembly and the Senate. Assembly deputies tried to reach a compromise between their preference for strict regulation and amendments passed by the Senate in its first reading, which would have overturned some aspects of the traditional strict regime. In its own second reading of the draft bill, the Senate accepted those compromises and retreated from its earlier more neo-liberal position. Nevertheless, even though the two chambers disagreed on particular issues, such as whether stem cell research should be permitted by default or only by a specific derogation, both legislative bodies adhered to a very different set of ethical principles to those dominating in the UK, suggesting that there is indeed an alternative to letting the market decide. For example, private umbilical cord blood banking will remain illegal in France, on the grounds that it takes away a valuable resource from the public banks, undermines solidarity and risks exploitation of parents at a vulnerable time. By contrast, in the UK private cord blood banking is permitted, although with some regulation by the Human Tissue Authority-but that body is soon to be abolished.

Whilst the Assisted Reproductive Technologies Regulation Bill, 2010, now before the Indian Parliament, is justifiably concerned with reducing exploitation of 'surrogate' mothers, it will also make commercial 'surrogacy' contracts legally binding, which the French bill explicitly rejects-just as it rejects markets in eggs. Although the UK does not propose to legalise commercial 'surrogacy' contracts at present, or to pay outright for eggs, the HFEA consultation was triggered, like India's legislation, by the rise of 'reproductive tourism' and by international markets in women's reproductive labour (4), which has been called "the purchase of fertility from poor women in the developing world". (5)

The fascinating juxtaposition of the three countries' fundamental debates on regulating (or not) reproductive medicine offers a timely opportunity to consider the contrasting underlying philosophical assumptions, which are too often overlooked. In this article I will concentrate primarily on the contrast between the UK and France, leaving the Indian audience to apply their own conclusions to their Assisted Reproductive Technologies Regulation Bill and to the question of whether there is indeed an alternative in Indian biomedical regulation to the increasingly dominant free-market position.

The institutional position: the UK and France

On January 17, 2011 the UK's HFEA announced a consultation on increasing the level of 'expenses' currently payable to egg donors, with the consultation running until April 8. (The consultation results had not been announced at the time this article went to press.) While *payment* for gametes is prohibited under a European Commission directive of 2004, it is left up to each EC country to decide what level of expenses it will permit, and also how to determine what counts as expenses. Article 12 of this EC Tissue Directive stipulates: "Member states shall endeavour to ensure voluntary and unpaid donations of tissues and cells. Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted."

The HFEA has previously taken the position that expenses do not include wages, but rather only direct costs-unlike Spain, for example, which interprets 'expenses' more leniently and allows up to 900-1200 Euros to be claimed. In contrast, expenses cannot at present exceed £250 in the UK, a sum last increased in 2006 as a result of a previous review, the Eggs, Sperm and Embryos (SEED) consultation. (6) Partly as a result, Spain's burgeoning private IVF clinics have made the country a prime destination for reproductive tourism from other European countries, including the UK. Concerned about the uncertainties these buyers face and perhaps also about the competition threatening private British IVF clinics (although it denies that), the HFEA now proposes, if the consultation permits, to reinterpret the level of allowable expenses. But it faces the obstacle of creating inducements that are impermissible under European law.

The way in which the HFEA consultation document attempted to get round this barrier was to make a distinction

between *creating 'incentives'* to donate and *removing existing 'disincentives'*. If women are eager to donate eggs but are being blocked by failure to pay sufficient expenses, on this reasoning that counts as a disincentive. In the HFEA's view, it could be removed by increasing the level of expenses, without breaching European law.

Apart from the lawyerliness of this reasoning, however, there are major questions about how accurately it reflects women's motivations. In the HFEA's own previous SEED review, women surveyed put lack of financial inducement at the very bottom of the list of reasons why they did not wish to donate eggs. At the top came justifiable concerns about the uncertainty of evidence concerning risks of ovarian hyperstimulation. The survey evidence also showed that only 10% of respondents thought that women should be compensated in the form of expenses, while 35% rejected any compensation, even for expenses-presumably as the beginning of a slippery slope towards a market in eggs.

Although France faces a similar problem of reproductive tourism, together with a shortage - estimated by the French *Agence de la Biomédecine* (Biomedicine Agency) - of about 700 egg donors a year (7), the draft French bill does not propose payment for gametes, not even by the back-door means of increasing expenses. Risks to the donor remained prominent in experts' testimony before the legislature; nor is this mere paternalism. It reflects genuine popular concern.

Before the draft bill was tabled, a series of two-day public consultation meetings was held - symbolically called the Estates-General of Bioethics, like the meetings which were of course the prelude to the French Revolution. Each of the three consultation meetings in different provincial cities authored its own report of its deliberations (whereas the HFEA writes the reports of its consultations, arguably more paternalistically). The Rennes panel, which debated questions about reproductive medicine, condemned any attempt to pay for eggs or sperm, consistently with the long-standing recommendations of the French National Ethics Committee (8)-indicating that distrust of the market is not just the opinion of a metropolitan elite, but also a popular view. The French will also continue to forbid commercial 'surrogacy', although in this case against popular opinion - with 65% of the French populace surveyed favouring de-criminalisation of surrogacy (though not necessarily commercialisation) - and despite a media petition by a number of French academics (9, 10).

While the HFEA consultation document downgraded ethical concerns as an obstacle needing to be 'balanced' against the need to increase donation, a group of French parliamentary deputies has stated that "Law, morality and progress are compatible." (11) These deputies were signatories to a petition demanding the Assembly's right to make key decisions in reproductive medicine, rather than devolving its powers to the national Biomedicine Agency. By contrast, the HFEA-even though it has demonstrated an increasingly pro-market slant in previous consultations as well as this one (4: 79 ff.) - is set to be abolished before the end of the current Parliament in

the current government 'bonfire' of regulatory agencies. Even though it also has a centre-right government, France appears willing to accept or even increase the role of state regulatory agencies, although not without debate.

Do the French purchase their generally stricter and more principled approach to regulating reproductive medicine at the cost of highly centralised control and government sclerosis? This is a common accusation: the sociologist Paul Rabinow, for example, concluded from his comparative study of US and French human genome research that France is poorly equipped to deal with the global biotechnology industry. He alleges that France is too accustomed to relying on the state to regulate, while the state is too inconsistent in its stance and too ponderous to deal with the quick cut-and-thrust of modern commercialised biotechnology (12).

True, there are some heavy-handed aspects to French regulation of reproductive technologies, most notably the long-standing restriction of IVF to heterosexual couples who are either married or in a long-term relationship. This issue was been freely debated during the bill's passage, and it appeared at one point that lesbian couples would be able to gain access to assisted reproductive techniques. That this measure eventually failed was indeed a disappointment to many. The level of debate was high and extensive, however, which would not be the case if the accusations of autocratic government were true. In general, the old stereotype of the French political system as statist and static looks increasingly threadbare to many observers (13) (14).

Indeed, some might feel that the UK that now possesses the unattractive combination of a highly centralised government, bent on implementing an unprecedented level of public services cuts not included in the party manifestos during the elections, with a lax regulatory regime for commercial interests and easier access for firms to government procurement. The *Guardian* reported on May 31, 2011, that the government was awarding £56 million a day to private companies in outsourced contracts, and that 3,000 new contracts had been issued since the start of the calendar year.

Philosophical assumptions and presumptions

Although the HFEA consultative report seemed to view ethical concerns as a nuisance to be 'balanced' against the need for increasing egg donations, of course it was implicitly taking an ethical position: a utilitarian one. The implicit presumption was that welfare would be maximised by increasing the level of egg donations, benefiting recipient couples directly by obviating the need to travel abroad and doing no harm to donor women, since their 'expenses' would be met. But the notion that ethical concerns can be 'balanced' against welfare also assumes that they are secondary to the production of favourable consequences, a position that would be challenged by philosophers from Plato to Kant (15). Although only three per cent of women surveyed for the previous SEED review considered low compensation to be the main barrier to egg donation, the HFEA position also made the materialistic

assumption that people are most reliably motivated by financial considerations.

There are other highly debatable moral positions at stake here as well:

- that the needs of egg purchasers are the primary consideration, rather than the possible vulnerability of egg providers;
- that individuals have rightful ownership of their body parts, allowing them to do whatever they like with their tissues;
- and that by giving their consent to donation in return for an increased level of expenses, egg providers have made an autonomous choice, which puts paid to any charges that they might be being exploited.

All these positions have been challenged in the bioethics literature, by feminist critics and many others (16-19), but they do continue to dominate ethical debate in the UK. Subsuming them all is a set of simplistic assumptions that biomedical science is best left to biomedical scientists, that those who propose regulation are anti-technological Luddites, and that the state's minimal role should be to provide the conditions in which commercialised biotechnology markets can flourish (20).

Not so in France, where parliamentary debate and the long consultation preceding it have turned on the values of non-commercialisation, dignity, bodily inviolability, justice and protection of the vulnerable. Where there is dispute, it tends to be over the question of who counts as vulnerable, with Roman Catholic commentators and those Assembly members sympathetic to them pressing strongly for the protection of the embryo as the most vulnerable party. But even between the 'Catho' commentators and the political Left, there is a surprising level of agreement on a communitarian approach to bioethics, emphasis on social solidarity and dislike of individualistic 'Anglo-Saxon attitudes.' This underlying French concept of governance is more influenced by Louis XIV and Jean-Jacques Rousseau than by Adam Smith and John Stuart Mill.

As I wrote earlier:

In France the effect of democracy, in its direct Rousseauesque variant, was to transfer the personality of the monarch wholesale to the entire people. It is the sovereign people which exercises power and enjoys rights in this formulation of democracy; individuals are also accorded rights by virtue of their membership in the collectivity, but not as individuals per se. The collectivity, or body public, is primary. Liberal democracy, by contrast, conceives of the individual in the state of nature as the basic building block, and of the state as secondary, formed through the social contract and limited by the rights of individuals. (16:150)

A striking example of this anti-individualistic approach in practice can be found in the official French view of gamete donation as a gift from a fertile couple to an infertile one—not, as in the United States, as a consumer good for which markets are stratified according to the buyer's preferences in

physical appearance, intelligence, and even such 'must-haves' as musical ability (21). The legislative passage of the French bill did take account of the legitimate charge that this official view discriminates against gay couples, but there was a stalemate between the Senate's preference for allowing lesbian couples to have access to IVF and the Assembly's rejection of this proposal on the grounds that infertility treatment should be for a 'medical' rather than a 'social' condition. (Either way gay men would have continued to be denied access to IVF, since they would require a 'surrogate' mother, which will remain illegal.)

In France there seems to be rare agreement among academics and politicians that the market approach to gametes is to be distrusted, along with other Anglo-American philosophical paraphernalia. According to Sylviane Agacinski, professor at the École des Hautes Études en Sciences Sociales (22), the individualistic view predominant in Anglo-Saxon culture ignores human dignity and societal justice. Individual informed consent is necessary but not sufficient, she argues. It is not the last word in any regulatory debate-as, for example, in the claim commonly heard in the Anglophone world that there is no affront to women's dignity in allowing them to sell their eggs, provided they have given an informed consent (23).

In the Anglo-Saxon countries, as Lisa Ikemoto has argued (24), the language of choice, autonomy and equality-originally liberating for women in the US abortion decision *Roe v Wade* (25)- has now become a justification for untrammelled free-market individualism. That linkage serves the interests of the US and global markets in 'baby-making,' including not only the monies paid to egg sellers but also the massive revenues to drug companies for fertility drugs and the profits of private IVF clinics (4:2). The language of choice and consent, then, is insufficient, and even misleading. Instead, the communitarian view argues, we must also consider the possibility that disadvantaged economic or social circumstances lie behind women's ostensible consent.

In France, Philippe Gosselin, a parliamentary deputy and secretary of the committee revising the bioethics laws, has insisted that the new legislation must continue to reject what he sees as the dominant utilitarian voice in the UK and elsewhere in Europe. "Neither objectification nor commodification," he insists. "A human being cannot be reduced to the level of a thing and should not become an object of commerce." (26)

Although Gosselin might not identify it as such, this is a Kantian position. While autonomy is of course central to Kant, those US and UK scholars who view choice as a knock-down argument ignore the way in which Kant himself *denied* that we are free to sell our own tissue or to buy the tissue of others. To treat parts of the body as fungible objects is to treat the provider not as an autonomous member of the kingdom of ends, but merely as a means, which is forbidden by one version of the Categorical Imperative. Even if the seller of tissue voluntarily consents to treat her own body in this fashion, it is still wrong for any would-be buyer to treat her in this fashion, because it is inherently degrading (27).

Many UK and US authors have of course provided substantial critiques of the dominance of autonomy in Anglo-American bioethics: most recently Amitai Etzioni's complaint that overemphasis on individual choice marginalises the broader interests of society (28)-and, one could add, does the socially dispossessed few favours. But what sets France apart is that those critical of commercialisation and markets are not voices crying in the wilderness; rather, they constitute the political mainstream. Their views often make public policy.

For example, France was the only country to ban the exhibition by Gunther von Hagens of plastinated bodies, on the grounds that it was a commercialised violation of individual dignity and that the donors' supposed consent was spurious, in light of indications that the bodies were those of executed Chinese criminals. From its beginnings the French national consultative ethics committee, the oldest in Europe, has consistently reiterated a stance against commodification of the body (8).

In the name of its cherished principles of altruistic and anonymous donation, France has also rejected proposals from private cord blood banks to set up operations there-a potentially lucrative market, given the high French birth rate. The value of social provision over private was restated in this context by Senator Marie-Thérèse Hermange: "Cord blood should be available to all, in a framework of public solidarity, at no cost, not privatised." (29) The country now has 10 public cord blood banks, with more being set up, but has rejected overtures from combined private-public banks as a Trojan horse enabling the private sector to infiltrate the public. As the medical evidence base suggests that publicly banked allogeneic blood is clinically more efficacious than privately banked autologous blood (30), this position makes both medical and ethical sense.

Conclusion

France is not a Shangri-La isolated from global markets and their accompanying neo-liberal economic orthodoxy. There are powerful voices arguing for the nation to move with the times, to become more internationally competitive in scientific research and biotechnological investment by embracing those distrusted Anglo-Saxon attitudes. Professor René Frydman, who helped to create the first IVF baby in France and who favours paid egg provision, has complained, for example, that his country "always prioritises risks before progress" and argues that "there can be no progress without commercialisation." (30, 31)

Nor is France a paradise; indeed, there are fears that it may become something more like a Paradise Lost. In the words of Emmanuel Hirsch, professor of medical ethics at the University of Paris-XI, "How long can our bioethical standards continue to resist the rise of other logics-particularly financial ones-which are worming their way into the governance of medical research and determining its objectives, its norms and its values, to the detriment of the common good?" (32) Given global trends in India, China and other developing countries-not just the dominant US and UK market-friendly systems of regulation-this is a serious and troubling question.

Hirsch's doubts were borne out during the Senate debate, in which some commentators detected an increasing influence of

commercialised biotechnology. As the senator Bruno Retailleau put it, "The Senate prides itself on protecting individual liberties, but at the risk of neglecting the public welfare," which he attributed to the way in which "the influence of the scientific lobby on the Senators grows and grows." The former director of the national research network INSERM, Professor Alain Privat, remarked that "This lobbying is incomprehensible from a medical or scientific viewpoint, unless you attribute it to the need for certain organisations to justify to their generous funders the highly important investments they've made in stem cell research, despite the fact that this research hasn't yet resulted in any effective therapies anywhere in the world." (33)

Some might contest my depiction, which I share with most French commentators, of the way in which market norms dominate Anglo-American regulation of reproductive medicine. The HFEA enjoys a global reputation for well-considered governance, particularly among US scholars who are troubled by their lack of any equivalent national regulatory agency. In the HFEA's most recent consultations, however, the balance seems to be increasingly tilting away from regulation towards permissiveness, as in the view of ethical considerations as something to be offset. It might be said that the ongoing and rather undeserved conviction that the UK's regime outshines that of other countries, France presumably included, resembles nothing so much as Thackeray's certitudes about the moral and physical superiority of the Englishman over the Frenchman:

I say to you [the English reader] that you are better than a Frenchman. I would lay even money that you who are reading this are more than five feet seven in height, and weight eleven stone; while a Frenchman is five feet four and does not weigh nine. The Frenchman has after his soup a dish of vegetables, where you have one of meat. You are a different and superior animal—a French-beating animal (the history of hundreds of years has shown you to be so); you must have, to keep up that superior weight and sinew... simpler, stronger, more succulent food. (34)

As I remarked in an earlier newspaper article (35), "Of course, we now know that a diet of bully beef is likely to result in hardening of the arteries, whereas the vegetable-centered Mediterranean diet is much better for human health. Enough said?"

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Note

All translations from the French are the author's own.

Commentary on HPV screening for cervical cancer in rural India

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Abstract

In 2009 Sankaranarayanan et al published their findings from a large cluster-randomized, controlled trial of a single round of HPV testing, cytology testing or visual inspection with acetic acid - with appropriate treatment for those confirmed positive - as interventions to decrease mortality from cervical cancer. The control arm did not receive any screening or treatment. Several issues are brought up through the approval and conduct of this trial, which was carried out among high-risk women in rural Maharashtra, India. Specifically, this trial offers an opportunity to further discussion around clinical equipoise, identification of primary endpoints, observation of null effects, and the informed consent process, within the context of a low-income setting. Such discourse may shed light on the necessity and manner of examining a biomedical intervention in low-income settings, when the intervention is already considered efficacious in high-income settings.

Introduction

Sankaranarayanan et al make a convincing case for human papilloma virus (HPV) screening leading to reduced mortality from cervical cancer in a population of largely unscreened rural women in India (1). It is true that, as the authors say, "The most persuasive scientific evidence for the efficacy of a cancer screening test comes from RCTs with reduction in incidence of or mortality from the disease of interest as the end point." (2). Yet, in light of the controversy around the standard of care offered to research participants in low-income countries, the design of this study offers an opportunity to advance this debate. In particular, an in-depth discussion of the various concerns regarding the protection of human subjects may prove valuable. Such discourse may shed light on the necessity and manner of examining a biomedical intervention in low-income settings, when the intervention is already considered efficacious in high-income settings.

The study discussed here is a cluster-randomized, controlled trial of a single round of cervical cancer screening by either HPV testing, cytologic testing or visual inspection with acetic acid (VIA), starting in 1999 in rural Maharashtra, India. The primary outcome for the adult women enrolled (n=131,746) was cumulative mortality from cervical cancer. Women with positive screening results had confirmatory tests and appropriate treatment was provided when cervical precancerous lesions were found. Women in control villages did not receive any screening or treatment. Results indicated that, relative to women in the control group, women receiving HPV testing experienced a reduction in cervical cancer mortality. Reductions were not evident for women receiving cytologic testing or VIA.

Establishing equipoise

Established recommendations around screening programmes indicate that screening should be implemented only when there is - for the local population - an acceptable balance of false positive and false negative test results, and that screening programmes should lead to entry into efficacious treatment. For cervical cancer, the diagnostic capability of cytology has been established in a range of settings, as is the high cure rate from early detection of cervical precancer (3). It is for these reasons that cervical cancer screenings have been an established element of the standard of care in high-resource settings (4), making it controversial now to relax screening frequency recommendations; it is beyond question whether any screening is better than no screening. Furthermore, in 2001 Sankaranarayanan et al point out: "Frequently repeated cytology screening programmes - either organized or opportunistic - have led to a large decline in cervical cancer incidence and mortality in developed countries. In contrast, cervical cancer remains largely uncontrolled in high-risk developing countries because of ineffective or no screening." (5) (emphasis added)

By conducting this trial, the investigators and their ethics review boards necessarily imply that clinical equipoise exists. The investigators implicitly posit that the sensitivity of the various screening methods is not necessarily better than diagnosing cervical cancer by chance, and/or that the mortality for women testing positive by these methods and treated will not necessarily be lower than those who are unscreened but positive. After establishing that cervical cancer is a major source of mortality throughout India, clinical equipoise is possible only through a combination of these factors.

On a related point, it would be of interest to know whether the study was powered to detect a clinically relevant effect for India, or whether there was enough prior evidence that a single screening would reduce mortality by 50%. Future randomized controlled trials of this nature should provide further detail on the selection of parameters for the power calculation, as the clinically relevant effect to justify wide-scale implementation of a screening will differ by setting.

Endpoints and null effects

As Cuzick et al have stated, "Although some have argued that there is no direct evidence of the impact of cytology screening on cervical cancer, such as evidence from a randomised clinical trial, there are overwhelming and convincing epidemiologic data to infer the impact of successfully implemented cytology screening on reducing cervical cancer rates." (6) We may take note of Cuzick's endpoint, "cervical cancer rates"; with

supportive evidence coming from papers published over the past three decades.

Indeed, it is of particular interest why cervical cancer mortality was a necessary endpoint; the authors themselves pointed out in 2005 that "The ultimate proof of efficacy of a screening test for cervical neoplasia is its ability to protect invasive cancer when implemented in a program setting."⁽²⁾ A non-mortality endpoint has been found acceptable in another low-resource setting trial (7), and can be incorporated into a cluster-randomised design that allows investigators to estimate the measure of effect, while eventually providing participants with the known benefits of screening (8,9). Others have mathematically modelled screening interventions using well-established parameters of screening sensitivity, specificity, risk factor prevalence and natural history, which can provide compelling evidence of effect (10,11). It is questionable, then, whether human experimentation is required to demonstrate a mortality benefit from cervical cancer screening.

One of the most striking features of this trial is that while the statistically significant result from HPV screening is given ample discussion, the two null results (for cytology and VIA screening) are scarcely mentioned. In a 'gold standard' trial design - the RCT - all results from pre-specified hypotheses should be given equal consideration, as they were all subject to clinical equipoise at the trial's start. For cytology, some of the investigators involved with this study have earlier written that the evidence that cytology reduces cervical cancer mortality is "overwhelming and convincing" (6). And VIA is a screening method that has been widely adopted in other low-income countries. As such, it is incumbent on the investigators here to give equal attention to the result from these two arms' null results as they did for the significant HPV arm result. The authors initiated this process in response to letters to the *New England Journal of Medicine* (13). But to the extent that clinical equipoise existed prior to the trial, the null results do not appear to have provided any clarity to the effectiveness of cytology or VIA screening on cervical cancer mortality. This calls attention as to why there were cytology and VIA screening arms in the first place, and thus why the investigators subjected thousands of additional women to this research experiment.

Informed consent considerations

It is crucial to consider what consenting women understood with regards to the research question. While women in the intervention arms may not have completely understood the nature of their respective screenings, the unscreened women were unblinded to their study arm. How did the investigators communicate the potential and real risks and benefits of screenings vs no screening to these women?

Perhaps the investigators can provide additional detail on the education programme in the control arm, so that only 5.8% of these women "requested early detection at [Nargis Dutt Memorial Cancer Hospital] during the period 2000-2003 as a result of health education."⁽²⁾ It is of interest to receive answers to a number of questions. First, what relationship

did the health educators have to the investigators? Second, how did the consented women demonstrate comprehension of the educational programme? Third, to what extent were these women aware of the known benefits of cervical cancer screening, and the fact that they were selected into the study because they were part of a high-risk developing country population? These are all crucial elements of the informed consent process, and require special attention, given that 70-73% of the women had "no formal education".

Finally, while it is true that "The randomization of groups of women in clusters minimized the possibility that those assigned to one study group would receive the intervention provided to another study group."⁽¹⁾, it is difficult to see how contamination of this intervention by study staff would be possible. If contamination would not be possible by staff, the investigators should identify how and why contamination would occur under an individual randomisation design. This is a critical aspect of intervention trial design; as cluster-randomisation increases the sample size needed to detect a given effect, relative to individual randomisation, the exact source of the contamination should be identified so as to inform future screening trials.

Conclusion

It is important to note that Sankaranarayanan's co-investigators are largely locally based and the study itself received approval from international and Indian national ethics committees. However, a discussion around these issues will be highly informative. There are numerous demonstrably effective routine screening programmes in high-income settings that detect conditions with significant burden in low-resource settings. It is incumbent on the public health community to establish whether randomised control trials are required to justify their implementation in the latter, and the informed consent process and standard of care used for a control group.

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Reply to S D Rathod's Commentary on HPV screening for cervical cancer in rural India

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The study in Osmanabad district, India (1), was organised to measure the effect of a single round of screening by HPV testing, or quality assured cytology, or visual inspection with acetic acid (VIA) on cervical cancer incidence and mortality, whereas reductions in disease have followed repeated rounds of high-intensity screening in developed countries. Prior to this study there was only evidence from model-based studies that a single round of screening may lead to significant reductions in disease burden. Thus, in contrast to the impression given by Rathod (2), this study was not a repeat of work conducted in developed countries but was unique in addressing the impact of a single round screening with different tests, with a research question and study design directly relevant to developing countries. It is crucial that this type of high-quality research is encouraged in order to inform public health decisions in regions where health services face difficult challenges.

The study was designed as a cluster randomised trial to avoid contamination between the study groups and for logistic convenience. We decided that providing services to clusters of women with a given screening test is more convenient in terms of clinic organisation than providing different screening tests in the same village clinic for a group of women based on individual randomisation. Moreover, it prevents any possible unintended error in providing appropriate screening test as per randomisation and women crossing over to different interventions at random.

The standard of care for cervical cancer control in India is clinical diagnosis and treatment of invasive cancer only when symptomatic women seek medical attention. There is no organised or large-scale opportunistic cervical cancer screening programme anywhere in the country. Around one million cervical smears are taken annually in a sporadic fashion, mostly in urban areas, in a country where there are more than 150 million women in the age group 30 to 59 years. For instance, only 8 of the 131,746 women aged between 30 and 60 years in our study population had ever had a Pap smear, indicating the scarcity of routine screening in the general population.

Whenever a new intervention is evaluated, it is compared with the standard of care existing in the country. It is important to know if a single round of screening has the ability to reduce disease burden significantly, over and above the existing care, before taking decisions on implementing them as a public health policy, particularly in poorly financed health services. Thus the control group in our study was not offered screening, but they were educated on a person to person basis on cervical cancer, its risk factors, symptoms and signs, its prevention, early detection, treatment and where to seek cytology and follow-up services, by the study health workers who interviewed them for socio-demographic factors. Probably due to the education received, 1,946 (6.2%) women in our control group sought Pap smear and among those 15 were detected with histologically proved high-grade disease, 41 were diagnosed with invasive cancer, and all were offered appropriate treatment.

The study was adequately powered to address the research question that we set out to answer and to detect a clinically relevant effect for India and other low-resource countries, as described in the manuscript. The death rate from cervical cancer in women aged 30 to 59 years was assumed to be around 20 per 100,000 women and the actual death rate in the control group was 25.8 per 100,000 person years.

Evidence on disease burden in terms of incidence and mortality, particularly from randomised controlled trials, provide the most persuasive evidence for the effectiveness of a novel screening approach, such as a single round of screening, rather than results of the accuracy, detection rates of precancerous lesions and model-based studies of screening tests which are unlikely to drive public health policy changes on their own.

Informed consent in studies in developing countries may be portrayed as contentious by researchers who have limited understanding of the prevailing socio-cultural context. In our study, the health workers read out the consent form in the local language, explained the interventions, responded to the participants' doubts and questions, and enrolled women who were willing to participate. There was no coercion whatsoever. It would be unfortunate to imply either that people in developing countries are unable to comprehend the risks and benefits of interventions provided to them simply because they have less formal education, or that researchers in developing countries administer the informed consent process in an ambiguous or incomplete manner. Furthermore, it is presumptuous to think rural women with no formal education are incapable of understanding and comprehending what is being offered to them and making a decision to participate or not or to withdraw from the study at any given time during its course.

The study was planned, conceived and implemented by a group of experienced investigators in India and abroad, who are well versed in the prevailing socio-cultural norms and health services in rural India. Particular care was taken to provide the entire continuum of services comprising education, accessible screening clinics, provision of quality assured screening tests

by trained providers, diagnosis, treatment and follow-up care of screen-positive women and effective information systems to monitor and evaluate the inputs and outcome as diligently and efficiently as possible. It is rather surprising to suggest that the project was implemented sub-optimally because certain interventions did not show mortality reductions in this study context. It is not surprising to find studies with contrasting findings. In addition, we have not precluded the possibility of under-diagnosis and underestimation of invasive cancer cases in the control group due to a relatively underdeveloped routine cancer health services in the region and a proportion of symptomatic cases not seeking diagnostic and treatment services (3). Perhaps this might be a reason for the lack of incidence effect in the study for all the arms and for the lack of mortality effects in the VIA and cytology arms. Alternatively, a single cytological screen or VIA screen might not have been consistently sensitive for detecting biologically significant high-grade precursors with the potential to progress to invasive cancer, due to the provider-dependent subjective nature of these tests. If this is true, repeated rounds of cytology may be necessary to reduce cervical cancer burden.

The high level of participation of the target population in screening, diagnosis, treatment and follow-up over several years in our study is an excellent testimony to the comprehension of the community, the general public, the women and their families, as well as the municipal and civic authorities in the study location. Their much appreciated cooperation in the successful conduct of this original piece of research allowed a crucial public health problem for many developing countries across the world to be addressed.

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Technology in health care: current controversies

Editors: Sandhya Srinivasan, George Thomas

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This collection of essays covers important discussions related to medical technology that have been carried in the *Indian Journal of Medical Ethics*. Each of the nine sections is preceded by a commentary by an expert in the field. The nine chapters cover placebo controls in research; intellectual property rights; family planning and population control; the HIV/AIDS programme and research; electro convulsive therapy without anaesthesia, liver transplant technologies, end-of-life care, medical professionals and law enforcement, and technology in public health programmes.

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Maternal deaths in Rajasthan: where does the buck stop?

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For centuries, the handling of childbirth and childcare was considered the domain of midwives and mothers. The second half of the 20th century witnessed a change in thinking. The role of the state in improving the health of people came to the forefront. In the opening years of the 21st century, the millennium development goals placed maternal and child health at the core of the struggle against poverty and inequality, as a human rights issue. With a booming economy and an improved standard of living, no mother should die in the course of the normal process of giving birth. However, more than 500,000 mothers are still dying each year, mostly of avoidable causes (1).

In February 2011, 13 pregnant women died within 12 days in Umaid and MGM hospitals, two government-run specialty hospitals affiliated to a medical college at Jodhpur, Rajasthan (2). Another five maternal deaths took the death toll to 18 in the next nine days (3). Following a public outcry, the government of Rajasthan instituted an enquiry into the matter. Experts from SMS Medical College, Jaipur, conducted the investigation. The report has pinpointed the contamination of intravenous fluid as the probable cause of maternal deaths. The government ordered the arrest of the owner of the IV fluid manufacturing plant, in addition to suspending three other low-ranking health department officials. The next of kin of each woman who died received Rs 5 lakh compensation.

The maternal mortality ratio of India was estimated to be 254 per 100,000 live births for the period 2004-06, a far cry from the national goal (4). The strategy adopted by the government of India through its reproductive and child health programme consists of: quality ante-natal care; essential obstetric care at the domiciliary level, and emergency obstetric care at first referral units. Cash incentives schemes were added later to promote institutional deliveries, viz. Janani Suraksha Yojana (JSY) under the National Rural Health Mission. Institutional delivery rates have been reported as showing a substantial increase since the introduction of the scheme. However, these have not translated into a reduction in maternal mortality ratios. The northern states, Punjab, Haryana, Uttar Pradesh and Rajasthan have not benefited from this intervention, the reasons for which need to be explored (5). Incidents of the kind that occurred at Jodhpur will be a serious setback to the government's programmes to promote institutional delivery. We need to critically reexamine our preparedness to ensure the safety of the women who come to hospital to give birth in a secure environment.

This incident also opens up several micro and macro level issues for deliberation.

The micro level issues are specific to attending hospital such as quality of care, infection control practices, standard operating procedures, inventory control and medical audit. Quality of care continues to be an issue of concern in public sector hospitals of India. A recent assessment of institutional delivery under the JSY in the neighbouring district of Jaipur states that "quality aspects of institutional deliveries are far from desired level mostly because of lack of resources, both manpower and materials; non achievement of Indian Public Health Standards". The quality of institutional delivery care was found to be better in private hospitals in comparison to public sector hospitals (6:177). Recent initiatives by the government of India, such as the introduction of Indian public health standards for public health institutions at different levels, and opening the doors to national accreditation, have not moved beyond the manuals and booklets.

At the macro level, such occurrences should stimulate introspection into the whole process of manufacturing, and distribution of drugs as well as the quality control at different levels. While the introduction of new drugs or vaccines into the market is governed by the Drugs Controller General of India, the manufacture of drugs is under the ministry of chemicals and fertilisers. India is perhaps the only country in the world where this is the case. Pharmaceutical manufacturers are supposed to comply with good manufacturing practices endorsed by WHO. Little is known about how good these good manufacturing practices are.

Finally, the key question is the preparedness of hospitals to ensure optimum maternal health. It is often said that every maternal death teaches the health system a lesson. How many maternal deaths do we need to witness before our health system becomes wiser and more responsible?

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National Rural Health Mission: the current scenario

The National Rural Health Mission (NRHM) claimed the lives of two senior doctors in Uttar Pradesh in the past year (1). Their only fault, it seems, was they had a large budget at their disposal and were trying to clean up the system.

The annual renewal of the Samvida staff for the year 2011-12 was due from April 1, 2011. At the time of renewal, those who wish to be reappointed are expected to pay up to two months' salary as commission. This comes to around Rs 40 lakh if just 100 staff members renew their contracts. Commissions are also taken with every monthly salary cheque. The Rogi Kalyan Kosh, at all primary health centres (PHCs), community health centres (CHCs) and district hospitals, has large budgets which come under the NRHM. So one can appreciate the sums of money involved in the day-to-day running of the department.

The effect of the second murder was that both health ministers in the state were sacked, and the health secretary and chief medical officer (CMO), Lucknow, were relieved of their posts.

The renewal of AYUSH doctors and staff has been put on hold till further orders. This is despite the fact that the NRHM scheme promotes the AYUSH system of medicine as a means to provide affordable health to all, and the state receives grants from the central government for this purpose.

In 2010, the post of district project officer was created to look after the implementation of NRHM. It was later renamed 'chief medical officer (family planning)'. This led to confusion as the Samvida staff came under the CMO (FP) but were posted in the PHC and additional PHCs under the CMO. Disputes arose about their jurisdiction, aggravated by the fact that large budgets were involved. There was a case where the CMO filed a report with the superintendent of police requesting police protection. Finally both the CMO and CMO (FP) were transferred out of the district as the situation was causing great embarrassment to the administration. Now the posts of additional CMO and deputy CMO, NRHM, have been created to supervise the programme.

After *IJME* published an article on the NRHM (2), salaries have been paid monthly by cheque. However, gratification must still be paid to get the cheque. Further, even now, deliveries under Rashtriya Janani Yojna are not above board. The ASHAs

fight amongst themselves to get credit for the deliveries and prefer to go to Auxiliary Nurse Midwife (ANM) centres and not the PHCs, as they make money for the deliveries; they do this even for high risk deliveries, which doctors would refer to a higher centre, in order to get the money which they lose when deliveries are referred. If there is a mishap, the Samvida doctor is made a scapegoat; he/she is the weakest link in the chain being a contract employee. At government hospitals, the pharmacist dispenses less than what is actually prescribed by the doctor on duty. But entries are made in the registers as though the correct drug and correct quantity have been dispensed.

Given these circumstances, one should not be surprised if one gets to hear of more doctors in government service being terrorised and murdered. The powers-that-be realise the potential of the money being generated in the NRHM and other national programmes. They will now demand their pound of flesh.

Under the Rashtriya Swasthya Bima Yojna, families certified as living "below the poverty line" and possessing a smart card are entitled to reimbursement of Rs 30,000 per family per year for medical treatment at approved government and private hospitals. This generates a huge amount of money for insurance company employees, doctors and government revenue staff. False smart cards have been manufactured and used to compensate for various treatments. Today smart card holders approach doctors or their close associates and ask them to create falsified records for operative procedures, and share the reimbursements under the scheme. Some arrests have already been made in this regard.

In such circumstances, to believe that the benefits of any scheme can percolate to those who need it would be asking for the sun.

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Editor's note: The name of the author is being withheld on request.

REPORT

The upgraded Clinical Trials Registry India: a summary of changes

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The Clinical Trials Registry-India (CTRI) was launched on July 20, 2007 and since then has grown to become a significant contributor to the global pool of accessible clinical trial data (1). Trial registration in the CTRI is now mandatory. Currently more than 1,800 trials are registered in the CTRI.

An upgraded version of the CTRI software application was launched on March 15, 2011 in order to simplify the trial registration process as well as improve the search facility. In the revised version, the dataset points remain much the same as before; a few sub-points have been added to ease data collection, analysis and retrieval. The major revisions are highlighted below.

Revised CTRI dataset points

The CTRI dataset form is divided into eight parts. Part 1 must be filled first; the remaining may be filled at the convenience of the registrant.

Study type: To enable better categorisation of trials, the dataset point 'study type' captures information regarding whether a trial is observational, interventional or post-marketing surveillance or a BA/BE study. Interventional trials are further expected to be categorised as per a defined list. Trials conducted as part of a postgraduate thesis submission are also recorded.

Site/s of study details: The earlier version of the CTRI did not have an "edit" facility in this section, making site detail modifications an onerous task, particularly for multi-centre trials. An edit facility has been included in the new version.

Name of ethics committee(s) and approval status: Two major revisions have been incorporated in this section. Ethics approval (and Drugs Controller General of India approval) documents are to be uploaded from the dataset form. The uploaded documents will, however, not be available in the public domain. This dataset point also collects information on the type of ethics committee, independent or institutional.

Multi-country global trials: In the earlier version of the CTRI, for multi-country trials, information regarding the Indian target sample size, date of first enrollment and status of recruitment was recorded in the Brief Summary. In the revised version of the CTRI, this information is captured in the main dataset form alongside the global information, in separate dedicated text boxes.

A separate field has been added for recording publication details that arise directly out of the trial.

Trial submission

In the earlier version of the CTRI, a trial could be submitted to the CTRI for review upon filling certain mandatory fields. However,

in the revised version, a trial is not submitted unless all dataset points have been filled. This feature has been introduced to ensure that complete trial information is recorded.

Review process

Unlike the earlier version, in which an entire trial was reverted to the Edit Mode, in the revised version, only the dataset points which need clarifications or modifications are modifiable, while the others are locked for editing to avoid the need for re-scrutiny of all dataset points.

Flagging of trials

In the revised version of the CTRI, upon registration, trials are immediately flagged according to the date of trial registration i.e. "retrospective" or "prospective" registration. "Prospective registration" indicates that the trial is registered before the enrollment of the first patient in India. "Retrospective registration" indicates that the trial is registered after the enrollment of the first patient in India.

Audit trail

On registration, a trial is expected to be regularly updated. In the revised version, these updates have been brought into the public domain and are now viewable under "modifications." This feature is expected to further enhance transparency and accountability of clinical trials.

Trial transfer

The need was felt for the option to transfer trials between registrants. In the revised version, it is now possible to transfer a trial from one registrant to another, within a company or between companies, upon submission of the appropriate authorisation documents.

Conclusion

The registration of trials in CTRI is online and free. Key information of registered clinical trials is freely searchable from the CTRI site. The revised and upgraded version of the CTRI software is designed to simplify the trial registration process as well as improve data retrieval. It is hoped that the information available in the CTRI / database will be used by patients, social activists, parliamentarians, healthcare professionals, the pharmaceutical industry, and healthcare policy makers.

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SELECTED SUMMARY

Short-term research projects in low-resource settings

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Audrey M Provenzano, Lauren K Graber, Mei Elansary, Kaveh Khoshnood, Asghar Rastegar, Michele Barry. Short-term global health research projects by US medical students: ethical challenges for partnerships. *Am J Trop Med Hyg.* 2010; 83(2): 211-4.

A chance to train in a low resource setting is a priceless experience for someone who aspires to pursue a career in international health. In recent years the number of US-based medical students undertaking short-term research in low-resource settings has gone up. The paper by Provenzano and others describes specific ethical concerns related to this phenomenon and suggests guidelines medical schools can adopt to ensure that such research is beneficial to both the host and collaborating institutions.

The cost of training medical students in international health research for two to three months, just enough time for them to get used to their research setting, is high. Much of this research does not translate to new scientific knowledge but it does provide opportunities to young medical students to gain experiences that help shape their careers. The authors therefore propose that such opportunities be given to students who possess excellent personal character, exhibit high calibre in academics and research and are highly motivated to work in the field of international health.

The authors use a vignette-based mode of lucidly describing the problems faced by medical students undertaking ethical short-term global health research:

1. Student researchers are not oriented towards the culture and language of their host countries. This makes it difficult for them to collect the data required for their research. The functioning of the health system is affected when already overworked staff must help solve students' problems.
2. Such research is often based on the priorities of funding organisations, neglecting the needs of the host institution and communities where research is done. Such prioritisation causes experts in the hosting institutions to neglect research that is important for their community.
3. Ethical clearance from the Institutional Review Boards at both the host and the collaborating institutions is usually given after examination of the informed consent process. However, the process of taking consent at the site of data

collection can be far from what the researcher envisaged. While collecting data without proper consent is unethical, there is a need to incorporate field requirements into this process.

The authors suggest a list of possible solutions:

1. Such projects must be undertaken within the context of a "highly comprehensive, collaborative, bilateral partnership between the US medical school and the host institution in the destination country."
2. It must be ensured that the research does not overburden the host institution.
3. There must be a longstanding partnership so that the US-based faculty would have lived at, worked at, or at least visited the intended site of research, and therefore is able to advise students on the barriers that may exist at the site of data collection.
4. Medical students should be trained in research methods, research ethics and local cultural requirements before their departure. They should have the help of a research advisor, interpreters and logistical support in order to undertake the research as planned in the host country, and the partnerships must provide for adequate compensation for their contributions.
5. Any comprehensive partnership should provide funding for professionals and students from the hosting institution to rotate at the collaborating institute. Such ventures will build better relationships between the researchers at both institutions.
6. Research in low-resource settings must be in response to the needs of the community. Such research can be achieved if the host institution consults its community and prioritises their needs. The topics in which research is desired can then be given in writing to the collaborating institute, which on its part can facilitate research in these topics by providing funding based on whether the student has chosen a priority topic.
7. A longstanding research partnership allows sustainable capacity building and strengthening of resources at the host institution. Medical students must be encouraged by their institutions to include partners from the host institution in different elements of the research process including authorship.

Commentary

While such efforts exist and have facilitated the development of guidelines for ethical partnerships that are meaningful to both collaborating and host institutions, collaborating institutions in the US will continue to have the bigger slice of the pie until host institutions have a say in funding and selection of topics for research and researchers. Until this happens, research will continue to be dominated by the interests of foundations and agencies with their own pre-conceived ideas about what the problems of the low-resource countries are and how they must be solved.

Student exchange programmes must be based on clear objectives and such students must have a clear idea of what they hope to gain professionally from the programme.

Such initiatives should also create opportunities for young researchers in resource-poor settings and not be driven by local hierarchies which may not necessarily build research capacities in host institutions. Unless there is mutual recognition of the relative advantages and disadvantages of such partnerships, no amount of guidelines will make a difference.

Indian Journal of Medical Ethics: selected readings 1993-2003

Editorial collective: Neha Madhiwalla, Bashir Mamdani, Meenal Mamdani, Sanjay A Pai, Nobhojit Roy, Sandhya Srinivasan

Published by: the Forum for Medical Ethics Society and the Centre for Studies in Ethics and Rights, Mumbai. November 2005. 248 pages. Rs 150.

This selection of essays previously published in the *Indian Journal of Medical Ethics* can serve as a short education on health care ethics in the Indian context. The articles are divided into five sections: personal integrity, communication, technology and social justice, research ethics, and law, policy and public health. The preface gives an overview on the emergence of medical ethics as a topic of interest in India. Introductions to each section and article give the reader a background to the discussions and their relevance today.

The topics covered include: the Hippocratic oath; ancient and modern medical ethics in India; problems in medical education; the relationship between physicians; the role of the pharmaceutical industry, informed consent, debates on medical technology, ethics committees, whistle blowing; how to interact with patients intending to try another system of medicine; AIDS vaccine trials; sexuality research; authorship; and violence and the ethical responsibilities of the medical profession.

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REVIEWS

More questions than answers

A MOHAN

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Mariette van Huijstee, Irene Schipper, editors. *Putting contract research organisations on the radar. Amsterdam: Centre for Research on Multinational Corporations (SOMO), Salud y Farmacos, Centre for Studies in Ethics and Rights; February 2011. ISBN 978-90-71284-68-7.*

The past two decades have seen the emergence of third world countries as important sites for drug trials and related clinical research sponsored by the pharmaceutical industry. As the authors of the report under review have noted, "fast recruitment of trial participants, presence of a broad spectrum of diseases, availability of human resources and technical skills, different ethnic responses to drugs and the availability of treatment naïve population" are powerful drivers of this phenomenon. In addition to such off-shoring, the authors have also drawn attention to outsourcing of trials to clinical research organisations (CROs). Considering the potential for abuse of rights and ethical deviations, such a study of this phenomenon was a pressing need.

The research questions the authors have raised are:

1. What are the characteristics of the CRO sector in general, and in off-shoring countries in particular?
2. What ethical risks are associated with the outsourcing of clinical research to non-traditional regions?
3. How do pharmaceutical companies safeguard the upholding of the ethical standards they are committed to when they outsource clinical research to CROs in non-traditional trial regions?

The authors' expectations at the initiation of this study were that:

1. The same problems with outsourcing - like lowering of labour and environmental standards - that have been observed in other industries would be observed here, too.
2. Despite outsourcing being a widespread practice, pharmaceutical companies do not recognise, *and implement*, their responsibilities down the chain, and
3. Outsourcing being a relatively new phenomenon, the distribution of liabilities between sponsor and CRO would not have crystallised.

The study involved a preliminary literature review, country-level studies in Argentina, Brazil, India and Peru, and interviews with clinical trial experts and pharmaceutical companies. Not surprisingly, they report that the realisation of the research ambition proved much harder than anticipated *because of the*

"extreme lack of transparency of CROs in particular and the pharmaceutical industry in general" - leading to delivery of "diverse and not necessarily comparable information". In other words, both CROs and pharmaceutical companies were not forthcoming with quality information.

The authors report on whether or not their expectations at the initiation could be conclusively confirmed:

1. Their first expectation that the standard of ethics would be lower was confirmed - ethics had to yield to speedy recruitment and cost containment.
2. Their second expectation - that industry may not take the responsibility for all players in the research and development process - could not be confirmed; while at the policy level protections seemed in place, there was lack of independent oversight on the part of regulators and ethics committees in the developing world.
3. Their third expectation also could not be confirmed, as responsibilities were fairly clear on paper with the sponsor remaining responsible for the ethical conduct of the clinical trial. What was not clear was: who would be responsible if there were negligence or misconduct, for example.

The authors have not been able to establish the extent of shift of responsibility from sponsor to CRO - for oversight and liabilities when there is an agreement to outsource. They were not privy to these agreements. As reported elsewhere (1)1, these agreements are not submitted to ethics committees or regulators; therefore, enforcement of this liability is a major issue.

The authors concede that the research throws up more questions than have been answered. Lack of investigative authority has forced them to depend on interviews rather than on documents. This is a major drawback. Pharmaceutical majors Bristol Myers Squibb, Eli Lilly, Merck/MSD, Pfizer-Wyeth and Roche did not participate at all. Janssen and Sanofi-Aventis only submitted written statements in response to questions. Abbot, AstraZeneca, GSK and Novartis gave complete interviews on the telephone or by email.

The report with seven chapters has been finalised after five phases of activity:

Phase 1 : preliminary, exploratory study; phase 2 : country-level studies; phase 3 : analysis and integration of country studies; phase 4 : interviews with pharmaceutical companies; phase 5: review by partners and companies.

The greatest attraction of this report is its lucidity. The conclusions are predictable, if a trifle disappointing. Despite the handicaps of the study, the authors identified the following as measures to be taken for protection of participants' rights:

- Setting up a worldwide, compulsory trial register in which all involved parties including the contractors and subcontractors are disclosed.
- Increasing the number of regulatory inspections of trial sites in non-traditional trial regions.
- Including in Marketing Authorisation Application procedures independent verifications that the drugs have been tested in accordance with the Declaration of Helsinki.

- Involving independent organisations that promote the interest of clinical trial participants in audits of trial sites conducted by sponsors and CROs.
- Involving clinical trial participants in inspections and audits, so that their perspective on the ethical conduct of the trial is included.
- Making audit and inspection results publicly available.

That would be a good way to go.

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Human building blocks of research

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Rebecca Skloot. *The immortal life of Henrietta Lacks*. Macmillan Publishers Ltd; 2010. pp. 368 £18.99

The immortal life of Henrietta Lacks is non-fiction of a rare quality in creative writing. The author, a science journalist, weaves a multilayered narration about medicine, medical research, faith, racism, poverty, and ethics with a skill that renders to her composition an "immortal quality".

Henrietta Lacks was an African-American woman, a mother of five children, who died of cervical cancer in 1951, at the age of 31. At the Johns Hopkins Hospital in Baltimore, United States, where she was receiving treatment, tissue specimens were taken from her cervix for research, without her knowledge. The specimens turned out to be the source of the first viable and amazingly productive cell line - the famous HeLa cells so familiar to all engaged in medical and cell biological research. The cells became the fountainhead of a range of medical discoveries, research applications, therapeutics and vaccines. The book provides a human face to the many ethical issues concerning the HeLa cell line.

The cervical tissue specimen was used by George Gey at Johns Hopkins. Gey's assistant labeled the tubes where the cells were stored "HeLa". The cells doubled in number every 24 hours and never stopped. Since then many trillions of cells have been produced and used in laboratories and factories all across the globe and are robust even after 60 years. The polio vaccine, the drug tamoxifen, gene mapping, in vitro fertilisation, treatments for influenza, leukaemia, Parkinson's Disease are all applications which have harnessed the biological potential of HeLa.

Science is not the only fascinating aspect of this book that lifts it to the rank of a best seller; nor is it the central theme. The

author, in her exploration along with Deborah, the daughter of Henrietta, who did not know her mother, has been able to knit together a story of the sad life of Henrietta, the racist norms of that period, the deprivations of African-Americans, and the almost non-existent research ethics of the mid 20th century. It is shocking that even after 20 years after HeLa became a famous biomedical research tool, Henrietta's family was unaware of these developments. Needless to say, they did not receive even a few pennies of the profits from the multimillion dollar industry in biological and cell culture based on her cells. Much later, they were even subjected to investigations without their informed consent.

In February 2010, Rebecca Skloot spoke at the Kimmel Cancer Centre in Philadelphia to a crowd of physicians and scientists, most of whom knew HeLa cells, but nothing else of their origin or history. She told the story of the young black woman who reported to the clinic at Johns Hopkins for treatment for a tumour in her cervix. She received the treatment of the time, a course in radiation. The diagnostic sample took a course of its own. It went to a cell biologist who knew nothing about its origin until it started producing manically upon culture. Mass production ensued. HeLa was distributed around the world. Skloot described the family's anguish at the fact that a vial of HeLa cells costs \$250 and some HeLa-derived products for treatment cost up to \$10,000, while many members of the Lacks family go without health insurance and treatment for their illnesses.

As research and discovery activities go global, there may be some warnings for us in India. Human subjects who participate in experiments give "informed consent". How informed is this consent? Does the consent form list all possible uses to which a specimen may be put? For example, DNA material is collected

from human subjects. Its use must be regulated and cannot be left to the goodwill and largesse of corporations which are driven by profits. What about pharmacogenetic information based on DNA collected from subjects in trials? This is of value to pharmaceutical companies.

A myriad possibilities exist and we can only address the issues by building trust and sharing among scientists, society and

industry. And we will have to travel some distance to reach that state of affairs. Unlike in the USA during Henrietta Lacks' period, we have no racial divide in India, but this is offset by economic and educational deprivation.

The book is a 'must read' for physicians, researchers, corporates in healthcare, social activists, and those engaged in medical ethics.

Talking reflections

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***Peepli [live]*. Aamir Khan Productions, 2010. Directors: Anusha Rizvi, Mahmood Farooqui. Hindi. 95 minutes.**

When Anusha Rizvi, a journalist who had no previous experience of movie making, came out with a movie on farmer suicides in Indian villages, the first reaction among many was surprise. It is not the sort of story one usually takes up for a career change. Neither is it part of the mainstream approach to Indian film making these days. In earlier times, meaningful stories were discussed by serious moviemakers like Shyam Benegal, Ketan Mehta, Goutam Ghosh, and others. As the intellectual middle class in our country has become more affluent, storytelling has moved from social issues to interpersonal conflicts. Still, with the change in focus we have had movies like *Firaaque* (by Nandita Das) with a serious discussion on social injustice.

Cinema has the power to remind us of the plain absurdity of our lives, and stimulate debate on how to deal with social issues. Anusha Rizvi's decision to present the subject as a satire and to underscore the callousness and hypocrisy of the media and political class in handling the plight of the poor in the country has worked perfectly. One reason for Rizvi's taking up such an approach could be because she herself knows the murkier side of Indian journalism. The race of journalists to get exclusive news for their channels and to accelerate their ratings is never ending. I remember BBC journalist Nik Gowing talking about the absurdity of television journalism, and the dangers of breaking news often without verifying facts. Satire is indeed the best way to bring out that dark side of journalism.

The movie *Peepli [live]* tells the story of two farmers, Natha and Budhia, living in a remote village, who are about to lose their land because of an unpaid bank loan. An easy solution to the problem was to avail of the government aid for families of farmers who have committed suicide because they are unable to pay off their debts. One English television channel picks up the story and, as expected, it becomes a national debate. Natha becomes a national symbol and every television channel anchor poses the question, will Natha actually commit suicide or not? Declaration of by-elections in that village also gives an extra insight on how

our government machinery works. Gradually, Natha, Budhia and family become just a backdrop and the whole scene is taken over by television journalists and politicians. Television anchors discussing farmers' suicides with politicians become the 'daily show' with 'breaking news' focusing on Natha's suicide threat. At once, we comprehend the striking similarity with our day-to-day prime time television viewing.

The advantage of satire is that one can extend the story to any level possible. Woody Allen uses satire to expose issues dealing with morality in man-woman relationships by creating characters that talk about whatever enters their minds. Chaplin used satire in his classic movie *Modern Times* to depict the plight of the working class in an industrialised society more vividly than any documentary film could have done. Here, in *Peepli [live]*, Rizvi has also tried to take it to the extreme. Besides all the laughs, the director is able to make the viewer think about the pathetic situation in which our country is. The brilliance of storytelling is in its details - like bringing in the deep-well pump into the house as one of the characters; the dream sequences of Natha; and the scene where all the characters are running around in circles trying to find Natha. The movie works by maintaining a hectic pace.

Besides, the music is a logical extension of the theme in the movie. The song *Des mera rangrez hai babu* almost summarises what present-day India is. ("*Arre India sir, ye cheez dhurandhar, Rang rangeela parjatantar*" Sir, this India is a great thing / This is a colourful democracy) A colourful democracy indeed! When the people are satisfied with the conclusion of the story (Natha's presumed death), all is quiet. The festival is over and everybody leaves the ground, except the people who live there. The character in the movie, digging the land as if to bury his own body, is a reminder that Natha's story never ends, because his life in the city could be another disaster in the making. Until he takes an unusual decision we never actually see people like him or worry about how they live. *Peepli [Live]* stands up as excellent art apart from being a mirror for our social conscience.

FROM OTHER JOURNALS

The Aruna Shanbaug judgment: 'next friend' the best friend?

In the context of the Supreme Court (SC) judgment in the Aruna Shanbaug case regarding passive euthanasia, this article looks at the judgment's implications for the right to autonomy and self determination of a person incompetent to consent. The writer argues that the judgment effectively denies this right, by giving priority to the views of the nursing staff of the hospital that looks after her over Aruna's own interests. The SC ruling is that in the case of an incompetent person, a next friend, who may be the guardian or the state, may be given the power to decide to withdraw life; expert panels with medical experts are to prevent misuse of this power.

The judgment has limited application and does not cover the plea for withdrawal of treatment by terminally-ill, conscious patients, a matter which has been treated as suicide. It also calls on Parliament to decriminalise attempted suicide; suicide in India is a criminal act though the irony is that only people who fail in their attempt can be punishable by law. The Law Commission report of 2008 states that criminalisation of attempted suicide has prevented provision of effective medical treatment to those who attempt it, and also hampers the implementation of efforts to prevent suicides. The report, while taking an empathetic view towards the person who attempts suicide, reaffirms that encouraging or supporting someone in an attempt to end his/her life is a punishable crime.

The author also discusses references to mercy killing found in different religious sects in India. In India where most healthcare is being privatised, the question of affordability of maintaining a terminally-ill patient on life support is being ignored. He argues that the denial of an option to end the life of a terminally ill patient is a denial of justice if there is no provision to provide healthcare for them.

Shukla R. Is the 'next friend' the best friend? *Econ Pol Wkly*. 2011 Apr 30-May 6: 10-13.

Semi-skilled doctors for rural areas?

Doctors are generally averse to working in rural areas. The number of doctors practising in urban areas is nearly four times that of the rural areas, while 75% of the population resides in rural areas. The Medical Council of India is trying to bridge the urban-rural divide by introducing a degree course of three and a half years' duration. Medical schools in district hospitals will offer the Bachelor of Rural Medicine and Surgery which would encourage students from rural areas to take up medicine and serve their own region.

The course material would be broadly based on the general medical curriculum. It would cover 60% of the syllabus of the medical curriculum. Graduates would be able to identify

and treat common illness. They will not be able to undertake surgical procedures on patients

The advantages of this course would be that the rural population would be provided with skilled medical professionals. But their level of skill is something to be worried about. District hospitals are already burdened with their patient loads. Will they be able to offer a teaching facility to students? Would we not widen the rural urban divide by providing semi skilled doctors to the rural areas?

Garg S, Grover M, Singh R. Bachelor of Rural Health Care: Do we need another cadre of health practitioners for rural areas? *Nat Med J India*. 2011; 24(1): 35-7.

Should physicians defy the Hippocratic Oath?

This essay looks at the question of whether doctors should be allowed to administer fatal injections to death row convicts. The argument for doing so is that death row prisoners are like terminal patients and they should be given humane treatment even during execution.

Three sets of drugs are required to kill a person, and each set has its specific purpose. Sodium thiopental is administered intravenously to anaesthetise the patient. Then pancurium bromide is given to paralyzes, and finally potassium chloride is injected to stop the heart.

The argument in support of doctor's participation is that only doctors can put convicts to death humanely. Improper administration of the drug would make death a very painful affair and only a trained person like a doctor should do it to reduce the condemned person's suffering. The argument against it is that doctors are supposed to treat patients, not kill them, and it is not ethically correct for doctors to carry out such acts under the state's instructions. It is also argued that these misdeeds may reflect in their practice.

The author concludes that capital punishment is against human rights, and we should first decide whether capital punishment should continue. If we cannot do away with capital punishment for heinous crimes then the execution of convicts by doctors is the best option.

Ashby B, Nelson L. Rethinking the ethics of physician participation in lethal injection execution. *Hastings Cent Rep*. 2011; 413: 28-37.

Maternal and child health in Brazil: still some way to go

Brazil has set an example for all to follow by replacing its multi-tiered health system with the Unified Health System (SUS) in three decades and offering universal healthcare coverage to its citizens. Maternal and child health is a leading parameter in measuring the true success of a nation's

efficiency in meeting its healthcare needs. Under the SUS, infant mortality rates dropped to 20 deaths per 1,000 live births in 2008; the prevalence of stunting in children under five years decreased to 7% in 2007; access to maternal and child health interventions increased sharply to almost universal coverage, and regional and socio-economic inequalities decreased substantially as a result of these. The average duration for which a child was breastfed increased from 2.5 months to 14 months by 2007. There is also a reported 4% decrease in maternal mortality rates.

However, even amidst all this brilliance, there is cause for concern: the overmedicalisation of childbirth in Brazil has reached a new high. Almost 50% of all births are through caesarian section, of which more than 80% take place in the private sector. This is much higher than in any other country, and far exceeds the 15% stipulated by the WHO. Section rates are higher among white, educated and upper middle class women. While in questionnaire-based surveys most would-be mothers document a preference for vaginal delivery, in-depth interviews suggest that women believe that caesarian sections are a safer and less painful form of delivery. Maternal deaths due to illegal abortions are also high and mostly unreported (since abortion, except for pregnancies caused by rape or when the woman's life is at risk, is illegal, even if the foetus suffers from severe congenital anomalies); and this form of death mostly afflicts non-white and rural women. The significant number of pre-term deliveries is also an issue that needs to be tackled. And despite the fall in the mortality rate of children under five years, the rate in itself is around seven times higher in Brazil than in countries with the lowest child-mortality. While countries like ours have a lot to learn from Brazil, Brazil itself cannot afford to be complacent. It has some way to go.

Victora CG, Aquino EM, do Carmo Leal M, Monteiro CA, Barros FC, Szwarwald C L. Maternal and child health in Brazil: progress and challenges. *Lancet*. 2011 May 28; 377(9780): 1863-76.

Revisiting Chernobyl: effects on public health yet unknown

As we look back on the many nuclear accidents over the years, it becomes clear that the 1945 nuclear catastrophe was only the beginning. There was the United Kingdom's Windscale in 1957, the United States' Three Mile Island in 1979, the then Soviet Union's Chernobyl in 1986, and most recently, Japan's Fukushima in 2011. Yet, we are still to learn important lessons. In the case of Fukushima, the damage is yet to be measured.

There has been a failure of the international institutions expected to have tools in place for measuring the immediate and future impact of such incidents. The lessons learnt from Chernobyl too have not been used effectively to map the Fukushima disaster. Recently, an in-depth review of health-related research, carried out by experts under the auspices of

a European Commission project, referred to the international response as "uncoordinated . . . forming a patchwork rather than a comprehensive, structured attempt to delineate the overall health consequences of the accident." Soon after Chernobyl, a professor from the Karolinska Institute identified an epidemic of stress-related disease attributable to public anxiety. This subsequently came to be known as the psychosocial effect, and is arguably Chernobyl's most serious health detriment to date, notwithstanding the more than 6,000 thyroid cancers cases. The health implications of Chernobyl have, since the incident occurred, been the "battle ground" for the lobbies for and against nuclear power, which seek to interpret the effects or absence of effects to their own advantage and are apparently unwilling to find the truth. Apart from exacerbating the psychosocial effects on those directly affected, this situation has prevented a comprehensive evaluation of the importance of the event to public health.

Baverstock K. Chernobyl 25 years on. *BMJ*. 2011 Apr 26; 342:d2443. doi: 10.1136/bmj.d2443.

Abortion: exploring more choices for women

The development of modern methods for medical abortion began in the 1970s. Since then, the drugs used have been refined and have led to safer abortions. Currently, medical abortion has become more common than surgical abortion, as it is also more cost effective. However, there have not been many studies to assess the risks and efficacy of medical abortion in adolescents. This retrospective cohort study examines this issue. Women must have more choices in abortions, since it is the larger issue of women's health and autonomy that is in question.

Grimes DA, Raymond EG. Medical abortions for adolescents: seems to be as effective and safe as in older women. *BMJ*. 2011 Apr 20; 342:d2185

Retaining staff under the National Rural Health Mission

Under the National Rural Health Mission (NRHM), the lack of skilled service providers in rural areas of India is a major challenge. The problem is more intense in tribal hilly areas of central India and the North-East. The authors look at this issue and come up with some solutions and lessons learnt on different approach of retaining health workers in rural India. The information was collected from a review of state programme implementation plans of the NRHM and from the responses to specific queries sent to state health directorates.

Since 2007, monthly financial incentives have been introduced for workers in difficult areas. Though the literature shows that incentives have a limited role in staff retention, the authors found that the schemes have been well accepted in all the areas. The authors apprehend that there is a temptation to consider the problem of retention as unsolvable. Another

approach in practice is workforce management by rotational posting in difficult areas, of course with a better residential infrastructure for all staff. Another strategy is to appoint staff on a contractual basis. There are some sponsored courses for those who are willing to work in the underserved areas. Continuous capacity building, including the rural medical practitioners and the field level health workers, is another alternative strategy. Though the authors found it too early to comment on all the strategies, they conclude that a regular evaluation has to be done for designing appropriate packages of retention strategies tailored to each state's requirements.

Sundararaman T, Gupta G. Indian approaches to retaining skilled health workers in rural areas. *Bull World Health Organ.* 2011 Jan 1;89(1):73-7.

Time for new clinical research guidelines?

The authors discuss the International Committee of Harmonisation's guidelines for Good Clinical Practice (ICH-GCP), used as the golden standard for conducting a clinical trial anywhere in the world. They argue that the guidelines, though extensive, can be cumbersome and also do not cover all critical areas of clinical research. They are designed primarily for product registration trials, and cannot be applied by, say, a researcher testing a new approach like home-based care, or doing an observational study. Yet, interpretations of the guidelines to suit such contexts are considered suboptimal and often rejected. The World Health Organisation's research guidelines are no less difficult to implement; they are as rigid as the ICH-GCP. The so-called industry standards are expensive to follow and discourage local researchers from pursuing research to find cost-effective remedies for local problems. There is also a gap in capacity building of researchers in developing countries, as most clinical trials from developed countries are outsourced and conducted through contract research organisations. The authors argue that a more commonsense, simple and pragmatic approach is what is needed to facilitate clinical research in developing countries.

Lang T, Cheah PY, White NJ. Clinical research: time for new sensible guidelines. *Lancet.* 2011 May 7;377:1553-4.

Medical complicity in torture

Despite international laws prohibiting torture, such practices exist in various forms in various countries. Further, doctors

may become unintentional accomplices when they provide medical care to those subjected to torture. This complicity is against international law and professional ethics. Doctors can find themselves coerced into being part of the team inflicting the torture. For example, in countries where amputation of limbs is a common form of punishment, it may be argued that a doctor should be present to ensure the wellbeing of the prisoner. There is also a dilemma as the professional code of ethics instructs the physician to restrain from being part of any torture and at the same requires that the doctor ensure that the patient receives proper and compassionate care irrespective of the circumstance, binding the doctor with the responsibility of ensuring the welfare of the prisoner/patient. Complicity in torture is also determined by the degree of assistance provided as well as the intention of the physician involved. Even though the torturer and the doctor might share the common goal of reviving the patient, the intentions might differ in that the doctor has the patient's welfare in mind whereas the authorities might be interested in interrogating him/her again. The consequences of the complicit action are personal, to the prisoner, and to the community.

Prisoner preferences are also factors which cannot be ignored while considering the ethics of medical complicity in torture. It has been recorded that doctors are able to talk to the prisoners about their treatment preferences even in the presence of security guards; however, this enquiry cannot be considered at par with the principles of autonomy and informed consent. It is also not clear how much the autonomy of the prisoner regarding his/her treatment is worth, and actual when the person is being tortured and his/her basic rights are being denied. There should also be a better international reporting system to which doctors can report incidents of torture without fearing for their own wellbeing.

Lepora C, Millum J. The tortured patient: a medical dilemma. *Hastings Cent Rep.* 2011 May- Jun;41(3):38-47.

Contributions by Bhaswati Sinha, Divya Bhagianadh, Mahua Ray, Rakhi Ghoshal and Sweta Surve

**Compiled by Divya Bhagianadh
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LETTERS

Women in the healthcare system

The comment on the manner in which women are treated in healthcare facilities (1) like others critiquing doctors' behaviour, comes from researchers in health management. Tragically, doctors don't seem to take notice of this problem. It may be that they are too busy curing the ill to notice the human, or because medical education lacks the ethics component.

I would like to add an insider's view to the article.

One such example is the HPV vaccine. The targeted group is young girls on the threshold of puberty. They are to be given the vaccine with the aim of protecting them from likely HPV infection that may lead to cervical cancer. Are girls informed about how and when they may encounter HPV, and how they can prevent it? How does this intervention fit the bill of a public health measure? Is it justified based on the cost of the intervention and its efficacy, and the incidence and prevalence of cervical cancer? The advertisements of this vaccine amount to emotional blackmail of parents who may not be able to afford it. However, all parents can afford to empower their little girls to take care of themselves and prevent HPV.

Privacy and dignity: Once, when we asked for RMOs to be instructed to keep women covered while doing gynaecological examinations, a senior (and sensitive) professor opposed the demand saying that if the hospital was unable to provide the sheets required, patients might start complaining! The hospital administration as well as supervisory staff must be required to provide private space and a comfortable setting for a very private examination like the gynaecological examination, which should be conducted in the presence of an attendant.

Cases like the ones narrated by the authors are rampant. Why are they not considered to be sexual harassment?

Refusal to answer questions: This is the most common professional misdemeanour doctors commit against their clients/patients. The reasons are many:

For one, doctors treat women as well as men as diseased bodies, not as humans with brains, anxieties and concerns, and believe themselves to be gods providing a cure. Secondly, some doctors do not know the answers to their patients' questions and fear a loss of face if their ignorance were to be revealed. Surely patients would respect doctors who are truthful in admitting their limitations. In my view, patients should be encouraged to ask questions as- the better they understand their problems, the less likely they are to have false hopes or expectations. Finally, patient education seems to be the last thing on a doctor's mind. This is especially true in the private services where doctors can charge what they want and patients pay out of their own pockets. In systems where the state pays, doctors are more careful.

Urban vis-a vis rural: Rural women are practically invisible.

But yes, even a well-off urban woman often goes through humiliation, harassment and violation of rights at the hands of doctors. She suffers quietly, for fear of being called either a prude or weak.

What are the solutions?

First, as in the Delhi High court judgement (2) on the examination of sexual assault victims, positive guidelines for gender sensitive healthcare must be brought out by state medical councils as well as the Medical Council of India.

Second, patients' rights charters must be displayed in all facilities. Third, clinical or applied ethics must be mandatory in all curricula.

Finally, male doctors must examine a woman client only in the presence of a nurse, ayah, female doctor or a relative with whom the client may be comfortable. Posters advising this must be put up in every chamber where a healthcare provider may examine a female client.

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2. High Court of Delhi. Judgment in the case of Delhi Commission of Women v Delhi Police. 2009 Apr 23. Writ Petition (criminal) No. 696 of 2008. 696/2008 http://www.ncw.nic.in/PDFFILES/Delhi_High_Court_judgement_on_guidelines_for_dealing_rape_cases_by_various_authorities.pdf

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The Clinical Establishment Act, 2010: need for transparency

The article on the Indian Medical Association and the Clinical Establishment Act (CEA), 2010 (1), was well written and showed the author's grasp of the state of affairs in the bureaucracy. The opposition to the CEA is largely because of private practitioners' fear of extortion in the hands of 'babus'. The government should let health be administered by health professionals rather than by babus who are typically both junior in service to government doctors and also have lower pay scales, at least at the district level. Since senior government doctors resent being commanded by a junior government officer, the honest and the expert keep away from government service. The CEA will bring private practitioners under the direct control of bureaucrats. This state of affairs is largely unacceptable to the medical profession, what with the rampant corruption in the bureaucracy. Extortion is already rampant in the case of the Pre-conception & Pre-natal Diagnostic Techniques Act, 1994. And if that law is any indication, the CEA, when it is implemented,

will turn out to be the biggest legalised extortion racket in the world. Obviously people cannot say this on public platforms, which is why there have been many voices saying different things which might sound like irrational ramblings. But the stand of the IMA -- that registration should be online (to eliminate the need to pay any *suvridha shulk*) and accreditation should be optional and done by an independent agency - more than speaks for the underlying apprehensions of its members.

Note: *The above is not an official communiqué but the personal views of the writer.*

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White coated corruption: time to begin even with small steps

This refers to a thought provoking article by Vijay Mahajan (1) and a commentary by Arun Sheth (2). What both authors have stated is, unfortunately, true. Dr Sheth's comments reflect the hopelessness of the situation, as he does not suggest any remedial steps except "time-tested, age-old golden practices in spirituality..." Dr Mahajan states that the list of things that doctors must do is long, and spells out a very long list of do's and don'ts for doctors, authorities and the people. He concludes: "Corruption is spreading its tentacles far and wide in the medical system. To restore its noble and distinct status, all sections of society must work together to stamp out the biggest killer in the medical system - corruption."

Is this corruption rampant and confined to the medical profession only? The answer is: no. Can we justify and continue to tolerate corruption in the medical profession because it occurs in even severe forms in the society? Again the answer is: no. It is high time for introspection and taking remedial steps. It is better to begin with small steps in the right direction rather than wait to work on all out measures all at once. There is an urgent need to make a beginning.

The January-March 2010 issue which published Mahajan's article had two articles on financial incentives for prescribing

newer and costly vaccines (3, 4). Both articles highlighted the huge margin between the maximum retail price (MRP) of some vaccines and the price at which they are sold to doctors. GSK, one of the manufacturers of the varicella vaccine, had, in the past, increased the MRP even as it lowered the cost of vaccine to doctors, thus increasing the margin of profit for doctors. Recently, GSK has reduced the MRP by Rs 200 per dose, but has not changed the price for doctors. This reduction in doctors' margin is a positive step and should be welcomed.

Referral of patients, especially for investigations, is a contentious issue that needs attention. Ideally, recommending investigations should be akin to prescribing drugs for a patient. Drugs may be purchased from any drug store; similarly investigations may be done from any diagnostic centre. If facilities exist in the same place that a doctor practises, the doctor may suggest getting these investigations done at that centre, but the patient or caregiver may opt for any other centre. Some doctors insist that investigations be done at a particular diagnostic centre only.

A doctor does not get any financial benefit from a drug store in the form of a cut or kick-back. Similarly a doctor is not supposed to get any financial benefit from laboratories conducting investigations. It is said that some manufacturers give monetary incentives to doctors for prescribing their products, which is outright reprehensible. Similarly, accepting monetary benefits in the form of a kickback or cut from a diagnostic centre is bad, but, is being practised in many places including some hospitals. This issue should be taken up by the Indian Medical Association, the Medical Council of India, or the *Indian Journal of Medical Ethics* by organising a national consultative meet to formulate comprehensive guidelines for the medical profession. The consultative meet should deliberate on all aspects, including guidelines for investigations suggested, accreditation, quality control, charges etc. of the diagnostic laboratory. Should some sort of incentive be paid or not be paid to the referring doctors and also the mode of payment in case payment is made? Thus, if payment is made it should become official, i.e. records be made so that it is treated as expenditure by the diagnostic centre, and payments made to the doctors be treated as income and taxed accordingly.

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CLINICAL TRIALS WATCH

This is the third factsheet collating data on clinical trials in India from the Clinical Trials Registry of India (CTR-I). The CTR-I is a dynamic database, where users can add, edit and remove records. Thus, there are constant changes in the data available on the registry. The data presented in this factsheet are based on a manual database which has been developed by downloading information for the CTR-I website and entering it into a spreadsheet. As this process takes place over a period of time, the data presented here are merely indicative of the trend.

During the early part of 2011, the CTR-I database was overhauled and thus data presented in the earlier factsheets are not comparable with the data presented in this fact-sheet.

In this factsheet, the data presented pertain only to active trials which are open to recruitment registered with the CTR-I between January 1, 2007 and December 31, 2010. These data were downloaded and entered into a database between April and May 2011.

Definitions used in this fact-sheet remain the same as used in the earlier factsheet published in the October-December 2010 issue of the *Indian Journal of Medical Ethics*.

There was a total of 670 active trials registered between January 1, 2007, and December 31, 2010, which were open to recruitment at the point of database development (April-May 2011).

Clinical Trials Watch			
Disease	Sponsor profile		
	Pharma	Institute	Others
Certain infectious and parasitic diseases	29	24	1
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	20	8	1
Diseases of the circulatory system	67	19	2
Diseases of the digestive system	28	16	3
Diseases of the nervous system	26	10	5
Endocrine, nutritional and metabolic diseases	63	13	3
Healthy volunteers	13	2	0
Neoplasms	100	20	5
Pregnancy, childbirth and the puerperium and perinatal conditions	2	16	7
Other diseases	108	35	24
Total	456	163	51

Trial type	Institute	Pharma	Not given
Placebo controlled trial	44	136	10
Active controlled trial	62	136	18
Single arm trial	17	59	10
Crossover trial	2	14	1
Multiple arm trial	16	53	2
Cluster randomised trial	2	0	0
Others	20	58	10
Total	163	456	51

Sponsor nationality	Phase I	Phase II	Phase III	Phase IV	Others
Foreign	13	67	164	30	18
Foreign, Indian	1	13	32	2	5
Indian	35	55	96	35	58
Not given	3	5	9	9	20
Total	52	140	301	76	101

It is interesting to note that 68% (456) of the total trials were sponsored by pharmaceutical companies alone, with the highest number of trials (100) being related to cancers (neoplasms). The other major focus areas for pharmaceutical industry-sponsored research were diabetes and cardiovascular diseases.

A significant proportion of registered trials were placebo controlled (28%), a large number of them being sponsored by pharmaceutical companies. On the other hand, there were only two cluster randomised trials registered, indicating that such research has not yet come into the purview of the CTR-I.

A substantial number of phase III trials are being carried out using foreign funding (164) as against Phase III trials receiving funding from India (96). This is in keeping with the observation that India has become a preferred destination for outsourcing clinical research because of its large treatment-naïve patient population.

An overview of the presented data indicates that there is an overwhelmingly high proportion of privately funded and pharmaceutical-placebo controlled-phase III trials, representing the current trend of clinical trial research in India.

Compiled by Chitra Borkar, Vivian David Jacob and Deepica Ravindran with assistance from Kinjal Vaid, Centre for Studies in Ethics and Rights, Mumbai

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The debate must go on

The fight for ethical healthcare research does not end with the setting up of research ethics committees. ECs face a number of challenges. Some of these are discussed in this special collection of essays on the ethics of ethics committees. Our guest editors for this issue, Dr Silke Schicktanz and Dr Michael Dusche, have tapped the experiences of those working in Israel, Germany, Romania, India, and among the ethnic communities of the USA.

New medical technologies are continually spawning new ethical challenges; and the question is: how can the regulatory system respond to them? This question comes up once again as The Assisted Reproductive Technologies (Regulation) Bill, 2010, is expected to be presented before Parliament. A scholar contrasts the *laissez faire* approach of the UK to the regulation recently passed in France. Another author examines the revamped Medicare system in the USA through the lens of ethics and equity.

An eloquent plea is made for laboratory facilities to be provided to rural primary health care centres which lack many essentials. On the other hand, vast funds meant for the NRHM are spirited away in scams conducted by the powerful, who have not stopped short of murder. Three doctors in UP have died in this war. This belies the hopes of all who believe that more funding within the system can cure our problems.

Two original studies, one each from India and Pakistan, scrutinise the claims made in drug advertisements; while a commentary deals with the ethics of a 'no-treatment arm' for community-based interventions and is accompanied by a response from the researchers. Finally, an editorial discusses the MCI's plans to introduce ethics into medical education.

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