

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

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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.

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