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Improving the knowledge and skill of faculty members in research methods and scientific writing using the workshop method

The Medical Council of India (MCI) is promoting quality research in institutions to encourage an evidence-based approach to health. Publication of research has been added to the eligibility criteria for a teacher by the MCI as an incentive for early promotions.[1] In 1997, MCI recommended the establishment of medical education units (MEUs) in each medical college to organize faculty development programmes (FDPs) for carrying out research.[2] A survey of medical colleges in India carried out in 2009 to assess MEUs and their role in FDPs highlighted that programmes on research methodology and medical ethics were rarely held.[3] The fact is that faculty members do research as part of their academic portfolios, regardless of their capability to conduct such research.[4] A need assessment among our faculty members revealed gaps in their understanding of research methodology. Hence, there was a felt need to improve their research skills. Based on this assessment, two workshops were planned on research methods and scientific writing.

The workshops were designed for 2 days each and were standardized by a group of faculty members considering adult-learning principles. Both workshops were facilitated by experts and had hands-on sessions. Participation was voluntary, with participants coming from all departments. Anonymous feedback was obtained for every session from the participants about the workshop; the first workshop also had a pre- and post-test. The first workshop had 14 participants and the second 27, ranging from assistant professors to professors. The mean (SD) pre-test and post-test scores were 4.14 (1.75) and 7.86 (1.96), respectively and the difference was significant ($p<0.00001$). Anonymous feedback revealed experts (50%) as the most facilitating factor and the majority of participants found the sessions useful for learning research methods and writing (50% in the first and 71% in the second workshop). About 25% of them wanted more such workshops.

Faculty development remains incomplete without gaining knowledge and skills in research methods and scientific writing. The need for training medical faculty in research methods has also been stated in the literature.[5] So far, there has largely been a module-based approach to teaching research methods.[6] Since adult learning is likely to be better with a higher engagement process, we chose the workshop mode. This workshop model was appreciated by the faculty members, as evidenced by the difference in pre- and post-test scores and feedback. Strengthening the capabilities of faculty members in research work will have the dual advantage of increasing their own research capability and in mentoring postgraduate students for their dissertations.

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Challenges to the legal systems of China in the implementation of organ transplantation laws: A multidimensional view

On 18 April 2011, China's Ministry of Health passed a circular announcing that it would launch a nationwide campaign to crack down on illegal organ trafficking. Zero tolerance was declared for violators, and doctors who perform organ transplants in violation of the laws would lose their medical licences. This announcement came rather late as an extension of the 2007 regulations passed by China's State Council (or Cabinet) on human organ transplants. These regulations banned organizations and individuals from trading in human organs in any form. While people wait keenly to see how strictly this decision would be enforced, it must be asked whether the implementation of this circular as a law is really as simple or easy as it seems. This question needs to be answered not only for the sake of better regulation of transplantation operations in China, but also in the context of the medical ethics codes prevalent globally. This delicate issue is reflected in the comments made by international organizations such as WHO, various transplantation societies[1] and at the Istanbul summit.[2]

China is one of the few countries where both the performance and success rates for organ transplantation are high. In 2006, China ranked second in terms of the number of transplants performed per country (11 000 transplants) and this figure has increased since.[3] For liver transplantation alone, there are more than 200 medical institutions with secondary or tertiary care designations in the People's Republic of China (the PRC). There are around 10 transplant centres located in Tianjin, Guangzhou, Beijing, Hangzhou, Shanghai, Chengdu and Wuhan. Each of these centres deals with more than 100 cases annually. Similarly, clinical registry data suggest that around 8000–12 000 renal transplant operations are performed in the PRC annually. This huge volume of successful transplant operations has made the

PRC emerge as an international centre for various organ transplants, especially for kidneys and liver.[4,5] As the scale of these critical surgical procedures continues to increase, the ethical and legal issues associated with them are bound to become more complicated. The Ministry of Health has been trying its best to deal with the new challenges in this field.

At present, there are two sets of laws governing organ transplantation in the PRC: (i) the Interim Provisions on the Administration of Clinical Application of Human Organ Transplant Techniques, which came into effect on 1 July 2006; and (ii) the Human Organ Transplantation Act, which came into effect on 1 May 2007.

The first of these sets of laws was published by the Ministry of Health in March 2006. It contains the following principles.

- Only medical facilities and physicians attaining a certified level can perform human organ transplantation.
- Organ transplantations will be monitored and supervised by the Organ Transplantation Technique Clinical Application and Ethics Committee.
- The doctor must follow the principle of informed consent and must have the donor's written consent.
- An adult's living donor organs must be genetically related to the recipient. No organ should be removed from the body of a living underage person for the purpose of transplantation.
- Organ trafficking is forbidden.
- The human body and its parts cannot be subjected to commercial transactions. The giving or receiving of payment for organs is prohibited.
- The allocation of organs must be according to need.
- The quality of organs must be established to prevent the dissemination of disease.
- The medical facility should report and register the category of the organ transplanted, the number transplanted and the result of the transplantation within a specific time.

The Human Organ Transplantation Act (2007) consists of more robust criteria for issues related to organ transplantation. It has four chapters, the first of which consists of general provisions, such as rules that strictly prohibit the sale of human organs in any form. Chapter 2 deals with the rights of the organ donor. It provides the donor full civil capacity to donate or withdraw the donation. Also, it makes provision for spouses, adult children and parents to jointly agree to the donation after the death of the individual. It prohibits the removal of organs before 18 years of age. It limits the donation of living organs to the donor's spouse or family members related to the donor within three generations. Chapter 3 proposes criteria for medical institutions for organ transplantation. It also specifies the information to be given to the health authorities by institutions performing transplantations. Every institution performing transplantation must establish an ethical committee, the job of which is to review and follow matters related to the operation, besides being responsible for any unlawful act of transplantation. The same chapter also deals with the duties related to the inspection of living donors, the need to inform the donor about the risks associated with the removal of organs, registration of the transplantation, follow-up of the donor and inspection. In addition, the chapter deals with transplantation from deceased individuals, for which ethical codes are to be followed. The transplanting team should not have any access to information related to the death of the deceased individual. The dignity of the deceased is to be maintained. Except for the organs being transplanted, the rest of the body should be restored to its original appearance. The chapter also deals with the cost of transplantation and mentions that patients should not be charged, whether in an open or disguised form, for anything other than the removal, preservation and implantation of organs. The specific measures to be taken by the institute to maintain the confidentiality of the donor as well as the recipient are also mentioned. Chapter 4 deals with the legal liability of not following the laws of the Act. In case of irregularities, a fine that is 8 to 10 times higher than the money gained by performing the transplant is to be imposed. Medical practitioners involved in malpractice shall lose their medical practice certificates. Even the national staff involved in illegal sale or trafficking will be dismissed or expelled. Further, criminal responsibilities will be borne by medical practitioners in such cases, if and when needed.

However, as Huang *et al.*[3] point out, regulations have lagged behind medical progress, with transplantation expanding in an under-regulated manner. There are several reasons for this lack of legal control in the PRC and these can serve as lessons for the rest of the world as well, where transplantation is on the rise or will be in the future. The most important of these is a shortage of organs for transplantation. In the PRC, as in other countries, among the greatest challenges in organ transplantation today is the limited deceased donor pool. This scarcity is the reason for increasing demand, which leads needy individuals to explore alternative and illegitimate means of obtaining organs. The second challenge is the wide disparity in technical competence among the more than 200 medical institutions. The variation in organ harvesting, storage and transplantation is the result of the existence of various individually tailored methods governed by institutions as well as religious codes of ethics. This makes it difficult to evaluate each specific method, especially the ethical merits of each. As a result, there are difficulties in assuring the quality of service and the legitimate rights of patients may be compromised. Finally, there is a lack of a well-organized administrative system responsible for national organ transplant registration, graft sharing, allocation and the implementation of national standards for outcomes. Article 4 of the Interim Provisions on the Administration of Clinical Application of Human Transplant Techniques stipulates the formation of a national Organ Transplantation Committee (OTC) which is to be responsible for consulting with the relevant national and international experts to formulate nationwide norms on clinical application of human organ transplantation. However, the exact role of the OTC as an administrative body is yet to be defined.

These practical problems have parallel legal counterparts which have been best summarized by Huang *et al.*[3] as the four major concerns for the PRC and the international community: (i) regulating quality; (ii) an organ market; (iii) tourism for transplantation; and (iv) the source and rights of the donor. The most important of these is the last. In this context, there are two main problems. The first is the prevalence of a unique range of ethical views in the PRC that poses a dilemma for the legal system. As Huang[6] points out, the ethical systems in the PRC consist of codes of conduct derived from Confucianism, Taoism and Buddhism rather than the Hippocratic system. Confucianists view medicine as a means of saving human life through love. This view entails three commitments for doctors: veneration of human life, respect for patients and universal love, which are incorporated in Chinese medical values. It requires doctors to be responsible in the course of diagnosis and treatment to avoid mistakes that would harm patients. It calls on doctors not to take advantage of their profession and to treat every patient equally. Taoism, regarded as the Chinese national religion, influenced the development of medical ethics in the country. The Taoists' quest for a long life may be pursued in either of two ways: (i) by taking special medicines made from plants, animals or minerals, or (ii) by performing good deeds that benefit others. The values central to Taoism are loyalty, filial piety, politeness, trust and humanity. Buddhism is also a very important thread in the fabric of Chinese medical ethics. To alleviate suffering and transcend the cycle of fate and rebirth, many Buddhists perform good deeds in the form of practising medicine. In all these systems, medical ethics is based on the cultivation of the self by the doctor, the focus thus being on personal virtues rather than strict laws. While all these ethical codes specify the need for

righteousness on the part of the practitioner, it is to be noted that they are based on individuality, which gives rise to variation in views regarding complicated issues such as transplantation. The exact status of organ transplantation in these religions is a complex subject and has been outlined by Tai.[7] On the one hand, the religions stress the importance of preserving the body as a gift from the parents, and on the other, organ transplantation can also be seen as the greatest form of compassion, which is the core of all the religions.[7] Evidently, striking a balance between these two extreme views is a Herculean task when it comes to the legal implementation of various organ transplantation laws. This is the most potent reason for the recent development of strict codes of ethics in Chinese medical practice that are actually derived from these religious virtues but, at the same time, are binding on practitioners.

The second problem, an oft-highlighted issue which has been mentioned earlier, is that of the extreme scarcity of donors. The Chinese Ministry of Health statistics suggest that up to 1.5 million patients in the PRC need organ transplants, yet only 10 000 such operations can be performed each year due to the lack of donated organs. Due to this scarcity, more than 90% of transplanted organs are obtained from executed prisoners. In the context of this specific subset of individuals, the legal system has to be vigilant to safeguard the rights of prisoners against the prevalent biases. For this reason, the ministry has come up with additional safeguards in the form of written consent, review of death sentences, prohibition of transplant professionals interacting with the family until death declaration has been done and participation of the Red Cross Society.[3] At present, only prisoners who are subject to capital punishment in the PRC are convicted criminals. In addition, the relevant governmental authorities require that prisoners or their families provide informed consent for the donation of organs after execution. However, the fact remains that prisoners' rights have always been undermined and thus there are often defects in the application of transplantation laws to this group of individuals in spite of additional safeguards. This specific area has been dealt with extensively by Cameron and Hoffenberg,[8] who say, 'The affront to human dignity and autonomy is not the removal of organs after execution, but the execution itself.' As he highlights, there are arguments both in favour of and against this practice. The arguments against the use of executed prisoners' organs include the possibility that the death sentence or process of execution itself might be manipulated for the express purpose of obtaining organs for transplantation. Although there is no evidence to support the argument that there are illegal aspects to organ transplantation from executed prisoners (manipulating death sentences and harvesting organs without the consent of the prisoner) in the PRC, this is an obvious concern which is of vital importance, not only for the organ transplantation community but for humanity as such. Internationally, there have been several condemnations of the organ transplant community in China.[9,10] Some of the allegations made relate to execution sentences driven by economic interest, illegal trafficking procedures and the violation of prisoners' rights.[10] Chinese surgeons, too, have condemned such practices in the PRC.[10,11] Perhaps it was the global calls that forced the Chinese government to implement a nationwide crackdown on such practices. As a result 10 hospitals were ordered to improve their transplant programme, seven had their qualification for transplantation suspended for 3–6 months, and one hospital was denied qualification.[11] Although prisoners have always had the right to donate their organs, it is only recently that the laws related to donation by prisoners are being executed properly.[11] These efforts of the Chinese government are also reflected in the progressively decreasing rate of executions in the past four years. No doubt China still has the highest rate of executions in the world, and it is alleged by the rest of the world that this is an indicator of illegal transplantation trafficking.[10,11] However, the marked reduction in the rate of executions (from nearly 10 000 in 2005[12] to about 1700 in 2009[13]) indicates that the PRC is becoming more alert to the ethical issues related both to execution and transplantation. There are also counter-arguments in favour of the use of executed prisoners' organs for transplantation. Among other things, these relate to the potential benefit of providing organs for the greater good of society and the opportunity for prisoners to 'repay' their debts to society.[8] Both the arguments and counter-arguments are of critical importance and are pertinent not only for the PRC, but also for the world at large in view of the growing influx of non-Chinese patients to China.

Dr Huang, Vice Minister of Health, the PRC has predicted that in the coming years, 'the Chinese legislation on organ transplantation will follow internationally recognized legislative principles with the characteristics of the statute of organ transplantation in the context of Chinese sociocultural reality'.[6] However, only time will decide whether internationally acceptable laws are applicable to the PRC. Nonetheless, faster modernization of our legal systems is the need of the hour to enable us to face the existing challenges and find a solution to them.

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Physicians and their conscience

I read with some dismay the 'Letter from Glasgow' by H.S. Kohli.[1] While I am in agreement with the second part of the article about physicians' relations with patients who have HIV or who have 'social' conditions, the first part contains sentiments that led to the deplorable actions of some of the medical fraternity in Nazi Germany. Dr Kohli finds it dispiriting that doctors act according to their conscience and that they may object to procedures or treatments to

which they have moral objections. He fears that this may lead to the denial of the best treatment for patients.

How is 'best treatment' to be defined? Does performing an abortion at the subject's request fall within best treatment? Would the selective euthanasia of the elderly and the mentally challenged during the Nazi quest for a 'master race' have been so considered by the state at that time? Does Dr Kohli feel that the German doctors of that era should have followed the German state's diktat even against their conscience? I am sure he does not.

In the case of abortion, which Dr Kohli cites as a touchstone for his views, there are a sizeable number of physicians who consider the procedure at variance with the physician's code of preserving life. Would it be correct to expect a doctor who holds such views to perform a procedure which she/he feels is akin to murder?

There can be no denying that the physician should explain all the options to the patient and the reason why she/he is unwilling to follow a particular line of treatment, but to say that a physician who is unwilling to perform a particular procedure because his conscience does not allow it is acting unprofessionally, is I feel unwarranted.

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Without evidence, we are indeed doomed!

I enjoyed reading Lt Gen Anand's well-referenced 'Socratic dissent'[1] against evidence-based medicine (EBM) in the *Journal*.[2] He raises many of the objections that have often been raised against EBM, without any coherent or convincing counters from his surgeon friend who is apparently a supporter of EBM. Unfortunately, this friend comes through as timid, naïve, bookish and under-confident, reinforcing the popular stereotype of the geeky and confused 'EBM enthusiast' in a 'complex world', pitted against the suave and worldly-wise dissenter.

No one can quarrel with the original definition of EBM proposed by David Sackett and colleagues: 'conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients, … integrating individual clinical expertise with the best available external clinical evidence from systematic research'.[3] It may be worthwhile going over the salient features of this definition for the sake of clarity.

The 'best available external evidence', as also pointed out by the author, comes from randomized controlled trials (RCTs) because they are the least likely to be biased. It is important to bear in mind that most treatment effects are modest and other study designs and individual experience cannot reliably detect these differences. This brings us to a variation of the question that dissenters commonly come up with: why do you believe in parachutes when there are no RCTs? The simple answer is that the effect size is very large: practically everyone who jumps off without a parachute will die and practically everyone who parachutes will live. Large effect sizes do not require an RCT; other designs or even anecdotes will suffice.

The other frequently debated part of the definition of EBM is the application of evidence generated from 'groups of people' to individual patients. Biological variation makes it impossible for us to predict the behaviour of any single patient, unless one does an 'N of 1' trial for all patients for all treatments (which is clearly not possible). Given this situation, the best estimate of the effect of any treatment is, counter-intuitively, the 'average' effect obtained from a large trial. In this context, it may be emphasized that while there may be quantitative differences in the effects of treatments between patients (low-risk patients benefit less than high-risk patients), qualitative differences (i.e. some patients benefit but others are harmed) are decidedly rare.[4] Therefore, data from large, pragmatic randomized studies are the best guides available to make treatment decisions for individual patients. A good example illustrating this is the use of oral anticoagulation therapy for patients with atrial fibrillation (AF).

Anticoagulation is clearly superior to any other therapy for preventing strokes in patients with AF. This means that all patients with AF are likely to have a similar relative risk reduction with oral anticoagulation, while their absolute risk reduction may vary depending on the baseline risk of ischaemic stroke. For a 50% relative risk reduction, a patient at a 1% annual risk of stroke would benefit less than one at a 10% risk in absolute terms (0.5% *v*. 5% absolute risk reduction). Because anticoagulants cause major bleeding, the risk–benefit trade-off will be in favour of starting treatment in patients at a higher risk of ischaemic stroke than those at a lower risk. While making judgements about initiating oral anticoagulation, clinicians should consider these trade-offs in their patients. It is impractical to expect that every single patient (with a unique risk profile) will have a randomized trial to guide his or her treatment; the best estimate of the effect of the treatment can be obtained from the compilation of all the available data. Having said that, EBM does not advocate the use of, say, the same dose of a drug for a 75-year-old when the data are from a study of young individuals. When there are strong reasons (drug pharmacokinetics and pharmacodynamics in this case) to believe that a particular patient will behave differently from patients in a particular trial, it would be foolhardy to apply the results of that trial to that particular patient. EBM does not ask its users to abandon common sense.

Conflicts of interest relating to the members of guideline development committees are a reality and efforts are being made to minimize these, but I do not see how this can be held against EBM. Do individual clinicians prescribing medications or performing procedures not have conflicts of interest?

Finally, EBM suggests that we use the best available evidence to guide our decisions. In the absence of RCTs, we move down the hierarchy to observational studies, case reports or even (as we do many a time) to 'gut feeling'. However, if there is no good evidence to go around for even some of the most commonly encountered conditions (as is the case with medical practice in India), then our patients are certainly doomed; doomed to receive treatment that may not be the best.

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