

## SELECTED SUMMARY

## Advancing physicians' skills versus safeguarding individual patient interests: an ethical dilemma

PRIYA RANGANATHAN<sup>1</sup>, C S PRAMESH<sup>2</sup>

<sup>1</sup>Associate Professor, Department of Anaesthesiology, Critical Care and Pain, Tata Memorial Centre, <sup>2</sup>Chief, Thoracic Surgery and Professor, Department of Surgical Oncology, Tata Memorial Centre, Mumbai 400 012 INDIA Author for correspondence: C S Pramesh e-mail: prameshcs@tmc.gov.in

### **Kendler S, Kodner IJ, Keune JD. The role of the poor in medical research and the physician's duty to protect. *Surgery*. 2013 Feb;153(2):287-91a**

The divide between medical innovation and routine clinical practice is a grey zone. Clinicians are often torn between their dual roles as healers and investigators, between the need to cure and the desire to improve existing practice. While medical research involves "experimentation" on human subjects to identify novel treatments, one is often tempted to use newer techniques to improve the outcomes of treatment in routine clinical practice. There is no controversy surrounding the adoption of a new therapy which has been proven to be superior to the existing methods of treatment and which can be delivered as well, if not better. However, a moral and ethical dilemma arises when the new therapy has not yet been proven to be superior and the treating physician is not certain that administering this treatment would be at least as good as providing standard care. This is especially so when dealing with potentially vulnerable patients. In procedure-related fields, such as surgery, endoscopy and interventional radiology or cardiology, this problem is compounded because the physician not only has to decide if the "new" treatment is truly experimental or just an adaptation of an established method, but also whether he/she possesses the skills and expertise required for the new procedure.

This paper uses a hypothetical clinical scenario to examine two very important ethical aspects of clinical practice, ie, the application of the principles of research ethics to routine clinical care and the challenges of using vulnerable populations as subjects for the training of clinicians. The case described is that of a semi-literate, uninsured patient who needs to undergo a standard surgical procedure (cholecystectomy). The surgeon wants to use this opportunity to improve his proficiency in an innovative technique – robotic surgery – which he wishes to master to perform robotic liver transplants subsequently. The complexity of the problem is enhanced because the subject is semi-literate and is therefore, not considered capable of giving truly "informed" consent for a procedure that is not standard-of-care. Also, since she will be getting the surgery done for free, she may feel inhibited about refusing to undergo the robotic cholecystectomy. The paper discusses the ways in which this situation can be handled and the ethical issues raised by each of the alternatives mentioned.

One option is to perform the experimental (robotic) technique and consider it justified for the following reasons. First, the patient is receiving free treatment from society and, therefore, should contribute to the progress of medical science. Second, using this patient for enhancing the surgeon's skills will be advantageous for many future patients. While this seems acceptable in the larger perspective of scientific advancement, it is a gross violation of the patient's personal right to autonomy, the physician's obligation to primarily provide benefit, and a breach of the principle of social justice. The second option is to offer the patient both treatment choices and attempt to obtain informed consent for robotic surgery. This involves several issues, such as the difficulty of explaining the technicalities of an experimental procedure to a semi-educated patient and the question of whether the consent would be truly "informed," which again defeats the principle of autonomy. The last alternative involves creating an independent committee to standardise and supervise the use of experimental procedures in vulnerable populations on a case-by-case basis to ensure that patients' rights are protected, while at the same time allowing medical science to progress. A practical difficulty could be the feasibility of getting prompt responses to such situations on a day to day basis to ensure that treatment is not delayed. However, this might be an ideal long-term solution, though it would need careful planning and investment of resources.

After careful consideration of the pros and cons of these options, the authors conclude that the ideal and safest option is to perform the surgery using the default technique (laparoscopy). In this way, the patient receives "standard" care, there is no experimentation and the dilemma of obtaining consent from a vulnerable patient for an experimental procedure is avoided. Though there is no long-term benefit to society, the patient's autonomy is protected and the principles of beneficence and justice are upheld.

We feel that the solution offered by the authors is conveniently safe, but overly simplistic. In this context, two issues must be considered. First, is a semi-literate patient incapable of understanding the difference between standard-of-care and experimental therapy, even if she cannot understand the actual technicalities of the procedure? Surely, a person who can give "informed" consent for a surgery as complex as a laparoscopic cholecystectomy should be able to decide if she wants to

undergo a novel procedure. Is it not being paternalistic and violating the patient's autonomy, to assume that she will not be able to comprehend the nuances of robotic surgery and, on this basis, deprive her of the opportunity to contribute to medical progress? The authors have briefly alluded to this, but have concluded that non-maleficence should parallel patient autonomy. The second issue relates to the training of doctors. Academic hospitals train people to become competent doctors and this is a necessary process to ensure that future generations get the same, if not better standards of medical care than we have today. This will not be possible if less-experienced doctors are not allowed to treat and carry out established procedures on patients, albeit with supervision, and also (as in this hypothetical scenario) unless experienced doctors are allowed to offer novel treatment and perform new procedures after obtaining informed consent. Every new technique has a learning curve and if doctors do not constantly practise and upgrade their skills, they will never achieve proficiency in the latest procedures. It would be naïve and unrealistic to expect that all physicians should perform new procedures only after they have been mentored by an expert till this learning curve is completed.

To sum it up, though in this particular case, performing a laparoscopic surgery on the patient would be more expedient, the other option, ie, explaining both procedures to the patient and allowing her the freedom to choose, would be communally advantageous and ethically appropriate, even if more complex. If during the counselling process, the surgeon genuinely feels that the patient does not understand what the new procedure is all about, he can resort to the default option of performing a standard surgery. If such situations are frequent, an experimental treatment research protocol could be developed to supervise such procedures – but this process should be applied to all patients potentially suitable for such procedures, irrespective of their level of education or paying capacity. The assumption that semi-educated or uneducated patients are incapable of understanding or that the poor have no altruism is both paternalistic and presumptuous. Socioeconomically backward patients depend on society to meet their healthcare needs and they should not be exploited and made guinea pigs for experimentation by virtue of this dependence; at the same time, they have the right to contribute to the progress of medical science and they should not be denied the opportunity to make this choice.

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