## **Bioethical Issues in Teaching Invasive**

## **Medical Procedures– An Ethical Analysis**



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#### Introduction

It is generally accepted that invasive medical procedures are safer when performed in the hands of skilled and experienced clinicians as opposed to being conducted by novices just learning. Still, health care workers do not leap fully trained into the medical world. Whether they are physicians, nurses, paramedics, or physician assistants, all must be taught a body of technical skills that society expects them to have.

This essay is concerned with investigating the notion of the extra risk ("risk burden") associated with novice health care providers learning to perform new medical procedures, especially those procedures that have the potential to physically harm patients [*Note 1*]. Among other things, the essay asks the question: "What, if anything, should patients in teaching hospitals be told about the additional risks that they face when they undergo medical procedures carried out by novices."



*Hippocrates of Cos (460-ca. to 370 BC)* 

# Primum

## non nocere

(First, do no harm)

#### **Medical Procedures**

Invasive medical procedures that advanced clinicians might reasonably be expected to be proficient are numerous, and all involve some potential risk to the patient. Some such procedures include:

(1) Placing a breathing tube (endotracheal tube) in a patient's windpipe or trachea. Known as tracheal intubation, this is a process involving opening the patient's mouth, inserting a laryngoscope (sort of a lighted metal tongue blade), and passing a flexible tube through the vocal cords) [Figure 1]. This is usually done to allow a patient to be mechanically ventilated instead of having the patient breath on his own.

(2) Placing a "central" venous line directly into the patient's heart through a needle puncture in the neck [Figure 2]. This is done both to monitor cardiac performance and as a means of drug delivery.

(3) Placing an epidural catheter in a patient's back as a means of allowing drugs to be administered for anesthesia or pain management [Figure 3]. This is frequently done to relieve the pain associated with childbirth.



Figure 1. Tracheal intubation being taught using fiberoptic imaging methods.



**Figure 2.** Cardiac monitoring catheter placed into the heart via the internal jugular vein via a puncture in the neck.





As noted, such procedures are not without significant potential risk. For instance, if not done correctly, placing a central venous line may collapse a lung, puncture an artery, produce a hematoma (collection of blood), introduce air into the circulation, lacerate the internal jugular vein, or cause other damage (Reichman & Simon 2003, Spitellie et al. 2002). A number of deaths associated with the procedure have also been reported (Spitellie et al. 2002).

But if not done at all, this may deny the patient needed intravenous fluid therapy or intravenous medication, or the ability of monitoring the performance of the heart via placement of a pulmonary artery catheter (needed to measure cardiac output, filling pressures and other cardiac parameters).

#### A Hypothetical Scenario

Let us consider the following hypothetical scenario in a typical academic medical center [*Note 2*]:

"Hello, Mr. Jones, I am Dr. Smith and with me is Dr. Walker, who graduated from a solid but second-tier medical school last June. ranked at the 53rd percentile overall. Dr. Walker would like to attempt to insert your epidural catheter that you are supposed to get as part of the anesthesia for your operation. He has read about the procedure and watched it in an instructional video, as well as in real life, but has never really done the procedure completely on his own. Now it is time for Dr. Walker to attempt the procedure all by himself, with me supervising. However, while Dr. Walker will be doing the procedure under my careful supervision, you should be aware that because the procedure involves a sense of "feel" as the needle passes into your back. I can't guarantee that the needle won't go too far and hurt you in some way. And if the needle does go in too far, or if something else bad happens, some really unpleasant or nasty things could happen to you (see Table 1). Still, the likelihood of any permanent injury to you is fairly small. Anyway, is it OK if Dr. Walker does his first epidural on you with me standing by?"

This scenario illustrates how many patients might reasonably refuse to participate as subjects if they were provided with full and complete details. This also helps explain why such details are often not provided.

#### Table 1 - Potential Complications of Epidural Anesthesia

(to accompany the hypothetical clinical scenario presented earlier)

If the epidural needle is accidentally introduced too deeply, it can enter the subarachnoid space, with loss of cerebral spinal fluid. This can sometimes result in a wicked headache ("post dural puncture headache").

Epidural anesthesia can also be associated with neurologic problems, ranging from headache to paralysis. These include: prolonged neural blockade, backache, trauma to nerve roots, cauda equina syndrome, epidural hematoma, epidural abscess, adhesive arachnoiditis, meningitis and postdural puncture headache.

More catastrophic nerve injuries have also been reported; these have been in association with epidural hematoma, epidural abscess, adhesive arachnoiditis, anterior spinal artery syndrome or cauda equina syndrome.

This is only a partial list.

Source: http://www.oyston.com/anaes/local/muir.html

#### **Teaching Invasive Medical Procedures**

Although the problem of how best to teach invasive medical procedures has not been exhaustively discussed in the medical ethics literature, some authors have written a little on the topic. For instance, Rosenson et al. (2004) express the problem this way:

"Teaching medical students to perform invasive procedures poses a number of difficult ethical issues. Patients typically want the most experienced clinician to perform the procedure, not a medical student or resident who is doing it for the first time. Students are often caught in the dilemma of wanting to learn the procedures necessary to gain competence in their profession while at the same time fearing that their own lack of expertise may inadvertently harm the patient. The opportunity to perform invasive procedures may occur infrequently, when there is the greatest impact on patient outcomes and the most dire risk of complications."

The manner in which invasive medical procedures are taught is frequently the "See one, Do one, Teach one" method (Schein 2000), although this is often preceded by a textbook review (or other didactic means) by the novice learning the procedure. This process is usually carried out with the supervising clinician carefully monitoring the novice as he or she progresses in the procedure. In cases where this method involves a substantial degree of visual feedback this supervisory process is generally effective. However, in procedures where visual feedback to the supervising clinician is limited (as

in tracheal Intubation using a conventional laryngoscope), supervision can be problematic. Similarly, procedures that are heavily based on tactile feedback (such as percutaneous placement of an indwelling arterial cannula, or insertion of an epidural catheter) may present special challenges to the supervising clinician.

Some patients are aware of the difficulties associated with teaching novices new medical procedures, either as a result of previous experiences, or based on anecdotal reports, or as a matter of "common sense". In my personal experience, based on two decades of clinical practice, I have had a number of patients specifically request that only fully trained staff perform certain procedures (although few patients ever object to medical students merely observing). It is my impression that such patients, often coming from the upper socioeconomic classes, tend to be somewhat more knowledgeable than the average patient [*Note 3*].

Medical students are not unaware of such issues and the various related ethical problems in medical education. For instance, one medical student writes (Rosenbaum 2004):

"We medical students hover in a conflicted space: far ahead of us lie the stunning abilities attributed to physicians, but, for now, our keenest diagnoses are often assessments of our own ignorance. The resulting intense drive to learn, and our overwhelming desire to be the physicians that others expect, can create ethical dilemmas unique to medical students."

In community hospitals where there are relatively few novices and where teaching is not an important part of the hospital's mission, the matter of such additional risk rarely presents a big problem. However, in academic medical centers where training doctors is central to the mission of the institution, the refusal of patients to participate as part of the medical education process can be decidedly problematic.

While respect for the patient's autonomy and the related consent issues dictate that no procedure be carried out on a patient without their permission, there are reasons why patients in teaching hospitals should generally agree to be participants in the medical education process. First, if everyone refused to have novices involved in their care; novices would never become experts. Secondly, some individuals argue that implicit in agreeing to be cared for in a teaching hospital is a willingness to be part of the process of teaching and learning, although in my experience patients are never asked to specifically sign any specific agreement to that effect.

For patients to provide genuine informed consent for procedures attempted by novices, a number of elements must be addressed. First, as with any medical procedure, the requirements for consent necessitate that the risks, benefits and alternatives of the proposed intervention be explained clearly to patients in terms that they can understand. Secondly, the patients should be informed about who will be doing the procedure and who will be supervising [*Note 4*].

But this approach to establishing consent for allowing novice doctors to do procedures under supervision may be rather inappropriate: the patient does not benefit when a novice does the procedure (indeed, the risks to the patient is increased) and the only alternative seems to be for the patient to "raise a fuss" about wanting someone more experienced to do the procedure. Perhaps this is why, as implied earlier, in the real world of academic medicine it is uncommon to specifically ask a patient if it is permissible for a novice to carry out a procedure under supervision.

#### Ethical Issues in Medical Education - A Brief Review of the Literature

During the past few decades concern about bioethical and medico-legal issues have led many medical schools and residency programs to formalize their teaching of medical bioethics. Most of this teaching focuses on dilemmas that clinicians may encounter in clinical practice, often based on a number of commonly accepted philosophical or moral principles (Beauchamp & Childress 1994). However, in more recent years, there appears to be a new emphasis on some of the bioethical concerns that arise in medical education. For instance, Hicks et al (2001) relate one such example:

"We were in seeing the patient and there were four medical students in there and this girl had already sat through an hour with me going through a complete history and physical. And then, the staff [clinical teacher] decided that he would use her for the rest of the two hours for all of us to do the exam on her and she

had no idea why we were there. One of the medical students was looking at her fundi and he couldn't see them. So, the staff was yelling, "Any idiot can see the optic fundus. How can you not see it? I can see it. Look! Why can't you see it?" Then he said, "I want each and every one of you to keep looking until you see it." So the poor girl is getting blinded by four of us trying to see her fundi . . . He was just so inappropriate, the poor girl was almost in tears . . . We were all very intimidated; we thought it was inappropriate and we all talked about it later, but he [the clinical teacher] put us all in a position where we were scared to death of him. We were afraid to say anything [although] he was probably wrong." [Note 5]

A more direct issue is whether consent should be required when teaching medical procedures on the recently deceased. Some experts have advocated that physicians learn these techniques by practicing on recently deceased patients (Brattebo & Seim 1988, Orlowski et al. 1988, Orlowski et al. 1990, Iserson 1991). They propose that society grant an exception to the usual requirement for informed consent in this special case because, (1) there is a substantial social benefit to be gained, (2) there is no risk to the deceased, and because (3) families could not realistically be expected to discuss consent issues at such a difficult time in their lives.

In the case of learning tracheal intubation, proponents of this training method argue for its use on the further grounds that it is nonmutilating, is brief in duration and because there is often no practical alternative. Even American Heart Association guidelines

support the use of the newly deceased, especially small infants, in teaching intubation (American Heart Association 1991).

On the other hand, Burns et al. (1994) argue that "this approach runs counter to an evolving norm of our society" and they "reject the arguments of those who want to make this practice an exception to widely recognized standards of consent", primarily on the grounds that such an approach "would cause further deterioration in the public's trust in the medical profession". They propose instead that, after a particular patient's death, the responsible physician "explain to the family the procedures that are to be performed and the personnel who will be involved and then summarize the discussion and the family's consent in the medical record." This position, however, has generated a substantial degree of controversy (Brattebo et al. 1995, Bloom 1995, Fernandes 1995, Finegold 1995, Iserson 1995, Denny & Kollek 1999, Hudson 2000, Fourre 2002).

In any event, it is apparent that in the real clinical world consent is rarely obtained from the family of the deceased in such situations (Denny & Kollek 1999, Hudson 2000, Fourre, 2002).

One theoretical possibility is to arrange prior consent by the patient and family, as is the case with organ donor cards. Of interest, despite the fact that the idea has considerable potential merit, it does not seem to have been specifically addressed in the bioethics literature. One scheme might be that at the time of hospital admission, patients would be offered a variety of participatory options concerning a possible postmortem role in

medical education, and discussion with a counselor would follow to ensure full informed consent. Critics of this suggestion, however, point out that such discussions might be particularly anxiety provoking to many patients, while the actual educational yield may be small, since the vast majority of patients (fortunately) survive their hospital stay.

Indeed, even the far more benign suggestion that patients merely undergo formal written informed consent regarding their role as teaching material presents a number of logistical and practical issues that must be dealt with. First, there is the realistic concern that large numbers of patients might simply refuse to be treated by medical students or residents, even with appropriate supervision, once they are made aware of this option. At a minimum, many might be expected to ask a time-consuming series of questions about the training, experience and qualifications of all clinical team members. In fact, many individuals believe that patients who refuse to have some of their care provided by residents and medical students should simply not be cared for in teaching hospitals. (This view may be hard-hearted, since may procedures like heart and liver transplants are not preformed in community hospitals.)

Second, some patients might agree to participate in medical education activities only if the medico-legal "liability balance" were shifted in their favor, such that obtaining compensation for any possible complications would not require a costly and very lengthy law suit and proof of negligence. Such an arrangement would be somewhat similar to a "no fault" insurance policy. Of course, the question of who would pay for such insurance would also need to be addressed.

Finally, the medical profession does not have any actual quantitative data to offer patients about the additional risks involved for the numerous procedures in which medical students and residents might be involved. Such data must be either be determined by lengthy empirical studies or at least estimated by sampling the opinions of experts, as discussed in Appendix 1.

#### **Use of Clinical Simulators**

Simulation refers to the artificial (and almost always simplified) representation of a complex real-world process with sufficient fidelity to achieve a particular goal, such as in training or performance testing. In recent years simulators have seen increasing use in training health care providers. Although the origins of computer simulation in medicine date back some four decades, it is only now, with the advent of inexpensive computers that this field has really taken off. Computer-based simulators used in medical education fall into three general categories:

- (1) Screen-based simulators
- (2) Mannequin-based simulators, and
- (3) Virtual reality trainers.

Screen-based simulators create scenarios in which the user picks one of several responses and, based on the chosen response, a new scenario is produced. For

instance, in a scenario involving a patient presenting with a severe headache, the user may be offered options such as prescribing an analgesic such as Tylenol or getting a CT-scan of the head. Based on the user's choice, a new narrative is then generated and more management choices are offered.

Mannequin-based simulators are almost always very expensive. The advanced models include a physical model of the human body and provide continuous signals representing physiological parameters such as electrocardiogram, blood pressure wave, capnogram signal and pulse oximetry signal. While some earlier systems required the intervention of a trainer to actively 'stage manage' the scenario in response to interventions, others make use of complex computer models of human physiology and pharmacology to automatically generate appropriate responses in the mannequin and signal outputs. In contrast to screen-based simulations, these simulators appear to recreate enough elements of reality to allow the acquisition of skills that are transferable back to the clinical environment.

Such advanced simulation methods have been advocated as a means of training clinicians in procedures before exposing them to real patients (Figure 4). This point was recently emphasized by Ziv et al. (2003) who note that inevitably "medical training must at some point use live patients to hone the skills of health professionals" but that this imperative can sometimes be in direct conflict with a physician's "obligation to provide optimal treatment and to ensure patients' safety and well-being". Noting that "balancing

these two needs represents a fundamental ethical tension in medical education", the authors argue that the use of simulation-based learning can help solve this dilemma.

Indeed, medical simulators can be helpful, as evidenced by a considerable number of studies (e.g., Berkenstadt et al. 2003, Dunkin 2003, Macedonia et al. 2003, Reznek et al. 2003).

That being said, simulators are not a panacea. First, they can be very expensive (both in terms of capital cost (about \$300,000 and up) as well as in terms of physical space requirements). Second, staffing requirements (for running simulations, for computer maintenance, for curriculum development etc.) can pose another sizable burden that many under funded training programs simply cannot afford. Third, the use of simulators can be spectacularly unsuccessful, at least on occasion (Olympio et al. 2003). And in any event, there is still a point where exposure to live patients becomes necessary in one's clinical training. (Of interest, this is in contrast to the case for commercial aircraft simulators, where pilots can become fully "type-rated" on some commercial aircraft without ever setting foot on the real thing.)



**Figure 4.** Medical simulation methods based on advanced computer technology have been advocated as a means of training clinicians in performing risky or painful procedures. This often involves the use of instrumented mannequins such as the one shown here. However, the fact that such systems cost about \$300,000 and require specially trained support staff, dedicated physical space and an ongoing maintenance program are significant impediments to their wide-spread adoption.

#### **Ethical Analysis**

I would finally like to examine matters from the viewpoint of ethical theory, including a discussion of a Kantian perspective. Ethical or moral theory can be approached from many viewpoints (Beauchamp & Childress 1994, Appendix 2). The *deontological* approach to morality (from the Greek word *deon*, or duty) is based on specific obligations or duties. These can be positive (such as to care for our family) or negative (such as not to steal). This approach is also sometimes called nonconsequentialist since these principles are held to be obligatory regardless of any good or bad consequences of that might result. For example, it is wrong to kill even if it results in great benefit.

Philosophers have subdivided deontological theories into a number of categories, of which the concept of the *"categorical imperative"* developed by the18th-century German philosopher Immanuel Kant is perhaps the best known. He said that we must "treat people as an end, and never as a means to an end", by which he meant that we should always treat people with humanity and dignity, and never use individuals as "mere instruments" as a means to our own happiness. Another version of the categorical imperative is: "Always act in such a way that the maxim of your action can be willed as a universal law." (Other deontological approaches are discussed briefly in Appendix 2.)

The concept of the categorical imperative can be used to help analyze matters. Cast in these terms, our problem becomes that of justifying the use of patients as "learning tools". For many, the justification is entirely utilitarian in nature: while *this* patient may

be exposed to a higher level of risk in a learning exercise, *future* patients are better off (in general) by having well-trained medical professionals to treat their maladies. Moreover, since *this* patient has likely benefited from the past risks that others have undergone for them (since they too were once in the class of future patients) then they ought to allow invasive procedures to be performed upon them by medical novices, as a matter of practical inconsistency (with proper supervision, of course.)

Against this line of argumentation we have the time-honored Hippocratic requirement to "first do no harm" as well as the Kantian principle to always treat patients as "ends in themselves." The Hippocratic requirement and various its modern equivalents can be answered through the utilitarian argument just presented. However, the Kantian position appears to require us, disastrously, to forgo allowing medical students and residents to treat patients at all. However, such a rigid interpretation need not apply. Deep down, the Kantian maxim only requires us to avoid treating patients as a "means only," i.e., we can use patients as learning tools if we continue to respect their autonomy and obtain their consent. Hence, the utilitarian argument, to have a sound ethical basis, must be supplemented by following proper Kantian "procedure," so to speak. The raving clinical instructor referenced earlier did not do this and reduced the poor adolescent in question to a mere object devoid of anything but instrumental value for frightened medical students.

To summarize, the pursuit of Kantian ethical principles would require instructors and students to get patient consent for using them for teaching purposes, for doing so means that the patient has *autonomously authorized* being so treated. Of course, in the case of conducting invasive medical procedures by medical novices this implies reasonable standards of disclosure in light of possible increased risk.

#### **Conclusions / Need for Further Work**

The issues relating to the balancing a physician's obligation to provide the best possible treatment to his or her patients with the obligation of the medical educator to help develop the skills of health professionals in training are far from resolved, and the conflict between these two responsibilities represents a deep-seated ethical dilemma in medical education that merits careful continuing study.

In the final analysis, the issue appears mainly to be one of informed consent, but despite the vast literature on the topic of informed consent, this aspect of the issue does not appear to have been well-developed in the literature. In any event, there is a need further exploration in the ethical and legal literature to seek out possible relevant discussions.

In addition, I suggest that two general forms of further study should be considered. First, there is a need for on-going theoretical / philosophical debate in this area, since, as noted above, the literature to date on this topic is relatively sparse. For instance, there is

a need for individuals to further discuss these issues from various theoretical frameworks, such as from the various deontological viewpoints of or from the viewpoint of principalism.

Second, there is a need for empirical studies of public opinion on this topic. To assist this process, I have developed a list of possible questions to consider. These are listed in Appendix 3.

#### References

American Heart Association. Emergency Cardiac Care Committee and Subcommittees. (1991). Guidelines for cardiopulmonary resuscitation and emergency cardiac care. Part VIII. Ethical considerations in resuscitation. JAMA, 266, 2837-42.

Beauchamp T & James F. Childress JF. Principles of Biomedical Ethics. 4th ed. Oxford University Press, 1994.

Berkenstadt H. Ziv A. Barsuk D. Levine I. Cohen A. Vardi A. (2003). The use of advanced simulation in the training of anesthesiologists to treat chemical warfare casualties. Anesthesia & Analgesia, 96,1739-42

Bloom JM. (1995). Using newly deceased patients in teaching procedures. New England Journal of Medicine, 332,1446

Brattebo G, Seim SH. (1988). Teaching and training of invasive procedures on cadavers. Lancet, 2,1078-9.

Brattebo G. Wisborg T. Oyen N. (1995). Using newly deceased patients in teaching procedures. New England Journal of Medicine, 332,1445

Burns JP, Reardon FE, Truog RD. (1994). Using newly deceased patients to teach resuscitation procedures. N Engl J Med, 331,1652-5

Denny CJ, Kollek D. (1999). Practicing procedures on the recently dead. J Emerg Med, 17, 949-952.

Dunkin BJ. (2003). Flexible endoscopy simulators. Seminars in Laparoscopic Surgery, 10, 29-35.

Fernandes CM. (1995). Using newly deceased patients in teaching procedures. New England Journal of Medicine, 332,1446

Fourre MW. (2002). The performance of procedures on the recently deceased. Acad Emerg Med. 9, 595-598.

Finegold L. (1995). Using newly deceased patients in teaching procedures. New England Journal of Medicine, 332,1446

Hicks LK, Lin Y, Robertson DW, Robinson DL, Woodrow SI. (2001). Understanding the clinical dilemmas that shape medical students' ethical development: questionnaire survey and focus group study, BMJ, 322,709-10.

Hudson TS. (2000). Is it ethical to practice intubations on the deceased? JONAS Healthc Law Ethics Regul, 2, 22-28.

Iserson KV. (1991). Requiring consent to practice and teach using the recently dead. J Emerg Med, 9,509-10.

Iserson KV. (1995). Using newly deceased patients in teaching procedures. New England Journal of Medicine, 332,1445-6

Macedonia CR. Gherman RB. Satin AJ. (2003). Simulation laboratories for training in obstetrics and gynecology. Obstetrics & Gynecology, 102, 388-92

Olympio MA. Whelan R. Ford RP. Saunders IC. (2003). Failure of simulation training to change residents' management of oesophageal intubation. BJA: British Journal of Anaesthesia, 91,312-8.

O'Neill O. (2003). Some limits of informed consent. Journal of Medical Ethics, 29, 4-7.

Orlowski JP, Kanoti GA, Mehlman MJ. (1988). The ethics of using newly dead patients for teaching and practicing intubation techniques. N Engl J Med, 319,439-41

Orlowski JP, Kanoti GA, Mehlman MJ. (1990). The ethical dilemma of permitting the teaching and perfecting of resuscitation techniques on recently expired patients. J Clin Ethics, 1,201-5.

Reichman E & Simon RB. Emergency Medicine Procedures. McGraw-Hill. 2003.

Reznek M. Smith-Coggins R. Howard S. Kiran K. Harter P. Sowb Y. Gaba D. Krummel T. (2003). Emergency medicine crisis resource management (EMCRM): pilot study of a simulation-based crisis management course for emergency medicine. Academic Emergency Medicine, 10,386-9.

Rosenbaum, L. (2004). Ethical Issues in Medical Education, JAMA 291, 118.

Schein M. (2000). See one, do one, teach one. Surgery, 128, 868-9.

Rosenson J, Tabas JA, Patterson P (2004). Teaching Invasive Procedures to Medical Students. JAMA, 291, 119-120.

Spitellie PH, Bowdle TA, Posner KL, Cheney FW, Domino KB (2002). Injuries from Central Lines: A Closed Claims Analysis. Anesthesiology, 96, A1124.

Ziv A, Wolpe PR, Small SD, and Glick S. (2003). Simulation-Based Medical Education: An Ethical Imperative Academic Medicine, 78, 783-788.

#### Notes

#### [Note 1a] Comment from Professor Harvey [paraphrased]

A similar state of affairs exists when experienced physicians themselves are learning to perform a new, invasive procedure that they have not often performed. Should they be required to tell their patients that they are relative novices?

#### [Note 1b]

Besides the issue of direct patient risks, it may also be of interest to consider indirect risks, such as the impact that monitoring the performance of medical novices assisting in the operating room has on diverting attention away from monitoring the patient's condition. That is, does the mental workload associated with medical supervision in the operating room significantly dilute attention that ordinarily should be focused entirely on the patient? A similar question asks whether attention devoted to didactic instruction in the operating room can ever be detrimental to patients.

#### [Note 2]

While some readers may take this scenario to be deliberately framed in a negative manner to scare readers and patients alike, the reality may actually be somewhat worse. For instance, many training programs do not have instructional video resources that residents can use for preparatory work. Also, it would be rare that residents would be formally tested on theoretical knowledge of epidurals before actually attempting one.

Finally, remember that, by definition, fully one half-of medical students graduate in the bottom half of their class.

#### [Note 3] Comment from Professor Harvey

"I would be surprised if they were not considerably more knowledgeable. Such class issues permeate the provision of care in our society. Those from lower socioeconomic classes invariably tend to believe that anyone in a white coat is a competent physician. Most medical professors and students are loath to disabuse the notion. As such, a "sin of omission" is seemingly perpetrated against them since most similarly situated reasonable people might certainly want to know that a medical procedure was about to be performed upon them by a novice. Sissela Bok discusses this form of implicit though intentional deception."

#### [Note 4]

Indicating exactly who will be doing what in a supervised medical procedure cannot always be established completely in advance, especially for complex procedures. Some supervisors "take over" when the slightest degree of difficulty is encountered, while others, presumably less anxious types, give their residents far more latitude, along with generous verbal guidance, and are apt to take over only when specifically asked or when the patient has suffered "too much" discomfort or danger. The latter individuals are more likely to get positive teaching evaluations from their residents.

#### [Note 5] Comment from Professor Harvey [paraphrased]

Such savage behavior reduces patients to mere objects. A Kantian ethical approach would require clinicians to avoid treating patients as a "means only," i.e., one may use patients as learning tools only with their consent and only if we continue to respect their autonomy. The raving staff member described clearly in the vignette did not do this and reduced the poor adolescent in question to a mere object devoid of anything but instrumental value for terrified medical students.

#### [Note 6]

It would be of interest to obtain estimates of the "risk ratio" (complication risk for novices divided complication risk for experts) for the various procedures. Such information would be helpful in informed consent matters. For instance, in the case of epidural insertion by novices as compared to insertion by experts, the main risk is that of obtaining a "wet tap" (a dural puncture with loss of cerebrospinal fluid). In this case, estimates might be obtained by sampling the opinions of a number of anesthesiologists, or by empirical studies.

#### Appendix 1

#### Estimation of Risk Ratio for Epidural Catheter Placement: Study Design Notes

Anesthesiologists will at random be sent either Letter A, B, or C via e-mail, asking them to provide a rough estimate of how much more frequent epidural "wet taps" are when done by residents just learning the procedure as compared to individuals at the peak of their skill.

#### Letter "A"

Please use your professional experience to provide me with a rough estimate of how much more frequent you think epidural "wet taps" are when done by residents just learning the procedure as compared to individuals at the peak of their skill in placing epidural catheters.

For instance, if you think that a wet tap is 1.5 times more likely in the hands of a novice, write "1.5" in the space below:

Your estimate \_\_\_\_\_

#### Letter "B"

Please use your professional experience to provide me with a rough estimate of how much more frequent you think epidural "wet taps" are when done by residents just learning the procedure as compared to individuals at the peak of their skill in placing epidural catheters.

For instance, if you think that a wet tap is 10 times more likely in the hands of a novice, write "10" in the space below:

Your estimate

#### Letter "C"

Please use your professional experience to provide me with a rough estimate of how much more frequent you think epidural "wet taps" are when done by residents just learning the procedure as compared to individuals at the peak of their skill in placing epidural catheters.

For instance, if you think that a wet tap is 100 times more likely in the hands of a novice, write "100" in the space below:

Your estimate

#### Appendix 2

#### Developing a Moral Theory: What are the Essential Characteristics?

Moral theory is the foundation for making good ethical decisions. This appendix is concerned with identifying the essential characteristics of a good moral theory. I make the case that while experts disagree on many of the details, a number of essential elements can nonetheless be found. A good moral theory should at least be consistent and universal, but the case for other requirements (as in being intuitive, coherent and practical) can also be made.

Moral theory can be approached from many viewpoints [1]. The deontological approach to morality (from the Greek word deon, or duty) is based on specific obligations or duties. These can be positive (such as to care for our family) or negative (such as not to steal). This approach is also sometimes called nonconsequentialist since these principles are held to be obligatory regardless of any good or bad consequences of that might result. For example, it is wrong to kill even if it results in great benefit.

Philosophers have subdivided deontological theories into a number of categories, of which the concept of the "categorical imperative" developed by the18th-century German philosopher Immanuel Kant is the best known. He said that we must "treat people as an end, and never as a means to an end", by which he meant that we should always treat people with humanity and dignity, and never use individuals as "mere instruments" as a

means to our own happiness. Another version of the categorical imperative is: "Always act in such a way that the maxim of your action can be willed as a universal law." Other deontological approaches include "duty theory" (defining duties to God, duties to oneself, and duties to others), "rights theory" (concerned with rights that all people have, and which the rest of us must respect), and a more recent theory developed by W.D. Ross, which emphasizes prima facie duties.

The consequentialist approach to moral theory determines moral responsibility by weighing the consequences of one's actions. According to the consequentialist view, correct moral actions are determined by a cost-benefit analysis concerning the consequences of an action. Several subtypes of consequentialism have been proposed: (1) the view that an action is morally correct if its consequences are more positive or favorable than negative to the person performing the action (ethical egoism), (2) the view that an action is morally correct if the consequences of that action are more positive than negative to everyone except the person doing the action (ethical altruism), and (3) the view that an action is morally correct if the action's consequences are more positive than negative to everyone (utilitarianism).

Any good moral theory should have a set of traits that defines them as being good. These characteristics are needed to avoid a number of philosophical flaws that might otherwise occur. These include: bias, cultural imperialism / cultural ideology, prejudice, racism, sexism and other defects in logic and thinking. I would hold that the following are desirable traits of any good moral theory. (1) It should be consistent – i.e., yielding

similar results in similar settings. (2) It should be universal - i.e., if the theory applies to one individual, then it should apply to all individuals. (3) It should be intuitive – i.e., the theory fits our moral intuition.

Other individuals might add other characteristics to this list, such a need for the theory to be understandable by nonphilosophers (certainly a requirement for any practical theory), or the need for the theory not to be based on any religious teachings (although I feel that this is already covered by my requirement (2) above). Others might add the requirements of being time-invariant (that the principles hold true over time) and transcultural (that the principles apply to all cultures), but I view these also as being covered by requirement (2). Still others might state that any moral theory must respect all forms of human life, no matter how degraded., while animal rights advocates might emphasize that a moral theory must necessitate respect for all sentient life forms, not just humans. Finally, Princeton's Professor Peter Singer would likely take issue with my third requirement that a moral theory be intuitive – his moral positions are often taken to be unintuitive and repugnant when first explained, especially in the matters of euthanasia and infanticide, although he makes his case forcefully and lucidly in his many writings.

Professor Paul Taylor, well-known for his writings in the domain of environmental ethics, argues that six characteristics are necessary for a philosophical principle to be a moral rule: (1) generality, (2) universality, (3) priority, (4) disinterestedness, (5) publicity, and (6) substantive impartiality. While his focus is on environmental ethics as opposed to

bioethics, it can be seen that his views are substantially similar to mine once the meaning of the terms he uses are fully understood [2].

Beauchamp and Childress offer a number of useful notions on morality in the first chapter of their classic bioethics text [3], but their focus is not on developing a list of specific characteristics as, for example, Taylor has done. Still, their second chapter discusses this matter at some length, introducing requirements of clarity, coherence, completeness, simplicity, explanatory power, justificatory power and practicability. Finally, with respect to people's personal beliefs in the development of a good ethical theory, as discussed in requirement (3) above, a good moral theory should be intuitive with respect to existing beliefs, but only when the personal beliefs meet the other requirements of consistency, time-invariance etc. as discussed above.

#### Sources

[1] Internet Encyclopedia of Philosophy, http://www.utm.edu/research/iep/

[2] Taylor P. "On Taking the Moral Point of View," Midwest Studies in Philosophy, III (1978), 35-61

[3] Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 4th Ed. New York:Oxford University Press, 1994

#### Appendix 3 – Possible Survey Questions

#### **Introductory Statement**

It is generally accepted that invasive medical procedures are safer when performed in the hands of skilled and experienced clinicians as opposed to being conducted by novices just learning. Still, health care workers do not leap fully trained into the medical world. Whether they are physicians, nurses, paramedics, or physician assistants, all must be taught a body of technical skills that society expects them to have. However, such procedures may entail significant potential risk when performed by a novice, even with optimal supervision. This survey is intended to explore people's opinion on this issue.

#### **Question 1**

What should patients be told when an invasive medical procedure is to be performed under supervision by a novice, in addition to the usual things patients are told as part of the usual informed consent process (involving a discussion of the risks, benefits and alternatives)?

#### **Question 2**

Should patients be told of the possible extra risks involved when a procedure is to be performed by a novice, even if such information may very likely make them anxious?

#### **Question 3**

Should patients be explicitly told under what circumstances they may decline to have a procedure done by a medical student or other novice, or is it acceptable to put the entire "burden of refusal" on the patient?

#### **Question 4**

Do patients in teaching hospitals have a responsibility to participate in the medical education process by allowing medical students and other novices to be involved in their care, under supervision?

#### **Question 5**

How should complications occurring in the hands of such novices be documented and explained to the patient, and how should responsibility be assigned should the novice get a complication because he (or she) did not follow instructions?