ISSUES ASSOCIATED WITH TEACHING AND LEARNING MEDICAL PROCEDURES: ETHICAL, PHILOSOPHICAL, AND LEGAL PERSPECTIVES

D. John Doyle

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This thesis has been
accepted by:

Brad Bell, PhD
Advisor

Chandra Richardson, PhD
External Reader

Elaine Bontempi, PhD
External Reader #2

Tracy Caldwell, PhD
Director of MA/LS Program

Donna Fish, PhD
Dean of Liberal Arts

VITAE

D. John Doyle is an academic anesthesiologist at Cleveland Clinic, in Cleveland, Ohio, where he holds the rank of Professor. He received the MD, PhD and FRCPC qualifications at the University of Toronto in Toronto, Canada in 1982, 1986 and 1986 respectively. Although he has numerous scholarly publications in the fields of medicine and anesthesiology, in recent years he has developed his long-standing interest in philosophy by branching into occasional research and academic writing in the fields of ethics and bioethics.

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ABSTRACT

The ethical conflicts relating to balancing a physician’s obligation to provide the best possible treatment to his or her patients with the concurrent obligation of the physician educator to help develop the skills of health professionals in training forms the basis for a deep-seated ethical dilemma that that remains largely unresolved to this day. In particular, a dilemma arises when patients are subjected to risky or painful invasive procedures such as central line insertion or insertion of an epidural catheter by novice doctors in training.

This dilemma occurs because despite the procedure being conducted under the supervision of an attending staff physician, the risk of complications is still likely to be higher than if the procedure were to be conducted instead by the presumably more experienced attending physician.

Despite its practical importance, this vital question has not been comprehensively addressed in the ethics literature. In this thesis, the ethical, medical and legal literature is explored to help clarify the many issues involved.

The case is made that the central concern is predominantly one of informed consent. In addition, an approach based on the Kant's Categorical Imperative is offered and its implications are considered. This approach is contrasted with a utilitarian approach in common clinical use.

Finally, the thesis appendix discusses how an electronic survey of public opinion on this issue might be conducted using the Internet.

In summary, this thesis provides an original contribution to the medical ethics literature on the difficult problem of how we should treat patients when used as teaching subjects.

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Chapter 1

INTRODUCTION

Medical education has served an important societal need from the first days of civilization. One of the earliest known medical educators was Hippocrates of Cos (460-ca. to 370 BC) who left behind both important texts as well as vital clinical principles that stand to this day (Strathern, 2005; see also Chapter 4). Since that time medical education has evolved over time as such notables as Galen, Vesalius, Harvey, Osler, and countless others have contributed to the landscape of medical education.

In more recent times Abraham Flexner permanently changed American medical education by introducing much needed reforms in the way doctors were trained. These landmark reforms placed a special emphasis on the application of the scientific method in understanding disease processes and medical therapeutics, and, perhaps most importantly, eliminated a number of substandard (usually proprietary) medical schools that were simply not up to the task of producing physicians trained in the

scientific method (Cooke, Irby, Sullivan, & Ludmerer, 2006).

The process of educating doctors and other health care professionals is different from many other educational undertakings in a number of important respects: the outcome can sometimes literally be a matter of life and death, the confidences of others are often trusted to the student, and the student may be learning procedures with the potential to maim or even kill, a theme explored in Chapters 5 and 7.

This last point is an important theme in this work. It is generally accepted that medical procedures with the potential for serious complications 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 clinical and technical skills that society expects them to have.

One theme this thesis will be exploring is the notion of the additional risk associated with novice health care providers learning to perform invasive medical procedures, especially those procedures that have the potential to

physically harm patients. I sometimes call this extra risk by the term “risk burden,” the burden placed on a patient when an inexperienced person performs a procedure under supervision rather than the supervisor performing the task directly. (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?)

Additionally, the thesis explores the question; “What, if anything, should patients in teaching hospitals be told about the additional risks that they may face when they undergo medical procedures carried out by novices?”

The thesis is organized along the following lines: Chapter 2 introduces some important principles in moral philosophy and bioethics that will serve as a backdrop for subsequent discussions. Chapter 3 briefly discusses a number of ethical issues associated with medical instruction using patients. Chapter 4 looks to the Hippocratic Oath as a possible source of guidance to answer bioethical questions. Chapter 5 focuses on notions of risk and benefit in the execution of medical procedures. To put the above issues and other matters in context, Chapter 6

provides an overview of medical education, focusing on the postgraduate years. Chapter 7 then discusses the issues in the teaching of invasive medical procedures with the potential to cause patient harm. Chapter 8 introduces the field of medical simulation and discusses the extent to which medical simulation technology may add to patient safety in the course of medical education. Chapter 9 explores the issue of consent from ethical and legal perspectives, with a discussion on obtaining consent in the course of medical teaching. Chapter 10 asks whether the notion of therapeutic privilege might be invoked as a means to get around the problem of obtaining patient consent in the course of medical teaching. Chapter 11 introduces Kantian and utilitarian perspectives to the discussion. Chapter 12 discusses conclusions and offers some ideas for future work. Finally, The Appendix discusses how an electronic survey of public opinion on these issues might be conducted using the Internet.

Chapter 2

ETHICAL THEORY

Moral or ethical theory can be approached from many viewpoints (Beauchamp & Childress, 2001; Lawlor, 2007). 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.

In this setting, the concept of the “Categorical Imperative” developed by the 18th-century German philosopher Immanuel Kant is particularly relevant (Secker, 1999). Kant said that we must treat people as an end, and never as a means to an end, by which he intended 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” popularized by Ross and “rights theory” (concerned with rights that all people have, and which the rest of us must respect) (Beauchamp & Childress, 2001). Ross’s duty theory defines duties of beneficence, non-malfeasance, justice, self-improvement, reparation, gratitude and promise-keeping. He calls these *prima facie* duties. This approach was developed as an alternative to utilitarianism because of perceived failures of utilitarianism as a satisfactory moral theory:

> [Utilitarianism] seems to simplify unduly our relations to our fellows. It says, in effect, that the only morally significant relation in which my neighbours stand to me is that of being possible beneficiaries of my action. They do stand in this relation to me, and this relation is morally significant. But they may also stand to me in the relation of promisee to promisor, of creditor to debtor, of wife to husband, of fellow countryman to fellow countryman, and the like; and each of these

> relations is the foundation of a...duty.... (Ross 1930,p.19).

As noted above, rights theory is concerned with rights that all humans have, and which other humans must respect. A right is a benefit (e.g., a liberty, a power, a prerogative, an immunity) that someone gains by virtue of his or her particular status as a citizen, a human being, a woman, a man, a child, a minority, a sentient animal etc. Rights can be positive, such as rights to food, clothing, and shelter, or negative, such as the right to be left alone. Rights theory thus offers an approach to moral action in that actions that violate the rights of others are said to be immoral.

In contrast to the various deontological approaches to morality, the *consequentialist* approach determines moral responsibility by weighing the consequences of one's actions (Beauchamp & Childress, 2001). 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*).

Utilitarianism

Utilitarianism is a school of moral philosophy frequently identified with the writings of Jeremy Bentham and John Stuart Mill (Gillon, 1985). Classical Utilitarianism advocates the principle of providing "the greatest happiness to the greatest number" as the basis for assessing the morality of various actions. Over the years utilitarianism has undergone a number of refinements, such as "act utilitarianism", "rule utilitarianism", "negative utilitarianism" and "preference utilitarianism" (Gillon, 1985).

Act utilitarianism takes the position that, when facing a moral choice, one must consider the expected consequences of various potential actions and, based on

this analysis, choose to do what we believe will generate most happiness or pleasure for the most people. A rule utilitarian, by contrast, analyses a moral dilemma by looking at potential rules of action that may be applicable, and adheres to the rule that would be expected to produce the most happiness or pleasure. Negative utilitarianism requires us to act so as to produce the least amount of evil or harm for the greatest number of people. In the case of preference utilitarianism, advocated by Professor Peter Singer (Jamieson, 1999), the goal is to meet the preferences of the greatest number of people.

An example adapted from Wikipedia may help. Consider a transplantation specialist with four patients. One needs a new liver, one needs a set of lungs, one needs a heart, and one needs a kidney. An act utilitarian would theoretically be comfortable with the idea of hunting down and kidnapping the first healthy person he encounters with a view to using him as an organ source. While this is obviously in violation of the rights of the kidnapped man, the fact that four other people and their families are made very happy by the arrangement makes it morally acceptable from the viewpoint of an act utilitarian.

By contrast, a rule utilitarian would look at the rule, rather than the act, that would apply to cutting up the kidnapped man for parts. Since the proposed applicable rule in this case – that one may kill a healthy man for his organs - if instituted widely would lead to particularly bad social consequences, a rule utilitarian would argue that we should in fact implement the opposite rule: "don't kidnap healthy people for their organs to transplant into sick people."

Since negative utilitarianism requires us to act so as to produce the least amount of evil or harm for the greatest number of people, kidnapping a healthy man as a source of organs would obviously be immoral.

In the case of preference utilitarianism, at issue is that all party's preferences are met as much as possible. In the macabre example above, it is very likely that none of the parties involved would prefer to kidnap a healthy man as a source of organs.

It should be noted that, while utilitarianism has had a strong influence of the intellectual landscape of recent philosophical discourse and, in particular, in ethical theory, as in the example above, sometimes falters badly

when it is applied to questions of social or individual justice. Because classical utilitarianism seeks to maximize the total amount of a particular “utility” (like happiness or preferences) over an entire society or social group, it seeks whichever arrangement achieves maximum utility. But, as already emphasized, such an arrangement might be achieved by distributing benefits and burdens in a way that violates common notions of justice.

Perhaps the most quoted example of how classical utilitarianism sometimes violates common-sense notions of justice is the scenario where killing one individual would save the lives of many. As already noted, under the act utilitarian ethical model such action would be appropriate. As another example, such a situation arose in the 1968 movie “The Magus,” where the mayor of a small Greek village under WW II German occupation is ordered by the Nazi Commandant to personally kill three Greek freedom fighters responsible for the death of German soldiers. If the mayor refused, the Germans would kill both the freedom fighters and all the villagers.

Another example: The use of slaves might greatly help maximize the *net* happiness in a society, but common-sense notions of justice almost always take slavery to be wrong (with apologies to both Aristotle and Thomas Jefferson, two great intellectuals who were unapologetic slave owners).

Another serious criticism of utilitarianism is that under the goal of maximizing happiness or some other utility, the wishes and desires of sadists and perverts are lumped in with the wishes and desires of everyone else when an overall determination of utility is made. By espousing a system in which the satisfaction of *all* desires are to be maximized, utilitarianism can end up violating our intuitive precepts of natural justice.

Such paradoxes led the philosopher John Rawls and others to take the position that we must reject most forms of utilitarianism and instead develop a genuine understanding of what is right and wrong as a basis for making ethical decisions. What is needed, Rawls argues, is moral theory with justice at its core (Rawls, 1971). Although a detailed explanation of Rawls's philosophy as set forth in his book *A Theory of Justice* (Rawls, 1971) is well beyond the scope of this thesis, in essence he argues

that a fair and rational person operating behind a “veil of ignorance” would choose two general principles as the basis for social justice.

The first principle would be the *Principle of Equal Liberty,* where each person in a society would have an equal right to the most extensive liberties compatible with similar liberties for all. The second principle, called the *Difference Principle* would require that any social and economic inequalities in a society should be the result of an arrangement that provides the greatest benefit to the least advantaged persons, and is associated with positions or offices open to all.

As can be seen from the above discussion, a number of moral theories are available to consider for adoption. What, then, are the characteristics of a “good” moral theory?

Characteristics of a Good Moral Theory

Arguably, 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) If at all possible it should also be intuitive – i.e., the theory ideally should fit our moral intuition. (In the requirements that a moral theory to be both consistent and universal, it will be immediately understood that an inconsistent theory or one that applied only to some people but not others would be undesirable. However it is less obvious that a moral theory should fit our moral intuition, since moral intuition may have strong cultural influences. On the other hand, a moral theory that fits our intuition is more likely to be understood and followed.)

Other individuals might add other characteristics to this list, such a need for the theory to be understandable by non-philosophers (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 trans-cultural (that the principles apply to all cultures), but I view these as being also 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 should 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 (Jamieson, 1999).

Chapter 3

ETHICS OF MEDICAL INSTRUCTION USING PATIENTS

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 ethics. Most of this teaching focuses on dilemmas that clinicians may encounter in daily practice, often based on a number of commonly accepted philosophical or moral principles (Beauchamp & Childress, 2001). However, in recent years, there appears to be a new emphasis on some of the bioethical concerns that arise in medical education (Hicks, Lin, Robertson, Robinson, & Woodrow, 2001; Rosenson, Tabas, & Patterson, 2004). These latter concerns deal primarily with the need for respect for the interests of the patients who are being used for teaching purposes, as well as concern for the welfare of medical students and residents.

Hicks, Lin, Robertson, Robinson & Woodrow (2001) relate an example of a concern that any medical student can relate to:

> 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 (p.710).

Related to concerns for the welfare of medical students and residents is a concern for the welfare of the

patients who, directly or indirectly, are used for teaching purposes. It is apparent that the savage behavior in the example above reduces patients to mere objects. As discussed later in Chapter 11, a Kantian ethical approach would require clinicians to avoid treating patients as a "means only," that is, one should 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 this vignette did not do this and reduced the poor adolescent patient in question to a mere object devoid of anything but instrumental value for terrified medical students.

Presumably, many patients are aware that clinical inexperience can be detrimental to their clinical care, and, not surprisingly, would prefer to avoid having medical students participating in their care. In a study by Simons, Imboden & Martel (1995) of patients in a general internal medicine practice, a third of the patients surveyed stated a preference to not have medical students participating in their care, preferring instead to see the attending physician alone.

A related issue is whether patients feel they are in a position to refuse to have medical students involved in

their care. In a Swedish study by Lynöe, Sandlund, Westberg, & Duchek (1998), 46% of patients who had medical students involved in their care agreed with the following statement: “I understood that medical students were present but did not feel that I had any possibility of declining to participate” (p. 468).

Some individuals might suggest that all patients should provide written informed consent regarding their role as a possible teaching subject, just as they might provide informed consent for surgery. However, this presents a number of logistical and practical issues that must be addressed. 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, however, since

many 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 changed such that obtaining compensation for possible complications would not require a costly 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 would have to either be determined by lengthy empirical studies or at least be estimated by sampling the opinions of experts.

Chapter 4

DRAWING OF THE HIPOOCRATIC OATH FOR GUIDANCE

Hippocrates (c. 460 BCE – c. 370 BCE) was a profoundly influential Greek physician born on the Greek island of Cos (Strathern, 2005). Many medical history scholars regard him as the greatest physician of ancient times. Hippocrates put special emphasis on clinical observation and the systematic study of the human body, and argued that all illness had a definite biological / rational explanation. He especially discouraged the then popular notions of evil spirits and angry gods as a cause of disease.

Upon starting his famed medical school in Cos, Hippocrates began documenting some of his many clinical observations. His translated writings can now be freely accessed online (Hippocrates, 1868). Some quotations from his works demonstrate his remarkable clinical insights (Table 1, next page).

Table 1. Selected Quotations from Hippocrates. From *Hippocrates' Aphorisms*. Accessed July 14, 2007 from http://etext.library.adelaide.edu.au/mirror/classics.mit.edu/Hippocrates/aphorisms.html

1. Life is short, and Art long; the crisis fleeting; experience perilous, and decision difficult. The physician must not only be prepared to do what is right himself, but also to make the patient, the attendants, and externals cooperate.
2. When sleep puts an end to delirium, it is a good symptom.
3. It is better that a fever succeed to a convulsion, than a convulsion to a fever.
4. Walking is man's best medicine.
5. To do nothing is sometimes a good remedy.
6. Persons who are naturally very fat are apt to die earlier than those who are slender.
7. Idleness and lack of occupation tend - nay are dragged - towards evil.
8. There are in fact two things, science and opinion; the former begets knowledge, the latter ignorance.

9. Things that are holy are revealed only to men who are holy.
10. Healing is a matter of time, but it is sometimes also a matter of opportunity.
11. Prayer indeed is good, but while calling on the gods a man should himself lend a hand.
12. Blood or pus in the urine indicates ulceration either of the kidneys or of the bladder.
13. When no swelling appears on severe and bad wounds, it is a great evil.

Not all of Hippocrates' teachings have stood the test of time. For instance, he taught that illness resulted from an imbalance of the four humors in the body: blood, black bile, yellow bile and phlegm (Strathern, 2005). He also taught that if one of these humors were present in excess, the excess material (known as *materia peccans*) was to be removed, for example through purges, through the use of enemas, or by blood-letting, depending on which material was in excess. Nevertheless, overall, Hippocrates' writings remain rich in clinical wisdom, and it is no surprise that

he remains in high esteem among clinicians to this very day.

Hippocrates is best known for his professional oath, which he developed for his student physicians to follow. In many parts of the world this ritual persists to this day Figure 1 provides the text for a translation of the original Hippocratic Oath.

The Hippocratic Oath for Physicians

I SWEAR by Apollo the physician, and Aesculapius, and Health, and All-heal, and all the gods and goddesses, that, according to my ability and judgment, I will keep this Oath and this stipulation - to reckon him who taught me this Art equally dear to me as my parents, to share my substance with him, and relieve his necessities if required; to look upon his offspring in the same footing as my own brothers, and to teach them this art, if they shall wish to learn it, without fee or stipulation; and that by precept, lecture, and every other mode of instruction, I will impart a knowledge of the Art to my own sons, and those of my teachers, and to disciples bound by a stipulation and oath according to the law of medicine, but to none others. I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to any one if asked, nor suggest any such counsel; and in like manner I will not give to a woman a pessary to produce abortion. With purity and with holiness I will pass my life and practice my Art. I will not cut persons laboring under the stone, but will leave this to be done by men who are practitioners of this work. Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption; and, further from the seduction of females or males, of freemen and slaves. Whatever, in connection with my professional practice or not, in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret. While I continue to keep this Oath unviolated, may it be granted to me to enjoy life and the practice of the art, respected by all men, in all times! But should I trespass and violate this Oath, may the reverse be my lot!

Figure 1. The original Hippocratic Oath. Translated by Francis Adams and obtained from the MIT tech classics collection.

As can be seen from the text in Figure 1, the original Hippocratic Oath forbids a number of activities, such as abortions, bladder and kidney stone surgery, euthanasia, disclosure of confidential information without the patient's permission, and sex with patients. However, some of these rules have changed over time and are no longer appropriate to contemporary medical practice.

For instance, a famous legal case from California established that physicians are obligated to disclose confidential information from their patients where the withholding of such information would put an individual at risk. In the landmark legal case of Tarasoff v. Regents of University of California, a psychiatrist, out of respect for patient confidentiality, failed to warn police that one of his patients was planning to harm someone (Jones, 2003). When the patient carried out his plans, the victim's family sued the psychiatrist's employer, the University of California, and won, arguing that there should be limits to medical confidentiality. The outcome was a clear legal ruling establishing that the principle of medical confidentiality can be trumped by concerns for the safety of third party individuals.

An even better known American legal case that goes against the Hippocratic Oath is Roe v. Wade, which established a woman’s right to obtain a therapeutic abortion in the early stages of pregnancy (Mcfarlane, 1993).

Both these legal cases have resulted in principles that are incompatible with the original Hippocratic Oath. As a consequence of issues such as these, while the popular perception, especially on television or in the cinema, is that physicians take the Hippocratic Oath on entry into clinical practice, the reality is rather different. In fact, while graduating physicians very often take a professional oath, it is almost always different from the original Hippocratic Oath in a number of important respects. While the principles Hippocrates advocates in his oath were perhaps appropriate to the times he lived in, like some of his aphorisms, some principles have not entirely held up over time. There are several reasons for this.

First, advances in medical technology and medical practice since the time of Hippocrates have changed the clinical landscape. This is exemplified by our current ability to very safely conduct kidney and bladder stone

surgery; this was simply not the case in the time of Hippocrates, which is likely why it was forbidden in the original Hippocratic Oath.

Second, important changes in medical ethics have occurred since the time of Hippocrates, as exemplified by many current codes of medical ethics that often permit therapeutic abortions in early pregnancy.

Third, important changes in the status of women have occurred since the time of the ancient Greeks. While the original Hippocratic Oath makes it clear that the practice of medicine is an enterprise intended just for men, today women form a slight majority of new medical graduates.

Finally, there have been important changes in how the general public is educated on medical matters, a fact that is readily apparent to anyone who watches Dr. Sanjay Gupta’s frequent appearances on CNN.

What does the Hippocratic Oath tell us about ethical conduct in the context of the issue of risk management during the teaching of invasive medical procedures? Unfortunately, the answer is “rather little”. While the Hippocratic Oath places considerable emphasis on the importance of medical teaching (“… to teach them this art, if they shall wish to learn it, without fee or

stipulation; and that by precept, lecture, and every other mode of instruction, I will impart a knowledge of the Art to my own sons, and those of my teachers, and to disciples bound by a stipulation and oath according to the law of medicine, but to none others.") the Oath offers little specific guidance about risk management during medical teaching.

One final point merits discussion. Many people would be surprised to know that, contrary to popular belief, the familiar Hippocratic teaching "First, do no harm" (*Primum non nocere* in Latin) is in fact not part of the Hippocratic Oath. Many scholars believe that the phrase actually originated in his book Epidemics, where one translation reads: "*Declare the past, diagnose the present, foretell the future; practice these acts. As to diseases, make a habit of two things — to help, or at least to do no harm.*" (Carrick, 2001, p. 178). It is perhaps this teaching - "First, do no harm" that we can best draw on for Hippocratic guidance in this setting.

Chapter 5

RISK AND BENEFIT IN MEDICAL PROCEDURES

Invasive medical procedures that advanced clinicians might reasonably be expected to be proficient at are numerous. Such procedures are especially commonplace in the course of patient resuscitation. And all these procedures involve some potential risk to the patient.

Examples of 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). 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. 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. This is frequently done to relieve the pain associated with childbirth.

(4) Percutaneous insertion of a catheter (tube) into an artery such as the radial artery at the wrist so as to allow beat-to-beat blood pressure monitoring as well as easy sampling of blood for laboratory testing.

(5) Placement of a “chest tube” (thoracostomy tube) to assist in the reinflation of a collapsed lung (pneumothorax).

As noted, such procedures are not without 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). A number of deaths associated with the procedure have also been reported (Domino, Bowdle, Posner, Spitellie, Lee & Cheney, 2004).

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

Recognizing that wise clinical decision making and the provision of informed consent requires accurate estimates of the risks of complications from invasive medical procedures, Schroeder, Marton & Strom (1978) cataloged the frequency of complications from invasive procedures in an internal medicine environment. The authors studied 231 invasive procedures performed on 303 patients in two clinical settings. Fourteen percent of patients had at least one complication. The authors noted that “while no permanent damage or deaths were observed, over three fourths of the complications either required specific therapy or prolonged hospitalization or both” and suggested that invasive procedures carry appreciable risks of serious complications.

In each such procedure, clinicians must weigh the potential risks against the anticipated benefits for the

individual patient, taking into account various factors such as the expected difficulty of the planned procedure (which are often more difficult in obese patients, for instance), clinical factors, such as whether the patient is predisposed to bleeding, as well as factors such as the experience of the operator and the expense of the equipment needed for the procedure. Almost always, there is little patient-specific data available to guide such decisions, but rather the decision is usually carried out in a "Gestalt" manner where experience and intuition are just as important as any available scientific data (Kushniruk, 2001; Al Sayyari, 2007).

Further complicating this issue is the fact that, although some risk data is available from studies such as the work of Schroeder, Marton & Strom (1978), there is evidence that physicians conducting invasive procedures may sometimes be badly misinformed about the degree of risk involved. A study by Kronlund and Phillips (1985) tested the knowledge of family physicians and general surgeons about the risks associated with common surgical and invasive diagnostic procedures. The authors found that "overall accuracy of physician knowledge was low, with 27% of responses correct, 26% underestimates, 27% overestimates

and 21% admitting no knowledge”. They also noted that “for every complication, many physicians made underestimation or overestimation errors by several orders of magnitude and a few consistently denied existence of any risk” (Kronlund & Phillips, 1985, p. 565).

In the final analysis it should be apparent that any hope of providing patients with specific empirical data about the extra risk (risk burden) associated with teaching invasive medical procedures is many, many years away.

Chapter 6

OVERVIEW OF POSTGRADUATE MEDICAL EDUCATION

Undergraduate medical education in the USA and Canada generally consists of 4 years of instruction, with the last two, known as the “clerkship” years, involving a considerable degree of patient contact, including some instruction in invasive medical procedures such as the insertion of intravenous catheters. However, it is predominantly during postgraduate medical education (internship and residency) that invasive procedures are taught. As a result, the discussion here will focus on postgraduate (post MD degree) medical education, commonly known as residency.

The concept of residency training is relatively recent in the history of medical education, beginning in the USA in the late 1800s in the field of surgery, a clinical specialty that began to thrive once the developments of anesthesia and antisepsis finally made complex surgical procedures possible (Ravitch, 1987; Cassell, 1999). Over the last century residency training has evolved from a simple apprenticeship to a complex training and education

process involving formal learning objectives and experience requirements, rigorous evaluation and examination processes, and numerous regulatory requirements.

The length of the different residency programs vary. Most Family Medicine programs require 36 months of postgraduate training, while (for instance) the Yale University Neurosurgical residency program is 72 months in duration. Some residency programs that require obtaining a PhD degree as part of their program are even longer in duration. Many surgical programs such as Neurosurgery, Orthopedic Surgery, Otolaryngology, and Urology have a single year of core experience and begin their specific specialty training during the second year. By contrast, the Plastic Surgery residency in the USA is of two years duration, but prerequisite training varies from three to five years of General Surgery or its equivalent.

The typical service on which the surgical “resident” or “house officer” serves (“rotates”) consists of staff surgeons, a chief resident, a senior resident, a second-year resident and two first-year residents. Several medical students may also participate. This team usually cares for 15 to 30 patients. Depending on experience, surgical residents are responsible for patient diagnostic workups,

bedside procedures (like insertion of catheters), the preoperative preparation of patients, and patient postoperative care. Under supervision by attending (staff) surgeons and more senior resident staff, junior surgical residents also perform basic surgical procedures, such as excision of skin lesions, appendectomy, herniorrhaphy and hemorrhoidectomy.

When time permits, residents are expected to prepare for the cases they participate in by reading. Teaching is also provided on both a formal and informal basis. The formal component includes sessions such as “Grand Rounds”, “Morbidity and Mortality Conference” and “General Teaching Conferences” that are usually held at 7:00 am (or earlier) or at 5:00 p.m. (or later). Lunch sessions are also held in some programs. “Journal Club” programs are often used to make residents aware of the latest journal articles and to learn how to critique scientific studies. In addition, residents are often sent to week-long review courses in preparation for their board examinations. Residents are also encouraged to present papers at national or international conferences.

In addition, informal teaching usually occurs one-on-one during the execution of the surgical procedure itself. The resident might be asked about particular anatomical structures pertaining to the surgery, about postoperative pain management, about the natural history of the patient’s disease, and so on.

The Accreditation Council for Graduate Medical Education (ACGME) is the agency responsible for establishing educational standards and evaluating the almost 8000 residency programs in the USA (Chapman et al., 2004). ACGME standards cover almost all aspects of residency training, including requirements regarding educational content, teaching program requirements, work and duty hour rules, patient care and supervision rules, minimal program resource requirements, etc. Stakeholders of the ACGME's endorsement process are the residency programs monitored; sponsoring institutions (universities and hospitals); residents, interns and medical students; patients and their families; all levels of government; and the general public.

In response to concerns about patient safety as a consequence of resident sleep deprivation from overwork, in

July 2003 the ACGME enacted rules which limit resident duty hours to a maximum of 80 hours a week and set other restrictions, such as a 24 hour limit on continuous duty time, with an added period of up to 6 hours for transfer of care and educational activities (Schroeder, 2004). They also require a minimum 10 hour rest period between duty periods and require programs to give residents at least one full day off from patient care responsibilities every week. As noted, these regulations are based on well-supported concerns that sleep loss affects cognitive and clinical performance and, possibly, patient care. Residency programs that fail to comply with the new regulations will face adverse consequences, including possible loss of program accreditation.

Residency involves two main processes: education and clinical service. This makes residency unique among educational programs, and the clinical service component explains why residents are paid a salary, usually at a rate comparable to what a nurse would make. The educational process is overseen locally by a program director and nationally by one or more accreditation bodies.

Residents are evaluated informally by their attending on a daily basis and formally by the Clinical Competence

Committee every quarter. However, to most residents the most important evaluation process is probably the board examination procedure. For instance, The American Board of Anesthesiology offers their written examination component each July, while the oral examination component is held twice each year, once in the spring and once in the fall. The total examination fee is $2,300.00.

A final issue that should be addressed concerns the teaching of medical ethics to residents. Presumably, training in medical ethics in this setting would impact on the manner in which residents deal with the issue of how to inform patients about the implications of their limited clinical experience.

Chapter 7

ISSUES IN THE TEACHING OF INVASIVE MEDICAL PROCEDURES

Let us consider the following hypothetical scenario in a typical academic medical center:

> *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. 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.

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.

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, Tabas & Patterson (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 (p. 119).

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, 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, while patients from lower socioeconomic strata are more likely to believe that anyone in a white coat is a competent physician. To the extent that some medical professors and medical students are loath to disabuse this incorrect notion, a “sin of omission” may sometimes be perpetrated against some patients.

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 (p.118).

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 and full 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.

With respect to the second issue, it should be noted that 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.

However, it may be that such an 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 rather uncommon to specifically ask a patient if it is permissible for a novice to carry out a procedure under supervision.

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.

Chapter 8

USE OF CLINICAL SIMULATORS IN TEACHING MEDICAL PROCEDURES

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 their choice, a new narrative is then generated and more management choices are offered.

Mannequin-based medical 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 This point was recently emphasized by Ziv, Wolpe, Small, & Glick (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” (p.783). 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, Ziv, Barsuk, Levine, Cohen & Vardi 2003). That being said, simulators are not a panacea. First, they can be very expensive (both in terms of capital cost (about $200,000 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. With respect to this issue, for instance, one rather distressing study showed that specialized airway simulation training did not improve residents' management of accidental esophageal intubation (Olympio, Whelan, Ford & Saunders, 2003). Finally, 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).

Chapter 9

INFORMED CONSENT ISSUES

Developments in medical sciences over the last few decades have led to special challenges in determining the ethically appropriate course in a number of complex clinical scenarios (e.g., Youngner & Arnold, 2001; Howsepian, 2004; Hurlbut, 2006). This has led to an interest in establishing a philosophical basis for addressing such issues. One commonly used approach to tackling bioethical problems in the Western world is to invoke the guiding principles of the “Georgetown School” of bioethics, a popular and profoundly influential philosophical school so named because of its origins in the University of Georgetown. The Georgetown School calls upon four ethical principles (Beauchamp & Childress, 2001). These are [1] *autonomy* (the right to actively participate in medical decisions concerning oneself without being dictated to or controlled by other parties); [2] *beneficence* (the requirement that caregivers, all else being equal, should to do what they can to improve the

patient’s situation); [3] *justice* (requiring the fair and impartial treatment of all persons, especially in the context of resource allocation); and [4] *nonmalfeasance* (the requirement to avoid bringing harm to the patient).

These principles, as discussed in the Belmont Report on the protection of human research subjects (The National Institutes of Health, 1979), are also the foundation for U.S. federal regulations that govern clinical research [e.g., Code of Federal Regulations; Protection of Human Subjects 45 CFR 50 and Code of Federal Regulations; Food and Drugs; Institutional Review Boards 21 CFR 56.]

Of these four bioethical principles, the principle of autonomy is especially important in framing any debate in relation to informed consent and therapeutic privilege. In particular, the issue of patient autonomy is one that is central to a good deal of contemporary bioethical discourse, and appears as an important issue in a number of present-day bioethical debates, such as therapeutic abortion, voluntary euthanasia, medical research on human subjects, and the right of patients to refuse clinically necessary medical treatments.

The historical origins for the principle of autonomy stems in part from a need to develop a philosophical framework for ethically managing randomized controlled trials (where patients are administered one of a number of forms of medical treatment on the basis of chance alone), as well as a response to clear ethical abuses that have occurred in the past, such as the appalling concentration camp experiments conducted by Nazi doctors such as Josef Mengele (Seidelman, 1996) or the infamous Tuskegee Study of Untreated Syphilis in the Negro Male (White, 2000). In addition, a number of legal decisions have reinforced the notion of patient autonomy; these will be discussed later.

Informed consent arises in two principal contexts: clinical and experimental, although overlap between the two does occur. In the clinical context, patients are provided with information pertaining to the risks, benefits, and the alternatives to proposed medical interventions such as surgical procedures. Usually, but not always, the process includes the use of a paper consent form that is signed, dated and witnessed.

In the experimental context, research subjects (who in medical research studies are often also patients) agree to participate in an approved experimental protocol that may

not have the benefit of the experimental subject as a primary or even as a likely outcome (e.g., testing the safety of a new drug on healthy human volunteers).

In either case, establishing informed consent from the individual is the central ethical concern, and both require that the individual is capable of understanding the issues involved and (in the case of research studies) additionally require that special safeguards be employed if the individual is a member of a “vulnerable” population, such as children, prison inmates, or pregnant women.

Consent can be implied or explicit, the latter involving a more or less formal process carried out verbally with or without explicit documentation in writing. Implied consent exists (for instance) when one unhesitatingly rolls up one’s shirt sleeve in preparation for a blood test or when an unconscious patient is taken to hospital for emergency treatment of life-threatening injuries.

Explicit consent is usually sought prior to clinical interventions that entail some risk of harm or have the potential to cause a substantial degree of pain or discomfort. Some institutions have a policy that a consent form must be signed by the patient prior to surgical

procedures but may not have a similar requirement for other risky interventions such as blood transfusion, central line insertion, or lumbar puncture. If a signed and witnessed consent form is not required, and the intervention involves a non-trivial risk, clinicians are usually advised to write a detailed note in the patient's medical record to establish that the consent process has taken place, with specific mention of risks, benefits, and alternatives.

As emphasized earlier, central to informed consent is an explanation of the risks, benefits, and alternatives associated with any proposed clinical or experimental intervention. However, in some cases, such data may not be fully available, while, in some other cases, the amount of information available may be so large that it has the potential to overwhelm even well-informed and experienced patients. In addition, special problems may occur in providing risk information to patients. For instance, the only risk information available for an intervention may be that for the medical community at large and may not be specific to a particular institution or a particular clinician.

In some situations, such as complex cancer treatments, the issues involved may be so multifaceted that, at times,

only highly-trained individuals can fully understand the issues involved. This is particularly true in controversial areas of medicine where competing viewpoints may arise as a result of methodological and even cultural differences. As a result, providing *full* information may potentially require special methods of patient education or may be so complex that it is beyond the cognitive capabilities of some patients.

A final issue concerns how much information to provide to patients. Some clinicians and bioethicists suggest that patients should be told of common risks with low morbidity as well as rare risks with a high associated morbidity, but need not necessarily be provided with an exhaustive list of all possible risks regardless of their likelihood or their severity. Of interest, this is precisely the position taken by some legal authorities (*vide infra*).

Legal Perspectives

Schloendorff vs. Society of New York Hospital

In the USA, the legal case that definitively established the right of competent adults to refuse medical treatment was tried in 1914 in a case known as Schloendorff vs. Society of New York Hospital (Schloendorff vs. Society

of New York Hospital, 105 N.E. 92, (1914), online synopsis available at http://wings.buffalo.edu/faculty/research/bioethics/schloen0.html.) In this case, the plaintiff agreed to undergo a gynecologic examination under general anesthesia, but she explicitly refused consent for any surgical intervention. However, at the time of the procedure, surgically correctable pathology was identified, and the surgeon decide to correct the problem despite instructions to the contrary.

Unfortunately for all parties, serious unexpected complications followed the surgery, and, as a result, a lawsuit was launched. The litigation was resolved in favor of the plaintiff. In his opinion, the presiding judge wrote, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body" (Sreenivasan, 2003, p. 2017). (Given that the plaintiff was a woman, the gender in the wording of the judge's opinion can only be viewed with dismay!)

Despite this favorable legal ruling, in the end, the patient actually lost her case because the hospital was a charitable institution and consequently was immune from liability under the laws of the time. Still, this case firmly established the notion of informed consent and of

the right of a competent adult patient to choose or refuse medical treatment. Since the time of this landmark case, a large number of American legal decisions have reinforced the right of a competent adult to choose his or her treatment, even when the decision is not clinically sound.

Malette vs. Shulman

In Canada, an important legal precedent regarding patient consent was the case of Malette vs. Shulman (Sneiderman, 1991) [Malette v Shulman (1990), 37 OAC 281 (CA)]. In this landmark case, the court established that emergency treatment should not be administered without patient consent if there is substantial reason to believe that the patient would refuse the treatment if he or she were able.

The specifics of the case are as follows. Dr. Shulman was an emergency room doctor caring for a woman who was unconscious as a result of hypovolemic shock from blood loss following a serious motor vehicle accident. After a quick clinical assessment, Dr. Shulman administered a medically necessary blood transfusion to the patient, saving her life as a result. Unfortunately for Dr. Shulman, the patient carried a wallet card indicating that she was a

Jehovah's Witness and did not want to receive a blood transfusion under any circumstances. Also, complicating this situation was the fact that the card was written in the French language, and was signed but undated and unwitnessed, thus casting some doubt on the legal significance of the card, at least in the mind of Dr. Shulman. However, in the end, Dr. Shulman weighed the pros and cons of transfusing and decided to go for life.

Although the blood transfusions Dr. Shulman administered were responsible for saving the patient from death, the patient sued. To the surprise of the Canadian medical community, the court found the Dr. Shulman liable for battery. In his decision, the judge wrote: “To transfuse a Jehovah's Witness in the face of her explicit instructions to the contrary would, in my opinion, violate her right to control her own body and show disrespect for the religious values by which she has chosen to live her life” (Sneiderman, 1991, p. 17).

Rogers vs. Whitaker

An important Australian case known as Rogers vs. Whitaker involved the issue whether a doctor has a duty to warn patients of any significant risk involved in a

proposed procedure (Chalmers & Schwartz, 1993). In this case, the plaintiff lost her sight after unsuccessful surgery in her right eye eventually led to “sympathetic” blindness in her left eye. This was a rarely encountered complication that occurs approximately 1 in 14,000 cases. The plaintiff argued that, while there was no question that the surgery had been performed with skill, the surgeon’s failure to warn that blindness in the good eye could develop constituted negligence. The defense position was that the doctor acted within the purview of common practice, a position that the court ultimately rejected.

Hills vs. Potter

The courts have not universally supported a position such that of Rogers vs. Whitaker. For example, in the British case of Hills vs. Potter (Great Britain. England. Queen's Bench Division. Hills v. Potter. All Engl Law Rep. 1983;3:716-29.), a patient who developed paralysis following elective neck surgery sued, arguing that the surgeon failed to provide information necessary to make an informed decision whether to undergo the surgery. However, the court dismissed her claim, rejecting the doctrine of informed consent commonly prevailing in American and

Canadian law, under which a physician has a duty to disclose all material risks which patient might view as being important. Legal decisions such as Hills vs. Potter serve to illustrate how courts in various nations may take very different perspectives on similar issues.

Informed Consent in the Clinical Teaching Setting

Issues of informed consent frequently arise in the setting of clinical teaching. Most patients expect that when a student is performing a procedure for the first time that this fact be disclosed. However, as Williams & Fost (1992) point out, this is not always the case. Using the spinal tap (lumbar puncture) procedure as an example, Williams & Fost surveyed 173 patients to determine how they felt about first time procedures by medical students, interns, and residents. The respondents “indicated that they would be willing to be the subject for a student's (52%), intern's (62%), or resident's (66%) first spinal tap” (p. 217).

In a study by Santen, Hemphill, Spanier, and Fletcher (2005) the authors sought to ”determine whether patients, when informed of the inexperience of a medical student,

would still consent to the procedure”(p.365). The procedures in question were wound suturing, establishing intravenous access or splinting. In the study, the medical student informed the patient of their limited experience and the patient was asked to consent to the procedure. Only 48% of patients surveyed understood that they might be the first patient on whom a medical student had performed the procedure, while two-thirds of the patients felt that they should be told if a student was performing their first procedure on them. The vast majority of patients consented to the proposed procedures, although for 7 of the 12 refusals, it would have been the student's first time attempting it. The authors concluded that “most patients will allow medical students to perform minor procedures, even when informed of the student's inexperience” (Santen, Hemphill, Spanier, & Fletcher, 2005, p. 365).

Graber, Pierre & Charlton (2003) conducted a questionnaire study of emergency department patients in a teaching hospital, asking them to state, among other things, the number of procedures a medical student should have performed before they would allow it to be performed on them. The authors found, in contrast to the findings of Santen et al. (2005), that given a preference, “only a

minority of patients would allow medical students to perform their first procedure on them", with (for example) only 7% who would be agreeable to allowing a medical student to perform a lumbar puncture for the first time. The authors concluded that their results had "implications for medical training and informed consent" (Graber, Pierre & Charlton, 2003), p. 1329).

In a follow-up study (Graber, Wyatt, Kasparek & Xu, 2005) the authors noted that "except for intubating and suturing, participants were more likely ($p < 0.05$) to allow a medical student to perform a procedure on them after simulator training" and noted that many patients "prefer not to have a medical student perform a procedure no matter how many procedures the student has done" (p. 635). The authors concluded that although "patients are more accepting of medical students performing procedures if the skill has been mastered on a simulator", "many patients do not want a medical student to perform a procedure on them regardless of the student's level of training" (p. 635).

Chapter 10

THERAPEUTIC PRIVILEGE

As noted earlier, "therapeutic privilege" refers to the withholding of material information by the clinician during the “consent” process in the belief that the disclosure of such information would lead to the psychological harm or unnecessary suffering for the patient. That is, therapeutic privilege is invoked as an exception to the doctrine of informed consent.

The philosophical argument behind "therapeutic privilege" is that beneficence should take precedence over autonomy in cases where a conflict between these two principles exists. Historically, therapeutic privilege was invoked by some doctors when they withheld the diagnosis of a terminal condition from patients whom they expected would not be able to handle the information, and would consequently lose an interest in living. In many cases, such information was withheld at the specific request of family members (Elwyn, Fetters, Sasaki, & Tsuda, 2002).

Another example concerns patients born with ambiguous genitalia. Some past practices involved the use of deception and/or incomplete communication of facts about the infant's condition and early surgical intervention to make a "definitive" sex and gender assignment (Cote, 2000).

Today, with the collapse of paternalism in modern clinical care, therapeutic privilege is invoked only rarely, if at all. This is so both as a result of medico-legal prudence (*vide infra*) and in response to modern cultural shifts. Furthermore, some clinicians argue that, if a person feels that providing a patient with relevant clinical information may be so upsetting to the patient as to cause extreme psychological harm, the patient should be assessed for mental competency.

Still, therapeutic privilege has its cautious supporters. For instance, Etchells, Sharpe, Burgess, & Singer (1996), discussing the Canadian situation, make the case that therapeutic privilege may sometimes be appropriate. They write:

> The need for sensitivity to cultural norms may potentially support the exercise of therapeutic

> privilege. In some cultures therapeutic privilege is widely invoked, and it is unclear whether patients from these cultures should always be subjected to Western standards of consent. However, given the legal status of therapeutic privilege in Canada, clinicians should avoid invoking therapeutic privilege. It is better for the clinician to offer information and allow the patient to refuse or accept further disclosure (p.389).

This brief review of therapeutic privilege was undertaken with a view to introduce the question as to whether the notion of therapeutic privilege might be invoked as a means to get around the problem of obtaining patient consent in the course of medical teaching.

With these introductory comments, we are now in a position to consider how the notion of therapeutic privilege might conceivably be applied to the problem of teaching invasive medical procedures. The argument would be that providing full details to patients undergoing such procedures might result in adverse clinical effects from

the resulting anxiety, and that this anxiety might be reduced, in part at least, by withholding some unpleasant details.

However, I do not find this argument to be particularly convincing. First of all, the same argument could be used to construct a case against providing informed consent in ordinary clinical procedures where no clinical instruction is involved. If withholding pertinent information is inappropriate in this ordinary clinical setting, surely it would also be inappropriate in the setting of teaching as well. In addition, while certainly it is conceivable, for example, that some patients with coronary artery disease could develop myocardial ischemia or other complications should tachycardia and hypertension develop as a result of extreme anxiety, such concerns, in my view, are more contrived and theoretical than real, and represent an equal concern to the problem of informed consent during ordinary circumstances.

Chapter 11

KANTIAN AND UTILITARIAN PERSPECTIVES

I would next like to examine matters from the viewpoint of Kantian ethical theory, including a discussion of his Categorical Imperative, as well as from a utilitarian perspective. It is my intent to compare these very different approaches to dealing with ethical problems from the perspective of tackling the ethical problem under discussion - how we should ethically deal with patients used for medical teaching.

Kantian Ethical Theory

Immanuel Kant (22 April 1724 – 12 February 1804) was a profoundly influential German philosopher of the Enlightenment. His work *The Critique of Pure Reason*, is often cited as one of the most significant works of modern philosophical history. Kant is particularly well known for his argument that moral obligations can be summarized by a single philosophical principle, which he called the "Categorical Imperative" and expressed this way: "Act only

according to a maxim by which you can at the same time will that it shall become a general law" (Nielson, 1969, p. 62). In other words, one should act only in such a way that one would want all men to act, and not treat individuals as mere “means to an end.”

The concept of the categorical imperative can be used to help analyze matters such as the ethical issues inherent in using patients for teaching. Cast in these terms, our ethical challenge 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 consistency (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 its various 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.

Utilitarian Ethical Theory

As discussed in Chapter 2, utilitarianism advocates the principle of providing the greatest “utility” to the greatest number as the basis for assessing the morality of various actions. Thus, good variously consists in providing maximal utility and the rightness of an action depends directly or indirectly on achieving this.

There are situations where the utilitarian approach conflicts with the duty-oriented Kantian approach discussed earlier. For instance, many individuals would argue that the first duty of teaching hospitals is medical education and research and not patient care. This belief, according to Silverman (1996) tends to foster a “convenient but anachronistic instrumentalism and paternalism” such as is reflected by the comments of one surgical resident: 'I'll practice on this guy tonight so that next year when some ninth grade girl gets shot like this I'll know how to do it. This may be the guy's only contribution to society....' (Silverman, 1996). That is, the teaching of many clinical procedures is guided by a utilitarian ethic where the rationale for learning how to do these procedures is in

benefiting future patients by improving overall standards of care.

According to Coldicott, Pope & Roberts (2003) “utilitarianism considers whether more people benefit from an action than are harmed by it” with the result that in a clinical setting utilitarianism dictates that “harm to one individual (the patient) may be sanctioned if it is for the benefit of a larger group (other patients)” (p.98).

Obviously, this utilitarian philosophical perspective is rather different than the Kantian and Hippocratic approaches discussed earlier. The Kantian and Hippocratic approaches emphasize the individual patient and his or her rights. These approaches are also more in tune with contemporary legal theory discussed earlier that recognizes the rights of the individual and patient autonomy as being more important than other considerations. Of interest, there now appears to be the beginnings of a shift in thinking towards the Kantian / Hippocratic among teaching clinicians. This is exemplified, for example, by the writings of Yentis (2005).

Chapter 12

CONCLUSIONS AND SUGGESTIONS FOR FUTURE RESEARCH

This thesis was concerned with the potential approaches to the need to balance a physician's obligation to provide optimal patient treatment with the concurrent obligation of the academic physician to help develop the skills of health professionals in learning risky, invasive medical procedures. The dilemma identified was that despite such procedures being conducted under supervision, the risk of complications is higher than if the procedure were to be conducted by the attending physician.

This thesis provides an original contribution to the medical ethics literature on this difficult problem - how should one treat patients who are used as teaching subjects. An approach based on the Kant's Categorical Imperative is offered and its implications are considered. This approach is contrasted with a utilitarian approach in common clinical use.

Commenting on the problem of medical students disclosing that they are performing procedures for the first time, Williams & Fost (1992) write: "Withholding this

information is a form of deception. It is justified on paternalistic grounds (it is in the patient's interest not to know), or on public policy grounds (given the choice, patients would refuse, thus compromising the training of future physicians)" (p. 217). It now appears that the clinical teaching community is slowly becoming aware of the fact that such deceptions are unacceptable.

Silverman (1996) has written about the need "to sensibly balance the needs of students and residents for hands-on training with the rights of patients to receive the highest quality of care" and notes that "although the law has ostensibly resolved the conflict between the goals of student participation and the principles of patient autonomy and informed consent, the record of medical practices is too often inapposite." He suggests that this dissonance is partly "attributable to medicine's autonomous professional culture, which undervalues patient involvement and reinforces benign paternalism" (p.227).

Clearly, the issues identified in this thesis are far from resolved, and the conflict between care and teaching responsibilities represents a deep-seated ethical dilemma in medical education that merits careful continuing study.

While the Hippocratic Oath does not explicitly deal with this issue, the Hippocratic aphorism “First, do no harm” would suggest that a physician’s obligation to provide the best possible treatment should take precedence over other concerns.

Also, while the notion of Therapeutic Privilege (discussed in Chapter 10), especially when invoked in a utilitarian ethical paradigm, might be used to justify withholding information from patients, it is clear that this notion is largely anachronistic and unsuitable for modern times.

In the final analysis, the issue appears to be mainly one of informed consent. Of interest, despite the vast literature on the topic of informed consent, this aspect of the issue has not been well-developed in the literature. In any event, there is a need for further discussion in the bioethical and medico-legal literature.

I suggest that two general forms of further study should be considered. First, as noted above, there is a need for more theoretical / philosophical debate in this area. For instance, there is a need for individuals to further discuss these issues from various theoretical frameworks, such as from the various deontological

viewpoints, from the viewpoint of principalism as well as from other ethical viewpoints.

Second, there is a need for empirical studies of public opinion on this topic. Certainly, it would be interesting to see how the general public feels about this issue, especially individuals who have had frequent encounters with the medical system. To assist this particular later process, in the Appendix I have developed a list of possible questions to consider.

APPENDIX

Design Notes for an Opinion Survey

One approach to exploring the varied issues identified in this thesis would be to conduct an empirical opinion survey. One possible survey of this kind is outlined here. Although attention was initially given to the idea of structuring a questionnaire so that the responses could be numerically scored, this was ultimately not felt to be the most valuable means to obtain new information and insights. Rather, it was felt that simply asking respondents to provide open-ended narrative responses to carefully crafted questions would likely be more helpful, particularly when surveying well-educated, articulate individuals. Thus, I propose that future work on this issue might employ a simple series of five brief “essay” type questions as the basis for a possible opinion survey. These are listed next, along with an introductory statement for the reader.

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.

In this context, I am writing to you to ask for your opinion on an issue involving the training of doctors. As part of a university study I am interested in knowing what people think should be told to patients who are having a medical procedure done by a novice, such as a medical student attempting a procedure for the first time, under supervision.

Since this is a university study, I can only ask my questions to certain people. So if you are a minor where you live, are pregnant, are a prisoner, or are mentally impaired in some way, you are not allowed to participate in this study. (This is because you would then be deemed to be a member of a “vulnerable group”, while this study is not approved for these groups.)

Participation in this study is absolutely voluntary. You do not have to answer this e-mail (although I hope you do).

If you are still interested, here are the details. As I indicated, I am interested in knowing what people think should be told to patients who are having a medical procedure done by a medical student or other novice attempting a procedure for the first time, under supervision. Here are some of the questions I have:

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? How should responsibility be assigned if the novice gets a complication because he (or she) did not follow instructions?

An important issue is the various study populations for any proposed survey. It was felt that surveying various different populations via the Internet might allow a number of viewpoints to emerge.

First and foremost, it was felt that the viewpoints of "ordinary individuals" (such as members of Internet-based discussion groups on automotive repair, gardening, cooking or the like) would be of interest. Such individuals would be contacted either by posting a request on the discussion page of the group or writing to the leader of the group.

Second, it was felt that it was important to pick one or more study populations of nonclinical individuals that would be expected to be able to provide unusually well-

reasoned, detailed and articulate responses. Such populations might include students at Excelsior College as well as members of American Mensa (The High IQ Society). Both these groups might reasonably be expected to provide unusually well-crafted responses.

Finally, it was felt that the viewpoints of medical school faculty members (who ordinarily supervise medical students and residents conducting invasive medical procedures) would also be of interest. Individuals in this group might be contacted via deans of various medical schools or by contacting academic societies such as the Society for Academic Emergency Medicine (http://www.saem.org) or the Society for Medical Women Faculty (http://smwf.georgetown.edu).

As a result the following four groups of possible target populations were identified: [1] Group 1 – a sample of “ordinary” adult individuals; [2] Group 2 – a sample of members of American Mensa (The High IQ Society); [3] Group 3 – a sample of Excelsior College students; and [4] Group 4 – a sample of academic (teaching) physicians.

It might also be a good plan to employ electronic survey methods to help reduce the effort and costs associated with implementing such a survey. After reviewing

the available means to conduct such surveys, I have tentatively settled on Survey Monkey (http://www.surveymonkey.com), which I have found to be a very interesting and potentially very valuable electronic survey system. For instance, with Survey Monkey, using just a web browser, one can create an elegantly formatted survey using a large variety of question types (single choice, multiple choice, rating scales, drop-down menus, essay questions etc.). Survey Monkey also offers options to allow one to require answers to any question, control the flow with custom skip logic, and even randomize answer choices to eliminate bias. An automated e-mail notification and list management tool can be used to track respondents. As the responses are automatically collected by Survey Monkey, one can obtain live graphs and charts or can download the raw data into Excel or SPSS.

Using the Survey Monkey system I have set up a prototype survey which can be accessed at the following URL: *http://www.surveymonkey.com/s.asp?u=79906288727*

It should be noted that conducting surveys in such a manner offers a great many advantages but also raises many questions that to date remain substantially unanswered: [1] How do individuals without Internet access differ from those who have Internet access?; [2] How does one ensure that the responses obtained are really from the individual you think they are?; [3] Do unsolicited survey solicitations sent in this manner constitute “spam”?; and [4] What is an “acceptable” response rate to a survey conducted electronically?

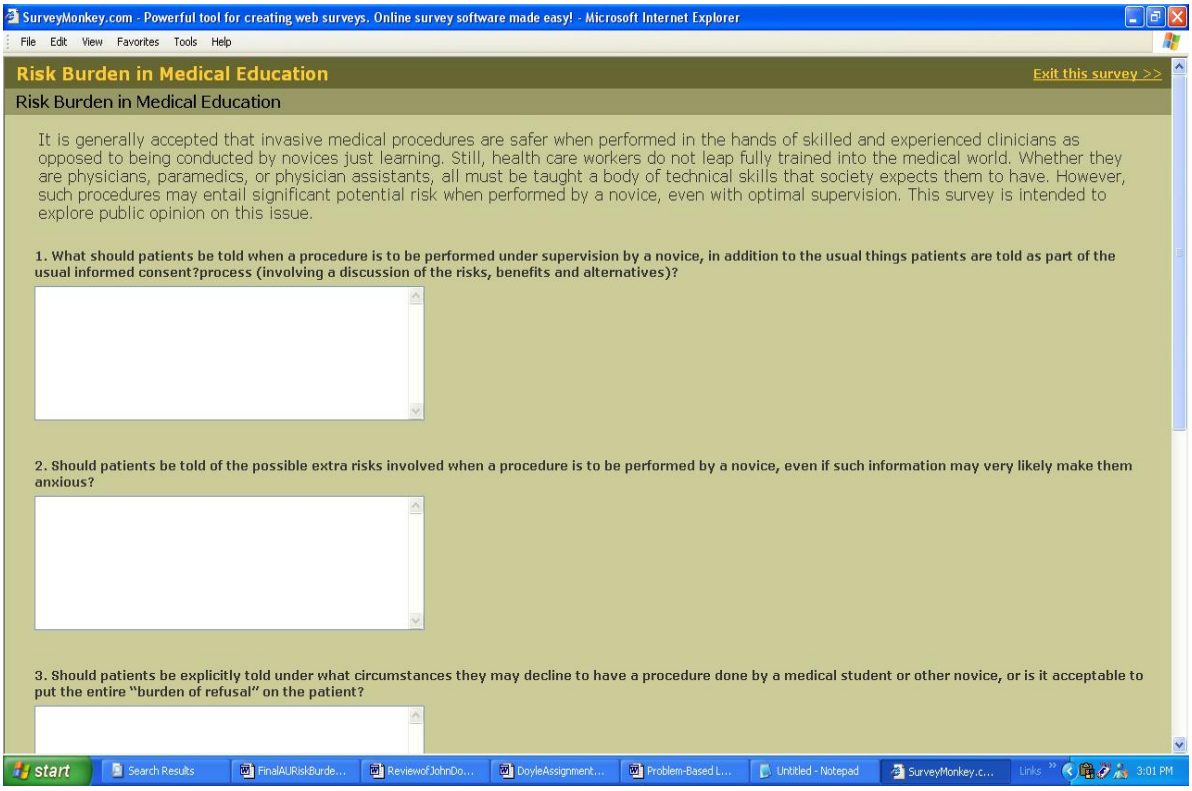

Figure 2. Prototype of the proposed survey form as implemented using the Survey Monkey system (www.surveymonkey.com). This Web-based software offers the ability to quickly construct elegantly formatted surveys with variety of question types (single choice, multiple choice, rating scales, drop-down menus, essay questions etc.). An automated e-mail notification and list management tool can be used to track responses. In this example, respondents enter their responses in the text boxes shown.

The methods of data analysis employed in any qualitative research study will depend substantially on the kind of questions asked, and the manner and setting in which they are asked. In the case of this proposed survey study, five questions are being asked, and respondents will be replying to each question with a narrative response that will need to be analyzed.

To a considerable degree, analysis of the obtained data would involve individually studying the obtained responses to systematically look for various underlying positions and themes, followed by writing a descriptive summary that integrates the information into a single narrative. It would also be necessary to look for possible differences in viewpoint between the various groups surveyed and comment on any differences noted.

Summary of Proposed Study Characteristics

Type of study - Narrative opinion survey conducted using single wave electronic mail.

Sample sizes - Not to exceed 250 solicitations in each group.

Study groups

- Group 1 – sample of “ordinary” adult individuals
- Group 2 – sample of members of American Mensa (The High IQ Society)
- Group 3 – sample of Excelsior College students
- Group 4 – sample of academic (teaching) physicians

Excluded individuals – Prisoners, minors, and mentally handicapped individuals (who are all considered to be “vulnerable individuals” in research ethics parlance).

Consent - Participation is completely voluntary. Subjects may withdraw from the study without prejudice at any time and/or refrain from answering whatever questions he or she prefers to omit. Any individual replying to our invitation

for commentary is presumed to be doing this with their consent. No signatures will be collected.

Confidentiality – All e-mails will be deleted immediately once responses have been archived (without identifying information). E-mail addresses of those requesting a report of the research will be compiled in a file separate from the survey responses. Neither the permanently archived materials nor the reports following from the study will contain any identifying names or e-mail addresses.

Analysis – The collected data will be analyzed using standard methods for qualitative research.

References

Al Sayyari, A.A. (2007). Diagnostic decision making in medicine. *Saudi J Kidney Dis Transpl*, *18*(3):448-51.

Beauchamp, T.L., & Childress, J.F. (2001). *Principles of Biomedical Ethics*. Oxford, UK: Oxford University Press.

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. *Anesth Analg*, *96*(6):1739-42.

Carrick, P. (2001). *Medical Ethics in the Ancient World.* Georgetown University Press.

Cassell, E.J. (1999). Historical perspective of medical residency training: 50 years of changes. *JAMA, 281*(13), 1231.

Chalmers, D., & Schwartz, R. (1993). Rogers v. Whitaker and informed consent in Australia: a fair dinkum duty of disclosure. *Med Law Rev, 1*(2), 139-59.

Chapman, D.M., Hayden, S., Sanders, A.B., Binder, L.S., Chinnis, A., Corrigan, K., et al. (2004). Integrating the accreditation council for graduate medical education core competencies into the model of the

clinical practice of emergency medicine. *Acad Emerg Med, 11*(6), 674-85.

Cooke, M., Irby, D.M., Sullivan, W., & Ludmerer, K.M. (2006). American medical education 100 years after the Flexner report. *N. Engl. J. Med, 355*(13), 1339-44.

Coldicott, Y., Pope, C. & Roberts C. (2003). The ethics of intimate examinations-teaching tomorrow's doctors. BMJ, *326*(7380):97-101.

Cote, A. (2000). Telling the truth? Disclosure, therapeutic privilege and intersexuality in children. *Health Law J, 8*, 199-216.

Domino, K.B., Bowdle, T.A., Posner, K.L., Spitellie, P.H., Lee, L.A., & Cheney, F.W. (2004). Injuries and liability related to central vascular catheters: a closed claims analysis. *Anesthesiology, 100*(6), 1411-8.

Elwyn, T.S., Fetters, M.D., Sasaki, H., & Tsuda, T. (2002). Responsibility and cancer disclosure in Japan. *Social Science & Medicine, 54*(2), 281-93.

Etchells, E., Sharpe, G., Burgess, M. M., & Singer, P.A. (1996). Bioethics for clinicians: 2. Disclosure. *Can Med Assoc J, 155*(4), 387-391.

Gillon, R. (1985). Utilitarianism. *Br Med J, 290*(6479), 1411-1413.

Graber M.A., Wyatt C., Kasparek L. & Xu, Y. (2005). Does simulator training for medical students change patient opinions and attitudes toward medical student procedures in the emergency department? Acad Emerg Med, *12*(7):635-9.

Graber, M.A., Pierre, J. & Charlton, M. (2003). Patient opinions and attitudes toward medical student procedures in the emergency department. Acad Emerg Med, *10*(12):1329-33.

Hicks, L.K., Lin, Y., Robertson, D.W., Robinson, D.L., & Woodrow, S.I. (2001). Understanding the clinical dilemmas that shape medical students' ethical development: questionnaire survey and focus group study. *BMJ,* 322(7288), 709-710.

Hippocrates. (1868). *The Genuine Works of Hippocrates* (C. D. Adams, Trans.). Retrieved April 14, 2008, from The Genuine Works of Hippocrates. Edited by: Charles Darwin Adams (trans.), New York: Dover, 1868 Web site: http://www.chlt.org/sandbox/dh/Adams/index.html

Howsepian, A.A. (2004). Sexual modification therapies: ethical controversies, philosophical disputes, and

theological reflections. *Christ Bioeth, 10*(2-3), 117-35.

Hurlbut, W.B. (2006). Framing the future: embryonic stem cells, ethics and the emerging era of developmental biology. *Pediatr. Res, 59*(4 Pt 2), 4R-12R.

Ijpma, F.F., van de Graaf, R.C., Nicolai, J.P., & Meek, M. F. (2006). The anatomy lesson of Dr. Nicolaes Tulp by Rembrandt (1632): a comparison of the painting with a dissected left forearm of a Dutch male cadaver. *J Hand Surg [Am], 31*(6), 882-91.

Jamieson, D. (1999). *Singer and His Critics*. Malden, MA: Blackwell.

Jones, C. (2003). Tightropes and tragedies: 25 years of Tarasoff. *Med Sci Law*, *43*(1):13-22.

Kronlund, S.F. & Phillips, W.R. (1985). Physician knowledge of risks of surgical and invasive diagnostic procedures. *West J Med*, *142*(4):565-9.

Kushniruk, A.W. (2001). Analysis of complex decision-making processes in health care: cognitive approaches to health informatics. *J Biomed Inform, 34*(5):365-76.

Lawlor R. (2007). Moral theories in teaching applied ethics. *J Med Ethics, 33*(6), 370-372.

Lynöe, N., Sandlund, M., Westberg, K. & Duchek, M. (1998). Informed Consent in Clinical Training - Patient Experiences and Motives for Participating. *Medical Education, 32*(5):465-471.

Manthous, C.A., DeGirolamo, A., Haddad, C. & Amoateng-Adjepong Y. (2003). Informed consent for medical procedures: local and national practices. *Chest*, *124*(5):1978-84.

Mcfarlane, D.R. (1993). U.S. abortion policy since Roe v. Wade. *Am J Gynecol Health*, *7*(4):98-106.

Neilson, F. (1969). *The Cultural Tradition.* Freeport, N.Y:Books for Libraries Press.

National Institutes of Health: The National Commission for the Protection of Human Subjects of Biomedical, & Behavioral Research. (1979). *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (The Belmont Report). Bethesda, MD: National Institutes of Health. Retrieved April 19, 2008, from Office of Human Subjects Research Web site: http:// ohsr.od.nih.gov/guidelines/belmont.htm

Olympio, M.A., Whelan, R., Ford, R.P. & Saunders I.C. (2003). Failure of simulation training to change

residents' management of oesophageal intubation. *Br J Anaesth*, *91*(3):312-8.

Rawls, J. (1971). *A Theory of Justice*. Cambridge, MA: Belknap Press.

Ravitch, M.M. (1987). The surgical residency: then, now, and future. *Pharos Alpha Omega Alpha Honor Med Soc, 50*(1), 11-16.

Remes, V., Sinisaari, I., Harjula, A. & Helenius, I. (2003). Emergency procedure skills of graduating medical doctors. *Med Teach*, *25*(2):149-54.

Reichman, E., & Simon, R.B. (2003). *Emergency Medicine Procedures*. New York: McGraw Hill.

Rosenbaum L. (2004). STUDENTJAMA. Ethical issues in medical education. JAMA, *291*(1):118.

Rosenson, J., Tabas, J. A., & Patterson, P. (2004). Teaching invasive procedures to medical students. *JAMA, 291*(1), 119-120.

Ross, W.D. (1930). *The Right and the Good.* Oxford: Clarendon Press.

Santen, S.A., Hemphill, R.R., Spanier, C.M. & Fletcher N. D. (2005). 'Sorry, it's my first time!' Will patients consent to medical students learning procedures? *Med Educ*, 39(4):365-9.

Schein, M. (2000). See one, do one, teach one. *Surgery, 128*(5), 868-9.

Schroeder, S.A., Marton, K.I. & Strom B.L. (1978). Frequency and morbidity of invasive procedures: report of a pilot study from two teaching hospitals. *Archives of Internal Medicine*, *138* (12): 1809 - 1811.

Schroeder, S.A. (2004). How many hours is enough? An old profession meets a new generation. *Ann Intern Med, 140*(10), 838-9.

Secker, B. (1999). The appearance of Kant's deontology in contemporary Kantianism: concepts of patient autonomy in bioethics. *J Med Philos, 24*(1), 43-66.

Seidelman, W.E. (1996). Nuremberg lamentation: for the forgotten victims of medical science. *BMJ*, *313*(7070):1463-7.

Silverman, D.R. (1996). Narrowing the gap between the rhetoric and the reality of medical ethics. *Academic Medicine*, *71*(3):227-235.

Simons, R.J., Imboden E. & Martel J.K. (1995). Patient attitudes toward medical student participation in a general internal medicine clinic. *Journal of General Internal Medicine, 10*(5):251-254.

Sneiderman, B. (1991). The Shulman case and the right to refuse treatment. *Humane Med,* 7(1), 15-21.

Sreenivasan, G. (2003). Does informed consent to research require comprehension? *Lancet,* 13;362(9400):2016-8.

Strathern, P. (2005). *A Brief History of Medicine: From Hippocrates' Four Humours to Crick and Watson's Double Helix*. New York: Carroll & Graf.

Tabas, J.A., Rosenson, J., Price, D.D., Rohde, D., Baird, C.H. & Dhillon N. (2005). A comprehensive, unembalmed cadaver-based course in advanced emergency procedures for medical students. *Acad Emerg Med*, *12*(8):782-5.

White, R.M. (2000). Unraveling the Tuskegee Study of Untreated Syphilis. Arch Intern Med, *160*(5):585-98.

Williams, C.T. & Fost, N. (1992). Ethical considerations surrounding first time procedures: a study and analysis of patient attitudes toward spinal taps by students. *Kennedy Inst Ethics J*, *2*(3):217-31.

Yentis, S.M. (2005). The use of patients for learning and maintaining practical skills. *J R Soc Med*, *98*(7):299-302.

Youngner, S.J., & Arnold, R.M. (2001). Philosophical debates about the definition of death: who cares? *J Med Philos, 26*(5), 527-37.

Ziv, A., Wolpe, P.R., Small, S.D. & Glick S. (2003). Simulation-based medical education: an ethical imperative. *Acad Med*, *78*(8):783-8.