

OPINIONS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinions, 1-5, were presented by Herbert Rakatansky, MD, Chair:

1. GENETIC INFORMATION AND THE CRIMINAL JUSTICE SYSTEM

HOUSE ACTION: FILED

At the 2000 Interim Meeting, the AMA House of Delegates reviewed and approved the recommendations of CEJA Report 6-I-00, "Genetic Information and the Criminal Justice System." This report provides guidelines to aid physicians in considering the ethical basis for the release of genetic information to the criminal justice system. The Council issues the Opinion derived from the conclusions of CEJA Report 6-I-00. It will appear in the next revised edition of *The Code of Medical Ethics*.

2.136 Genetic Information and the Criminal Justice System

The release of genetic information from a physician's records without the consent of the patient constitutes a breach of confidentiality. Opinion 5.05, "Confidentiality," acknowledges that law and overriding social considerations may permit physicians to disclose confidential information in limited circumstances. However, such circumstances present ethical challenges. The following guidelines are intended to aid physicians in considering the ethical basis for the release of genetic information to the criminal justice system:

1. Physicians should release a patient's genetic information only with the patient's consent or in compliance with a warrant or other order of a court of law. The circumstances in which law enforcement may seek a suspect's genetic information from the suspect's physician depend on whether any specific suspect has been identified, and if the suspect is in custody.
 - (a) If law enforcement personnel have identified a suspect and the suspect cannot be located to provide a genetic sample, physicians should release clinical genetic information only when a warrant or court order mandates such a release.
 - (b) When law enforcement personnel have identified a suspect, and the suspect has been located but refuses to provide a sample or is deceased (but his or her body is available), physicians should not be required to release genetic information as in these circumstances a court can authorize collection of a sample from the suspect or from postmortem tissue.
 - (c) Searching clinical and research databases of genetic information, or extracting and analyzing DNA from clinical or research tissue repositories, should not be conducted for the mere possibility that there is a match to a suspect's DNA unless there is a warrant or court order to do so.
2. When genetic information is provided to the judicial system, physicians should provide the minimum amount of information necessary for the explicit identification procedure being performed. Other elements of the medical record, or the results of any genetic testing or genetic diagnosis, should not be released without the patient's consent or further warrant or order of the court.
3. It is unethical for any genetic information obtained from a physician for identification purposes to be used subsequently for other purposes, such as research, unless appropriate ethical guidelines are followed and the informed consent of the individual is obtained (or the legally appropriate surrogate if the individual is incompetent or deceased, in compliance with Opinion 5.051, "Confidentiality of Medical Information Postmortem").
4. Databases that contain only the genetic identifiers from the specific loci that are typically used for identification purposes do not present the same ethical concerns that are presented by databases which contain genotypic or phenotypic information. Physicians participating in the creation of genetic databases for the exclusive use of the criminal justice system should ensure that the database is not used inappropriately for purposes other than identification.

5. In general, requiring that the genetic sample be destroyed or returned after the analysis necessary for identification is performed affords protection against inappropriate uses.
6. When the criminal justice system seeks genetic information for the purposes of identifying a deceased victim, the above relevant guidelines also apply. (III, IV)

2. MEDICAL STUDENT INVOLVEMENT IN PATIENT CARE

HOUSE ACTION: FILED

At the 2000 Interim Meeting, the AMA House of Delegates reviewed and approved the recommendations of CEJA Report 2-I-00, "Medical Student Involvement in Patient Care." This report provides guidelines on the balance between the educational needs of medical students and benefits to patients derived from student involvement in their care. The Council issues the Opinion derived from the conclusions of CEJA Report 2-I-00. It will appear in the next revised edition of *The Code of Medical Ethics*.

8.087 Medical Student Involvement in Patient Care

1. Patients and the public benefit from the integrated care that is provided by health care teams that include medical students. Patients should be informed of the identity and training status of individuals involved in their care and all health care professionals share the responsibility for properly identifying themselves. Students and their supervisors should refrain from using terms that may be confusing when describing the training status of students.
2. Patients are free to choose from whom they receive treatment. When medical students are involved in the care of patients, health care professionals should relate the benefits of medical student participation to patients and should ensure that they are willing to permit such participation. Generally, attending physicians are best suited to fulfill this responsibility.
3. In instances where the patient will be temporarily incapacitated (e.g., anesthetized) and where student involvement is anticipated, such involvement should be discussed before the procedure is undertaken whenever possible. Similarly, in instances where a patient may not have the capacity to make decisions, student involvement should be discussed with the surrogate decision-maker involved in the care of the patient whenever possible. (V, VII)

3. MANAGING CONFLICTS OF INTEREST IN THE CONDUCT OF CLINICAL TRIALS

HOUSE ACTION: FILED

At the 2000 Interim Meeting, the AMA House of Delegates reviewed and approved the recommendations of CEJA Report 3-I-00, "Managing Conflicts of Interest in the Conduct of Clinical Trials." This report provides guidelines on conflicts of interest in the conduct of clinical trials in both academic and community-based settings. The Council issues the Opinion derived from the conclusions of CEJA Report 3-I-00. It will appear in the next revised edition of *The Code of Medical Ethics*.

8.0315 Managing Conflicts of Interest in the Conduct of Clinical Trials

As the biotechnology and pharmaceutical industries continue to expand research activities and funding of clinical trials, and as increasing numbers of physicians both within and outside academic health centers become involved in partnerships with industry to perform these activities, greater safeguards against conflicts of interest are needed to ensure the integrity of the research and to protect the welfare of human subjects. Physicians should be mindful of the conflicting roles of investigator and clinician and of the financial conflicts of interest that arise from incentives to conduct trials and to recruit subjects. In particular, physicians involved in clinical research should heed the following guidelines:

1. Physicians should agree to participate as investigators in clinical trials only when it relates to their scope of practice and area of medical expertise. They should have adequate training in the conduct of research and should participate only in protocols which they are satisfied are scientifically sound.
2. Physicians should be familiar with the ethics of research, and should agree to participate in trials only if they are satisfied that an Institutional Review Board has reviewed the protocol, that the research does not impose undue risks upon research subjects, and that the research conforms to government regulations.
3. When a physician has treated or continues to treat a patient who is eligible to enroll as a subject in a clinical trial that the physician is conducting, the informed consent process must differentiate between the physician's roles as clinician and investigator. This is best achieved when someone other than the treating physician obtains the participant's informed consent to participate in the trial. This individual should be protected from the pressures of financial incentives, as described in the following section.
4. Any financial compensation received from trial sponsors must be commensurate with the efforts of the physician performing the research. Financial compensation should be at fair market value and the rate of compensation per patient should not vary according to the volume of subjects enrolled by the physician, and should meet other existing legal requirements. Furthermore, according to Opinion 6.03, "Fee Splitting: Referral to Health Care Facilities," it is unethical for physicians to accept payment solely for referring patients to research studies.
5. Physicians should ensure that protocols include provisions for the funding of subjects' medical care in the event of complications associated with the research. Also, a physician should not bill a third-party payor when he or she has received funds from a sponsor to cover the additional expenses related to conducting the trial.
6. The nature and source of funding and financial incentives offered to the investigators must be disclosed to a potential participant as part of the informed consent process. Disclosure to participants also should include information on uncertainties that may exist regarding funding of treatment for possible complications that may arise during the course of the trial. Physicians should ensure that such disclosure is included in any written informed consent.
7. When entering into a contract to perform research, physicians should ensure themselves that the presentation or publication of results will not be unduly delayed or otherwise obstructed by the sponsoring company. (II, V)

4. THE ETHICAL IMPLICATIONS OF XENOTRANSPLANTATION

HOUSE ACTION: FILED

At the 2000 Interim Meeting, the AMA House of Delegates reviewed and approved the recommendations of CEJA Report 4-I-00, "The Ethical Implications of Xenotransplantation." This report provides guidelines for ethical concerns associated with xenotransplantation research. The Council issues the Opinion derived from the conclusions of CEJA Report 4-I-00. It will appear in the next revised edition of *The Code of Medical Ethics*.

2.169 The Ethical Implications of Xenotransplantation

Xenotransplantation includes any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a non-human animal source; or (b) human body fluids, cells, tissues or organs that have had ex vivo contact with live non-human animal cells, tissues, or organs. Although xenotransplantation offers a potential source of tissue and organs for medical procedures, research in this area may uncover physical and psychological conditions that require medical attention. As such, physicians need to be involved in developing and implementing guidelines for continued research. Therefore, the following guidelines are offered for the medical and scientific communities:

1. Physicians should encourage education and public discussion of xenotransplantation because of the potential unique risks such procedures pose to individual patients and the public.
2. The medical and scientific communities should support oversight for the development of clinical trial protocols and for ongoing xenotransplantation research.
3. Given the uncertain risk xenotransplantation poses to society, participants in early clinical trials may have to agree to (a) post-operative measures such as life-long surveillance, disclosure of sexual contacts, autopsy; and (b) a waiver of the traditional right to withdraw from a clinical trial until the risk of late xenozoonoses is reasonably known not to exist. These requirements may continue even if the transplanted tissue is rejected or removed. The informed consent process should include a discussion of the above issues as well as potential risks to third parties and psychological concerns associated with receiving an organ or tissue graft from an animal. Careful attention must be paid to both the content of the consent disclosure and the manner in which consent is obtained.
4. It would be ethical to include children and incompetent adults in xenotransplantation research protocols only when the patients are terminally ill and alternative treatments are not available.
5. Allocation protocols must be fair and in accordance with Opinion 2.03, "Allocation of Limited Medical Resources," which recommends that decisions regarding the allocation of medical resources among patients be based only on ethically appropriate criteria relating to medical need. These criteria include, but are not limited to, the likelihood of benefit, the urgency of need, the change in quality of life, the duration of benefit, and, in some cases, the amount of resources required for treatment.
6. Sponsors of xenotransplantation research should assure that adequate funding exists for life-long surveillance and treatment of complications arising from xenotransplantation procedures on research subjects.
7. At a minimum, all ongoing research should adhere to the Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation, FDA guidelines relating to xenotransplantation, Opinion 2.07 "Clinical Research," and any additional precautionary measures believed to minimize potential risks to the public or to patients. It is inappropriate to participate in xenograft procedures outside federal guidelines.
8. All xenotransplantation research should continue to promote high standards of care and humane treatment of all animals used in research (H-460.979, AMA Policy Database) and to apply these standards to the care and treatment of animals used as sources of transplantation material. (IV, VII)

5. PATIENT RESPONSIBILITIES, AMENDMENT

HOUSE ACTION: FILED

At the 2000 Interim Meeting, the House of Delegates adopted Resolution 8-I-00, "Patients' Responsibilities for Keeping Appointments." The Council on Ethical and Judicial Affairs reviewed the Resolution and proposes the following amendment to Opinion 10.02, "Patient Responsibilities," to reflect patients' obligations to maintain agreed-upon appointments. The revised Opinion will appear in the next edition of the *Code of Medical Ethics*.

10.02 Patient Responsibilities

It has long been recognized that successful medical care requires an ongoing collaborative effort between patients and physicians. Physician and patient are bound in a partnership that requires both individuals to take an active role in the healing process. Such a partnership does not imply that both partners have identical responsibilities or equal power. While physicians have the responsibility to provide health care services to patients to the best of their ability, patients have the responsibility to communicate openly, to participate in decisions about the diagnostic and treatment recommendations, and to comply with the agreed upon treatment program.

Like patients' rights, patients' responsibilities are derived from the principle of autonomy. The principle of patient autonomy holds that an individual's physical, emotional, and psychological integrity should be respected and upheld. This principle also recognizes the human capacity to self-govern and choose a course of action from among different alternative options. Autonomous, competent patients assert some control over the decisions which direct their health care. With that exercise of self-governance and free choice comes a number of responsibilities.

1. Good communication is essential to a successful patient-physician relationship. To the extent possible, patients have a responsibility to be truthful and to express their concerns clearly to their physicians.
2. Patients have a responsibility to provide a complete medical history, to the extent possible, including information about past illnesses, medications, hospitalizations, family history of illness and other matters relating to present health.
3. Patients have a responsibility to request information or clarification about their health status or treatment when they do not fully understand what has been described.
4. Once patients and physicians agree upon the goals of therapy and a treatment plan, patients have a responsibility to cooperate with that treatment plan and to keep their agreed-upon appointments. Compliance with physician instructions is often essential to public and individual safety. Patients also have a responsibility to disclose whether previously agreed upon treatments are being followed and to indicate when they would like to reconsider the treatment plan.
5. Patients generally have a responsibility to meet their financial obligations with regard to medical care or to discuss financial hardships with their physicians. Patients should be cognizant of the costs associated with using a limited resource like health care and try to use medical resources judiciously.
6. Patients should discuss end-of-life decisions with their physicians and make their wishes known. Such a discussion might also include writing an advance directive.
7. Patients should be committed to health maintenance through health-enhancing behavior. Illness can often be prevented by a healthy lifestyle, and patients should take personal responsibility when they are able to avert the development of disease.
8. Patients should also have an active interest in the effects of their conduct on others and refrain from behavior that unreasonably places the health of others at risk. Patients should inquire as to the means and likelihood of infectious disease transmission and act upon that information which can best prevent further transmission.
9. Participation in medical education is to the mutual benefit of patients and the health care system. Patients are encouraged to participate in medical education by accepting care, under appropriate supervision, from medical students, residents, and other trainees. Consistent with the process of informed consent, the patient or the patient's surrogate decision maker, is always free to refuse care from any member of the health care team.
10. Patients should discuss organ donation with their physicians and, if donation is desired, make applicable provisions. Patients who are part of an organ allocation system and await needed transplant should not try to go outside of or manipulate the system. A fair system of allocation should be answered with public trust and an awareness of limited resources.
11. Patients should not initiate or participate in fraudulent health care and should report illegal or unethical behavior by physicians and other providers to the appropriate medical societies, licensing boards, or law enforcement authorities.

REPORTS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1-6, were presented by Herbert Rakatansky, MD, Chair:

1. THE PATIENT-PHYSICIAN RELATIONSHIP

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

INTRODUCTION

At the center of the history of the American Medical Association lies its *Code of Medical Ethics*. The original *Code* of 1847 promulgated an ethic that emphasized conduct rather than character. It was premised on the understanding that the very nature of the physician's responsibility consisted of caring for the sick and that this was a responsibility owed by all physicians to all patients. Also, building upon the Hippocratic tradition, physicians were called upon to hold a sense of ethical obligation that rose above considerations of personal advancement. According to one commentator, "the central moral commitment of the code was its dedication to something other than the physician's self-interest, that something being the primacy of the welfare of the patient."

The current *Code's* focus on the relationship between physician and patient is exemplified by the *Fundamental Elements of the Patient-Physician Relationship* issued in 1990. In particular, physicians are to foster this partnership by providing information and allowing for autonomous decision-making, acting respectfully and in a timely manner, preserving confidentiality, ensuring continuity of care, and facilitating access to care. Despite this list of features of the relationship patients can expect from physicians and which physicians must strive to fulfill, the very nature of the patient-physician relationship remains unexamined.

The patient-physician relationship, which is at the heart of the AMA's *Code of Medical Ethics*, is the focus of this report.

CONCEPTUALIZING THE PATIENT-PHYSICIAN RELATIONSHIP

According to one medical ethicist, there is no single characterization that can properly do justice to the patient-physician relationship "given the complexity of professional styles, patient expectations and values, and contexts in which the relationship is established." For example, patients treated for chronic diseases may have long-established relationships with their physicians, or may be interacting with a specialist for a single consult.

Irrespective of the circumstances of the encounter between patient and physician, medical ethicists have characterized it in terms of a moral activity. This has been found to arise from the condition that brings patients into contact with physicians, namely illness. "Healing is sought for concerns that go to the root of human existence: fears of death, deformity, and disability." Patients have been described in terms of their vulnerability, and consequently exploitable state, and their dependence on the medical expertise and the compassion of physicians. In order to maintain good health or to secure the treatments that will alleviate their ills, patients, or surrogate decision-makers on their behalf, agree to enter into relationships with physicians. At times, the agreement to enter into a relationship is implied, such as when a patient is unconscious and in need of emergency care, or when physicians provide a specific service at the request of the treating physician (e.g., the services of a pathologist). Physicians also agree to enter the relationship; either directly, as agents, or by previous contractual arrangements to treat a group of patients. The relationship, therefore, is established by mutual agreement. In some rare instances, such as legally mandated treatment as described in Opinion 2.065, "Court-Initiated Treatments in Criminal Cases," treatment may be provided by a physician even though a patient has not consented to entering into a relationship. In such circumstances, physicians remain bound by the same obligations.

Once the relationship has been established, patients should be confident that they are receiving the best medical care their physicians can provide, uncompromised by external factors. However, the medical profession currently finds itself amidst tensions between physicians' altruistic covenant to provide needed medical care to patients and the market ethos of profit-making.

ETHICAL OBLIGATIONS OF PHYSICIANS

Trust is central to the patient-physician relationship. Physicians provide specialized knowledge and expert skills that are relied upon by patients. Physicians also hold considerable control over medical resources used for the benefit of patients.

Many ethicists have emphasized the obligation of fidelity that is owed whenever the physician establishes a relationship with the patient. One important manifestation of this obligation of fidelity is the ethical obligation not to abandon a patient, which would undermine physicians' trustworthiness. CEJA Opinion 8.115, "Termination of the Physician-Patient Relationship," embodies this obligation to ensure continuity of care. Viewed from a different perspective, medicine is an act of "profession" whereby physicians promise to use their knowledge to help and to heal.

The patient-physician relationship is held to high standards of conduct, as embodied in the *Code of Medical Ethics*. This characterization of the patient-physician relationship differs significantly from the contractual view of the relationship in which patients seek care and physicians provide it. Ethically, it would be insufficient to view health care as an ordinary service and to allow care that patients request from physicians to be governed by the maxim "let the buyer beware."

However, much of the current health care delivery system operates according to the dynamics of the market. According to many participants in this system, profit-making is a legitimate goal and financial incentives are important tools in controlling health care resources. This reality confers even greater importance onto the principal feature of the patient-physician relationship, which require that patients' interests be given priority. Therefore, external factors that may result in compromising medical judgment deserve careful examination.

CONFLICTS OF INTEREST

Many ethicists have long argued that some effacement of self-interest is morally obligatory for physicians. This notion is captured throughout the *Code of Medical Ethics*.

Conflicts between Physicians' and Patients' Interests

Physicians' self-interest that may conflict with the interests of patients is addressed in unambiguous terms in Opinion 8.03, "Conflicts of Interest: Guidelines," which states that "Under no circumstances may physicians place their own financial interests above the welfare of their patients....If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit."

More troubling in this era of managed care are some of the methods used to accomplish cost containment. Specifically, various risk-bearing arrangements that affect physicians' incomes according to their use of health care resources may lead to limitations that could be harmful to patients. In Opinion 8.054, "Financial Incentives and the Practice of Medicine," physicians are advised to evaluate financial incentives included in managed care contracts to ensure that quality of patient care is not compromised by placing physicians' payments at excessive risk or by setting unrealistic expectations for utilization. The Opinion also recommends that large financial incentives should be limited in order to prevent physicians' personal financial concerns from creating a conflict with their role as individual patient advocates.

Conflicts between Individual Patients and Patient Populations

Managed care's use of financial incentives to influence physicians' decision-making also has led to a shift from patient-focused medicine to population-based medicine. In order to stay within budgetary limits, physicians are urged, often through financial and other incentives, to consider the impact of the decisions they make on an entire group of patients, rather than on a single patient. Physicians who allow such incentives to color medical judgement become primarily agents of the health plan rather than of individual patients. It would seem more likely that patients' trust in physicians will be best preserved if those who are ill can expect their physicians to be advocates for optimal care and not just some minimal standard. However, systemic budgetary constraints may in fact prevent patients from obtaining access to the optimal level of care necessary to treat a condition. Faced with such prospects,

patients must find allies who will assist them in gaining access to the resources needed to treat their condition. In an earlier report, the Council clearly identified that physicians have a duty of patient advocacy that should not be altered by the system of health care delivery, and that requires physicians to advocate for any care they believe will materially benefit their patients.

CONCLUSION

The medical profession must strive to preserve the trust patients hold in their physicians. It cannot abandon ethical standards to economic forces. As individual physicians advocate for the care their individual patients require, so must the medical profession advocate for access to care for all. Individual physicians must work to forge strong alliances with their own patients, and the medical profession with the public, to preserve the integrity of the profession.

RECOMMENDATIONS

The Council recommends that the following be adopted and the remainder of the report be filed:

The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between patient and physician is based on trust and gives rise to physicians' ethical obligations to place patients' welfare above their own self-interest and above obligations to other groups, and to advocate for their patients' welfare.

A patient-physician relationship is generally created by mutual agreement between physician and patient (or surrogate). In some instances the agreement is implied, such as in emergency care or when physicians provide services at the request of the treating physician. In rare instances, treatment without consent may be provided under court order (see Opinion 2.065). Nevertheless, the physician's obligations to the patient remain intact.

Within the patient-physician relationship, a physician is ethically required to use sound medical judgment, holding the best interests of the patient as paramount.

(References pertaining to Report 1 of the Council on Ethical and Judicial Affairs are available from the Department of Ethical Standards.)

2. ETHICAL CONSIDERATIONS IN INTERNATIONAL RESEARCH

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

INTRODUCTION

In this report, the Council on Ethical and Judicial Affairs undertakes the analysis of ethical dilemmas faced by US physicians either in their role as investigators conducting research in other countries or as decision-makers involved in deliberations related to funding or in the review of research to be conducted in other countries, in particular countries with developing economies and with health care infrastructures that are considered underdeveloped. However, it is worth noting that difficulties may arise any time research is conducted in a country with differing cultural traditions, health care systems, ethical standards, and laws, and that in all such instances, physicians will be called upon to recognize such differences and work to reconcile them in a manner that is consistent with high ethical standards. Also, the Council recognizes that multiple international entities already have promulgated guidelines on international research. It is not the intention of the Council to resolve the discrepancies that may exist among these documents, nor to endorse any particular document or specific set of guidelines, but rather to offer US physicians ethical guidance that can assist them in evaluating the dilemmas inherent to international research.

In essence, ethicists have debated whether US standards and regulations ought to govern research conducted in another country. Proponents of applying uniform standards have spoken of “universal” standards, which they oppose to a more “pluralistic” or “relativistic” ethical stance that would allow greater flexibility and arguably less stringent standards to govern research in developing countries. Others have viewed this position as “imperialistic” and have argued that local standards better reflect the cultural norms and economic resources that influence the conduct of research in the country. However, all fundamentally seek to avoid the exploitation of human subjects, even though they may argue over what constitutes exploitation and how best to protect against it.

This report begins with a short overview of the historical developments of ethical standards in the conduct of human experimentation before examining recent debates that erupted regarding the appropriate application of US research ethics standards. The report also reviews relevant AMA policy. Building on this account of the development of international standards and the current challenges faced in their application, the analysis focuses on a determination of the relevant ethical considerations that should guide the ethical conduct of international research involving US researchers.

HISTORICAL DEVELOPMENT OF RESEARCH ETHICS GUIDELINES

In order to examine the merits of the various arguments being put forward regarding the most appropriate standards for international research, it is important to be reminded, albeit briefly, of the historical development of international guidelines and the ethical principles that they embody. This exploration can begin with the Nuremberg Code, which emerged out of experiments conducted during the World War II. Specifically, the Nuremberg Code consists of 10 principles that appeared as part of the written judgment in the *Trials of War Criminals Before the Nuremberg Military Tribunals*. These judiciary proceedings were undertaken to investigate the inhumane treatment research subjects--mostly prisoners detained in concentration camps--had suffered at the hands of Nazi scientists.

The provision of the Nuremberg Code that is most often referred to states in part: “The voluntary consent of the human subject is absolutely essential.” This first provision also provided the various elements that now comprise the requirements of informed consent in research, namely the legal capacity to give consent; the ability to exercise free power of choice (voluntariness), and knowledge and comprehension of the elements of the subject matter involved as to enable participants to make a decision (disclosure). Other provisions addressed the nature and conduct of the research, such that experiments should be purposeful rather than random and unnecessary, and should be conducted in such a manner as to avoid all unnecessary suffering. Even if the Nuremberg Code was not statutorily enacted in its entirety by any nation and did not have an immediate impact on the way experiments were conducted in the US, its basic requirement of voluntary consent evolved into a cornerstone of ethics in human experimentation.

Within a decade, the World Medical Association identified the need for a document written by physicians that also would address “therapeutic” experiments, in addition to the “non-therapeutic” experiments performed by Nazi scientists, which were detached from any intent to provide a therapeutic effect. The document that became known as the Declaration of Helsinki was issued in 1964 and has been revised sporadically. It recently underwent a fifth revision, discussed below.

Other than the two documents referred to above, there has been a proliferation of research guidelines by international and national entities. Among them, the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization issued in 1993 the “International Ethical Guidelines for Biomedical research Involving Human Subjects.” Because it was developed more recently, this document benefited from a considerable wealth of material on ethical issues in international research. The development of the document also drew from a broad group that was culturally and professionally diverse. A co-chair of the steering committee that drafted these guidelines has argued that although they build on the legacy of the Nuremberg Code and the Declaration of Helsinki, they have avoided many of the pitfalls that were identified in the other two documents, and therefore should be considered as superseding them. The CIOMS guidelines specifically address the situation where research is conducted in a host country that is different than the country which is sponsoring, financing or carrying out the research, in part or in whole. Two ethical obligations are set forth: (1) the research protocol should, at a minimum, meet the ethical standards that apply to research conducted domestically; and (2) the proposed research should be submitted for ethical review to appropriate authorities in the host country, so that they may determine whether it conforms to their own ethical standards.

RECENT CONTROVERSY IN CONDUCTING INTERNATIONAL RESEARCH

As early as 1988, it was predicted that investigators conducting research in developing countries would face considerable ethical challenges, particularly in regard to AIDS research. (Much of the ethical debate regarding international research is centered on HIV/AIDS, which ranked fourth among the top ten causes of the global burden of disease, 98% of which is borne by countries with low or middle incomes.) Pointing out that many researchers were unfamiliar with the cultures, customs and economic pressures faced by those countries, one author emphasized that guidance already existed through the ethical principles of autonomy, non-maleficence and beneficence, and justice.

In an accompanying editorial, Marcia Angell asked the questions that would become the focus of the debate that erupted almost ten years later: "Is it proper for Americans to insist that their ethical standards be applied to clinical research performed in other countries? Should ethical standards be substantially the same everywhere, or is it inevitable that they differ from region to region, reflecting local beliefs and custom?" Angell favored the view that ethical standards are not a matter of custom and that basic human rights must be honored universally, although some accommodations could be necessary to respect local sensitivities.

In September 1997, two commentators reported in the *New England Journal of Medicine* that studies on the reduction of maternal-fetal HIV infection being conducted in developing countries and funded by the US government were ethically at variance with similar studies conducted in the US, in that participants in the control arm were given a placebo instead of zidovudine, which was considered the standard of care in the US.

In the ensuing debate as to the appropriate standards that should be applied in conducting research in developing countries, both sides agreed that "identifying less expensive and similarly effective interventions would be of enormous benefits, given the limited resources for medical care in most developing countries." Proponents of placebo-controlled studies believed that such a design would be preferable to comparing shorter regimens to the standard one. They also believed placebo-controlled trials were ethical since subjects receiving the placebo were receiving the country's standard care. Opponents of placebo trials counter-argued that the studies were not undertaken in a state of equipoise. Furthermore, they argued that justifying the use of a placebo in terms of a local standard fails to differentiate between a standard that is established among known medical options and a standard that is the result of economic constraints.

Officials of the funding agencies that had made those trials possible responded to the criticisms by explaining that interventions that could be conducted in the US might well be beyond the financial resources of developing countries or the capacity of their health care systems. Also, some study could be more compelling in those countries because of the burden of disease. These authors suggested that placebo-controlled trials could be justified on the basis that the assignment to the placebo group carried no risk beyond that associated with standard practice, that such trials provided a faster answer with fewer subjects, and that answers about safety and the value of the intervention were definitive. Such answers could then allow a country to make a sound judgement about the appropriateness and financial feasibility of the intervention.

REVISION OF THE DECLARATION OF HELSINKI

It is against this backdrop that the World Medical Association recently undertook its 5th revision of the Declaration of Helsinki. In particular, changes were favored by those who viewed the Declaration of Helsinki as defective in that it inappropriately maintained a distinction between therapeutic and non-therapeutic research and was out of touch with current ethical thinking, and therefore was violated frequently. In particular, some argued that the requirement that every participant, including those in a control group, receive the best proven intervention was outmoded since it resulted in limiting the use of placebos to instances where no proven intervention existed when in practice placebo were much more widely used. Other analysts, however, were concerned that such revisions could lead to an erosion of the protections offered to human subjects and that greater emphasis on utilitarian factors would dominate.

The revision adopted in October 2000 abandoned the long standing distinction between therapeutic and non-therapeutic research, but now refers to "basic principles for all medical research" and "additional principles for medical research combined with medical care." It also emphasizes that a population can be chosen to participate in an experiment only if it is to benefit from the experiment. The World Medical Association maintained the

requirement that new treatments be compared to the best existing methods, limiting the use of placebo to instances where the prevailing treatments are unproven. According to the leaders of the WMA, the protections of research participants had been strengthened through this round of deliberation, lasting 3 years. Such strengthening, however, may amount to an emphasis of the general nature of ethical standards as opposed to legal standards, namely that guidelines are normative and often aspirational.

NATIONAL BIOETHICS ADVISORY COMMISSION

American ethicists and researchers alike have recognized that much of the controversy that erupted over HIV research in developing countries stemmed from the application of the US federal regulations, known as the Common Rule. In part, this led the National Bioethics Advisory Commission to investigate this debate and make recommendations regarding international research that could be implemented in the US and govern investigators and sponsors conducting research abroad. A draft report was issued in the September 2000, preceding by a week the revised Declaration of Helsinki. Although a final report is still pending, the extensive analysis of the Commission provides a valuable contribution to understanding the ethical issues at stake from a US perspective. In particular, the Commission identifies two types of ethical requirements: substantial ones and procedural ones. This dichotomy also exists in relation to the substantial and the procedural requirements of informed consent.

Overall, the National Commission emphasized that research conducted in developing countries should correspond to health needs of the host country; that participants in the control arm generally should receive established, effective treatments that exist at the time the research is undertaken; that there be meaningful community involvement in the design and implementation of the research; that the substantive requirement of informed consent be complied with, that there be post-trial benefits to the community, as required by the principle of justice as reciprocity, and that efforts be made to enhance international collaborative research.

AMA POLICY

Principally, three existing Opinions of the *Code of Medical Ethics* address ethical issues related to the conduct of research. All were developed in the context of research performed in the US, but their framework may be applicable to research performed elsewhere.

Opinion 2.07, "Clinical Investigation," which first appeared in the 1969 edition of the *Code of Medical Ethics* and was substantially amended by addition in 1994 and 1998, builds on the foundation of the Nuremberg Code by stating that "No person may be used as a subject in clinical investigation against his or her will." This Opinion also mirrors the distinction that formerly was drawn in the Declaration of Helsinki regarding therapeutic and non-therapeutic research, referring to "clinical investigation primarily for treatment" and "clinical investigation primarily for the accumulation of scientific knowledge." In the former case, the physician cannot abandon the role of clinician and must exercise professional judgement and skill in the best interest of the patient, whereas in the latter case, social policy dictates that concerns for the individual must be primary and the advancement of scientific knowledge secondary. Also, in the context of clinical research mixed with treatment, disclosure should include possible therapeutic benefits, as well as a disclosure of alternative therapeutic options, two requirements that are not listed in the case of purely experimental clinical investigation. Finally, the guidelines provide two additional considerations in the context of clinical investigation mixed with treatment that are not discussed in the context of clinical investigation for scientific advancement. First, when the experimental treatment is the only potential treatment for the patient and full disclosure would pose such a psychological threat of detriment to the patient, such information can be withheld, a doctrine known as the "therapeutic privilege." In addition, although consent should be written, in circumstances where this is not feasible due to the physical or emotional state of the patient, exceptions are permitted.

Opinion 2.075, "The Use of Placebo Controls in Clinical Trials," issued in 1997, addresses the circumstances when it may be permissible to use a placebo. The Opinion emphasizes informed consent, and the role of Institutional Review Boards and investigators to ensure that each subject has been adequately informed and has given voluntary consent. To that effect, the Opinion requires that subjects be made aware that they can terminate their participation in a study at any time. In addition, the Opinion lays out a gradation along which the use of placebo is permissible. Specifically, it states that when research pertains to a condition that causes death or irreversible damage, a placebo cannot be employed if an alternative treatment would prevent or slow the progression of the illness. Where research is conducted on an illness that is characterized by severe or painful symptoms, the use of placebo may be

permissible. However, the more severe the condition, the less justifiable would be the use of a placebo as a substitute for an existing suitable therapy. A similar methodology was reiterated in Opinion 2.076, "Surgical Placebo Controls," issued in 2000.

Finally, in Opinion 2.071, "Subject Selection for Clinical Trials," which was issued in 1998, the Council on Ethical and Judicial Affairs specifically recognized the need to protect socioeconomically disadvantaged populations but also found that such populations should not be categorically excluded or discouraged from participation in research. Also, the Opinion emphasizes that when a subject has received a clear medical benefit from the experimental intervention that is under consideration for market approval by the Food and Drug Administration, the patient's physician, the investigator, and the product sponsor, should seek to provide access to the intervention, for example by having recourse to one of the FDA's special exception to final review and approval.

INTERNATIONAL RESEARCH: APPLICABLE ETHICAL STANDARDS

The fundamental question that is raised by international research is a matter of determining which standards should be applied when those of the country of origin of the investigators or sponsors differ from the standards that exist in the region where the research is to be conducted. In practice, this question has arisen primarily when Western researchers have conducted research in developing countries.

This single question, however, seems to be split into two lines of inquiry: first, whether the same ethical standards apply regardless of the location where the research is conducted; second, whether the standard of medical care that is offered in the control arm of the trial ought to be the standard available in the country of origin of the investigators or sponsors, or whether the experimental intervention can be measured against the local standard of care. It is important to note that these two questions often have been confounded.

Uniform Ethical Standards: The Role of Informed Consent

As multinational research trials become more of a common occurrence, the question of whether universal ethical standards govern the conduct of human subject research has become a controversial topic. At the core of this question lie the notions of autonomy and informed consent.

As briefly described above, informed consent emerged as a central requirement of human experimentation through the Nuremberg Code. Until the adoption of these guidelines, the ethical concern governing research had been one of beneficence: to control the risks presented to subjects. The Code shifted the focus to include the distinct principle of respect for persons such that participants exercised their autonomy in deciding whether or not to volunteer in research. In the US, the Belmont Report, which was issued in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, identified informed consent as one of the basic ethical principles that should underlie the conduct of biomedical research on human subjects.

Since these developments, other ethical guidelines regarding research have been crafted around values of individualism to emphasize individual rights, autonomy, and self-determination. Some commentators, however, reject the idea that such standards cut across time, place, and culture. In particular they question the relevance of the principle of informed consent in cultures that do not promote individualism in the same manner that it is protected in Western countries. In this regard, they point to non-Western countries where people have a more relational understanding of personhood and place greater emphasis on collective rights to ask whether informed consent has meaning where personal choice is limited in relation to community good. There is concern that overriding the norms and values of a culture that grants decisional-making authority to the village chief, the local leader, or the head of the family may be disrespectful. To insist on obtaining consent from each potential research subject in these cultures may be morally incongruous.

Proponents of the universal moral status of individual informed consent contend that the obligation to obtain consent transcends local custom or law, in that it is derived from a fundamental human right, the right to self-determination. Some, in an effort to acknowledge and respect the local sensitivities of certain cultural settings, suggest that consent be required from community authorities, in addition to individual consent. Others simply propose that the local authorities be informed of the research. They all agree, however, that community involvement cannot override or substitute an individual's acceptance or refusal to participate. Indeed, such substitution would fail to promote respect for the individual, and thereby deviate from the substantive ethical standard of informed consent.

The fundamental concern of research ethics is to prevent the mistreatment of human subjects. The principal safeguard, in the context of research, is to seek informed consent from each potential subject. Regardless of whether the ethical standard of individual informed consent is universal, it becomes necessary to obtain it when research is conducted and participants solicited.

Carrying out the process of informed consent in various cultural settings remains a challenge and requires an understanding of the values from which community members derive meaning. Therefore, research investigators will need to devote careful attention to the design of the informed consent process, identifying sources of approval or authorization that are necessary, in addition to the consent of the potential participant. Investigators also should seek to ascertain that consent or refusal to participate is voluntary.

Standards of Care

The second component of the debate focuses on whether the best proven therapy must be used or whether placebo-controlled trials are justifiable in the developing world when a proven treatment already exists in developed countries. Fundamentally, this dilemma is one that translates into an ethical issue of risks and benefits. It requires the same analysis that is required of all protocols, namely a determination to be made by investigators and review boards as to whether the trial design stems from a state of equipoise, such that there is genuine uncertainty among the clinical community as to the comparative merits between the experimental intervention and the control treatment.

From this perspective, researchers must use all the means at their disposal to review existing data, and those in charge of reviewing research protocols must use their scientific judgement to evaluate the hypothesis that is being studied. If the question is one that is scientifically unanswered, then the study should be designed to minimize the risks in the face of uncertainty. If a review board then determines that risks and benefits are favorably balanced, the research usually is deemed ethical. Indeed, there are no substantive guidelines as to what constitute an unacceptable risk or a significant benefit.

Clearly, difficulty remains in evaluating risks and benefits, including the risk of exploiting participants. This concern is heightened in the context of unbridgeable disparities in health care resources among countries, whereby populations of developing countries may be used to advance scientific knowledge that result in greater or more immediate benefit to the industrialized world.

To ensure that international research does not result in an exploitative outcome, arguments have been advanced that research should respond to needs of the local community and its research participants and that measures should be negotiated at the outset to ensure the implementation of a successful experiment among them. In this regard, some have called for "fairness as the principal rule of engagement" and have invited the broad participation of all stakeholders.

CONCLUSION

Ethical research generally results from research designs that have been developed according to a sound scientific inquiry. Review boards are then required to safeguard research participants against coercion or abuse. Through the process of informing a potential participant of the nature of the research endeavor, and by seeking the participant's voluntary consent, the process of informed consent is viewed as the principal ethical means to ensure the respect of individual participants. Overall, respect for persons, through the informed consent process, fosters trust, a necessary condition to the ethical advancement of science.

The protection of participants also requires review boards to determine that risks have been minimized and that potential benefits are in a favorable ratio. In the context of international research, the risk of exploitation warrants special attention and can best be attended to by obtaining relevant input from the host country to ensure that the chosen population will not face unjustifiable risks. Despair or dire need for basic medical care should not justify undue risk, just as they cannot substitute for voluntary and informed consent.

RECOMMENDATIONS

The Council recommends that the following be adopted and the remainder of the report be filed:

Physicians, either in their role as investigators or as decision-makers involved in the deliberations related to the funding or the review of research, hold an ethical obligation to ensure the protection of research participants. When the research is to be conducted in countries with differing cultural traditions, health care systems, and ethical standards, and in particular in countries with developing economies and with limited health care resources, US physicians should respect the following guidelines:

1. First and foremost, physicians involved in clinical research that will be carried out internationally should be satisfied that a proposed research design has been developed according to a sound scientific design. Therefore, investigators must ascertain that there is genuine uncertainty within the clinical community about the comparative merits of the experimental treatment and the one to be offered as a control in the population among which the study is to be undertaken. In some instances, a three-pronged protocol, which offers the standard treatment in use in the US, a treatment that meets a level of care that is attainable and sustainable by the host country, and a placebo (see Opinion 2.075), may be the best method to evaluate the safety and efficacy of a treatment in a given population. When US investigators participate in international research they must obtain approval for such protocols from US Institutional Review Boards (IRBs).
2. IRBs, which are responsible for ensuring the protection of research participants, must determine that risks have been minimized and that the protocol's ratio of risks to benefits is favorable to participants. In evaluating the risks and benefits that a protocol presents to a population, IRBs should obtain relevant input from representatives from the host country and from the research population. It is also appropriate for IRBs to consider the harm that is likely to result from forgoing the research.
3. Also, IRBs are required to protect the welfare of individual participants. This can best be achieved by assuring that a suitable informed consent process is in place. Therefore, IRBs should ensure that individual potential participants will be informed of the nature of the research endeavor and that their voluntary consent will be sought. IRBs should recognize that, in some instances, information will be meaningful only if it is communicated in ways that are consistent with local customs.
4. Overall, to ensure that the research does not exploit the population from which participants are recruited, IRBs should ensure that the research corresponds to a medical need in the region where it is undertaken. Furthermore, they should foster research with the potential for lasting benefits, especially when it is undertaken among populations that are severely deficient in health care resources. This can be achieved by facilitating the development of a health care infrastructure that will be of use during and beyond the conduct of the research. Additionally, physicians conducting studies must encourage research sponsors to continue to provide beneficial study interventions to all study participants at the conclusion of the study.

(References pertaining to Report 2 of the Council on Ethical and Judicial Affairs are available from the Department of Ethical Standards.)

3. FILMING PATIENTS IN HEALTH CARE SETTINGS

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

INTRODUCTION

Patient privacy and confidentiality of medical information are the bedrock of the patient-physician relationship. A patient's knowledge that he or she can reveal personal information to a physician, and that the physician must keep this information confidential, is what enables patients to candidly disclose to their physician information that they might not want generally known. Knowing this information is what allows physicians to provide care effectively. This fundamental element of the patient-physician relationship is potentially compromised when film crews are allowed to film, videotape, or otherwise record, (hereafter film) patients in the clinical setting. Such filming has recently proliferated with the advent of reality-based television shows featuring health professionals.

The laudable objective behind publicly broadcasting such films of patients is to inform and educate the public about the health care system and medical care. It is possible that this can even reduce injury and disease prevalence through education about risk factors. However this educational objective must be balanced against the competing and arguably more fundamental right to privacy and confidentiality held by patients.

A potential compromise between public education and privacy may exist when patients consent to being filmed for the purpose of public viewing. However, when it is not possible for patients to consent to being filmed, for example when a patient arrives at an emergency department (ED) unconscious, there is no clear ethical consensus as to whether privacy can be compromised. Current practice appears to allow the filming to precede consent, and for consent to be obtained subsequently, but prior to the broadcast. Indeed, there appears to be a general consensus that it would be unethical to air any footage acquired without obtaining consent from the patient or the patient's surrogate decision-maker. However, it is unresolved to what extent the initial filming represents a breach of the patient's privacy and confidentiality.

In this report the Council provides guidance regarding ethical filming of patients by discussing the scope of patient privacy and confidentiality; the responsibility to obtain informed consent; and the importance of ensuring the objectives in filming are first and foremost educational.

PATIENT PRIVACY AND CONFIDENTIALITY

The areas of both privacy and confidentiality are important when contemplating the issue of filming and broadcasting patient encounters. In the realm of privacy, patients are ethically, and to a great extent legally, entitled to have only those individuals who are involved in their medical care examine them, or observe their examination. Opinion 5.04, "Communications Media: Standards of Professional Responsibility," states that "Physicians are ethically and legally required to protect the personal privacy and other legal rights of patients." Thus the presence of the film crew may be an infringement of the patient's privacy.

Protecting confidentiality arises from the need of patients to share personal information with their physicians in order for them to provide medical care. This privileged communication is a voluntary surrender of privacy with the expectation that some control over the information is retained, namely that the information will not be disclosed beyond the person with whom it was entrusted, or to others directly involved in the patient's care. According to Opinion 5.05, "Confidentiality," information that is shared with a physician should not be further disclosed unless disclosure can be "ethically and legally justified because of overriding social considerations," or the patient gives consent to the release of the information. Exceptions that are contemplated by the Opinion include physical threats and other circumstances related to the potential harm of self or others, such as physical violence, and communicable disease. Also, according to Opinion 7.025, "Records of Physicians: Access by Non-Treating Medical Staff," patients are entitled to have their medical information accessed only by individuals directly involved in their medical care.

In considering the issue of filming, it is important to consider the general expectation of privacy in the health care setting and how this might be compromised by filming, particularly when individuals not necessary for the medical care of the patient are present.

Expectation of Privacy in Health Care Settings

First, it is important to note that the nature of the professional interaction between a patient and his or her physician renders this interaction private, and therefore there likely is an expectation that the setting in which the patient-physician interaction occurs, be it a hospital room or a private office, is a private rather than a public space. *Black's Law Dictionary* defines a public space as:

A place to which the general public has a right to resort; not necessarily a place devoted solely to the uses of the public, but a place which is in point of fact public rather than private, a place visited by many persons and usually accessible to the neighboring public (e.g., a park or public beach). Also, a place which the public has an interest as affecting the safety, health, morals, and welfare of the community. A place exposed to the public, and where the public gather together or pass to and fro.

Certain parts of a hospital might fit within this public space definition, but the immediate moment that a space is used for interaction between a patient and his or her physician renders that space private.

This is important because courts have held that surveillance or recording without consent or court order is impermissible in areas where there is a reasonable expectation of privacy. In cases when the media have broadcast footage or published photographs of patients without their consent, courts have ruled that such broadcast or publication was an unlawful violation of privacy. It does not appear that courts have yet ruled on whether the act of filming alone (without the subsequent broadcast) likewise constitutes an unlawful invasion of privacy. However, even if it is determined that similar legal protection is not necessary (because for instance, the potential harm in being seen by millions of people via broadcast is not the same as the harm in being seen by a film crew), this does not preclude the establishment of ethical standards to offer greater protection of patient privacy, and to also protect the patient-physician relationship from being hindered by third parties for purposes of questionable benefit.

Presence of Non-Health Care Professionals

Another privacy and confidentiality concern involves the presence of film crews composed of non-health care professionals in the clinical encounter. Unless a stationary camera is used, or a health professional performs the filming, someone is present to film who is not essential to the medical care of the patient. If the patient subsequently does not provide consent, this invasion of privacy cannot be undone. Furthermore, film crews, unlike health care professionals, are not bound by professional duties to keep medical information confidential. Thus, even if consent to broadcast was denied, and the tape destroyed, there is no guarantee that the film crew will maintain the confidentiality of the information they obtained as observers.

Some physicians who have participated in filming of reality-based television shows contend that the crews blend in, and feel like "...an ancillary member of the team." In fact, it may be very difficult for patients to distinguish members of the film crew from members of the health care team because the film crews may dress like the medical staff, a source of concern for some.

Justifiable Breaches of Privacy and Confidentiality

In certain circumstances, the "overriding social considerations" set out in Opinion 5.05 may warrant not only breaches of confidentiality but also an invasion of patient privacy. For instance, when a person is suspected of physically abusing someone under his or her care (often a child, but possibly the elderly or physically or mentally impaired), Factitious Disorder by Proxy (also known as Munchausen syndrome by proxy) must be considered, and it may be appropriate to implement covert video surveillance (CVS) to monitor for the occurrence of such abuse. Also, it may be beneficial for medical education purposes to film patient encounters or procedures with the understanding that such footage will not be publicly released. In the conduct of forensic medical examinations or interviews, particularly for psychiatric consultation, filming may be requested by the court. The conduct of telemedicine also often may result in a filmed record. Finally as a standard security measure, medical facilities often employ security cameras in corridors and other public areas.

In the above scenarios, it is always desirable to obtain the patient's consent prior to filming, or at a minimum, disclose to the patient that filming will occur (although it is understood that if CVS is being performed, disclosure or consent would undermine the purpose of the filming). Additionally, impartial review by an entity such as an institutional review board or hospital ethics committee is an appropriate mechanism for ensuring that patients' rights are protected. After any patient footage has served its purpose, additional protection against unauthorized use is to destroy the tape.

Additionally, in all the above scenarios the film is not made available for public viewing, but rather is narrowly used for purposes which have clear benefits to patients, the health care system, and society as a whole. When the use is for the education of medical professionals, the presumption of confidentiality (non-public viewing only), the ability to remove or obscure the patient's identity, the use of health professional or stationary cameras in performing the filming, and the ability to control possession of the footage, create circumstances that are significantly different from filming with the intent of broadcast for public viewing. The American College of Emergency Physicians (ACEP) Ethics Committee states:

Recorded images that are used for education and training are in a different category. Here the audience is clearly not just the people who needed the information to further the patient's interests. One can argue, however, that the public good is served by educating physicians and others with the most accurate materials available. If the patient gives consent for this use prior to obtaining the images, and the audience is limited to persons within the bounds of this consent, then privacy and confidentiality expectations are met.

Use of recorded images for training, if done automatically, or at least by someone who is part of the caregiver facility, may be appropriate. The process must be carefully controlled, and consent must be obtained before any use of the images. With these careful limits, it can be argued that the public good outweighs the problem of obtaining consent after the fact, and in any case the tapes are not released without the patient's permission.

INFORMED CONSENT

The discussion above illustrates patients' rights to both privacy and confidentiality and the physician's duty to protect these rights. Unless the patient provides informed consent, breach of privacy or confidentiality can only occur because of "overriding social considerations." In Opinion 8.08, "Informed Consent," the Council discusses a framework within which a patient actively participates in choosing among "therapeutic alternatives." The Opinion also recognizes that sometimes patients may refuse treatment all together. Exceptions to obtaining consent are provided in relation to individuals who are "unconscious or otherwise incapable of consenting." Under such circumstances, treatment is undertaken based on the implied consent doctrine that a reasonable person capable of consenting would want to receive medical care that is in his or her best interests. However, since filming a patient confers no therapeutic benefit, this standard should not be applied to unconscious or incapable patients when the issue in question is filming.

The process of obtaining informed consent is intended to allow the patient to make an informed decision based upon the likely risks and benefits of a course of action. Ideally, this assumes that there is sufficient time to explain precisely what the patient is consenting to, time to resolve any questions or concerns the patient may have, and time for the patient to reflect on the implications of what he or she is consenting to. When the filming is being performed with emergent patients it is ethically questionable whether it is wise to spend time obtaining consent for anything that is not of therapeutic benefit to the patient.

Additionally, even if a patient is conscious, it is important to evaluate whether he or she is competent to consent to something that is not of medical benefit and poses a potential violation of privacy. The ACEP Ethics Committee notes that "An alert patient can presumably give...consent, but the very nature of emergency medicine suggests that the patient is under some duress, which may cloud their thinking."

Since the objective of informed consent is to ensure that the patient is informed of all elements that they are consenting to, it is important to have more than one mechanism in which the information is disclosed. Thus, signs should be posted in and around the area where filming is to occur, indicating that filming is in progress. These signs are of benefit not only to patients but also to the medical staff, who should likewise have an opportunity to consent or object to being filmed.

When Consent is Denied or Withdrawn

Consent is a dynamic process, not a static one, and once a patient consents to filming, he or she reserves the right to rescind consent, right up until the time the footage is to be broadcast. This was established when the Federal District Court for the 9th Circuit ruled in *Virgil v. Time, Inc.* that "...if consent is withdrawn prior to the act of publicizing, the consequent publicity is without consent." One way to ensure that patients do not have reservations about giving consent is to provide them with an opportunity to view the final edit of the material prior to it being broadcast.

If a patient initially consents to filming and subsequently withdraws that consent, the highest ethical standard would be to destroy the filmed record. This would also apply in the less desirable scenario of initial filming occurring without the patient's consent, and subsequently the patient refuses to consent to broadcast. Another possibility that would protect patient confidentiality, although not privacy, would be to edit the patient out of the filmed record, or obscure visual and voice recognition of that patient.

Consent by Surrogate Decision-Makers

The utilization of surrogate decision-makers to provide consent for a party who does not have the capacity to consent typically involves two assumptions: (1) that it is necessary for a decision to be made one way or another (between two courses of action or therapies for instance); and (2) that absent any advance directive, the person in question would want medical care in his or her best interests which provides the greatest probability for a successful

outcome. When the issue in question involves filming patients for public viewing, neither of the above assumptions can be affirmed--it is not necessary for the decision to be made for the person's medical care, and the filming itself will not provide medical benefit. Furthermore, the domain of surrogate decision makers in the health-care setting is appropriately limited to making health-care decisions. For instance, because a surrogate is empowered to decide between therapeutic alternatives when the patient cannot decide, he or she would not automatically be empowered to sell the patient's house. Thus it is not permissible to allow a surrogate to provide consent for the party being filmed. Consent must be obtained from competent patients themselves.

A possible exception exists when the patient is permanently or indefinitely incompetent and a parent or legal guardian is legally empowered with the ability to make all decisions for that person using a best interests standard. Examples of such exceptions might include minor children, mentally retarded individuals, or persons in a permanent vegetative state. In these instances, if the parent or legal guardian provides consent, filming may occur.

Is the Film Part of the Medical Record?

One legal question that deserves some attention is whether once a filmed record is made, does it constitute part of the medical record? If it is considered part of the medical record, it would potentially be unlawful to destroy it. The federal Interagency Committee on Medical Records (ICMR) does not consider videotapes part of the medical record, although its policy is advisory and does not specifically mention footage taped for broadcast purposes. Notably, the Joint Commission on Accreditation of Healthcare Organizations states in its policy clarification that absent consent, the filmed record should be destroyed. Physicians should comply with local regulations pertaining to whether the film is part of a medical record, and should not destroy the tape if contrary to local law.

Consent of Medical Staff

While the medical staff are not in the vulnerable position that patients are in, filming can represent an invasion of their privacy. Furthermore, filming may be an especially sensitive area for those in undergraduate or graduate medical education and still developing their clinical skills. In these circumstances, filming may create a source of anxiety that could induce medical errors, although some physicians have commented that they slow down and are more careful when they are being filmed because they fear that a mistake may be recorded. Other physicians have expressed concern about being filmed during emotional moments, such as the death of a patient. For these reasons, every effort should be made to obtain consent not only from patients, but also to obtain consent from the medical staff.

EDUCATIONAL VERSUS COMMERCIAL PURPOSE

Some have argued that medical reality shows are educational and benefit the public. This issue has been discussed in light of fictional medical dramas, which sometimes give false impressions of medical care in general and "injury management and survivability" in particular. Recent research has verified that these dramas can convey health information, but that sometimes this information is inaccurate. This raises concern about the educational purpose of these shows, and their responsibility to be accurate.

Additionally, the increased exposure that is provided for the medical center and the medical staff cannot be ignored. Referring to one of the recent programs, Jerome Kassirer, editor-in-chief emeritus of the *New England Journal of Medicine*, noted that "The program glorified the [medical center's] staff...[and] seemed intended more for public relations than for public service."

Furthermore, many outrightly question whether the viewers of these shows have any "academic or clinical interest in emergency medicine," but rather assert that "They watch the shows for the same reasons people gawk at accidents--out of morbid curiosity and prurient interest." In fact, the time slot during which one network features its shows is called "The Adrenaline Rush Hour" and its web site encourages people to "experience the rush of life-and-death situations and intense conflict in and out of the emergency room." This may suggest that the audience for these shows are more likely to be thrill seekers than those curious about medical care or the health care system.

Financial Compensation

The majority of recent television shows featuring patients have been on commercial networks, indicating that profit making is an important motive behind the production of these shows. This raises the potential question of whether patients or the medical staff (who essentially star in these shows) should receive financial compensation for their appearance in the broadcast but raises additional questions as to whether compensation would constitute a coercive pressure for either patients or physicians to participate in filming. Factors that might be important include whether the broadcast was on a commercial or public broadcast station, the potential for revenue from the broadcast of the show, and who might receive that revenue. To ensure that such coercive pressure is not present, any remuneration or other form of compensation, such as reimbursement for the care that was received at the time of the filming, probably should be donated directly to the health care institution.

CONCLUSION

Filming in health care facilities affords the opportunity to inform the public about the health care system, and even the possibility of reducing injury and disease through education about risk factors. While these are worthwhile endeavors, they are not of sufficient benefit to warrant undermining patient privacy and confidentiality. For this reason, filming should only proceed when the patient (or the patients' surrogate decision-maker) and all medical staff treating the patient, explicitly consent to the filming.

RECOMMENDATIONS

The Council recommends that the following be adopted and the remainder of the report be filed:

The use of any medium to record (hereafter film) patient interactions with their health care providers requires the utmost respect for the privacy and confidentiality of the patient. The following guidelines are offered to assure that the rights of the patient are protected. These guidelines specifically address filming with the intent of broadcast for public viewing, and do not address other uses such as in medical education, forensic or diagnostic filming, or the use of security cameras.

1. Educating the public about the health care system should be encouraged, and filming of patients may be one way to accomplish this. This educational objective is not severely compromised by filming only patients who can consent, and when patients cannot consent, dramatic reenactments utilizing actors should be considered instead of violating patient privacy.
2. Filming patients without consent is a violation of the patient's privacy. Consent is therefore an ethical requirement for both initial filming and subsequent broadcast for public viewing. Because filming cannot benefit a patient medically, and moreover has the potential of causing harm to the patient, it is appropriate to limit filming to instances where the party being filmed can explicitly consent. Consent by a surrogate decision-maker is not an ethically appropriate substitute for consent by the patient because the role of surrogates is to make medically necessary decisions in the best interest of the patient. A possible exception exists when the person in question is permanently or indefinitely incompetent (e.g., permanent vegetative state or minor child). In such circumstances, if a parent or legal guardian provides consent, filming may occur.
 - (a) Patients should have the right to have filming stopped upon request at any time and the film crew removed from the area. Persons involved in the direct medical care of the patient who feel that the filming may jeopardize patient care should also request that the film crew be removed from the patient care area.
 - (b) The initial granting of consent does not preclude the patient from withdrawing consent at a later time. After filming has occurred, patients who have been filmed should have the opportunity to rescind their consent up until a reasonable time period before broadcast for public viewing. The consent process should include a full disclosure of whether the tape will be destroyed if consent is rescinded, and the degree to which the patient is allowed to view and edit the final footage before broadcast for public viewing.
 - (c) Due to the potential conflict of interest, informed consent should be obtained by a disinterested third party, and not a member of the film crew or production team.

3. Information obtained in the course of filming medical encounters between patients and physicians is confidential. Persons who are not members of the healthcare team, but who may be present for filming purposes, must demonstrate that they understand the confidential nature of the information and are committed to respecting it. Where possible, it is desirable for stationary cameras or health care professionals to perform the filming.
4. Physicians, as advocates for their patients, should not allow financial or promotional benefit to the health care institution to influence their advice to patients regarding participation in filming. Because physician compensation for participation in filming may cause an undue influence to recruit patients, physicians should not be compensated directly. To protect the best interests of patients, physicians should participate in institutional review of requests to film.

(References pertaining to Report 3 of the Council on Ethical and Judicial Affairs are available from the Department of Ethical Standards.)

4. SURROGATE DECISION MAKING

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

INTRODUCTION

At the 1991 Annual Meeting, the American Medical Association adopted the report of the Council on Ethical and Judicial Affairs, "Decisions to Forgo Life-Sustaining Treatment for Incompetent Patients." The recommendations of the report were the basis for amendments to Opinion 2.20, "Withholding or Withdrawing Life-Sustaining Medical Treatment." The report itself provides guidelines for physicians who may have to identify a surrogate decision maker, assist a surrogate or proxy in making decisions for incompetent patients, and resolve conflicts that may arise between decision makers, or between the decision maker's choice and medically appropriate options. Since the incorporation of these guidelines into the AMA's *Code of Medical Ethics*, the Council has deferred to Opinion 2.20 to address inquiries involving surrogate decision making, even though the guidelines presented in this Opinion refer only to decisions made near the end of life.

With continued discussion concerning health care preferences for all patients, including those who are incompetent, and greater options available to secure health care directives, the involvement of third parties in a patient's health becomes more likely in decisions that may occur in instances other than the end of life.

In addition, the Council recognizes that there is a spectrum of decision-making capacity ranging from immaturity, to mental illness, to serious brain damage, and that health care decisions often must be made for individuals with diminished decisional faculties over extended periods of time. The Council offers the following report to expand on its previous guidelines and to identify features related to a meaningful and effective physician-proxy relationship.

The report begins by defining a number of terms related to health care directives before presenting theoretical frameworks used in making decisions for incompetent patients. It then provides a protocol for identifying a surrogate decision maker as well as guidance for physicians who may run into conflict either assisting the surrogate in coming to a decision or with the decision itself. Finally, the report offers guidelines for nurturing an effective physician-proxy relationship.

Defining Key Terms

An advance directive is a document that enables competent persons to exercise their rights to direct medical treatments in the event that they lose their decision-making capacity. Previously, the Council on Ethical and Judicial Affairs considered two general categories of advance directives: 1) a living will, which indicates the types of treatment an individual wishes to receive or forgo under specified circumstances, and 2) a durable power of attorney for health care (or a health care proxy appointment), which designates another person to make health care decisions on behalf of the patient.

Confusion and debate over advance directives grouped in the second category arises primarily from inconsistencies in identifying different types of decision makers, and determining the scope of their authority. This may result from the fact that although all fifty states have established laws that govern advance directives, either statutorily or through case law, each differs in its standards and terminology. There are also a number of different advance directives currently available, offering varying degrees of empowerment to the decision maker. Some advance directive forms combine a proxy designation with specific instructions for the proxy so that the distinctions between a living will and a durable power of attorney for health care are beginning to blur. For the purposes of this report, the term “proxy” will be used to refer to a person who has been chosen by the patient, through a documented advance directive, to be the substitute health care decision maker, while the term “surrogate” will refer to a person whose authority to make health care decisions for a patient is based on state statute, case law, or a decision made by the medical team such as a physician or ethics committee.

MAKING DECISIONS FOR INCOMPETENT PATIENTS

There are two basic principles that should guide any treatment decisions: respecting and promoting patient autonomy, and fostering the well-being of the patient. The same right of self-determination that underpins the doctrine of informed consent provides legitimacy for the use of advance directives; that is, the patient’s right to choose a course of action remains after he or she loses decision-making capacity. Likewise, provisions should be made to respect the patient’s wishes even after competence is lost.

To protect the well-being and autonomy of the incompetent patient, three standards have been established in ethics and law to such guide decisions. These standards are referred to as: (1) the documented advance directive, (2) substituted judgment, and (3) the best interest standard.

Documented Advance Directives

The designation of a proxy through a durable power of attorney for health care and the implementation of a living will are often effective ways to ensure the appropriate implementation of the patient’s preferences with regard to health care decisions. While a detailed living will may ensure that decisions will accurately reflect the patient’s wishes in anticipated situations, a pre-designated proxy may be more suitable to interpret the patient’s wishes in unforeseen circumstances. To have the benefits of both a living will and a durable power of attorney, patients may document a proxy designation and, while competent, discuss with their proxy the preferences, values, or specific instructions that should be considered when making treatment decisions. Traditionally, advance directives have been associated with end-of-life decisions. However, health care directives that can be used in any circumstance in which a patient is incompetent or incapacitated are more effective and desirable.

Substituted Judgment

When a patient does not have documented treatment preferences or goals, decisions concerning the incompetent patient’s health care should proceed by substituted judgment. Substituted judgment asks that someone who knows the patient attempt to make a decision in the manner that the patient would (if he or she were capable of making the decision). The decision maker should look to the patient’s previously expressed preferences and values to determine what the patient would have decided. Substituted judgment is a valuable guiding principle because it gives weight to the subjective nature of medical decisions.

However, much empirical research indicates a low correlation between proxies’ decisions and what patients would have decided in hypothetical situations. Because there is no direct deductive relationship between values and a particular choice, or between previous decisions and current positions, the surrogate is often left to make an approximation of what the patient would have wanted. At best, substitute decision making requires great imaginative effort to process a patient’s web of values, preferences, and medical judgments.

With the recent criticisms of the substituted judgment standard, some authors have offered an alternative that is similar and in some ways more amenable to thinking about a medical decision. Rather than attempt to predict what the patient would say about treatment preferences, the patient’s life story is considered, and a particular option is evaluated in terms of its “fit” with the elements of the patient’s life story. This narrative model rests on the idea that individuals create an identity for themselves through their life story and it is through this narrative that persons conceptualize themselves. Thus, the physician and the surrogate have a *prima facie* moral obligation to continue the story in a manner that is meaningful and consistent with the patient’s self-conception. It is possible that more than

one choice is compatible with the patient's self-conception. Thus, the narrative approach seems to avoid the problems that arise from trying to predict which single course of action the patient would have decided when competent, as well as problems that arise when making decisions for patients who may have never been completely competent.

Best Interest Standard

Traditionally, when there has been no reasonable basis for interpreting how the patient would have decided, surrogate decision makers have based treatment decisions on predicted outcomes that would most likely promote the patient's well-being. This guiding principle is referred to as the "best interest" standard and is most often invoked for patients who have never possessed decision-making capacity or for those whom an appropriate surrogate cannot be identified. Making a decision based on another's best interests is less an act of respecting the patient's autonomy than it is an expression of beneficence. Employing this standard requires a more objective analysis of the harms and benefits of various options. Factors that should be considered when weighing the harms and benefits of various options include the pain and suffering associated with treatment, the degree and potential for benefit, and any impairments that may result from treatment.

While some courts and scholars have used the term "objective standard" to characterize best interest reasoning, the subjective perspective of the surrogate decision maker will unavoidably enter into judgments concerning the patient's quality of life. In the more difficult cases, the best interest standard for decision making is essentially a judgment about quality of life. For the surrogate to make an impartial decision using the best interest standard, he or she should measure quality of life as the worth to the individual whose course of treatment is in question, and not as the social worth of that life. One way to test whether a decision is inappropriately influenced by the surrogate's own values is to ask if the decision is one that most reasonable persons would choose for themselves in similar circumstances.

WHO SHOULD DECIDE

When a medical decision needs to be made for an incompetent patient, physicians should first inquire whether the patient had directly expressed wishes in a written document, such as a living will or a durable power of attorney for health care. If the patient has not left such a document, a surrogate should be appointed. Many states have codified protocols for identifying surrogates in the absence of any prior designation. In general, these statutes indicate that the family of the patient should be responsible for medical decisions. "Family" is generally understood to be the person's closest biological or legally recognized relations. Many states have established a hierarchy for identifying a surrogate decision maker in the absence of a documented advance directive. The order of priority for appointing a surrogate is often listed as legal guardian of the patient first, then a spouse, adult children of the patient, a parent of the patient, an adult sibling, and finally a close friend of the patient.

In this report, family includes whoever is closely associated with the patient. For instance, unmarried living partners and close friends should be considered as appropriate decision makers in addition to spouses, children, parents, or siblings. Recognizing this extended concept of "family" is increasingly important as alternatives to marriage and the nuclear family unit become more common. In the case where there is no person who is closely associated with the patient, but there are persons who both care about and have some relevant knowledge of the patient, these persons should participate in the decision-making process, and in some situations, may be appropriate surrogates.

The family's default authority to make medical decisions for an incompetent patient rests on a number of bases. It is often claimed that families have an intimate knowledge of the patient's values and can best make the same medical care decisions that the patient would have made. In addition, because an individual's values are developed primarily in the family, family members are most familiar with the patient's entire life context. Moreover, family members are generally the most concerned with the patient's welfare for it is the family who has traditionally provided for the patient's comfort, care, and best interests. Finally, participation "in an intimate association is one important way in which individuals find or construct meaning in their lives."

While it is common to assume that family members are best suited to determine what the patient would have decided, there is significant evidence indicating a lack of concordance between patients' treatment preferences and family members' prediction of those preferences. Such information has caused many to question the moral authority of the family to make decisions. However, most of these studies offer no alternative "default surrogate" that fares

any better at predicting patient choices. Furthermore, the moral importance of the family as a social unit in which values and preferences are fostered and realized is consistently promoted and, in this case, codified into most regulations that designate a procedure for designating surrogacy.

Resolving Conflicts

Decisions which profoundly affect a loved one who is incompetent to make medical decisions can be difficult for a family due to the emotional distress resulting from the situation. It is essential for physicians and other health care providers to be sensitive to the range of emotional and psychological responses of the family. Emotionality should not be interpreted as irrationality and used to justify overriding the family's decision-making authority. Rather, if a physician feels that the decision-making capacity of the family as a surrogate is significantly diminished by emotional distress, efforts should be made to help the family in its decisions. Offering counseling services or the assistance of an ethics committee or chaplain are examples of such efforts.

Not only is effective communication between the physician and the surrogate essential for appropriate decision making, but it also goes far in preventing major disputes among family members and health care providers. Physicians should offer relevant medical information and explanations as well as medical opinions based on professional expertise. In the absence of a documented advance directive, physicians should explain to the surrogate that decisions should be based on substituted judgment when possible, and otherwise on the best interest principle.

Disputes Among Family Members

Surrogates often make decisions as members of a family unit whose relationship will continue after a particular decision is made. These relationships deserve the respect of the health care team, and physicians should seek to maintain family harmony. Accordingly, physicians should not intentionally pit the interests of a particular family member against those of other family members to advocate for what the physician believes to be the most appropriate course of treatment.

In some instances, it may be appropriate to have recourse to an ethics committee. However, physicians and ethics committees should generally refrain from making treatment decisions. Rather they should attempt to mediate disputes. Family members may disagree when they do not understand the medical circumstances, each other's view points, or that decisions should be made using a substituted judgment standard whenever possible. Physicians and ethics committees should try to facilitate an understanding of these factors.

Sometimes, a single designated surrogate can resolve a case in which several family members disagree. However, differences may arise when the patient has not designated a proxy and the family cannot agree on which member should act as the surrogate. Physicians or ethics committees should explain that the people who have the best understanding of the patient's values will likely make a decision that reflects what the patient would have decided. Specifically, this refers to people who have had fairly involved and recent discussions with the patient about life, death, illness, religion, and/or specific treatments. Therefore, factors that may guide the search for an appropriate surrogate include the amount of personal contact with the patient, amount of recent personal contact, and the amount of dedication to the patient.

Disputes Between Physicians and Surrogates

Physicians should generally respect decisions based on well-reasoned substituted judgment or the best interest standard, even if the decision results in a different course of treatment than the physician recommended. Religious and culturally based decisions that reflect beliefs or values held by the patient also should be respected. However, no choice, no matter how well intentioned, should make physicians agents of harm. Such conflicts pit the professional integrity of the physician and well-being of the patient against the ethical obligations to respect the patient's delegated autonomy.

When a physician challenges the decision of a surrogate, an ethics committee should first verify that the challenge is based on a belief that the decision is clearly not what the patient would have decided or, cannot reasonably be judged to promote the patient's well-being. In most cases, a negotiated understanding of the patient's values or best interests offers the best protection for the relationship between physicians and surrogates.

In the event that a conflict is intractable, even after consulting an ethics committee, the dispute should be referred to the courts. A tremendous disservice is done to the family and the patient when the decision-making process is unnecessarily brought into a forum that is burdensome and adversarial. Traditionally, ethics committees are more informal than the courts, and can maintain the privacy of the family decision-making process better than judicial review, putting less strain on the family and its relationship with the physician or hospital. It is strongly encouraged that when judicial review becomes necessary, the courts appoint an appropriate surrogate to make decisions rather than making treatment decisions.

THE PROXY-PHYSICIAN RELATIONSHIP

With the rise in the use and discussion of advance directives and surrogate decision makers, the doctor-proxy relationship has fallen under increased scrutiny. Research has shown that proxies and surrogates frequently feel marginalized in the decision-making process. This may be a result of misunderstandings regarding the role and authority of health care proxies and surrogates, or that physicians tend to predetermine the “correct” medical decision and promote that option before the decision maker. While some physicians feel that a medical decision should be discussed only among the family members or decision makers, proxies and surrogates are usually eager to receive information about the patient’s condition and appreciate guidance helping them to make decisions that reflect the patient’s wishes or best interests.

Recognizing the proxy or surrogate as an extension of the patient, entitled to the same respect and professional obligations as the decisionally capable patient, and eliciting his or her active participation in discussions and decisions can only enhance the quality of care provided to the patient. These obligations include, but are not limited to, providing the decision maker with timely and accurate information about the patient’s diagnosis, prognosis, and treatment options; confidentiality of the discussion between physician and proxy or surrogate; and an acknowledgement that he or she is entitled to receive advice, guidance and support. Surrogates are frequently asked about further treatment at the same time they are given the news about their loved one becoming incompetent. If possible, surrogates should be given time to absorb this new information before being asked about further treatment.

When disputes or conflicts arise, physicians should use this time to address the barriers to agreement. For instance, a physician could hold a family meeting to elicit and respond to the concerns of the entire family. Mediation and negotiation techniques are important to resolving any sort of dispute. If a physician simply facilitates discussion to help parties clarify issues and come to a mutually satisfactory solution, he or she becomes less of an arbiter and may avoid appearing confrontational. This allows physicians to support a family’s final decision and to share the burden of more difficult decisions with the decision maker or surrogate. The uncertainty that accompanies many medical decisions is compounded by knowing that the consequences of the decision will affect a vulnerable and dependent loved one. Thus, support for decision makers should be offered so that they do not feel alone in their decisions. Such support may include counseling services, access to an ethics committee, social services, or spiritual support.

Although patients cannot always anticipate their future medical conditions or health care needs, they can begin the process of advance care planning. Physicians should urge each of their patients to appoint a health care proxy and to discuss with that person health care wishes and goals. Physicians should also present other options such as a living will. During these discussions it is important for physicians to remain sensitive to and respect religious and cultural issues that may be central to the patient’s identity. If physicians take the time to encourage advance care planning with competent patients, they may avoid the difficulties associated with seeking out and appointing an appropriate surrogate.

CONCLUSION

To ensure that the autonomy of an individual patient is maintained in the case of injury or illness that results in incompetence, physicians should respect any advance directive that a patient holds. To further secure the autonomy of an incompetent patient in the absence of an advance directive, a surrogate decision maker should be identified. In this case, the decision maker should adhere to a substituted judgment standard when there is evidence of what the patient would have decided or, in the absence of such evidence, select the course of treatment that most likely promotes the patient’s well-being. Physicians should discuss with patients various options related to advance directives and the benefits of having directives in place before the need for such decisions arise.

RECOMMENDATIONS

The Council recommends that the following be adopted and the remainder of the report be filed:

Competent adults may formulate, in advance, preferences regarding a course of treatment in the event that injury or illness causes severe impairment or loss of decision-making capacity. These preferences should be followed by the health care team out of respect for patient autonomy. Patients may establish an advance directive by documenting their treatment preferences and goals or by designating a proxy to make health care decisions on their behalf.

If an incompetent patient is to receive medical treatment, a reasonable effort should be made to identify the presence of an advance directive. When such a patient lacks a documented advance directive, or when reasonable efforts have failed to uncover such documentation, physicians should defer to state law to identify a surrogate decision maker. In the absence of state law, the patient's family, or persons with whom the patient is closely associated, such as close friends or domestic partners, should become the surrogate decision maker. In the case when there is no family, but there are persons who have some relevant knowledge of the patient, such persons should participate in the decision-making process. In all other instances, a physician may wish to utilize an ethics committee to aid in identifying a surrogate decision maker or to facilitate sound decision making.

When there is evidence of the patient's preferences and values, decisions concerning the patient's care should be made by substituted judgment. This entails considering the patient's advance directive (if any), the patient's values about life and how it should be lived, how the patient constructed his or her identity or life story, and the patient's attitudes towards sickness, suffering, and certain medical procedures.

In some instances, a patient with diminished or impaired decision-making capacity can participate in various aspects of health care decision making. The attending physician should promote the autonomy of such individuals by involving them to a degree commensurate with their capabilities.

If there is no reasonable basis on which to interpret how a patient would have decided, the decision should be based on the best interests of the patient, or the outcome that would best promote the patient's well-being. Factors that should be considered when weighing the harms and benefits of various treatment options include the pain and suffering associated with treatment, the degree of and potential for benefit, and any impairments that may result from treatment. Any quality of life considerations should be measured as the worth to the individual whose course of treatment is in question, and not as a measure of social worth. One way to ensure that a decision using the best interest standard is not inappropriately influenced by the surrogate's own values is to determine the course of treatment that most reasonable persons would choose for themselves in similar circumstances.

Physicians should recognize the proxy or surrogate as an extension of the patient, entitled to the same respect as the competent patient. Physicians should provide advice, guidance, and support; explain that decisions should be based on substituted judgment when possible and otherwise on the best interest principle; and offer relevant medical information as well as medical opinions in a timely manner. In addition to the physician, other hospital staff or ethics committees are often helpful to providing support for the decision makers.

In general, physicians should respect decisions made by the appropriately designated surrogate on the basis of sound substituted judgment reasoning or the best interest standard. In cases where there is a dispute among family members, physicians should work to resolve the conflict through mediation. Physicians or an ethics committee should try to uncover the reasons that underlie the disagreement and present information that will facilitate decision making. When a physician believes that a decision is clearly not what the patient would have decided or could not be reasonably judged to be within the patient's best interests, the dispute should be referred to an ethics committee before resorting to the courts.

Physicians should encourage their patients to document their treatment preferences or to appoint a health care proxy with whom they can discuss their values regarding health care and treatment. Because documented advance directives are often not available in emergency situations, physicians should emphasize to patients the importance of discussing treatment preferences with individuals who are likely to act as their surrogates.

(References pertaining to Report 4 of the Council on Ethical and Judicial Affairs are available from the Department of Ethical Standards.)

5. PERFORMING PROCEDURES ON THE NEWLY DECEASED FOR TRAINING PURPOSES

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

Resolution 1 (I-00), "Requesting Consent for Invasive Procedures on the Newly Deceased Patient," introduced by the Medical Student Section, instructed the AMA to address the ethical concerns associated with using recently deceased individuals for training and other educational purposes. The resolution was forwarded to the Council on Ethical and Judicial Affairs.

INTRODUCTION

The newly deceased often are used in the teaching of life-saving procedures. These include endotracheal intubation, placement of central venous catheters, surgical venous cutdown, thoracotomy, pericardiocentesis, cricothyroidotomy, liver biopsy, and intraosseous needle placement. According to a 1992 survey, nearly 40% of US training programs in critical care used newly deceased patients.

This report explores whether it is necessary to obtain informed consent before training procedures can be performed on the newly dead. To answer this query, two apparently conflicting considerations need to be weighed: the importance of protecting the integrity of the newly deceased with respect to the family, society, and the profession, and the need to educate health care providers. It may be instructive to draw comparisons from ethical guidelines on organ donation. In cadaveric organ donation, body parts are used to benefit third parties and families often are involved in the informed consent process.

IS INFORMED CONSENT REQUIRED TO PRESERVE THE INTEGRITY OF THE NEWLY DECEASED?

Central to the debate over the use of newly deceased patients for training purposes is the concept of autonomy. While the issue of a deceased person's claim to autonomy is less clear, concerns over respecting the wishes of the family, being responsive to the sentiments of the health care team and trainees, and maintaining the integrity of the educational endeavor all must be addressed. On a broader level, this guideline attempts to balance the importance of having a constant source of properly trained physicians, with the imperative of individuals and society trusting physicians with their care.

Existing Ethical Guidelines

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research addressed the issue of using cadavers for teaching purposes. In its report entitled "Research Involving Comatose and Cadavers," it stated that "those conducting the research are expected to make a reasonable effort to obtain specific consent from next of kin when the research is 'beyond the normal scope of teaching and research.'" Some have interpreted these words to suggest that the Commission condones the performance of minimally invasive procedures, such as intubation, on the newly dead without the consent of next of kin.

More recently, the American Heart Association (AHA) considered the ethics of practicing intubation skills on the newly dead as part of comprehensive guidelines for cardiopulmonary resuscitation and emergency cardiac care. It has stated that the practice is ethically justifiable, adding that "the sensibilities of family and staff should be compassionately respected and consent obtained whenever practical."

Addressing Concerns Related to Obtaining Consent

The principal argument put forward by those who consider it unnecessary to obtain informed consent to perform procedures on the newly dead focuses on necessity and the benefit gained. The argument relating to medical necessity relies not only on the ongoing need for newly trained physicians, but also on the idea that alternative models for teaching, such as mannequins, animals, or video, are inadequate. While alternative models are useful in teaching a number of procedures, studies have shown that using animal models or mannequins were unsuitable to teaching certain procedures. Given that some important medical procedures have no adequate alternative models for teaching other than actual patients, it is further argued that the value of performing procedures on newly deceased patients resides in the benefit society derives from having well-trained medical providers.

In contrast, a strict requirement to obtain consent from an individual patient before undertaking any medical procedures stems from respect for patient autonomy. This perspective prohibits the use of individuals merely as a means to an end, even if that end is beneficial. While arguments for autonomy may apply easily to live patients, it is less clear how they apply to cadavers. Those who argue that consent is not necessary prior to the performance of procedures on dead bodies emphasize that the right of privacy, which includes decision making over one's body, cannot be exercised after death. In other words, it is argued that dead persons have no claim to autonomy. In support of this view, courts generally have held that no individual rights survive death.

Some have justified performing procedures on the newly dead before obtaining explicit consent through the notion of presumed consent. This doctrine generally applies to circumstances in the emergency department where patients often arrive unconscious and are provided with treatment that is expected to save their lives. In the case of practicing procedures, the doctrine would be expanded: it would be presumed that a patient consents to all that follows from admission, including the possible use of the cadaver for training, unless a preference has been stated otherwise. Such an extension is problematic, however, since patients who receive life-saving treatment without their consent benefit from the procedures, whereas dead patients who are used for training purposes do not. The doctrine of presumed consent also has been examined in the context of organ donation. The Council, in Opinion 2.155 on "Mandated Choice and Presumed Consent for Cadaveric Organ Donation," found that a policy of presumed consent, even one that allows an "opt-out" mechanism, raises serious ethical concerns in the absence of effective means to document and honor refusals.

Whether or not patients have autonomy interests that survive death, there is still the question of what interests the family has in controlling what happens to the body. Courts have recognized the interest of next-of-kin to claim the body for burial services, from which a protection against mutilation has been derived. In addition, under model legislation provided by the Uniform Anatomical Gift Act (Sec. 2), next-of-kin are given the choice to make a gift of a deceased person's organs or tissue. Thus it appears that the family of a deceased patient has a legally recognized interest in how the remains of the body are to be treated.

Advocates for the use of cadavers without consent raise the practical concern that, if families were asked to consent to the use of newly deceased patients for training purposes, most would refuse, which would result in a decrease of the number of training opportunities. There is little support for this view in the medical literature.

Studies specific to gaining consent for performing procedures on the newly deceased demonstrate that consent can be obtained from a majority of families, particularly when requests are made in a sensitive manner and are framed in terms of the importance of enabling physicians to save other lives. In two clinically-based studies, two populations of 44 families were asked for their consent to allow physicians to perform endotracheal intubation on their deceased infant or wire-guided retrograde tracheal intubation, which involves a small incision in the neck, on their deceased adult relative. The researchers found that 32 families (73%) granted consent for intubation of their newly deceased infant for training purposes, and that 26 families (59%) granted consent for wire-guided retrograde intubation. The majority of individuals surveyed in later studies would agree to subject themselves or a relative to training procedures after death, and only a minority of respondents would allow such procedures without prior permission. This suggests that most families of deceased patients want to help in the educational endeavor and that trust in individual physicians is central to families who consent to such procedures. Likewise, greater trust in the profession can be instilled in the public if consent is gained before such procedures take place.

Closely linked to securing this trust is the finding that feelings of apprehension and discomfort among medical trainees and staff are intensified when the newly deceased are used in clinical training without consent. One study reported feelings of hesitation and uneasiness among medical trainees who had performed intubation procedures on newly deceased infants. Some of the trainees indicated that they were more comfortable with the procedures once they knew consent from the parents had been granted. Furthermore, a subsequent study indicated that a majority of the nursing staff and student nurses surveyed had discussed their personal feelings about using the newly deceased for educational purposes with colleagues. Thus, requesting consent from the family to perform such procedures is important to respecting sensitivities not only of the family, but also of the medical team. Moreover, carrying out procedures on the newly deceased without consent may have an undesirable effect on impressionable trainees: weakening rather than strengthening their appreciation of the ethical requirement for holding the interests of individual patients above social needs or desires for personal training. Although physicians would rather not approach the family to gain consent for potentially objectionable procedures at an inopportune time, this discomfort does not seem to override the benefits of gaining consent.

We also observe that there are risks, which may be substantial, associated with performing procedures on newly deceased individuals without consent. One is the risk of damaging trust in the medical profession should such practices become public knowledge. There are recent examples of the damage done by revelations of uses of dead bodies without consent. Moreover, performing procedures on a newly deceased individual without obtaining consent could contravene state laws on the handling of corpses. Such actions also may result in undue emotional distress to the family of the deceased, a potentially actionable offense.

Guidelines for the Ethical Use of the Newly Deceased for Training Purposes

An ethically sound policy on the performance of procedures on the newly deceased must ensure that the interests of all parties involved (i.e., patients, families, health care providers, trainees and society) are respected. This can be achieved if a few preliminary considerations are addressed before medical trainees perform procedures on the newly deceased. For instance, the teaching of life-saving skills should be the culmination of a structured training sequence, rather than rely on random opportunities. Use should be limited to those procedures that are best learned using anatomic structures that are lifelike in softness and pliability. Training should be performed under close supervision, in a manner and environment that respects the wishes and values of all involved parties.

Finally, an ethical policy on performing procedures on newly deceased patients must respect the fundamental principle of autonomy, which medicine has embraced and expanded over the past several decades. If patients have had an opportunity to express preferences regarding what is to be done with their bodies after death, such preferences must be respected. In the absence of expressed preferences, families should be consulted, as is the norm for organ donations and autopsies. Training procedures on newly deceased patients should not be undertaken without reasonable efforts to obtain informed consent, as would be done for other medical decisions. When efforts to obtain consent within a reasonable time frame fail, training supervisors must forego the training opportunity. In the case that consent has been granted, any procedures performed on a newly deceased individual should be limited to those practices to which consent has been granted.

Physicians should explain to families the educational needs that are served by the use of newly deceased patients. When discussing the benefits of educating future health care providers with the family, some researchers have found that framing the request as an attempt to elicit the substituted judgement of the dead person makes consent more likely. For example, asking whether the patient had discussed the choice to be treated at an educational institution or whether the patient was generous and interested in helping others. Requesting consent in this manner respects both the wishes of the family and the memory of the deceased.

CONCLUSION

Performing procedures on the newly deceased without attempting to gain consent from the family or relying on the application of presumed consent in this context “runs counter to an evolving norm of our society and threatens to erode further the trust of the community in the medical profession.” Although there are some situations that may justify a waiver of informed consent, or an extension of presumed consent, such doctrines cannot be relied upon in the use of newly deceased for training purposes. The benefits of neglecting consent in this case do not outweigh the impositions placed on patient autonomy, trainee and staff comfort, and family interests, as well as risks to trust in the medical profession and potential legal liabilities.

RECOMMENDATIONS

The Council recommends that the following be adopted and the remainder of the report be filed:

Physicians should work to develop institutional policies that address the practice of performing procedures on the newly deceased for purposes of training. Any such policy should ensure that the interests of all the parties involved are respected under established and clear ethical guidelines. Such policies should consider rights of patients and their families, benefits to trainees and society, as well as potential harm to the ethical sensitivities of trainees, and risks to staff, the institution, and the profession associated with performing procedures on the newly deceased without consent. The following considerations should be addressed before medical trainees perform procedures on the newly deceased:

1. The teaching of life-saving skills should be the culmination of a structured training sequence, rather than relying on random opportunities. Training should be performed under close supervision, in a manner and environment that takes into account the wishes and values of all involved parties.
2. Physicians should inquire whether the deceased individual had expressed preferences regarding handling the body or procedures performed after death. In the absence of previously expressed preferences, physicians should request permission from the family before performing such procedures. When reasonable efforts to discover previously expressed preferences of the deceased or to find someone with authority to grant permission for the procedure have failed, physicians must not perform procedures for training purposes on the newly deceased patient.

(References pertaining to Report 5 of the Council on Ethical and Judicial Affairs are available from the Department of Ethical Standards.)

6. AFFILIATE MEMBERSHIP

HOUSE ACTION: ADOPTED

The Council on Ethical and Judicial Affairs recommends the following individual for affiliate membership in the American Medical Association:

Individuals Who Have Attained Distinction in Their Field of Endeavor

Jonathan L. Burkhart

Mr. Burkhart is Associate Director, House of Delegates Affairs at the American Medical Association. In this capacity, he is responsible for many of the programs, projects, and planning for the House office and the provision of assistance to the Speakers of the House. Previously he served as Director of Young Physician Services at the AMA, where he directed the activities of the Young Physicians Section. He has been an AMA employee for 15 years, and was certified by the Young Physicians Section.