

OPINIONS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinions, 1-6, were presented by Frank A. Riddick, Jr., MD, Chair:

1. THE PATIENT-PHYSICIAN RELATIONSHIP

HOUSE ACTION: FILED

At the 2001 Annual Meeting, the American Medical Association House of Delegates reviewed and approved the recommendations of CEJA Report 1-A-01, "The Patient-Physician Relationship." The report provides guidelines to aid physicians in considering the ethical basis for the patient-physician relationship. The Council issues this Opinion, which is derived from the conclusions of CEJA Report 1-A-01. It will appear in the next revised edition of *The Code of Medical Ethics*.

10.015 The Patient-Physician Relationship

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.

A patient-physician relationship exists when a physician serves a patient's medical needs, generally by mutual consent 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.

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.

Within the patient-physician relationship, a physician is ethically required to use sound medical judgment, holding the best interests of the patient as paramount. (I, II, VI, VIII)

2. ETHICAL CONSIDERATIONS IN INTERNATIONAL RESEARCH

HOUSE ACTION: FILED

At the 2001 Annual Meeting, the American Medical Association House of Delegates reviewed and approved the recommendations of CEJA Report 2-A-01, "Ethical Considerations in International Research." The Report provides guidelines to physicians conducting international research. The Council issues this Opinion, which is derived from the conclusions of CEJA Report 2-A-01. It will appear in the next revised edition of *The Code of Medical Ethics*.

2.077 Ethical Considerations in International Research

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. (I, IV, VII, VIII, IX)

3. FILMING PATIENTS IN HEALTH CARE SETTINGS

HOUSE ACTION: FILED

At the 2001 Annual Meeting, the American Medical Association House of Delegates reviewed and approved the recommendations of CEJA Report 3-A-01, "Filming Patients in Health Care Settings." The report provides guidelines to aid physicians with ethical considerations when proposing to film patients in the healthcare setting. The Council issues this Opinion, which is derived from the conclusions of CEJA Report 3-A-01. It will appear in the next revised edition of *The Code of Medical Ethics*.

5.045 Filming Patients in Health Care Settings

The use of any medium to film, videotape, or otherwise 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; 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. Also, persons involved in the direct medical care of the patient who feel that the filming may jeopardize patient care should 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.

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. (I, IV, VII, VIII)

4. SURROGATE DECISION MAKING

HOUSE ACTION: FILED

At the 2001 Annual Meeting, the American Medical Association House of Delegates reviewed and approved the recommendations of CEJA Report 4-A-01, "Surrogate Decision Making." The report provides guidelines to aid physicians in considering the ethical basis for surrogate decision making. The Council issues this Opinion, which is derived from the conclusions of CEJA Report 4-A-01. It will appear in the next revised edition of *The Code of Medical Ethics*.

8.081 Surrogate Decision Making

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 specifying either appropriate surrogate decision makers or a process to identify them, the patient's family should become the surrogate decision maker. Family includes persons with whom the patient is closely associated such as close friends or unmarried living partners. 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. (I, III, VIII)

5. PERFORMING PROCEDURES ON THE NEWLY DECEASED FOR TRAINING PURPOSES

HOUSE ACTION: FILED

At the 2001 Annual Meeting, the American Medical Association House of Delegates reviewed and approved the recommendations of CEJA Report 5-A-01, "Performing Procedures on the Newly Deceased for Training Purposes." The report provides guidelines to aid physicians with ethical considerations in the context of performing procedures on the newly deceased. The Council issues this Opinion, which is derived from the conclusions of CEJA Report 5-A-01. It will appear in the next revised edition of *The Code of Medical Ethics*.

8.181 Performing Procedures on the Newly Deceased for Training Purposes

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 of the body or procedures performed after death. In the absence of previously expressed preferences, physicians should obtain 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.

In the event postmortem procedures are undertaken on the newly deceased, they must be recorded in the medical record. (I, V)

6. CONFIDENTIALITY OF MEDICAL INFORMATION POSTMORTEM, AMENDMENT

HOUSE ACTION: FILED

Although Resolution 7 (A-01), "Ethical Guidelines for the Survival of the Patient-Physician Privilege Postmortem," introduced by the North Carolina Delegation, was not adopted, the Council on Ethical and Judicial Affairs nevertheless took under consideration whether Opinion 5.051 could be clarified to address some of the issues raised in the resolution. Accordingly, CEJA proposes the following amendment to Opinion 5.051, "Confidentiality of Medical Information Postmortem." The revised Opinion will appear in the next edition of the *Code of Medical Ethics*.

5.051 Confidentiality of Medical Information Postmortem

All medically related confidences disclosed by a patient to a physician and information contained within a deceased patient's medical record, including information entered postmortem, should be kept confidential to the greatest possible degree. However, the obligation to safeguard patient confidences is subject to certain exceptions that are ethically and legally justifiable because of overriding societal considerations (Opinion 5.05, "Confidentiality"). At their strongest, confidentiality protections after death would be equal to those in force during a patient's life. Thus, if information about a patient may be ethically disclosed during life, it likewise may be disclosed after the patient has died.

Disclosure of medical information postmortem for research and educational purposes is appropriate as long as confidentiality is maintained to the greatest possible degree by removing any individual identifiers. Otherwise, in determining whether to disclose identified information after the death of a patient, physicians should consider the following factors:

1. The imminence of harm to identifiable individuals or the public health;
2. The potential benefit to at-risk individuals or the public health (e.g., if a communicable or inherited disease is preventable or treatable);
3. Any statement or directive made by the patient regarding postmortem disclosure;

4. The impact disclosure may have on the reputation of the deceased patient; and
5. Personal gain for the physician that may unduly influence professional obligations of confidentiality.

When a family or other decision maker has given consent to an autopsy, physicians may disclose the results of the autopsy to the individual(s) that granted consent to the procedure. (IV)

Issued December 2000 based on the report "Confidentiality of Medical Information Postmortem," adopted June 2000. Updated December 2001.

REPORTS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1-5, were presented by Frank A. Riddick, Jr., MD, Chair:

1. ENCOURAGING PILOT STUDIES OF FINANCIAL INCENTIVES FOR CADAVERIC ORGAN DONATION

HOUSE ACTION: REFERRED

INTRODUCTION

It is widely recognized that the number of cadaveric organs procured by the current system fails to alleviate the shortage that exists today. This results in a large number of potentially preventable deaths. Whether this failure is due to a lack of knowledge or interest on the part of the public or of health care professionals, public distrust of the transplantation enterprise, insufficient effort by procurement organizations, or the absence of incentives to persuade potential donors to consent to donation, the fact remains that the list of potential recipients appears to be growing at a rate four times greater than the rate of donors.

Yet, over the last 25 years, countless programs have been devised to increase the number of organ donors. Most of these initiatives have focused on what motivates or hinders a person's decision to become an organ donor. Programs to improve organ donation rates have been aimed at public and professional groups. These have included widespread educational campaigns aimed at motivating individuals to become donors. They also have included mandated choice legislation, the establishment of the Organ Procurement and Transplantation Network (OPTN), donor card programs, and the creation of specialized organ donation teams within hospitals that discuss organ donation with families and patients. Despite these efforts, cadaveric donation rates have remained nearly stable over the past decade.

The Council offers the following report to encourage the medical and scientific communities to reexamine donor motivation. Building on the work it had done in 1993, which led to the current Opinion on "Financial Incentives for Organ Donation," this report reexamines the ethical implications of financial incentives and the impact they may have in shaping decisions to donate organs. In particular, this report considers the value of pilot studies that would help measure the effect of incentives, not only on donation rates, but also on public perception of the transplant enterprise and of the meaning of organ donation.

For the purposes of this report, donation and procurement of organs is considered independently from the allocation of organs. It is assumed that no changes would be made to the current system of organ distribution, such that allocation algorithms developed by the OPTN would continue to govern, and transplant recipients would continue to be selected according to ethically appropriate criteria related to medical need rather than ability to pay.

The ethical principles underlying this report are physicians' paramount obligation to their patients (Principle VIII), their responsibility to contribute to the improvement of the community (Principle VII), and their support of access to care (Principle IX). Based on these Principles of Medical Ethics, the Council encourages physicians to support exploration of new alternatives in the pursuit of ethical means to increase the organ supply.

DONOR MOTIVATION

Determining how best to motivate a person to become an organ donor is essential to increasing the number of potential donors. The National Organ Transplant Act of 1984 (NOTA) forbade the provision of any "valuable consideration" to organ donors, ruling out any form of reward or compensation of expenses engendered by donation. It also created the OPTN to be managed by a private nonprofit organization. The contract was awarded to the United Network for Organ Sharing (UNOS).

While one of the major purposes of UNOS is to encourage organ donation, it is the position of UNOS that the only ethically sound motivation for donation is altruism (i.e., the absence of any personal benefit beyond the satisfaction of giving). Thus, most of the educational and motivational campaigns to increase donation have appealed to the altruistic aspect of saving the lives of others. Some feel that appealing only to potential donors' altruistic motivations is limiting and may foreclose a broad range of programs that also might motivate organ donation. Others feel that diluting the altruistic intent of donating organs might undermine important social values and elicit negative responses that could decrease the number of organ donors.

Considering that the most common reason for missed donation opportunities is denial of consent by the donor's family, any effort to increase the rate of organ donation would likely need to be directed beyond individuals in order to target donor families as well. Many states are currently considering legislation that would prohibit a family from overruling a patient's documented wish to be an organ donor. Yet, it is still unclear whether prohibiting families from overriding documented wishes would result in a net increase of organs.

POTENTIAL STRATEGIES

In a survey of the general public, 85% of respondents supported organ donation and 69% of those surveyed indicated that they were likely to want their own organs to be donated. In practice, requests for donation are granted only about half the time. This decline in people's support for donation between the time they answer a questionnaire and the time they are asked to authorize the donation of a deceased person's organs may be explained in part by the fact that transplantable cadaveric organs are usually obtained from people who died suddenly in an unexpected and untimely manner. Families may be asked about donation at a time when they are deeply distressed. Also, many people have religious or personal beliefs that bodies should be buried intact. Others may not trust the health care system as a whole, or the providers who were involved in the care of their now deceased relative. Still others have deep misunderstandings about the meaning of brain death, or about the value of transplantation, and may not be open to learning more about these matters when they are facing the loss of a loved one.

Carefully determined financial incentives may provide additional motivations to induce marginally resistant families to agree to donate; several models have been proposed. Some would benefit the donor directly, while others, as in the case of future contracts, would benefit a deceased patient's family. By entering into a future contract, a competent adult would agree to donate his or her organs after death. In return, the appropriate agency would agree to provide some financial remuneration to the donor's family or estate after the organs had been retrieved and judged suitable for transplantation. A bill currently before Congress, for example, would allow for the implementation of a future contract that includes a tax credit of up to \$10,000 on the estate of the deceased donor. CEJA Report 6-I-93, "Financial Incentives for Organ Procurement: Ethical Aspects of Future Contracts for Cadaveric Donors," supports the implementation of a pilot program to study the influence of future contract incentives on organ donation rates. Another proposal that would provide financial support directly to the donor's family has been developed in Pennsylvania, where a law was passed that allows compensation for some of the funeral expenses incurred by the family of the donor. However, this program has still not been implemented because of NOTA's prohibition against any valuable consideration for organ donation.

Direct monetary payments to families who agree to donation has also been recommended. One study has shown that payment of \$500 to \$1000 for donation would increase donation rates sufficiently to nearly eliminate the kidney waiting list.

CONCERNS

The degree to which any financial incentive will diminish the number of patients who die on the waiting list each year is unknown. Therefore, the potential benefits to be gained from each proposal discussed above remains speculative and must be weighed against possible harms before any such program is widely implemented. This highlights the importance of doing empirical studies to allow weighing of benefits and harms. For example, if a program produces little discernable harm to potential donors or their families and also saves lives due to increased organ donation rate, everyone benefits. But if certain harms are found, in the face of saving a certain number of lives, then the best resolution of the resulting conflict may not be readily apparent to physicians or to policymakers. This may be a particular problem for physicians, who have the potentially competing ethical interests in respecting the autonomy and dignity of potential donors and their families, and in improving the care of patients in need of organs.

These competing ethical considerations also have broader social implications, including the possibility that incentives might dilute a desirable spirit of altruism, might imply that the human body and its parts can be treated as commodities, and could undermine the voluntariness of organ donation.

Reducing Altruism

Under the existing organ procurement system, the only acceptable motivation for organ donation is altruism. Many who are opposed to financial incentives fear that removing organ donation from an altruistic framework would alienate people who until now have supported organ donation. They are concerned that, as a result of introducing these incentives, the number of potential donors would decrease. It should be noted, however, that a fall in donor numbers has not been observed in the context of blood donation, where payment for blood has been introduced in addition to voluntary programs.

Moreover, financial incentives per se may not eliminate altruism as a motivation for organ donation. The motive to donate may be in part self-interested if there is an incentive, but still accompanied by altruistic motives. Because altruism is a personal characteristic, it is possible that a certain level of financial incentive may be sufficient to change a non-donor to a donor, while having no effect at all on that individual's nor the overall level of society's altruism.

Financial benefits to families could be viewed as a token of societal gratitude, similar to tax incentives for donations to charitable organizations. The degree to which altruism might be changed by financial incentives remains unexplored even though appropriately designed pilot studies could provide empirical evidence to help answer this question.

The Human Body as a Commodity

Another argument in opposition to incentives holds that such programs would fuel an already disturbing trend towards viewing the human body as a source of profit. Although it is acknowledged that one's body is significantly different from other forms of property, some limited ownership rights to the body are recognized. For example, blood, reproductive material, and other tissues can be sold. There seems to be no compelling reason why viable solid organs should be treated differently from less complex tissues on moral grounds. Moreover, donation itself implies a property right in organs. As one author puts it: "Donation itself depends on some notion of property rights, for presumably one cannot give away what one does not own any more than one can sell it."

Finally, given the pluralistic expression of religious and moral beliefs tolerated and even encouraged in this country, the extent to which such commodification could be viewed as disrupting our social fabric is unclear. Sociological methodologies are available to examine empirically the strength of social fabric, so even this soft factor can be measured.

Voluntariness of consent

Fundamental to the concept of consent is the element of voluntariness. To coerce a person into making a medical decision is to violate the person's right to make an autonomous decision concerning the use of his or her body. Thus, protecting the voluntariness of the decision to become a donor must remain an important consideration for any program offering financial incentives.

In particular, some hold that socioeconomically disadvantaged individuals or their families would more easily be influenced to become donors due to their financial situation, seriously undermining society's egalitarian ideals, and placing much of the burden of organ donation on those less well off. However, we find little difficulty in allowing poorer members of society to make many choices due to their financial circumstances, such as working at jobs avoided by most because they are undesirable, uncomfortable, or dangerous. Some have argued that the idea of coercion is best understood as forcing others to do things they would not otherwise choose to do.

Even if such concerns were valid, financial incentives such as tax credits or payment to a charitable organization selected by the donor could reduce the possibility of undue influence. For example, in the case of tax credits, the donor would have to possess a significant estate to take advantage of the tax credit. Overall, programs could be conceived that would combine direct payments and estate tax credits so that donation would be equally attractive over the entire socioeconomic spectrum.

In the case of future contracts, some have argued that they would appeal mostly to lower socioeconomic groups, who would therefore bear most of the burden of organ donation. Others have countered that it is paternalistic to deny the poor a choice that could improve their condition.

THE NEED FOR EMPIRICAL DATA

In the previous section, ethical concerns regarding the potential harms that could come from the use of financial incentives for organ donation were surveyed. However, it is important to note that there is a dearth of empirical evidence supporting those concerns. Nearly all of the arguments against financial incentives are based on assumptions that can be proved or disproved by empirical study. Factual evidence that would determine the presence or absence of harm to individuals or groups of individuals could in fact resolve many of the policy debates between those who object to financial incentives for cadaveric organ donation and those who favor such incentives.

A thorough discussion of this matter also must include an examination of the costs of foregoing such studies. Currently, about 15 patients die each day waiting for an available organ. If policymakers, ethicists, or legislators prohibit the implementation of programs that could be shown to increase the number of available organs and reduce the number of deaths, then they must bear some moral responsibility for the patients who die from lack of an organ transplant. Therefore, a better informed debate is necessary, one that can occur only after the effectiveness of various incentive models has been measured.

CONCLUSION

The chronic shortage of organs available for transplantation results in a large number of potentially preventable deaths. In the last two decades, efforts to increase organ donation through public and professional education have failed to meet the growing demand for organs. More innovative methods to increase the number of cadaveric donations are required to help address the shortage that can be tested in limited pilot studies.

Pilot studies should be undertaken to measure the impact of incentives on the rate of donation and on some of the values that, until now, have been assumed to be central to organ donation, namely altruism, the non-commercial nature of the body and its parts, and the voluntariness of donation. Because of the uncertainty of benefits and harms that might arise and because of likely resistance by some to the idea of financial incentives, initial studies should be limited in scope. Such studies should be designed carefully, so as to meet all ethical standards that are generally applied to research. Moreover, given the pluralism of American society, any pilot study should be consistent with the needs, values, and mores of the particular population under study; therefore, these initiatives should solicit guidance and advice from the intended study population at the outset. Pilot studies should be limited to small populations, perhaps no larger than states or transplantation regions, have clearly measurable outcome variables to assess their effectiveness, and should be completed within defined time frames.

Current federal law prohibits the types of proposals examined in this report; Congressional action would be required to waive the law for all such pilot studies. However, we have provided reasons to pursue pilot programs, in order to obtain much needed data on the effectiveness of incentives in increasing the rate of donation without causing harm to patients or groups of patients, and without damaging the social fabric or undermining the ethical foundation of transplantation.

RECOMMENDATION

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

Financial incentives to increase the rate of cadaveric organ donation have generally been viewed as being unethical, despite cogent countervailing arguments. Many of the assumptions underlying this debate are amenable to empirical investigation. With the aim of saving many lives by increasing the rate of organ donation, pilot studies that measure the effect of financial incentives on the rate of cadaveric organ donation may provide evidence of various strategies' benefits or harms to patients and to communities.

Physicians should encourage pilot programs that investigate the effects of financial incentives for cadaveric organ donation. Such pilot studies should be implemented only after certain considerations have been met. Prior to the implementation of pilot studies:

- consultation and advice from the population in which the study is to take place should be sought;
- objectives and strategies, as well as sound scientific design, measurable outcomes and set time frames should be clearly defined in written protocols; and
- such protocols should be publicly available and approved by appropriate oversight bodies, such as institutional review boards.

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

2. PRIVACY IN THE CONTEXT OF HEALTH CARE

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

Recently, the Council on Ethical and Judicial Affairs (CEJA) presented a report addressing ethical concerns raised by filming patients in health care settings. In so doing, it came to the attention of the Council that, although Opinions included in the AMA's *Code of Medical Ethics* allude to the concept of privacy, none speaks to the issue directly. Therefore, the Council offers the following report to provide general ethical guidance on the issue of privacy.

SCOPE

The Council recognizes that the topic of privacy has received considerable attention by Congress; medical privacy and confidentiality of identifiable health information have been subject to federal legislation. The Health Insurance Portability and Accountability Act (HIPAA) was enacted in 1996 and included provisions directing Congress to pass privacy legislation by August 1999. After Congress was unable to pass the legislation which was intended to regulate the use of health information created or maintained by health care providers, the Secretary of Health and Human Services (HHS) issued a set of privacy rules. The specific rules that were developed created a considerable amount of concern among health care professionals as to whether the privacy protections might hinder the patient-physician relationship more than enhance it. Recently, HHS addressed some of these concerns in order to balance the need to respect patient privacy and confidentiality with the need to ensure efficient medical care. Essentially, the rules attempt to strike a balance between privacy protection and public health considerations, including access to records for public health uses including public health, research, and investigation of abuse, neglect, and violence.

Regardless of the effectiveness of the current federal privacy regulations, underlying these regulations are important ethical concepts of which all physicians should be respectful and which, therefore, warrant further analysis by the Council.

CONCEPTUAL DEFINITIONS OF PRIVACY

In the United States, privacy is linked to freedom from intrusion by the state or other persons. It also is understood to refer to a domain of personal decisions about important matters. In less legalistic forms, privacy can be viewed as a necessary condition for maintaining intimate relationships that entail respect and trust, such as love or friendship.

Respect and trust are also important in professional relationships, such as between patients and physicians. Moreover, in the health care setting, privacy has come to be linked most directly with one's ability to make decisions related to one's body without intrusion by others.

According to two leading bioethicists, several forms of privacy are particularly relevant in the context of health care: (1) physical, which focuses on individuals and their personal spaces; (2) informational, which involves specific personal data; (3) decisional, which focuses on personal choices; and (4) associational, which refers to family or other intimate relations. Such respect for patient privacy is a fundamental expression of patient autonomy and is a prerequisite to building the trust that is at the core of the patient-physician relationship.

From the perspective of the HIPAA regulations, informational privacy has been the focus of most debates since it relates to matters such as the disclosure of health information, more specifically disclosure of health information via electronic transmission, and the use of electronic communication. However, to view privacy as merely limiting access to information about an individual misses significant components of privacy that are of particular concern in the context of health care. Specifically, physical privacy is an issue that has been neglected in recent debates but remains important to many patients. Although there are limitations to the physical privacy in a health care setting, physicians can strive to protect it, for example by providing care in a more private area when possible.

Privacy as it relates to confidentiality

Confidentiality is one of the oldest medical ethical precepts, dating back to the Hippocratic Oath: “What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about.” Drawing from its rich history, confidentiality remains widely acknowledged as a fundamental ethical tenet of medicine, as patients must be willing to confide sensitive and personal information to health care professionals. Therefore, its value in the context of the patient-physician relationship stems partly from the need for patients to trust their physicians, and for physicians to express their loyalty to patients.

Privacy and confidentiality are companion concepts. Both are in the opposite realm of what is defined as “public,” and relinquishing personal privacy is always a precondition for establishing confidentiality. However, it is also important to note that they differ. In particular, privacy can refer to singular features of persons such as thoughts or feelings. Most importantly, it has been considered as a right or interest. In contrast, confidentiality always refers to a relational context whereby a person makes a promise, that information divulged by another person will not be further disseminated.

Even though many patients view confidentiality as an unwavering safeguard, there are of course exceptions. Similarly, privacy is not absolute. The provision of affordable and efficient care often requires that patients come to health care facilities, rather than receive care in their home. In such settings, space is relatively scarce, and unavoidably patients must share many common areas, and even rooms. Disclosure of personal information will be required for effective treatment, and many health care providers, and ancillary parties will know any decisions made.

ETHICAL FOUNDATIONS AND IMPLICATIONS

According to the concept of autonomy, an individual has the ability to act freely in accordance with a self plan, and can participate in the decisions that influence his or her “fundamental sense of personhood.” The principle of respect for autonomy can be viewed in two ways: as either a negative or a positive obligation. As a negative obligation, the principle states that autonomous actions should not be subjected to the constraints of others. Respect for autonomy as a positive obligation requires promoting decisions based on choices that reflect an individual’s values and preferences.

Clearly, autonomy has direct bearing on the manner in which a patient receives care. Physicians respect patient autonomy by ensuring that a patient is given appropriate information on which a decision regarding medical care can be based. Furthermore, in the context of health care, the concept of autonomy often intersects with the concept of privacy. For instance, the lack of physical privacy can influence a patient’s actions or decisions. A patient may be preoccupied with his or her environment because it lacks privacy to the point where it is not possible for the patient to engage in an open discussion. This would result in undermining the informed consent process, such that decisions made by the patient would be a poor reflection of his or her true values or preferences.

As briefly discussed above, the concept of privacy is linked to confidentiality as a means of protecting patients’ informational privacy. In effect, confidentiality concerns the communication of private and personal information from one person to another, where it is expected that the recipient of the information will not disclose it to a third party. This concept is reiterated in Principle IV of the AMA’s *Code of Medical Ethics*, which states, “A physician...shall safeguard patient confidences and privacy within the constraints of the law.” The belief that information will be appropriately handled extends to another key ethical concept, that of trust--or reliance upon the moral character and competence of another person. When patients trust their health care providers, their decisions are an expression of their autonomy. In contrast, when a lack of trust exists, a breakdown in communication is more likely to occur, such that choices are not adequately presented to a patient or the patient is reluctant to express preferences.

CONCLUSION

Aside from the legal protections that are offered by the right to privacy, there are such important ethical elements that it ought to receive careful consideration in the context of health care. Indeed, whether it is physical, informational, decisional, or associational, each manifestation of privacy has direct repercussions on the ability of a patient to act autonomously. Moreover, it is important to recognize that confidentiality speaks primarily to the issue of informational privacy, but that the notion of trust, which is a cornerstone of the patient-physician relationship, requires that a patient's privacy be respected in all of its aspects.

RECOMMENDATION

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

In the context of health care, emphasis has been given to confidentiality, which is defined as information told in confidence or imparted in secret. However, physicians also should be mindful of patient privacy, which encompasses information that is concealed from others outside of the patient-physician relationship.

Physicians must seek to protect patient privacy in all of its forms, including (1) physical, which focuses on individuals and their personal spaces; (2) informational, which involves specific personal data; (3) decisional, which focuses on personal choices; and (4) associational, which refers to family or other intimate relations. Such respect for patient privacy is a fundamental expression of patient autonomy and is a prerequisite to building the trust that is at the core of the patient-physician relationship.

Privacy is not absolute, and must be balanced with the need for the efficient provision of medical care and the availability of resources. Physicians should be aware of and respect the special concerns of their patients regarding privacy. Patients should be informed of any significant infringement on their privacy, of which they may otherwise be unaware.

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

3. FAMILIAL NATURE OF GENETIC INFORMATION

HOUSE ACTION: REFERRED

INTRODUCTION

In the past, information about genetic status has been sought primarily in the context of reproductive counseling. It is now being obtained by a broader patient population, such that healthy people who wish to learn whether they have a predisposition to adult-onset genetic conditions are now requesting genetic testing. Consequently, more people are obtaining individual genetic information that, unlike other medical information, directly concerns not only the tested individuals (proband), but their biological relatives (kindred) as well. It is this familial aspect that poses new ethical quandaries for physicians by challenging the limits of medical confidentiality.

According to many commentators, the role of genetic testing in medicine has not fundamentally changed the responsibility of physicians to respect patient autonomy and act in their patients' best interests. However, according to others, it has raised new questions regarding physicians' responsibilities when an individual patient's genetic information could reveal information about biological relatives.

This report explores whether the informed consent process is any different in the context of genetic testing, discusses circumstances where the familial quality of genetic information compromises the duty of confidentiality, and addresses under what circumstances, if any, a physician should take steps towards disclosing a patient's information that could avoid harm to relatives.

GENETIC INFORMATION AND CONFIDENTIALITY

In general, AMA ethics policy includes and is derived from principles that recognize physicians' duty to safeguard the confidences of their patients (Principle IV) to whom their responsibilities are paramount (Principle VIII). Physicians, as such, have a general duty to treat information acquired from the patient in the context of the patient-physician relationship as confidential. As stated in Opinion 5.05, "Confidentiality," "the physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by the law."

Some commentators who focus on the sensitivity of genetic information have called for more stringent confidentiality measures to protect it. Genetic testing has the potential to reveal information, until then unknown, that presents some risk for an unsuspecting individual and biological relatives. The uneven scientific validity and reliability of these findings, the variable penetrance of genes, and the absence of medical interventions for some identified risks are some of the many reasons why individuals may wish to protect even more securely their genetic information. Regardless of whether genetic information signals risks that exist and are likely to materialize into an illness or disability, such information also may warrant special protection for fear of discrimination and stigmatization.

Other commentators who focus on the non-individualistic or biological cohort ownership of genetic information question the practice of asking physicians to protect the confidentiality of this information from potentially affected relatives. Among holders of this view, there are those who would argue that the familial quality of genetic information, in fact, requires extending the obligation of physicians beyond the patient, to include immediate biological relatives. The rationale behind this position is that a physician's knowledge of information that pertains as much to the patient as to the family creates a professional obligation that extends to other affected parties--nowhere more perhaps than when the physician already has a professional relationship with the patient's biological relatives. Under this view, confidentiality's basis in the claim of individual privacy is significantly compromised in the family context, where the information is at once individual and familial. Beyond the circle of affected relatives, however, the physician's obligation towards the confidentiality of patient information is considered to remain unchanged.

Finally, a third perspective exists among those who reject genetic exceptionalism. The limits of confidentiality are no more and no less than those that already exist for other kinds of medical information. As such, confidentiality is near absolute: physicians have a duty to maintain the confidentiality of genetic information about a patient, save "certain exceptions which are ethically and legally justified because of overriding social considerations."

INFORMED CONSENT

Genetic information poses some special challenges, due to its inherited, and therefore shared, nature. Challenges can arise when the need to maintain an individual patient's confidentiality and autonomy conflicts with the duty to inform other biological family members. The pre-testing period offers health care professionals the opportunity to educate and counsel their patients in an effort to prepare for these difficult situations or, better yet, to prevent them.

Before they can arrive at a voluntary, informed decision about whether to undergo genetic testing, individuals need to receive information regarding the overall risks and benefits associated with the procedure, including potential implications of test results for them and immediate biological relatives. They need to understand why their relatives may have a clear interest in genetic information and in deciding whether to seek treatment, to make informed reproductive decisions, or to consider lifestyle changes. Patients also need to understand why anyone affected by a genetic condition would prefer to not know out of fear of social stigmatization, fear of insurance, or work-related discrimination.

Once individuals understand the consequences for themselves and for others of obtaining genetic test results, they can address another important step of the pre-testing phase. Guided by their physician they can begin to contemplate, before any information is uncovered, the importance of inviting biological family members to participate in the testing process--directly by undergoing testing, or indirectly, by receiving the information.

For individuals who are comfortable with notifying immediate biological relatives that they intend to undergo genetic testing, the pre-testing period is an opportune time to communicate their plan to family. Physicians can help individuals inform their relatives by providing them with educational materials aimed at lay audiences and by offering themselves or another appropriate person as a resource.

In the same manner that families can benefit from discussing advance care planning or other health care matters before there is reason for concern, they can benefit from exploring considerations that surround genetic testing, so as to clarify individuals' preferences, before pressures interfere with the decision-making process. Relatives' early involvement means there will be ample time to offer family members genetic counseling to help them make an informed decision about whether they would like to share in the findings once results from the patient's genetic testing become available. Knowing their preference at this stage will shield physician and patient from the awkward situation of trying to determine whether to involve family members after important information has been uncovered. It will also help prevent the unfortunate circumstance where results for which relatives are unprepared are accidentally communicated to them by a family member before the relative could receive counseling or arrive at an informed decision about the willingness to share in the results. Physicians cannot predict how individuals will react to genetic information, but they have the ability and the responsibility to encourage people to seek appropriate counseling to prepare them to receive results from testing.

Some will prefer not to share with their immediate biological relatives that they are contemplating testing. Even when this is clear from the start, there are still benefits to discussing the possibility of discovering familial genetic risk before testing is done. Physicians can help their patients reach a decision about what they will do, if the information they learn from the test results could be important to immediate biological relatives. Patients can be educated that, in the event they should decide to share genetic information with affected relatives, they must encourage family members to seek genetic counseling before revealing any information. Regardless of whether genetic information is reassuring, neutral, or alarming, relatives may not want to know. If they do, they deserve to be prepared.

Finally, addressing the implications to biological relatives of genetic information gives professionals an opportunity to outline the exceptionally rare circumstances under which they would feel compelled to notify affected family members of the availability of genetic information. The use of the so-called "genetic Miranda warning" gives the patient the opportunity to decline testing if the physician's conditions seem unacceptable.

DISCLOSURE OF FAMILIAL RISK

An adequate informed consent is likely to address or prevent a majority of difficult situations where the physician would be caught between the competing obligations to respect the patient's confidentiality and to avoid harm to third parties. By discussing up-front the individual and familial implications of test results and by establishing during the pre-testing phase the individual's intended uses of the information, patient and physician will almost certainly identify any fundamental disagreements about which exceptional circumstances would justify the disclosure of results to immediate biological relatives, even without the patient's approval. If the patient still wants to be tested and disagrees with the physician's conditions for disclosure, the physician is ethically obligated to refer the patient to another provider.

There are bound to be some rare situations, where despite a satisfactory informed consent process, patient and physician find themselves at odds, after testing has occurred, about who should share in the information revealed by test results. Where no consensus can be reached, the burden falls to the physician to demonstrate that more harm would result from non-disclosure than from immediate breach of confidentiality without the patient's consent. Breach of patient confidentiality, against the patient's will, compromises the physician-patient relationship. It represents an instance where the physician places obligations to a third party ahead of obligations to the patient, where the health interests of the third party are given more weight than the patient's interest in determining how confidential information about the self will be disclosed.

The American Society of Human Genetics (ASHG), in *Professional Disclosure of Familial Genetic Information*, warns that social, psychological, and financial harms as well as discrimination and stigmatization can accompany genetic findings. Failure to disclose the availability of genetic testing results to a patient's affected family members can also lead to harm--particularly when knowledge could result in avoidance, treatment, or prevention of a genetic condition or in significant changes to reproductive choices or lifestyle.

ASHG guidelines for familial disclosure are related to the magnitude of harm that may be incurred. Accordingly:

“Disclosure should be permissible where: attempts to encourage disclosure on the part of the patient have failed; the harm is highly likely to occur and is serious, imminent, and foreseeable; the at-risk relative(s) is identifiable; and the disease is preventable, treatable, or medically accepted standards indicate that early monitoring will reduce the genetic risk....The harm from failing to disclose should outweigh the harm from disclosure.”

These guidelines establish a standard that is so stringent that it may only exist as a theoretical requirement--one that is unlikely to be met in practice. That genetic information would reveal the high likelihood of imminent harm seems impossible in light of what we know about genetic medicine at the present time. For practical purposes the ASHG's guidelines would not allow a physician to breach patient confidentiality to notify immediate biological relatives of genetic information that might impact their health. At this time, the harm from disclosing the information against the patient's wishes is likely to exceed the harm from non-disclosure.

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research had arrived at similar, but more measured, conclusions when it stated that disclosure without the patient's consent is only justified if:

1. “Reasonable efforts to elicit voluntary consent to disclosure have failed;
2. There is a high probability both that harm will occur if the information is withheld and that the disclosed information will actually be used to avert harm;
3. The harm the identifiable individuals would suffer would be serious; and
4. Appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease in question is disclosed.”

The Commission's conclusions were less stringent than the ASHG's in that they did not require the harm from withholding information to be immediate. Still, the requirements they established, especially those included in (2.), were such that only in very rare circumstances would the harm revealed by genetic information justify breach of confidentiality.

CASE LAW

Case law also recognizes physicians' competing obligation to be mindful of the health care interests of patients' immediate biological relatives, when testing results reveal that family members are at risk for serious genetic conditions that could be avoided or treated with timely intervention. These cases, however, have taken a more nuanced approach to defining when a physician should notify biological relatives against the patient's will.

In *Pate v. Threkel*, the court held that in the exceptional circumstances that might warrant disclosure of genetic information to family members, it would often be too difficult and impractical for physicians to seek out and notify a patient's immediate family relatives. The court found that a physician's duty to warn about the transferability of a genetic condition would be satisfied by educating the patient about the implications for affected relatives of the information: the patient could be expected to pass on the warning.

In the case of *Safer v. Estate of Pack*, a woman brought suit against her deceased father's physician for failing to warn her of her hereditary risk for multiple polyposis. The case was initially dismissed at the trial court level, as the judge concluded that there was no patient-physician relationship between the woman and the physician and that a warning would not have prevented the woman from having the gene. The appellate court, however, recognized a physician's duty to warn, not only the patient, but also immediate biological relatives who might be adversely affected by non-disclosure of avoidable risk from genetic causes. The appellate court emphasized that a physician could identify and warn at-risk relatives without too much difficulty, thereby helping them avoid substantial future harm.

Both cases recognized a physician's duty to warn--though they arrived at very different conclusions about what warning might entail. One case took the approach that a physician's duty to warn is limited to warning the patient of the familial implications of genetic testing--a step this report recognizes as a requirement of the informed consent process. The other case demands more of the physician who, within reasonable limits, must identify affected family

members to warn them of their at-risk status. The latter model is more burdensome for the physician, who must try to find family members and breach patient confidentiality.

CONCLUSION

It is crucial that individuals who contemplate undergoing genetic testing receive adequate education and counseling from a qualified healthcare professional as part of the process of informed consent. Before deciding to have the test, individuals should understand the consequences of the information, both for themselves and for their biological relatives. Before they can communicate any of these details to patients accurately and thoroughly, many physicians will need to become more educated about the role of genetics in medicine and specific conditions for which they offer testing.

Patients must be informed in advance which information will be disclosed, and to whom. The biological relatives, whom physicians need expend only reasonable efforts to find, should receive adequate education and counseling, before being given the option to learn results. Only very exceptional circumstances would justify disclosure of information against a patient's will. Specifically, the information revealed by genetic testing would have to be such that it places the identifiable biological relatives at imminent, serious danger that could be averted if the relatives obtained the information.

RECOMMENDATIONS

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

1. Physicians have a professional duty to protect the confidentiality of their patients' genetic information.
2. Physicians who order genetic tests should have adequate knowledge to impart accurate information to patients. In the absence of adequate expertise in pre-test and post-test counseling, the primary physician should refer the patient to an appropriate specialist.
3. Pre-test counseling should include implications of genetic information for patients' biological relatives. At the time when patients are considering undergoing genetic testing, physicians should discuss with them the importance of informing those family members.
4. Physicians should inform patients what exceptional circumstances would ethically compel the physician to attempt to contact potentially affected biological relatives, even without the patient's approval. The physician should apply the most stringent standard of disclosure--immediate and preventable harm to identifiable biological relatives--in determining whether it is ethically justifiable to breach confidentiality. It should be noted that currently these guidelines establish a standard for situations that are unlikely to occur in practice.
5. Physicians should support the strengthening of genetic education at all levels of medical education.

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

4. THE USE OF DNA DATABANKS IN GENOMIC RESEARCH: THE IMPERATIVE OF INFORMED CONSENT

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

INTRODUCTION

Genomic research, which uses DNA to identify the gene(s) responsible for complex diseases, relies upon large DNA databases to facilitate population-based research. These databases derive their power from integrating different kinds of information about large samples of individuals--genetic and clinical data, data on health, lifestyle, and environment. Using statistical analysis, the databases can be used to analyze correlations that may enable new therapeutic developments.

The use of DNA databanks in genomic research brings new challenges related to the scope of research as well as to the nature and use of the samples and information archived in such databases. This report identifies these issues and considers their relation to the current standard of informed consent in human research.

NEW CHALLENGES

Nature of DNA Material

At the outset, several characteristics that are unique to DNA material (DNA samples or information derived from them) should be acknowledged. For instance, DNA material may include information about patients and their immediate biological family members that is entirely unknown to any of them--either because it has not been analyzed or because, in the absence of more advanced technology, it is not yet decipherable. Another characteristic specific to genetic information includes the fact that it can forecast disease long before a person shows any symptom. Also, given the stability of the DNA molecule, the nucleotide sequence in samples is usually immutable. More importantly with regard to research, once collected and stored, a DNA sample can be duplicated almost indefinitely by polymerase chain reaction (PCR) and used in the future to answer questions that were not contemplated at the time the sample was obtained. Once a researcher has a subject's DNA material, the stored sample or the data derived from it can be used for any number of future research protocols.

These various features may raise special risks for individual research subjects whose DNA material is stored in databanks. The harms that could result to subjects from these risks are distinct from the physical harms that generally are associated with clinical research trials, such as the harm caused by the side effect of an experimental drug. Foreseeable harms from genomic research include insurance, employment, and education discrimination, social stigmatization, improper attempts to influence reproduction decisions, and distress caused by information regarding the statistical possibility of disease. These may be a source of distress not only for research subjects, but for also their family members.

Another new challenge that arises from genomic research is that some risks may extend beyond individuals to an entire population. This can happen when DNA data sets are constructed around relatively homogenous populations to increase the chances of detecting genetic variation within the less than 0.1% deviation that exists between any two persons in the world. Any benefits population-based genomic research presents must be weighed against the possibility of stigmatization and discrimination.

These considerations make it necessary to examine whether current standards that govern research can minimize the risks inherent to genomic research and sufficiently protect individual subjects as well as populations adequately.

Uses of the Data

In addition to acknowledging concerns that arise from the nature of the information archived in genomic databases, it is necessary to address intended uses of DNA material. Participating individuals and groups may have reservations about their information being utilized for certain types of research projects. Therefore, it is important that subjects have the opportunity to be informed about, evaluate, and consent to the goals of the intended research.

THE STRUCTURE OF CONSENT

Population-based genomic research raises the question of whether consent need be obtained solely from individuals or whether review by the target population is needed as well. The concept of community review, also referred to as community consultation, may prove to be a successful method to minimize harm to certain groups and to help identify community support for population-based research endeavors. When a community is opposed to the research, the study should not be conducted. When a proposal is met with support from the community, it nevertheless remains important to obtain individual subjects' consent. Community consultation cannot be used as a substitute for informed consent. Instead, it should precede and complement the process, serving as an opportunity to begin educating members of the group from which research subjects will be drawn.

Informed Consent

Though an imperfect safeguard, self-determination through informed consent has been considered an important mechanism to protect subjects from abuses in research. When the process is carried out properly, it should prepare individuals to identify, understand, and consider the relevant risks and benefits that a research protocol presents. As a result of the new challenges that genomic research poses, additional safeguards may be necessary to address risks that arise from archived information and subsequent studies.

Consistent with the informed consent process in any type of human subjects research, subjects in genomic research should be informed of the: (1) purpose of the research; (2) overall risks and benefits associated with participation; (3) possible clinical findings that may result from the research and whether they will be disclosed to subjects; (4) possibility for commercial gain from the research endeavor (as addressed in Opinion 2.08 of the Council on Ethical and Judicial Affairs); (5) possible conflict of interests that investigators face (as discussed in Opinion 8.0315); and (6) right to withdraw from the research at any time.

In addition, disclosure should include information regarding: (1) measures to protect privacy; (2) the scope of any additional research foreseeable at the time the sample is collected; and (3) the time and manner in which archived information and samples will be discarded.

With regard to privacy, subjects should be told whether their materials will remain *identified* (i.e., will contain personally identifiable information such as their name or social security number). The confidentiality of their materials will be protected more completely, however, if data are stripped of all identifiers (i.e., *de-identified*). One shortcoming with this method is that completely de-identified information and samples lose some of their application. Instead, it is customary to code personal identifiers, such that only the investigator can trace material back to specific individuals (i.e., *coded* samples).

Coding may be useful if it is anticipated that subjects may wish to learn of relevant findings and, therefore, will need to be contacted. Use of coding also allows subjects to remain easily accessible to enroll in subsequent research. More importantly, it gives subjects the option to remove their information and samples from the database if they decide to withdraw from the investigation. De-identified samples, while they offer greater protection of confidentiality, do not have any such flexibility.

Discussing foreseeable future genomic research with potential subjects enables them to evaluate and decide whether participation in the overall investigation is consistent with their moral beliefs and personal preferences. It is paramount that subjects understand, from the disclosure process, the nature of the protocol in which they are enrolling, namely whether the material will remain personally identified, be coded, or be completely de-identified. In addition, if data are to remain identified or coded, subjects should be told whether they can expect to be contacted in the future to share in findings or to consider participating in additional research, which may relate to the current protocol or extend to other research purposes. Individuals should always be free to refuse the use of their biological materials in research, without penalty.

Waiver of Consent

According to the American Society of Human Genetics' (ASHG) official statement on informed consent for genetic research, it is inappropriate to obtain a subject's blanket consent for the use of their archived information and samples in subsequent research if these materials contain information that can identify the individual.

The National Bioethics Advisory Commission (NBAC) takes a different position. Assuming an analogy between the materials contained in DNA databanks and healthcare data recorded in medical records, its standards reflect federal regulations that allow research to proceed without the requirement of obtaining consent from subjects, where participation risks are no more than minimal. This position has drawn criticism from commentators who stress the unique nature of risks associated with genetic information. It is their belief that federal regulations, which were written mostly to anticipate physical risks, do not provide an adequate framework to protect subjects in genomic research.

Finally, the argument can be made that even de-identified materials--whether newly or previously collected--should not be used in ways to which subjects did not specifically consent. Based on the principle of respect for autonomy individuals can refuse to participate or to have their information used in research that is contrary to their values and preferences.

Presumed Consent

Under the presumed consent standard that Iceland has adopted, the willingness of an individual to participate in research is assumed unless the individual takes appropriate measures to formally opt out. However, this standard can only function as an effective safeguard if concerned individuals are informed of:

- the risks and benefits associated with the proposed research;
- the fact that participation is optional (i.e., individuals who choose not to participate will not be penalized for their decision);
- the appropriate steps to follow in order to opt out;
- their status as subjects unless they formally opt out; and
- the contact information for a person who can provide them with further clarification and answers to their questions.

This model of presumed consent for participation in research has never been proposed in the United States. However, it has been adopted in Iceland where it is the source of some controversy. A genetic company was granted a twelve year exclusive license by the Icelandic government to extract information from the Iceland Health Sector Database (HSD). A majority of Icelandic people voted in support of the creation of the database during a referendum, as a community consent process. As a result, competent Icelandic people are presumed willing to have information from their medical records entered into the database, unless they take necessary measures to opt out of the HSD.

None of the guidelines that govern the practice of research in the United States permit use of the standard of presumed consent as an alternative to informed consent. In fact, the general attitude towards presumed consent seems to be that it is inconsistent with the principle of autonomy, upon which ethical protections for research subjects are built. This sentiment may change if developments in genomic research suggest that highly important and unique opportunities to gain new knowledge are being missed. Pressure toward change may come from the biotechnology industry if it becomes too cumbersome to conduct research that fulfills the informed consent requirement.

CONCLUSION

The use of DNA databanks for genomic research raises new scientific possibilities as well as new challenges. Suggestions have been made to relax the standards that govern research, in an attempt to promote the acquisition of valuable information, although the need for strict interpretation of informed consent may be needed to protect subjects and the communities from which they are drawn from new forms of risks. Without proper education of potential subjects, genomic research may face severe setbacks. Therefore, it is imperative that physicians be prepared to discuss with their patients and/or potential subjects this new biomedical revolution.

RECOMMENDATIONS

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

The following safeguards should be applied to the use of databases for the purpose of population-based genomic research:

1. Physicians who participate as investigators in genomic research should have adequate training in genomic research and related ethical issues so as to be able to discuss these issues with patients and/or potential research subjects.

2. If research is to be conducted within a defined subset of the general population, that is, an identifiable community, then investigators should consult with the community to design a study that will minimize harm not only for individual subjects, but also for the community. When substantial opposition to the research is expressed within the community, investigators should not conduct the study. When the community supports a proposal, investigators nevertheless should obtain individual consent in the usual manner. The same procedure should be followed whether the investigators intend to collect new samples and data or whether they wish to use previously archived data sets.
3. When obtaining the informed consent of individuals to participate in genomic research, standard informed consent requirements apply (see Opinion 2.07). In addition:
 - (a) Special emphasis should be placed on disclosing the specific standards of privacy contained in the study: whether the material will be coded (i.e., encrypted so that only the investigator can trace materials back to specific individuals) or be completely de-identified (i.e., stripped of identifiers).
 - (b) If data are to be coded, subjects should be told whether they can expect to be contacted in the future to share in findings or to consider participating in additional research, which may relate to the current protocol or extend to other research purposes.
 - (c) Individuals should always be free to refuse the use of their biological materials in research, without penalty.
 - (d) Disclosure should include information about whether investigators or subjects stand to gain financially from research findings (see Opinion 2.08). Such disclosure should refer to the possible conflicts of interest of the investigators (see Opinion 8.0315).
 - (e) Subjects should be informed of when, if ever, and how archived information and samples will be discarded.
4. To strengthen the protection of confidentiality, genomic research should not be conducted using information and samples that identify the individuals from whom they were obtained (i.e., by name or social security number). Furthermore, to protect subsets of the population from such harms as stigmatization and discrimination, demographic information not required for the study's purposes should be coded.

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

5. A DECLARATION OF PROFESSIONAL RESPONSIBILITY

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

MEDICINE'S RESPONSE TO THREATS TO HUMAN HEALTH

Bioterrorism, the AIDS pandemic, and the potential misuse of genetic science pose unprecedented threats to the health and well-being of humanity. While these threats are new, medicine's response to these challenges is guided by a centuries-old ethic of caring for the sick and the suffering.

In light of these new threats, the AMA is positioned to lead the world community of physicians in joining together across geographical and political divides in a public recommitment to medicine's guiding principles. The *Declaration of Professional Responsibility: Medicine's Social Contract with Humanity* (see Appendix) is an instrument for demonstrating that unity. The *Declaration* affirms (1) the ideals that, throughout history, have motivated individuals to enter the profession of medicine, and (2) the conduct that has given life to those ideals and earned society's trust in the healing profession.

DECLARATION OF PROFESSIONAL RESPONSIBILITY

The *Declaration of Professional Responsibility* is a public reaffirmation of physicians' dedication to the ideals and obligations of the profession. These ideals and obligations transcend physician roles and specialties, professional associations, geographic boundaries, and political differences, uniting all physicians in a community of service to humankind.

The *Declaration* is enforced solely by the honor of its signatories and their respect for the profession. In this regard, it differs from codes of ethics used in the adjudication of legal and ethical issues by professional boards and courts of law. The *Declaration* is a powerful symbolic statement calling all physicians to uphold and celebrate medicine's historical covenant with society.

Because of its context and symbolic nature, the *Declaration* employs language appropriate to the historical moment in which it arises, and it adopts a tone intended to inspire reflection and rededication. Its language frames medicine's ideals and physicians' duties in terms to which all those who respect the profession's obligations to care for its sick and suffering can subscribe. Greater specificity would compromise the universal applicability of the *Declaration* and possibly divide rather than unite physicians. All physicians, for example, can pledge to "respect human life and the dignity of every individual" (#1). More specific language might engender division and argument over definitions of personhood. Similarly, the duty to refrain from supporting or committing crimes against humanity (#2) enjoins physicians from engaging in biochemical warfare research and a host of other acts that would result in human suffering, and the duty to treat the sick and injured with competence and compassion and without prejudice (#3) prohibits racial, ethnic, and other forms of bias.

The *Declaration's* nine duties and obligations speak to physicians in their roles as clinicians (#3-#5), researchers (#6), educators (#7, #9), and members of a civil society (#1, #2, #8). The *Declaration of Professional Responsibility* asks physicians to use their skills beyond the bounds of the traditional patient-physician relationship in responding to exceptional global conditions and need for care. Thus, the Preamble to the *Declaration* concludes by stating, on behalf of the community of physicians, that "humanity is our patient." This is more than rhetoric, for in disasters and epidemics, few of the afflicted are able to become "patients" in the traditional sense, yet many need care.

RECOMMENDATION

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

That our American Medical Association adopt the Declaration of Professional Responsibility and disseminate it to all medical societies within and beyond the Federation and to national medical societies around the world for their support.

APPENDIX - DECLARATION OF PROFESSIONAL RESPONSIBILITY: MEDICINE'S SOCIAL CONTRACT WITH HUMANITY

Preamble

Never in the history of human civilization has the well-being of each individual been so inextricably linked to that of every other. Plagues and pandemics respect no national borders in a world of global commerce and travel. Wars and acts of terrorism enlist innocents as combatants and mark civilians as targets. Advances in medical science and genetics, while promising to do great good, may also be harnessed as agents of evil. The unprecedented scope and immediacy of these universal challenges demand concerted action and response by all.

As physicians, we are bound in our response by a common heritage of caring for the sick and the suffering. Through the centuries, individual physicians have fulfilled this obligation by applying their skills and knowledge competently, selflessly and at times heroically. Today, our profession must reaffirm its historical commitment to combat natural and man-made assaults on the health and well being of humankind. Only by acting together across geographic and ideological divides can we overcome such powerful threats. Humanity is our patient.

Declaration

We, the members of the world community of physicians, solemnly commit ourselves to:

1. Respect human life and the dignity of every individual.
2. Refrain from supporting or committing crimes against humanity and condemn any such acts.
3. Treat the sick and injured with competence and compassion and without prejudice.
4. Apply our knowledge and skills when needed, though doing so may put us at risk.
5. Protect the privacy and confidentiality of those for whom we care and breach that confidence only when keeping it would seriously threaten their health and safety or that of others.
6. Work freely with colleagues to discover, develop, and promote advances in medicine and public health that ameliorate suffering and contribute to human well-being.
7. Educate the public and polity about present and future threats to the health of humanity.
8. Advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being.
9. Teach and mentor those who follow us for they are the future of our caring profession.

We make these promises solemnly, freely, and upon our personal and professional honor.