

Rationale for Institutional Decisionmaking Protocols

This report focuses on the formal policies and guidelines' through which health care institutions articulate decisionmaking procedures and identify permissible options regarding the use of life-sustaining treatments for adult patients in their care. Like the ethical dilemmas they seek to address, these policies and guidelines (referred to collectively throughout this report as "institutional protocols" or "decisionmaking protocols") are recent developments and still controversial. They are promoted by some—and decried by others—as facilitators of the complex and momentous decisions made daily in health care institutions throughout this country.

Protocols for making decisions about life-sustaining treatments are used to reach decisions to provide *and* decisions not to provide particular treatments. Thus, they proceed from the belief that withholding or withdrawing life-sustaining treatment is sometimes the right decision. Some people reject this basic position and, with it, they categorically reject the idea of decisionmaking protocols. Others reject the idea of decisionmaking protocols because of their potential for misuse. It is certainly true that, if poorly designed or wrongly applied, decisionmaking protocols can legitimize bad decisions, diffuse responsibility, or be too rigid.

This report proposes that well-designed decisionmaking protocols at the institutional level offer positive benefits. Institutional protocols are not held out as a panacea, nor as a way to make treatment decisions easy. Moreover, no single protocol will suit all institutions. However, thoughtfully designed and accurately implemented protocols are one promising and feasible method to foster clinical decisions that are responsive simul-

taneously to the needs of patients and the obligations of health care institutions and professionals.

The need to improve clinical decisionmaking as well as the belief that institutional protocols will help to do so find strong support in OTA's 1987 report *Life-Sustaining Technologies and the Elderly (156)*. For each of five life-sustaining medical technologies (cardiopulmonary resuscitation (CPR), mechanical ventilation, renal dialysis, nutritional support (tube and intravenous feeding), and antibiotic therapy for life-threatening infections), OTA reported on how clinical decisions are made for elderly persons with life-threatening conditions, including who is involved and how decisionmaking varies from case to case and institution to institution.

Despite general acknowledgment of patients' rights, OTA found that, in practice, treatment decisions are sometimes made unilaterally by physicians or other caregivers without knowing, or without following, the wishes of individual patients. Further, the serious clinical, legal, and ethical uncertainties that prevail result in decisions that are inconsistent and, too often, wrong. In addition to the exigencies of each case, the type of institution in which the patient receives care, the State in which it is located, and the particular treatment being considered are among the variables that affect how and by whom treatment decisions are made. Frequently, neither patients nor health care professionals know ahead of time what an institution's response to particular treatment requests will be. OTA found both intense interest in means to reduce decisionmaking problems and mistakes and widespread optimism about the potential value of institutional protocols.

The suggestion that there might be a role for Congress in this matter derives from the fact that many hospitals and most nursing homes in this country currently have no formal procedures regarding decisionmaking about life-sustaining treatments. Moreover, the vast majority of existing in-

¹See app. D for definitions. The protocols that are the subject of this report apply to health care decisions for adults of all ages. Protocols for decisions about the care of newborns or minors, for whom different considerations may be indicated, are not addressed.

stitutional protocols are narrow in scope and leave important questions unanswered. There is evidence of considerable interest in decisionmaking protocols among health care institutions, as well as forceful incentives in the form of new accreditation standards (see ch. 2). However, serious questions remain about whether voluntary incentives go far enough and whether they are sufficient to overcome serious inter- and intra-institutional barriers to the development and implementation of effective decisionmaking protocols. Thus, the central congressional issue can be identified at the outset: **What steps, if any, should Congress take with respect to institutional protocols for decisions about life-sustaining treatments for adults?**

In this era of concern about health care costs, skeptics warn that interest in institutional protocols, including the Government's interest in them, might be motivated by efforts to reduce health care costs—by reducing care. Certainly, recent changes in public and private reimbursement programs (e.g., Medicare's prospective payment

system and capitated payment agreements) provide strong incentives for health care institutions to restrain the use of expensive technologies (33). Institutions' financial survival is now linked directly to their ability to control costs generated by individual patient care decisions. Thus, protocols that make it easier to limit care might be adopted as a way to control costs. This potential for abuse necessitates careful articulation of the public interests to which health care institutions are accountable—in addition to cost containment and institutional survival.

Cost containment, especially in the form of limited health insurance benefits, also affects patient decisionmaking, forcing some patients to forgo beneficial treatments they otherwise would wish to receive. Institutional protocols that make it easier for patients to refuse treatment must not at the same time make it harder for those who want recommended treatment to get it. Questions about how financial considerations affect treatment decisions are beyond the scope of this paper. Nevertheless, they warrant careful study.

SOCIAL AND HISTORICAL CONTEXT OF DECISIONMAKING PROTOCOLS

The impetus for development of decisionmaking protocols can be traced to broad social trends and to specific events within health care institutions. Traditionally, hospitals and other health care institutions were seen as places in which patients would be provided whatever treatments—and only those—deemed useful and appropriate based on medical criteria (85). Challenges by patients to a paternalistic model of health care were rare, health professionals seldom challenged their colleagues, and administrators entrusted clinical decisionmaking to the clinicians.

Scientific, technological, social, and economic developments over the past three decades have brought major changes throughout the health care system. An impressive array of “life-sustaining” technologies, including new drugs, devices, and procedures, emerged, and these technologies rapidly became available in hospitals and other treatment settings throughout the country. These powerful medical technologies have brought pa-

tients, health professionals, and families new hope—and new, often difficult, choices.

Difficult choices about medical care have been accompanied by new attitudes and behaviors that are characterized, at least in part, by greater insistence on accountability. For example, interest in human rights and consumer advocacy of all kinds has led to the articulation of and demand for patients' rights. A general diminution of respect for and trust in traditional authority, including medical authority, has contributed to increased malpractice claims, peer review of physicians, and increased regulation of health care facilities. Multiple caregivers, the patient, and sometimes the patient's family members now expect to participate in treatment decisions. New treatment options, patient autonomy, the protection of vulnerable patients, consideration of costs, and institutions' need to manage all sorts of “risks” have been added to the decisionmaking equation. In this environment, the complex relationships between phy-

sicians and patients, physicians and nurses, staff and administrators, and institutions and the public have been increasingly tested.

The special requirements of one particular life-sustaining technology stimulated thinking about and development of decisionmaking protocols. Effective techniques for cardiopulmonary resuscitation were introduced in the late 1950s.² This technology is distinguished by the need to apply it, if at all, immediately. Once a cardiac arrest occurs, taking time to deliberate or to consult would render efforts at CPR uniformly useless. This fact resulted in a general presumption in favor of providing CPR, a presumption that came to be embodied in a "standing order."

Although it was acknowledged that CPR is unwarranted if it is known in advance that a patient cannot be saved, the standing order could not be ignored. In response to this dilemma, an Ad Hoc Committee of the American Heart Association and the National Academy of Sciences described the "do not resuscitate" (DNR) order, a physician's order to countermand the standing order for CPR (118). The first hospital DNR policies were developed in the late 1960s.

It was another 10 years before institutional protocols regarding other life-sustaining treatments received explicit attention. Following the 1976 decision in the landmark case of Karen Ann Quinlan (75), an editorial published in the *New England Journal of Medicine* proclaimed that "limiting medical treatment" was "out of the closet" (55). The same issue included the policies of two hospitals regarding how decisions about life-sustaining technologies were to be made in these institutions (99, 132). These were not the first such institutional protocols, but their assertive presentation marked a new phase.

Institutional resuscitation policies and guidelines received an important boost a few years later

when they were advocated by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (130). Presently, DNR policies remain the most common form of institutional protocol regarding life-sustaining treatment.

In some institutions, early DNR policies have now been revised to reflect changes in thinking and changes in needs. One significant change is explicit concern with the patient wishes regarding resuscitation, not just medical judgments about its appropriateness or likely outcome. Also, some institutions have developed decisionmaking protocols that go beyond considerations of resuscitation to address other life-sustaining treatments. But many institutions are still struggling to get resuscitation protocols in place, and others have not yet reached even that point. Among those without a protocol in place, the reasons range from ignorance, to opposition, to practical difficulties (57, 80) (see ch. 2).

Decisionmaking protocols within health care institutions need to be understood as just one of several complementary mechanisms for improving clinical decisionmaking for persons with life-threatening conditions. Legal tools for appointing a surrogate (or proxy) decisionmaker (especially durable power of attorney statutes) or for specifying advance directives (living will statutes) now exist in many States. New Jersey has established a Commission on Legal and Ethical Problems in the Delivery of Health Care, and New York State has a Task Force on Life and the Law, to advise their respective legislatures. Another approach is professional education and research by public and private agencies, professional associations, and individuals. Complementing this, some educational and advocacy groups (e.g., American Association of Retired Persons, Nursing Home Action Group, Concern for Dying, Oregon Health Decisions, Vermont's "Taking Steps," Society for the Right to Die, and Americans Against Human Suffering) direct their activities toward the general public. Institutional ethics committees, now commonplace in hospitals and beginning to appear in nursing homes, also fill a combination of relevant educational, advisory, and patient advocacy roles.

²CPR refers to a range of technologies that restore heartbeat and maintain blood flow and breathing following cardiac or respiratory arrest. Procedures range from "basic life support," which uses manual, external cardiac massage and mouth-to-mouth ventilation, to "advanced life support," which may include prescription drugs and sophisticated devices such as an electrical defibrillator, temporary cardiac pacemaker, and mechanical ventilator (156).

OBJECTIVES OF DECISIONMAKING PROTOCOLS

Decisionmaking protocols mediate the various parties and interests to which health care institutions are accountable. If well-crafted and if implemented, they offer patients and their families protection from poorly considered or imposed treatment decisions; offer health care professionals and institutions much needed guidance about ethical and legal dilemmas and a degree of protection from censure or liability by directing them toward acceptable practices; and permit customization to the needs of individual institutions,

It is essential to recognize that the individuals for whom institutions' decisionmaking protocols become important are an extraordinarily heterogeneous population (156). A person dependent on a mechanical ventilator might be lying in a coma or, as was so dramatically shown by Senator Jacob Javits, flying around the country giving speeches, contributing to public life and savoring his own.

To help illustrate the objectives of decisionmaking protocols (and, in app. A, the implications of specific design features), it is useful to describe some of the people who face decisions about life-sustaining treatments. The four hypothetical cases presented in box A (and referred to throughout the report) differ in diagnosis, prognosis, wishes regarding life-sustaining treatments, and capacity to participate in a treatment decision; they are in different kinds of settings and in very different social and economic circumstances. A hypothetical physician is also described to give some feel for the ethical dilemmas that confront health care professionals.

Objectives Related to Clinical Decisions

Although ethical, legal, and professional codes always presume in favor of sustaining life, there is wide consensus that this presumption must be ratified for each patient (62, 129, 130, 156). Life-sustaining treatment may be forgone when an informed patient declines it or when treatment would be futile. Similarly, withdrawal of treatment is not permitted without the patient's (or surrogate's) consent. Thus, treatment decisions must be individualized, in light of each patient's clinical situation, treatment objectives, and the bene-

fits and burdens of the particular treatment being considered.

Encouraging appropriate, individualized clinical decisionmaking is a major purpose of protocols for decisions about life-sustaining treatments. This involves creating treatment plans that accommodate Robert Swanson's categorical rejection of CPR as well as his wish to receive other indicated life-sustaining treatments in some circumstances. It involves creating institutional means to allow Mary Hinkel to reject aggressive life-sustaining treatments while assuring she will receive care to maintain her comfort and dignity. It involves creating procedures to ensure that Thomas Johnson's appointed surrogate will be allowed to serve in that capacity. And it involves procedures that protect Mae Carver from decisions based on the judgment of other persons about the quality of her life.

In addition to the overriding theme of individualizing clinical decisions, decisionmaking protocols purport to improve clinical decisions through aiming to: clarify the rights, interests, and obligations of all involved, i.e., patient, family members, and health care professionals; communicate practice standards; establish mechanisms for implementation of treatment plans, for staff accountability, and for resolution of disputes; provide evidence of an institution's effort to educate its staff as to standards of clinical practice; and facilitate review to confirm either that proper care has been given or that some changes are in order.

More specifically, proponents believe institutional protocols can improve clinical decisionmaking if they:

- decrease staff uncertainties about what practices are permitted, particularly in such unclear areas as termination of life-sustaining treatments, decisionmaking for incompetent patients, and decisionmaking when family members disagree;
- reduce stress and conflict among health care professionals, patients, and families concerning controversial, difficult, or complex treatment plans, by focusing discussion and offering ethical guidance;

Box A.—Profiles of Individuals Facing Decisions About Life-Sustaining Treatments

Robert Swanson is an 84-year-old resident of the intermediate care section of a private nursing home. He is without family but active in the affairs of the home. He has stated clearly and consistently that he does not want any attempt at resuscitation in the event of a cardiac arrest, and he does not want any form of life-sustaining treatment if he has lost the ability to interact with other persons. However, he has stated with equal force that, as long as he remains able to interact socially, he does wish to receive aggressive life-sustaining treatment and emergency treatment to relieve symptoms of potentially fatal conditions.

Mae Carver is 64 and aphasic (unable to comprehend or express language), paralyzed on one side, and incontinent of urine since a massive stroke 2 years ago. She has resided for 8 years in the skilled nursing section of a private nursing home, at public expense. She appears to enjoy food, television, and the companionship of the nurse's aides. She is not capable of clearly expressing any preferences regarding her health care, and she has no family.

Mary Hinkel is a 47-year-old woman whose advanced cancer has progressed despite surgery, chemotherapy, and radiation. She has just been readmitted to the community hospital where she was previously in the care of an oncologist. Now she is back in the care of her family physician, who had not seen her for 2 years. Hospital nurses know this patient from her many previous admissions. They have discussed with her many times her wish to receive only palliative care and to forgo any treatments that would prolong her life. Mrs. Hinkel is confined to bed and near death.

Thomas Johnson is a 35-year-old with acquired immunodeficiency syndrome who is currently living at home. He is well aware that, as his disease progresses, he may suffer serious cognitive losses and eventually become incapable of participating in treatment decisions. For now, despite his physician's reservations, he says that he wants all life-sustaining measures including CPR. But he strongly opposes life-sustaining treatment in the event of permanent loss of cognitive function. Mr. Johnson is estranged from his family. His male companion has offered to serve as his surrogate if one is needed. Mr. Johnson wants to be assured that his wishes regarding life-sustaining treatments will be honored, whether he is still at home or in a health care institution, and that, if he cannot do so himself, this friend will be allowed to speak on his behalf.

Dr. Ruth Levin is medical director of Torah Home, a nursing home created and supported by a large Orthodox Jewish congregation. Torah Home mainly serves elderly members of the congregation but is open to noncongregants as well. Dr. Levin regularly encourages her staff to reflect on the ethical aspects of their work. She, the rabbi, and the staff of the home are aware of recent court cases regarding discontinuation of nutritional support. While this is not an immediate clinical issue in their facility, they do not want ever to be compelled, against their moral beliefs, to withhold or withdraw this particular life-sustaining treatment from any resident.

- reduce ad hoc decisionmaking procedures and arbitrary decisions;
- increase patient or family involvement in treatment decisions, by explicitly affirming the principles of patient autonomy and shared decisionmaking, and by empowering patients;
- improve the accuracy with which decisions about life-sustaining treatments are implemented, by clarifying terminology and procedures for implementing treatment plans;
- decrease confusion and conflict regarding the implementation of plans or orders to limit treatment, by clarifying professional duties, and by suggesting processes and procedures for making and implementing treatment decisions;
- improve accountability for decisions, by specifying duties and requiring signed documentation;
- reduce unwarranted fear of litigation, by sanctioning deliberative consideration and by requiring documentation;
- reduce bad clinical practices such as deliberately ineffective resuscitation efforts, called "slow codes," either by prohibiting them or by offering morally and administratively acceptable alternatives;
- increase caregivers' empathy toward dying

patients, by creating processes that articulate positive health care goals other than sustaining life, when this is no longer possible or wanted; and

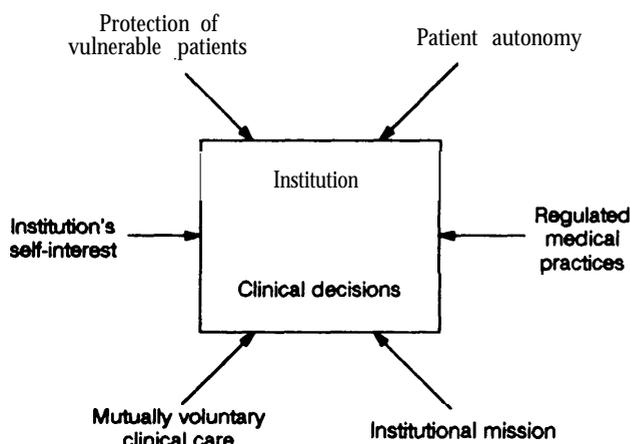
- improve the ability to audit the quality of care, by establishing written accountability for significant treatment decisions.

Objectives Related to Institutional Responsibilities

The second major focus of decisionmaking protocols is on institutional responsibilities to a variety of public and private interests that are broader than those of any individual patient (see figure 1). These responsibilities are the substance of “institutional conscience,” a conscience that is partly moral (as in the case of Dr. Levin’s Torah Home), partly practical (as in the need to be Medicare-certified), and partly legal (as in the need to comply with State guardianship regulations). These diverse interests are embodied in law, accreditation requirements, a facility’s elected mission, or professional codes. The responsibilities, and perceptions of them, constitute the governance agenda of the institution, and they powerfully shape the actions that are permitted or encouraged, and that are openly or covertly practiced.

protocols for decisions about life-sustaining treatments provide formal mechanisms to address

Figure 1.- Public Interests and Institutional Responsibilities



SOURCE: Office of Technology Assessment, 1988

institutional responsibilities. Specifically, these institutional policies and guidelines address the following objectives:

1. Promote the institution’s responsibility to safeguard the patient’s right to exercise autonomy in personal health care decisions.

The principle of patient autonomy (as distinct from the autonomy of a particular patient) is widely supported in statutory, constitutional, and case law and by a consensus of bioethicists (62, 75, 85, 130, 156). Further, the patient’s right to accept or refuse life-sustaining treatments is the foundation for institutional practices and procedures to formulate and implement treatment plans (6, 62, 130, 156).

In practice, however, patient autonomy is often lost or denied. Many patients are unable to communicate their preferences and did not do so in advance; health professionals sometimes fail to fully inform patients about options regarding life-sustaining treatments or they proceed to provide treatment without a patient’s (or surrogate’s) consent (156). Institutional protocols aim to support the treatment preferences of all patients—those, like Robert Swanson and Thomas Johnson, who are decisionally capable and have expressed clear and firmly held treatment preferences, as well as patients like Mary Hinkel, who previously expressed her treatment preferences but can no longer do so,

Patient autonomy is not, however, absolute. Thus, when forgoing life-sustaining treatment would result in direct harm to a patient’s minor children, autonomy may be restricted (18). Conversely, patient autonomy does not mean there is an unrestricted right to all health care a person may want. Decisionmaking protocols intend to ensure that patients receive desired treatments that offer them a chance of survival or improved health, but they do not protect a claim on cosmetic surgery or other treatments that are not medically indicated.

2. (Above and beyond #1): Promote protection of vulnerable persons from decisions that are counter to their preferences or interests.

Health care institutions are legally (77) and morally accountable to the public interest to pro-

tect vulnerable patients.³ Protocols seek to advance the welfare of vulnerable persons by ensuring proper oversight and deliberation of treatment decisions. Surgeon General C. Everett Koop and others have asserted that nursing home residents are especially vulnerable to having medical treatment improperly withheld because of prejudiced evaluations of the quality of their lives (67, 68, 69, 73, 74, 87). This suggests that the protection of vulnerable persons may be a particularly important objective for nursing home protocols.

3. Promote the institution's particular medical or moral mission.

Many health care institutions are committed to a particular medical or moral mission (125, 150) that determines what treatment options will be available. This mission may reflect interests of the community that formed and supports the facility or it may be a strategy to attract patients with a certain viewpoint. For example, Dr. Levin's Torah Home is accountable to a moral view that purports to enrich patient care by serving the needs of a particular community. By formulating protocols that address their mission, institutions assert and seek to protect their individuality. Thus, a Catholic hospital might use an institutional protocol to state its policy of not performing abortions (124). Hospices can describe their view of appropriate care for persons with advanced cancer; tertiary cancer treatment and research centers can do likewise.

Clear, timely, public statements of an institutional mission may also help avoid conflict over treatment plans. To a certain extent, patients and health professionals can choose institutions whose mission is compatible with their personal interests, or at least avoid institutions with incompatible missions. It is unlikely that an institution's mission (whether expressed in standards for minimal care or commitment to some religious doctrine) would have legal precedence over the contradictory

³All patients with life-threatening conditions are vulnerable. In this report, the term "vulnerable patients" refers specifically to persons who are so ill or disabled that they are unable to leave a facility or challenge its practices; lack decisionmaking capacity or the ability to protect their own interests; lack family or friends to advocate their interests should they be unable to speak on their own behalf; or belong to classes of persons, like the elderly, whose interests may be threatened by prejudice or stereotyping.

wishes of patients or their surrogates. However, if a patient claims a right to treatment that is incompatible with the institution's mission, it might be necessary to transfer the person to a different institution, with a different mission.

4. promote the public interest in protecting the civil liberties of individual staff, so as not to compel them to perform duties to which they have a moral objection.

Health care facilities employ individuals who often have their own deeply held views about the use of life-sustaining treatments. The value this society places on moral pluralism and voluntarism weighs against compelling health care staff to carry out treatment decisions to which they object (96). As long as it does not restrict a patient's right to refuse treatment, individual staff may be permitted to excuse themselves from patient care (39).

Institutional protocols can anticipate possible staff conflict by making provisions both for excusing staff who have conscientious objections and for transferring their patients to other providers, when necessary. For example, by permitting a physician to withdraw from a case, a protocol could enable Robert Swanson's physician to stand by his or her belief that it would be unconscionable to withhold cardiopulmonary resuscitation from a previously healthy 84-year-old.

s. Promote clinical practices that conform to public policies, including statutes, regulations, and common law, as well as to voluntary standards.

Health care institutions are accountable to the rules and norms of society, and practices within such institutions must be consistent with these. Thus, certain clinical practices are precluded, and no protocol will change this. The intentional administration of a lethal drug, for example, is prohibited, even if a patient like Thomas Johnson or Robert Swanson should request it. Similarly, instituting mechanical ventilation in a patient like Mary Hinkel, who has a clear, contrary directive, might constitute battery.

Protocols that encourage conformity to voluntary standards also serve practical goals. For example, regulations of the Health Care Financing

Administration requiring physicians to be responsible for treatment orders must be met for eligibility for financial reimbursement, and standards of the Joint Commission on the Accreditation of Healthcare Organizations must be met for accreditation.⁴ Health care facilities that violate accepted standards face possible criminal, regulatory, or civil sanctions—including fines, ineligibility for reimbursement, loss of required or desired accreditations, loss of licensure, placement in public receivership, suspension of admissions, or loss of teaching programs or prestigious affiliations (58, 68, 77, 79).

⁴In 1987, the Joint Commission on the Accreditation of Hospitals was renamed Joint Commission on the Accreditation of Healthcare Organizations. Hereinafter, it is referred to as JCAHO or as the Joint Commission.

6. Protect the institution from public notoriety.

Protocols that promote decisions that are consistent, ethical, and humane offer health care providers a degree of protection from public notoriety. In addition, it appears that well-designed decisionmaking protocols can reduce the risk of legal action, and thereby also remove some of the unwarranted fear of litigation that at times constrains ethical practice. Neither Robert Swanson's nursing home, nor Mary Hinkel's hospital, nor Thomas Johnson's physician has any legitimate fear that should cause them to fail to record and honor the preferences of these individuals for limited life-sustaining treatment. On the contrary, faithful implementation of decisionmaking protocols that honor the treatment preferences of individual patients will help keep health care providers out of the public eye.

CONCLUSION

Society has charged health care institutions to conserve a diverse set of public interests and, simultaneously, to protect the interests of individual patients. In general, since public interests are grounded in a vision of good health care, they converge with the interests of patients. For example, patients are generally served by principles embodied in accreditation standards, as well as by an institution's cautious self-interest in not cutting corners in health care. As members of sectarian communities, patients are served by the availability of health care facilities that strive to provide care that respects the patient's own moral views. Disabled and vulnerable persons are served by a special public interest in their welfare.

At times, however, necessary clinical choices pit public against private interests, or one public (or

private) interest against another. Containment of Medicare costs versus assuring access to care is one example. Striving to provide optimal health care while respecting a patient's right to refuse treatment is another. The high stakes in every decision about initiating, withholding, or withdrawing treatment that is potentially life-sustaining escalate the seriousness and urgency of these conflicts.

Institutional decisionmaking protocols that establish procedures and identify the range of acceptable choices offer a measure of guidance and authority to assist the individuals who ultimately must make treatment decisions. Implementation of these protocols helps assure that similar cases will be managed consistently and in accordance with shared values.