

Prevalence of Institutional Protocols: Current Status and Future Prospects

This chapter examines the extent to which decisionmaking protocols already exist in hospitals, nursing homes, and other health care institutions, and considers current activities within the public and private sectors that may encourage or im-

pede future development. Taking these existing incentives and barriers into account, the final section identifies and discusses five congressional options for promoting wider adoption and use of decisionmaking protocols.

CURRENT SITUATION

Several surveys have tried to determine the prevalence of decisionmaking policies and guidelines in hospitals and nursing homes, but available data are incomplete and inconclusive. The data do reveal substantial growth in the prevalence of protocols over the last decade, but they also suggest serious remaining deficits. In addition, differences in focus, methods, and timing of completed surveys leave some important questions unanswered. Some studies focus exclusively on do-not-resuscitate (DNR) policies; others report on broader guidelines to limit treatment. Unspecified definitions leave unclear what it means to have an “informal” protocol, to be “considering” developing a protocol, or to “accept” orders from another institution.

National estimates of the prevalence of decisionmaking protocols come from a survey conducted in 1986 for the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) (93). Data were obtained from a stratified, random sample of four kinds of health care institutions: acute care hospitals, long-term care facilities, psychiatric hospitals, and hospice organizations. The report provided national estimates of the prevalence of DNR policies as well as limited information about the prevalence of policies for “withholding and/or withdrawal of [other] treatment.”

In Hospitals

Of the four types of institutions surveyed, the Joint Commission found that acute care hospitals were the most likely to have a policy regarding resuscitation. Fifty-seven percent of acute care

hospitals reported that they had a “formal” DNR policy in place in 1986; another 28 percent said they had an “informal” policy. The national survey found (and this is consistent with findings from smaller surveys) that DNR policies were most common in large, urban hospitals, especially those with academic or religious affiliations. Most of the hospitals with no resuscitation policy were small and located in rural areas. Only 20 percent of all responding hospitals reported that they addressed issues of withholding and withdrawing treatments other than resuscitation (93).

Published examples of hospital protocols include those by: F.P. Arena et al. (15); Beth Israel Hospital (26); City of Boston, (36); F. Davila et al. (46); R.S. Duff (50); M. Halligan and R.P. Hamel (60); Los Angeles County (94); M. Mahowald et al. (97); Massachusetts General Hospital (99); A. McPhail et al. (100); A. Meisel et al. (104); S.H. Miles et al. (107); Northwestern Memorial Hospital (123); Presbyterian University Hospital (128); T.E. Quill et al. (131); Somerville Hospital (140); St. Joseph’s Hospital, St. Paul, MN (143); St. Joseph’s Hospital, Orange, CA (144); University of Wisconsin Hospital (155); J. Van Eys et al. (159); L. Volicer (162); and Yale New Haven Hospital (169).

National data obscure possible State-to-State and regional variations. Information on the prevalence of decisionmaking protocols in different parts of the country comes from a handful of surveys conducted within single States and one multi-State survey. A survey in five Midwestern States (Illinois, Indiana, Iowa, Michigan, and Wisconsin) found that 35 percent of the responding hospitals had

a formal DNR policy in 1982, and an additional 24 percent were in the process of developing one (117). The next year, a survey of Minnesota hospitals found that 44 percent of acute care hospitals had adopted DNR protocols and another 8 percent had protocols for "supportive care only" (see figure 2 and app. A) (110). A 1986 survey by New York State's Task Force on Life and the Law (122) found that only 29 percent of the responding hospitals had written guidelines for determining a patient's capacity to participate in a treatment decision.

The fact that large numbers of hospitals have no decisionmaking protocol or have one that deals only with resuscitation increases the probability that the treatment preferences of the hypothetical patients described in chapter 1 would be carried out, if at all, only partially, and largely by chance. The majority of acute care hospitals apparently do have a protocol that provides a means to implement a DNR order. If Mary Hinkel is ad-

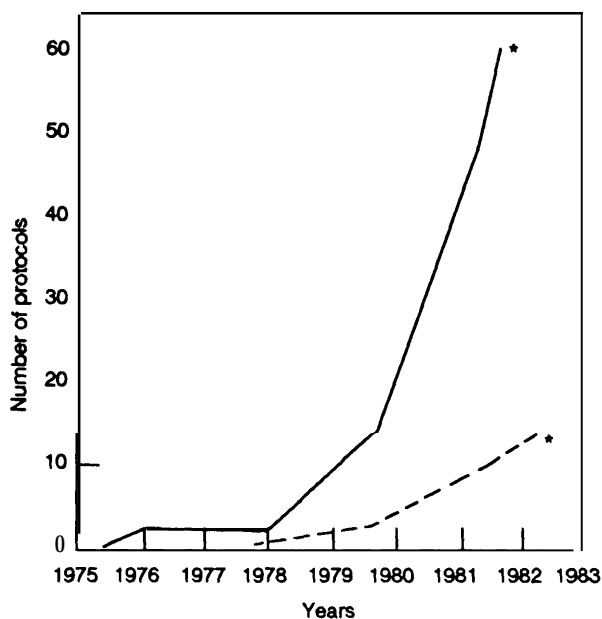
mitted to one of those hospitals, her advance directive rejecting cardiopulmonary resuscitation (CPR) is likely to be implemented. But how many patients know, upon admission, whether the hospital has a protocol or what it says? Further, even while honoring her DNR request, on-call personnel might also provide Mary Hinkel with unwanted diagnostic tests or unwanted, potentially life-sustaining treatments such as intravenous antibiotics. For patients like Thomas Johnson, even where there is a protocol permitting the treatment he wishes, problems can still arise if the protocol does not specify who may serve as decisionmaking surrogate.

In Nursing Homes and Other Health Care Institutions

The first nursing home protocols regarding decisions about life-sustaining treatments were developed several years after hospital ones, and their prevalence remains much lower. In 1986, only 20 percent of nursing homes reported having a written DNR policy and another 29 percent said they had an "informal" policy (93). Published examples of nursing home protocols include those by: King County Medical Society (86); S.A. Levenson et al. (88); J.D. Hoyt and J.M. Davies (67, 68); Task Force on Supportive Care (149); and R.F. Uhlmann et al. (152).

A 1984 sample survey of nursing homes in Minnesota found that only 10 percent of the responding institutions had a DNR protocol and 16 percent had institutional protocols for "limited treatment." At the same time, the majority of these institutions said that they "accept DNR orders" (73 percent) or "accept orders for limited treatment" (66 percent) (112). A 1984 survey of all licensed nursing homes in the Portland, OR, metropolitan area reported that 41 percent of the responding institutions had a policy regarding resuscitation (89). New York State's Task Force also surveyed nursing homes, but did not ascertain the prevalence of resuscitation protocols. It was determined that only 13 percent of New York's nursing homes, in 1986, had written guidelines for determining residents' capacity to participate in treatment decisions, despite the fact that staff estimated nearly half their residents had no ca-

Figure 2.-Adoption of Decisionmaking Protocols In Minnesota Hospitals



KEY: Solid line: Do-Not-Resuscitate protocols
Broken line: Supportive-Care-Only protocols

*Asterisk indicates first quarter.

SOURCE: S.H. Miles and D.G. Moldow, "The Prevalence and Design of Hospital Protocols Limiting Medical Treatment," *Archives of Internal Medicine* 144(Sept.):1841-1843, 1984. Copyright 1984, American Medical Association. Reprinted by permission.

capacity and a fourth had only partial capacity to make decisions (122).

This low level of formal protocols in nursing homes means that for a patient like Robert Swanson, refusal of CPR will be difficult to implement. Moreover, his ability to prevail in rejecting life-sustaining treatments other than CPR would be limited by the particular provisions of the nursing home's protocol and by his ability to clearly express his qualified request. For a patient like Mae Carver, who cannot speak for herself, the absence of a protocol that makes the decision process explicit and opens it to public questioning can invite inattention to her wishes or best interests.

In 1986, 15 percent of nursing homes reported that they had protocols addressing withholding and withdrawing life-sustaining treatments other than resuscitation (93). Examples described in the literature consider decisions about nutritional support, antibiotic therapy, and transfer to hospitals (25, 30, 59, 64, 88, 112).

The Joint Commission's national survey also obtained data for representative samples of hospice programs and psychiatric hospitals across the country (93). In 1986, 43 percent of hospice programs reported that they had a formal DNR policy in place. Among psychiatric hospitals, only 11 percent had such a policy. About 12 percent of the hospices and fewer than 2 percent of the psychiatric hospitals said they had protocols on withholding or withdrawing other life-sustaining treatments.

In Emergency Medical Services

Decisionmaking protocols also have a place in emergency medical services (EMS). Paramedics

and technicians employed by most emergency medical services are required to provide aggressive life-sustaining treatment, without asking questions. This practice can conflict with an order in a patient's record or with a patient's advance directive, especially in a health care system that tends to automatically transfer people to a hospital when a cardiac or respiratory arrest occurs (63).

To date, very few emergency medical services have developed protocols that allow paramedics to honor a DNR order received from a nursing home or hospice home care program (98, 108, 116). Thus, nursing home and home care patients like Robert Swanson or Thomas Johnson might have their rejection of life-sustaining treatments honored so long as they remain in the nursing home or at home, but they might face unwanted treatment if transferred. In some places, the only apparent way to avoid an EMS standing order for CPR is to not call the service if a patient who has declined CPR has a cardiac or respiratory arrest (25, 64, 88). This practice would protect patients like Robert Swanson and Thomas Johnson from unwanted CPR, but it could also deprive them of desired treatment for reversible conditions or for the prompt relief of severe distress.

Ideally, a single, coordinated set of protocols would be in place for the emergency medical service and the health care institutions that might call it, but this exists in very few places. In Minneapolis, the EMS developed a model protocol for nursing homes and for home care programs to go along with its own (108, 116). Detailed discussion of interfacility protocols and the portability of protocols is beyond the scope of this report. (For further information on this subject see, e.g., the article by S.H. Miles (106) or the forthcoming book by S.H. Miles and C. Gomez (109).)

INCENTIVES FOR PROTOCOL DEVELOPMENT

Within both the public and the private sector, a variety of incentives and requirements push health care facilities to develop decisionmaking protocols. To date, the action likely to have the most far-reaching impact is adoption by JCAHO of an accreditation requirement regarding resuscitation protocols.

Accreditation Standards

JCAHO accredits more than 5,000 of the 6,000 general hospitals in this country and over 3,000 other health care facilities. Thus any Joint Commission position on decisionmaking protocols carries great weight. In spring 1987, the Joint Com-

mission approved a new standard that requires all accredited hospitals to adopt a policy on "withholding of resuscitative services" (78). Hospitals were required to have a resuscitation policy in place by January 1, 1988; nursing homes must do so by July 1988; and psychiatric facilities must have one by January 1989. Similar standards for hospice programs accredited by the Joint Commission preceded these by a few years.

For hospitals and nursing homes, the Joint Commission's new standards are essentially the same. They direct the chief executive officer to provide for development and implementation of a resuscitation policy that is developed in consultation with medical staff, nursing staff, and "other appropriate bodies." The Joint Commission requires that:

- the resuscitation policy be designed "to assure that patients' rights are respected,"
- procedures be described for reaching decisions about withholding resuscitation and for resolving conflicts,
- orders regarding resuscitation be written by the physician primarily responsible for the patient,
- orders be documented in the patient's medical record, and
- the medical staff of the hospital (or physician members of the nursing home's professional staff) and governing body of the institution give formal approval before the resuscitation policy takes effect.

This action by the Joint Commission will undoubtedly lead to development of a DNR policy in many institutions that currently do not have one. Even institutions that are not applicants for accreditation by the Joint Commission may be motivated to develop DNR protocols because standards of that influential body can serve as quasi-legal standards of practice to which any institution may be held accountable (see section on legal considerations). For hospitals, moreover, accreditation by JCAHO confers "deemed status" for purposes of Medicare certification. Still, the influence of any voluntary incentive clearly is not unlimited. In addition, JCAHO's requirements are conservative, in that they say nothing about life-sustaining treatments other than resuscitation.

Other Incentives in the Private Sector

Incentives for developing decisionmaking protocols also come from the professional associations to which institutions or their staff belong. Numerous associations of health care institutions have developed position papers or educational materials promoting development of decisionmaking protocols, though most have stopped short of specifying procedures to follow (156). The "Patient's Bill of Rights" of the American Hospital Association (AHA) endorses the patient's right to receive information about his or her diagnosis, treatment, and prognosis, and to refuse treatment "to the extent permitted by law" (7). A 1983 position paper of the AHA (134) encouraged development of institutional protocols regarding resuscitation decisions.

The American Health Care Association, representing about 9,000 (out of approximately 17,000) nursing homes (158), circulated a report on "Health Care Decisionmaking in Long-Term Care Facilities" (6). This report encouraged development of institutional protocols for "life-and-death" decisions and identified topics that should be addressed. The Catholic Health Association of the United States (CHA) provides educational programming, consultation, and publications to encourage establishment of institutional ethics committees, institutional protocols, and use of advance directives. Upon request, CHA distributes samples of decisionmaking protocols to member hospitals and nursing homes, currently numbering over 900 (17).

Associations of health care professionals also support various means of improving and standardizing decisionmaking procedures. The biennial *Current Opinions of the Council on Ethical and Judicial Affairs* of the American Medical Association (AMA) spells out standards of conduct for physicians in relation to withholding or withdrawing a variety of life-sustaining treatments. In 1986 the AMA took the controversial position that "life-prolonging medical treatment includes medication and artificially or technologically supplied respiration, nutrition or hydration" (10). In December 1987, the AMA Council on Ethical and Judicial Affairs recommended to the AMA House of Delegates that "hospital medical staffs, with the approval

of governing boards, adopt statements of policy regarding do not resuscitate (DNR) orders." The report stated that "DNR policies should be based on medical, ethical, legal, and community standards and should be consistent with any religious principles adhered to by the hospital," and it included some specific suggestions individual hospitals might consider in drafting a DNR policy (11).

State medical societies also influence the activities of their members and the hospitals and nursing homes in which these professionals work. Minnesota's was the first State medical association to adopt DNR guidelines, in 1981. This provided a model for physicians belonging to that association and for the medical associations of some other States. By 1985, 40 percent of all State medical associations had adopted a model policy or model guidelines for DNR decisions (105). One physician specialist association that has addressed the subject of institutional protocols directly is the American College of Emergency Physicians. The association has resolved to develop a model protocol on how emergency medical services should address DNR orders (1, 2) and has taken the position that decisions to forgo resuscitation in the field must be in accord with written protocols (3).

The American Nurses' Association (ANA) and some State nurses' associations encourage their members to consider the appropriate role of nurses in decisionmaking about withholding or withdrawing life-sustaining treatments and to create formal documents on these topics. Examples include the ANA's *Guidelines for Nurse Participation and Leadership in Institutional Ethical Review Processes* (12), the California Nurses' Association "Statement on the Nurse's Role in Withholding and Withdrawing Life-Sustaining Treatment" (32), and the Florida Nurses Association resolution on "Clients Rights Regarding Administration of Artificial Sustenance" (52).

Decisionmaking protocols have also been devised and encouraged by individual researchers and by research organizations. A notable example is a 1987 publication by the Hastings Center, *Guidelines on the Termination of Life-Sustaining Treatment and the Care of the Dying* (62). In addition, citizens' groups (149, 152) and State and local health departments (36, 94, 145) have promoted decisionmaking protocols.

Incentives and Obligations in the Public Sector

The Veterans Administration (VA) exemplifies a large, public network of health care institutions in which central management now requires decisionmaking protocols for life-sustaining treatments. Throughout the VA system, the norm has been to provide CPR to every patient who sustains a cardiopulmonary arrest "except where the medical record contains a DNR order or resuscitation would be futile or useless." A new chapter in the VA *Manual* makes explicit the autonomy of terminally ill patients (VA Manual, M-Z, Pt. 1, ch. 30, change 81, Aug. 18, 1987), requiring that all VA Medical Centers develop a protocol "for dealing with issues involved when terminally ill patients request no CPR." At the discretion of individual VA hospitals, "(terminally ill)" can be broadened to include persons who are chronically ill with no hope of recovery (133).

Another new chapter of the VA *Manual* will address life-sustaining treatments other than resuscitation and the withholding and withdrawing of these treatments in situations other than cardiopulmonary arrest.^{*} The DNR protocols of individual VA Medical Centers may vary, but all must address the provisions and principles outlined by the Central Office. Following the VA model, decisionmaking protocols could be imposed by central management in other public health care systems and in jointly owned or managed private hospital and nursing home chains.

The approach taken in New York State illustrates another way public action can lead to decisionmaking protocols in health care institutions. In July 1987, New York enacted legislation that clarified the rights and obligations of patients, family members, and health care professionals in making decisions about resuscitation (N.Y. Pub. Health Law §§ 2960-78). The legislation, effective April 1, 1988, requires all hospitals, nursing homes, and mental health facilities in the State to develop DNR protocols consistent with the provisions of the legislation. The law was enacted in response to two widespread problems: the entry of DNR orders

^{*}Chapter 31 of the VA Manual (M-Z, Pt. 1) is currently undergoing final review (133).

without the consent of patients or family members, and the provision of resuscitation when it was medically futile because of fear of liability for entering a DNR order explicitly.

Legal Considerations

The central legal problem related to institutional protocols is whether or not they have the force of law (103). These protocols may be characterized as a form of private, interstitial lawmaking (35, 103)—private lawmaking in that they are created by nongovernmental entities yet may turn out to have legal force; interstitial lawmaking in that they make rules on topics that are not governed (or not governed clearly) by existing judicial, statutory, or regulatory law.

Like judicial, statutory, and regulatory law (i.e., public law), institutional protocols establish substantive standards for conduct and set forth rules of procedure for determining the applicability of those standards to particular cases. Unlike public law, however, it is uncertain whether institutional protocols will be found by the ultimate arbiters of law—the courts—to have the force of law. The result is serious uncertainty about the role of protocols in potential litigation concerning life-sustaining treatments.

The potential role of institutional protocols in litigation is a key concern of litigation-conscious health care institutions and health professionals. To date, the subject has received little explicit consideration, and it remains an “open question” (35). The possible effects of protocols range from preventing litigation to inviting it. And if litigation does ensue, protocols may constitute evidence that ranges from irrelevant to conclusive. In this uncertain environment, counsel for different health care institutions will continue to offer different advice about the pros and cons of protocols and about their particular provisions. However, some of the factors likely to determine the role of protocols in litigation can be identified and controlled, thus increasing the probability that protocols are to the institution’s, as well as the patient’s, advantage.

Whether protocols forestall or invite criminal or civil litigation depends mainly on three factors: consistency with existing Federal and State law,

consistency with accepted standards of practice, and faithful implementation (113). Protocols that meet these conditions can be expected to provide a degree of legal protection to institutions and to persons who are responsible for their adoption or implementation. Thus implementation of a hospital protocol to withdraw mechanical ventilation from a brain-dead patient is legally low-risk if the protocol’s provisions for determining brain death meet accepted professional standards and if State law recognizes brain death. On the other hand, when a protocol conflicts with the law or fails to meet professional standards, litigation—with a decision against the institution—is a realistic concern. A New York grand jury, for example, concluded that a hospital’s use of colored dots on a nonpermanent record (rather than use of a written DNR order) “eliminated professional accountability, invited clerical error, and discouraged physicians from obtaining informed consent” (47, 58, 170).

The first factor in determining the effect of institutional protocols is consistency with existing law. The effect of a protocol is safest, from the perspective of institutional liability, and most certain when the protocol accurately embodies State law. While such protocols (or particular provisions of them) may perform important educational functions within health care institutions, they have no independent legal effect because health care providers who rely on them are in reality relying on existing law.

Protocols that go beyond the law—in that they stake out institutional positions on issues that have not been addressed (or have not been thoroughly or clearly addressed) in legislation, regulation, or judicial decision—are more helpful to health care professionals, but their legal effect is less certain. For instance, an institutional protocol may recognize and give effect to living wills, even in States that have no living will law. (As of January 1987, 38 States and the District of Columbia had enacted living will laws (156).) The legality of withholding or withdrawing life-sustaining treatments in reliance on such a protocol is uncertain.

Institutional protocols that clearly and directly conflict with existing State law are an invitation to litigation, the result of which may be adverse to the health care institution, its employees, and

staff acting in reliance on the protocol. For example, the living will statutes of at least eight States specifically proscribe the withholding or withdrawing of nutritional support (156). At the same time, many institutional protocols regard artificial nutrition and hydration as medical treatments that may, like other life-sustaining treatments, be withheld from terminally ill patients who refuse them. It would appear that to follow such a protocol raises serious legal risk. In fact, however, courts have repeatedly concluded that the living will statute is only one way to exercise the right to refuse treatment and that the right to reject artificial feeding exists independently (40, 42, 70, 71, 76).

Some institutional protocols conflict with the spirit, but not the letter, of existing law. An example would be a protocol that permits withholding or withdrawing of artificial nutrition and hydration at the request of a patient who is able to make and express a contemporaneous, informed decision, in a State where the living will statute precludes withholding of artificial nutrition and hydration. Natural death acts apply specifically to the advance directives of patients who are currently unable to participate in decisions about their care. It can be inferred that the legislative intent is to prohibit the withholding of artificial nutrition and hydration. On the other hand, in the absence of clear legislative history, it is also reasonable to conclude that the legislature merely meant to prohibit the withholding of artificial nutrition and hydration from patients who lacked the capacity to make a contemporaneous decision about so significant an issue, rather than to override the clear preferences of a decisionally capable patient (103).

An institutional policy is more likely to be creditable to a court, and thus more likely to provide a defense in litigation, if it is embodied in writing and formally adopted by the institution. The New Jersey Supreme Court would not support a nursing home's wish to discharge a patient whose treatment preference (discontinuation of nutritional support) was morally objectionable to the facility (73). Instead, the Court ordered the nursing home to discontinue tube feeding for Nancy Jobes, who was in a persistent vegetative state for 7 years (72). In doing so, the court noted

that the nursing home's '(policy' against discontinuing nutritional support was unwritten and that the patient's family had not been informed of this policy before requesting that treatment be discontinued. The opinion left open the question of whether the institution's obligation might have been interpreted differently had the patient's family been prospectively informed of the informal policy. (Ultimately, Mrs. Jobes was transferred to Morristown Memorial Hospital, where nutritional support was discontinued and she died.)

Protocols that go beyond existing law (but do not clearly conflict with it) are more likely to be recognized by courts as valid (and therefore to provide protection from liability) if they are consistent with prevailing professional standards of practice. In legal procedures, a protocol could be variously interpreted as evidence of a standard of care, as a safety code, as defendant's own rules, as a learned treatise, or as inadmissible evidence (35). Since the 1965 *Darling* decision (45), policies of health care institutions pertinent to their duty to patients have been consistently admissible as evidence of a standard of care and, as such, considered along with other relevant evidence.

The standard of care, established by common law or statute, is the criterion by which health care professionals can be found liable if their conduct results in injury to a patient, or by which health care institutions can be found liable for negligence if conduct of their employees results in injury to a patient. Traditionally, the standard of care is established by the common law standard of "reasonable care." That is, in order not to be held liable, an individual must act as a reasonably prudent person would under like circumstances. Where the person sought to be held liable is a professional, the "usual and customary" standard of practice of the profession is strong evidence of what constitutes reasonably prudent care.

In the *Darling* decision, standards of JCAHO were for the first time accepted as evidence of a standard of practice (24, 127). Based on failure to meet the Joint Commission's standards of practice regarding appropriate care of a patient's broken leg, as well as violation of its own internal policies, the hospital was held directly liable for

injuries to the patient. Since *Darling*, standards of JCAHO have been used routinely by the courts to determine negligence by health care institutions. Although such institutions may not be explicitly required to conform to standards proposed by professional associations or accrediting bodies, nonconformity—if causally connected to a patient injury—can be used as evidence of negligent institutional administration. This lends added import to the Joint Commission's new standard calling for resuscitation policies.

In summary, the legal effects of protocols have not been tested directly, and thus will be viewed

differently in different places. However, there is no evidence that institutional protocols that are consistent with the law and with standards of practice increase legal risk, and there is some evidence they reduce risk, especially compared with resort to ad hoc or halfway procedures, such as "slow codes" and undocumented DNR orders (82). Accumulating case law, statutes like New York's, and new accreditation standards make a strong case for the legal benefits of protocols.

BARRIERS TO PROTOCOL DEVELOPMENT AND IMPLEMENTATION

As noted in chapter 1, substantial consensus already exists among the public, the health professions, and the law regarding fundamental principles for shared decisionmaking and patient autonomy. However, considerable work remains to be done to realize this consensus in practice, and theoretical and practical problems impede efforts to develop and implement protocols that have this goal. Moreover, consensus appears a long way off on some issues, especially appropriate use of nutritional support and appropriate care of uncommunicating, dying persons who did not previously express treatment preferences.

Barriers to development and implementation of protocols for decisions about life-sustaining treatments extend all the way from private fears of death to political and practical problems in effecting institutional and public policy change. The intensity and complexity of these private anxieties and public interests suggest there is no simple means to overcome them. In addition, these barriers are interconnected, each reinforcing the others. For example, Mary Hinkel's difficulty in raising her wishes with her physician accommodates the physician's reluctance to yield a paternalistic claim on medical decisionmaking. Robert Swanson's complex and conditional care plan goes beyond the simplified assumptions of many nursing homes' supportive care policies (see app. A). Health care facilities that are sensitive to the needs of vulnerable persons like Mae Carver have no framework for balancing the benefits of treat-

ment, the burdens of overtreatment, and their own financial interests.

Thus, the first hurdle for those trying to develop a decisionmaking protocol may be to revise the goal of accomplishing what is ultimately hoped for or what seems intellectually complete in favor of goals that are attainable in the short term and that at least improve the status quo. Development of decisionmaking protocols is best seen as an incremental process, building over time on an existing, evolving consensus. In addition, because the barriers are interrelated, efforts to resolve them will involve cooperation among health care institutions, practitioners, educators, patients, associations, foundations, and government agencies.

Barriers to development and deployment of institutional protocols, as well as some potential solutions, are discussed here under three general rubrics: barriers within health care institutions, in the domain of public policy, and in interpersonal encounters between patients and health care professionals. As will be indicated, problems arise in each stage of protocol development.

Barriers Within Health Care Institutions

Different kinds of health care institutions face different problems in attempting to develop and then implement decisionmaking protocols. Variations in institutional mission, patient population

served, staff size and composition, available treatments, regulatory requirements, and organizational complexity are among the major variables that distinguish health care institutions from each other and that may facilitate or impede protocol development. Other distinctions—including whether nonprofit or proprietary, with academic or without academic affiliation, sectarian or nonsectarian, urban or rural, and government or private—are also important. The following barriers can occur in any kind of institution.

Inadequate Multidisciplinary Staff Forums

Health care institutions are staffed by diverse groups of professionals with different perspectives, knowledge, roles, and interests. Physicians, nurses, social workers, allied health workers, lawyers, and administrators have different relationships with patients and with each other. (And the patterns are different in different types of institutions.) As a result, their views on the use of life-sustaining treatments and on what constitutes appropriate decisionmaking often conflict (54, 156, 168). Forums for communication and exchange among those who are responsible for making treatment decisions and those who must carry them out provide a base for developing protocols that effectively integrate treatment planning, caregiving, and legal responsibility.

Several existing types of multidisciplinary forums could be instrumental in protocol development and, later, can play a key role in implementing the protocols by educating staff about their rationale, interpretation, and use. Ethics committees have already assumed an active role in protocol development. However, one-fourth to one-half of all hospitals (especially small and rural ones) still have no ethics committee (156). In nursing homes, well over 90 percent may have no ethics committee. (A national survey found “a minimum of 2 percent” of nursing homes do have an ethics committee (56).) (For a review of the purposes, uses, and forms of institutional ethics committees, see, e.g., the book by R. E. Cranford and A. E. Doudera (44), the report of the president’s Commission (130), or the article by F. Rosner (135).)

Patient care conferences are another forum from which protocols could emerge, provided time

is reserved from talking about day-to-day details for more generalized discussion of ways to improve patient care. In some institutions, ad hoc protocol committees, study groups, or investigative task forces have been convened. Another possible forum for consideration of protocols is utilization review committees; however, because the primary agenda of these committees is cost containment, some people warn against this (105).

For a variety of reasons, health care institutions have limited ability to establish and sustain the multidisciplinary interaction necessary to create and implement decisionmaking protocols. In some facilities, especially small nursing homes and rural hospitals, limited staff size (both in absolute numbers and relative to the workload) is a major obstacle. Many clinicians resist committee work; crowded schedules, competing demands, and lack of interest incline them against it. In most nursing homes, physicians’ limited presence makes collaboration with other staff difficult. This works against the resolution of role-related tensions and agreement on treatment plans or policy issues.

Inadequate Expertise

Another substantial barrier to protocol development is inadequate expertise among staff in either clinical ethics or health care law. Health care staff are often not fully informed of current opinion in clinical ethics, especially in complex, constantly evolving areas such as surrogate decision-making. professional ethicists are increasingly seen in hospitals, but institutions with a staff ethicist are still very exceptional. Approximately 300 professional ethicists are employed by hospitals in this country (80).

Many health professionals also have mistaken views of their legal and professional duties (83). Moreover, misconceptions among health professionals are sometimes amplified by lawyers for the institution or by insurance companies that issue malpractice policies (23). Also, attorneys who are unfamiliar with recent developments in medical ethics or with the constraints of clinical practice (as well as those inclined to rely on the judicial process for dispute resolution) may give inaccurate or unrealistic advice regarding oversight, surrogate designation, or dispute review. For example, lawyers for health care institutions

may conclude that lack of absolute protections offered by explicit governance of clinical decision-making does not warrant the effort required to develop a protocol. Indeed, as noted earlier, some lawyers believe that a decisionmaking protocol could increase the institution's risk of liability or public notoriety.

Obtaining or building the necessary expertise will require personal and institutional commitments of time, money, and support for ethics and legal education to develop a core of staff to serve as resources in every health care facility. Once staff are trained and protocols are developed, ongoing programs of staff education will be required to encourage implementation of improved decisionmaking practices.

Inadequate Leadership

Some health care institutions, especially nursing homes, lack leaders who can identify the need for decisionmaking protocols and can initiate and sustain the multidisciplinary effort needed to develop and implement them. Inadequate leadership may take the form of resistance to protocols. Despite publicity and pressure on health care institutions about the value of decisionmaking policies and guidelines, observers report that many people still believe such protocols are not needed (80) or that they will have no effect on health care (159), will abridge physicians' prerogatives (100), will increase patients' anguish (21, 91, 141, 160), or will be used to discriminate against persons with severe disabilities (41). Others charge that decisionmaking protocols are an attempt to engineer rather than to inculcate values into practice (84).

Inadequate leadership is often associated with inadequate resources for ethics activities, especially shortages of financial support, staff time, and clerical assistance. Lack of leadership to create and sustain multidisciplinary staff forums is a common problem, as noted earlier. Unpublished data suggest that many nursing homes have not developed protocols because no one in the institution has identified their function or need (33).

Leadership might be strengthened through educational programs within health care facilities, focused on the fundamental issues of good clinical decisionmaking practices. Such programs would be appropriate for all staff and administrative groups. One element of this education might be the dissemination of prestigiously endorsed model protocols that could be adapted to individual facilities. External pressures, such as JCAHO standards, might also effectively encourage leadership within institutions.

Public Policy Barriers

Inadequate Theory of Institutional Governance

The individual goals and responsibilities of institutional governance with regard to decisions about life-sustaining treatments have not been adequately defined or interrelated. Public attention has so far focused on distinct clinical decisionmaking principles, such as patient autonomy, not on how to integrate treatment decisions into a comprehensive understanding of a health care facility's total governance duties. The uncertainty that results when diverse responsibilities conflict (see app. A) is a disincentive to creating institutional protocols. Another problem is that public policy (in the form of statutes, case law, and institutional protocols) can leave unclear the interpretation of such key concepts as "decisionmaking capacity" and medical "futility." In addition, as discussed, basic questions about the legal status of institutional decisionmaking protocols remain unanswered. All these problems impede both development and implementation of protocols.

For nursing homes, an additional public policy problem is related to the highly regulated environment in which they operate. Federal and State regulations, and especially what some people perceive as their inconsistent interpretation, create what may be a unique and serious barrier to development of protocols in nursing homes. A nursing home surveyor may judge a decisionmaking protocol either as an asset or as an outrage. Un-

able to predict which, some nursing home administrators believe that a protocol with which a nursing home surveyor might find fault is worse than no protocol at all (61). This kind of uncertainty argues for examining the regulations and making sure they are understood by those who enforce them.

Questions involving the interrelationships of the various responsibilities that health care institutions must balance warrant careful study. Better understanding of these interrelationships would help guide both public policy and clinical policies toward the goal of improving decisions and advancing public interests.

Inadequate Financial Support for Ethics Programs

The costs to health care institutions of employing professional ethicists, establishing and maintaining an ethics committee, and training health care staff in clinical ethics are high. Health care institutions that undertake these initiatives currently do so without public support, often by absorbing the expense into their net costs. Ethics consultations, education, and related activities (especially ethics education of those who teach core staff in all health care disciplines) are essential to improving health care decisionmaking. Requiring certain minimum standards of ethics programming would help ensure that health care facilities allocate funds, staff, and other support.

Financial support might come from Federal, State, or private sources. Grants would be especially appropriate for support of academic or research initiatives, such as evaluative research on protocol design and pilot programs for staff and patient education and counseling, as discussed earlier. The day-to-day operation of ethics programs within health care facilities will probably need to be supported as a general administrative cost. Some commentators have proposed that physician time to educate and inform patients about options regarding life-sustaining treatments be directly reimbursed by health insurance (53).

Present data and auditing procedures do not allow good estimates of the costs of protocol design, staff education, the operation of ethics committees, or related activities. To a certain extent, the reduction of misdirected or unwanted medical treatment and litigation would offset the costs of this programming.

Barriers Within Patient-Provider Encounters

Patients' Inadequate Knowledge or Motivation

Implementation of a decisionmaking protocol requires a degree of support and cooperation on the part of patients or their surrogates. That is, while protocols specify procedures to follow when the patient cannot participate in a treatment decision and when no surrogate has been designated, they assume that when the patient is able to participate and when a surrogate is designated, he or she will in fact do so—either by taking part in discussions at the time the treatment is being considered or by making a clear directive or appointing a surrogate in advance.

However, some patients who are decisionally capable and the surrogates for some patients who are not decisionally capable have great difficulty discussing such personal and serious problems frankly, or they are unable to grasp the medical and legal information presented to them. Some patients choose to defer decisionmaking responsibility to their physician or to a family member (156). Others resist giving an advance directive, fearing its mere existence might preclude discussion even while they remain able to participate in a decision (66). After 15 years of spirited public debate, only a small percentage of patients have discussed treatment preferences with their families or physicians or have written an advance directive such as a living will.²

²The only known data on this subject come from a 1986 survey of Oregon households. Researchers found that adults in 82 percent of sampled Oregon households had heard about living wills. However, respondents in only 16 percent of households said they had a living will. In households with one or more person(s) over age 65, 23 percent reporting having a living will (20).

One way to reduce this problem is public education regarding patients' rights and principles for responsible decisionmaking. A major objective would be to foster dialog within families as well as between patients and health professionals. Such public education would primarily aim to protect patient autonomy through encouraging advance planning for health care decisions. For efficiency, the educational effort could be directed to individuals whose progression toward death or incompetence is foreseen.

Health Professionals' Inadequate Knowledge or Motivation

Like patients, staff of health care institutions often have a poor understanding of decisionmaking principles or, more likely, lack the fortitude to apply them in difficult clinical cases. In caring for patients who are critically or terminally ill, health professionals' personal fear of death and

fear of failure as a healer may make them delay raising the subject of life-sustaining technologies or may make them unable to discuss treatment options with sensitivity and openness. Timely and skillful communication with patients and their loved ones are basic to the implementation of decisionmaking protocols.

One solution is to translate the principles for good communication and shared decisionmaking into practical terms so that health professionals are motivated and capable of applying them consistently and in timely fashion. Professional training of those who care for persons with potentially life-threatening conditions must also inculcate realistic attitudes toward death and dying and toward the role of health care professionals, to promote beneficial communication. Part of this education would focus on clinical ethics and, in particular, respect for persons who are elderly, disabled, or otherwise vulnerable.

ESSENTIAL STEPS IN PROTOCOL DEVELOPMENT

Development and adoption of decisionmaking protocols appear to have four distinct stages. The resources and routines of health care institutions may be challenged at each stage, and the incentives and barriers just described can influence developments throughout the process.

Recognition of Need

The first step in developing a decisionmaking protocol is to recognize that decisionmaking problems exist, to embrace the idea that a formal protocol will reduce these problems, and to put protocol development on the institutional agenda. Anecdotal accounts (100, 159) suggest that the specific events and individuals within a facility that propel protocol development are quite varied: a new kind of case may raise legal and ethical uncertainties; difficult treatment decisions for a favorite patient may cause staff conflict; a lawsuit against the facility (actual or threatened) or a publicized legal case elsewhere may heighten legal fear; awareness that a neighboring facility has a protocol may stimulate competition; concerned

staff may believe that a decisionmaking protocol will improve responsiveness to patients' needs; or consumer groups such as nursing home residents' councils may push for clarification of decisionmaking practices.

The events and perspectives that sometimes stimulate development of protocols exist in all kinds of health care institutions. These may reinforce and help prepare the way for any legal or accreditation requirements that, in effect, force institutions to recognize their need for a decisionmaking protocol. Because the events and their interpretation vary, they may lead to different kinds of protocols. For example, if a CPR case triggers discussion, CPR maybe all the resulting protocol addresses. Conversely, if the precipitating problem concerns other treatments, the protocol that is developed may be more inclusive.

Formation of a Drafting Committee

Another prerequisite to protocol development is committed leadership. This may come from the

administration, ethics committee, chaplaincy office, or clinical staff. Protocol drafting maybe assigned to an existing group, often an ethics committee, or to a special task force (e.g., of a medical practice review board). Self-selected, ad hoc drafting committees are seldom empowered by the highest governing boards, though they may receive encouragement from senior administrators. Rather, their strength stems from their internal leadership and the commitment of a core group of respected staff associated with their effort. Official empowerment may come later, when the group's purpose and track record are clearer.

For reasons discussed in the preceding section, successful protocol development is greatly facilitated by a multidisciplinary staff team. Typically, this includes physicians, nurses, social workers, clergy, ethicists, and administrators. The actual composition depends in part on the size and nature of the facility's staff: physicians tend to be more prominent in hospital committees; nurses and social workers, in nursing home committees. Other staff members will round out the group. Some people believe that involvement of the institution's legal counsel throughout the process of protocol drafting is especially valuable. This helps ensure that counsel has an understanding of clinical and ethical issues, without which he or she may be unable to provide either constructive evaluation of the finished protocol or realistic advice during the drafting process.

Protocol Drafting

The drafting process commonly begins with several meetings to allow members to express their concerns and set an agenda for member education. To start, drafting committees need familiarity with and understanding of current policies and practices within their institution regarding decisions about life-sustaining treatments. The head of one drafting committee reported that an informal survey of staff helped identify sources of confusion, conflict, and consensus, and thereby helped focus the work of the committee (80).

Although decisionmaking protocols are meant to fit the specific interests and circumstances of individual institutions, this does not mean that each drafting group must "recreate the wheel."

Published protocols provide a range of starting points and ideas. Some drafting committees start with a published policy or set of guidelines or use a protocol of a neighboring facility as the basic structure. Other committees rely on "model" protocols to guide their work. These are advisory documents, developed by institutions or individuals claiming special expertise or authority, for the express purpose of assisting health care facilities in developing their own policies or guidelines. (Examples of model protocols include those by: American Hospital Association (9); Bar Association of San Francisco (19); Hastings Center (62); J.D. Hoyt and J.M. Davies (67, 68); Joint Commission (78); Medical Association of Alabama (101); Medical Society of NY (102); Minnesota Medical Association (115); Task Force on Supportive Care (149); R.F. Uhlmann et al. (152); Veterans' Administration (161); and S.H. Wanzer et al. (165).)

Amendments to a good model should be vigorously debated, but they may be necessary when, to cite one consideration, external agencies impose requirements on a facility that are not adequately addressed in the model. For example, existing models for DNR protocols will have to be amended if they fail to meet specifications of the Joint Commission's new standard. Models also might be amended to conform to local usage of key terms, in order to decrease confusion among practitioners working at several different institutions, or to improve communication in interfacility transfers (106).

Adaptations may be made to conform to special moral (150) or medical (159) missions, or to identify specific officers or bodies responsible for implementing and revising the protocols (114). A nursing home chain operating within a single State should be able to design a model that can be used by all its facilities with a minimum of modification. However, models proposed by national groups may need to be substantially changed if they are to work in diverse facilities in different States. In anticipating the diverse needs of the institutions starting from a single model, some models provide a "menu" of optional provisions, applicable or acceptable to certain institutions and certain purposes. After dissemination of a model, followup research could look at the adaptations made by different institutions and evaluate whether

these suggest needed changes in the model itself (111).

Drafting an original protocol or adapting an available model does more than produce a protocol for a particular facility. The process is a crucial one, through which health care staff can learn the intent and operation of the protocol and come to “own” its provisions. This is another reason it is important to have wide representation in the drafting and review process. Restricting discussion to the administrative or trustee level, as has sometimes been done, is bound to create problems later.

Health care institutions usually crosscheck the proposed protocol at several levels. Most protocols go through numerous drafts within the committee, where terms and concepts are vigorously debated. Early drafts might be circulated among clinical supervisors and other key personnel, and later drafts among the entire staff for comment and revision. In addition to permanent medical staff, it is important to include housestaff and nurses—the individuals who often must implement the protocols. This process is crucial if a facility like Torah Home is to claim that the protocol represents the moral position of staff or of the institution. Institutions may enlist outside ethics consultants or lawyers before finalizing a decisionmaking protocol. Some people take the position that representatives of all groups that will be affected by the protocol should have a say in its development. This suggests that patients and family representatives should also be involved in the drafting or review (23, 80).

Protocol drafting is a difficult process that can take a longtime. Moreover, the importance of the

protocol and the educational value of the process itself argue against rushing (171). Personal accounts of experience in several large university hospitals suggest that, from start to finish, protocol drafting and adoption often takes a full year, and sometimes 2 years (16, 80, 104, 171).

Staff Education and Commitment

It can never be assumed that creation and adoption of a decisionmaking protocol ensures its accurate and reliable implementation. Ideally, the process of protocol development has created a multidisciplinary core of staff who understand the rationale for the policy or guideline and its application to their work, and who will help to educate their trainees and coworkers. Provision for ongoing staff education to promote familiarity with, understanding of, and commitment to the protocol is an important component of the total effort to develop a decisionmaking protocol. Moreover, the agenda for staff education is broader than the procedures outlined in the protocol. It includes education in the ethical and legal principles that underlie good decisionmaking and their application to clinical care.

Protocol implementation also requires sustained and coordinated leadership and commitment by the institution's administration. This must extend beyond the leadership of the individuals or committees that initiated development of the protocol. Only institutional leadership can establish mechanisms for the periodic review of adopted protocols and for allocation of funds and staff time for ethics committees and in-service training.

CONGRESSIONAL OPTIONS

The central issue for congressional consideration was identified at the outset of this report.³

³Many of the congressional policy options presented in chapter 1 of OTA's report *Life-Sustaining Technologies and the Elderly* (156) pertain to improved decisionmaking. In particular, OTA identified strategies that address access to health care, patients' rights, and support for research to improve clinical decisionmaking. The options presented here expand on that discussion.

What steps, if any should Congress take with respect to institutional protocols for decisions about life-sustaining treatments for adults? The potential range of congressional responses is as follows:

- **Option 1:** Take no action.
- **Option 2:** Seek more information.
- **Option 3:** Encourage and facilitate, within

the private sector and the States, voluntary approaches to addressing problems in clinical decisionmaking.

- **Option 4:** Encourage States and voluntary agencies to adopt consistent and enforceable standards for decisionmaking.
- **Option 5:** Instruct the Health Care Financing Administration (HCFA), the Public Health Service, other agencies of the Department of Health and Human Services (DHHS), the VA, and the Department of Defense to adopt regulations to require health care facilities under their authority to do one of the following:
 - 5a: Adopt a resuscitation protocol comparable to that required by JCAHO;
 - 5b: Adopt a decisionmaking protocol that contains, as a minimum, elements specified directly or indirectly by Congress; or
 - 5c: Adopt a protocol prescribed by Federal law.

Any congressional action to encourage and improve institutional protocols for decisions about life-sustaining treatments will proceed in the context of ongoing private-sector and State and local initiatives. It could be argued that the activities of non-Federal legislatures, courts, and regulatory bodies, as well as private voluntary organizations, collectively provide sufficient incentives and assistance to promote better decisionmaking regarding life-sustaining treatments. If this is the case, congressional initiatives in this area would be unnecessary or redundant, and no congressional action is warranted (Option 1).

Among the members of OTA's workshop panel for this project, representing many of the major associations of health care institutions and professionals, the option of no congressional action received only one strong vote of support. The chairman of AMA's Council on Ethical and Judicial Affairs indicated that he "and probably most doctors" would find congressional action in this area unwarranted and unnecessary.

Many people, including the vast majority of OTA's workshop panelists, argue that Congress could play a helpful role by actively seeking more information on how treatment decisions currently are made, on the effects of decisionmaking protocols, and on the adequacy of voluntary measures to promote them (Option 2). This could be

accomplished by holding hearings or by appropriating support for research through DHHS. Advocates of such research include the American Bar Association, whose February 1988 conference on Birth, Death and Law recommended that research on treatment decisions precede any effort to encourage new legislation, since existing law may be adequate (92).

Various aspects of the research agenda for supporting optimal decisionmaking protocols have been discussed in the preceding sections. These include study of how best to meet the objectives of protocols and how to overcome barriers to their adoption and implementation, specifically:

- research that tests the basic assumptions of institutional protocols—i.e., that they improve clinical decisionmaking and reduce legal risk to health care institutions;
- trials of various model protocols and of methods to train health care professionals in their use, especially addressing protocols in nursing homes, emergency medical services, and home care, where experience is most limited, to determine what specific design features work best;
- research to refine definitions of critical concepts used in decisionmaking protocols and health law, e.g., "decisional capacity," "terminal illness," and "treatment futility"; and
- research on model legislation for advance directives and interfacility communication of them.

If such research substantiates the presumed benefits of institutional protocols, its dissemination might help to encourage their wider adoption. Also, specification of the impact of various protocol designs could assist Congress, as well as the States and individual health care institutions, to formulate effective solutions to meet particular needs.

Option 3 is for Congress to encourage and promote, within the States and the voluntary sector, activities that are related broadly to reducing problems in clinical decisionmaking. Activities already occurring at the State level that may warrant congressional acknowledgment and support include passage of living will legislation; development of commissions to advise State legislatures on mat-

ters of health care ethics (New Jersey and New York); and development of grassroots organizations concerned with ethical dilemmas in health care (California, Oregon, Vermont, and elsewhere). The contributions of professional associations, individual health care institutions, and private organizations include education, advocacy, and research. Emphasizing State-level and voluntary activities would maximize flexibility and creativity, and take advantage of existing initiatives. A serious reservation, however, is that many States do not have the committed leadership or resources to take up matters of health care decisionmaking in an effective or timely way. The Federal Government could facilitate dissemination of information among the States.

Another approach is for Congress to encourage States and non-Federal health care systems to voluntarily develop and adopt enforceable standards that support consistent and ethical decisions about life-sustaining treatments (Option 4). Among the diverse examples are the decisionmaking guidelines developed for nursing homes in California by that State's department of health, New York's legislation on resuscitation, and JCAHO's standard requiring resuscitation protocols in the institutions it accredits. Development of such standards might be encouraged by Federal grants to support State and local legislation, research, education, and institutional initiatives. Financial support would facilitate and stimulate a variety of local solutions, from which much could be learned. It would also signal the seriousness and urgency with which Congress views this matter.

Option 5 would provide more definitive congressional leadership by imposing Federal regulation on decisionmaking practices within health care institutions. This could be accomplished by mandating the adoption of decisionmaking protocols in all Federal health care institutions and by adding decisionmaking protocols to the requirements for certification for Medicare and Medicaid. The vast majority of hospitals and nursing homes in the country would thus be affected.

In mandating decisionmaking protocols, Congress could leave a great deal, or nothing at all, to the discretion of individual institutions. One possibility (Option 5a) is to require that institu-

tions adopt the resuscitation standard of JCAHO. This standard indicates general topics that must be addressed in any resuscitation protocol without specifying what the protocol will or will not allow. Alternatively, Congress could require all Federal health care institutions as well as non-Federal institutions that receive Medicare or Medicaid reimbursement to adopt decisionmaking protocols that go beyond decisions about resuscitation and that include certain specific features (Option 5b). Finally, Congress could prescribe complete decisionmaking protocols and insist on their adoption without modification (Option 5c).

The idea of congressionally mandated protocols (whatever the degree of specificity) assumes that private-sector and local initiatives are and will remain inadequate. Such a mandate was strongly advocated by only one OTA workshop participant, the director of a nursing home. He argued that protocols are far less likely to be developed if left to voluntary efforts and that, in many places, for Congress to "not mandate" is equivalent to "allow not to be done." The majority of workshop participants believed that the intense pursuit of these questions by the health care sector, State legislatures, legal groups, patient advocacy groups, and academic centers suggests no lack of will. Still, some would argue, Congress could assume leadership in this area.

If Congress were to mandate adoption of decisionmaking protocols, this could be in accord with one or more long-range goals. For example, the goal might be for all health care institutions to have a protocol in place by some specified future date, say 1990 or 1992. Alternatively, Congress could set target dates by which hospitals, then nursing homes, and then other kinds of health care institutions would have a protocol in place. This type of long-range plan would encourage experimentation and permit time for research and accumulating experience to be put to good use.

With Option 5a, resuscitation protocols would be adopted throughout the health care system, based on the most current and most widely accepted of private-sector standards, namely those of JCAHO. Determination of specific provisions of protocols would be left to the individual institutions, as would be the work of protocol devel-

opment, but the standards of JCAHO would provide guidance. Current HCFA regulations for Medicare and Medicaid certification have no analog to the recent JCAHO requirement for a resuscitation protocol.

Option 5a is really a conservative step in that the new decisionmaking protocols it requires would not necessarily address life-sustaining treatments other than resuscitation, despite a growing consensus that this is important. Further, the majority of non-Federal hospitals are already obliged to meet the Joint Commission's resuscitation standard, and many Federal institutions (notably VA facilities) are already required to have a resuscitation protocol. The main effect of Option 5a would thus be to increase the adoption of resuscitation protocols in private institutions that are currently not accredited by the Joint Commission. The effect in nursing homes would be more significant than in hospitals since the majority of nursing homes are not accredited by JCAHO.

Option 5b is for Congress to mandate that all Federal hospitals and nursing homes and all non-Federal institutions that receive Medicare or Medicaid funds adopt a decisionmaking protocol that meets certain specified, minimal requirements. Regulations associated with Option 5b could, for example, specify that protocols must address decisions about life-sustaining treatments in addition to resuscitation. Minimal, essential elements of protocols could be identified without imposing rigid solutions and without attempting to be comprehensive. For example, Congress could insist that protocols indicate how the patient's capacity to participate in a decision will be assessed,

without imposing a method for this assessment. Further, Congress could insist that all protocols address assessment of capacity and documentation of decisions without suggesting that these essential elements make a complete protocol.

Support for mandatory decisionmaking protocols that are partially or totally prescribed by Congress assumes that Congress or the agency to which protocol design would be assigned is well-qualified for this task. Among participants at OTA workshop, some strongly opposed the idea of Congress mandating protocols with content even partially specified. Some people reject, in principle, legislative involvement in the details of clinical practice. Others appreciate the laudatory intent, but fear that the actual regulations would quickly exceed the few ideas on which there is a sound and stable consensus.

The most active congressional role would be to dictate specific conditions and procedures for decisions about the use of life-sustaining treatments (Option 5c). This approach would eliminate the variability that now exists from institution to institution and State to State. However, objections to Option 5b apply and are multiplied. Lack of empirical research on the strengths and weaknesses of particular features of protocols suggests it would be premature for Congress (or for any other group) to attempt to write an acceptable "national" protocol. Congressional action to direct clinical decisionmaking in advance of a consensus from leadership within the health care industry would be immensely controversial, would be unlikely to succeed, and might preempt constructive public discussion,