

Content and Format of Decisionmaking Protocols

General Comments

Decisionmaking protocols currently in use differ in scope, content, format, and style. In this section, three general protocol designs and some significant differences of style and content are described.

While considering the differences among protocols, it is useful to remember that all have the same principal goal: to help a physician and patient (or surrogate) choose the most appropriate care for an individual patient. Each approach to protocol design has advantages as well as disadvantages, and each has features that fit particular circumstances better or worse. It is probably premature to conclude that any single approach is best or that any approach should be avoided.

Some advocates of institutional protocols believe that the essential test is whether a protocol indeed works, i.e., whether it successfully encourages dialog about treatment questions and subsequent development and implementation of appropriate treatment plans (16). Delineating the effects of different types of protocols and of specific features will require careful empirical studies. Such evaluative studies could accompany the ongoing process of protocol design and updating.

There has so far been very little investigation of the effects of institutional protocols on decisionmaking practices. Thus, numerous studies have reported that physicians often do not involve patients in decisions about resuscitation (21, 22, 51, 138, 153, 156, 166, 172, 173) but very few studies relate this finding to the presence or absence of a do-not-resuscitate (DNR) protocol. Two hospital studies reported that the use of DNR orders increased after a DNR protocol was introduced and that understanding of DNR orders improved (22, 131). Another study reported that hospital staff read the DNR protocol and said it helped their practice because it clarified the processes of making and implementing decisions to withhold life-sustaining treatment and encouraged more open dialog (100). More detailed

studies of protocols and of specific design features could lead to more effective protocol design.

Voice: Prescriptive v. Advisory

One key distinction among decisionmaking protocols is the “voice” with which the processes of making and implementing decisions are addressed. These processes may be addressed either by a prescriptive voice (characteristic of policies) or an advisory voice (characteristic of guidelines). The difference should be kept in mind in order to avoid using prescriptive language for principles that are intended to be advisory, or vice versa.

Hallmarks of the prescriptive voice are precise assignment of responsibility for decisions and detailing of procedures to be followed in implementation. “The nurse acknowledges the order by co-signing the ‘levels of treatment order sheet’,” for example, is a policy statement (154). This is quite unlike the advisory statement “It is wise for the primary physician to ensure through further discussion that the patient family has full understanding of the decision” (37). The prescriptive voice is especially appropriate for stating fundamental institutional precepts, directing that essential procedures be accomplished, and coordinating interactions among health care professionals. Prescriptive language is less well suited to directing the subtle encounters of physicians, patients, and family (84), especially in areas where practice standards are incompletely defined. (Published policies include those by: Beth Israel Hospital (26); City of Boston (36); Los Angeles County (94); Massachusetts General Hospital (99); A. McPhail et al. (100); Northwestern Memorial Hospital (123); Presbyterian University Hospital (128); Somerville Hospital (140); E.V. Spudis et al. (142); University of Wisconsin Hospital (155); L. Volicer et al. (163); and Yale New Haven Hospital (169).)

The advisory or teaching voice of guidelines seems better suited for assisting health care professionals.

Guidelines suggest approaches to morally and legally difficult decisions about life-sustaining treatment while allowing interpretive latitude to accommodate the ambiguity of clinical situations. Guidelines can elaborate on fundamental principles (e.g., patient autonomy), explain the rationale for policy provisions (e.g., the role of an ethics committee), or suggest approaches for difficult clinical situations (e.g., assessment of decision-making capacity or initiation of discussion about limiting treatment). (Examples of published guidelines include those by: M. Halligan and R.P. Hamel (60); Hastings Center (62); S.A. Levenson et al. (88); J. Van Eys et al. (159); St. Joseph's Hospital, St. Paul, MN (143); St. Joseph's Hospital, Orange, CA (144); and S.H. Wanzler et al. (165).)

The flexibility of guidelines can accommodate the nuanced and idiosyncratic physician-patient-family encounter (129, 139). This flexibility also allows for an initial, provisional articulation of an emerging consensus within an institution regarding how to address decisions about life-sustaining treatments. Some people believe that the flexibility of guidelines should be retained in the final protocol; others maintain that guidelines are an agreement on principles for decision-making about life-sustaining treatments, from which more detailed procedural duties might later be derived (159).

Prescriptive and advisory language are often combined in a single protocol (e.g., 26, 104, 107). Ideally, the prescriptive language sets minimal standards for procedural accountability and implementation, and the advisory language elaborates on subjects or ideals that are too elusive to be captured in prescriptive language. Protocols that employ prescriptive language to state advisory principles lead to confusion. Examples include protocols that restrict the right to refuse life-sustaining treatment to persons who are "terminally ill." Omission of any reference to persons who have *not* been diagnosed as terminally ill implies that they do not have the same right (100, 161).

Other Elements of Style

Several general principles can be recommended based on experience to date with protocols in health care facilities across the country.

Protocols are intended to influence medical, nursing, and social work practice and should be written for the practitioners who use them. This suggests that:

- s protocols should not employ arcane or legalistic language,
- protocols should be formatted to facilitate locating desired information, and

c protocols should be as brief as possible so that health care staff can grasp the totality of their intent and implementation (though a longer, companion protocol could include rationale and fuller explanations).

With model protocols, designed to address the diverse needs of numerous health care facilities, length is less important. The expectation is that models will be shortened in creating individual protocols. Because it is assumed that model protocols will be interpreted and adapted by a facility's "ethics experts," models may also be relatively complex. Still, designers of a model should recognize that expertise in medical ethics or law may be scarce among those charged with adapting it.

Paradigms of Decisionmaking Protocols

There are three basic types of decisionmaking protocols, distinguished by whether they provide for do-not-resuscitate orders only, care categories based on either "treatment levels" or "treatment goals," or detailed treatment plans. (Examples of each appear in app. B.)

Do-Not-Resuscitate Protocols

Protocols providing for implementation of do-not-resuscitate orders were the first, and remain the most prevalent, form of decisionmaking protocol (65, 110, 117). Numerous samples have been published. (Examples of DNR protocols include those by: Beth Israel Israel Hospital (26); City of Boston (36); Cleveland Clinic (38); Los Angeles County (94); M. Mahowald et al. (97); A. McPhail et al. (100); S.H. Miles et al. (107); National Institutes of Health (120); Northwestern Memorial Hospital (123); Somerville Hospital (140); St. Joseph's Hospital, St. Paul, MN (143); St. Joseph's Hospital, Orange, CA (144); and University of Wisconsin Hospital (155).)

DNR orders provide an exception to a unique standing order to provide cardiopulmonary resuscitation (CPR). The order is directed to on-call staff who, because of the urgency of cardiac arrest, are unable to consult with the patient or primary physician about the desired course of therapy (170). DNR orders are commonly written on general medical wards and in intensive care units (ICUs) (51, 90, 153, 166, 172). The DNR protocol (usually called a "policy") typically indicates the conditions under which DNR orders may be written; the roles of the patient, physicians, and other parties; and how the order is to be documented and carried out.

Protocols concerning CPR, more than any other life-sustaining treatment, became an urgent institutional need. The practice of universal standing orders for CPR could not be abandoned in favor of individual CPR orders upon admission because the latter approach would seriously endanger patients for whom a CPR order might inadvertently be omitted, either because of oversight or failure to anticipate a cardiac arrest.

Experts agree that DNR orders should apply exclusively to CPR and should not restrict other life-sustaining treatments or lessen measures to prevent cardiac arrest (9, 48, 107, 119, 130, 134, 156, 161). Some clinical studies document this intended effect (34, 131, 172); however, other studies show that DNR protocols can lead to limitation of a cluster of life-sustaining treatments (22, 51, 90, 104, 138, 151). A DNR protocol invites this mistake if it fails to include clear definitions of the specific procedures that constitute resuscitation and the intent of the order (170).

Experience with DNR protocols has helped to focus discussions of protocol design and to identify crucial content areas (such as documentation and decision-making principles, for persons with and without decisionmaking capacity) that may be applicable to other types of decisionmaking protocols as well. In addition, the uniquely auditable written DNR order has permitted research about CPR decisions that maybe helpful in understanding decisionmaking about other life-sustaining treatments (21, 51, 90, 151, 153, 156, 166, 172).

DNR protocols address a decision of limited scope, a single element in a treatment plan. As such, DNR protocols do not fully address the needs of any of the hypothetical patients described in chapter 1: not Robert Swanson, whose DNR request is made in concert with conditional decisions that address other treatments; not Thomas Johnson, who wants CPR now but wants it withheld if he becomes irreversibly incompetent; and not Mary Hinkel, who wishes to reject all forms of life-sustaining treatment.

Care-Category Protocols: Treatment Levels and Treatment Goals

The narrow scope of DNR protocols has engendered interest in approaches that address a broader range of treatment issues. Care-category protocols are one result. This type of protocol is based on the assumption that patients can be classified into one of several categories that signify a particular treatment plan. Two major types of care-category protocols have been proposed, one based on categories of treatment levels and the other on categories of treatment goals.

Treatment-level protocols define clusters of treatments, order them hierarchically, and assign each patient to a single category. (Examples have been published by: F.P. Arena et al. (15); F. Davilla et al. (46); S.A. Levenson et al. (86); Massachusetts General Hospital (99); A. Meisel et al. (104); Presbyterian University Hospital (128); T.E. Quill et al. (131); L. Volicer (162); and Yale New Haven Hospital (169).) Patients in a given category are considered eligible for all treatments in that category and any lower categories, but ineligible for treatments in higher categories. The protocol of Pittsburgh-Presbyterian Hospital (104, see app. B) sets up the following levels of “acceptable orders” to facilitate communication when detailed orders are not available:

1. All But Cardiac Resuscitation (i.e., vigorous treatment, including measures to prevent cardiac arrest, but no CPR except in special, defined circumstances);
2. Limited Therapy (i.e., no new therapy except for hygiene and comfort; new drug therapy included in special circumstances); and
3. Comfort Measures Only (i.e., discontinue all treatments not related to comfort and hygiene).

Other protocols differentiate treatment levels by the decisions on whether to provide CPR, whether to hospitalize, or whether to admit to an intensive care unit.

Treatment-goal protocols define categories of treatment in terms of goals such as to “palliate without prolonging life” or to “preserve comfort, hygiene and dignity, but not to prolong life” (28, 60, 110, 149). These care categories are typically referred to as “Supportive Care,” “Comfort Care,” or “Routine Terminal Care.” Implementation of this type of protocol, most commonly found in nursing homes, presumes that prolongation of life is no longer a treatment goal (112).

Conceptual and operational difficulties attend both types of care-category protocols. First, specification of the care categories is very problematic. Although health professionals might place all antibiotic therapy in a single treatment level, patients might place intravenous antibiotics in one category and oral antibiotics in another. This problem becomes acute in determining “comparable” treatments that constitute a category. Some protocols would place Robert Swanson, based on his refusal of CPR, in a care category that precludes other treatments he might elect. In this way, predetermined treatment categories may abridge the patient’s ability to autonomously define his or her overall treatment plan (95, 151).

Similar problems occur with categories of treatment goals. Patients like Robert Swanson may reject CPR

in order to avoid the burden of that particular treatment, not because they reject the goal of prolonged life (164). In contrast, Mary Hinkel has rejected all treatments that might sustain her life. These individuals do not have the same goal; there maybe no single care category that meets both their needs. In addition, treatment-goal categories are too broad to address some patient goals, such as to stay at home as long as possible, to see a sister one last time, or to protect life savings,

Conceptual difficulties with care categories become practical concerns when they must be interpreted by staff who are unfamiliar with particular patients and must make momentous decisions about their care. Care categories aggregate urgent, discrete interventions like CPR with less urgent or more complex interventions like the use of antibiotics or transfer from a nursing home to a hospital.

Care categories that limit transfers from chronic to acute care settings or from a general hospital unit to an ICU seem especially arbitrary. Patients maybe more closely monitored in an ICU, and treatment more closely supervised. Intensity of care is not a clear principle by which to distinguish acceptable from unacceptable therapies. Even patients who have rejected all life-sustaining treatments, Mary Hinkel for example, might opt for transfer to an ICU if severe pain could not be controlled elsewhere (95).

Likewise, a “supportive care plan” would be a dangerous way for Robert Swanson to avoid CPR and mechanical ventilation. If he were to develop dysuria and fever during the night, on-call staff implementing this plan could legitimately withhold antibiotics, a step that could lead to Mr. Swanson’s premature death.

Care-category protocols may help patients, families, nurses, and physicians who are grappling with complex questions about the nature and purpose of medical care, by clarifying their thinking or communication about medical treatment. They may have a continuing role in patient education and counseling. For instance, the concept of treatment-goal categories may help Robert Swanson understand whether he means to reject medical care altogether, or only to avoid the burdens associated with particular treatments. As the patient comes to understand the options implicit in choosing among categories, he or she can be offered the opportunity to individualize the treatment plan, and the individualized plan can be entered in the medical record.

Still, use of care categories for counseling is not a substitute for individualized treatment planning. The use of such categories as orders or as designations in

the medical record or nursing plans could foster stereotyping and undermine the nuances of autonomous decisionmaking. This, in turn, could endanger patients by inviting on-call personnel to implement sweeping life-or-death decisions without consulting the primary physician,

Treatment-Plan Protocols

Treatment-plan protocols allow for fully individualized treatment plans in a manner analogous to traditional medical orders. They attempt to be more comprehensive than DNR protocols and to avoid the problems of care categories. Some, like the new policy called “Limiting Life-Sustaining Treatment” from University Hospitals of Cleveland (154) (see app. B), offer specific nontreatment choices. The first consideration is DNR, which is specifically defined as a decision to withhold resuscitation (defined to include mechanical ventilation, endotracheal intubation, chest compression, and the administration of emergency medication or fluids) in the event of an arrest.

Once the DNR order is written, nontreatment of life-threatening conditions short of an arrest (but likely to lead to one) maybe considered. The potential treatment limitation and the clinical situation in which it applies, e.g., “no intubation” in the event of dyspnea or “no defibrillation” for ventricular fibrillation, are clearly spelled out, to avoid the possibility of misinterpretation. A patient designated DNR but not designated “no defibrillation” would thus be defibrillate in the event of a severe arrhythmia, but would not be resuscitated in the event of an arrest (171).

Another example of a treatment-plan protocol is the model developed by the Minnesota Hospital Association (114). In this, the available treatments are not listed, but critical terms that must be understood, including “life-sustaining treatment,” “DNR,” and “DNI” (do-not-intubate), are clearly defined (see app. B).

Treatment-plan protocols are a quite recent development; longer experience with them is required before they can be evaluated. These protocols probably point to the eventual development of a new section in the medical chart, for recording treatment objectives, treatment decisions, conditions in which the patient’s wishes change, and designated proxies. Forerunners of this type of chart section are seen in some unpublished nursing home protocols (although many of these bear the name of a care-category protocol, i.e., “Supportive Care Plan”),

Treatment plans address the individuality of Mary Hinkel’s, Robert Swanson’s, or Thomas Johnson’s wishes, but sacrifice the simplicity of DNR or care-

category protocols. Critics of treatment-plan protocols suggest that it is impractical to prospectively consider every potential life-sustaining treatment. Supporters of these protocols argue that the relative complexity of treatment-plan protocols could be managed with more intensive staff education—which is required in any event to prevent misinterpretation of DNR or care-category protocols, as has been discussed.

Specific Provisions

A protocol for decisionmaking about life-sustaining treatments must be designed with full understanding of what the instrument is to accomplish, with respect to both clinical care and other institutional responsibilities, and with a realization of the various constraints that need to be overcome in order for it to be effective.

Provisions for Meeting Institutional Responsibilities

Health care institutions are responsible to a diverse set of public interests that pertain to decisions about life-sustaining treatment (see ch. 1). This section examines ways that decisionmaking protocols may articulate and help in fulfilling these responsibilities.

Assurance of Patient Autonomy.—Protocols often explicitly state the institution’s commitment to the principle of patient autonomy (60, 68, 104, 114, 132, 152). This commitment requires that protocols provide a decisionmaking process that identifies and honors the current or previously expressed wishes of patients.

An explicit affirmation of the principle of patient autonomy can serve several useful purposes. It helps focus the development of the rest of the protocol’s procedures. It may be appealed to as a way to resolve dilemmas not anticipated by other provisions of the protocol. For example, though a hospital or nursing home may not have anticipated a request like Thomas Johnson’s for a nonfamily proxy, a formal expression of commitment to patient autonomy would go a long way toward clarifying duties in this specific case. An explicit affirmation of autonomy can also help educate staff to view treatment decisions as involving more than clinical indications and professional judgment. Finally, patients, when informed of the institution’s commitment to patient autonomy, may feel reassured about their future and may be empowered to speak to staff forthrightly about their treatment preferences.

Surgery raises special considerations that can be addressed in decisionmaking protocols. Typically, surgery is performed by someone other than the patient’s primary physician; it sometimes entails use of inva-

sive life-sustaining technologies, either during or immediately after the operation. Some protocols suspend all orders to withhold life-sustaining treatment during and immediately following surgery. Honoring patient autonomy requires that patients are informed of this practice prior to consenting to elective surgery, for example, for a hernia repair (114).

Protection of vulnerable Patients.—Decisionmaking protocols can promote this interest with language affirming the equal value of the lives of elderly, disabled, or indigent persons, and a commitment to non-discrimination against them in the provision of treatment (68, 114). An institutional commitment to protect patients who are vulnerable due to decisional incapacity or other causes can also be advanced by procedural provisions (5, 43, 46, 87, 124) that include:

1. requiring or encouraging the use of an ethics committee or prognosis committee, particularly for patients who are decisionally impaired or when the institution has a financial or other interest in the outcome of a treatment decision (44);
2. having surrogates to advocate on behalf of all patients who lack decisionmaking capacity (43, 152);
3. ensuring that staff are aware of State or local laws regarding decisions for vulnerable persons who have neither a surrogate nor an advance directive (73);
4. ensuring that staff, families, and patients are aware of decisionmaking principles, procedures, and advocacy resources (68, 146);
5. ensuring that staff and other caregivers are aware of procedures and duties to report any abuse of vulnerable patients (68);
6. facilitating formation of independent patients’ rights committees and/or quality assurance mechanisms to audit protocols and individual decisions to limit treatment (68); and
7. providing for accountability of health care professionals in all aspects of treatment planning and implementation (discussed later in this app.).

Some commentators have suggested that protocols that facilitate the patient’s choice to refuse life-sustaining treatment by privatizing decisionmaking within the health care staff, patient, and family encounter may endanger vulnerable patients (13, 49, 68, 87). A private decision based on “substituted judgment” or “best interests” by even well intentioned professional caregivers regarding life-sustaining treatment for an incontinent, aphasic, isolated, financially dependent patient like Mae Carver raises troubling issues about social prejudices, caregiver fatigue or frustration, and public resources. (If Mae Carver is under public guardianship, the facility may be obliged to follow very spe-

cific procedures; if there is no guardian, she may still be protected by regulatory or professional standards, such as vulnerable adult protection acts.)

The duty to ensure that vulnerable persons are respectfully and equitably treated is a serious and difficult challenge. Fundamentally, this responsibility rests with individual staff who are sensitive to the needs, values, and perspectives of vulnerable patients, and who are aware of the special dangers that arise from social stigmatization and patients' inability to protect their own interests. Such sensitivity will need to be inculcated and cannot be fully protected by procedural mechanisms.

Promotion of Institutional Mission.—All health care institutions are members of a professional tradition that strives to promote beneficence, especially health, life, restoration of function, and alleviation of suffering. Many protocols explicitly state their commitment to this moral mission (68, 104, 114). A commitment to beneficence underlies the “fail-safe” provisions of decisionmaking protocols, like the universal standing order for CPR. It also guides treatment decisions in cases of attempted suicide and in emergencies when a patient's prognosis and preferences are unknown.

Some authorities have proposed that the principle of beneficence be formulated in standards for minimal care, consisting of specific treatments (usually nourishment) that may never be withheld (87, 112). A few nursing home protocols have done so.

Some health care institutions have specific medical missions that determine the treatment options that will be available to patients and that staff will be expected to carry out. Hospices are one example. In addition, some institutions are associated with sectarian communities or organizations that have religiously based positions regarding the provision or discontinuation of life-sustaining treatments. A decisionmaking protocol is one mechanism by which to state this mission, for the benefit of both patients and staff.

Accommodation of Staff Objections.—Some protocols affirm respect for the personal moral sentiments of staff and exempt designated staff from participating in treatment plans to which they object (60, 62, 104, 152). For example, the guidelines of Pittsburgh-presbyterian Hospital permit physicians, but not nurses, to excuse themselves from participation in treatments to which they have a moral objection (104). This type of provision goes beyond the section of the Health Programs Extension Act of 1973 (Public Law 93-45) that prohibits hospitals receiving certain Federal funds from requiring staff with moral objections to par-

ticipate in abortions and sterilizations (42 U.S.C. 300a- 7(b,d)).

Such provisions can foster moral deliberation by staff and help maintain staff morale. These provisions need not be based on an interest in the general “moral integrity of the medical profession, ” an interest that has not been found to outweigh a particular patient's preferences. They might, however, be supported by an affirmation of a mutually voluntary treatment relationship between patients and health care staff (129). Thus, Torah Home may choose to inform residents that it supports Dr. Levin's personal right to refuse, on moral grounds, to participate in certain treatment plans, even if those plans are not inconsistent with standards of the institution. Torah Home might promise, in such cases, to try to find another physician who is willing to provide the full range of treatment options implicitly or explicitly promised.

Reconciliation of Conflicting Responsibilities.—The diversity of institutional responsibilities brings the potential for tension or conflict. This is manifested in two particularly troublesome ways, both of which bear on protocol design. First, a tension exists between the unencumbered exercise of patient autonomy and the procedural oversight needed to protect the interests of vulnerable persons. Procedures to advance the public interest in the protection of vulnerable persons such as Mae Carver should not be so complex or costly as to effectively destroy Robert Swanson's ability to direct his care. Thus, it is unreasonable to propose a legal requirement that all life-sustaining treatments be given unless prior court approval to do otherwise has been obtained. However, procedures to permit patients to decline life-sustaining treatments cannot be so perfunctory as to compromise protection for patients who might be improperly induced to refuse treatment or misconstrued as having refused life-sustaining treatment (87, 95). For example, a nursing home policy that leaves all orders regarding life-sustaining treatments in the hands of the physician would make it easier to act in accordance with Robert Swanson's clearly stated treatment preferences. But the same policy may not provide adequate oversight to protect Mae Carver, who cannot express her treatment preferences.

Second, there is sometimes tension between patient autonomy and institutional mission. A patient beliefs can and often do diverge from customary sectarian positions or from an institution's expressed view of its mission. It is important to note that the diversity of missions reflects the diversity of moral communities in this society. Thus, differences between a patient preference and Torah Home's mission do not constitute a gratuitous threat to patient autonomy, but rather

the meeting of moral differences between a patient and persons who have joined together to provide health care in a manner consonant with their moral views. If moral communities are to be able to operate institutions that reflect their values, an accommodation on this issue is needed.

Public policy could preemptively solve the difficulties raised by contending public and patient interests either by dispensing with some of them or by arranging them in a rigid hierarchy. One way would be to compel health care institutions to obey any patient or proxy wish. However, this would undermine the institution's accountability to other public interests. The complexities and tensions that emerge from institutions' diverse responsibilities indicate the importance of the competing claims and values to which institutions are accountable. In the last analysis, this debate cannot be preempted.

Provisions for Good Decisionmaking

Protocols can include provisions to facilitate a good decisionmaking process without proposing rigid algorithms that would dictate a particular treatment plan (156). This prudent approach reflects the complexity of decisions about life-sustaining treatments and respect for moral pluralism and patient autonomy.

Some protocols contain principles for making decisions about life-sustaining treatments but do not suggest any procedures for implementation (28, 60, 159, 165). Others mandate detailed procedures for implementing decisions. While some discussions of good decisionmaking allude to professional virtues, such as compassion, respect for life, and beneficence (159), others emphasize patients' rights (7, 68, 146).

Assessment of Decisional Capacity. -Decisional capacity is a watershed assessment: Adult patients who are decisionally capable have the legally protected right to accept or refuse any medical treatment, whereas patients who are deemed decisionally incapable or adjudicated incompetent can participate in treatment decisions only through a proxy or an advance directive. A large proportion of patients for whom life-sustaining treatment is considered are in the latter categories due to permanent or temporary loss of consciousness, profound confusion, or depression (156). Victims of cardiac or respiratory arrest, for example, are typically unconsciousness or in a severely compromised mental state. A survey in New York nursing homes found that almost half of all elderly residents are disoriented or have impaired memory (157). (Disorientation or memory impairment was defined in this survey as inability to remember dates or time, to identify familiar loca-

tions or people, to recall important aspects of recent events, or to make straightforward judgments.)

Decisionmaking protocols are a vehicle for addressing the essential concept of decisional capacity, to help ensure that it is clearly understood and accurately assessed. The two major definitions are: "competence," a global assessment that can be determined only in a legal proceeding, and "decisionmaking capacity," a task-specific assessment that is determined without legal involvement (13, 130, 156).

Protocols handle this topic in a variety of ways. Some discuss definitions of decisional capacity (62, 114, 169). Others note the procedural significance of this assessment without proposing definitions (100, 115).

Some protocols include precautionary provisions for assessment of decisional capacity. One such safeguard is to state a presumption in favor of the direct participation of all patients in treatment decisions unless a basis for the conclusion of decisional incapacity has been recorded in the medical record. For example, the protocol of University Hospitals of Cleveland states, "competent patients must be consulted and have a right to refuse treatment" (154). Some protocols point out that a patient preference that contradicts medical advice (e.g., Thomas Johnson's request for CPR should it be needed, despite his physician's contrary view) should never, by itself, be taken as proof of decisional incapacity.

Few protocols address the issue of who should assess decisional capacity; most that do so leave it to the attending physician (60, 104, 130) or a consulting psychiatrist.

Patients Who Are Decisionally Capable.—In support of patient autonomy, institutional protocols often state that decisionally capable patients, like Robert Swanson or Thomas Johnson, should be fully informed of treatment options and given an opportunity to express their treatment preferences. Many protocols also state that the institution will honor an advance directive of a patient who later loses decisionmaking capacity.

To further patient participation, institutions often try to foster communication between their staff and patients. protocols may advise patient counseling, stating that health care staff are responsible for initiating dialog about life-sustaining treatments or for creating a climate in which Robert Swanson or Thomas Johnson's friend would feel comfortable raising treatment issues (62, 137). Hospital protocols often assign to the physician the responsibility for initiating this conversation (60, 104, 107). Nursing homes are more likely

to give more responsibility to nurses or social workers in initiating these discussions (112), reflecting their role in creating treatment plans for nursing home residents and the more limited presence of physicians (25, 130). Some protocols, while presuming that physicians play a central role in the treatment decision, encourage nurses to record patients' preferences in the chart, to inform physicians of these preferences, and then to record that the physician has been so informed (110, 134).

Recognizing that many acute life-threatening events can be expected to leave their victims, at least temporarily, incapable of expressing treatment preferences, newer protocols commonly encourage prospective decisionmaking through advance directives like living wills or proxy designations (62, 94, 100, 107, 130, 152). Some facilities distribute forms for advance directives upon admission. In some nursing homes and hospitals, admitting social workers or nurses are responsible for informing persons like Robert Swanson or the families of patients like Mary Hinkel of the possibility of writing an advance directive. This practice has been criticized by people who believe that initiating discussion of life-sustaining treatments before staff-patient relationships are established may increase patient or family fear and distrust. Fears that the hospital or nursing home is a place to die, that the facility would try to save money by limiting treatment, or that the patient will be abandoned might lead some patients or families to initially express treatment preferences they later disavow. Advocates of advance directives view these forms as a way to prevent the unnecessary circumvention of patient preferences in medical emergencies.

Patients Who Are Not Decisionally Capable.—Published reviews emphasize that medical decisionmaking for patients who are not decisionally capable should still respect their autonomy and should honor their previously expressed treatment preferences and values, by seeking a surrogate who has intimate, loving knowledge of the patient, and by being mindful of social prejudices (14, 62, 129, 130, 156). In addition, because many patients have medical histories that portend loss of decisional capacity, health professionals and institutions share responsibility for ascertaining treatment preferences while this is still possible.

Institutional protocols have addressed the special features of decisionmaking for decisionally incapable patients in several ways. As with decisions for capable patients, the decisionmaking process can begin in advance of medical crises, sometimes in advance of institutionalization, so that appropriate parties and proxies can be fully empowered and so that important

clinical decisions can be fully considered. To this end, some protocols, especially in nursing homes or in hospital units working with persons with dementia, require prospective family conferences with physicians, nurses, and social workers (100, 162). Such conferences can help ensure that interdisciplinary communication occurs. In such meetings, for example, Mary Hinkel's nurses would be able to communicate to her new physician her wish to have only palliative care.

Increasingly, protocols recognize that decisionally impaired patients may need a proxy decisionmaker (5, 62). For patients with caring and involved family members, many protocols simply accept family members into treatment planning. Family members can be invaluable sources of information about a patient's preferences, and family acceptance of a treatment plan as being in the patient's best interest or consonant with the patient's wishes is an important safeguard for vulnerable persons. Family involvement is also evidence of a prudential approach to decisionmaking. Despite the value of family in these roles, health care facilities should be mindful of State laws that pertain to family proxies; family members are not legally empowered to act as surrogate decisionmakers in all States (14, 136).

In several situations, selection of proxies is of special concern. Some protocols propose or require legally appointed proxies for decisions to forgo certain life-sustaining treatments, especially when family members are not available or are in disagreement, or when a treatment decision is not adequately supported by substituted judgment (5, 104). Thus, even though it seems clear that Robert Swanson desires to have no life-sustaining treatments when he loses his ability to interact, to ensure his preference is interpreted as he would wish, he should be encouraged to appoint a proxy as a part of creating his treatment plan. Thomas Johnson, like many patients with acquired immunodeficiency syndrome (147), wishes to designate a non-family proxy even though family members are available. When prospective planning is possible, such patients might use a durable power of attorney to appoint a proxy of their choice and to avoid any deference to family. Even without formal assignment, however, nonfamily proxies may be given great weight if they have demonstrated significant, caring knowledge and regard for the patient's preferences and interests. For patients like Mae Carver who are without family or proxies to represent their interests, protocols might provide for referral to appropriate Government offices when reporting is legally mandated or when the treatment decisions are of great consequence (5).

Medical Criteria for Limiting Treatment.—Some protocols establish medical criteria that must be met

before certain treatment decisions are allowed. For example, some require that patients be diagnosed as “terminally ill” before withholding of life-sustaining treatment will be permitted (100, 110, 112, 126, 161). Some suggest conditions, like “serious disability,” where treatment might be limited (112, 149).

The use of medical criteria in protocols for decisions about life-sustaining treatments is controversial, in part because of conceptual difficulties. “Terminal illness” is not clearly distinguished from chronic, progressive disease. Treatment “futility” can be defined as either the inability to prolong life or the inability to reverse disability. Moreover, reliable clinical measures of these concepts are not available (156).

There are also fears that negative and sometimes subjective assessments like “(terminally ill, ” “brain damaged,” or “severely disabled” may lead health care staff to withhold life-sustaining treatment unjustly from people described by these terms (67, 68). Furthermore, some people believe that using criteria like terminal illness as a prerequisite for decisions to forgo life-sustaining treatments wrongly restrains patient autonomy (126) by discouraging or preventing a person who is not terminally ill from articulating or effectively communicating treatment preferences.

Despite objections to including medical criteria in decisionmaking protocols, many people argue that decisions about life-sustaining treatments are not an issue when the treatment in question cannot prevent an imminent death (27). Thus, even some protocols that strenuously protect the rights of vulnerable patients have attempted to differentiate patients who are “imminently dying” from those who are not (68). For a patient like Mary Hinkel, this type of provision may permit health care staff to suspend customary aggressive care in the event of cardiac arrest.

The Role of Ethics Committees.—Ethics committees have a role in the creation of protocols, in their implementation through staff education, and in prospective treatment conferences. Ethics committees can also assist health staff by providing information pertinent to controversial procedural questions (such as Thomas Johnson’s nonfamily proxy) or by advising on difficult clinical decisions. Ethics committees provide a forum for collection and communication of information among multiple caregivers and perspectives.

Few institutional protocols require that ethics committees be routinely involved in treatment decisions (11 O). Some protocols propose or require use of such groups to address controversial or disputed decisions or as a safeguard for vulnerable patients (44, 62, 100, 104, 121, 132, 169). Some require ethics committees

to review decisions to limit life-sustaining treatment for decisionally incapable patients (5, 29).

It is not clear whether health care institutions can lessen their risk of adverse legal action by imposing procedural consultation requirements, and such requirements sometimes create obstacles to decisionally capable patients who would decline life-sustaining treatment. Courts have been variously disposed toward the necessity or authority of ethics committees in decisions about life-sustaining treatments (167).

The Role of the Courts.—There is wide agreement, especially among health care providers and lawyers, that the courts should be drawn into decisions about life-sustaining treatments only in exceptional cases (62, 121, 156). Court hearings are used routinely to name legal guardians or surrogate decisionmakers for persons who lack decisional capacity. Courts may also be called upon when there is an irreconcilable controversy about proxy selection, about a decision made by a proxy, or when no proxy is available and life-or-death decisions are being made (5). Some protocols state that, as a general principle, judicial intervention or guidance is unnecessary except where all other means of dispute resolution have failed (104). Others specify the situations in which resort to the courts is appropriate.

Provisions for Implementing Decisions

A major purpose of institutional decisionmaking protocols is to provide for proper implementation of treatment decisions once they have been made (62, 81, 130, 156). Health care facilities are complex institutions; many persons are involved in creating and carrying out treatment plans. There are many opportunities for miscommunication, disagreement, and errors. Often, the staff who carry out a treatment plan are unfamiliar with the patient or have not been involved in treatment decisions. In this environment, the role of protocols in trying to facilitate the proper implementation of treatment decisions is as important as their facilitation of good decisionmaking itself.

Protocols can address treatment plan implementation through provisions for:

- accurate communication of treatment intentions;
- treatment plans that are “fail-safe)” to prevent unintended withholding of life-sustaining treatment;
- accountability of individual staff for the implementation of decisions to limit treatment;
- assistance to health care staff, families, and patients in complex, controversial decisions;

- ensuring compliance with the requirements of agencies external to the health care institution; and
- implementation of the protocol itself.

Accurate Communication.—To facilitate accurate implementation of decisions about life-sustaining treatments, protocols need to provide for unambiguous communication of the treatment plan from decision-makers to on-call staff. It may be inadequate to simply assert that the physician should convey information about the treatment plan to health care staff involved in the patient's care (26, 115, 132, 169), especially in long-term care settings, where physicians frequently are not available.

Protocols usually state that treatment intentions, such as Robert Swanson's DNR request, are to be implemented by explicit, permanently recorded medical orders signed by the physician (62, 78, 130). In addition to orders, many protocols say that the medical record should contain a note by the physician discussing the genesis and intent of the treatment plan (19, 26, 104, 114, 132). This note should record the diagnosis, prognosis, patient or proxy wishes, recommendations of the treatment team, treatment objectives, and a discussion of key treatment decisions. In the case of decisionally incapable patients, the note should document the finding of incapacity, record the basis of that assessment, the identity of the proxy decision-makers, the rationale for selecting them as proxies, and the proxy's directive. This more complete documentation can convey the complexity of Robert Swanson's or Thomas Johnson's treatment plan and also Johnson's wish to have a nonfamily proxy,

Protocols that apply to patients who are terminally ill, imminently dying, or permanently unconscious require definitions of these terms and documentation that the criteria are fulfilled (67, 100). Some nursing home protocols establish separate areas of the medical record for documentation of the assumptions that are to govern decisions about life-sustaining treatments. For outpatients, like Thomas Johnson, the treatment plan will be maintained in the physician's office record. Patients and their proxies should be aware of the location of this material, to help bring it to the attention of hospital staff in a medical emergency. Some hospitals give patients DNR wristbands so that off-ward staff can be instantly aware of each person's treatment intentions (114).

To promote accurate communication, protocols often define important and commonly used terms, like DNR, do-not-intubate, or care categories (19, 108, 115, 130, 154). Misinterpretation of terms, as has been discussed, may also be anticipated and addressed.

Accurate and reliable communication of treatment plans for patients transferred between health care facilities poses especially difficult problems. So that interfacility transfers can proceed smoothly, protocols should conform to the procedural format used by ambulance services (108). Most importantly, the possibility of an interfacility transfer should be anticipated so that patient preferences with regard to such transfers or to the treatment provided at the receiving facility can be elicited and incorporated into treatment planning (62).

Interfacility protocols need to provide for common usage of terms, to ensure accurate communication of treatment intentions (62, 108). This type of protocol also helps to assure the receiving institution that treatment directives have been properly made, since patients often will be unable and proxies unavailable to reconstruct the decisionmaking process. For Mae Carver and Robert Swanson, interfacility communication can occur in the context of an agreement between the emergency medical service and community nursing homes and hospitals. For outpatients like Thomas Johnson, good communication is needed between individual physicians and community hospitals. The latter is much more difficult and, to date, depends on the initiative of individual physicians, institutions, and patients or their proxies,

Fail-Safe Provisions. -Many decisionmaking protocols contain provisions that intend to ensure that, in the absence of unambiguous and properly formulated directives, treatment assumptions will "fail safe" in favor of sustaining life. Standing orders for emergency life-sustaining treatment, especially CPR, are a common fail-safe provision (19, 46, 114). In nursing homes, another normal provision is a standing order to call an ambulance service in every medical emergency. The rationale for such provisions is that some individuals who desire a potentially beneficial treatment (especially CPR) would otherwise not get it.

Some emergency medical systems that accept DNR orders do not accept vague directives to limit life-sustaining treatments, e.g., orders for "supportive care." For patients like Robert Swanson, whose wishes are tied to his ability to interact with others, an order for "no heroic measures" is confusing. If an unclear order is presented, customary standing orders for CPR are to be followed (108, 140),

Some health care institutions provide for the revocation of an order to limit treatment when there is reason to believe it no longer reflects the patient's wishes or interests. This type of provision recognizes

the possibility that a patient's condition or his or her acceptance of it may change.

Many protocols state that a decision about life-sustaining treatment may be changed at any time. One unpublished nursing home protocol allows patients to revoke a DNR order by notifying a nurse, who is empowered to revoke the DNR order in the name of the medical director. The patient's attending physician is notified of this revocation so that further discussions between the patient and physician can occur. Comparable provisions in some hospital protocols authorize family members to revoke a DNR order with the same ease (100). A Minneapolis area emergency medical service policy covering CPR specifies that for home care patients, like Thomas Johnson, a patient's destruction of the home care form restores the standing order for aggressive treatment.

As a further fail-safe measure, some protocols revert to a presumption in favor of treatment unless the treatment decision is reaffirmed. Thus, some protocols provide for automatic expiration of orders to limit treatment after a certain time in order to ensure that orders undergo continual review by the patient and his or her physician (26, 46, 114, 140). In nursing homes, the period of time is usually from 1 to 3 months; in hospitals, it is typically from 1 to 7 days (110, 112).

Some facilities prohibit discharge documents from carrying orders to limit medical treatment beyond the time required to transfer the patient to another health care facility (114). The intent is to ensure that a physician is continually responsible for treatment orders. Other protocols provide for continuity by recommending that transferring physicians inform receiving physicians of any decisions about life-sustaining treatments (62). Information about the patient's history is especially important when the patient has become decisionally incapable. New York State's 1987 legislation allows the receiving physician to accept a DNR designation from a transferring facility, to enter it in the patient's record, and to accept responsibility for it (121).

Provisions for Accountability

Accountability to Coworkers.—Professional accountability for decisions about life-sustaining treatments is addressed by two principal provisions: assignment of staff responsibilities for the formulation and implementation of decisions about life-sustaining treatments, and requirements for signed staff documentation during this process.

Protocols define a variety of physician responsibilities. The consensus is that physicians should sign all

treatment orders in the medical record (78, 130). In addition, many protocols require a **signed description of the intent of limited treatment plans**. Most teaching hospitals require attending staff physicians to **countersign any orders to limit treatment that are written by interns or residents**. This ensures that senior physicians are aware of and accountable for all such decisions.

Some protocols require nurses to record critical procedures for implementing decisions about life-sustaining treatments (110, 112). These include any discussions between nurses and patients about treatment decisions, notification of physicians about such discussions, the implications of treatment decisions for nursing care, and the communication to emergency medical service personnel of directives to withhold life-sustaining treatment. Specification of these duties can be an effective way to ensure that critical information, like the conversations between Mary Hinkel and her nurses, are entered into the medical record. Some policies direct nurses to challenge resuscitation orders if the patient has not been involved in decisionmaking (110, 134).

Some protocols address orders that physicians occasionally give to nurses by telephone to withhold life-sustaining treatment. A telephone order may represent an ad hoc decision, rather than a carefully thought out plan based on discussion with the patient. Other protocols prohibit telephone directives (104). Those that do permit telephone orders might require that nurses record all such telephone conversations, or they might provide for the automatic expiration of any telephone order that the physician does not countersign within 24 to 72 hours (111, 112, 123).

Accountability to Patients—The effect of protocols in promoting optimal communication and understanding between health care staff and patients or their proxies is a matter of considerable dispute. Certainly, the protocol framework emphasizing good decision-making principles, articulating institutional mission, detailing staff responsibilities, establishing reliable interstaff communication, and providing ongoing staff education contributes to a good decisionmaking environment. Some protocols go farther and promote specific decisionmaking encounters (62).

Some institutions, mainly nursing homes, give all newly admitted residents or their family members an opportunity for initial discussion of the purposes of life-sustaining treatments and the possibility of requesting that their use be limited. New York State's law regarding resuscitation requires that physicians discuss resuscitation with all decisionally capable patients and

enter a DNR order only with the patient's prior consent, unless such discussion would cause "severe and immediate harm to the patient" (121). Similarly, some hospitals require that, for all patients admitted to an ICU, physicians note the objectives of and possible limits on the use of life-sustaining treatments.

The use of admission conferences to determine the patient's wishes regarding life-sustaining treatments has some limitations. First, this could be the first meeting of patient and health care staff, and trust may be lacking. Second, crucial prognostic information may not yet be available. Third, it is difficult within the compressed time of an admission to inform patients and their families fully about the range of choices available. Fourth, patients newly admitted to a health care facility are usually ill and under considerable stress; their ability to participate in treatment decisions may be severely compromised.

Despite these reservations, admission or soon thereafter can be a good time to raise questions about life-sustaining treatments and to make patients aware there will be future opportunities to discuss any concerns and preferences. Some institutions distribute information packets that include forms for designating treatment preferences or surrogate decisionmakers (148), or that introduce care categories as a way to inform patients of the range of treatment options. Some admission procedures include asking patients to designate a surrogate decisionmaker in the event one will be needed. The opportunity for knowledgeable counseling should be offered whenever such information is distributed and when such questions are asked. In some institutions, nurses or social workers coordinate initial discussions with patients, to prepare them for more detailed discussions with their physicians (112).

Some institutions require all patients for whom life-sustaining treatments are to be limited to sign a living will. This provision may be difficult to implement in that many people are not psychologically able to commit themselves in writing to a course of action they otherwise might affirm. A less rigid variation on this type of provision is Pittsburgh-Presbyterian Hospital's requirement that when a signed advance directive is available, it must be included in the patient's chart (104). Another is Yale New Haven Hospital's policy asking the patient (or surrogate) to sign an authorization for a DNR order if there is reason to believe that the order will be disputed (169).

Compliance With External Agencies—Protocols must be consistent with legal requirements regarding living wills, durable powers of attorney, and other relevant matters (e.g., organ donation, brain death) (152).

Many local or State governments have requirements as to the handling of DNR orders for incompetent patients who are under State guardianship or without close family. Some protocols identify the classes of persons to whom such laws apply and refer decisions to the institution's lawyer or to the identified government body. Generally, protocols do not list the special requirements or restrictions that pertain to orders to limit treatment for such persons, in order to avoid giving the impression that such restrictions apply to all persons.

Provisions for Implementing the Protocol

Implementation of protocols occurs within the much broader context of administrative responsibilities for monitoring health care practice and assuring quality care. Some protocols include a provision identifying the individual office or official with specific responsibility for ensuring that the protocol is used routinely and as intended. For example, the Joint Commission on the Accreditation of Healthcare Organizations assigns responsibility for implementation (as well as development) of DNR policies to the hospital's chief executive officer. The model protocol by the Minnesota Hospital Association provides for similar specification in stating "Implementation of this policy is the responsibility of [officer]" (114).

Beyond this, the protocol may indicate what means will be used to ensure implementation by staff. The Minnesota Hospital Association model indicates that the "[named officer] shall establish procedures to familiarize medical staff in its provision and provide for its implementation." It further specifies that this officer is responsible for "regular review and updating of the policy," to ensure it meets current legal, clinical, ethical, and procedural needs.

Staff involvement in the process of developing the protocol helps establish initial familiarity with the protocol as well as commitment to it, but this is not enough. Changes in staff as well as revisions in the protocol necessitate ongoing efforts to educate staff regarding the rationale for and specific provisions of the protocol. Without continuing staff education, breakdowns in the implementation of protocols are likely to occur.

In addition, implementation of a decisionmaking protocol assumes that administrators will supply any documents or agents referred to in the protocol. This includes, for example, establishing and supporting ethics committees, retaining legal counsel, and making living will documents available.