

5.2 Advance Directives

Respect for autonomy and fidelity to the patient are widely acknowledged as core values in the professional ethics of medicine. For patients who lack decision-making capacity, these values are fulfilled through third-party decision making and the use of advance directives. Advance directives also support continuity of care for patients when they transition across care settings, physicians, or health care teams.

Advance directives, whether oral or written, advisory or a formal statutory document, are tools that give patients of all ages and health status the opportunity to express their values, goals for care, and treatment preferences to guide future decisions about health care. Advance directives also allow patients to identify whom they want to make decisions on their behalf when they cannot do so themselves. They enable physicians and surrogates to make good-faith efforts to respect the patient's goals and implement the patient's preferences when the patient does not have decision-making capacity.

An advance directive never takes precedence over the contemporaneous wishes of a patient who has decision-making capacity.

In emergency situations when a patient is not able to participate in treatment decisions and there is no surrogate or advance directive available to guide decisions, physicians should provide medically appropriate interventions when urgently needed to meet the patient's immediate clinical needs. Interventions may be withdrawn at a later time in keeping with the patient's preferences when they become known and in accordance with ethics guidance for withdrawing treatment.

Before initiating or continuing treatment, including, but not limited to, life-sustaining interventions, the physician should:

- (a) Assess the patient's decision-making capacity in the current clinical circumstances.
- (b) Ascertain whether the patient has an advance directive and if so, whether it accurately reflects his/her current values and preferences. Determine whether the patient's current clinical circumstances meet relevant thresholds set out in the directive.
- (c) Ascertain whether the patient has named a health care proxy (e.g., orally or through a formal legal document). If the patient has not, ask who the patient would want to have make decisions should he or she become unable to do so.
- (d) Document the conversation, including the patient's goals for care, and specific preferences regarding interventions and surrogate decision maker, in the medical record; incorporate any written directives (as available) into the medical record to ensure they are accessible to the health care team.
- (e) When treatment decisions must be made by the patient's surrogate, help the surrogate understand how to carry out the patient's wishes in keeping with the advance directive (when available), including whether the directive applies in the patient's current clinical circumstances and what medically appropriate interventions are available to achieve the patient's goals for care. When conflicts arise between the advance directive and the wishes of the patient's surrogate, the attending physician should seek assistance from an ethics committee or other appropriate institutional resource.
- (f) When a patient who lacks decision-making capacity has no advance directive and there is no surrogate available and willing to make treatment decisions on the patient's behalf, or no surrogate can be identified, the attending physician should seek assistance from an ethics committee or other appropriate resource in ascertaining the patient's best interest.

- (g) Document physician orders to implement treatment decisions in the medical record, including both orders for specific, ongoing interventions (e.g., palliative interventions) and orders to forgo specific interventions (e.g., orders not to attempt resuscitation, not to intubate, not to provide antibiotics or dialysis).

AMA Principles of Medical Ethics: I,IV

Background report(s):

CEJA 3-A-16 Modernized *Code of Medical Ethics*

CEJA 5-A-97 Optimal use of orders not to intervene and advance directives

5.2 Advance Directives

Respect for autonomy and fidelity to the patient are widely acknowledged as core values in the professional ethics of medicine. For patients who lack decision-making capacity, these values are fulfilled through third-party decision making and the use of advance directives. Advance directives also support continuity of care for patients when they transition across care settings, physicians, or health care teams. [New content sets out key ethical values and concerns explicitly.]

Advance directives, whether oral or written, advisory or a formal statutory document, are tools that give patients of all ages and health status the opportunity to express their values, goals for care, and treatment preferences to guide future decisions about health care. Advance directives also allow patients to identify whom they want to make decisions on their behalf when they cannot do so themselves. They enable physicians and surrogates to make good-faith efforts to respect the patient's goals and implement the patient's preferences when the patient does not have decision-making capacity.

An advance directive never takes precedence over the contemporaneous wishes of a patient who has decision-making capacity. [New content clarifies key ethical values.]

In emergency situations when a patient is not able to participate in treatment decisions and there is no surrogate or advance directive available to guide decisions, physicians should provide medically appropriate interventions when urgently needed to meet the patient's immediate clinical needs. Interventions may be withdrawn at a later time in keeping with the patient's preferences when they become known and in accordance with ethics guidance for withdrawing treatment. [New content addresses gap in current guidance, consistent with 5.3, 5.4.]

Before initiating or continuing treatment, including, but not limited to, life-sustaining interventions, the physician should: [New content clarifies guidance.]

- (a) *Assess the patient's decision-making capacity in the current clinical circumstances. New content addresses gap in current guidance.]*
- (b) *Ascertain whether the patient has an advance directive and if so, whether it accurately reflects his/her current values and preferences. Determine whether the patient's current clinical circumstances meet relevant thresholds set out in the directive. [New content addresses gap in current guidance.]*
- (c) Ascertain whether the patient has named a health care proxy (e.g., orally or through a formal legal document). If the patient has not, ask who the patient would want to have make decisions should he or she become unable to do so.
- (d) Document the conversation, *including the patient's goals for care, and specific preferences regarding interventions and surrogate decision maker*, in the medical record; incorporate any written directives (as available) into the medical record to ensure they are accessible to the health care team. *[New content clarifies guidance.]*
- (e) *When treatment decisions must be made by the patient's surrogate, help the surrogate understand how to carry out the patient's wishes in keeping with the advance directive (when available), including whether the directive applies in the patient's current clinical circumstances and what medically appropriate interventions are available to achieve the patient's goals for care. When*

conflicts arise between the advance directive and the wishes of the patient's surrogate, the attending physician should seek assistance from an ethics committee or other appropriate institutional resource. [New content addresses gap in current guidance.]

- (f) *When a patient who lacks decision-making capacity has no advance directive and there is no surrogate available and willing to make treatment decisions on the patient's behalf, or no surrogate can be identified, the attending physician should seek assistance from an ethics committee or other appropriate resource in ascertaining the patient's best interest. [New content addresses gap in current guidance.]*
- (g) *Document physician orders to implement treatment decisions in the medical record, including both orders for specific, ongoing interventions (e.g., palliative interventions) and orders to forgo specific interventions (e.g., orders not to attempt resuscitation, not to intubate, not to provide antibiotics or dialysis). [New content addresses gap in current guidance.]*

AMA Principles of Medical Ethics: I,IV

CEJA Report 5 – A-97

Optimal Use of Orders Not to Intervene and Advance Directives

INTRODUCTION

Continuing difficulty in tailoring end-of-life care to the preferences of patients so that they can experience a satisfactory last chapter to their lives has prompted the Council on Ethical and Judicial Affairs (henceforth, the Council) to examine this issue again. In addition, two resolutions at the 1996 Annual Meeting called for better availability and tracking of advance directives, and more uniform adoption of form documents that can be honored in all states of the United States. Resolutions 1-A-96, introduced by the Medical Student Section, and 7-A-96, introduced by the Illinois Delegation, were replaced with Substitute Resolution 1 which states:

RESOLVED, That the American Medical Association encourage the various state medical associations to work with their state bar associations and others, as appropriate, to produce standard forms regarding a Durable Power of Attorney for Health Care and a Living Will, in accordance with the standards of legal and medical practice of the state, and in endorsing their use by patients receiving their medical care in that state; and be it further

RESOLVED, That the AMA explore additional tracking mechanisms which would improve physician access to patients' advance directives at the time of treatment; and be it further

RESOLVED, That the AMA Board of Trustees report on actions taken on this resolution at the 1997 Annual Meeting of the House of Delegates.

In response to the demonstrated need for more rigorous efforts in advance care planning, the Council presents the following report and recommendations.

THE USE AND MISUSE OF CARDIOPULMONARY RESUSCITATION AND OTHER LIFE-SUSTAINING-INTERVENTIONS

After the introduction of cardiopulmonary resuscitation (CPR) in the 1960s, use of the intervention spread far beyond the originally intended and reported application, which was for young, elective surgery patients with anesthesia-related intraoperative arrest.¹ Eventually, almost all hospital and many out-of-hospital arrests were subject to resuscitation attempts. Since, by definition, the alternative was death, the perceived imperative to attempt resuscitation was strong. It was also fitting with the prevailing social and medical culture of the times in which saving life was emphasized over reaching peaceful acceptance of inevitable death. However, in the ensuing decades, attention began to shift to the low CPR survival rate in the all encompassing population of dying people on which it was used, and to the poor quality of life among survivors of CPR. A landmark article introduced the notion of Do Not Resuscitate (DNR) orders, and this concept was endorsed by many including the Council.^{2, 3} Studies gradually began to occur, first on preferences and survivor opinions regarding CPR, and on prognoses and illness categories in relation to CPR outcome, and then on the possibility of not even offering CPR to patients unlikely to benefit from it.^{4, 5, 6, 7}

Other life-sustaining-interventions (LSIs) had a similar evolution in the history of their use. For instance, when the iron lung developed into intubation-based respiratory support, the imperative to use it became strong for all patients for whom respiration could not be maintained in other ways. Many cases of protracted respiratory support occurred, even in the face of vastly diminished quality of life. The difficulties culminated with the quandaries posed by the persistent vegetative state, which state began to occur after partially successful life-

A version of this Report was published as "Optimal Use of Orders Not To Intervene and Advance Directives" (*Psychology, Public Policy, and Law*. 1998; 4: 668-674)

sustaining interventions. A series of legal cases evolved. These included the widely reported cases of Karen Quinlan and Nancy Cruzan, and eventually produced a strong body of case law to support the right of patients to be free of unwanted intervention including artificial nutrition and hydration, even if their non-initiation or removal resulted in death.^{8, 9, 10} In parallel with this development came the movement for advance care planning in which living wills and health care proxy designation can help limit unwanted intervention. Advance care planning received wide endorsement from all sectors of society, as well as helpful directions for its appropriate use, again including from the Council.

LIMITATIONS: THE DO NOT RESUSCITATE ORDER AND OF ADVANCE CARE PLANNING TO RESTRICT LIFE-SUSTAINING-INTERVENTIONS

However, difficulties also became apparent in achieving appropriate use of DNR orders and advance directives. All too frequently, the job of “securing a DNR” was assigned to the medical student or nurse. The process and content of the discussion was suboptimal whether the attending physician or another conducted it.¹¹ Biased framing of issues occurred so that obtaining a DNR order was more a matter of the physician’s wish than the patient’s. Some patient preferences were unstable, and even when stable were not known to the physician or were over-ridden.^{12, 13} Further, many noted that DNR decisions had become a stand-in or signal for an all-encompassing decision to forgo an interventionist approach, so that patients with a DNR order were sometimes automatically declined an intensive care unit bed, or received less nursing attention, or went without the opportunity to consider an appropriate intervention unrelated to resuscitation.¹⁴ Some physicians noted that DNR discussions were difficult for physicians to handle. Many discussions ended up happening on an urgent basis and/or in awkward circumstances, and all too often by covering physicians. Others noted that while patients were generally very open to broad based end-of-life care discussions, isolated CPR decisions seemed to trigger emotional and existential turbulence, enhancing the likelihood of unstable decisions and adverse relationships.¹⁵

Several proposals began to coalesce around the general theme of comprehensive advance care planning in order to broaden and render routine a full range of advance end-of-life decisions. Three features to this theme were critical. One was to encourage prior decision-making, especially in the out-patient setting, so reducing the need for disturbing decisions about CPR or DNR at the hospital bedside.¹⁶ A second feature was to broaden the scope of decisions to include general strategy items such as whether or not to hospitalize the patient at all, or whether or not to use intensive care unit or only regular ward facilities. A third feature of this theme was to broaden the scope of interventions considered to include, for instance, whether or not to accept chemotherapy, dialysis, antibiotics, nutrition and hydration, and so forth.¹⁷ But again, a parallel evolution of problems that plagued DNR decisions occurred with advance care planning. These impediments remained despite a Federal law, the Patient Self Determination Act, which aimed to promote advance care planning.¹⁸ The discussions were not taken up by physicians, the process of discussion when it occurred was suboptimal, questions arose about the stability of decisions, there were concerns over assumptions among professionals that a patient with an advance directive was to be ineligible for all intervention, and over assumptions that such plans became operative from the time of filling out a document rather than from the onset of decision-making incapacity.^{19, 20} But most perplexing of all, advance care planning discussions were not occurring, either with physicians or with patients’ family or proxy, and documents were not being completed.

The discouraging evidence of inadequate end-of-life decision-making indicated the necessity of several improvement strategies.

NEW SOLUTIONS

Backing patient preferences effectively

Since early on in the move toward restricting life-sustaining-intervention, concerns focused on whether or not such restriction might constitute or be construed as intentional ending of life and so might open well-intentioned physicians to litigation. In addition to the developing body of case law that protects a patient's right to be free of unwanted intervention even if the consequence was death, another approach was important. This was to provide specific legal backing to physicians for following patient preferences. Over a period of time all states passed statutes, which often contained model forms that met statutory requirements, to give physicians immunity from malpractice for following a patient's wishes.

While laudable and necessary, these statutory documents were not designed to helpfully elicit and record a patient's preferences. Unfortunately, many people used the state statutory forms as the 'legally endorsed' form, often doing so with their lawyer rather than their physician, so conflating the provision of physician immunity with documenting the patient's preferences in ways that can be used for actual medical decisions. It became critical to distinguish state statutory documents from advisory documents. Advisory documents aim to accurately represent a patient's wishes and are legally binding under constitutional law.

In order to secure accurate representation of patient wishes and the physician's freedom to follow them, patients need both a good advisory document and a state statutory document. Some state medical associations and other groups combined the forms to assist patients and physicians toward this end.²¹ Others without this convenient format simply added an advisory document to their state statutory form.

Documenting patient preferences effectively

Knowing that patients often found it hard to think about the significance of resuscitation decisions, it became important to inquire how people could comfortably reason through end-of-life decision-making and come up with enduring decisions. What, after all, is a good advisory document? Different approaches were developed. Some approaches emphasized the need to articulate a patient's values, leaving the proxy and physician to extrapolate these to medical decisions.²² Although this preserved flexibility and avoided forced decision-making for unknown future circumstances, the weakness of this approach was that extrapolation of general values to medical decisions can be virtually impossible without specific guidance from the patient.²³ Other approaches noted that advance medical decision-making could sometimes not be done well and emphasized that in these cases proxy designation should be a sufficient form of planning.^{24, 25} Another approach started by emulating the ways in which moral reasoning is thought to actually occur in real life, namely with a combination of applying general principles and balancing intermediate goals both in light of the actual confronting circumstances. This approach noted that medical decision-making is possible for most patients, and if done with the physician involved, would allow physicians to apply patients' preferences accurately.^{vii, 26, 27}

In all of the attempts to document patient preferences effectively, a shared concern was how to be sure that the preferences were authentic and enduring.²⁸ It became apparent that documents should be subject to validation, just as is expected for any other clinical instrument that is used to elicit and assess a patient's subjective matters (such as scales for depression, assessments of alcoholism, survey's of satisfaction or opinion, or criteria for competence), and this approach has guided the development of some generic and illness-specific approaches to designing advance care planning documents.^{29, 30}

Facilitating discussions to effectively elicit patient preferences

A common end-point to all these developments was a reorientation toward the importance of having effective discussions with patients about their preferences. Without these discussions, patients cannot know their preferences, physicians cannot know them, they cannot be recorded well, and they cannot be implemented. Indeed, this gap may have been a major cause of the troubles surrounding effective use both of orders not to intervene and of advance directives. A number of initiatives have begun in order to train physicians to structure an advance care planning discussion. Such training, after all, is extensive for taking a medical history, and is necessary for acquiring the skills of structuring advance care planning discussions too so that this potentially unwieldy inquiry is to the point and sensitive. Use of validated worksheets to structure this discussion is one effective approach.³¹ These instruments can then be completed and documented as a formal advisory document (and added to relevant state statutory forms). A delineation of steps in a longitudinal process of discussion that weaves into the normal course of clinical encounters has been offered.^{xxxii} The physician should be involved in one or two key steps of the process, leaving other steps to the patient's time. These key steps include a) structuring a core discussion, and b) after patient reflection, co-signing and insuring that a completed document is recorded in the medical record.

Maximizing the availability of patient preferences at the time of decision-making

Many difficulties have been documented in getting patient preferences honored. Barriers include not only the above difficulties with their discussion, documentation and implementation but with simply having relevant documents available at the relevant time to the relevant attending physician. Proposals for portability of directives have been made, and a Uniform Model Statute has been proposed.^{32, 33} In addition, proposals have been made for a central repository of directives, along with bracelets and or wallet cards. These can notify physicians in emergency or urgent situations that there is an advance directive and can insure rapid communication of the full recorded wishes, along with location information for the physician and the proxy who were involved in discussing and recording the patient's preferences.³⁴

The Doctor's Order Sheet: Using a range of patient-tailored treatment avoidance orders

The end result of all these improvements for any given patient's admission or for standing orders for home care patients must be reflected on the Doctor's Order Sheet, or else all other interventions will have been in vain.

For patients who elect comfort care only, a full array of intervention avoidance orders may be written on the order sheet along with any relevant orders for active comfort care. Treatment avoidance orders might include, along with a DNR order, some of the following: Full Comfort Care Only (FCCO); Do Not Intubate (DNI); Do Not Defibrillate (DND); Do Not Leave Home (DNLH); Do Not Transfer (DNTransfer); No Intravenous Lines (NIL); Do Blood Draws (NBD); No Feeding Tube (NFT); No Vital Signs (NVS); and so forth. One common new order, Do Not Treat (DNT), is specifically not included in this list, since it may unintentionally convey the message that no care should be given and the patient may lose the intense attention due to a dying person; FCCO serves the same purpose without the likely misinterpretation. As with DNR orders, these treatment avoidance orders should be revisited periodically to ensure their continued applicability. Active comfort care orders might include Allow Visitors Extended Hours (AVEH); Inquire About Comfort (IAC) b.i.d. (twice daily); and so forth.

For patients who opt for a moderated approach there should be orders for selected therapeutic intervention along side an appropriate array on orders not to intervene and orders for active comfort care. So, for instance, antibiotics, and even dialysis (whether to relieve uncomfortable ascites or to avoid death by renal failure) or similar patient-tailored orders could be quite compatible with an array of orders to avoid other specific interventions and to aggressively pursue comfort.

RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends that:

- 1) Patients and physicians make use of advisory as well as statutory documents.
- 2) Advisory documents be based on validated worksheets, thus ensuring reasonable confidence that preferences can be fairly and effectively elicited and recorded, and that they are applicable to medical decisions.
- 3) Physicians directly discuss these issues with their patients and the patient's proxy. These discussion should be held ahead of time wherever possible, and the key steps of structuring a core discussion and of signing and recording the document in the medical record should not be delegated to a junior member of the health care team.
- 4) Central repositories be established so that completed advisory documents, state statutory documents, identification of a proxy, and identification of the primary physician, can be obtained efficiently in emergency and urgent circumstances as well as routinely.
- 5) Health care facilities honor, and physicians use, a range of orders on the Doctor's Order Sheet to indicate patient wishes regarding avoidable treatments that might otherwise be given on an emergency basis or by a covering physician with less knowledge of the patient's wishes.

REFERENCES

1. Kouwenhoven WB, Jude JR, Knickerbocker GG. "Closed-chest cardiac massage." *JAMA*. 1960;173:1064-1067.
2. Rabkin MT, Gillerman G, Rice NR. "Orders not to resuscitate." *New Engl J Med*. 1976;295:364-366.
3. Council on Ethical and Judicial Affairs. "Do-not-resuscitate orders." In: Proceedings of the House of Delegates of the AMA; December 1987; Chicago, Ill:170-171.
4. Bedell SE, Pelle D, Maher PL, Cleary PD. "Do-not-resuscitate orders for critically ill patients in the hospital: how are they used and what is their impact?" *JAMA*. 1986;256:233-237.
5. Bedell SE, Delbanco TL. "Choices about cardiopulmonary resuscitation in the hospital: when do physicians talk with patients?" *N Engl J Med*. 1984;310:1089-1093.
6. Braithwaite S, Thomasma DC. "New guidelines on forgoing life-sustaining treatment in incompetent patients: an anti-cruelty policy." *Ann Intern Med*. 1986;104:711-715.
7. Blackhall LJ. "Must we always use CPR?" *N Engl J Med*. 1987;317:1281-1284.
8. *In re Quinlan*, 70 NJ 10 (1976).
9. *Cruzan v. Director, Missouri Dept of Health*. Docket no. 88-1503. 1989.
10. Annas GJ, Glantz LH. "The right of elderly patients to refuse life-sustaining treatment." *Milbank Quarterly*. 1986; 64(suppl 2): 95-162.
11. Younger SJ. "Do-not-resuscitate orders: no longer secret, but still a problem." *Hastings Cent Rep*. 1987;17:24-33.
12. Everhart MA, Pearlman RA. "Stability of patient preferences regarding life-sustaining treatments." *Chest* 1990;97:159-164.
13. The SUPPORT Principal Investigators for the SUPPORT Project. "A controlled trial to improve care for seriously ill hospitalized patients: the Study to Understand prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT)." *JAMA*. 1995;274:1591-1598.
- 14.
15. Uhlmann RF, Cassel CK, McDonald WJ. "Some treatment-withholding implications of no-code orders in an academic hospital." *Crit Care Med*. 1984;12:879-881.
16. Emanuel LL. "Structured discussion of advance care planning in action." *Contemporary Internal Medicine*. 1996;8:10-16.
17. Emanuel LL. "Does the DNR Order Need Life-Sustaining Intervention? Time for Comprehensive Advance Directives." *Am J Med*. 1989;86:87-90.
18. Emanuel LL, Emanuel EJ. "The Medical Directive: A New Comprehensive Advance Care Document." *JAMA* 1989;261:3288-3293.
19. Fiscal year 1991 reconciliation issues relating to durable medical equipment, clinical laboratory services, and other issues under the medicare program. Subcommittee on Health. Committee on Ways and Means. May 22, 1990; Serial 101-103:81-147.
20. Emanuel EJ, Weinberg DS, Gonin R, Hummel LR, Emanuel LL. "How Well is the patient Self-Determination Act Working?: An Early Assessment." *Am J Med*. 1993;95:619-628.

21. Wolf SM, Boyle P, Callahan D, et al. "Sources of concern about the patient self-determination act." *N Engl J Med.* 1991;325:1666-71.
22. The Durable Power of Attorney for Health Care and Emanuel Medical Directive Chart. Tennessee Medical Association, Nashville, Tennessee.
23. Doukas DJ, McCullough LB. "The Values History: The Evaluation of the Patient's Values and Advance Directives." *J Fam Prac.* 1991;32:145-53.
24. Schneiderman LF, Pearlman RA, Kaplan RM, et al. "Relationship of General Advance Directive Instructions to Specific Life-Sustaining Treatment Preferences in Patients with Serious Illness." *Arch Int Med.* 1992;152:2114-2122.
25. Lynn J. "Why I Don't Have a Living Will." *Law, Medicine & Health Care.* 1991;19:101-4.
26. Emanuel LL, Barry MJ, Stoeckle JD, Ettelson LM, Emanuel EJ. "Advance Directives for Medical Care - A Case for Greater Use." *N Engl J Med.* 1991;324:889-895.
27. Teno JM, Hill TP, O'Connor MA. "Advance Care Planning. Priorities for Ethical and Empirical Research." *Spec Suppl Hast Cent Rep.* 1994;24:S1.
28. Emanuel LL. "What Makes a Directive Valid?" *Spec Suppl Hast Cent Rep.* 1994;24:S27-S29. Berry SR, Singer PA. "Development and Evaluation of a Cancer Living Will." *J Gen Int Med.* 1995;10:105.
29. Markson LJ, Fanale J, Steel K et al. "Implementing Advance directives in the primary care setting." *Arch Intern Med.* 1994;154:2321-2327.
30. Morrison RS, Morrison EW, Glickman DF. "Physician reluctance to discuss advance directives: An empiric investigation of potential barriers." *Arch Intern Med.* 1994;154:2311-2318.
31. Reilly BM, Magnussen R, Ross J et al. "Can we talk? Inpatient discussion about advance directives in a community hospital." *Arch Intern Med.* 1994;154:2299-2308.
32. Emanuel LL, Danis M, Pearlman, RA, Singer PA. "Advance Care Planning as a Process: Structuring the Discussions in Practice." *JAGS.* 1995;43:440-446.
33. Miles S. "Advance Directives to Limit Treatment: The Need for Portability." *JAGS.* 1987;35:74-76.
34. Teno JM, Parisier LA, Sabatino C, Rouse F, Lynn J. "The impact of the Patient Self-Determination Act's requirement that states describe law concerning patients' rights." *J Law Med.* 1993;21:102-108.
35. Emanuel EJ, Emanuel LL, Orentlicher D. "Advance Directives." *JAMA.* 1991;266:2563.