

THE MEDICAL FUTILITY GUIDELINES OF SOUTH FLORIDA

*“Life is short, and the Art long; the occasion fleeting;
experience fallacious, and judgment difficult.”*

Aphorisms, Hippocrates, 460 BC

Prepared by

The Health Care Ethics Committee
of
The Health Council of South Florida

February 2000



ACKNOWLEDGEMENTS

The Health Council of South Florida, Inc. would like to thank its Health Ethics Committee for their dedication throughout the development of the *Medical Futility Guidelines of South Florida*. The knowledgeable contributions that they made throughout the development of the Guidelines is greatly appreciated.

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The Health Council of South Florida, Inc. also wishes to acknowledge the contribution of the communities of South Florida who participated in the various public venues to develop the Guidelines.

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EXECUTIVE SUMMARY

The Health Council of South Florida, Inc.* has been engaged in the study of health care ethics for over ten years. During this philosophical journey, the Council's Health Care Ethics Committee has been charged with providing guidance on a wide array of issues ranging from health care access and affordability of care to end-of-life issues and advance directives. Indeed, if there is any tenet where the Health Council has clearly taken an ethical stance, it is on the importance of individual autonomy and the patient's right to refuse unwanted medical treatment. The right of refusal is of significant importance and should be observed even when the patient may benefit from treatment, in recognition of a competent adult's right to self-determination. This right of refusal, however, does not extend to the right to demand treatment, especially those treatments that would serve no medical benefit. This type of scenario, exemplified by the case study discussed in the prologue, is often referred to as a medically futile situation, one in which medicine has no clinical benefit to the patient. In its simplest form, this could include the demand for antibiotics for treating a viral infection, or invasive cancer surgery or therapy when there is no detection of the disease. In a more complicated form, it can involve medical uncertainty of the clinical outcome or effect, coupled with extraordinary conflict within families, with the potential for resultant guilt and remorse. At its worst, it can also entail needless pain and suffering for the languishing patient.

There is significant legislation at the federal and state levels pertaining to patients and their right to refuse unwanted medical intervention. These include the Patient Self-Determination Act and Florida's recently amended Advance Directives law. At the other end of the spectrum, there is no statutory provision for when the patient and his/her family are demanding treatment for conditions when there is no medical benefit. The guiding principles of medicine offer instruction to physicians that they may apply in their practices. Additionally, there are many policies that institutions such as hospitals and nursing homes abide by in the rendering of medical care. While many approaches may be cited, until now there have been no uniform guidelines for Medical Futility. In the absence of such direction, and for those cases where there is conflict between the attending physician's opinion of futility and the patient's (or family's) wishes for continuing treatment, the Council's Health Care Ethics Committee embraced the task of developing community-wide Medical Futility Guidelines. It was the intent of this Committee that these Guidelines could be applied across multiple settings, tailored to the individual provider's needs and culturally appropriate to South Florida's multi-faceted community.

The Medical Futility Guidelines of South Florida were developed via a structured process of community inclusion and input, and they reflect the varied cultural, ethnic and religious contributions of this diverse region. Through community forums, public presentations, and media involvement, the Council engaged many professionals, community leaders and local residents of various ages, cultures, religions and perspectives. From the extensive community involvement and public discourse, the resultant Medical Futility Guidelines of South Florida

* The Health Council of South Florida, Inc. is a non-profit organization with a mission to improve health care in Miami-Dade and Monroe Counties.

were born. The Guidelines are just that: a straightforward, philosophical, process-oriented approach to resolve the conflict that occurs when addressing medically futile situations. Much still needs to be done, particularly to promote clear communication between patients and their physicians and a discussion of the patient's wishes. Too, there needs to be extensive social marketing and public education so that the Guidelines can be used constructively by both consumers (patients) and providers alike. The entire patient care team must be able to discuss the goals for treatment and have an honest understanding of the family's expectations and – often alternatively –of the limitations of medicine and technology. While the patient's recovery or maintenance of health is always the highest goal, there are various gradations of health thereafter, and continuance of caring should always be present. Hence, when there is little that can be offered to promote restoration of health, there remains the need and the ethical obligation to provide the most comfortable palliative care possible. Physicians, nurses, social workers and the family and patient his/herself all have an important role in assuring the comfort of the patient at all times.

Finally, as we consider the work accomplished in other parts of the U.S as well as that of the American Medical Association, we see that the issue of medical futility is taking on heightened awareness across the country. Some of the most noteworthy efforts (such as the Houston Model, the Colorado Collective for Medical Decisions and Sacramento's "Extreme Care-Humane Options" or ECHO) are discussed in this report.

The Medical Futility Guidelines of South Florida represent the only initiative of its kind in the state of Florida, and we are proud to present them for your review. Please use this report freely as a reference tool and as an educational venue, taking the best from each of the models and applying them to your respective health delivery system or milieu. Our hope is that these Guidelines, developed with the intention to help others avoid needless pain and suffering, can assist you – whether you are a physician, a hospital administrator, a minister, a patient or a family member – in resolving conflict at the end of life.

Sonya Albury
Executive Director
Health Council of South Florida, Inc.
Miami, Florida
January, 2000

PROLOGUE

When treatment is futile but the patient (or the family or health care surrogate) insists on “doing everything possible to keep him or her alive,” what process exists to resolve the conflict? Who decides what to do when treatment is futile, the physician or the patient? How can physicians and institutions best comfort the dying who have no hope of recovery? How can communities educate the stakeholders – patients, families, physicians, hospitals, and nursing homes – in order to prevent this conflict at the end of life?

Why Develop Medical Futility Guidelines? A Case Study

Mr. Jones, a 72-year old male, was admitted for coronary artery bypass surgery. The bypass surgery itself was successful, but Mr. Jones suffered a stroke during the procedure and never regained consciousness. During his lengthy stay in the hospital, he was placed on kidney dialysis, was permanently on a ventilator, had a feeding tube inserted and received several transfusions. After several months, he was diagnosed by his physician, Dr. Lee, as being in a persistent vegetative state (PVS).

Mr. Jones was transferred back and forth to a transitional care unit, the hospital and eventually to a nursing home that had the resources for ventilator support and dialysis. After returning to the nursing home for a second time, his condition again deteriorated and he was transferred again to the hospital. This transfer to the hospital was precipitated by a serious bout of gangrene and his left leg was amputated below the knee. While in the hospital, his daughter was appointed his legal guardian.

Dr. Lee began to have serious doubts with the earlier decision to continue to treat Mr. Jones so aggressively. Mr. Jones, still in PVS, was by now a full code. His daughter insisted on *“doing everything possible to keep him alive.”* At one point, her father’s minister was called in to assist in making the decision whether to continue treatment or not. The minister believed that the aggressive treatment should be stopped. The daughter refused to listen and asked that the minister not be allowed to see her father. Neither of the brothers was willing to disagree with what their sister was demanding. The lawyer on the hospital ethics committee was consulted, and consequently asked the court to permit the discontinuation of aggressive treatment by withdrawing the ventilator and dialysis. The court did not agree. Mr. Jones still languishes in the hospital bed.

What will happen to Mr. Jones?

As biotechnology offers new hope for a quality of life never before experienced, it also is capable of raising the expectations of patients and their families beyond the limits of medicine. As a result -- and like Mr. Jones -- many people may suffer a prolonged period of agony during the dying process in the pursuit of a desire to “do everything possible” even when it has been medically determined that continued treatment is “futile.” With the continuing advance of technology in health care, an intense debate has arisen over the concept of medical futility. Some patients and families are demanding unnecessary treatments that provide no medical benefit, at great expense. Concurrently, many physicians are practicing defensive medicine fearing that anything less than careful application and administration of medical treatments would be less than required by their Hippocratic oath and could make them legally vulnerable. These situations – fraught with conflict and indecision – may promote unnecessary and unwanted suffering while wasting resources that could be allocated to other patients with a higher degree of positive outcomes. Although federal and state legislation as well as the courts have guided the issue of advance directives, there is little direction available as to what standards are adequate when treatment is futile but the patient (or the family, proxy or health care surrogate) insists on continuing treatment. The resulting industry and community confusion reflects a need for the dissemination of clear guidelines developed through an inclusionary process and declared openly as educational tools to provide a process – fair, equitable and humane – by which conflict at the end of life can be resolved and comfort for the dying can predominate.

The stakeholders in this ethical dilemma are the patients and their families, proxies or health care surrogates, the physicians and the other members of the health care team, and the hospitals and nursing homes. The premise of the dilemma is based on the themes of medical knowledge and quantifiable experience; the availability of technology; the values, mores, and religious beliefs of the patient; the costs of the medical care and the concern for the payment of this care; issues of liability; the management of pain; the provision of palliation and comfort; the assessment of the quality of life . . . and the attempt to appraise a reasonable and acceptable quality of life.

The Ethics Committee of the Health Council of South Florida’s recognized the lack of information available to stakeholders when faced with this ethical dilemma. Also, the Committee realized that the decisions about how to proceed in specific cases involving questions of futile treatment appeared to be made in an *ad hoc* and individualized manner without a set of agreed-upon standards to refer to for guidance. In addition, the unique population of South Florida, composed of a diverse ethnic, religious, and socio-economic cohorts, made the review of other early standards developed by communities such as Houston an excellent beginning but one that would need to be tailored to a multicultural community with a myriad of beliefs, norms and health care practices. Recognizing these facets of the system, the Ethics Committee agreed to develop guidelines for medical futility to be used in those cases when the patient wishes to continue receiving treatment, which the physician has determined is futile. Furthermore, these guidelines had to be flexible in their application to the South Florida community, derived by a process that included and involved the diversity and value systems inherent in it. The HSCF Medical Futility Guidelines serve as a framework for institutions to develop their own specific policies.

INTRODUCTION

One reality of medicine today is the innovative technological advancements in treatments. Advanced medical treatments have created a continuum of intermediate stages between health and death. Current technology provides a significant number of ways to capture patients in the final moments preceding death and pull them back to life, sometimes with limited or no recovery of vital organs such as the brain. Today, patients are being kept alive who cannot participate in, or even experience, the most minimal human activities. This technological capacity presents ethical problems about the goals of medicine that were not at issue thirty years ago.

Another reality of medicine today is the increasing circle of participants in health care decision-making. A patient's case is often no longer a private matter between the patient/family and the physician. The decision-making process has been altered and now physicians, nurses, hospital administrators, ethicists, social workers, lawyers, judge and third-party payers all participate in determining the best course of care.

These two realities may have taken the focus of health care away from the patient. In response, efforts have been made to redirect the focus back to the patient by promoting and respecting a patient's autonomy. The trend of enacting advance directive legislation illustrates the success of these efforts. These statutes provide a variety of mechanisms for patients to express their health care wishes in the event of their incapacitation. Some patients seek to forego treatment, especially in the case of life-prolonging procedures that have no curative properties. However, other patients and/or their families or surrogates demand treatments that physicians regard as having no medical benefit to the patients. These requests for unlimited use of limited resources to no benefit of the patient are the basis for the Medical Futility Guidelines explored in this report. Stakeholders must understand that the role of medicine is not – and never has been – to offer futile treatment. It is possible, too, that the medical futility debate has focused too narrowly on whether or not to use a particular treatment and has neglected to recognize the physician's obligation to alleviate suffering, enhance well-being, and support the dignity of the patient in the last days of life.

This report has several purposes:

1. First, it expounds on the South Florida experience of developing community-based Medical Futility Guidelines that are useful for patients, physicians, and institutions when faced with the conflict of patient wishes versus medical determination of futility. The Guidelines, developed by the Health Care Ethics Committee of the Health Council of South Florida, Inc. can be extrapolated from the report and used as an alternative method in conflict resolution for those medical futility cases where the patient or his/her agent insists on continuing treatment.

2. Secondly, the report serves as a compendium of selected other guidelines that have been established throughout the country. Its purpose is to facilitate the conflict resolution process by providing resources from several national experiences that can be applied to end-of-life scenarios.

The report includes the Medical Futility Guidelines from the Health Council of South Florida, Inc. (HCSF), and compares them to the Colorado Collective for Medical Decisions, Inc. (CCMD), and the Sacramento Healthcare Decisions' ECHO Project; the process whereby these documents were derived is also noted. In addition, a current update of three other experiences - Toronto, Houston and Oregon - in creating Medical Futility Guidelines or policies is included.

3. Thirdly, the report intends to provide an educational venue by which stakeholders can be educated so that conflict at the end-of-life can be mitigated. A person's last moments should not only be as free of pain as possible, but should also be free of continued indecision and prolongation of suffering. The advances in technology should not be afforded more promise than can be offered, and the importance of providing comfort care continues to be an essential component of the process of end-of-life care.

KEY ISSUES IN MEDICAL FUTILITY

Defining Futility

The goals of medicine have been identified as the provision of benefit to the patient including to restore, to heal and to make whole. Most experts, therefore, do not offer treatments that fail to achieve these goals, and would consider them as futile medical treatments. Currently, most experts believe that medical futility is a poorly defined concept that does not provide clear legal or ethical guidance for decision-making. Most, however, have tried to identify the meaning of this term and have yet to reach a consensus on its definition, scope and implications.

The Hastings Center Guidelines defined "physiologic futility" as the application of treatment that clearly would not achieve its physiological objective and therefore offer no physiologic benefit to the patient.¹ Schneiderman and Jecker objected to this definition because it prohibited physicians from regarding treatment as futile as long as it could maintain the function of any part of the body whether the patient was conscious or in the last moments of a terminal condition.² Others have supported definitions of futility that referenced a benchmark probability of success – a concept that underwent much scrutiny by those who argued that each patient could be the exception to the statistical profiling.³

¹ Guidelines on the Termination of Life-Sustaining Treatment and the Care of the Dying (Briarcliff Manor, N.Y.: Hastings Center, 1987).

² L.J. Schneiderman, N.J., Jecker, and A.R. Jonsen, "Medical Futility: Its Meaning and Ethical Implications," *Annals of Internal Medicine* 112 (1990): 949-54, at 952.

³ Tomlinson & Czlonka, *supra note 1*, at 31-32; R. Cranford and L. Gostin, "Futility: A Concept in Search of a Definition," *Law, Medicine and Health Care* 20, no 4 (1992): 307-9.

Defining Futility (continued)

A belief later emerged that the most useful definition of medical futility had both a quantitative and a qualitative component.⁴ Quantitative futility referred to the high reliability rather than certainty of a particular clinical conclusion. For example, a procedure like CPR is quantitatively futile if it has less than a one percent probability of succeeding. This determination requires empirical studies that identify patient populations with specific medical conditions under particular circumstances that have an unlikely prognosis for cure or survival in response to certain treatments. However appealing a statistical basis for futility might be, the distinction between “futile” outcomes and “unlikely” outcomes which an informed, risk-taking patient might choose, is really a value judgment. Qualitatively, a procedure may be viewed as futile if it fails to provide a benefit to the patient. For example, some experts assert that a procedure is qualitatively futile if it merely preserves permanent unconsciousness or fails to end total dependence on intensive medical care.⁵ Qualitative futility raises the issue of who is authorized to define an outcome as “non-beneficial.”

In 1994, the American Medical Association’s (AMA) Council on Ethical and Judicial Affairs stated that futility “could not be meaningfully defined” but that “denial of treatment should be justified by openly stated ethical principles and acceptable standards of care.”⁶ As a result of not having been able to state an objective, absolute, and concrete definition for futility by 1999, the AMA Council published a set of guidelines that followed a process-based approach to futility determinations. The AMA Council felt that these guidelines were much needed because defining futility had been difficult due to the inherent value judgments involved.⁷

Economics at the End-of Life

Calls for reform on health care costs have led to proposals to control costs at the end of life. For example, one proposal asked for hospitals to be required to establish guidelines to identify and reduce futile care. However, upon reviewing the economics of care at the end-of-life, a study on the effect of offering advance directives on medical treatment and costs found that there was not a significant difference between individuals who had an advance directive and those who did not.⁸

⁴ Schneiderman & Jecker, *supra note 2*; S.H. Miles, “Medical Futility,” *Law, Medicine and Health Care* 20, no. 4 (1992): 310-15, at 311.

⁵ *Wrong Medicine: Doctors, Patients and Futile Treatment* (Baltimore: Johns Hopkins University Press, 1995).

⁶ Council on Ethical and Judicial Affairs, American Medical Association. *Code of Medical Ethics*. Chicago, Ill: American Medical Association; 1994.

⁷ Medical Futility in End-of-Life Care: Report of the Council on Ethical and Judicial Affairs. *JAMA*, Vol. 281(10), 937-941, 1999.

⁸ Effects of Offering Advance Directives on Medical Treatments and Costs. *Ann Intern Med*, 1992, Vol. 117.

Economics at the End-of Life (continued)

**American Medical Association
Council on Ethical and Judicial Affairs
Code of Medical Ethics
2.035 Futile Care**

Physicians are not ethically obligated to deliver care that, in their best professional judgment, will not have a reasonable chance of benefiting their patients. Patients should not be given treatments simply because they demand them. Denial of treatment should be justified by reliance on openly stated ethical principles and acceptable standards of care, as defined in Opinions 2.03 and 2.095, not on the concept of “futility,” which cannot be meaningfully defined.

The AMA endorses the use of advance directives. In October of 1995, the AMA in conjunction with the American Association of Retired Persons (AARP), and the American Bar Association (ABA) released a guide entitled “Shape Your Health Care Future with Health Care Advance Directives.” In addition to educating the public, the guide also serves to familiarize physicians and physician leaders about advance directives.

Addressing Medical Futility

Physicians generally establish therapeutic goals for treatments based on some fundamental goals of medicine such as promoting or preserving health, minimizing disability, and reducing pain and suffering. If medical intervention is unlikely to provide an overall improvement in the physical or mental condition of the patient, it is often regarded as outside the boundaries of appropriate medical practice. In such cases, according to Tomlinson and Czonka, continued medical treatment of any kind cannot achieve the fundamental goals of medicine. Sneiderman and Jecker assert that the current futility debate has focused too narrowly on whether or not to use a particular treatment, and has neglected to recognize the physician’s obligation to alleviate suffering, enhance well-being, and support the dignity of the patient in the last few days of life.

Physicians continue to play a central role in how people confront and manage end-of-life issues. When physicians must deem medical treatment futile or when they have to provide their patients with options other than healing they may experience a considerable degree of internal conflict. A conflict occurs between what they must do and what they were taught to do – to provide direct medical interventions and health care services in order to extend and/or improve a patient’s quality of life. However, physicians have been found to be more willing than patients and family members to withhold or withdraw life-sustaining treatments, and family members have been

Addressing Medical Futility (continued)

found to be more hesitant to withhold or withdraw life-sustaining treatment than the patients themselves.⁹

In 1995, the American Medical Association established the Task Force on Quality Care at the End of Life. One of the objectives set by the task force was to assist physicians in identifying when it was necessary for them to reach an agreement with patients and their families with regard to intensive care that had been deemed futile by the physician. The task force also sought to define what constitutes futile treatment and to identify ways in which the quality of life for those receiving end-of-life care could be improved.

Resuscitation Guidelines Address Futility

In 1995, Tomlinson and Czlonka developed a model policy which stated that cardio-pulmonary resuscitation should be attempted unless (1) a patient is brain dead (and declared legally dead), (2) the patient has a DNR order, or (3) a physician determines that resuscitation would be futile or harmful. They also included guidelines for (1) confirmation of futility judgment, (2) disclosure for futility judgments to patients or patient representatives, and (3) provisions in case a patient disagreed with said judgments, or in case an incompetent patient had no representative.¹⁰

A recent study in California recommended for a patient to be pronounced dead at the scene of an injury when paramedics cannot find a pulse and an EKG shows that the victim is pulseless. This conclusion was reached after the researchers studied the survival to hospital discharge of 604 trauma victims who suffered cardiac arrest and were then tended by emergency personnel at a California medical hospital between 1991 and 1996. Contrary to popular belief, trauma victims have a survival rate of less than 5 percent if they require CPR.¹¹ Therefore, these researchers suggested that resuscitation efforts are “futile” in pulseless patients who virtually have no chance for survival.¹²

The AMA’s Resuscitation Guidelines published in 1999 address futile treatment and state that “efforts should be made to resuscitate patients who suffer cardiac or respiratory arrest except when circumstances indicate that CPR would be futile or not in accord with the desires or best interests of the patient.”¹³ These Guidelines also allow the attending physician to enter a Do-Not-Resuscitate (DNR) order into the patient’s record if he or she feels that CPR would be futile. The physician must inform and explain to either the patient or the incompetent patient’s

⁹ The Economics of Dying – The Illusion of Cost Savings at the End of Life. The New England Journal of Medicine, February 24, 1994, Vol. 330, No.8.

¹⁰ Futility and Hospital Policy. Hastings Center Report, Vol. 25(3): 28-35, 1995.

¹¹ Field Triage of the Pulseless Trauma Patient. Archives of Surgery, 1999, Vol. 134: 742-746.

¹² Source: Resuscitation ‘Futile’ in Pulseless Trauma Victims, Reuters Health News, July 23, 1999.

¹³ H-140.972 Guidelines for the Appropriate Use of Do-Not-Resuscitate Orders. The American Medical Association, 1999.

Resuscitation Guidelines Address Futility (continued)

surrogate why the DNR order was given, as well as discuss with him or her the right to a second opinion or the transfer of care to another physician.

Futility and Hospital Policy

A few hospitals throughout the nation have created and implemented futility policies as a means to manage this topic that continues to confound the field of medical ethics. In March of 1999 the American Medical Association's Council on Ethical and Judicial Affairs recommended a fair-process based approach to attempt to reach a more rational resolution to this issue. The Council suggested the use of the following case-by-case four-step process that involves negotiation, patient/proxy-physician decision-making, the use of professional ethics consultation services and the involvement of ethics committees in determining what care is futile and what is necessary. If agreement is reached at any one of outlined steps, there is no need to continue following the remainder of them.¹⁴

Medical Futility in the End-of-Life Care Four-Step Process

- | |
|---|
| <p>I. Prior Deliberation of Values
Earnest attempts should be made in advance to deliberate over and negotiate prior understandings between patient, proxy and physician on what constitutes futile care for the patient, and what falls within acceptable limits for the physician, family, and possibly also the institution.</p> <p>II. Joint Decision-making Using Outcomes Data and Value Judgment
Joint decision-making should occur between patient or proxy and physician to the maximum extent possible.</p> <p>III. Involve Consultant(s)
Attempts should be made to negotiate disagreements if they arise, and to reach resolution within all parties' acceptable limits, with the assistance of consultants as appropriate.</p> <p>IV. Involve Ethics Committee
Involvement of an institutional committee such as the ethics committee should be requested if disagreements are irresolvable.</p> |
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Reprinted from the American Medical Association, Policy and Advocacy Report, Policy H-140.948

¹⁴ American Medical Association, Council on Ethical and Judicial Affairs, Code of Medical Ethics, Rule No. 2.037, 1998-1999.

Futility and Hospital Policy (continued)

According to AMA policy on ethics consultation, all hospitals and other health care institutions should provide access to ethics consultation services and there should be true institutional support for the service. Those who provide ethics consultation should have extensive formal training and experience in clinical ethics and the services should be financed by the institution.

Consultation services may provide either one of the following: information and education, a forum for discussion but not advice, mediation, or the handling of administrative or organizational ethics issues. Each institution should set explicit structural standards that state the role of the consultation service and the types of cases that will be addressed.

In cases where the utilization of the above process does not lead to the resolution of conflict, then the two-step process outlined below should be utilized.

Medical Futility in End-of-Life Care Two-Step Process

I. Attempt to Transfer Care within Institution

If the institutional review supports the patient’s position and the physician remains unpersuaded, transfer of care to another physician within the institution may be arranged.

II. Transfer to Another Institution

If the process supports the physician’s position and the patient/proxy remains unpersuaded, transfer to another institution may be sought and if done should be supported by the transferring and receiving institution.

Reprinted from the American Medical Association, Policy and Advocacy Report, Policy H-140.948

According to the AMA, once these steps have been followed through and the patient cannot be transferred to another institution, then the futile intervention need not be offered. (Please see Appendix A for AMA’s Rule 2.037 - Medical Futility in End-of-Life Care).

The Medical Futility Guidelines of The Health Council of South Florida, Inc.

ABSTRACT

Medical futility is a value-laden concept that often encompasses treatment situations in which there are different beliefs, opinions and goals for the patient. Whenever possible, potential conflicts should be mitigated through effective communication between the entire medical care team, including the patient and his/her family (or the health care surrogate). When a conflict does occur, however, there needs to be a process under which decisions regarding treatment are made.

The Medical Futility Guidelines developed by the Health Care Ethics Committee of the Health Council of South Florida, Inc. describe a conflict resolution process whereby medically futile treatment may be withheld or withdrawn from a patient on grounds that such measures hold no reasonable promise of benefit to the patient. The process by which these Medical Futility Guidelines were derived is distinctive in that it included community input. The community that provided this input was marked by its diversity. This community-based approach and the resulting Guidelines intend to share the decision-making process, in the case of conflict, supporting the patient's rights of informed consent or informed refusal of treatment and, at the same time, balancing the competing interests of respect for patient autonomy with respect for professional and institutional integrity.

A Model Community Involvement Process to Develop the Medical Futility Guidelines

The Health Council of South Florida, Inc. (HCSF) is a not-for-profit corporation that provides health planning services for the South Florida counties of Miami-Dade and Monroe, and promotes the development of health services, manpower and facilities that meet identified health care needs in an efficient and cost-effective manner. The HCSF plays an active role in increasing community awareness of significant health issues through the collection and analysis of meaningful data, the development of recommendations, and the publication of policy papers, reports and health care plans. Special technical advisory committees appointed by the HCSF Board of Directors provide direction and assistance on specific health care issues.

In 1990, the Board appointed a special task force, the Health Care Ethics Committee, to provide expertise, direction, planning and education on critical bioethical issues in health care. The current Health Care Ethics Committee members include physicians and representatives from

health services administration, pastoral care, university professors and administrators, the legal system, the business community, consumers and the health technology industry.

Because most Medical Futility Guidelines around the country had been developed with minimal community input – and to a much lesser extent from a community that was as ethnically diverse as South Florida’s -- the Health Care Ethics Committee saw the need for Medical Futility Guidelines that were developed with the feedback and assistance of a community that could embrace and ultimately use them. Given the diverse values and beliefs of the South Florida community (Hispanics comprise 55 percent of the population in Miami-Dade County), the Health Care Ethics Committee examined some major issues involving medical futility by surveying the ethics committee members and administrators at ten hospitals, one nursing and rehabilitation center, one health center in Miami-Dade County and one hospital in Monroe County. The findings of this survey were remarkable: many of the institutional Ethics Committees in these facilities were struggling with the issue of futility; most significantly, none of the facilities had existing futility policies and the overwhelming majority (75%) supported the development of community based Guidelines. The results of this pilot study indicated a need for increased discussion about Guidelines for coping with futile medical treatment in South Florida.

Once the need for guiding principles in medical futility was established, then the Health Care Ethics Committee developed a working draft of Medical Futility Guidelines to use as a catalyst for community discussion and education. From January to April 1997, the draft Medical Futility Guidelines were presented and discussed with the ethics committees and medical staff of more than 12 hospitals and nursing homes in Miami-Dade and Monroe Counties. In addition, the following supplementary strategies were implemented to assure the participation of the community in the development of the Medical Futility Guidelines:

- The Health Council’s Medical Futility Guidelines were presented at the 1997 University of Miami Forum for Bioethics and Philosophy’s Clinical Ethics Conference.
- The Medical Futility Guidelines were posted publicly on the Health Council’s website at <http://www.med.miami.edu/HCSF>. An interactive questionnaire soliciting comments on the Guidelines was included.
- The Ethics Committee hosted a breakfast symposium, “When Enough is Enough: A Discussion of End of Life Issues,” in April 1997 to address concerns about end of life treatment decisions and compassionate clinical management. Over 100 community leaders participated in this symposium.
- The symposium generated a series of six public forums, entitled “When Enough is Enough: Coping with the Limits of Medicine,” from summer 1997 to fall 1998 to publicly discuss the ethical and philosophical considerations in medical futility in a way that was sensitive to the South Florida community.

These discussions sought to include all community perspectives – ethnic, cultural, age-specific and religious and to give the public a sense of ownership of the Guidelines. The

premise was that the community would later use the Medical Futility Guidelines to resolve conflicts at the end of life if it had an active voice in their development. The six public forums were sponsored in part through grants from the Florida Humanities Council, The Dade Community Foundation, and the Hospice Foundation of America.

A local community organization or association that worked directly with each targeted population coordinated each forum. The targeted populations included the major ethnic groups in South Florida -- including Hispanics, African Americans and Haitians – as well as varied age groups such as elder and adolescents. Health care professionals, religious leaders of all faiths and denominations, and persons living with HIV/AIDS were also represented in these forums. In addition and to further ensure the appropriate inclusion of all diverse community groups, the forums were held in different geographical neighborhoods within Miami-Dade County. (See Table 1).

Table 1: South Florida Community Forums, Summer 1997 – Fall 1998

Location	Target Population	Participation (Number of Attendees at Each Public Forum)
Miami Beach Senior High School	Adolescents	25
Baptist Hospital	Health care professionals	Approximately 80 people, including several community members who were not health care professionals
South Beach Police Station	People living with HIV/AIDS (PWAs)	Approximately 16 people, including seven PWAs
Opa-Locka Senior Focal Pointe	African American senior citizens	Approximately 60 African-American and Haitian seniors
Archdiocese of Miami	Religious leaders	Approximately 20 people, including people representing the Protestant, Catholic and Jewish faiths in a variety of settings such as the Chaplain of the Everglades Correctional Institute and the President of the Theological Society
Coral Gables Congregational Church	Hispanics	Approximately 20 people, including men and women of varying Hispanic countries of origin (e.g., Venezuela, Cuba, and Colombia)
		Total Participants: 206

- To increase even further the diversification of perspectives on this issue, a humanities scholar knowledgeable in the area of Bioethics was brought in to help analyze the results of the public forums. The Humanities Scholar provided comments on philosophy, ethics, theology, religious studies and the difficulties in communication.
- A final evaluation of the results of the public forums was conducted by a local independent evaluator from Nova University who was considered knowledgeable in the fields of Humanities and Ethics.

The extensive process used to assure that the perspectives of the diverse community of South Florida were included was used to revise the draft Medical Futility Guidelines. The revised model Guidelines, presented in this report, encompass the consensus of the Health Care Ethics Committee and the participants from the South Florida community. It is hoped that the number of individuals engaging in this dialogue will continue to grow and will use these Medical Futility Guidelines to begin discussions early on regarding their wishes, goals, and expectations to help prevent conflicts at the end-of-life.

The Philosophy of Care Behind the HCSF Medical Futility Guidelines

The discussions from the public forums catalyzed the “Philosophy of Care” that drives the Medical Futility Guidelines of the Health Council of South Florida, Inc. This Philosophy of Care that emerged from the public discussions centered on how a physician can fulfill the goals of promoting healing, preventing disease and relieving suffering when the patient wishes to pursue treatment but the physician has determined that it is futile. The Medical Futility Guidelines reflect the principles and ideals of the South Florida community as expressed through the community process undertaken, which include:

- The emphasis on comfort care throughout the conflict resolution process and, particularly, once the determination of medical futility has been accepted by the patient, the family or the health care surrogate.
- The importance of asking what it is that the patient wishes to do, and the health care team’s awareness of these patient objectives (or of those of the family or health care surrogate);
- The role of educating people about treatment preferences among families prior to the end of life;
- The encouragement of communicating what those treatment options may be prior to the end of life;
- The importance of immediate open communication between providers and patients, families and health care surrogates; and,
- The need to respect cultural and religious differences.

The Use of the HCSF Medical Futility Guidelines in Conflict Resolution

At all times and in all cases of medical futility, the patient's ethical right to autonomy and self-determination should be the guiding principle by which any and all resolutions abide. The patient – or his/her family, health care surrogate, or proxy – should always be encouraged to speak openly and to state his or her goals; these goals should be interpreted as “wishes” and should be reasonably accommodated by the attending physician and the health care team. Many families first “wish” to try continued treatment for some time; often, the acceptance of medical futility takes time, and is confirmed only by the patient's worsening condition. The Medical Futility Guidelines described herewith assume that the end of life is a process – never easy – but one that can avoid undue conflict and prolongation of suffering.

If the determination of futility becomes an issue of conflict – when the patient insists on receiving continued futile treatment -- then there needs to be a process under which decisions regarding treatment are made. The HCSF Guidelines describe a process whereby, in the case the patient resists the determination of medical futility by the attending physician, then medically futile treatment may be withheld or withdrawn from a patient on grounds that such measures hold no reasonable promise to benefit the patient.

Also, when applying these Guidelines, the premise is that the patient's health care team will have discussed with the patient, or health care surrogate, the following key issues beforehand:

- the patient's goals for treatment;
- the nature of the condition,
- the range of options available for care, including palliative care and hospice services,
- the prognosis, and
- reasons why the treatment is futile.

The HCSF Medical Futility Guidelines present a concise, 7-step conflict resolution process to be used to assist institutions in developing their own specific policies when the patient (or health care surrogate or proxy) wishes to continue futile treatment:

1. The patient's attending physician documents the judgment of “medical futility” in the patient's medical record.
2. The patient's attending physician is under no obligation to initiate or to continue the futile treatment.

The Use of the HCSF Medical Futility Guidelines in Conflict Resolution (continued)

3. The health care team explains to the patient that, although the requested intervention may not be provided, the health care team will not abandon the patient and will continue to provide appropriate medical care and humane care, including care to promote comfort, dignity, emotional and spiritual support. Ceasing aggressive forms of treatment does not mean the end of supportive or palliative care.
4. The health care team discusses with the patient (or health care surrogate or proxy) the options of
 - (a) consulting an independent medical opinion regarding the medical futility of the requested intervention,
 - (b) transferring to another physician or institution, or
 - (c) otherwise negotiating an acceptable solution.
5. The health care team discusses with the patient (or surrogate or proxy) the option of consulting the institutional review process, including the time, location and possible outcomes of the review.
6. If the institutional review process affirms the determination of futility of the treatment, then such treatment should be withdrawn or not given.
7. A plan of care that addresses the patient's comfort and dignity will be continued.

The HCSF Medical Futility Guidelines mention that considerations related to cost-effectiveness, rationing issues, and ability to pay should have “no relevance” to the assessment of medical futility. Additionally, the Guidelines promote an educational outreach component to encourage the health care industry to engage in community education and dialogue. The Guidelines have no recommendation or reference to physician assisted suicide. In the section preceding the seven-step Guidelines, the document provides a detailed discussion of the decision-making process itself, emphasizing comfort care and patient-physician communication. The Guidelines focus on open and continued dialogue between the physician, the patient (or family, proxy or surrogate) and the health care team. Assuring open and constant communication is encouraged for all members of the health care team including the dying patient (or the family, proxy or surrogate). The health care team ought to assure the presence and involvement of persons trained and capable of opening and maintaining the lines of communication, and are encouraged to be particularly sensitive to a patient's dignity, values, religion, or ethnic mores.

Current and Future Directions: Evaluation of the Guidelines

In March 1999, the Health Council of South Florida assessed the impact of the HCSF draft Medical Futility Guidelines on those facilities that were involved in the initial phase of the HCSF Medical Futility Study. All facilities that had participated initially were asked for their assistance in completing a brief questionnaire. In Miami-Dade County, six hospitals (Jackson Memorial, Mercy, Miami Children's, Miami Veteran Administration Medical Center, Pan American and South Shore) and one nursing/rehabilitation center (Mt. Sinai – St. Frances) responded either via telephone or fax. The following are key findings from the Miami-Dade County assessment:

Ethics Committee Composition:

- ◆ All facilities surveyed have an in-house Ethics Committee.
- ◆ Ethics Committees were primarily composed of physicians, nurses, hospital administrators, social workers, and clergy.
- ◆ Jackson Memorial Hospital has the most comprehensively constituted Ethics Committee. Its composition includes residents, a pediatric psychologist, a psychiatrist, and a county attorney in addition to the above listed members of the other Ethics Committees.
- ◆ Ethics Committees primarily serve in an advisory role and assist in the development of policy recommendations. Some perform consultations on individual cases.

Policies on Advance Directives and Medical Futility:

- ◆ All facilities surveyed have a policy on Advance Directives.
- ◆ Three of them have made changes to their policies in the past two years.
- ◆ Only Jackson Memorial Hospital has defined the term “medical futility” whereas the rest have chosen not to define it as of the date of the survey.
- ◆ Only Jackson Memorial Hospital and the Miami VA Hospital have a formal policy on medical futility.
- ◆ Jackson Memorial Hospital and the Miami VA Hospital have implemented their policies and have applied them to certain cases.

Utilization of HCSF Medical Futility Draft Guidelines:

- ◆ The draft Guidelines were reviewed and discussed by 70 percent of the facilities.
- ◆ Miami VA Hospital modified and incorporated some areas of the HCSF Guidelines that were related to process into their own policies. The HCSF Guidelines were also used to enhance family-physician communication and to lend family support for decisions.

Current and Future Directions: Evaluation of the Guidelines (continued)

- ◆ Jackson Memorial Hospital and Mt. Sinai – St. Frances Hospital did not utilize the HCSF Guidelines.

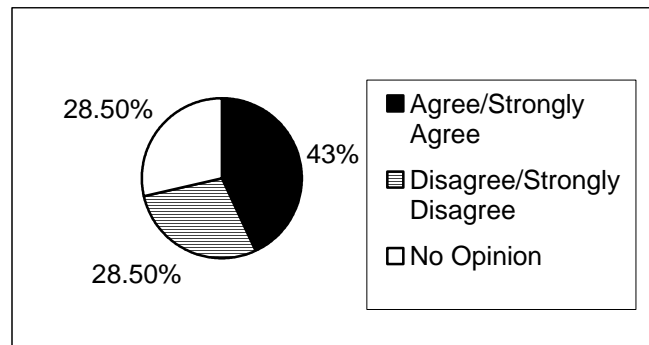
Educational Programs on Advance Directives:

- ◆ All facilities offer some type of educational program on advance directives.
- ◆ The majority of the responding institutions offer in-service training for staff and physicians on advance directives.
- ◆ Two facilities were interested in further assistance in developing educational programs on advance directives.

Opinions on HCSF Medical Futility Draft Guidelines:

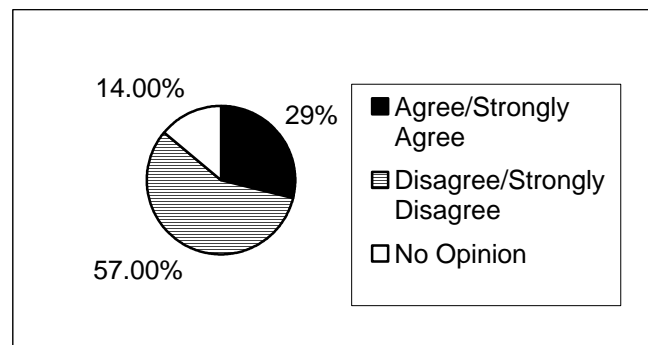
- ◆ “Guidelines were useful to facilitate education and dialogue in our facility.”

Most responding institutions agreed that the Guidelines had been useful to facilitate education and dialogue. Almost one-third disagreed with the statement, and close to another third had no opinion.



- ◆ “Guidelines have been useful to resolve conflicts over particular treatments.”

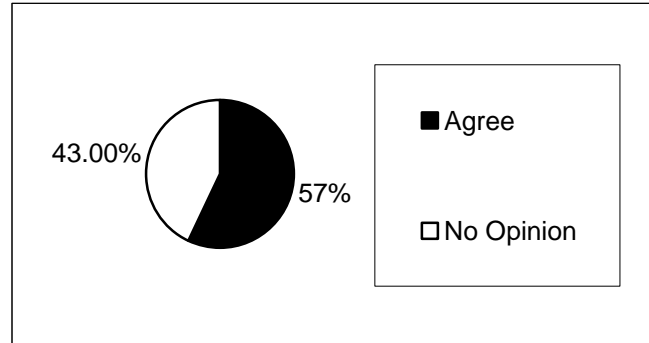
Over half (57%) of the responding institutions disagreed with this statement, one third agreed with it, and only a few responders had no opinion.



Current and Future Directions: Evaluation of the Guidelines (continued)

- ◆ “Conflict resolution procedure provided is adequate and needs no further modification.”

The majority (57%) of responding institutions agreed, and the remainder (43%) had no opinion.



HCSF Medical Futility Guidelines Successes (note: these are direct comments from the facilities):

- ◆ The Guidelines provide a good working document.
- ◆ There is noticeable improvement in Guideline text from previous drafts.
- ◆ The extensive research that has been done in the development of the Guidelines has facilitated physician acceptance of them.

Suggested Changes to HCSF Medical Futility Draft Guidelines: (note: these are direct comments from the facilities):

- ◆ More clarification is needed regarding legal rights.
- ◆ The Guidelines should also address the initiation of palliative care treatments that may be necessary in light of the withdrawal of futile treatment.

The Health Care Ethics Committee of the Health Council of South Florida plans to engage in a Community Outreach and Education Phase of the HCSF Medical Futility Project. In this phase, the Health Council hopes to:

- 1) educate the public on medical futility, discussing how cooperative Guidelines can be beneficial for both individuals and the community;
- 2) promote policy promulgation at the institutional level within hospitals and nursing homes;
and
- 3) promote dialogue on a larger statewide and national level directed to foster development of Guidelines in other geographic areas.

Attached are the Medical Futility Guidelines developed by the Health Care Ethics Committee of the Health Council of South Florida, Inc., a non-profit organization dedicated to health planning and the resolution of health issues of concern to the South Florida community.

The Health Care Ethics Committee hopes that these Medical Futility Guidelines will serve the community well, and that they be used to help resolve the conflict that occurs when a patient (or the family or health care surrogate) wishes to continue to receive treatment after a medical determination has made that such treatment is futile.

The Health Care Ethics Committee wishes to express its appreciation for the involvement of the community in the process through which these Medical Futility Guidelines were derived.

The Medical Futility Guidelines of South Florida

Developed by the
Health Council of South Florida, Inc.
Health Ethics Committee

PREAMBLE

Medical futility involves a value-laden, context-dependent judgment and requires balancing respect for patient autonomy with respect for professional and institutional integrity. The value of patient autonomy provides a basis for preventing physicians and institutions from forcing unwanted treatments on patients. The values of professional and institutional integrity provide a basis for preventing patients and families from forcing physicians and institutions to give treatments which they have concluded to be futile. The attached Guidelines describe a general philosophy of care and a process for shared decision-making in identifying the limits of medical intervention when a particular treatment may be considered futile.

PHILOSOPHY OF CARE

The primary goals of health care are to promote healing, prevent disease, forestall untimely death and relieve suffering. When possible, the physician and the entire medical team should treat to cure and bring about full functional recovery. However, when the patient's disease process or injury exceeds medicine's ability to bring about recovery, the health care team should offer palliation for the patient's discomfort and help the patient cope with his or her condition.

In pursuing these goals, the health care team must observe several professional duties. They include the duty to avoid harm to the patient, to respect the patient's dignity and autonomy, to uphold the ethical principles of medicine, and to observe professional standards of practice. The health care team should have cultural sensitivity and awareness of the objectives of the patient's family. Taken together, these duties suggest a partnership between physician and patient regulated by the ethical principles of shared decision-making and mutual respect. Treatment decisions are best made in the context of mutually agreed-upon goals, identified early in the course of the illness and frequently re-evaluated through discussion with the patient, family, and all members of the health care team. Patients are encouraged to communicate their treatment preferences, preferably beforehand, to more than one family member to ensure adherence to their wishes. In planning and delivering health care, the principle of autonomy is generally considered to be of paramount importance. That is, it is recognized that patients or

their surrogates have a prima facie right to make decisions regarding the course of treatment and to control what happens to them. These decisions reflect the patient's individual goals and assessment of the benefits and burdens of proposed treatments.

The principle of shared decision-making supports the patient's rights of informed consent or informed refusal of treatment. Correlative with these rights are the physician's obligations to inform the patient about his or her medical condition, prognosis, and treatment options together with their likely risks and benefits. The care offered to the patient should reflect the physician's best medical judgment and conform to professional standards. Although the decision whether to refuse or to accept any treatment, including life-sustaining treatment, ultimately belongs to the patient, the principle of mutual respect implies that neither the physician nor the patient may reduce the other to a mere instrument of will. The physician must respect the patient's right to refuse offers of treatment as well as to accept them. The patient must respect that it is the physician's responsibility to determine the appropriate treatment options from which he or she may choose.

In the face of terminal illness or fatal injury, observing these ethical requirements is especially important. The patient's disease, injury or treatment itself may deprive the patient of capacity to exercise directly his or her right to informed consent or informed refusal. If a terminally ill patient loses decision-making capacity and has made it clear by written or by oral declarations that he or she does not want to be kept alive by extraordinary means or by artificial nutrition and hydration then, and consistent with good medical practice, the patient's wishes should be honored. If the patient has a living will or has executed a health care surrogate or durable power of attorney addressing health care, then these expressions of the patient's wishes should be respected as authoritative.

In the absence of formal evidence of the patient's wishes, it is customary and appropriate to rely on the patient's guardian, spouse, close family member(s) or other person(s) with fair claim to best represent the patient in decision-making. Whoever bears the responsibility for exercising the patient's rights of informed consent or informed refusal of treatment should regulate his or her decision-making role by the doctrines of "substituted judgment" or of "best interests."

Under the doctrine of “substituted judgment,” the patient’s representative attempts to determine whether the patient would have consented to or refused treatment by reference to the patient’s expressed wishes, value system, or other reliable evidence of the patient’s wishes. If no such evidence exists, the patient’s representative should consider accepting or rejecting treatments by appeal to the patient’s “best interests,” or by asking what a reasonable person would want for him or herself were he or she in the patient’s circumstances.

The physician has a responsibility to offer an optimum care plan that responds to changes in the patient’s condition and accords with professional standards of practice.

MEDICAL FUTILITY

The term “medical futility” should be defined relative to the articulated goals of medicine. A determination that a particular treatment is “medically futile” is always a value-laden, context-dependent judgment. A futile intervention may be defined as any intervention that does not achieve its intended goal. For example, if a physician wants to cure a viral sore throat, then there would be little controversy that penicillin would be a futile intervention. This example describes a situation of “physiologic objective” and provides a basis upon which most reasonable parties can reach agreement. The difficulty in determining that a particular intervention is futile arises when reasonable parties disagree as to what the intended goal should be. For example, the patient may have expressed that he/she views prolongation of life, -- regardless of quality -- as a goal, whereas the health care team may believe that mere continuation of life in a patient who is deeply and reversibly comatose is not a rational goal. However, patients may have some conditions where consensus may exist among members of the health care team that nearly all interventions would not achieve any rational or useful goal of benefit to the patient. Additionally, comfort measures shall never be defined as futile treatment.

If the patient’s attending physician believes that any intervention is futile, the physician should discuss this promptly with the patient or the patient’s representative(s). In their discussion, the physician should explain the reasons why he/she believes the intervention to be futile. The physician should consult and explore the patient’s goals for treatment. Ideally, the patient should understand and concur with the decision to withhold or withdraw medically futile

interventions. If the patient’s representative is participating in the discussion, the representative should convey that which the patient would have wanted. Open communication between providers and families regarding diagnosis, prognosis and treatment alternatives is encouraged as soon as appropriate. This will enable that patient representative and/or family members to be aware of possible outcomes early in the course of illness in order to make an informed decision more effectively. However, neither the patient nor the patient’s representative may compel the physician to act contrary to his or her best medical judgment¹⁵.

CONFLICT RESOLUTION PROCEDURE

If futility is thought to be an issue of conflict, then there needs to be a process under which decisions regarding treatment are made. The following describes a proposed process whereby medically futile treatment may be withheld or withdrawn from a patient on grounds that such measures hold no reasonable promise to benefit the patient. This process intends (a) to balance the competing interests of respect for patient autonomy with respect for professional and institutional integrity; and (b) to recognize the importance of thorough institutional review of every case involving conflict. Nothing in these Guidelines infringes or impairs any right of the patient or any responsibility of the patient’s health care provider.

When the patient’s health care team¹⁶ determines that the available treatment holds no reasonable promise to benefit the patient medically¹⁷, and the health care team has discussed with

¹⁵ Current AMA guidelines on futile care address physicians’ obligations to offer futile interventions in a manner entirely consistent with the policy recommendations herein. “Council on Ethical and Judicial Affairs. Code of Medical Ethics – Current Opinions with Annotations.” *AMA*, (1998): 9, “Physicians are not ethically obligated to deliver care that, in their best professional judgment, will not have a reasonable chance of benefiting their patients. Patients should not be given treatments simply because they demand them. Denial of treatment should be justified by reliance on openly stated ethical principles and acceptable standards of care, as defined in Opinions 2.03 and 2.095, not on the concept of “futility,” which cannot be meaningfully defined.”

¹⁶ “Health care team” refers to the attending physician and everyone who consults on the particular patient’s case such as nurses, specialty consultants, representatives from pastoral care, social services, patient care and others.

¹⁷ For example, when the available intervention holds no reasonable promise for contributing to or for bringing about the patient’s recovery, would impose burdens grossly disproportionate to any expectable patient benefit, and would fail to palliate the patient’s discomfort.

the patient (or health care surrogate or proxy) (a) the patient's goals for treatment, (b) the nature of the condition, (c) the range of options for care including palliative care and hospice care, (d) the prognosis, and (e) the reasons why the particular treatment(s) is (are) futile; and the patient (or health care surrogate or proxy) insists that the treatment be provided, the steps to be taken are as follows:

1. The patient's attending physician should document these judgments in the patient's medical record.
2. The patient's attending physician is under no obligation to initiate or to continue the futile treatment.
3. The health care team should explain that, although the requested treatment intervention may not be provided, the health care team will not abandon the patient and will continue to provide appropriate medical care and humane care, including care to promote comfort, dignity, emotional and spiritual support. The patient (or health care surrogate or proxy) should be reassured that ceasing aggressive forms of treatment does not mean the end of supportive care.
4. The health care team should discuss with the patient (or health care surrogate or proxy) the options of (a) consulting an independent medical opinion regarding the medical futility of the requested intervention, (b) transferring to another physician or institution, or (c) otherwise negotiating an acceptable solution.
5. The health care team should discuss with the patient and family the option of consulting the institutional review process¹⁸, including the time, location and possible outcomes of the review.
6. If the institutional review process affirms the determination of futility of the treatment, then such treatment should be withdrawn or not given.
7. A plan of care addressing the patient's comfort and dignity will be continued.

¹⁸ The *institutional review process* should be clearly established and may involve the institution's ethics committee, a health care ethicist, pastoral care services and other related sources or processes.

The patient has the right to transfer to another institution at any point during this process and this option must be explored as a possibility in some cases. The health care team must ensure the health care surrogate's or family member's decision is respected in this regard.

Considerations related to cost-effectiveness, rationing issues, or ability to pay should have no relevance to assessments of benefits or futility. These considerations may be integral to society's debate regarding the health care system but have no role in establishing futility in specific patient situations.

Hospitals and medical facilities are encouraged to provide community outreach and education on end-of-life decisions. Discussion of end-of-life decisions should not be delayed until the end of life. In many cases, society's knowledge of what medicine can and cannot accomplish is based on unrealistic accounts of medical technology as portrayed by the media. Furthermore, dialogue may reduce the need for legal intervention. Increased levels of awareness can lead to better communication between the health providers and patients and/or surrogates, reduce or resolve conflict, and avoid unwanted treatments that are futile.

A COMPARISON OF OTHER EFFORTS IN THE UNITED STATES TO DEVELOP MEDICAL FUTILITY GUIDELINES

As of 1999, three major initiatives in the United States have been launched that have culminated in the development of specific medical futility recommendations, guidelines or policies. There are areas of similarity and difference in each of the three reviewed documents. The organizations that have developed Medical Futility Guidelines or policies include:

- ◆ the Health Council of South Florida, Inc. (HCSF),
- ◆ the Colorado Collective for Medical Decisions, Inc. (CCMD), and
- ◆ the Sacramento Healthcare Decisions' ECHO Project.

With continued strides in medical technology coupled with the increasing amount of information available to the consumer, it is evident that the conflict of requesting or withholding “medically futile” interventions will grow. Proposed guidelines, whether based on clinical scenarios or conflict resolution, will continue to shed light on a subject many health professionals and their patients have struggled to address prior to a crisis situation. Regardless of the differences, the three documents have succeeded in achieving educational milestones for both providers and consumers in the health care arena.

Both CCMD and ECHO mention specific clinical situations providing examples of when interventions should and should not be utilized. Another similarity between ECHO and CCMD is the inclusion of specific newborn guidelines. CCMD includes the phrase, “stewardship of medical resources.”

HCSF's Medical Futility Guidelines differ from the other two documents dramatically in that they focus on *conflict resolution* procedures rather than hypothetical medical situations. They were also developed using a community-based approach that was sensitive to the ethnic and cultural uniqueness of the South Florida community and placed a high priority on communication, goal clarification and comfort care.

The ECHO project in Sacramento is innovative in its approach in that it specifically includes the roles of health care payers. This added facet challenges HMOs, PPOs and other health insurance providers to participate in this important initiative that affects individuals from all walks of life. ECHO also includes an in-depth look at improving communication about treatment decisions. ECHO is receiving a great amount of attention due to the endorsement by the California Public Employees' Retirement System (CalPERS). CalPERS is the largest public pension system in the nation and the largest purchaser of employee health coverage in California, second only to the federal government in the nation. This support may pave the way for future discussions about end-of-life decisions both in California and nationally.

The Guidelines of CCMD and ECHO are included in this report as Appendices. In addition, the three sets of Guidelines are available on the Internet as follows:

The South Florida Guidelines are available on the Internet at the Health Council of South Florida web site at <http://www.med.miami.edu/HCSF/>

The Colorado Collective for Medical Decisions Guidelines can be obtained from CCMD at: 77 Grant Street, Suite 206, Denver, CO 80203-email ccmdco@aol.com An overview of the Guidelines is available on the Internet at the Rocky Mountain Center for Healthcare Ethics web site at <http://www.healthcareethics.com>

The ECHO Guidelines are available on the Internet at the CalPERS web site at <http://www.calpers.ca.gov>

Comparison Indicators for Medical Futility Guidelines

	HCSF* Guidelines	CCMD	ECHO
Year Initiated	1995	1993	1994
Participant Type	<ul style="list-style-type: none"> ◆ health care providers ◆ community participants 	<ul style="list-style-type: none"> ◆ health care providers ◆ community participants 	<ul style="list-style-type: none"> ◆ health care providers ◆ community participants
Conflict Resolution Procedures	Yes	No	No
Diagnosis Specific Guidelines	No	Yes	Yes
Proposed Audience	<ul style="list-style-type: none"> ◆ health care institutions and providers ◆ patients/health care decision makers 	<ul style="list-style-type: none"> ◆ health care providers ◆ patients/health care decision makers 	<ul style="list-style-type: none"> ◆ health care providers (specifically physicians, acute care, long term care) ◆ health plans ◆ patients/health care decision makers
Principles/Goals	<ul style="list-style-type: none"> ◆ community perspective and education ◆ cultural sensitivity ◆ communication of treatment preferences 	<ul style="list-style-type: none"> ◆ improved care ◆ better communication ◆ public participation ◆ stewardship of health care resources 	<ul style="list-style-type: none"> ◆ community perspective and education ◆ cultural sensitivity ◆ communication of treatment preferences
Comfort Care Addressed	Yes	Yes	Yes
Community Education Component	Yes	Yes	Yes
Cultural Sensitivity Addressed	Yes	Yes	Yes
Advance Directives Addressed	Yes	No	Yes
Resource Allocation Element	<ul style="list-style-type: none"> ◆ considerations related to cost-effectiveness, rationing issues, and ability to pay should have no relevance to the assessment of futility 	<ul style="list-style-type: none"> ◆ promotes and addresses responsible stewardship of health care resources 	<ul style="list-style-type: none"> ◆ promotes wise use of societal and personal resources

* Health Council of South Florida

Colorado Collective for Medical Decisions, Inc. **(Please see Appendix B)**

Organizational Background

The Colorado Collective for Medical Decisions (CCMD) is a not-for-profit organization located in Denver, Colorado with the purpose of “working with health care professionals and community members to develop community-based guidelines that encourage better decision-making and improve end-of-life care.” CCMD, formerly known as GUIDe or Guidelines for the Use of Intensive Care in Denver, began as a multi-hospital consortium with representation from a majority of Denver’s health care institutions in 1993. CCMD was funded through a three-year grant awarded to them by The Colorado Trust – a philanthropic foundation established in 1985 through an endowment from the proceeds of the sale of Presbyterian/St. Luke’s Medical Center in Denver, Colorado. In addition to this source of funding, CCMD has also received “in-kind” donations, which have, at various times, provided them with meeting spaces, materials, and other types of support.

Guideline Development Process

CCMD has taken a unique approach to medical futility policies by creating separate draft guidelines for adults and children, specifically infants. CCMD established two distinct committees to consider end-of-life issues facing these differing populations. Each committee was chaired by a physician (a Neonatologist and a Geriatrician). In addition to physicians and nurses, committee members included social workers, chaplains, students, public advocates, hospice representatives, and health care administrators. CCMD’s Board of Directors was not involved in the guideline development process.

CCMD’s mission is to “promote public awareness and discussion about medical treatment priorities at the end of life.” CCMD’s goals include:

- 1) improved care for dying patients;
- 2) better communication among medical providers, patients and caregivers;
- 3) more available pain management, hospice and palliative care;
- 4) public participation in setting priorities and goals of medical treatment; and
- 5) responsible stewardship of health care resources.

CCMD has developed two sets of guidelines for both community discussion and possible implementation by health care providers. The guidelines are purposely left in draft form, a common characteristic among proposed medical futility guidelines across the country. This allows for the opportunity to make continuous revisions to include all perspectives and voices. CCMD also emphasizes that the guidelines were intended to provide “helpful frames of reference” for patients and health care providers, but not to replace clinical judgments or opinions by a physician. Additionally, CCMD disclaims the intention of the guidelines to infringe upon relationships between a patient and his/her physician. CCMD also indicates they do not promote or address assisted suicide or abortion as part of the draft guidelines.

Guideline Development Process (continued)

CCMD Adult Committee's Community-Based Guidelines

I. Appropriate End-of-Life Care

- A. Medical care for a person approaching the end of life should focus on comfort care, including control of pain and meeting other personal needs.

II. Comfort Care

- A. Doctors and nurses should recognize the need for comfort care and encourage its timely use.
- B. Each hospital and nursing home should provide comfort care.

III. Shared Decision-Making

- A. Hospitals and nursing homes should encourage nurses, social workers and chaplains to discuss appropriate end-of-life care with doctors, patients, families and friends.

IV. Cardiopulmonary Resuscitation

- A. CPR should not be performed when the person has indicated that CPR is not desired.
- B. CPR should not be continued when there has been no favorable response after 30 minutes of CPR (except in cases of hypothermia).
- C. CPR should not be performed when recovery is known to be extremely unlikely.

V. Permanent Vegetative State

- A. People in a permanent vegetative state should receive comfort care instead of life-sustaining interventions.

VI. End-Stage Dementia

- A. People with end-stage dementia should receive comfort care instead of life-sustaining interventions.

VII. Tube-Feeding

- A. Long-term tube feeding should not be used for people in a permanent vegetative state or with end-stage dementia.

VIII. Dialysis

- A. Long-term dialysis should only be used for people who can cooperate with treatments.
- B. Short-term dialysis should not be used for people who have a negligible chance of survival.

Guideline Development Process (continued)

- C. Long-term dialysis should not be used for people in a permanent vegetative state.

Through these guidelines, CCMD encourages the protection of respect and preservation of the patient's dignity. CCMD suggests focusing on the following two barriers to improved end-of-life care: (1) the difficulty of including individuals, other than physicians, in the decision-making process, and (2) lack of "comfort, peace and closeness with family and friends" in what is currently offered by hospital and nursing home environments. Expansion of comfort care measures in these settings is advocated.

The document emphasizes the fact that medical technology is often used even when it cannot cure disease, prevent illness, preserve or enhance function, or relieve symptoms. Long-term dialysis, CPR, prolonged mechanical ventilation and long-term feeding tubes are listed as examples of interventions that may be inappropriate when used near the end of life. Toward this end, CCMD defines dementia as a "progressive and irreversible condition" and therefore does not condone life-sustaining interventions.

Overall, the guidelines address specific clinical situations on a case-by-case basis, and indicate whether treatments are appropriate in these instances. Resource allocation is rarely mentioned, except in the case of dialysis, where it states, "long-term dialysis requires ongoing commitment and resources by many people;" still, one of the stated project goals is "responsible stewardship of health care resources". CCMD does not approach the issue of conflict resolution procedures among families and providers, behaviors and the roles of ethics committees and institutional reviews, or financial considerations such as cost-effectiveness, rationing issues or ability to pay. CCMD excludes any attempt to define what "medically futile" means.

Current and Future Directions

CCMD has made every effort to disseminate its guidelines to local hospitals, long-term care staff, and geriatric outpatients, as well as to any individual, group or organization that requests them. Through the dissemination of these guidelines, CCMD feels that the public will be more knowledgeable about the benefits and burdens of using advanced medical procedures. With access to this information, they will be able to make more informed choices with regard to the type of care that they would like to receive at the end of life, as well as recognize that they have to make these wishes known prior to a health care crisis. The goal of CCMD's current implementation effort is for hospitals, long-term care facilities, home-health care organizations, and hospices throughout Colorado to view the guidelines as a valuable "starting point" for further discussion and consideration of medical futility related issues. Individualized clinical judgment on a case-by-case basis is also strongly supported.

Subsequently, CCMD has conducted the following extensive surveys throughout Colorado: 4,100 surveys with hospital and long-term care staff; 575 interviews with geriatric outpatients; and two statewide demographically sampled household telephone surveys. Focus groups were

Current and Future Directions (continued)

also held with the public of rural Colorado communities, with health care providers (critical care nurses and physicians), and with people with disabilities, African-Americans, and Latino populations of the Denver area.

Some key findings from these informal evaluations of the impact that the guidelines have had on the Colorado community are that:

- ◆ Ninety-one percent (91%) felt that terminally ill patient care should focus on keeping the patient comfortable, rather than on prolonging life, and 87% supported the availability of comfort care in hospitals.
- ◆ Eighty-three percent (83%) said that there are circumstances where it is appropriate to stop life-prolonging treatment for terminally ill patients.
- ◆ Fifty-three percent (53%) believe that aggressive medical treatment is used too often to prolong the lives of terminally ill patients and
- ◆ 77% of Coloradans support the use of community-based guidelines established by medical professionals to assist in making end-of-life medical decisions.

Survey respondents were also provided with specific critical medical situations and were asked to choose among two or more courses of action. Results from these surveys can be found in Appendix B.

CCMD is pleased that they have been able to develop end-of-life care guidelines that were consensually agreed upon by CCMD's medical subcommittees. Also, a recent success of CCMD has been the completion of a draft version of the *Faith Discussion Guide*. This guide was prepared so that members of the clergy could follow an outlined format that could assist them in facilitating group discussions within their congregation about death and dying. It was the result of a collaborative effort between CCMD and members of the clergy.

CCMD is currently doing a formal evaluation of the impact that the guidelines have had at the institutions that implemented them. The evaluation phase should be completed and a formal report made available by summer of 1999.

ECHO
(Extreme Care, Humane Options)
Sacramento Healthcare Decisions
(Please see Appendix C)

Organizational Background

Sacramento Healthcare Decisions (SHD) is a not-for-profit organization, characterizing itself as a “non-partisan community organization.” SHD’s mission is based on the premise that “the public’s voice must be included in healthcare changes, identifying and incorporating public values.” ECHO, or *Extreme Care, Humane Options*, is an organizational project under the direction of SHD, developed over a two year period between 1994 and 1996.

Guideline Development Process

The ECHO project had a multi-disciplinary Advisory Board to whom they reported. Three-quarters of the 20-member group were health care professionals. Special funding from a local health care foundation was used to develop the recommendations. The ECHO project sought to include both clinical dialogue and public dialogue to create a document with varied perspectives. ECHO engaged in comprehensive public discussions in four different counties in Northern California, holding 92 discussion sessions. Each discussion was similarly structured, each two hours in length, with “trained” moderators. ECHO reports involvement of 972 residents in this outreach. Additionally, a telephone survey was conducted at random to 1,022 persons. The project also held focus groups with families who “recently experienced difficult end-of-life decisions.”

To incorporate clinical perspectives, the ECHO project developed three committees: (1) Adult Intensive Care, (2) Neonatal Intensive Care, and (3) Long Term Care, each meeting for about one year. An additional committee discussing conflict resolution issues also met. A survey entitled “Physician Survey on End-of-Life Ethics” was developed and distributed to nine area hospitals including approximately 1,300 doctors, to adequately reflect the physician perspective.

Prior to publishing the guidelines for implementation, the draft version was reviewed by bioethics committees, health care professionals and community groups, independent of the staffed committees. The ECHO project sites the following beliefs as the underlying principles behind their recommendations:

- Patient Autonomy
- Avoiding Harm
- Benefiting the Patient
- Medical Integrity and the Goals of Medicine
- Wise Use of Societal and Personal Resources

Acute Care Facilities

The ECHO project has set five goals for acute care facilities with accompanying strategies. They are to:

- I. Develop treatment options that are responsive to the needs of dying or irreversibly ill patients and their families.
- II. Identify patients at risk of inappropriate or unwanted medical treatment.
- III. Improve communication among patients, families, other health care team members and health care settings in order to foster informed timely and mutually satisfactory treatment decisions.
- IV. Assure that the patient/surrogate is the primary decision-maker in choosing among appropriate treatment options.
- V. Support effective processes for preventing and resolving conflicts regarding treatment decisions that respect patient values and the professional integrity of health care providers.

To appropriately develop treatment options, ECHO suggests incorporating a statement of principles, implementing comfort care protocols and providing training for physicians and staff for the provision of comfort care. The ECHO project also proposes that facilities define their expectations and train health care teams for communications about end-of-life care. Additionally, facilities are encouraged to provide emotional support and grief counseling to patients, families and the health care teams to encounter these situations.

As part of the guidelines, ECHO puts forth strategies to help identify patients at risk for inappropriate medical treatment. They include ongoing reviews of ICU patients for determination of appropriate treatment measures, adherence of advance directives and educational programs. Educational programs can focus on institutional policy, common areas of miscommunication and misunderstanding, and the use of Bioethics Committees for internal staff. A community education component can offer insight on advance planning for end-of-life.

Indicators of Comfort Care

The ECHO Guidelines go a step further and actually define when palliative or comfort care is indicated:

“If cure-oriented treatment is no longer medically appropriate or desired by the patient/surrogate, then the principle of beneficence obligates the healthcare provider to make comfort care available. If the patient has not explicitly indicated – verbally, in writing or through a surrogate – a desire to forego cure-oriented treatment, comfort care should nevertheless be considered and discussed with the patient/surrogate if:

Indicators of Comfort Care (continued)

- *The patient is terminally ill.*
- *A profoundly diminished quality of life is imminent or has been established as irreversible.*

After presenting the guidelines for acute care facilities, the ECHO document analyzes clinical indicators in which comfort care would be most appropriate. The document cites the following clinical indicators or conditions as warranting the use of comfort care measures for adult patients or their surrogates. The ECHO Guidelines clearly articulate that in the following circumstances, comfort care *must* be offered as an option:

- Persistent vegetative state
- Minimal cognitive function (absence of self awareness or awareness of others) that is irreversible
- The burdens to the patient of cure-oriented treatment are greater than the medical benefit to the patient
- Irreversible and irreparable (multi) organ failure
- Imminent demise.

The ECHO project also drafted a set of guidelines warranting the use of comfort care for nonviable or irreversibly ill newborns. The guidelines advise that determination of medical treatment of infants should include the evaluation of both burdens and benefits, and be in the best interest of the newborn, not simply an extension of the dying process through advanced medical technology. The ECHO document offers the following indicators for comfort care in infants:

1. Conditions for which life expectancy is severely limited even with aggressive therapy. Current examples include but are not limited to:
 - Profound perinatal asphyxia
 - Prematurity less than 23 weeks and under 500 grams
 - Severe multiple congenital anomalies
2. Conditions for which cognition may reasonably be expected to be absent or profoundly limited. Current examples include but are not limited to:
 - Anencephaly
 - Trisomy 18
 - Trisomy 13
3. Conditions for which morbidity is so great and care is so extremely burdensome to the patient that quality of life is severely impaired. Current examples include but are not limited to:
 - Osteogenesis imperfecta type 2
 - Multisystem organ failure

Roles of Key Health Care Providers

The ECHO project offers a unique perspective by providing a framework for the roles of key health care providers in settings other than acute care hospitals. In this section of the document, ECHO defines physicians as “the authorities on realistic and feasible medical treatment options.” Many physician responsibilities are identified to support this definition. It is suggested that physicians should be proactive in the determination of those patients at risk for requesting inappropriate treatment. Once this determination is made, physicians can initiate discussion and engage in outreach education. According to ECHO, physicians are expected to be informed on current issues and comfort care measures. Physicians can ease end-of-life decisions by providing information about advance directives in their waiting rooms, addressing patient inquiries and incorporating advance directives in a patient’s medical record.

ECHO provides a set of roles for long-term care settings as well as health plans and payers. ECHO deems health plans responsible for sponsoring physician education seminars on end-of-life issues, providing advance directive documents to members, working with community-based organizations in planning and conducting consumer education programs on advance directives as well as encouraging consumer responsibility for communicating personal end-of-life values.

Current and Future Directions

In November of 1997, the California Public Employees’ Retirement System (CalPERS) endorsed the ECHO end-of-life recommendations. As part of this endorsement the organization plans to distribute the recommendations to its members, which total 1 million members statewide. CalPERS is the largest purchaser of employee health in California, and only second to the federal government in the nation. It is the largest public pension system in the United States.

In addition, Sacramento Health Decisions received a two-year grant in 1997 from Sierra Health Foundation to further develop end-of-life care initiatives. The grant will fund the following three new phases focused on community education:

- ◆ “*Finding Your Way: A Guide for End-Of-Life Medical Decisions*”, a fourteen page consumer guidebook to help with difficult decision making. Information is presented for both families and patients on how to plan before serious health conditions arise and when decision-making is imminent. The publication also identifies responsibilities for providers and patients.
- ◆ The *Decisions* series, a six-week set of articles on end-of-life decisions will be developed and inserted into the congregation bulletins of 55 local religious congregations. The articles discuss medical dilemmas facing providers, patients and families. They also stress the importance of communication with loved ones about wishes prior to a “crisis” situation. This idea was developed by the California Association of Catholic Hospitals with the goal of bringing together health care professionals and clergy.

Current and Future Directions (continued)

- ◆ An organized end-of-life education program attended by 83 physician assistants, nurses, social workers and chaplains from fourteen area hospitals. The 1½ day session focused on improving communication and palliative skills. The session was designed to provide skills which could be incorporated in their daily practice as well as teach to their colleagues.

ECHO's Phase II also incorporates a long-term care component. A regional/state task force was convened to look at how long-term care facilities utilize the ECHO goals and strategies. With this area of the initiative, SHD strives to "identify ways to remedy existing barriers to high quality end-of-life care".

SHD is also engaging in an innovative project to establish "End-Of-Life Care Performance Measures." This effort is in partnership with the California Institute of Health Systems Performance (CIHSP), a not-for-profit public health benefit corporation that establishes quality measures to increase provider accountability. The performance measures will be based on ECHO's already developed end-of-life care recommendations.

SHD is pleased that they have been able to create recommendations that reflect what both the public and the health professionals wanted. The only limitation that SHD has noted is that they did not involve more of the disenfranchised population, such as minority groups and the uninsured, therefore poorly representing these groups in the project. Currently, SHD is in the process of evaluating the impact that its recommendations have had on the 13 hospitals that officially endorsed and implemented them. Since their endorsement, these hospitals have developed new specific policies and pathways as evidence of their implementation. Only one acute care hospital did not endorse the recommendations. In addition to continuing in its efforts to locally implement ECHO's recommendations, SHD is currently a Partner with a Robert Wood Johnson Foundation funded project to apply the recommendations statewide.

Other Experiences

Toronto (Please see Appendix D)

The University of Toronto Joint Centre for Bioethics and the University of Toronto Critical Care Medicine came together through a Task Force on Ethical Issues in Critical Care and developed a Model Policy on Appropriate Use of Life-Sustaining Treatment and a companion policy on Quality of End-of-Life Care.

Similar to the HCSF policy, the Toronto Guidelines were designed to provide a framework for resolving conflicts in situations of disagreement about appropriate use of life-sustaining treatment, including admission to the intensive care unit. The policy also reinforces the patient's right to receive quality end-of-life care including palliative care. The process for decision making is mapped out in an 11-step process to include the following:

1. Interprofessional Team Consensus
2. Communication
3. Negotiation
4. Intensive Care Consultation
5. Second Opinion
6. Trial of Therapy
7. Patient Transfer
8. Mediation
9. Arbitration/Adjudication
10. Notice of Intention to Withhold or Withdraw Life-Sustaining Treatment, and
11. Withholding/Withdrawal of Life-Sustaining Treatment.

Because this policy is focused on intensive care, it reinforces the primary goal of this level of care, which is: “to prevent unnecessary suffering and premature death by treating reversible illnesses for an appropriate period of time.” The policy further defines situations where there is a provider consensus regarding a standard of care for intensive care to include imminent death, lethal condition, and/or severe/irreversible condition.

Survey Results

In order to obtain an update on the current status of the Toronto experience, as well as two other initiatives (Oregon and Houston) – the Health Council of South Florida, Inc. surveyed leaders of the various initiatives and asked them to critique the process they undertook to develop their guidelines. A matrix of the survey results is included in Appendix H and a narrative summary of the survey results follows:

Toronto (continued)

The University of Toronto Joint Centre for Bioethics' funding sources include the Ontario Ministry, the Toronto Hospital, and the University of Toronto. In collaboration with its Board Members, the Centre developed its guidelines – an initiative that received special funding from the Medical Research Council of Canada. Guidelines were disseminated to the eight teaching hospitals located in the metropolitan Toronto area and the impact that these guidelines have had on these organizations is currently being evaluated with the assistance of special grant money received to conduct this assessment. Early indications appear very promising.

Toronto views its greatest success to be the de-escalation of conflict. Presently, the Centre feels that the current medical definition of futility is not acceptable and that it is impossible to define futility because there are many factors that need to be taken into account, such as cultural, philosophical, personal and legal aspects. In retrospect, the Centre would have liked to have focused more of its attention on improving communication between physicians, patients, and families instead of concentrating so much of its efforts on defining medical futility. In so doing, a better understanding of a patient's perspective can be attained. Toronto is continuing to implement its guidelines and evaluate them in a qualitative manner by interviewing those families who have used the futility guidelines and by measuring the effectiveness and usefulness that the guidelines had on each individual situation.

Oregon (Please see Appendix E)

The Oregon Health Sciences University (OHSU) in Portland has a Board to whom they report. Unfortunately, extensive information could not be obtained from OHSU since a representative could not be formally interviewed. The following, therefore, is information extracted from an electronic message sent to the Health Council of South Florida, Inc. earlier this year.

In July of last year, OSHU decided to withdraw its medical futility policy and re-examine it. This came about due to several concerns/issues that were identified during its periodic review of policies. One of its concerns was that the current definition of futility was not very helpful to clinicians facing day-to-day increasingly complex situations. Presently, OHSU has developed a task force that is re-examining its policy on futility. The task force is completing a comprehensive review of the literature, interviewing stakeholders and identifying key issues for which recommendations can be reached and shared with the administration. A central issue, which is going to be addressed is the resolution of disagreements between care providers, as well as between providers, families, and patients. In retrospect, OHSU recognizes that one of its failures was that in the process of developing its guidelines, very narrow language was used in defining futility. This has allowed for the possibility for two doctors to decide that continued care is futile and consequently override the decision already made by either the family and/or the patient.

Houston (Please see Appendix F)

The Houston Bioethics Network, a consortium of representatives of Ethics Committees in the greater Houston area, was not directly involved in the development of the multi-institution futility policy in Houston, Texas. Rather, it created an Ad Hock Task Force in August 1993 to accomplish this task. Since there were minimal costs involved for the development of the guidelines, special funds for this endeavor were not necessary.

Once the guidelines were formulated, they were disseminated to local hospitals, medical societies and to the American Medical Association (AMA). Houston has evaluated the impact that its guidelines have had on these institutions. One of their significant impacts has been that the AMA endorsed the guidelines in December of 1996. Another success has been that the AMA now endorses Processed Based Futility Policies. In retrospect, Houston would not do anything differently and it feels that it has been effective in its community since all but one institution has adopted the guidelines. Houston's future endeavor is to continue gathering data so that it can continue being in the forefront of this imperative issue.

APPENDICES

APPENDIX A

**❖ American Medical Association
Council on Ethical and Judicial Affairs
Code of Medical Ethics – Current Opinions with Annotations**

**American Medical Association
Council on Ethical and Judicial Affairs**

Code of Medical Ethics

2.35 Futile Care

Physicians are not ethically obligated to deliver care that, in their best professional judgment, will not have a reasonable chance of benefiting their patients. Patients should not be given treatments simply because they demand them. Denial of treatment should be justified by reliance on openly stated ethical principles and acceptable standards of care, as defined in Opinions 2.03 and 2.095, not on the concept of “futility,” which cannot be meaningfully defined. (I, IV)

Issued June 1994.

2.36 Medical Futility in End-of-Life Care

When further intervention to prolong the life of a patient becomes futile, physicians have an obligation to shift the intent of care toward comfort and closure. However, there are necessary value judgments involved in coming to the assessment of futility. These judgments must give consideration to the patient’s or proxy’s assessment of worthwhile outcome. They should also take into account the physician or other provider’s perception of intent in treatment, which should not be to prolong the dying process without benefit to the patient or to others with legitimate interests. They may also take into account community and institutional standards, which in turn may have used physiological or functional outcome measures.

Nevertheless, conflicts between the parties may persist in determining what is futility in the particular instance. This may interrupt satisfactory decision-making and adversely affect patient care, family satisfaction, and physician-clinical team functioning. To assist in fair and satisfactory decision-making about what constitutes futile intervention:

- (1) All health care institutions, whether large or small, should adopt a policy on medical futility; and
- (2) Policies on medical futility should follow a due process approach. The following seven steps should be included in such a due process approach to declaring futility in specific cases.
 - (a) Earnest attempts should be made in advance to deliberate over and negotiate prior understandings between patient, proxy and physician on what constitutes futile care for the patient, and what falls within acceptable limits for the physician, family, and possibly also the institution.
 - (b) Joint decision-making should occur between patient or proxy and physician to the maximum extent possible.

2.37 Medical Futility in End-of-Life Care (continued)

- (c) Attempts should be made to negotiate disagreements if they arise, and to reach resolution within all parties' acceptable limits, with the assistance of consultants as appropriate.
- (d) involvement of an institutional committee, such as the ethics committee, should be requested if disagreements are irresolvable.
- (e) If the institutional review supports the patient's position and the physician remains unpersuaded, transfer of care to another physician within the institution may be arranged.
- (f) If the process supports the physician's position and the patient/proxy remains unpersuaded, transfer to another institution may be sought and, if done, should be supported by the transferring and receiving institution.
- (g) If transfer is not possible, the intervention need not be offered. (I,V)

Issued June 1998 based on the report, "Medical Futility in End-of-Life Care," adopted December 1996.

APPENDIX B

❖ **CCMD Guidelines**

❖ **CCMD Scenarios**

Colorado Code of Ethics for Healthcare

The Colorado Code of Ethics for Healthcare is a practical document, intended to draw attention to real and potential ethical challenges in healthcare delivery and reception. The Code is designed to guide participant deliberations, decisions, and behaviors.

Throughout the project, participants expressed concern about the implementation and enforcement of the Code. The Code was developed with the belief that providers, physicians, practitioners, employers, and health plans should voluntarily adopt and implement the Code, as part of a larger effort to increase consumer and patient confidence and trust. Consumers and patients need significant education and support to meet the standards and use the Code to evaluate the ethical performance of other participants.

The Rocky Mountain Center for Healthcare Ethics will assist those who deliver and receive healthcare to implement and use the Code to improve their ethical performance. The Center will pursue this objective through consultation to healthcare organizations, applied research and publications, education of healthcare professionals, and community outreach.

Principles, Value Statements, and Standards

The Colorado Code of Ethics for Healthcare consists of seven principles. These principles reflect significant ethical challenges associated with healthcare delivery and reception. Each principle is introduced by a value statement followed by several standards. The importance of each principle is described by the value statement. Standards delineate behavioral expectations for the ethical delivery and reception of healthcare. Individuals and organizations are to use the standards as quality indicators or benchmarks of ethical performance.

I. Improving the Health of the Public

Value Statement:

The goal of healthcare is to maximize the health of individuals and populations. All participants share in the responsibility to contribute to improving the health of the public.

Standards:

- A. Regardless of the competitive environment, participants collaborate to improve the health of the public.

- B. Health plans, providers, physicians, practitioners, purchasers, and employers demonstrate a commitment to provide appropriate healthcare services to those uninsured and underinsured.
- C. Health plans participate in, fund, and share outcomes of clinical research and professional education.
- D. Health plans, providers, physicians, practitioners, purchasers, and employers support healthcare consumers by demonstrating a commitment to prevention, education, and wellness in addition to the treatment of illness and injury.
- E. Consumers and patients are responsible for their personal health promotion and disease prevention.

II. Using Resources Appropriately

Value Statement:

Recognizing that resources are limited, health plans, providers, physicians, practitioners, purchasers, and employers must administer health benefits and provide quality patient care efficiently. Patients and consumers are responsible for using resources appropriately.

Standards:

- A. Treatment allocation decisions are based on clinical, scientific, and financial evidence, which is evolving, and at times, incomplete.
- B. Health plans, providers, physicians, and practitioners do not allow payment methods to compromise clinical care.
- C. Health plans, providers, physicians, practitioners, purchasers, and employers assure the provision of quality care which is defined in terms of patient satisfaction, outcomes, and cost benefit analysis.
- D. Health plans, providers, physicians, practitioners, and patients will collaborate to assure that healthcare services are timely and delivered by appropriate professionals in appropriate settings.

III. Promoting Fairness, Equality, and Just Treatment of Individuals

Value Statement:

Healthcare resources allocated by health plans, providers, physicians, practitioners, purchasers, and employers will be justly distributed among members. Individuals will be treated with fairness and respect, regardless of race, culture, national origin, religion, gender, age, disability, sexual orientation, genetic make-up, socio-economic status, health status or source of payment.

Standards:

- A. Health plans, purchasers, and employers assure that every member covered by the same benefit plan has equal access to benefits.
- B. Health plans, providers, physicians, and practitioners assure that services are provided in a way that respects the individual's needs.

IV. Advancing the Exchange of Information, Education, and Shared Decisionmaking

Value Statement:

A variety of information is required in order to deliver and receive healthcare responsibly. Patient information is necessary to manage and improve quality of care, to develop practice parameters, to aggregate data for public health monitoring, and most critically, to assist patients and their families in making important healthcare choices. Health plans, providers, physicians, practitioners, purchasers, and employers are obligated to provide information to consumers, patients, and surrogate decisionmakers to foster knowledgeable and responsible use of healthcare resources. Patients, consumers, and surrogate decisionmakers will seek, understand, and be guided by information.

Standards:

- A. All participants share the responsibility for information exchange and education.
- B. Health plans, providers, physicians, and practitioners communicate openly and honestly, and share decisionmaking responsibilities with patients and surrogate decisionmakers.
- C. Patients, consumers, and surrogate decisionmakers participate as informed decisionmakers by obtaining relevant information from health plans, providers, physicians, practitioners, and other healthcare resources.
- D. Employers offering health insurance benefits provide accurate, complete and usable information to employees about health plan selection, benefits, inclusions and exclusions, and utilization management procedures.

- E. Health plans provide information about benefit inclusions and exclusions, accessing and navigating the system, and outcomes in language that can easily be understood by consumers and patients.
- F. Health plans, providers, physicians, practitioners, purchasers, and employers share information about financial arrangements and comparative costs of care (e.g., type of delivery system, financial incentives and disincentives, and costs for which the patient is responsible) with all participants.
- G. All participants collaboratively define and use participant specific information and data in a responsible and meaningful manner. All comparative information is verifiable.

V. Assuring Privacy and Confidentiality

Value Statement:

Privacy and confidentiality of individual persons is respected. Patient information is not used inappropriately.

Standards:

- A. Health plans, employers, providers, physicians, and practitioners inform consumers and patients that their clinical records will be disclosed to those participating in the delivery or management of their healthcare. Appropriate consent is obtained prior to the release of records. Mechanisms are created to assure reasonable security of patient information.
- B. Health plans, providers, physicians, practitioners, purchasers, and employers are responsible to safeguard patient information and ensure that it is not used for anything other than the intended clinical, financial or legal purpose.
- C. Health plans, providers, physicians, practitioners, purchasers, and employers aggregate patient data when possible so that they are not individually identifiable.

VI. Supporting Participant Relationships

Value Statement:

Health plans, providers, physicians, practitioners, purchasers, and employers are obligated to assure quality care and to increase the confidence and trust patients and consumers have in the delivery of their healthcare. Cooperative relationships among and between purchasers, employers, health plans, providers, physicians, practitioners, consumers, and patients are crucial to the provision of healthcare. The structure of organizing, financing, and delivery of healthcare should be designed to foster and support these relationships.

Standards:

- A. Providers, physicians, and practitioners inform health plans of their ethical concerns of their patients.
- B. Health plans do not unduly interfere in the individual physician*-patient relationship.
- C. Providers, physicians, practitioners, and health plans address their problems and conflicts without unduly involving patients.
- D. Purchasers and employers take responsibility for the impact of their healthcare benefits decisions on the individual physician*-patient relationship.

* or practitioner

VII. Achieving Ethical Behavior and Accountability

Value Statement:

Ethical tensions and conflicts are inevitable in situations involving healthcare delivery and reception. Participants must work individually and collectively to identify and seek to resolve ethical concerns.

Standards:

- A. Participants promote integrity in all relationships and hold one another accountable for ethical behavior.
- B. Health plans, providers, physicians, and practitioners promote ethical practices by adopting codes, policies, procedures, and guidelines consistent with ethical, legal, and regulatory standards.
- C. Health plans, providers, physicians, and practitioners implement mechanisms and participatory processes for consideration of ethical issues. Consumers and patients use these processes to express their ethical concerns and seek resolution.
- D. Employers take responsibility for the ethical implications of selecting, purchasing, and managing employee healthcare benefits.

HOW TO USE THE CODE

There are numerous ways to creatively implement the *Colorado Code of Ethics for Healthcare*. Individuals and organizations may use the Code to understand their ethical responsibilities and those of the other participants in the delivery and reception of healthcare. Participants can use the Code to assist them in their relationships with other participants. The following represent only a few suggestions.

Consumers and Patients:

The Code defines consumer and patient responsibilities and what they can expect from the other participants. The Code can assist consumers and patients in assessing the ethical status of providers, physicians, practitioners, employers, and health plans. It can support consumers and patients in addressing specific ethical issues in the delivery of healthcare. Consumers and patients may want to build their healthcare relationships based on those who have a commitment to the code.

Providers, Physicians, and Practitioners:

Providers, physicians, and practitioners may use the Code standards to address specific issues and/or evaluate the ethical performance of their practice. Providers, physicians, and practitioners who adopt the Code may use it as a guide when seeking affiliations or partnerships. The Code may be used to review and/or develop policies and procedures and to support professional decisionmaking.

Purchasers and Employers:

Purchasers and employers may use the standards to review and evaluate the ethical commitment and performance of health plans. Business affiliations and partnerships may be sought with others committed to the Code. Employers may choose to review and/or develop policies and practices that support the Code standards. The Code can be used to assist employees through informational and educational forums to disseminate and discuss the Code.

Health Plans:

Managed care organizations may establish ethics committees or internal processes to methodically address the ethical challenges presented in the Code standards. Organizational processes, procedures, and policies can be reviewed for consistency with Code standards. Managed care organizations can use the Code to evaluate other participants, demonstrate accountability, and seek out business affiliations and partnerships with other like-minded participants.

DEFINITIONS

Confidentiality

The obligation to keep all communication and records pertaining to the care of an individual from being revealed to others, unless the person is first made aware of and consents to its disclosure.

Consumers

Persons who potentially use healthcare services, but are not currently engaged in an episode of care.

Ethics

The process of navigating and negotiating values, commitments and principles in order to act with integrity as an individual, professional or organization.

Employers

Businesses that purchase health benefits for the workforce.

Health plans

Any form of insurance, such as HMOs, PPOs, third party administered plans, self funded plans, or other entity that covers healthcare services.

Participants

Consumers, patients, providers, physicians, practitioners, purchasers, employers, and health plans.

Patients

Persons receiving healthcare services.

Practitioners

All types of individuals who provide traditional and complementary healthcare services, such as nurses, physical therapists, dietitians, and massage therapists.

Privacy

The right of an individual to limit access to some aspect of their person.

Providers

Healthcare organizations and businesses, such as hospitals, home health agencies, long term care facilities, hospice, pharmaceutical companies, and durable medical equipment suppliers.

Purchasers

Individuals who buy health insurance.

Rationing

A method for allocating scarce resources.

CCMD Scenarios

Comfort Care vs. Medical Technology for Infants

The first scenario dealt with an infant born 3 ½ months prematurely and who was not expected to survive regardless of treatment. Seventy percent (70%) of those surveyed felt that “keeping the child comfortable” should be the preferred treatment approach, whereas 27 percent felt that “all available treatment” should be provided. However, when the infant was likely to survive for a few years, even with disabilities, then all respondents were more likely to provide all possible treatment. In regards to whether infants who are likely to survive should be given all medical treatments even if they will have mental or physical limitations, 60 percent agreed, whereas 22 percent disagreed.

For an infant born with a fatal birth defect, 73 percent felt that the baby should be kept comfortable, without aggressive treatment, while 23 percent felt that the infant should receive all available treatment. If death is most likely inevitable even if the child were to live for a few years, 60 percent felt that they would select to keep the infant comfortable versus 34 percent who felt that all treatment should be provided.

Comfort Care vs. Medical Technology for Adults

Prolonged Coma For an adult patient who was in a coma for over 3 months, who was not expected to ever regain consciousness, and who was being fed by a tube into his stomach, 69 percent said that tube feeding should be stopped and that comfort care provided until the person dies; 18 percent said that tube feeding should be continued and treatment given for all problems with all available means; 11 percent felt that tube feeding should be continued but if the person becomes ill with another condition (such as pneumonia) then tube feeding should be continued but the new illness should not be treated.

Kidney Failure An elderly woman with several major medical problems experiences kidney failure and is not expected to recover. Although dialysis would remedy the kidney failure, it would not reverse the other medical problems that would most likely result in death. 77 percent felt that dialysis should be stopped and comfort care provided; 18 percent said that long term kidney dialysis should be provided.

Alzheimer’s Disease A man with advanced, irreversible Alzheimer’s disease is completely bedridden and unable to communicate. He develops pneumonia and although it may be cured with medication, it will not change the degenerative course of his Alzheimer’s. Sixty-one percent said do not treat the pneumonia but provide comfort care. Thirty-eight percent said treat the pneumonia with all available means. In a separate question, 70 percent said do not use tube feeding for an advanced Alzheimer’s patient, but do provide comfort care, while 16 percent would initiate tube feeding, but 12 percent would not treat additional medical problems as they arose.

CPR – Should Doctor’s Always Follow Patient’s Request? Ninety-one percent said that CPR should not be performed when the patient has indicated that it is not desired, and 59 percent say that CPR should not be performed when recovery is known to be extremely unlikely. Eighty-eight percent felt that CPR should not be continued when there has been no favorable response after 30 minutes (except in cases of hypothermia, where there is a chance that CPR will still be beneficial).

Who Should Decide Treatment? The respondents were asked to explore the issue of who should be involved in the decision about life-prolonging medical treatment for the terminally ill. Forty-one percent of the respondents reported to have been involved in making a medical treatment decision when it appeared that the patient would not survive. Responses varied by age of the respondent. Older ones were much more likely to feel that aggressive treatment happens too often. The older the respondent, the more likely they were to choose comfort care in every situation presented to them except for the continuation of CPR after 30 minutes.

The majority of the respondents (73%) stated that the patient should make the decision with the doctor or with the doctor and other people involved, such as social workers, clergy and family members. Twenty-four percent felt that the patient and the doctor together should decide on medical treatment. Hardly anyone (1-2%) felt that the decision should be made solely by the doctor himself or by the family alone.

Half of the respondents said that doctors should provide the treatment requested by the patient and the family, even if the requested treatment is not appropriate according to the professional judgement of the physician. Forty percent disagreed with this statement. A second opinion from a panel of doctors outside the hospital or the health care plan was the solution shared by ninety-two percent of the respondents when asked what should be done when a patient and a doctor disagree on the best course of action. Eighty-four percent also found that professional mediation services would be of interest and 86 percent of these individuals would be willing to pay a nominal fee for these types of services.

Who Should Pay for Treatment? Forty-six percent (46%) felt that the patient should be held financially responsible for life prolonging treatment; 23 percent believed that the burden should be shared by the insurance and the patient; and 12 percent said that the insurance should be solely responsible for the payment. None of the respondents mentioned that taxpayers alone should be responsible for the costs of treatment, although a minority felt that they could share the cost with either the insurance or the patients.

Survey results of the public and 4,192 Colorado Health Care Providers

Colorado health care practitioners more strongly believe doctors and nurses should recognize the need for comfort care and encourage its timely use.

- ◆ 88% of the public agreed. 96% of health care providers agreed.

Colorado health care practitioners more strongly believe each hospital and nursing home should provide adequate comfort care.

- ◆ 87% of public agreed. 97% of health care providers agreed.

Colorado health care practitioners more strongly believe that people in a permanent vegetative state should receive comfort care instead of life-sustaining interventions.

- ◆ 69% of public agreed. 82% of health care providers agreed.

Colorado health care practitioners more strongly agreed that people with end stage dementia should receive comfort care instead of life-sustaining interventions.

- ◆ 61% of public agreed. 75% of health care providers agreed.

The public more strongly believes extremely premature infants who are unlikely to survive should receive comfort care instead of aggressive life sustaining interventions.

- ◆ 70% of public agreed. 58% of health care providers agreed.

Conversely, when it is believed that the infant's survival will include short lifetime filled with significant suffering, health care providers more strongly believe comfort care should be provided instead of life sustaining interventions.

- ◆ 60% of public agreed. 72% of health care providers agreed.

Source: Colorado Citizens Speak Out About End-of-Life Medical Care: Majority of Coloradans Think Life Sustaining Technology Should Not be Used. Press Release, January 26, 1999.

APPENDIX C

❖ ECHO Recommendations

ECHO

Extreme Care, Humane Options

Community Recommendations for Appropriate, Humane Medical Care for Dying or Irreversibly Ill Patients

INTRODUCTION

Development of these recommendations

This document is the result of a multiyear, inter-organizational project called Extreme Care, Humane Options (ECHO) under the direction of Sacramento Healthcare Decisions (SHD), a non-profit, nonpartisan community organization. This is based on the work of multidisciplinary committees composed of local physicians and other healthcare professionals, and the views and values of local citizens. Information on ECHO and those who participated is included in the appendix.

Expectations for hospitals and other providers

The ECHO Steering Committee urges acute care hospitals in Sacramento, Yolo, Placer and El Dorado counties to adopt the Goals and Strategies included in this document and establish plans to prioritize and implement these strategies.

The relationships among hospitals, physicians, long-term-care settings and health plans necessitate a cooperative approach for the successful implementation of these recommendations. The section Roles of Other Key Healthcare Providers proposes specific actions for these groups.

Cure-oriented vs. comfort care

Medical interventions for dying or irreversibly ill patients can be described as either cure-oriented care or as comfort care. Specific procedures may fall into either of these categories. The distinction between them lies in the *purpose* of the intervention.

Cure-oriented interventions are those with the primary purpose of attempting to achieve a cure, reverse or stabilize the disease process, or bring about a meaningful and measurable improvement in the health status of the patient. These are often invasive procedures such as dialysis, ventilators and cardiopulmonary resuscitation (CPR) but may also include less invasive interventions such as intravenous hydration, antibiotics and diagnostic tests.

Comfort care (or palliative care) interventions have the **primary** purpose of alleviating distressing physical symptoms and addressing psychological, social, emotional and spiritual needs associated with the disease process. The goal is a more comfortable existence without prolonging the dying process or aggressively sustaining a quality of life that would be unacceptable to the patient. Comfort care may include invasive interventions (such as transfusions, surgery, radiation) for pain or other symptoms. More often, comfort care uses less

invasive methods to support the patient’s physical and emotional well-being, such as medication, physical therapy and relaxation techniques, counseling and spiritual guidance.

Principles on which these recommendations are based

Medical science provides physicians with the means of improving the health and prolonging the lives of most patients. However, interventions are sometimes applied in circumstances or in ways that may not serve the goals of both patients and physicians.

The decision to use medical interventions relies not only on medical science but also on patients’ perspectives on quality of life, risk-taking and what constitutes beneficial care. Goals and values of patients and their families are fundamental to decisions to accept or refuse medical treatment. Healthcare providers also have goals, values and professional standards that guide their recommendations of treatment options. Central to ECHO is the belief that medical treatment decisions should involve a mutually respectful partnership among the patient, family and healthcare team.

Note: For the purpose of this document, the term **patient/surrogate** refers to whoever is considered the patient’s decision-maker. This could be the patient, the family, a legal guardian or conservator, or a significant other.

Goals and Strategies for Acute Care Facilities

Goal 1:

Develop treatment options that are responsive to the needs of dying or irreversibly ill patients and their families.

Strategies

- 1.1 *Incorporate a statement of principles regarding the institution’s role in the care of terminally or profoundly, irreversibly ill patients.*
- 1.2 Develop and implement comfort care protocols, including procedures for transitioning patients and families from cure-oriented to comfort care and timely referral to hospice.
- 1.3 Provide training for physicians and multidisciplinary staff in the provision of comfort care in all hospital settings.

Goal 2:

Identify patients at risk of inappropriate or unwanted medical treatment.

Strategies

- 2.1 Adopt and implement **Indicators for Offering Comfort Care** (page 65)

- 2.2 Establish and maintain an ongoing process for reviewing ICU patients for appropriate treatment: cure-oriented or comfort care.
- 2.3 Include in quality-of-care activities evaluation mechanisms for the appropriate use of comfort care protocols, adherence to advance directives, etc.
- 2.4 Sponsor educational programs for health professionals on the identification of at-risk patients and the availability and use of hospice and other community services.

Goal 3:

Improve communication among patients, families, physicians, other healthcare team members and healthcare settings in order to foster informed, timely and mutually satisfactory treatment decisions.

Strategies

- 3.1 Define expectations for communication about end-of-life care.
- 3.2 Train healthcare personnel in communication about end-of-life care, which takes into account cultural and religious differences.
- 3.3 Initiate institutional changes for eliciting, documenting and sharing relevant information among patient/surrogate, primary care physician, specialists, other healthcare professionals and between acute and long-term-care settings.
- 3.4 Provide emotional support/grief counseling for patients, families and the healthcare team confronting end-of-life treatment decisions.
- 3.5 Develop materials and training for patients/surrogates and community members concerning their rights and responsibilities in communication about end-of-life issues.

(See **Improving Communication about Treatment Decisions**, page 69)

Goal 4:

Assure that the patient/surrogate is the primary decision-maker in choosing among appropriate treatment options.

Strategies

- 4.1 Evaluate current presence of, and compliance with, advance directives in patient charts; establish objectives for improvement.
- 4.2 Educate patients/surrogates and healthcare professionals about institutional policies (including the use of the Bioethics Committee) that address ethical concerns about treatment decisions.
- 4.3 Develop and sponsor community education programs to increase public awareness of, and participation in, advance planning for end-of-life decisions.

Goal 5:

Support effective processes for preventing and resolving conflicts regarding treatment decisions that respect patient values and the professional integrity of healthcare providers.

Strategies

- 5.1 Educate healthcare professionals and consumers about common areas of miscommunication or misunderstanding concerning end-of-life treatment decisions.
- 5.2 Improve the knowledge, skills, visibility and accessibility of the institution’s Bioethics Committee.
- 5.3 Improve physicians’ understanding of current legal and ethical rights and obligations in providing and withholding life-prolonging treatment.
- 5.4 Explore an open and fair process that considers and resolves physicians’ concerns about demands for medically inappropriate care.

Indicators for Offering Comfort Care

Adult patients or their surrogates

If cure-oriented treatment is no longer medically appropriate or desired by the patient/surrogate, then the principle of beneficence obligates the healthcare provider to make comfort care available.

If the patient has not explicitly indicated – verbally, in writing or through a surrogate – a desire to forego cure-oriented treatment, comfort care should nevertheless be considered and discussed with the patient/surrogate if:

- The patient is terminally ill.
- A profoundly diminished quality of life is imminent or has been established as irreversible.

In the following circumstances, comfort care *must* be offered as an option:

1. Persistent vegetative state
2. Minimal cognitive function (absence of self-awareness of others) that is irreversible.
3. The burdens to the patient of cure-oriented treatment are greater than the medical benefit to the patient.
4. Irreversible and irreparable (multi) organ failure
5. Imminent demise

Nonviable or irreversibly ill newborns

Advances in medical technology have improved the outcomes of many infants born prematurely or with complex medical conditions. It is not possible to keep devastated newborns alive for long periods of time. An unintended consequence of such treatment is a prolonged dying process for some newborns or the survival of some infants with severely debilitating conditions. Medical treatment of infants should be based on consideration of the benefits and burdens of life-sustaining medical treatment and determination of what is in the infant's best interest. Reaching these decisions through collaboration between the parents and the healthcare team is the goal.

In considering situations where comfort care for the infant may appear to be the most appropriate intervention, physicians must be well informed of changes in medical science. The dynamic nature of medical knowledge may lead to successful interventions for conditions that were previously untreatable. Furthermore, family and medical circumstances may vary greatly between cases, requiring each case to be considered individually. With an uncertain diagnosis or prognosis, cure-oriented treatment is generally indicated. Modifications may be initiated as the physician's experience with the infant increases. In those tragic situations where medical science currently has no effective remedy, it is critical that parents be told so.

Comfort care may be the most appropriate option to offer parents in a variety of situations, such as:

1. Conditions for which life expectancy is severely limited even with aggressive therapy. Current examples include but are not limited to:
 - Profound perinatal asphyxia
 - Prematurity less than 23 weeks and under 500 grams
 - Severe multiple congenital anomalies
2. Conditions for which cognition may reasonably be expected to be absent or profoundly limited. Current examples include but are not limited to:
 - Anencephaly
 - Trisomy 18
 - Trisomy 15
3. Conditions for which morbidity is so great and care is so extremely burdensome to the patient that quality of life is severely impaired. Current examples include but are not limited to:
 - Osteogenesis imperfecta type 2
 - Multisystem organ failure

Roles of Other Key Healthcare Providers

Appropriate end-of-life care is an inter-institutional, interdisciplinary obligation. The goals stated in this document are relevant not only to acute care facilities but also to long-term-care settings, physicians groups, health plans, professional associations, regulatory agencies and others. The interdependence of healthcare providers and settings is such that success in achieving appropriate care for dying patients *requires* a coordinated and cooperative approach.

The ECHO project urges other providers to also commit to ECHO goals and strategies that are relevant to their setting or constituency.

Physicians/medical groups

Physicians are increasingly expected to do more for patients in less time, making discussions about end-of-life care more difficult. Physicians are, however, the authorities on realistic and feasible medical treatment options and should not abdicate their role in discussing these issues with patients/surrogates.

Physicians should be responsible for the following:

1. Identifying patients most at risk of unwanted or inappropriate medical treatment (e.g., residents in long-term-care settings; those with progressive, incurable conditions) and initiate discussions before a medial crisis occurs.
2. Provide patients/surrogates with clear, understandable information regarding condition, prognosis, treatment options, risks/benefits and potential outcomes.
3. Be familiar with the principles and application of comfort care interventions.
4. Improve their communication skills in discussing end-of-life decisions with patients/surrogates.
5. Involve other members of the healthcare team – nurses, social workers, clergy – to assist with patient/surrogate communication.
6. Provide advance directive materials for patients (e.g., in waiting rooms and other outpatient settings) and include advance directive inquiries on information sheets for new patients.
7. Assess the decision-making capacity of patients.
8. Assure that patients' competed advance directives forms and/or chart notes about patient wishes become part of inpatient medical records.

9. Stay informed on institutional policies, procedures, legal and ethical issues related to end-of-life decisions; consult with the Bioethics Committee to seek advice, as needed.

Long-term-care settings

Existing policies for skilled nursing facilities (SNFs) directly affect when and why terminally or irreversibly ill patients are transferred to and from acute care facilities. These policies – determined by regulatory, financial and logistical circumstances – may impede the provision of comfort care interventions within the SNF setting.

Most of the goals and strategies listed previously also apply in long-term-care settings, especially skilled nursing facilities. To assure that these recommendations can benefit SNF patients and their families, the ECHO project recommends that a task force be convened of local and state leaders from the long-term-care industry. This task force should explore existing barriers and propose changes that will facilitate the provision of comfort care in all long-term-care settings and improve communication and coordination between SNF's and other providers.

Health plans and payers

As healthcare systems evolve, there are opportunities to develop new approaches to end-of-life care. Health plans and payers must be responsive to the need to support and strengthen appropriate and humane end-of-life care both within and outside the hospital setting. Consistent with health plans' role in providing member education, information and preventive services, plans should also assume greater responsibility for educating healthcare professionals and consumers about end-of-life care.

Health plans should be responsible for the following:

1. Sponsor physician education seminars on such subjects as:
 - Physician-patient/surrogate communication skills concerning end-of-life decisions.
 - Sensitivity to cultural and religious differences
 - Comfort care plans including pain management.
 - Ethical and legal standards concerning termination of treatment.
2. Develop mechanisms that encourage physicians to conduct planned and purposeful discussions with high-risk patients (those with progressively debilitating or terminal illnesses) about their values and goals related to end-of-life treatment.
3. Work with community-based organizations in planning and conducting consumer education programs designed to educate the public about advance directives and encourage consumer responsibility for communicating personal end-of-life values.

4. Provide educational tools – e.g., videos, informational booklets, discussion guides – related to end-of-life decisions for use by health plan members, physicians, nurses, clergy and community organizations.
5. Provide advance directive documents for any health plan member upon request.
6. Sponsor educational programs specifically for public and private guardians or conservators as medical surrogates.
7. Review health plan benefits to assure consistency in support of the provision of comfort care interventions.

Improving Communication About Treatment Decisions

Improving communication is key to achieving all five goals. In considering the strategies for Goal 3, the ECHO project has identified important elements that could be incorporated into policies or procedures.

Adult patients or their surrogates

Identifying and responding to patients who are at risk of non-beneficial or unwanted medical treatment are the responsibilities for the patient's primary physician in conjunction with other healthcare professionals: specialists, nurses, social workers and clergy. A multidisciplinary approach is recommended. Communication and decision-making among patients, families and providers can be improved by adoption of the following.

A. Elicit and share relevant information

Under the direction of the primary physician (or, when appropriate, the midlevel practitioner), the team has the responsibility to elicit, document and share with other team members relevant information about the patient's values and end-of-life preferences. Others involved with the care of the patient also have the responsibility to share relevant information with team members.

Ideally, planning for future care with the patient/surrogate should take place over time, on a regular basis and as needed by changes in the patient's clinical condition. There may be many opportunities and methodologies for gathering and sharing information.

The healthcare team should be responsible for the following:

1. Provide clear and timely information to the patient/surrogate regarding diagnosis, prognosis, expected level of functioning and extent of medical and social needs required by the patient.
2. Seek to understand the patient/surrogate's goals and expectations.
3. Present treatment options that are congruent with the patient's goals.

4. If cure-oriented treatment cannot be recommended, explain to patient/surrogate the medical reasons for that judgment.
5. Be aware of, and sensitive to, cultural, religious and social differences that may influence the roles which the patient and family play in medical decision-making.
6. To the extent possible, provide patient/surrogate the time needed for making or accepting treatment decisions.
7. Follow established protocols for assessing patient's decision-making capacity.
8. Establish timely and effective mechanisms for receiving and sending advance directives and patient preference information between healthcare facilities and agencies involved in the patient's care.
9. Document clearly the communication held with patient/surrogate about these issues.

The patient/surrogate is always central to decision-making. As such, he or she must be as informed as possible regarding issues related to personal treatment choices and actively participate in communication and decision-making.

Patients/surrogates should be responsible for the following:

1. Discuss end-of-life treatment choices with family members, significant others, clergy and healthcare providers within the context of patients' cultural or religious beliefs.
2. Be receptive and available to the healthcare team for discussing patient's condition, needs, goals, expectations and treatment options.
3. Be protective in soliciting the involvement of the primary physician in discussing end-of-life treatment options.
4. Alert providers if an advance directive has been completed and provide a copy of the document for inclusion in the patient's medical record.
5. Consider designating one family member to be the main contact with the healthcare team if communication between the family and team is complex.

B. Have sufficient understanding of ethical, legal and institutional policies

Healthcare professionals and patients/surrogates should know, for example, that:

1. Treatment choices may include the option *not* to treat.
2. “Not treating” is not the same as doing nothing; comfort care protocols should be described as a treatment option.
3. The plan of action for the patient can be changed as circumstances change; the option to *stop* treatment may become as important as the option to *start* treatment.
4. There are institutional processes for clarifying ethical or legal uncertainties and to help resolve conflicts between the patient, surrogate and healthcare team.

C. Assure appropriate decisions about terminating life-support in the absence of a competent patient or surrogate

When the patient is not competent to make his or her own decisions and there are no family members or surrogates who can speak on the patient’s behalf, then any decision to terminate cure-oriented management should be reviewed (in advance, when possible) with the institution’s bioethics committee or other designated team.

Patients in long-term-care settings can be particularly vulnerable to the inappropriate provision (or withholding) of cure-oriented medical treatment, and a system for patient review should be in place.

Parents of a nonviable or irreversibly ill newborn

Communication with parents is a critically important responsibility of all members of the healthcare team. In order to achieve maximum effectiveness, communication needs to be ongoing, planned and purposeful in nature. The following principles should be incorporated in the policies and procedures for each labor and delivery department, newborn nursery and neonatal intensive care unit:

A. Elicit and share relevant information

The healthcare team should be responsible for the following:

1. Make every effort to reach agreement among the healthcare team before presenting and recommending treatment options to the parents.
2. Keep parents apprised of all aspects of care and treatment of their infant, including treatment options, their consequences and the types of immediate and long-term care needs.
3. As needed, offer assistance to help them understand what the long-term consequences may be for an infant with a devastating condition.

4. Elicit from parents their willingness and ability to care for an infant who will need complex support at home.
5. To the extent possible, provide parents the time needed for making or accepting treatment decisions.
6. If cure-oriented treatment cannot be recommended, physicians should explain to parents the medical reasons for that judgement.
7. Provide emotional support to families and assure parents that their child has value, regardless of decisions made or treatment outcome.

B. Make and reconsider treatment decisions

Healthcare team responsibilities:

1. It is generally better to resuscitate and later forego support if that becomes appropriate, rather than to not provide support initially in situations where:
 - The parents are ambivalent or there is disagreement between the parents.
 - The physician is uncertain about viability.
 - Sufficient time before delivery did not allow a discussion to develop
 - Sufficient time before delivery did not allow a discussion to develop between the parents and physician.
2. Make recommendations only for options that are consistent with sound medical practice.
3. When cure-oriented intervention has been agreed upon, the decision should be revisited:
 - If the infant fails to show the expected response.
 - Whenever there is a significant change in the infant's health status.
 - When a parent or healthcare professional asks for re-evaluation.
4. In the face of new information, everyone should be prepared to alter decisions.
5. When further discussion is necessary, it is important to continue supporting the infant until areas of controversy can be resolved.
6. When comfort care is offered, it is offered as respectful and compassionate treatment.

The parents are always central in the decision-making process. For parents to make informed decisions, it is important that they be as active as possible in discussions related to treatment choices.

Parents responsibilities:

1. Be available to discuss issues related to the infant's condition, treatment options, their consequences and the types of immediate and long-term care.
2. Be timely in responding to the informational needs of members of the healthcare team.
3. Identify those family members who are the key decision-makers for the infant.
4. Seek assistance from members of the healthcare team when more information is needed.
5. Seek information from community resources to fully understand the support required for a severely impaired child.
6. Be prepared to alter decisions in the face of new information.

APPENDIX D

**❖ University of Toronto
Joint Centre for Bioethics Model Policy**

University of Toronto Joint Centre for Bioethics

Model Policy on Appropriate Use of Life-Sustaining Treatment

This model policy was developed and unanimously endorsed by the multi-disciplinary, multi-institutional University of Toronto Critical Care Medicine Program Joint Centre for Bioethics Task Force on Ethical Issues in Critical Care. It does not represent the official policy of any organization, including the Joint Centre for Bioethics which does not advocate positions on specific issues, although its individual members may do so. It is intended to stimulate discussion and debate, and is recommended to hospitals for possible adoption or adaptation.

A. PREAMBLE

Health care providers have an ethical obligation to provide quality end of life care. This includes appropriate palliative care, and helping patients and families make decisions regarding life-sustaining treatment. The health care team values the provision of compassionate care for dying patients. These important issues are addressed in the companion policy on Quality of End of Life Care.

Infrequently, a patient or the substitute decision maker of an incapable patient requests treatment be initiated or continued that health care providers actively involved in the care of the patient believe is inappropriate. This situation causes distress for patients, families and health providers. There is no available framework to mediate this conflict. Such a framework could help in these situations by providing a fair process for decision making.

B. PURPOSE

The purpose of this policy is to provide a framework for resolving conflicts in situations of disagreement about appropriate use of life-sustaining treatment, including intensive care admission.

The focus of this policy is on situations where a patient or the substitute decision maker of an incapable patient requests treatment be initiated or continued that health care providers actively involved in the care of the patient believe is inappropriate. There is no clearly established ethical and legal framework for this situation. By contrast, there are clearly established ethical and legal principles in Ontario for situations where patients/substitute decision-makers decline treatment proposed by health care providers. In this latter situation, the legal principles in the *Health Care Consent Act* will supersede this policy. This policy may also be useful in resolving conflicts among family members or among different members of the health care team.

The focus of this policy is on intensive care, defined as advanced and highly specialized care provided to medical and surgical patients whose conditions are life-threatening and require comprehensive care and constant monitoring usually administered in specially equipped units of a health care facility (National Library of Medicine, 1992). However, it is impossible to separate intensive care from other life-sustaining treatments provided in the hospital. For instance, the provision of cardiopulmonary resuscitation anywhere in the hospital, if successful, will likely

lead to consideration of admission to the intensive care unit. Therefore, this policy will apply throughout the hospital.

C. PRINCIPLES

1. Patients have a right to receive quality end of life care including appropriate palliative care and help making decisions regarding life-sustaining treatment. This principle is contained in the companion policy on quality end of life care.
2. Patients have a right to receive life-sustaining treatments that meet the standard of care, defined as the care provided by a reasonable health care provider who possesses and exercises the skill, knowledge and judgment of the normal prudent practitioner of his or her special group (Picard and Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 1996). However, health care providers are not obliged to provide treatments that lie outside the standard of care. The consensus of health care providers regarding the standard of care with respect to appropriate use of life-sustaining treatment is described in section E of this policy.
3. Patients and substitute decision-makers have a right to a fair process when there is disagreement between them and health care providers about the appropriateness of life-sustaining treatment. The process to be followed is described in section D of this policy.

D. PROCESS FOR DECISION MAKING

This section describes the steps that should be followed when there is disagreement between patients/substitute decision makers and health care providers about the appropriateness of initiating or continuing life-sustaining treatment including intensive care. This process should commence as soon as the health care provider becomes aware of potential for future conflict. Although the steps are presented in the order they will most likely occur, the order of steps 1-8 may be varied and several steps may occur simultaneously. The patient's condition may not permit completion of this process.

1. Interprofessional team consensus – The health care team should reach consensus regarding the range of appropriate treatment.
2. Communication – In collaboration with other members of the health care team, the most responsible physician should:
 - a) as early as possible, discuss with patients while capable, their prognosis and wishes for treatment
 - b) explore why the patient or substitute decision maker wishes treatment to be continued and address these issues directly

- c) discuss with the patient and/or substitute decision maker the rationale for withholding or withdrawing life-support treatment
 - d) describe palliative care measures which emphasize patient comfort and dignity
 - e) offer hospital resources such as social work, chaplaincy, or bioethics to assist the patient/family with their psychosocial, cultural, spiritual, and informational needs
 - f) document pertinent details of this communication in the patient's health record
3. Negotiation – The most responsible physician or other designated member of the health care team should attempt to negotiate a plan of treatment that is acceptable to both the patient/substitute decision-maker and the health care providers actively involved in the care of the patient.
 4. Intensive care consultation – If intensive care admission may be required, a consultation from an intensive care physician should be obtained as early as possible.
 5. Second opinion – The patient or substitute decision-maker should be given an opportunity to request a second opinion, and assisted by the health care team to obtain one.
 6. Trial of Therapy – A time-limited trial of therapy may result from the negotiation described in step 3 above.
 7. Patient Transfer – The patient or substitute decision-maker should be given an opportunity to identify another provider willing to assume care of the patient, and assisted by health care team to do so.
 8. Mediation – A person designated by the hospital for this purpose should meet with the patient/substitute decision maker and health care team to attempt to mediate the disagreement.
 9. Arbitration/adjudication – If mediation fails, the hospital's lawyer should be consulted regarding the appropriateness of an appeal to the Consent and Capacity Board (under section 37 of the *Health Care Consent Act*), arbitration, or court proceedings.

10. Notice of intention to withhold or withdraw life-sustaining treatment – If the health care team intends to withhold or withdraw the disputed life sustaining treatment, the patient or substitute decision-maker should be informed, given an opportunity to challenge this decision in court, and assisted by the hospital to do so.
11. Withholding/withdrawal of life-sustaining treatment – If all the procedures in this policy have been followed, the health care provider may withhold or withdraw the disputed life-sustaining treatment including intensive care.

E. PROVIDER CONSENSUS REGARDING STANDARD OF CARE

In developing this policy, the following consensus emerged among intensive care providers representing all intensive care units in the University of Toronto Critical Care Medicine Program regarding the standard of care with respect to appropriate use of life sustaining treatment.

1. The goal of intensive care is to prevent unnecessary suffering and premature death by treating reversible illnesses for an appropriate period of time.
2. Imminent death: A patient facing imminent death has an acute illness whose reversal or cure would be unprecedented and will certainly lead to death during the present hospitalization within hours or days, without a period of intervening improvement. “Life-sustaining treatments” or intensive care cannot achieve their intended effect, and lie outside the standard of care.
3. Lethal conditions: A patient with a lethal condition has a progressive, unrelenting terminal disease incompatible with survival longer than 3-6 months. Intensive care should not be provided for the underlying condition, since this is inconsistent with the goal of intensive care (see above). Life-sustaining treatment including intensive care should be provided to treat superimposed, reversible illness only with clearly defined and achievable goals in mind. For instance, life-sustaining treatments may be used to permit provision of an experimental treatment which may cure or alleviate the underlying condition, or to help the patient achieve a personal goal (e.g., seeing a loved one for the last time who is flying in from afar). These goals should be mutually agreeable to the patient/substitute decision-maker and health care providers. Section D of this policy provides a process for resolution of disagreement.
4. Severe, irreversible condition: A patient has a severe and irreversible condition impairing cognition or consciousness but death may not occur for many months. Examples of such conditions include persistent vegetative state and severe dementia. Intensive care should not be provided for the underlying condition, since this is inconsistent with the goal of intensive care (see above). Life-sustaining treatment including intensive care should be provided to treat

superimposed, reversible illness only with clearly defined and achievable goals in mind. For instance, life-sustaining treatments may be used to help the patient achieve a personal goal (e.g., seeing a loved one for the last time who is flying in from afar). These goals should be mutually agreeable to the patient/substitute decision-maker and health care providers. Section D of this policy provides a process for resolution of disagreement.

Posted 18 June 1998

University of Toronto Joint Centre for Bioethics Model Policy on Quality End of Life Care

This model policy was developed for possible adoption or adaption by hospitals. It is not the official position of the University of Toronto Joint Centre for Bioethics. As stated in our mission statement, the Joint Centre for Bioethics does not advocate positions on specific issues, although its individual members may do so.

[Name of Hospital] is committed to providing high quality care for patients at the end of life. Therefore, the hospital strongly supports appropriate palliative care* and decisions regarding life-sustaining treatment. These practices are ethically uncontroversial and legally permissible under appropriate circumstances.

By contrast, euthanasia† and assisted suicide‡ are ethically controversial and clearly illegal under the Criminal Code of Canada. The hospital does not support these practices.

The hospital supports criteria developed by The Chief Coroner of Ontario to distinguish palliative care from euthanasia: palliative care is intended to relieve the person's suffering; administered in response to symptoms or signs of the patient's suffering and commensurate with that suffering; and not the deliberate infliction of death.

For questions about this policy, or about provision of end of life care in a particular case, contact [institutional contact here].

*Palliative care, as a philosophy of care, is the combination of active and compassionate therapies intended to comfort and support individuals and families who are living with a life-threatening illness. During periods of illness and bereavement, palliative care strives to meet physical, psychological, social and spiritual expectations and needs, while remaining sensitive to personal, cultural and religious values, beliefs and practices. Palliative care may be combined with therapies aimed at reducing or curing the illness, or it may be the total focus of care.

Palliative care is planned and delivered through the collaborative efforts of an interdisciplinary team including the individual, family, caregivers and service providers.

It should be available to the individual and his/her family at any time during the illness trajectory and bereavement.

While many service providers may be able to deliver some of the therapies that provide comfort and support, the services of a specialized palliative care program may be required as the degree of distress, discomfort and dysfunction increases.

Integral to effective palliative care is the provision of opportunity and support for the caregivers and service providers to work through their own emotions and grief related to the care they are providing.

(Canadian Palliative Care Association Standards Committee Working Definition of Palliative Care, 1995)

† “Euthanasia” is a deliberate act undertaken by one person with the intention of ending the life of another person to relieve that person’s suffering where that act is the cause of death. (Special Senate Committee on Euthanasia and Assisted Suicide, 1995)

‡ “Assisted suicide” is the act of intentionally killing oneself with the assistance of another who provides the knowledge, means, or both. (Special Senate Committee on Euthanasia and Assisted Suicide, 1995)

Posted 6 January, 1998

APPENDIX E

❖ Oregon Health Sciences University (OHSU)

Oregon's POLST Program

Implementing End-of-Life Treatment Preferences Across Clinical Settings

Since the late 1980s, out-of-hospital Do Not Resuscitate protocols have spread like wildfire, according to Charles Sabatino, Assistant Director of the American Bar Association's Commission on Legal problems of the Elderly.

Now operational in 41 states, these protocols protect people from unwanted, aggressive life-sustaining treatment by Emergency Medical Service personnel. Since EMS responders are required to take heroic measures unless otherwise directed by valid physician orders, advance directives will generally not stop the uncoiling spring of high-tech EMS "rescue."

In Oregon, as in many other states, the first impetus for change came from family and health provider reports of tragedies caused when "rescue" mandates overrode documented patient wishes to die in familiar settings without extraordinary life support:

- an 84-year-old nursing home resident in advanced heart failure is transported to the hospital, given CPR en route, dying a painful death among strangers;
- a 91-year-old nursing home resident with dementia fractures her hip, is appropriately transported to the hospital for surgery, but then is sent to an ICU for pneumonia (where she later dies on a ventilator), instead of being sent back to the nursing home for palliative care;
- a frail 90-year-old man in adult foster care has a massive stroke during a weekend; fearful of being deemed negligent, the on-call doctor orders hospital transport and aggressive treatments; the man survives but never regains his previous level of functioning.

As members of the Consortium of Oregon Ethics Resources began sharing such stories and related systems problems, the idea of portable physician orders that could operate as a summary plan of care in all clinical settings was born. In 1990, Oregon's Center for Ethics in Health Care convened the multidisciplinary POLST Task Force, and, in 1995, launched POLST as a voluntary, statewide protocol.

More than a form, POLST is a program that comprises the Task Force's continuing leadership, scientific research, education for providers, and a set of strong health care resources to support families and patient who choose to die out of hospital.

Developing POLST

“We began by choosing representatives from all sectors and developing relationships of trust with people and institutions,” says Patrick Dunn, M.D., chair of the POLST Task Force. “Creating the POLST form and implementing it were secondary steps. We listened closely. Our attitude was, ‘How can we be of service to you,’ not, ‘Have we got a plan for you!’”

This approach also reflected the Task Force’s very pragmatic decision to bypass the Oregon State Legislature. “We explored the legislative route,” says Dunn, “but worried the outcome might not be as comprehensive.”

Instead, the Task Force successfully sought to modify an Oregon Board of Medical Examiners’ administrative rule defining the scope of practice for emergency medical technicians (EMT), first responders, and supervising physicians. The revised rule directs providers to respect patient wishes regarding life-sustaining treatment and comply with treatment orders (such as POLST) executed by a physician. Strongly supported by the EMT community, the rule provides both a mandate and a legal shield.

Although not intended specifically for POLST, a 1993 overhaul of the state’s advance directive statute helped enable the protocol by establishing a liberal surrogacy provision, mandating comfort care in explicit terms, and rescinding presumed consent for tube feeding.

The Task Force’s chief focus was on perfecting the protocol through research, pilot-testing, successive revisions, and intensive training for EMS personnel.

Evaluation played a seminal role in POLST development. In 1992-94, Dunn spearheaded provider focus groups to refine the form and then asked cohorts of 87 acute and long-term care providers to indicate their treatment approaches to three different simulated protocol scenarios. The question: Would anything on the form promote undertreatment or negligence? The study demonstrated over-whelmingly that providers liked and would use the form and that it was helpful rather than harmful in making decisions about life-sustaining treatment (JAGS 44:785-791, 1996).

In 1995-96, as POLST was being put into practice, a second study asked a group of health care providers and a few patients to rate the form’s user-friendliness. Since much of the form’s early language had been taken directly from statute, the news was not good, so Task Force members made sweeping changes. “We still use medical terms,” says Susan Tolle, M.D., director of the Center for Ethics in Health Care, “but how we emphasize comfort care is different; if you are refusing treatments you may fear abandonment, so we wanted to create opportunities for saying more than ‘NO,’ opportunities for patients to lay claim to dignity and comfort.

Task Force members and health care providers say POLST was initially piloted in the Portland Metro Area, in Bend (central Oregon), and in the coastal area of Coos Bay. Now most Oregon nursing homes and hospice programs are using POLST, and several major managed care systems, including Kaiser Permanente, have adopted the protocol for patients in long-term care. While acute care hospitals typically respect POLST forms (for patients being admitted), they rarely initiate the form's use. The Center has distributed 185,000 forms within the state, but no comprehensive data on patient use exist.

“It takes tremendous effort to change the culture to use this instrument,” says Dunn. “Not just years – decades. We need to plug away at the education and implementation piece. But we are over the hump: POLST is evolving into Oregon’s standard of care.”

The Hot Pink Form: Special features and Clinical Use

POLST is designed first and foremost to help patients near the end of their lives reflect on the goals of their treatment. Each set of options in sections A-D demarcates the same clear fork in the road: “Given my health as it is now, do I want comfort or curative measures if I experience a serious medical event?” Taken together, patient choices become a summary plan of care that goes well beyond narrow EMS-DNR orders (Section A) to provide clear treatment directions (Sections B-D).

POLST’s brevity, simplicity, high visibility, portability, and authority as physician orders help ensure that patient preferences, once recorded, can be operationalized quickly and will not be lost or overridden.

To be ethical and effective, the form must create occasions for meaningful, non-coercive discussions among patients, surrogates, and care givers. Are such conversations occurring? According to Task Force members and health care personnel, nurses, social workers, admissions coordinators, and nursing home administrators are typically the front-line implementors of POLST. They facilitate POLST discussions at the time of admission (or sometime later), record patient preferences, and then refer the form to the physician for signature. Anecdotal evidence suggests that these “admissions” discussions elicit and respect patient preferences; less is known about the communication that may occur between doctor and patient. “As long as POLST facilitates discussion and communication of preferences and is updated when the clinical situation changes – it’s great,” says Ira Byock, M.D., Research Professor of Philosophy, University of Montana (Missoula). “If not, it’s a problem.”

Evaluating POLST's Effectiveness

Does POLST really help systems of care honor dying patients' treatment preferences?

To begin to answer this question, Tolle, Dunn, and researchers Virginia Tilden, D.N.Sc., R.N., and Christine Nelson, R.N., M.S., from the Program of Research on End-of-Life Care (Oregon Health Sciences University) tracked for one year 180 adults with completed POLSTs from eight geographically diverse long-term care facilities. The study sought to determine whether DNR and "Transfer Only if Comfort Measures Fail" orders were heeded and whether POLST led to more or less attention to comfort measures, such as the use of opioids to control pain.

"A Prospective Study of the Efficacy of the POLST (1995-1997)" found that, of the 180 subjects, 55 (31%) experienced a serious medical event during the study year. Among them,

- no patient who asked for DNR was resuscitated
- no patient who asked for a focus on comfort received ICU or ventilator support
- only four patients (2%) were hospitalized to extend life
- other hospitalizations were for fractures or wound care
- of the 38 who died, only two (5%) died in hospital (as compared to rates ranging from 18-23% in a comparable state); and, 63% had an order for opioids (the highest rate investigators could identify for nursing home patients nationally);

The study also suggests that the protocol promotes additional comfort measures for residents and families, and that POLST's claims or portability across clinical settings are valid: only 6% of POLST forms were "missing" at the end of the study (JAGS 46: 1097-1102, 1998).

"What this shows," says principal investigator Tolle, "is that the POLST form focuses efforts on comfort, creating a positive plan that serves the patient."

POLST's Implications for Other States

Given the remarkable nationwide growth in EMS-DNR protocols, might Oregon be a bellwether state for advance care planning tools like POLST? End-of-life care reformers in Oregon and elsewhere suggest that the answer to that question is a qualified yes.

With the initial leadership from staff of the Midwest Bioethics Center (MBC), two new POLST-inspired pilot projects are under way in Kansas City, Missouri: one in a large retirement facility; the other involving a collaboration between two hospitals with a common ambulance service. "Out-of-hospital DNR is pretty well established in our area," says Don Reynolds, J.D., Director

of Special Projects (MBC), “so it’s a matter of moving from a good thing to a better thing. These pilots should help us make progress later at the community-wide level. I think POLST has great power.”

Bernard Hammes, Ph.D., Director of Medical Humanities at Gunderson Lutheran Medical Center (LaCrosse, Wisconsin) has spearheaded the implementation of a successful regional POLST protocol in western Wisconsin. Covering LaCrosse County and parts of three other counties, the protocol was adopted as an alternative to a statutorily mandated DNR bracelet protocol that Hammes and many physician colleagues vehemently oppose as being “for the convenience of EMT,” says Hammes. “It doesn’t serve the values of patients and doctors. Our leadership locally has said we will move ahead, further develop our model, and increase pressure on the state to reconsider existing legislation and regulations.”

As in Oregon and Kansas City, LaCrosse’s POLST protocol builds on a pre-existing infrastructure – in this case a community-wide advance directive project in place since 1991, and the educational and administrative muscle of the two largest health care systems in the region.

Without such an infrastructure, POLST cannot succeed and could be misused, according to those who have had experience launching the protocol. “I have grave concerns,” says Tolle, about the implementation of POLST in states where key support systems are not in place. “I worry that some legislative leaders may find POLST attractive as a money-saving measure. But it would be unethical to implement POLST without ensuring proper education of the public and providers and without appropriate supports for in-home care for people at the end of life who want to avoid hospital admission. And POLST may need to be modified for use in inner-city environments where support systems may be weak and trust in providers low. You can’t let people choose to limit care unless they have other real choices.”

For more information about POLST or to be connected with a member of the POLST Task Force, fax or e-mail information requests to The Center for Ethics in Health Care at (503) 494-1260 or ethics@ohsu.edu. The Center’s web site has a POLST information page and an order form (web site: www.ohsu.edu/ethics).

Sample POLST Form
Back

How to Change this Form

This form (POLST) should be reviewed periodically and if:

- ◆ The patient/resident is transferred from one care setting or care level to another, or
- ◆ There is substantial change in patient/resident health status, or
- ◆ The patient/resident treatment preferences change.

First, review "Patient/Resident Preferences as a Guide for this POLST Form" (Section F). Second, record the review in "Review of this POLST Form" (Section G).

Finally, if this form is to be voided, draw a line through the "Physician Orders" and/or write the word "VOID" in large letters, then sign or initial the form. After voiding the form, a new form may be completed. *If no new form is completed, full treatment and resuscitation may be provided.*

Patient/Resident Preferences as a Guide for this POLST Form			
Section	F		
F	<p>I have given significant thought to life-sustaining treatment. I expressed my preferences to my physician and/or health care provider(s). This document reflects my treatment preferences. The following have further information regarding my preferences:</p> <p>Advance Directive <input type="checkbox"/> NO <input type="checkbox"/> YES - Attach copy Court-appointed Guardian <input type="checkbox"/> NO <input type="checkbox"/> YES - Attach copy of documentation</p> <p>Please review these orders if there is a substantial change in my health status such as:</p> <p>Close to death Improved condition Advanced progressive illness Extraordinary suffering Permanent unconsciousness</p> <p>Signature of Patient/Resident or Guardian/Health Care Representative (optional)</p>		
	Signature of Person Preparing Form	Preparer Name (print)	Date Prepared
Section	G		
G	Review of this POLST Form		
	Date of Review	Reviewer	Location of Review
			Outcome of Review
			<input type="checkbox"/> No change <input type="checkbox"/> FORM VOIDED, new form completed <input type="checkbox"/> FORM VOIDED, <i>no</i> new form
			<input type="checkbox"/> No change <input type="checkbox"/> FORM VOIDED, new form completed <input type="checkbox"/> FORM VOIDED, <i>no</i> new form
			<input type="checkbox"/> No change <input type="checkbox"/> FORM VOIDED, new form completed <input type="checkbox"/> FORM VOIDED, <i>no</i> new form
			<input type="checkbox"/> No change <input type="checkbox"/> FORM VOIDED, new form completed <input type="checkbox"/> FORM VOIDED, <i>no</i> new form
			<input type="checkbox"/> No change <input type="checkbox"/> FORM VOIDED, new form completed <input type="checkbox"/> FORM VOIDED, <i>no</i> new form
ORIGINAL FORM SHOULD ACCOMPANY PATIENT/RESIDENT WHEN TRANSFERRED OR DISCHARGED			
© CENTER FOR ETHICS IN HEALTH CARE, Oregon Health Sciences University ♦ Form developed in conformance with ORS 127.605 et seq. ♦ October 1997			

APPENDIX F

❖ Houston's Multi-Institution Collaborative Policy on Medical Futility

Guidelines on Institutional Policies on the Determination of Medically Inappropriate Interventions

Policy

The traditional goals of medicine have been to heal and to relieve suffering and pain. In recent years, the goal of respecting autonomous patient choices has motivated the establishment of policies which permit patients (or surrogate decision makers) to exercise that autonomy by refusing or limiting an unwanted intervention. These policies are limited to situations in which patients (or surrogate decision makers) refuse an intervention. This current policy, designed to supplement rather than to supplant currently existing policies on limiting life-prolonging therapies provides a conflict resolution mechanism to follow when a patient (or surrogate decision maker) requests, rather than refuses, an intervention which the responsible physician* assesses to be medically inappropriate (commonly referred to as medically futile).

This policy affirms both the traditional goals of medicine and the moral value of physician and institutional integrity in discerning the limits of medical interventions. Respect for this integrity provides the basis for the right to refuse to provide a medically inappropriate intervention. It complements the right of patient determination that must be given both voice and effect in any forum for medical decision making. This appeal to integrity is generally rooted in a combination of concerns such as avoiding harm to patients, avoiding provision of unseemly care, and just allocation and good stewardship of medical resources. This policy affirms this value of integrity so long as appropriate institutional review supports the determination of medical inappropriateness.

After following the procedures set forth in this policy, a medically inappropriate intervention may† be withheld or withdrawn without obtaining the agreement of the patient (or surrogate decision maker).

Procedures

1. When the responsible physician determines that an intervention is medically inappropriate but the patient (or surrogate decision maker) insists that it be provided, the responsible physician should discuss carefully with the patient (or surrogate decision maker) the nature of the ailment, the options including palliative care and hospice care, the prognosis, and the reasons why the intervention is medically inappropriate. The responsible physician should explain that not providing the intervention in question does not mean abandoning appropriate medical care and humane care designed to promote comfort, dignity, emotional, and spiritual support.
2. The responsible physician should address with the patient (or surrogate decision maker) the options of patient transfer to another physician or to another institution and of obtaining an independent medical opinion concerning the medical inappropriateness or medical futility of the intervention in question. The responsible physician should also provide the patient (or surrogate decision maker) with a copy of these guidelines.‡
3. The assistance of institutional resources (such as nursing, patient care representatives, chaplancy, social services, or the biomedical ethics committee) shall be made available to the patient (or surrogate decision maker) and to the responsible physician.
4. If, after reasonable effort by the responsible physician using the available institutional resources, agreement is not reached between the responsible physician and the patient (or surrogate decision maker), the responsible physician who still wishes to limit the intervention must obtain a second medical opinion from a physician who has personally examined the patient and must present the case for review by an institutional interdisciplinary body and must provide to that body clinical and scientific information pertinent to the determination that the intervention is medically inappropriate.
5. The responsible physician must notify the patient (or surrogate decision maker) that this process has been invoked, what it involves and what are its possible outcomes, when and where the review will take place, and that the option of transfer before the meeting exists, but that arranging such a transfer is the responsibility of the patient (or surrogate decision maker). Absent patient (or surrogate decision maker) consent to an earlier time, the meeting cannot take place for at least 72 hours after the patient (or surrogate decision maker) is notified.
6. During the institutional review process, the responsible physician and the patient (or surrogate decision maker) are encouraged to be present together to express their views for consideration including alternative plans of care.

7. If a finding of medical inappropriateness is affirmed§ by the institutional review body, medically inappropriate intervention may† be terminated and a plan of care established tat addresses comfort care and the preservation of patient dignity. If, however, the institutional review body does not concur with the responsible physician’s determination of medical inappropriateness, then orders to limit the intervention will not be recognized as valid without patient (or surrogate decision maker) agreement.
8. If the institutional review process agrees with the determination of medical inappropriateness, intrainstitutional transfers of the are of the patient to another physician to provide palliative care are allowed. However, intrainstitutional transfers to another physician to provide the intervention that has been judged by the institutional review committee to be medically inappropriate will not be allowed.
9. The procedures set forth in this policy may be invoked only by the responsible physician or as otherwise authorized by the hospital’s medical staff by-laws. Concern on the part of other health care providers, hospital officials, or family members should be addressed through already existing institutional mechanisms.

The term “responsible physician” should be defined by each institution.

† Institutions may wish to substitute “...must be terminated even though the agreement of the patient (or surrogate decision maker) has not been obtained.”

‡ Each institution may insert the title of its policy.

§ Each institution should determine the voting requirements for its review mechanism affirmation.

APPENDIX G

❖ Health Council of South Florida Follow-up Survey Tools

Local Survey Questionnaire

- Fisherman's Hospital
- Jackson Memorial Hospital
- Mercy Hospital
- Miami Children's Hospital
- Miami VA Medical Center
- Mt. Sinai – St. Francis Nursing and Rehabilitation Center
- Pan American Hospital
- South Shore Hospital

Nationwide and International Survey Questionnaire

- Colorado
- Oregon
- Sacramento, California
- Texas
- Toronto

Health Council of South Florida, Inc.
Ethics Survey 1998
Follow Up

1. What is the Committee membership composition? Has it changed in the past 2 years?
2. What influence, if any, does the Committee have? Has it changed in the past 2 years?
3. Does your organization have a policy and/or procedure on advance directives? Has this changed in the past two years?
4. How does your organization define medical futility? Has this definition changed in the past 2 years?
5. Does your organization have a formal/written policy and/or procedure concerning medical futility?
6. If yes, has your organization implemented its medical futility policy and/or procedure?

If yes, please give an example.
7. Did your organization utilize the draft futility guidelines developed by the Health Care Ethics Committee of the Health Council of South Florida?
8. If yes, for what purpose (e.g. reference, model for development, educational tool)?
9. If the guidelines were applied for a given case, what was the outcome? (e.g. patient was transferred; patient's family changed their treatment preferences; more physician communication was offered, etc.)
10. Does your organization have educational programs on advance directives and/or end-of-life issues?
11. If yes, please describe these programs and indicate how long they have been offered.

If not, are you interested in obtaining assistance in facilitating or developing these programs?

Opinion Statements: Guidelines

Please circle one of the following for each of the statements according to the following choices:

Strongly Agree	5
Agree	4
Disagree	3
Strongly Disagree	2
No Opinion	1

1. These guidelines were useful to facilitate education and dialogue in our facility.
5 4 3 2 1
2. These guidelines have been useful to resolve conflicts over particular treatments.
5 4 3 2 1
3. The conflict resolution procedure provided in these guidelines is adequate and needs no further modification.
5 4 3 2 1

Additional Comments

1. Please comment on what you like about the guidelines.

2. Please comment on any changes to the guidelines you would suggest.

Medical Futility Guidelines Nationwide Follow Up Survey

ORGANIZATION: _____
Address: _____
Phone#: _____ **Fax#:** _____ **E-mail:** _____
Contact Person: _____

A few months ago, the Health Council of South Florida through its Healthcare Ethics Committee developed and disseminated *Medical Futility Guidelines* to healthcare providers and other organizations in our community. As part of our project follow up and self-evaluation, we are conducting a survey of other groups nationwide who have undertaken similar initiatives. We appreciate you taking a few minutes to answer our questions and would be happy to share the results of our survey with you.

Organization: (First, we would like to know about your organization.)

1. **Governance:** Do you have a Board or Advisory Group to report to?

Were they involved in the development of your guidelines?

2. **Funding:** What are your organization's funding sources?

Did you receive any special funding to develop your Guidelines?

Results: (We are very interested in seeing how communities have received these Guidelines.)

1. **Dissemination:** To what organizations did you distribute the Guidelines?

___ Hospitals

___ HMO's

___ Other Community Based organizations: _____

2. **Evaluation:** Have you evaluated the impact of these guidelines on the system/these organizations?

If yes, what impact, if any, have the guidelines had on these organizations? On the community?
Have any organizations adopted your guidelines or policies?

If no, do you plan to conduct an "outcomes-based" type evaluation?

The Process: (We are interested to hear what you learned from the process.)

1. What would you say are your biggest successes?

2. What would you say are your failures?

3. Knowing what you know now, what would you do differently, if anything?

What's Next? What are your next steps?

APPENDIX H

❖ Guideline Survey Matrix

**Miami-Dade County Hospitals & Nursing Rehabilitation Center
Monroe County – Fisherman’s Hospital
National Organizations
International Organizations**

Miami-Dade County Hospitals & Nursing/Rehabilitation Center

	Q1. Committee Membership Composition	Q1a. Changed in past 2 years?	Q2. Committee Influence	Q2a. Changed in past 2 years?
Jackson Memorial Hospital	<ul style="list-style-type: none"> ◆ 6 Physicians (Critical Care, NICU, Surgery, Child Protection, General Rehab, and Infectious Diseases) ◆ Hospital Administration ◆ 4 Nursing ◆ 2 Residents ◆ Pediatric Psychologist ◆ Social Worker ◆ Child Life ◆ Clergy ◆ County Attorney ◆ Psychiatrist 	<ul style="list-style-type: none"> ◆ No. ◆ Composition has not changed but members rotate on and off. 	<ul style="list-style-type: none"> ◆ Consultation on individual cases. ◆ Develops policy recommendations. 	
Mercy Hospital	Subcommittee: <ul style="list-style-type: none"> ◆ 3 Physicians ◆ 1 Nurse Clinician ◆ 2 Sisters from Ethics Committee 	<ul style="list-style-type: none"> ◆ Yes. ◆ Could not say prior composition 	<ul style="list-style-type: none"> ◆ Advisory role. ◆ Makes recommendations to Medical Staff. 	◆ No.
Miami Children's Hospital	<ul style="list-style-type: none"> ◆ 1/3 Physicians ◆ 1/3 Community Representatives ◆ 1/3 Other (hospital employees) 	◆ No.	<ul style="list-style-type: none"> ◆ Fairly influential. ◆ Conduct education programs. 	◆ No.
Miami VA Medical Center	<ul style="list-style-type: none"> ◆ Physicians, Nurses, Administrators ◆ Clergy ◆ Social Worker ◆ Lawyer ◆ Risk Management 	◆ No.	<ul style="list-style-type: none"> ◆ Consultative ◆ Recommend policy. 	◆ No.
Pan American Hospital	<ul style="list-style-type: none"> ◆ Physicians, Nurses, Administration, ◆ Social Workers, Wellness Staff. ◆ Pastoral Counselor, Ethicist 	◆ No.	<ul style="list-style-type: none"> ◆ Reviews ethical issues. ◆ Ethical decisions are brought to the Executive Committee for final disposition. 	◆ No.
South Shore Hospital	<ul style="list-style-type: none"> ◆ 2/3 Nurses ◆ 1/3 Medical Staff & Administrators 	◆ No.	<ul style="list-style-type: none"> ◆ Little influential. ◆ Recommend policies 	◆ No.
Mt. Sinai – St. Francis Nursing & Rehab. Ctr.	<ul style="list-style-type: none"> ◆ Medical Director, Doctors, Administrator, ◆ Social Workers, DON, Nurses, Other Staff. ◆ Legal Attorney ◆ Rabbi, Priest ◆ University Professor, Students. 	◆ No.	<ul style="list-style-type: none"> ◆ Current ethical issues are discussed as well as internal issues with residents. 	◆ No.

Miami-Dade County Hospitals & Nursing/Rehabilitation Center

	Q3. Policy on Advance Directives.	Q3a. Policy changed in past 2 years?	Q4. Define Medical Futility?	Q5. Formal policy on Medical Futility?
Jackson Memorial Hospital	◆ Yes.	◆ No.	◆ Medical futility is a situation where reasonable expectation is that treatment will either cause harm or provide no benefit. Benefit can, however, be psychological, not just physiological.	◆ Yes.
Mercy Hospital	◆ Yes.	<ul style="list-style-type: none"> ◆ Yes. ◆ Patient Admitting Sheet asks patient if he would like to receive information on advance directives. ◆ Found Summary Form of the 5 Wishes very helpful because it walks the patient through the whole process. They would like for this Summary to be made part of their Guidelines when they formulate them. 	◆ Chosen not to define it.	◆ Not really. They speak about it but it is not addressed as a set policy.
Miami Children's Hospital	◆ Yes.	◆ Technically speaking, yes. Technical writing revisions.	◆ Do not define it.	◆ No.
Miami VA Medical Center	◆ Yes.	◆ Yes.	◆ Have not defined it.	◆ Yes.
Pan American Hospital	◆ Yes.	◆ No.	◆ Have not defined it.	◆ No.
South Shore Hospital	◆ Yes.	◆ No.	<ul style="list-style-type: none"> ◆ Do not define it yet. ◆ However, they recently went to the Medical Executive Committee and asked them if they would like for the Ethics Committee to begin the process of defining medical futility. They have not received a response yet. 	◆ No.
Mt. Sinai – St. Francis Nursing & Rehab. Ctr.	◆ Yes.	◆ No.	◆	<ul style="list-style-type: none"> ◆ No. ◆ Have discussed it in many of their quarterly meetings.

Miami-Dade County Hospitals & Nursing/Rehabilitation Center

	Q6. Implemented policy? Q6a. If yes, give example.	Q7. Utilize draft futility guidelines? Q8. If yes, for what purpose.	Q9. What was the outcome?
Jackson Memorial Hospital	<ul style="list-style-type: none"> ◆ Yes. ◆ Removal of ventilator support for a newborn with emgenital toxoplasmosis, parental agreement. 	<ul style="list-style-type: none"> ◆ No. 	
Mercy Hospital		<ul style="list-style-type: none"> ◆ Reviewed them. ◆ Would not implement them but would study them and utilize those aspects considered appropriate for their patients. 	
Miami Children’s Hospital		<ul style="list-style-type: none"> ◆ Reviewed and discussed the guidelines. ◆ Did not use it for developing their own policy. 	<ul style="list-style-type: none"> ◆ The guidelines were not applied for a given case.
Miami VA Medical Center	<ul style="list-style-type: none"> ◆ Yes. ◆ Applied to cases. 	<ul style="list-style-type: none"> ◆ Yes. ◆ Reviewed it, discussed the data and the points made. ◆ Modified and incorporated some issues as it relates to process. 	<ul style="list-style-type: none"> ◆ Family-physician communication, family support for decision.
Pan American Hospital		<ul style="list-style-type: none"> ◆ Yes. ◆ Reference. 	<ul style="list-style-type: none"> ◆ Not applied for a particular case.
South Shore Hospital		<ul style="list-style-type: none"> ◆ Reviewed it. ◆ Will probably use it if they go ahead and implement a medical futility policy and/or procedure. 	<ul style="list-style-type: none"> ◆ Not applied for a given case.
Mt. Sinai – St. Francis Nursing & Rehab. Ctr.		<ul style="list-style-type: none"> ◆ No. 	

Miami-Dade County Hospitals & Nursing/Rehabilitation Center

	Q10. Offer Educational Programs on Advance Directives? Q11. Program Description and Length.	Q12. Interested in assistance if no programs offered.
Jackson Memorial Hospital	<ul style="list-style-type: none"> ◆ Yes. ◆ Social work involvement. ◆ In effect for more than 3 years. 	
Mercy Hospital	<ul style="list-style-type: none"> ◆ Yes. ◆ Pain Management Workshops that offer both medical and spiritual support. ◆ Use the following materials: <ul style="list-style-type: none"> - Coalition for Compassionate Care - Living and Healing during Life Threatening Illnesses. - Catholic Health Association's Reliving Pain. 	
Miami Children's Hospital	<ul style="list-style-type: none"> ◆ Yes. ◆ 2 hour End-of-Life Decision-Making Workshop open to anyone in the hospital. ◆ Other programs – did not remember specifics. 	
Miami VA Medical Center	<ul style="list-style-type: none"> ◆ Yes. ◆ In-service training for RN staff ◆ Public TV Program 	<ul style="list-style-type: none"> ◆ Interested.
Pan American Hospital	<ul style="list-style-type: none"> ◆ Yes. ◆ Periodically offer in-services for staff and physicians. ◆ Last 5 years. 	
South Shore Hospital	<ul style="list-style-type: none"> ◆ Yes. ◆ Attorney did presentation for the Medical Executive Committee ◆ Staff Orientation concerning End-of-Life Issues. ◆ Once a year (both) 	<ul style="list-style-type: none"> ◆ Would like some assistance
Mt. Sinai – St. Francis Nursing & Rehab. Ctr.	<ul style="list-style-type: none"> ◆ Yes. ◆ In-services provided on a yearly basis or as needed. ◆ New Employees are in-serviced on Advanced Directives and the importance of executing one – either a Living Will or a Health Care Surrogate. ◆ During Annual Review, the Social Services Dept. re-inservice all employees on Advance Directives. ◆ Discussed during Family Support Group and Resident Structure Programs. 	

Miami-Dade County Hospitals & Nursing/Rehabilitation Center

	Guidelines were useful to facilitate education and dialogue in our facility.	Guidelines have been useful to resolve conflicts over particular treatments.	Conflict resolution procedure provided is adequate and needs no further modification.	What you like about the Guidelines.	Suggested Changes to the Guidelines.
Jackson Memorial Hospital	◆ No Opinion	◆ Agree.	◆ Agree.		
Mercy Hospital	◆ Agree	◆ Disagree.	◆ Agree.	<ul style="list-style-type: none"> ◆ Guidelines provide a good working document to used by a facility when they begin to address these issues. ◆ Text in April'98 guidelines are a lot better than those of prior guidelines sent to them by HCSF. 	◆ Guidelines address the withdrawal of futile treatment but it needs to also focus on 1) the starting of treatments that may be needed and 2) evaluating patient care.
Miami Children's Hospital	◆ Disagree.	◆ Strongly Disagree.	◆ No Opinion – could not recall the specifics.	◆ Nothing specific.	◆ Nothing specific.
Miami VA Medical Center	◆ Agree.	◆ Disagree.	◆ Agree.	◆ The emphasis on process and communication.	◆ More clarification on legal rights.
Pan American Hospital	◆ No Opinion.	◆ No Opinion.	◆ No Opinion.	◆ No Comment.	◆ No Comment.
South Shore Hospital	◆ Strongly Agree.	◆ Strongly Agree.	◆ Agree.	<ul style="list-style-type: none"> ◆ Outline given with regards to what the physicians are required to do was very helpful. ◆ Amount of research done in formulating the guidelines facilitates physician acceptance of them. 	◆ Nothing Specific.
Mt. Sinai – St. Francis Nursing & Rehab. Ctr.	◆ Strongly Disagree	◆ Strongly Disagree.	◆ No Opinion.		

Monroe County – Fisherman’s Hospital

Q1. Committee Membership Composition	<ul style="list-style-type: none"> ◆ Advisory MD ◆ Director of Social Services ◆ DON ◆ Business Office Manager ◆ MIS Manager ◆ Board of Trustees Representative ◆ URRN ◆ Marketing Director
Q1a. Changed in past 2 years?	<ul style="list-style-type: none"> ◆ Yes. ◆ Addition of Business Office and Marketing
Q2. Committee Influence	◆ Major source of information and is proactive in disseminating it.
Q2a. Changed in past 2 years?	◆ No response.
Q3. Policy on Advance Directives?	◆ Yes.
Q3a. Has the policy changed in past 2 years?	◆ No.
Q4. Define Medical Futility?	◆ Treatment is no longer effective or beneficial to patient – only in increasing staff’s awareness.
Q5. Formal policy on Medical Futility?	◆ Yes.
Q6. Implemented policy? Q6a. If yes, give example.	<ul style="list-style-type: none"> ◆ Yes. ◆ Patient on ventilator, prognosis poor (no chance of recover), assisted family with stopping treatment and removing life support.
Q7. Utilize draft futility guidelines?	◆ Yes.
Q8. If yes, for what purpose?	◆ Educational tool.
Q9. What was the outcome?	◆ No response.
Q10. Offer Educational Programs on Advance Directives? Q11. Program description and Length	<ul style="list-style-type: none"> ◆ Yes. ◆ Patient Rights Education at New Employee Orientation ◆ Could not say length of program.
Q12. Interested in assistance if no programs offered?	
Guidelines were useful to facilitate education and dialogue in our facility.	◆ Agree.
Guidelines have been useful to resolve conflicts over particular treatments.	◆ Agree.
Conflict resolution procedure provided is adequate and needs no further modification.	◆ Agree.
What you like about the guidelines.	◆ No response.
Suggested changes to guidelines	◆ No response.

National Organizations

	Colorado	Oregon *
Guideline Development:		* Information drawn from an electronic message sent to HCSF
1. Do you have a Board or Advisory Group to whom you report?	◆ Yes.	◆ Yes.
1a. Were they involved in the development of the guidelines?	◆ No.	
2. Organization's funding sources	◆ Colorado Trust (3-year grant). ◆ "In-kind" donations	
2a. Receive special funding to develop your Guidelines?		
Results:		
1. To what organizations did you Distribute the Guidelines?	◆ Hospitals ◆ Long-term care staff ◆ Geriatric outpatients ◆ Individuals, groups and organizations that requested them.	
1a. Have you evaluated impact of these Guidelines on these organizations?	◆ Currently evaluating.	
2a. If yes, what impact, if any, have the Guidelines had on these organizations?		◆ Futility definition not very helpful to clinicians facing day to day situations.
Process:		
1. Biggest successes?	◆ Draft version of a <i>Faith Discussion Guide</i> for facilitation of discussion groups about death and dying by members of the clergy. ◆ Development of a mediation model for conflicted end-of-life cases. ◆ Completion of in-depth research (surveys, interviews).	
2. Failures?	◆ No failures stated.	◆ Policy utilized very narrow definition language in the guideline allowed for the possibility of 2 doctors to decide that continued care was futile and override family/patient decision.
3. What would you do differently?	◆ No Comment	
What's Next:		
1. What are your next steps?	◆ No Comment.	◆ Re-examine policy, comprehensive review of literature, interview stakeholders, identify key issues, make recommendation to administration ◆ Focus on resolution of disagreements between care providers, and care providers as well as families and patients.

National Organizations

	Sacramento, California	Texas
Guideline Development:		
1. Do you have a Board or Advisory Group to whom you report?	◆ Yes.	◆ Yes.
1a. Were they involved in the development of the guidelines?	◆ Yes.	◆ Ad Hoc Task Force created the guidelines.
2. Organization's funding sources	◆ Philanthropic grant contributions.	◆ None.
2a. Receive special funding to develop your Guidelines?	◆ Local health care foundation.	◆ No. ◆ Minimal cost involved. ◆ Expenses minor (postage & administrative expenses).
Results:		
2. To what organizations did you Distribute the Guidelines?	◆ Targeted local acute care hospitals.	◆ Hospitals ◆ Medical Societies ◆ AMA
1a. Have you evaluated impact of these Guidelines on these organizations?	◆ Currently evaluating. ◆ 14 of the 15 hospitals officially endorsed them.	◆ Yes.
2a. If yes, what impact, if any, have the Guidelines had on these organizations?	◆ New policies and pathways are in place.	◆ AMA endorsed guidelines in December 1996.
Process:		
1. Biggest successes?	◆ Created recommendations that reflected what the public and the health professionals wanted.	◆ Changes made in AMA policy. ◆ AMA now endorses Processed Based Futility Policies.
2. Failures?	◆ Not able to involve more of the disenfranchised population (minorities, the poor). These groups are poorly represented in their project.	◆ Not all institutions have adopted the guidelines. There is 1 major institution in their community that is still worried about legal liability and are therefore waiting for another institution to go to court to see what happens.
3. What would you do differently?	◆ Accurate not taking when they were evaluating the process of how the public weighs conflicting values. A lot was discussed and notes were not taken.	◆ Nothing.
What's Next:		
1. What are your next steps?	◆ Continue working on locally implementing the recommendations. ◆ Implementing recommendations statewide as a Partner on a RWJ Project on End-of-Life Care.	◆ Continue gathering data.

International Organization – Toronto

Guideline Development:	
Do you have a Board or Advisory Group to whom you report?	◆ Yes.
1a. Were they involved in the development of the Guidelines?	◆ Yes.
2. Organization's funding sources?	Public funds ◆ Toronto Hospital ◆ Ontario Ministry ◆ University of Toronto
2a. Receive special funding to develop your Guidelines?	◆ Yes. ◆ Medical Research Council of Canada.
Results:	
To what organizations did you distribute the Guidelines?	◆ 8 Teaching Hospitals in the metropolitan Toronto area.
Have you evaluated impact of these Guidelines on these organizations?	◆ Currently assessing it. ◆ Received grant money to do this.
2a. If yes, what impact, if any, have the Guidelines had on these organizations?	
Process:	
1. Biggest successes?	◆ De-escalation of conflict.
2. Failures?	◆ It is impossible to define futility. ◆ Medical definition not acceptable.
3. What would you do differently?	◆ Focus more on communication between physicians, patients, and families than on trying to define medical futility.
What's Next:	
1. What are your next steps?	Continue implementation and evaluate its impact in a qualitative way. ◆ Will interview families who used the futility guidelines and measure the effectiveness and usefulness of the guidelines in each particular situation.
Additional Information:	
1. Comment on JAMA article	◆ Focus should be on increased communication between physicians, their patients and their families so that there can be a better understanding of a patient's perspective.
2. Controversy	◆ Controversy surrounding medical futility has reduced. ◆ A lot of controversy in the US with regards to defining medical futility. ◆ Rather than trying to re-define futility there should be more of a focus on mediation between physicians, their patients and their patient's families.
3. History	◆ Defining medical futility is very difficult because there are many factors that need to be taken into account, such as cultural, philosophical, personal and legal aspects.
4. Response	◆ Early indications are very good. ◆ Currently in the process of assessing guideline impact in their community.



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