

# Flagler Hospital

## HOSPITAL ETHICS HANDBOOK

### 1<sup>st</sup> Edition

There are times, in the course of caring for patients and their families, when ethical issues arise regarding care and/or treatment rendered. The Flagler Hospital Ethics Committee has been established to assist the clinical staff and our patients in resolving these issues.

This handbook has been prepared by the Flagler Hospital Ethics Committee to provide staff and our community with easy access to information about the Committee. It also provides information regarding guidelines and policies that have been adopted by this institution for responding to ethical issues in the care of patients.

The handbook will be revised and expanded as needed. Suggestions for revisions or additions are welcome. Please forward to the Ethics Committee Chair or Vice Chair.

Requests for ethics case review with the Hospital Ethics Committee can be made by contacting the Flagler Hospital Medical Staff Office at 904-825-4497. After hours you may contact the operator who will be able to contact the Ethics Committee Chair or Vice Chair.

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## **B. Policies and Guidelines adopted by Flagler Hospital**

For the following policies and guidelines, please refer to the Flagler Hospital General Policies and Guidelines available from the administration.

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  2. Code of Ethics and Professional Conduct
  3. Requests for Relief from Participation in Aspects of Care
  4. Privacy/Confidentiality
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## **A. Policies and Guidelines adopted by the Ethics Committees**

### **A1. ACCESSING THE ETHICS COMMITTEES**

The Hospital Ethics Committee may be accessed 24 hours a day by calling the Hospital's page operator at 819-5155, and asking the page operator to page the designated Ethics Committee Chair or Vice Chair.

Every member of the committee welcomes any questions or requests for informal discussion of clinical ethics at any time. A number of members of these committees have formal training in clinical ethics and most have served for several years on these committees. A roster of current members can be obtained from the Chair or Vice-Chair of the committee as well as the Medical Staff Office and the Flagler Hospital Intranet site.

### **A2. ETHICS COMMITTEES MISSION STATEMENT**

The Hospital Ethics Committee of the Flagler Hospital serves the entire medical center, and our public by encouraging and supporting: ethical reflection, mutually respectful dialogue, critical analysis and standards of conduct which reflect this institution's commitment to patient-centered care.

### **A3. POLICIES AND PROCEDURES: HOSPITAL ETHICS COMMITTEE**

#### I. Function

The Hospital Ethics Committee (hereafter referred to as "the committee") will have three functions or roles:

##### A. Education

In cooperation with the hospital administration, its various departments and divisions, and its medical/nursing and allied health professional staff, the committee will undertake educational efforts in clinical ethics. Depending on the availability of resources, the committee will develop or assist others in the development of lectures, seminars, workshops, courses, rounds, in-service programs and the like in clinical ethics. The aims of these educational efforts will be to provide participants with access to the language, concepts, principles and body of knowledge about ethics that they need in order to address the complex ethical dimensions of contemporary hospital practice.

##### B. Policy Review and Development

committee may provide analysis of the ethical aspects of existing or proposed policy or assist in the development of new institutional policy in areas of need.

### C. Case Review

An important function of the committee will be its role as a forum for analysis of ethical questions which arise in the care of individual patients. In most circumstances these questions concern appropriate care of patients with diminished capacity to participate in decision making regarding their care. In this role the committee will attempt to provide support and counsel to those responsible for treatment decisions including health care providers, patients, surrogates and members of the patient's family.

Case review is particularly recommended in three specific categories of decision making:

1. decisions involving significant ethical ambiguity and perplexity in which case review may provide insight into complex ethical issues;
2. decisions involving disagreement between care providers or between providers and patients/families regarding the ethical aspects of a patient's care; or
3. decisions that involve withholding or withdrawal of life-sustaining treatment which are not adequately addressed in policies and procedures included in this Handbook.

In this role the committee will not act as a decision-making body, but will attempt to assist and to provide support to those who do have this responsibility. Its role in all such cases shall be advisory, the committee will propose, not impose.

## **II. Appointment and Membership**

The committee membership will be multidisciplinary. A majority of the membership will be non-physicians. Additional membership will include as available at least the following disciplines: nursing, social work, pastoral care, clinical ethics, law, respiratory care, and dietetics and nutrition. In view of the unique ethical problems involved in situations involving pregnant women, one physician member shall be from the Department of Obstetrics and Gynecology. The Chief Executive Officer of the Hospital (or designee), the Chief of the Medical Staff (or designee), and an attorney employed by the Medical Center shall be ex-officio, non-voting members. The committee will also identify and nominate for appointment at least one community representative who is not an employee of Flagler Hospital.

New members will be approved by the Committee and the Chief Operating Officer of the Hospital. The Chair of the committee will be a physician appointed by the President of the Medical Staff. The Vice-Chair of the committee, also a physician, will be chosen by the membership of the committee. It is recommended that the Vice-Chair be identified from among those who have served on the committee at least one year.

Due to the nature of the committee, and the length of time required to gain expertise in this discipline, appointments to the committee will be for a minimum of 5 years.

### **III. Jurisdiction**

The committee's jurisdiction will include the unique ethical issues involved in decision making involving all patients both adult and pediatric, to include pregnant patients and their unborn child.

### **IV. Procedures**

#### **A. Educational Functions**

A primary educational emphasis for the committee is its own education and mechanisms to ensure its continuing education. The field of clinical ethics is a new, broad and rapidly evolving one. In order to maintain an appropriate level of expertise, the committee will develop means of providing members information about clinical ethics and access to the rapidly expanding body of literature in this field. Methods may include orientation of new members, specific reading assignments, an annual retreat, seminars, mock case/policy review exercises and the like. In addition, the committee may participate in networking with other area/regional ethics committees and participate in continuing educational programs for ethics committee members as feasible.

Any educational efforts undertaken by the committee for members of the hospital staff will be coordinated with existing educational efforts as much as possible. Primary emphasis will be on assisting departments and divisions to incorporate material about the committee and the field of clinical ethics into their existing educational programs and activities.

#### **B. Policy Review and Development Functions**

At the request of the Chief Operating Officer of the Hospital, the Chief of Medical Staff, or the Executive Committee of the Medical Staff, the committee will undertake review of any existing policy, protocol or procedure; provide analysis of the ethical issues involved; and, provide recommendations regarding appropriate modifications, where needed. With the approval of the Chief Operating Officer of the Hospital, the committee may also undertake such review at the request of any member of the hospital staff.

In addition, when requested, the committee will assist the hospital and/or its staff in the development of new policies in areas that involve significant ethical questions or problems. If the committee feels that there is a need for policy development in order to address a significant ethical issue, it will submit a written recommendation to this effect to the Chief Operating Officer of the Hospital and request permission to develop a policy statement. Any recommendations for modification of existing policies or development of new policy must be submitted in writing to the Chief Operating Officer of the Hospital.

### **C. Case Review**

The Flagler Ethics Committee, whether an individual, a team or the full committee will be approaching all ethical issues by applying the "Four Topics" method, previously presented to the medical staff. These include : Quality of Life, Contextual Features, Medical Indications and Patient Preferences. These will cover the four primary ethical principles developed over the past 1200 years and allow us to do an "ethical case work-up".

#### **Principle of Respect for Autonomy**

#### **Principle of Beneficence**

#### **Principle of Non-maleficence**

#### **Principle of Loyalty and Fairness**

1. Access to Committee. During regular business hours a request may be made to the Medical Staff Office or after hours to the Flagler Hospital operator to initiate a case review. A roster of committee members will be available in the Medical Staff Office and with the Flagler Hospital operator. A case review team can be assembled to respond to requests for case review at any time. A Team Leader will be appointed by the committee Chair or Vice Chair with at least 2 other members to undertake case review in response to a reasonable and appropriate request for review by either (1) any of the following persons who is involved in the case: a member of the medical staff, hospital staff, or hospital administration, or (2) the patient, patient's guardian, surrogate or a member of the patient's family. The Team Leader will attempt to have an initial discussion with the person making the request within 2 hours of the request, whenever possible. Prior to proceeding with the consult, the Team Leader will notify the patient's designated attending physician of the request for review, discuss the possible basis for the review and request his/her support and involvement.
2. Informal and Formal Case Review. Committee members will be available to provide advice regarding a case in both an informal and formal manner. The remaining portions of this section (C) relate only to requests for formal case review. In the case of a request for informal case review, no documentation of the comments of any committee member will be placed in the patient's medical record. Informal requests for case review will, however, be reported by the involved committee member to the full committee at the next regularly scheduled meeting of the committee.
3. Determination of Need for Review by Full Team. Following the receipt of a request for case review, the Team Leader will determine whether or not there is a need to present the case before the full team. In most situations, there is likely to be no such need, and the Team Leader can, on his or her own, proceed to review the case, and provide a recommendation, as is otherwise described in the remainder of this section. Formal case review by the entire team will most likely be advisable in cases that involve especially complex ethical issues.
4. Preparation for Review Team Meeting. Following a decision by the Team Leader that it is appropriate to have review by a team, the team will consist of two to five members of the committee and will reflect the multi-

disciplinary composition of the committee. The Team Leader will review the request to determine the nature of the case, the status of the patient, the ethical question(s), concern(s) or problem(s) prompting the request and any other information needed in order to determine if review is appropriate.

If in the judgment of the leader of the case review team the request is appropriate, he/she will contact the patient's physician to discuss the request, to request his/her participation and to schedule the case review meeting. In addition, absent special considerations, the patient or the patient's family or surrogate decision makers, as the case may be, should also be notified that the case review will be taking place, and invited to participate. Their decision not to participate, or their objection to the consult, should not prevent a formal ethics consult from taking place, assuming the consult is otherwise determined to be appropriate by the Team Leader. If the patient's attending physician believes that ethics case review is not appropriate, this conflict should be referred immediately to the Chief of Medical Staff for resolution. In the event of a persistent conflict, the Chief of the Medical Staff will assist in the orderly transfer of responsibility to another attending physician who is willing to permit the case review to go forward.

The members of the team may determine that it is appropriate to invite other participants to some or all of the meetings in which the team discusses the case. Among those persons who might be invited so such meetings are: members of the professional staff who are directly involved in providing care to the patient; resource personnel with special expertise; and the patient and/or members of the patient's family.

If in the judgment of the case review team, the request for ethics case review is inappropriate, the Team Leader will so inform the party requesting review and/or the attending physician. This action will also be reported to and reviewed by the full committee at its next regularly scheduled meeting.

5. Conduct of Case Review Meeting. At the meeting the leader of the team will instruct all non-members present regarding the advisory role of the committee; the intent of the committee to serve as a supportive forum for those who have the primary decision-making responsibility; and the need for strict confidentiality of all material presented and discussed.

If the patient's attending physician and other health care providers are present, it will likely be appropriate for them to present information to the review team regarding the history of the patient, the present condition of the patient, the prognosis and any other material believed to be relevant to the case review. The leader might then find it useful to ask those involved, including patient/family members if present, to describe what specific ethical questions, problems or issues prompted the request for case review.

Following appropriate discussion of these and issues identified by members of the team, the Team Leader may, if non-members were present during the earlier portions of the meeting, convene a

“closed” (members only) session in order to develop a specific recommendation if appropriate.

Members of the case review team may also decide before or after the case review meeting that formal review of the case by the entire ethics committee is appropriate. In this case, the leader of the review team will notify the Chair (or designee) who will convene an emergency meeting of the entire committee as soon as possible.

6. Recommendations. The results of the case review and any recommendations will be communicated to the individual who requested case review; to the attending physician; to other members of the staff; and, to the patient/family as appropriate. Following these discussions, and with the concurrence of the attending physician, the Team Leader will record the results of the ethics case review in the patient’s medical record. These results will also be reported to, and reviewed by, the full committee at its next meeting.

## **V. Meetings**

The committee shall meet every other month in addition to any meetings called for specific case review. An agenda will be developed by the Chair and distributed one week prior to the meeting. Meetings which do not involve discussion of specific case material will be open to any member of the hospital community. Guests and other interested parties will be allowed to attend at the discretion of the chair. For purposes of conducting business, seven members shall constitute a quorum. Actions of the committee shall be taken by the vote of a majority of the members attending the meeting. Each member will be required to attend at least five of the committee’s regularly scheduled meetings each year. Failure to do so can be considered to constitute a resignation and the vacancy shall be filled by appointment of a new member.

## **VI. Record Keeping**

The committee will maintain minutes of all of its meetings which will include summaries of all case reviews and recommendations. Minutes will be submitted by the chair for approval by the committee and forwarded to the Chief Operating Officer of the Hospital. Records will not include identifying information about specific patients, family members, individuals requesting case review or professional staff participating in the case review process. These records will be maintained in accordance with hospital policy and applicable law governing the confidentiality of records of medical review committees.

## **VII. Liability**

The Hospital will take whatever steps are necessary in order to provide liability protection for committee members who do not have such protection by virtue of their status as members of the professional staff.



## **VIII. Adoption and Approval of Policies and Procedures**

Policies and procedures of this committee will be reviewed as deemed appropriate by the membership of the committee. Proposed modifications of approved policies or procedures will be submitted to the committee in writing at least four weeks in advance of a regularly scheduled meeting. Following approval by the committee, they will be forwarded to the Medical Executive Committee of the hospital and the Chief Operating Officer of the Hospital for review and approval.

### **A4. PATIENT RIGHTS**

Patients have a fundamental right to considerate care that safeguards their personal dignity and respects their cultural, psychosocial and spiritual values. These values often influence patients' perceptions of care and illness. Understanding and respecting these values guides the provider in meeting the patient's expectations. Thus, access, treatment, respect and conduct affect patient rights.

Flagler Hospital's standards address the following processes and activities:

1. Promoting consideration of patient values and preferences, including the decision to discontinue treatment;
2. Recognizing the hospital's responsibilities under the law;
3. Informing patients of their responsibilities in the care process; and
4. Managing the hospital's relationships with patients and the public in an ethical manner.

While in general, questions which may arise involving patient's rights will be addressed by the Quality Assurance Office of Flagler Hospital, unresolved issues may be brought to the Ethics Committee for review and discussion.

### **A5. ADVANCE DIRECTIVES**

#### **I. Introduction**

This statement seeks to provide guidance to members of the hospital staff and to promote increased support and recognition of the concept of the autonomy or right of self-determination of the patients of this Medical Center. One of the major goals of this policy is to encourage patients and their health care providers to make plans regarding treatment in situations in which patients are likely to lose the capacity to participate in decision making. Discussion and planning are particularly essential

when patients are diagnosed as having conditions that may eventually raise questions about limitation or termination of certain forms of treatment.

An advance directive is a document allowing a person to give directions about future health care, or to designate who should make decisions regarding care if he/she should lose the capacity to do so. There are at present two types of documents used for this purpose. One type is used to provide health care providers and institutions directives regarding treatments that a person wishes to receive or forego should he/she lose decision-making capacity, such as a "living will". The other type allows a person to designate a "Health Care Surrogate" would be authorized to make treatment decisions on behalf of the individual should he/she be unable to make such decisions. These two types of directives may also be incorporated into a single form. Such a form will be available through Hospital Administration, Department of Social Services, or the committee.

## **II. Treatment Directives and Living Wills**

Any individual with the capacity to make decisions concerning health care can prepare a document providing directions about treatments he/she might wish to receive or to forego in the event of his/her future incapacity to make such decisions. Such a document might indicate general treatment preferences, include a list of specific treatments, contain statements about palliative care, appoint another person to serve as Health Care Surrogate and might include a variety of other provisions. Individuals preparing such documents must inform appropriate health care professionals, family members, friends, and health care institutions to which they are admitted of the existence and contents of any such directive. Such a directive should also be reviewed and revised regularly or as required. The individual is also free to revoke the directive at any time.

The State of Florida in its "Natural Death Act" recognized the "right of an adult person to make a written declaration instructing his or her physician to withhold or withdraw life-sustaining procedures in the event of a terminal condition." The law additionally stipulates a number of procedures that must be followed in order that a "declaration" (Living Will) be legally valid. Although a "qualified patient" may include other specific directions, the declaration must be "substantially" in the form provided in the law. It is important to note that at the present time this is the only legally valid form of advance "treatment directive" in the State of Florida. Its use is limited to adults "who have been diagnosed and certified in writing to be afflicted with a terminal condition by two physicians who have personally examined the patient."

Treatment directives or Living Wills which are prepared by individuals who are not "qualified patients" as defined by the Florida Natural Death Act, or documents which are not executed according to the provisions of this law, are not legally binding on health care providers or institutions. However, such a document may well provide important insight and helpful guidance to health care providers and family members or surrogate decision-makers in the event that the patient loses the capacity to participate in decision making. Knowledge of the patient's values, preferences and wishes can be essential in evaluating the ethical aspects of treatment decisions.

It is also important for health care providers to understand that completion of a directive does not in itself change the interests or status of a patient. For example, providers should not make assumptions about treatment preferences based on the mere existence of a Living Will, but rather see the directive as an instrument by which an individual seeks to provide direction regarding certain specific treatment options.

It should also be understood that a competent adult patient need not utilize this mechanism in order to have his/her present directives regarding utilization of life sustaining treatments respected. Competent adults clearly have the legal and ethical right to forego any or all life sustaining procedures.

### **III. Health Care Surrogate**

Alternative means for providing advance directives are instruments that allow an individual to appoint another person to make his/her health care decisions in the event of the loss of capacity to do so. Any individual can prepare a written statement authorizing another person to act as their proxy or surrogate. Such a designation can be very helpful to health care providers since it identifies for them the appropriate surrogate decision maker. This surrogate can then participate on behalf of the patient in addressing the ethical aspects of decision making and in making decisions regarding utilization of life-sustaining treatments in persons who are no longer capable of participating in the decision making process.

In the State of Florida an individual may complete a "Health Care Surrogate Agreement" as a mechanism for designation of a surrogate decision maker. This law allows the individual ("principal") to designate another as their "agent" for making health care decisions "upon the disability or incapacity of the principal." "All acts done by an agent . . . have the same effect as if the principal were competent and not disabled." This law allows an individual to convey to the agent a broad range of authority including, but not limited to the following: to consent, refuse consent or withdraw consent to any care, treatment, service or procedure; to make all necessary arrangements regarding admission to a health care institution; to employ or discharge health care professionals; and to have access to information including all medical and hospital records. The law also requires that the document be in substantially the form of a model document included in the law.

### **IV. Implementation**

An essential aspect of implementation of this policy will be the willingness of health care providers and the institution to make information regarding advance directives available to patients. In particular, physicians working with individuals facing life-threatening, chronic, and/or terminal illness have the responsibility of encouraging patients to make plans about treatment in advance of a crisis and to engage in an on-going dialogue regarding mechanisms by which their values, preferences, and directives might be respected in the event of their loss of capacity to participate in decision making. It will also be essential that the information about advance directives be incorporated into in-service and other educational programs and into patient education programs and materials.

It will also be necessary for each department and division to develop procedures necessary to allow these advance directive mechanisms to be effective. Admission procedures will need to be developed for ascertaining if the patient has completed an advance directive document. Hospital medical record personnel will need to develop mechanisms for incorporation of such documents into the records of the Hospital.

## **A6. GUIDELINES FOR "DO NOT RESUSCITATE" (DNR) ORDERS**

### **I. Rationale and Objectives**

The utilization of cardiopulmonary resuscitation (CPR) has become routine in almost all hospitals in the United States. In fact, it is one of the few medical interventions

which can be undertaken without a physician's order. Yet, when effectiveness of CPR is measured in terms of the patient's surviving to the point of discharge from the hospital, studies of CPR of hospitalized patients demonstrate only a 5% to 20% success rate. This rate is even lower in select patient populations such as those with metastatic cancer, chronic debilitating illness or multiple organ failure.

These guidelines recommend the procedures to be followed in making and implementing a decision to withhold utilization of these emergency resuscitation techniques. If a patient has included directives regarding such treatment as part of an "advance directive" such as a Living Will, the provisions of that declaration and related legislation will apply. (See section A5, "Advance Directives.")

## **II. Definitions**

"Competent Adult Patient" - patient of at least eighteen years of age who is determined to have the capacity to make his/her own treatment decisions, i.e. the capacity to understand relevant information, reflect on it in accordance with his/her values, and communicate with caregivers.

"Incompetent Adult Patient" - patient who has been legally declared incompetent or a patient who is determined to have an irreversible lack of decision making capacity.

"Pediatric Patient" - patient of less than eighteen years who is not otherwise legally emancipated.

"Cardiopulmonary Resuscitation" - emergency treatment of acute failure of cardiac or respiratory systems (cardiac and/or respiratory "arrest") usually including at least one of the following procedures: chest compressions ("closed chest" cardiac massage), intubation/ventilation, and cardiac defibrillation.

## **III. Procedures for Implementation**

### **A. Guidelines for Decision making**

Evaluation and Discussion - A DNR order should be considered in any clinical situation in which resuscitation would likely be futile or in which the utilization of such treatment would be inappropriate in view of the patient's diagnosis and/or prognosis. The patient's attending physician has the primary responsibility to evaluate the patient and to facilitate discussion with patient and/or family in situations in which such an order is judged to be appropriate. Nursing staff can also play an important role in this evaluation process and in supporting discussion with patient and/or family.

Identification of Decision-maker - If the patient is a competent adult, discussion and decision-making regarding a DNR order need only involve the patient. A DNR order for such a patient should be written only with his/her informed consent. If the patient has been adjudged to be mentally incompetent by a court, the primary decision-maker is the patient's guardian. If the patient is determined to lack the capacity to participate in the decision-making process, the physician should determine if the patient had previously indicated a choice of the appropriate individual to act as decision-maker or seek to identify a member of the patient's family who will act as a surrogate decision-maker.

Making the Decision - The decision about the DNR order should be made in accordance with the expressed wishes of the patient or in accordance with the explicit directives of the patient, i.e. "advance directives" or in accordance with the known preferences and values of the patient. Lacking any of the

above, the decision should be based on a careful and reasoned consideration of the patient's interests.

Conflict/Disagreement - Since decision-making regarding DNR orders will frequently involve shared responsibility, there may be situations in which there is disagreement among health care providers or between providers and surrogate decision makers regarding the appropriateness of a DNR order. Such disagreements should be discussed and examined thoroughly and efforts made to achieve agreement. If they cannot be resolved, additional consultation and/or referral to the Ethics Committee should be considered.

### **B. DNR Orders**

All orders not to resuscitate must be written or signed by the patient's attending physician on the Physician's Order Sheet. It is imperative that caregivers and patients/families realize that resuscitative measures (calling a "Code Blue" and initiation of CPR) will be performed routinely on all patients for whom there is not a written DNR order.

In addition to the order "Do Not Resuscitate (DNR)", the physician may wish to modify the order by including instructions regarding specific resuscitative interventions.

Verbal DNR orders can be received only from a licensed physician and must be witnessed. Verbal or telephone orders must be countersigned within 12 hours by the attending physician who gave the order.

### **C. Documentation**

In addition to the order itself, physicians must make certain that the patient's medical record provides adequate documentation of the evaluation, discussion and decision-making process. A specific entry attendant to the order should be considered which includes: a short description of the patient's condition and prognosis, reference to any consultations which corroborate a DNR order, reference to discussions concerning the order with the patient, guardian, and/or family.

## **IV. Related Issues and Policies**

### **A. Level of Care.**

Although a DNR order may be part of an overall treatment plan which involves reduction of the level or intensity of care the patient is receiving, caregivers, patients and families must understand that the order not to resuscitate has no implications for any other treatment decisions. Patients with DNR orders on their charts may remain candidates for all vigorous care, including intensive levels of care.

### **B. Terminal Illness.**

It should also be understood that a candidate for a DNR order need not be suffering from a terminal illness. Many chronically ill, debilitated or elderly patients may wish to forego this particular form of life-sustaining treatment.

### **C. Surgery, Anesthesia, and Invasive Procedures.**

When a patient with a DNR order is to undergo surgery, receive an anesthetic agent and/or be subject to an invasive procedure that may be associated with risk to cardio-pulmonary function, it is the obligation of the physician

performing such procedures to discuss the DNR status with the patient or surrogate decision-maker as part of the consent process. (See section A8, "Honoring DNR Orders During Invasive Procedures.")

#### **D. Communication and Notification.**

Consideration must be given to mechanisms by which various departments and divisions will establish appropriate procedures to insure adequate communication and notification of the existence of a DNR order when patients are transported, sent off the nursing unit for procedures and/or treatment, transferred to other institutions, and the like.

### **A7. PRE-ADMISSION AND POST-DISCHARGE DNR ORDERS**

The state of Florida standard "DNR" Request Form can be used for patients before they are hospitalized or following discharge from an area health care institution. This form can also be utilized for patients who are out-patients, who are in home care programs, or who are being transferred to another health care facility. The form will be honored by all area emergency medical personnel in response to, for example, an "emergency" or "911 call". The form must be signed by the patient/guardian or surrogate and by the patient's physician.

### **A8. HONORING DNR ORDERS DURING INVASIVE PROCEDURES**

#### **Background**

Health care facilities accredited by The Joint Commission have been required to have written policies and procedures allowing patients to forgo cardiopulmonary resuscitation, so called "Do Not Resuscitate" (DNR) policies, since January 1988. However, questions have persisted about honoring DNR orders when a patient undergoes an operative or invasive procedure. Often in the past, DNR orders were disregarded under such circumstances. However, this approach is clearly incompatible with the goals and principles of the Patient Self-Determination Act of 1990. Patients' legal and ethical rights to direct the course of their health care include the right to refuse resuscitative procedures.

Most invasive procedures undertaken on patients with DNR orders are of limited duration and directed toward specific objectives; therefore, disregarding DNR orders during invasive procedures has been common. The rationale behind DNR orders acknowledges that the underlying disease will be allowed to take its course undeterred by medical intervention. Many anesthesiologists, surgeons, and physicians undertaking invasive procedures have felt a responsibility to treat any cardiopulmonary arrest their treatment may precipitate. When a patient with a standing DNR order has an arrest during the course of an invasive procedure, these professionals often believe that their failure to treat the arrest is responsible for the death of the patient and that they will be held accountable for the death. Quality assurance and related policies must be adapted to reflect that when personnel undertake an invasive procedure on a patient with a DNR order, they are not responsible for the death of such a patient if death results from withholding resuscitation.

It is also the case that many procedures undertaken in operating rooms can be classified as forms of resuscitation - such as, intubation, the use of ventilators, and drugs to control heart rate and blood pressure. An arrest in the operating room or during the course of an invasive procedure may result from the use of anesthetic agents, the procedure itself, the underlying disease, or a combination of factors. The majority of these arrests can be promptly treated with no long lasting or residual effects.

It is essential that a DNR order be reviewed and discussed prior to an invasive procedure. A critical aspect of this review is consideration of the patient's rationale for the DNR order. For example, if the patient is requesting a DNR order on the basis of an unacceptable quality of life, suspension of such an order during the invasive procedure may be inappropriate. On the other hand, if the refusal is based on consideration of the burdensomeness of resuscitative measures, suspension of the order may be appropriate since the burdensomeness of the procedure may be considerably reduced by anesthesia. Given the higher success rate of resuscitation undertaken during invasive procedures, especially when anesthesia is the presumed cause, a DNR order based on the futility of such resuscitation or fear of long term ventilator dependence might also be reconsidered.

### **GUIDELINES**

1. These guidelines refer to cardiac and/or respiratory arrest which occurs inadvertently during an invasive procedure. Correcting this condition may require closed cardiac compression, artificial respiration, counter-shock and other resuscitative measures.
2. A cardiac and/or respiratory arrest is a condition separate from that requiring the invasive procedure. Patients/surrogates who consent to anesthesia, surgery, or other invasive procedures may not necessarily consent to treatment of such an arrest.
3. For purposes of these guidelines an invasive procedures should be understood as one during which cardiac and/or respiratory arrest is a foreseeable risk. Obviously this is a risk for procedures undertaken in the operating room, particularly those involving the use of general anesthesia. However, it is also a risk for many procedures, such as those involving the use of anesthetic techniques like "conscious sedation," whether undertaken in the operating room or not. It may also be assumed that most procedures for which written informed consent is required are "invasive" in this sense. If the individual undertaking a procedure is unable to determine whether or not cardiorespiratory arrest is a foreseeable risk of the procedure, prior discussion regarding appropriate interpretation of the patient's DNR status is recommended.
4. Treatment for an arrest under these circumstances can, like other treatments, be accepted or refused by patients with capacity or by the appropriate surrogates of patients without decisional capacity. Health care providers have a responsibility to honor such acceptances or refusals.
5. Before a patient on DNR status undergoes an invasive intervention, at least one physician (surgeon or anesthesiologist, physician performing the invasive procedure, or the patient's attending physician) must engage in discussion with the patient or surrogate regarding the handling of the DNR order. Discussion needs to include the following elements:
  - the original rationale for the DNR order as previously documented in the patient's medical record;
  - information about the likelihood of requiring resuscitative measures;
  - a brief description of standard resuscitative measures;

- the chance of successful resuscitation; and,
- possible outcomes with and without resuscitation.

Salient features of this discussion must be documented in a brief note in the progress notes section of the medical record. Either a DNR order or an order indicating that the DNR order is suspended -including the period of time for which the order should be suspended - must be entered on the pre-operative or pre-procedure order form.

6. If the patient wants the DNR order suspended during an operative or invasive procedure, the terms of the suspension must be discussed. The duration of the suspension of the DNR order may include the period during which the patient is in the operating room or undergoing the invasive procedure and the time when the patient is recovering from the procedure, e.g., confinement in a recovery unit. Some patients may wish to have their DNR order suspended for only part of this period. The discussion should also include procedures that may be necessary during this period such as short term need for ventilatory support.

7. Communication regarding plans to honor a DNR order in this situation must take place among all staff involved in the procedure. A patient's/surrogate's decision to refuse resuscitation during an invasive procedure is compatible with maximal therapeutic efforts. This decision does not imply limits on any other forms of care, such as intensive care.

8. A physician who is unwilling to honor a patient's DNR decision while undertaking an invasive procedure, must notify the patient's attending physician so that arrangements can be made for identifying an alternative provider of care.

## **A9. ETHICAL GUIDELINES FOR DECISION MAKING: WITHHOLDING OR WITHDRAWING LIFE SUSTAINING TREATMENT (ADULTS)**

### **I. Introduction**

Increasing technological capacity to sustain life has created the need for critical examination of when such treatments are and are not appropriate. The traditional assumption that health care professionals have an obligation to prolong life provides inadequate guidance since this obligation often conflicts with the obligation to relieve suffering and to not "prolong dying". It is also increasingly recognized that patients and families have an essential role to play in health care decision making. For example, the concept of informed consent includes the right of the patient to refuse treatment, even life sustaining treatments. Yet the decision to forego life sustaining treatment - particularly a decision to withdraw a treatment that may be sustaining the patient's life - poses significant psychological difficulties for providers, patients and families. These guidelines have been developed to provide support and guidance for those faced with the responsibility of making these hard choices. (For decisions involving pediatric patients, see section A10, "Ethical Guidelines for Decision-making: Withholding or Withdrawing Life Sustaining Treatment (Children).")

### **II. Definitions**

Adult Patient - Any patient who can provide legally valid consent, includes most patients greater than 18 years of age and "emancipated minors".



Comfort Care - A range of interventions intended to provide relief of pain and/or suffering, control symptoms, reduce anxiety and provide comprehensive physical, psychological and spiritual support to patients. Such care is often referred to as "palliative" care - care which serves to relieve or alleviate without attempting to cure.

Competence - Legal status of adults who have not been found and declared incompetent by a court.

Decisional Capacity - Term used to reflect the ability of a patient to make a specific decision, i.e. the ability to understand the relevant information, to reflect on it in a manner consistent with their own life goals and values, and to communicate his/her wishes to providers.

Health Care Surrogate Agreement -Legal mechanism by which any adult can delegate the legal authority to make health care decisions. [See section "Advance Directives".]

Foregoing - Refers to a decision to withhold an intervention or to withdraw a treatment already begun. It is assumed that in any situation in which there is significant uncertainty about the appropriateness of foregoing treatment, it will be administered on the basis of a time-limited trial since it can be ethically withdrawn should it prove futile or not in the patient's best interests.

Guardian - Individual appointed by a court to act on behalf of another who has become a ward of the court usually as the result of a finding of legal incompetence.

Life Sustaining Treatment - Interventions which are judged likely to be effective in prolonging the life of a patient or which are being utilized to sustain the life of a patient.

Living Will - Document which can be completed by any adult to provide advance directives regarding treatment in the event that the individual became unable to participate in decision-making.

Surrogate - When a patient lacks decision-making capacity, he/she should participate in the treatment decision as fully as possible; however, another individual - the surrogate decision-maker must work with the providers to make decisions. The appropriate surrogate may be: 1) delegated by the patient through an advance directive instrument, 2) designated by a court (e.g., a guardian), or 3) the adult who is most involved with the patient and most knowledgeable about his/her personal values and preferences. Providers should work closely with the patient's friends and relatives to identify the appropriate surrogate. If agreement cannot be reached regarding the selection of a surrogate, the provider should seek appointment of a guardian.

Terminal Illness - An illness which because of its nature can be expected to cause the patient to die; usually used to refer to an irreversible and unrelenting condition for which there is no known effective treatment or cure.

### **III. Ethical Principles**

Health care has traditionally been based on the assumption that life is an important and essential good and that it should be preserved whenever possible. Prevention of premature or avoidable death is seen as part of the goal of health care. However, the principle or duty to prolong/preserve life does not provide an adequate basis for making decisions about when treatments may be withheld or withdrawn.

### **A. The principle of autonomy**

Patients have the right to make decisions about the course of their life for themselves. This is often called the patient's right of self-determination or autonomy. Important aspects of autonomy include: the concept of informed consent, the presumption that patients have the capacity to make decisions, the presumption that patients have a right to delegate decision-making authority, the patient's right to be adequately informed, and the right to authorize or refuse any medical treatment.

### **B. The principle of "do no harm" (non-maleficence)**

One of the most established principles of health care ethics directs providers to avoid or minimize harm to patients. Providers are obligated to carefully weigh the burdens and risks associated with any proposed treatment. When treatment no longer provides reasonable benefits or becomes unacceptably burdensome from the patient's perspective, it should be stopped.

### **C. The principle of beneficence**

The obligation to promote the good of the patient is basic. Attempting to extend life usually promotes the good of the patient. However, the patient's life may, for example, be full of pain and suffering and the patient may prefer to forego the treatment even though it means an earlier death. The obligation to promote the patient's good involves identifying the possible benefits from the patient's perspective. If the patient or surrogate judges that continuing to provide a treatment offers inadequate benefits, it should be stopped.

### **D. The principle of justice as fairness**

Considerations of procedural justice or fairness require that decisions about withholding and withdrawing treatment should involve shared decision-making by patients/surrogates and providers. The magnitude of such decisions requires that they should reflect the ideals of due process for decision-making including appropriate respect for all parties involved in the decision, open and sustained dialogue, careful consideration of all options, appropriate consultation and/or review, mechanisms for addressing differences of opinion and the like.

### **E. The principle of equity (distributive justice)**

Serious problems regarding the just distribution of health care resources exist in the United States. The lack of guidance and support for withholding and withdrawing of inappropriate life sustaining treatments may contribute to the unjust distribution of these resources.

## **IV. Presumptions Regarding Decisions to Forego Life Sustaining Treatment**

A. A patient's decision to forego such treatment does not constitute a decision to commit suicide. A decision to withhold or withdraw such treatment from a patient does not involve "killing", "causing a person to die", or "active euthanasia".

B. Health care providers who have a conscientious objection to a patient's decision to forego a life-sustaining treatment should, if necessary, inform the patient or surrogate of their position, and must arrange for the orderly transfer of responsibility for care to another provider.

C. Any life-sustaining treatment may be withheld or withdrawn. If doubt exists regarding the possible benefits of a treatment, time-limited trials of treatment should usually be undertaken.

D. Treatments involving provision of life-prolonging artificial nutrition and/or hydration may be withheld or withdrawn under appropriate circumstances.

E. When a decision to forego a particular life-sustaining treatment or treatments is made, both health care providers and the institution have a continuing obligation to provide a comprehensive range of supportive care and treatment including consideration of alternative methods of care such as hospice programs.

F. Providers usually have the obligation to respect the requests of patients/surrogates to be provided or to continue to receive a life-prolonging treatment. However, providers are not obligated to provide treatments that are clearly futile (meaning that they will not produce the physiologic result desired by the patient or surrogate), treatments that are felt to have a greater potential for harm than for benefit, treatments that are considered medically inappropriate by an appropriate professional organization, and treatments that cannot reasonably be provided by virtue of economic or institutional constraints.

## **V. General Guidelines for Decision Making**

### **A. Model of Shared Decision Making**

These guidelines presume that the ideal model for making such decisions is one in which the responsibility is shared by providers and patients or surrogates. It is assumed that all members of the health care team and the patient or surrogate must have the opportunity to participate actively in all such decisions. This model also presumes that such decisions will not be implemented unless there is consensus among those responsible regarding the appropriateness of the decision. When there are conflicting judgments regarding the appropriateness of such a decision, mechanisms must be available to address and, hopefully, resolve such conflict.

### **B. Role of the Health Care Provider(s)**

Providers have the responsibility for ensuring that comprehensive and accurate evaluation of the patient's condition has taken place, that the entire range of treatment options has been carefully considered, that appropriate therapeutic trials have been considered and conducted where appropriate, and that the patient or surrogate are informed and involved in the process.

### **C. Role of the Patient or Surrogate Decision-maker**

#### **1. Patient With Decisional Capacity**

A decision to forego a potentially life-sustaining intervention in the case of a patient with decisional capacity requires the informed consent of the patient. Adults with decisional capacity, even when not terminally ill, have the right to refuse to authorize any medical intervention even interventions that are potentially life prolonging.

#### **2. Patient Who Has Executed an Advance Directive**

Where a patient without decisional capacity has previously executed a directive (Living Will) that a life sustaining treatment be withheld or withdrawn and/or has appointed a surrogate to make such decisions, such advance directives and decisions should be respected.

#### **3. Patient Without Decisional Capacity Who Has Not Executed an Advance Directive**

Where possible, providers of such patients should work with the patient's family and appropriate others to identify an appropriate surrogate decision-maker. If the patient has been declared legally incompetent, the surrogate would normally be the court appointed guardian. If not, the appropriate surrogate is that individual who is most available, involved and concerned

about the patient, most knowledgeable about the patient's values and preferences, and most willing to apply the patient's values to making the decision.

Appropriate criteria for use in surrogate decision-making are:

a. Substituted judgment decisions: If the providers and surrogate agree that foregoing life sustaining treatment is clearly in accord with the patient's values and previously expressed preferences, that plan of care should be pursued.

b. Best interest decisions: If the providers and surrogate are not certain that foregoing life sustaining treatment is in accord with the patient's values and preferences, then decisions should be based on what is in that patient's best interest. Another way of expressing "best interest" criteria is to choose so as to promote the patient's interests as they would be conceived by a reasonable person in the patient's circumstances.

#### **D. Role of the Surrogate**

The role of a court appointed guardian or a surrogate appointed by the patient (Health Care Surrogate Agreement) is to substitute for the patient in the decision-making process. If the surrogate has not been empowered by a court or the patient, the role of the surrogate is to work with the providers to determine the appropriate course of action.

#### **E. Role of the Institution and Ethics Committee**

One of the primary roles of the Ethics Committee is that of providing a forum in which questions and/or disagreements regarding decisions to forego a life sustaining treatment can be discussed and resolved. Committee case review will only be undertaken in response to a formal request by a professional directly involved in the care of the patient, by a guardian or surrogate, or by the patient. Such review should be strongly considered in cases in which an appropriate surrogate cannot be identified for a patient without decisional capacity and in cases in which there is persistent disagreement among those responsible for making the decision.

#### **VI. Documenting the Decision**

All discussions regarding and decisions to withhold or withdraw a life sustaining treatment should be documented in the medical record. Documentation should include both orders necessary to implement such decisions and appropriate documentation of the rationale for and the process by which the decision was made.

#### **VII. Changing the Decision**

All parties to decisions to forego a life sustaining treatment should be aware that such decisions can be changed at any time if desired by the patient (surrogate) or if such a change is felt to be required in view of a reassessment of or change in the condition of the patient.

## **A10. ETHICAL GUIDELINES FOR DECISION MAKING: WITHHOLDING OR WITHDRAWING LIFE SUSTAINING TREATMENT (CHILDREN)**

### **I. Introduction**

These guidelines have been developed to provide the health care providers of this institution, their child patients and the parents of those patients with support and guidance in making decisions to withhold or withdraw a life sustaining treatment. They also represent the dedication of the institution to ensure that all such decisions reflect a clear commitment to serve the needs and best interests of the pediatric patient; that they are made carefully and in an informed manner; and, that they involve the participation of health care providers, parents and the child (to the extent of his/her capacity) in the decision-making process. Every effort should be made to obtain the informed permission of the parent(s) and to solicit the assent of the child patient (where feasible) prior to any decision to forego a life sustaining treatment.

### **II. Definitions**

"Pediatric patient" is used to refer to patients who are not empowered to provide authorization (informed consent) to their own medical care. With exceptions (e.g. "emancipated" or "mature" minors) such patients are those who are less than 18 years of age.

"Life sustaining treatments" are those interventions which are judged likely to be effective in prolonging the life of the patient.

"Foregoing" refers to any decision to withhold an intervention or to withdraw a treatment already begun. Clearly in situations involving significant uncertainty, treatment of potential benefit should be started since such treatment can be ethically withdrawn should it prove futile or not in the patient's interests.

"Parental permission" includes all the basic elements of the concept of informed consent: the duty to inform parents of the nature of the child's condition; the duty to disclose the risks and benefits of the various alternative treatments; and the obligation to obtain, free of coercion or manipulation, their permission to proceed with the proposed course of action, i.e. in this case, the foregoing of a life sustaining treatment.

"Assent of the child" includes the following elements: the obligation to assist the child in developing an age appropriate awareness of the nature of his/her condition; the obligation to disclose to the child the proposal to forego a treatment and what he/she is likely to experience in foregoing the treatment; and the responsibility of soliciting the child's expression of willingness to forego the treatment. Assent in this context would rarely be solicited in children less than seven years. The dissent of an older child or adolescent to a proposal to forego must be given appropriate respect and consideration including formal procedures to resolve conflict and/or referral to the Pediatric Ethics Committee.

### **III. Presumptions**

- That decisions to forego a life sustaining treatment would be considered only after comprehensive evaluation of the patient and all appropriate therapeutic trials.

- That parents as the legal guardians of the child (unless otherwise specified by law) are entitled and obligated to actively participate in the decision-making process.

- That health care providers are legally and ethically obligated to act in the best interests of the child patient.
- That children as patients should be allowed to participate to the extent of their capacity in decisions being made regarding their health care.
- That decisions to forego a life sustaining treatment do not entail or involve actions intended to end the life of the child (active euthanasia or "mercy killing").
- That pediatric patients from whom a life sustaining treatment has been withheld or withdrawn will continue to receive competent and compassionate health care including a wide range of supportive care services such as emotional and physical comforting; management of pain and other discomforts; and other palliative measures as appropriate.

#### **IV. Decision Making Process: Delegation of Responsibility**

##### **A. Health Care Providers**

Although orders to forego life sustaining treatment must ultimately be written by the patient's attending physician, these decisions require sustained and effective communication among all of those providing care to the child. The process by which such decisions are made can be initiated by any professional directly involved in the care of the patient and begins with communication between that individual and the attending physician. Providers have the responsibility for ensuring that comprehensive and accurate evaluation of the child's condition has taken place; that the entire range of treatment options has been carefully considered; that appropriate therapeutic trials have been considered and conducted where appropriate; and that the parents and child are appropriately informed and involved in the decision-making process.

##### **B. Parent(s)/Guardian**

As legal guardians, parents have a fundamental interest and obligation to share in the decision-making process. Parents must be informed and provided support necessary for them to actively participate in this process. Parents may initiate this discussion with the child's health care provider(s) and/or request consideration of foregoing a life sustaining treatment. If the parent(s)/guardian concur with the evaluation of the child's condition and request or give permission to the foregoing of the treatment, it may be withheld or discontinued. After allowing sufficient time for deliberation and consultation, if the parents are unwilling to give permission to a recommendation that a treatment to be withheld or withdrawn, the attending physician should request formal review of the case by the Pediatric Ethics Committee. Parent(s)/Guardian may also request review by the committee in cases in which they feel that a treatment recommended or being provided to their child should be withheld or withdrawn.

##### **C. Child/Adolescent Patient**

The patient should be encouraged and allowed to participate in this decision-making process to the extent of his/her capacity. Providers should solicit the assent of the child to any proposal to forego a life sustaining treatment. Persistent disagreement between the child and his/her parent(s)/ guardian regarding such a decision should prompt appropriate conflict resolution measures and/or review by the Ethics Committee.

##### **D. Pediatric Ethics**

One of the primary roles of the committee is that of providing a forum in which questions and/or disagreements regarding decisions to forego a life sustaining

treatment can be discussed and resolved. Committee case review will only be undertaken in response to a formal request by a professional directly involved in the care of the patient, parent(s)/guardian or the patient. Requests for case review with the committee should be communicated directly to the committee chair or vice chair. The committee will make every effort to provide support for those with the responsibility of making these decisions and for ensuring that conflicts are appropriately addressed and resolved. In the unlikely event that such conflicts could not be resolved, the committee would recommend to the hospital and the involved parties that appropriate legal mechanisms be sought.

#### **V. Documenting the Decision**

All discussions regarding and decisions to withhold or withdraw a life sustaining treatment should be documented in the medical record including both orders necessary to implement such decisions and appropriate documentation of the rationale for and the process by which the decision was made.

#### **VI. Changing the Decision**

All parties to decisions to forego a life sustaining treatment should be aware that such decisions can be changed at any time if such a change is felt to be required in view of a reassessment of or change in the condition of the child. The judgment that such a change is necessary should be communicated to the attending physician who would then facilitate appropriate discussion and reevaluation of the situation.

### **A11. GUIDELINES FOR WITHHOLDING OR WITHDRAWING LIFE-SUSTAINING MECHANICAL VENTILATION**

#### **I. Introduction**

The process by which decisions should be made to use or not to use a life-sustaining medical technology involves consideration of a wide range of issues. This statement is intended to serve as an outline for that process when the treatment under consideration is mechanical ventilation, i.e. use of a respirator. The basic ethical values involved are those of patient well-being and patient self-determination. Ethical duties, obligations, rights and responsibilities of the health care providers, patients and families are based on these values. Important considerations include: Is the use of the treatment likely to promote the well-being of the patient? What are the anticipated benefits and burdens of treatment from the patient's perspective? Do the burdens outweigh benefits? How is the patient's right of self-determination to be respected?

Other considerations deal with the decision-making process itself and include:

A. The obligation of health care providers to provide critical on-going evaluation of patients, especially in terms of the chronic use of life sustaining treatments, and to initiate and facilitate discussion with the patient (and family and/or others if the patient wants them involved) regarding the use or continued use of such treatments.

B. Identification of the key decision-maker, i.e. assessing the decision-making capacity of the patient and/or identification of a surrogate. (If the patient is a minor, see "Ethical Guidelines for Decision-making: Foregoing Life Sustaining Treatment in the Care of the Pediatric Patient".) A surrogate may have been designated by the patient (see policy on "Advance Directives"), appointed by a court ("guardian"), or may need to be identified from amongst adult family members or concerned friends.

C. Making the decision: 1) the roles of providers, patients and surrogates; 2) the criteria for making decisions when the patient lacks the capacity to decide, i.e. the prior expressed wishes of the patient (see section A "Advance Directives"), the known preferences and values of the patient (sometimes called "substituted judgment") or, the "best interests" of the patient as they would probably be conceived by a reasonable person in the patient's circumstances, 3) documentation of the basis for the decision, and 4) implementation of the decision into the total care plan for the patient.

## **II. Withholding and Withdrawing Ventilatory Support**

Health care providers often find it easier to make a decision to withhold a life-sustaining treatment or to allow a patient to forego its use than to discontinue or withdraw the same life-supporting treatment. This is particularly true in the case of the use of respirators. However, from an ethical point of view it is clear that there is no ethical requirement to continue a treatment merely because it has been started. To continue to impose a treatment against the wishes of patient or surrogate when it is felt to be more burdensome than beneficial is clearly wrong. There is actually strong reason to prefer withdrawal in spite of the psychological difficulties it poses for patient and provider since it allows for time-limited trials of treatments to establish the benefits and burdens of the treatment. A decision to withhold or forego a treatment cannot be made with the same degree of certainty. When there is doubt about the potential benefits of providing respiratory support, it should be started preferably on the basis of a time-limited trial.

## **III. Anticipating the Need for Ventilatory Support**

In many illnesses - such as. progressive neuromuscular diseases, cystic fibrosis, chronic obstructive pulmonary disease - the natural history of the disease process includes predictable respiratory insufficiency and eventual failure. Health care providers have the obligation to prepare patients for this phase of their illnesses, especially in terms of initiating and facilitating a dialogue about the possible role of chronic ventilatory support. This dialogue will allow patients to assess the likely benefits and burdens of such treatment and to provide advance directives regarding such support prior to the onset of respiratory failure.

## **IV. Ventilatory Support in Emergency Situations**

In emergency settings appropriate time for adequate analysis of the situation as well as important information about the patient's medical condition are frequently unavailable. In the context of acute respiratory failure it is rarely possible to reliably ascertain the patient's wishes regarding the use of ventilatory support. Therefore, in an emergency situation, it is almost always the case that ventilatory support should be initiated. Once the patient's condition has stabilized, the appropriateness of continued use of the respirator should be carefully reviewed.

## **V. Communication with the Respirator Dependent Patient**

In order to facilitate discussion of the continued use of a respirator, to ascertain the patient's preferences, and to assess the decision-making capacity of the patient, it is imperative that providers utilize all available aids to communicate with a patient who is on a respirator and usually unable to speak. Providers should consider: consultations with communication specialists, use of written communication, use of communication boards, or use of electronic devices to vocalize.

## **VI. Weaning from the Respirator**

Under most circumstances it is appropriate to attempt to wean patients from ventilatory support in order to evaluate the extent to which they are dependent on



such support. If the health care provider believes on the basis of such trials that weaning may prove successful, it should be attempted. However, if a decision to discontinue respirator use has been made such trials are not ethically required.

### **VII. Alternatives to Discontinuing Ventilatory Support**

If it is established that a patient has become permanently dependent on ventilatory support, every effort should be made to discuss alternatives to its discontinuation. Since many of these alternatives will involve careful assessment of resources available to the patient following discharge from the acute care setting, consultation with Social Services should be sought. Considerations to be discussed would include at least the following: methods of decreasing the discomfort and burdens of chronic respirator use, alternative forms of ventilatory support, development of home-based treatment plan, and methods to increase mobility such as the use of a portable respirator.

### **VIII. Care of the Patient Foregoing or Discontinuing Life-Sustaining Ventilatory Support**

Patients with significant respiratory insufficiency who forego or discontinue ventilatory support will often experience significant degrees of discomfort and difficulty breathing. Often they will experience frightening "air hunger". Maximal supportive care to insure comfort must be provided to such patients including any or all of the following: supplemental oxygen, adequate suctioning, intermittent assisted ventilation, and sedation. If relief of extreme discomfort requires the use of sedation which decreases respiratory effort and/or renders the patient unconscious, it is ethically acceptable to do so with the consent of the patient or surrogate. Provisions should also be made to provide company to such patients. If desired by the patient, family and friends should be allowed maximal access to the patient. They should also be provided the emotional support they may need to participate in this process. If it is anticipated that a patient's death from respiratory failure will occur shortly after discontinuation of the respirator, it is recommended that the attending physician discontinue the respirator and remain at the bedside. If he/she is unable to do so, this important responsibility can be delegated to an appropriately trained member of the professional staff attending the patient.

### **IX. Care for Bereaved Family and Friends**

Adequate consideration should be given to mechanisms to provide support to bereaved members of the patient's family or friends. Decisions to forego or discontinue ventilatory support are often associated with feelings of significant doubt and guilt in addition to those associated with the anticipated grieving process.

## **A12. CARE OF PATIENTS IN A PERSISTENT VEGETATIVE STATE**

The vegetative state is a clinical condition of complete unawareness of the self and the environment accompanied by sleep-wake cycles with either complete or partial preservation of hypothalamic and brain stem autonomic functions.

**I. Persistent Vegetative State (PVS)** can be defined as a vegetative state present at one month after acute traumatic or non-traumatic brain injury, and present for at least one month in degenerative or metabolic disorders or developmental malformations.

**II. Diagnosis:** PVS can be diagnosed on clinical grounds in adult and pediatric patients after careful, repeated neurologic examinations. (Note that PVS is different from brain death, and a person in PVS would not meet the criteria for being declared brain dead as set out elsewhere in this Handbook.) The diagnosis of PVS should be established by a physician who, by reason of training and experience, is competent in neurological function assessment and diagnosis. Reliable criteria do not exist for making a diagnosis of PVS in infants under three months of age, except in patients with anencephaly. Criteria for diagnosis include:

- No evidence of awareness of self or environment.
- An inability to interact with others.
- No evidence of sustained, reproducible, purposeful, or voluntary behavioral responses to visual, auditory, tactile, or noxious stimuli.
- No evidence of language comprehension or expression.
- Intermittent wakefulness manifested by the presence of sleep-wake cycles.
- Sufficiently preserved hypothalamic and brain stem autonomic functions to permit survival with medical and nursing care.
- Bowel and bladder incontinence.
- Variably preserved cranial nerve (papillary, oculocephalic, corneal, vestibulo-ocular, gag) and spinal reflexes.

**III. Categories and Clinical Course of PVS:** There are four major categories of diseases in adults and children that result in PVS. The clinical course and outcome of PVS patients depends on the specific etiology. The first etiology listed is the only cause due to trauma; the remaining three are considered to be non-traumatic etiologies.

**A. Acute traumatic brain injury:** PVS usually evolves from (1) a state of eyes-closed coma to (2) a state of wakefulness (without awareness) with sleep-wake cycles and preserved brain stem functions, within one month of injury.

**B. Acute non-traumatic brain injury:** Ischemic and anoxic brain injury secondary to cardiac arrest or intracranial hemorrhage leads to a condition similar to that of a metabolic or degenerative disorder, described in (C), below.

**C. Degenerative and metabolic disorders of the brain:** Many degenerative and metabolic nervous system disorders in adults and children inevitably progress toward an irreversible vegetative state. Patients who are severely impaired but retain some degree of awareness may lapse briefly into a vegetative state from the effects of medication, infection, superimposed illnesses, or decreased fluid and nutritional intake. Such a temporary encephalopathy must be corrected before establishing that the patient is in PVS. If the vegetative state persists for several months, recovery of consciousness is unlikely.

**D. Severe developmental malformations of the nervous system:** The developmental vegetative state is a form of PVS that affects some infants and children with severe congenital malformations of the nervous system. These children do not acquire awareness of the self or environment. This diagnosis can be made at birth only in infants with anencephaly. For children with other severe malformations who appear vegetative at birth, observation for three to six months is recommended to determine whether these infants acquire awareness. The majority of such infants who are vegetative at birth remain vegetative; those who acquire awareness usually recover but are severely disabled.

**IV. Prognosis for Recovery:** The available data indicate that recovery of consciousness from post-traumatic PVS is unlikely after 12 months in adults and children. Recovery from non-traumatic PVS is exceedingly rare after 3 months in both adults and children and those who recover are almost always severely disabled.

**V. Survival of Patients:** The life span of adults and children in PVS is substantially reduced. For most PVS patients, life expectancy ranges from two to five years. Survival beyond 10 years is unusual. The chance for survival of greater than 15 years is approximately 1/15,000 to 1/75,000. Note that the survival of patients in PVS is strongly influenced by the degree of medical intervention, e.g., the use of feeding tubes.

**VI. Management Guidelines:**

A. When a patient has been diagnosed as being in PVS by a physician skilled in neurological assessment and diagnosis, it is recommended that a physician skilled in rehabilitation medicine also evaluate the patient to assist in identifying appropriate patient care goals and the level of nursing care required.

B. Physicians have the responsibility to discuss with the family or surrogate the probability of the patient remaining in PVS.

C. Patients in PVS should receive appropriate medical, nursing, or home care to maintain their personal dignity and hygiene.

D. Once PVS is considered to be permanent, a "Do Not Resuscitate" (DNR) order is appropriate. Such a decision should, however, be made in a manner consistent with the rules for making health care decisions for an incompetent patient, as discussed elsewhere in this Handbook. The decision to implement a DNR order may be made earlier in the course of a patient's illness, again assuming such a decision is made in a manner consistent with the rules for making decisions for an incompetent patient.

E. Physicians and the family should determine appropriate levels of treatment relative to the administration, the forgoing, or the withdrawal of:

1. Medications and other commonly ordered treatments

2. Supplemental oxygen and use of antibiotics

3. Complex organ sustaining treatments such as renal dialysis

4. Administration of blood products

5. Artificial hydration and nutrition, including use of a permanent gastric tube

F. Many individuals in PVS are candidates for foregoing or withdrawal of any or all of the above interventions. (See appropriate sections of this Handbook with regard to making such decisions.)

**A13. PROCEDURES FOR DETERMINING BRAIN DEATH**

There are two well established methods that can be used to determine that death has occurred: (a) use of cardiopulmonary criteria to assess whether circulatory and respiratory functions have irreversibly ceased, or (b) use of neurological criteria to assess whether all brain functions have irreversibly ceased when cardiopulmonary

functions are maintained artificially. This policy outlines the procedures to be used for declaring death based on neurological criteria.

## **I. General Guidelines.**

Brain death is the absence of clinical brain function (including the brain stem) when the proximate cause is known and demonstrably irreversible.

Brain death is a clinical diagnosis. Special studies such as nuclear brain scans, electroencephalography or cerebral angiography are never sufficient and usually not necessary for the declaration of death by neurological criteria.

To declare death by neurological criteria, the attending physician must be thoroughly familiar with accepted criteria for determining brain death, or obtain consultation from a physician who is thoroughly familiar with these concepts. Neurologists, neurosurgeons, and intensivists often have this familiarity.

Federal regulations require that all deaths and imminent deaths be referred to the designated Organ Procurement Organization (OPO) to be screened for donation potential. Imminent death, for this purpose, is defined as a Glasgow Coma Score of 5 or less. An early screening for donation potential can guide and expedite the process. (Example: If there is no donation potential, confirmatory testing might be deferred and the family need not be offered the option of donation.)

To avoid the appearance of a conflict of interest, physicians involved in the determination of death by neurological criteria will not be members of an organ transplant team or involved in the care of a potential organ recipient.

It is important to note that the family's permission should not be sought and is not required for treatment cessation when a patient has been declared dead by neurological criteria.

## **II. Specific Procedures for the Declaration of Brain Death.**

**A. A patient greater than 2 years of age** may be declared dead by brain criteria when paragraphs (1) through (4), below, are all satisfied:

1. All of the following prerequisites are met:

Clinical or neuroimaging evidence of an acute CNS catastrophe that is compatible with the clinical diagnosis of brain death.

Exclusion of complicating medical conditions that may confound clinical assessment (absence of severe hypotension, electrolyte, acid-base, or endocrine disturbance).

No drug intoxication or poisoning.

Core temperature greater than or equal to ( $\geq$ )32°C (90°F).

2. The three cardinal findings of brain death—coma, absence of brainstem reflexes, and apnea—are present.

Coma or unresponsiveness – no cerebral motor response to pain in all extremities (nail-bed pressure and supraorbital pressure).

Absence of brainstem reflexes.

Pupils: No response to bright light. Size: mid-position (4 mm) to dilated (9 mm).

Ocular movement: No oculoccephalic reflex (Testing only when no fracture or instability of the cervical spine is apparent.). No deviation of the eyes to irrigation in each ear with 50 ml of cold water. (Allow one minute after injection and at least five minutes between testing on each side.).

Facial sensation and facial motor response: No corneal reflex to touch with a throat swab. No jaw reflex. No grimacing to deep pressure on nail bed, supraorbital ridge, or temporomandibular joint.

Pharyngeal and tracheal reflexes: No response after stimulation of the posterior pharynx with tongue blade. No cough response to bronchial suctioning.

Apnea-testing performed as follows:

Prerequisites: Core temperature  $\geq 36.5^{\circ}$  C or  $97^{\circ}$  F. Systolic blood pressure  $\geq 90$  mm Hg. Euvolemia.

Measure baseline arterial  $PO_2$ ,  $PCO_2$ , and pH.

Hyper-oxygenate the patient for a period of 10 minutes.

Connect a pulse oximeter and disconnect the ventilator.

Deliver 100%  $O_2$  6 L/min, into the trachea.

Look closely for respiratory movements (abdominal or chest excursions that produce adequate tidal volumes).

Measure arterial  $PO_2$ ,  $PCO_2$ , and pH after approximately 8 minutes and reconnect the ventilator.

If respiratory movements are absent and the arterial  $PCO_2$  is  $\geq 60$  mm Hg (or  $\geq 20$  mm Hg over the patient's baseline  $PCO_2$ ), the apnea test result is positive (i.e., it supports the diagnosis of brain death).

If respiratory movements are observed, the apnea test result is negative (i.e., it does not support the clinical diagnosis of brain death).

Connect the ventilator if, during testing, the systolic blood pressure becomes  $\leq 90$  mm Hg or the pulse oximeter indicates significant oxygen desaturation and cardiac arrhythmias are present. Immediately draw an arterial blood

sample and analyze arterial blood gas. If  $PCO_2$  is  $\geq 60$  mm Hg (or  $\geq 20$  mm Hg over the patient's baseline  $PCO_2$ ), the apnea test result is positive (it supports the clinical diagnosis of brain death); if  $PCO_2$  is  $< 60$  mm Hg (or  $PCO_2$  increase is  $< 20$  mm Hg over the patient's baseline  $PCO_2$ ), the result is indeterminate and an additional confirmatory test can be considered.

If no respiratory movements are observed,  $PCO_2$  is less than 60 mm Hg, and no significant cardiac arrhythmia or hypotension is observed, the test may be repeated with 10 minutes of apnea.

3. Coma and absence of brainstem reflexes persist after an observation period. These two criteria must therefore be evaluated at both the beginning and end of the observation period. The interval of the observation period is arbitrary.

4. Confirmatory Laboratory Tests: Brain death is a clinical diagnosis. A confirmatory test is not mandatory but is desirable in patients in whom specific components of clinical testing cannot be reliably performed or evaluated (e.g., surgical pupils or medical instability limiting the apnea test). The enumerated results of the following tests support a clinical diagnosis of brain death:

Conventional angiography. No intracerebral filling at the level of the carotid bifurcation or circle of Willis. The external carotid circulation is patent, and filling of the superior longitudinal sinus may be delayed.

Electroencephalography (EEG). No electrical activity during at least 30 minutes of recording that adheres to the minimal technical criteria for EEG recording in suspected brain death as adopted by the American Electroencephalographic Society, including a 16-channel EEG instruments.

Technetium-99m hexamethylpropylene-amineoxime brain scan. No uptake of isotope in brain parenchyma ("hollow skull phenomenon").

**B. The determination of brain death in patients less than 2 years of age** is similar to that of patients greater than 2 years of age except that longer observation intervals and some confirmatory tests are recommended.

1. Age 1 year to 2 years:

A minimal observation interval of 12 hours is recommended for most causes of coma. A 24 hour observation period should be considered if hypoxia/ischemia is the proximate cause.

A confirmatory test is needed to reduce the observation interval. Otherwise, confirmatory tests are not required.

2. Age 2 months to 1 year:

The minimum recommended observation interval between clinical exams is 24 hours.

Two EEGs demonstrating electrocerebral silence separated by 24 hours. A repeat examination and EEG are not necessary if a concomitant cerebral radioactive angiographic study demonstrates no visualization of cerebral arteries.

3. Age 7 days (assuming > 38 weeks gestational age) to 2 months

The minimum recommended observation interval between clinical examinations is 48 hours.

Two EEGs demonstrating electrocerebral silence separated by 48 hours.

4. Determination of death by neurological criteria is not recommended for infants less than 7 days old (assuming > 38 weeks gestational age).

**C. Special situations.**

In the event a determination of brain death is being considered in a patient who is known to be pregnant, obstetrical consultation should be arranged.

Although the determination of brain death itself is not an ethical dilemma, ethical issues commonly coexist in this setting. Consultation with the Hospital Ethics Committee may be appropriate.

**IV. Procedures following the first exam that reveals absence of brain function.**

Two exams separated by an observation period are required for the declaration of brain death. The absence of brain function at the time of the first exam, in the appropriate clinical circumstance, is often an indicator that death is imminent. Under these circumstances, to comply with regulations implemented in August 1998 by the Health Care Financing Administration, now known as the Centers for Medicare & Medicaid Services, the Transplant Network will be notified of the potentially imminent death. Information required to make an assessment of the patient's suitability for organ and tissue donation will be provided to the screening coordinator.

As it would be inappropriate for the family to make a decision regarding organ and tissue donation prior to the determination of death, the family will not be offered the option of donation until it has been determined from a second exam that brain death has occurred. (See Section V.)

**V. Procedures following the declaration of death by neurological criteria.**

A. In patients declared dead by neurological criteria, a note signed by the attending physician must document the following elements:

1. Etiology and irreversibility of condition.
2. Presence of unresponsive coma at the beginning and end of the observation interval.
3. Absence of brainstem reflexes at the beginning and end of the observation interval.
4. The duration of the observation interval.

5. Absence of respiration with  $PCO_2 \geq 60$  mm Hg (or  $\geq 20$  mm Hg over the patient's baseline  $PCO_2$ ).

6. Justification for confirmatory test and result of confirmatory test.

7. The time death was certified.

B. Death, based on fulfillment of all diagnostic criteria for brain death and certification by the attending physician, is declared while the artificial respirator is still ventilating the patient. The patient's family is not asked to participate in or to make the decision that the patient is brain dead. Once the family has been informed and a declaration of death has been made, and all decisions and measures relating to possible organ donation have been completed, treatment of the patient should cease. Consent or permission of the family is not required for treatment cessation.

Under federal regulations, only trained requestors may offer the option of organ donation (when appropriate). It is hospital policy that a representative of the Midwest Transplant Network, the local Organ Procurement Organization (OPO), will offer the option of organ donation after the attending physician has made a declaration of death and informed the family. It is recommended that the family be told by the attending physician:

1. That the attending physician has determined that the patient is dead and that a declaration of death has been made and documented in the patient's medical record.

2. That the patient's body is being maintained by mechanical ventilation and pharmacologic measures for a period of time while donation options are considered.

3. That resources (such as the local OPO staff) are available to support them and explain their options. The physician will work collaboratively with the OPO coordinator to determine how and when the coordinator will be introduced to the family. The coordinator will offer the option of organ donation and assist the family as needed in making an informed decision.

If a decision is made that the patient will not serve as an organ donor, interventions being used to maintain the patient's body should be discontinued. Family members should be allowed to accompany the patient's body before, during and/or after these interventions are withdrawn.

## **V. References**

*Neurology* 1995; 45:1012-1014.

*Neurology* 1987; 37:1077-1078.

## **A14. RESEARCH INVOLVING HUMAN SUBJECTS**



All research activities undertaken at Flagler Hospital which involve the use of human subjects must be reviewed and approved by the Institutional Review Board before they are begun. This requirement applies not only to research which involves direct participation by a human subject, but any activity which involves material derived from or collected from a human subject, and activities which involve use of data, photographs, images or records of human subjects. That committee also has responsibility for continuing review of all on-going research.

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