Inappropriate or Nonbeneficial Treatment: A Model Policy Template

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I. POLICY STATEMENT

The Florida Bioethics Network recognizes that physicians are not obligated to provide medical treatments that professional judgment identifies as not expected to benefit patients. Indeed, physicians ought not provide treatments regarded as non-beneficial. A non-beneficial albeit potentially life-prolonging intervention need neither be offered nor provided, including in circumstances in which it is believed or known that a patient or legally authorized representative is demanding the treatment.

II. PREAMBLE

Physicians must determine which treatments should be recommended or offered based on current medical practice and experience, medical evidence, and specific patient's clinical condition and prognosis. A physician may determine that the goals of care cannot be reasonably accomplished, the burdens to the patient outweigh the benefits to an unreasonable degree, and thus determine that medical intervention is inappropriate and should be withdrawn or withheld.

Medical interventions typically considered life-sustaining may be determined to be non-beneficial when:

1. The patient has a terminal or end-state condition or is in a persistent vegetative state, as these defined in Florida Statute 765.
2. The patient has a condition in which medical intervention would, according to reasonable medical judgment, serve only to prolong the dying process – a process that the physician determines is already and irreversibly underway;
3. The patient has a medical condition for which the physician does not expect medical interventions to achieve the patient's minimal acceptable outcomes as expressed by the patient, known by the legally authorized representative, or determined by the legally authorized representative as in the patient's best interest.

In such circumstances, the attending physician and one other physician may determine that a medical intervention is non-beneficial and may withhold or order the withdrawal of non-beneficial treatment.

Patients, surrogates or proxies sometimes believe that interventions should not be withheld or withdrawn and that aggressive measures should be continued. Such requests are motivated by many factors, including love, loyalty, grief, guilt, disbelief in a prognosis, distrust of the care team, etc. They should be met with compassionate communication, gentle responsiveness, and offers of spiritual care and ethics support and guidance.

However, when two attending physicians determine, according to reasonable medical probability that a patient is dying, and that aggressive medical treatment is or would be ineffective or of no demonstrable benefit, the request for such treatment does not impose an obligation on the healthcare team to offer or provide the treatment. Indeed, it will be ethically offensive to some to undertake such inappropriate interventions.

When disagreements arise about withholding or withdrawing life-sustaining interventions, all parties are best served by a process that acknowledges and respects the various perspectives, the patient's autonomy and dignity, and the rights and professional obligations of physicians and others on the healthcare team.

NB: Though individual institutions and clinicians may choose to invoke a nonbeneficial policy in support of a decision not to provide cardiopulmonary resuscitation, under Florida Statute 765, the concurrence of the legally authorized repesentative is a necessary condition for writing a Do-Not-Resuscitate Order.

III. PURPOSE

The purpose of this policy is to:

1. Provide guidance for developing and implementing policies and procedures for withholding or withdrawing inappropriate, ineffective or non-beneficial medical interventions.purpose of this policy is to:
2. Provide a process for resolving disagreements between clinicians and patients, surrogates, or proxies concerning the appropriateness of medical interventions.
3. Provide a framework for addressing conflict when the patients or legally authorized representatives request treatment that physicians believe to be medically or ethically inappropriate.
4. Assist healthcare teams in recognizing and effectively managing conflicts with patients and families about withdrawal or withholding of life-sustaining technologies.

IV. DEFINITIONS

“Non-beneficial treatment” is any medical treatment, intervention, or diagnostic procedure that a physician determines in the exercise of professional judgment will not cure a disease, correct a malady or otherwise improve or help a patient, i.e., would be ineffective. An intervention or treatment might be nonbeneficial if it will not work or is thus ineffective/futile, is inappropriate, or harmful without a reasonable probability of countervailing benefit. For instance, an intervention or treatment may be regarded as nonbeneficial if, within a reasonable degree of medical probability, the intervention or treatment:

- Will not return a patient to a level of health that permits survival outside of acute care setting;
- Will not achieve a patient’s own goals as stated in an advanced directive or by other clear and convincing evidence;
- Will cause undue suffering, loss of dignity, or unnecessary pain;
- Will not be effective in producing the physiological effect that the patient, surrogate or proxy desires or expects;
- Will produce no effects that can reasonably be expected to help a patient achieve an expressed and otherwise obtainable goal;
- Will harm the patient;
- Will not return a patient to a level of health adequate for survival outside an acute care hospital.

Note that the concepts of “nonbeneficial” and “futile” are recognized in Florida Statute 765’s definition of “end-stage condition” (FS765.101[4]: “an irreversible condition that is caused by injury, disease, or illness which has resulted in progressively severe and permanent deterioration, and which, to a reasonable degree of medical probability, treatment of the condition would be ineffective). Other salient definitions are available in FS765.101.

V. PRINCIPLES

Patients have the right of self-determination or autonomy and therefore to make informed decisions about their medical care, including the right to accept or refuse treatment. This right generally extends to a surrogates or proxies when patients lack the capacity to make their own decisions. However, patient autonomy does not include the right to demand treatments or services determined to be of no medical benefit, as determined by evidence-based criteria. Note that surrogates and proxies are to be regarded as “legally authorized representatives” and so have the duty to signal what a patient would want if capacitated. Surrogates and proxies ought not consent to or refuse treatment based in their – the surrogates’ – hopes or values. Rather, they must represent those of the patient.

The healthcare team will respect patient dignity at all times.

Physicians have a professional and ethical responsibility to offer patients only such treatments that are medically appropriate for their patients. They are not obligated to provide treatments that compromise personal or professional integrity. Neither ought they offer or provide treatments which, in their judgment and to a reasonable degree of medical probability, are nonbeneficial, harmful, or will not be effective.

A shared decision-making process between the physician and the patient or the patient’s legally authorized representative is always to be preferred. The physician supplies objective information about credible treatments’ effectiveness or benefit, or the absence of such effectiveness or benefit. The patient or surrogate/proxy then consents to or declines treatment based on the patient's values and goals of care.

Views on whether an intervention is non-beneficial can be value-laden and often depend on how benefits and burdens are defined. These issues reflect deeply held beliefs and values on the part of the patient, surrogates and proxies, and clinicians. Physicians should not substitute their own values for those of their patients.

Financial issues about treatment should not be a factor in assessing whether interventions are beneficial or not.

Disputes about non-beneficial interventions often reflect tensions among the values of individual autonomy, professional integrity, and institutional commitments; they can reflect different beliefs regarding what counts as a benefit or burden.

The decision to withhold or withdraw non-beneficial interventions must not disadvantage any minority population or people with disability or who are poor or uninsured.

VI. PROCESS

When two attending physicians determine, according to a reasonable degree of medical probability, that a patient is dying and that life-sustaining medical treatment is or would be ineffective or of no demonstrable benefit, then the request for such treatment does not impose an obligation on the healthcare team to offer or provide the treatment.

PREVENTIVE ETHICS

High-quality end-of-life care is shaped by open, compassionate, and candid communication. It is always inapt to delay such conversations until an emergency arises or a patient is actively dying. Generally, and in non-emergency situations, members of the healthcare team should confer with the patient or surrogate/proxy upon admission or soon thereafter and document in the medical record goals of care, medical condition or diagnosis, prognosis, range of options for care, and patient's wishes or, when applicable, the patient's wishes as communicated by a surrogate or proxy.

Completing an advance directive – especially appointing a surrogate –is strongly encouraged.

Discussions about credible goals of care should take place throughout the course of treatment. If it is determined that the patient will be unable to return to a previous level of functioning, new goals should be identified.

ASSESSMENT of "NON-BENEFICIAL"

Assessments of effectiveness or benefit should be made based on the likelihood of medical success and not on the patient's current or projected quality of life. The assessment should emphasize the patient's physiological status and not the physician's estimation regarding the quality of life likely to follow the attempted treatment.

A treatment might be non-beneficial if it

- is physiologically futile
- will not restore a patient to a prior baseline state
- will not prolong life for a nontrivial period, or
- prolongs and/or increases suffering without countervailing benefit

Note that some such assessments are fallible and probabilistic. This is often the case in medicine and nursing. There is however, no standard, tradition or credible custom to provide medication or attempt interventions when such treatments cannot be justified by clinical knowledge and discernment and within a reasonable degree of medical probability. That is, clinicians should not undertake interventions that violate their clinical judgment.

There is no good ethical reason to attempt nonbeneficial or futile interventions.

Consider clear cases:

- A surgeon determines that a patient is not a candidate for an operation. Though the patient or a colleague might urge a reconsideration, the final decision whether to operate must be that of the surgeon who would conduct the procedure. It would be poor judgment to "give it a go" if the surgery meets any of the four criteria enumerated just above. Note that we do not require surgeons to have "futility policies" in place before declining to operate.
- A family physician receives a request for an antibiotic from a patient with a head cold or other virus. It is wholly inappropriate to prescribe an antibiotic for that patient. This is perhaps the best example of physiological futility: it simply will not work. That no few physicians have indeed written such prescriptions has created a public health problem in the form new strains of drug-resistant bacteria.
- A patient dying of cancer has undergone two courses of chemotherapy under carefully evaluated oncology protocols. The treatment has failed. The patient then asks for a third course. Cancer drugs are highly toxic, and the patient's oncologist knows that more will be harmful. The physician cannot credibly be said to have any obligation to accede to such a dangerous request.

These examples illustrate the important distinction between refusals and requests. The former, expressed by adequately informed and capacitated patients acting voluntarily are generally dispositive and should be honored. Requests, however, must always be subjected to clinicians' judgment. The mere making of a request, no matter how sincere or impassioned, cannot in itself impose a duty on the clinician.

DOCUMENTATION

The determination that a treatment or intervention is nonbeneficial should be documented in the patient's medical record by at least one attending physician. Concurrence by another physician is helpful, if for no reason other than reassure patients and surrogates/proxies that the conclusion is not idiosyncratic. Reasons why a treatment is non-beneficial should be articulated.

Some institutions also recommend or require that physicians document the patient has a terminal and/or end-stage condition as defined in Florida Statute 765:

- Terminal condition
- End-stage condition

This is good practice, time permitting. Unlike other states, Florida lacks an explicit futility law. Nevertheless, the concept is clearly implied in these definitions. It would, for instance, rarely make sense to honor requests for nonpalliative treatment that will not prevent the death of a patient. Put differently: If a patient will die no matter the treatment, it is usually inapt to attempt the treatment.

With this documentation in place, an attending physician must inform the patient or surrogate/proxy of the determination as soon as possible, and explain what it entails, i.e., to make clear which interventions and escalations, for instance, will not be attempted. This communication should, as appropriate, include the salient diagnosis or diagnoses, prognosis, the reasons why specific interventions have been determined to be medically inappropriate or medically nonbeneficial and any alternative treatment options, including palliative care and hospice. It can be helpful for the attending physician to make clear that withholding a nonbeneficial/ineffective treatment in no way constitutes abandonment or neglect, and that appropriate comfort care will never be withheld. Clinicians have found it helpful, and patients have appreciated, this clarification: The decision at hand is not between life and death – the patient will die no matter what – but between dying well, peacefully and with dignity, and not otherwise.

EARLY INTERVENTION: "PREVENTIVE ETHICS"

Clinicians who are good communicators know that honest, accurate and compassionate communication is a powerful tool in all contexts. This is especially the case when a patient's condition is worsening or is likely to worsen. Skillful communicators will refrain from fostering false hope; will gently manage unrealistic expectations; and will be ready to counsel and reassure, even when the news is bad.

It is important that hospital teams be univocal, that is, that patients and surrogates/proxies not receive conflicting or mixed messages. Even casual remarks can be misunderstood and instill beliefs that the situation is better than it is. If a patient is dying of metastatic cancer and multisystem organ failure, it is erosive to observe aloud that "her blood gases are looking good today," for instance.

Clinicians should try to preempt conflict by using the tools of gentle, truthful communication, better to avoid or resolve misunderstandings or disagreements.

The attending physician should review the goals of care and attempt to determine what the patient would have chosen or preferred. The legally authorized representative is bound by standards of surrogate decision making to honor the patient's expressed wishes and values, if known, and, if unknown, the patient's best interests in deciding whether to accept the recommendations to withhold or withdraw non-beneficial interventions. Surrogates and proxies are – and ought to be regarded as – representatives, not "decision makers."

The attending physician should enlist the support of other appropriate team members throughout the process, especially when decisions to withhold or withdraw medically inappropriate treatment are considered.

The interdisciplinary team should provide:

1. Ongoing and updated medical information about the diagnosis, treatment options, and prognosis;
2. Consistent and supportive communication aimed at providing information and promoting trust;
3. Ongoing dialogue about patient wishes or advanced directives as appropriate to the situation;
4. Comfort care for the patient;
5. Emotional support for the patient and family.

If the goals of care cannot be agreed upon, the attending physician should consider a meeting that could include key members of the healthcare team, consulting physicians, the patient's primary care or community physician, the patient or legally authorized representative, family members who know the patient and perhaps others as requested by the family. The aim of the meeting is to facilitate open and productive communication so that all involved have the same information. A summary or copy of the institution's non-beneficial treatment policy may be offered to the patient or representative and family members.

IF CONFLICT ARISES

When a conflict exists between the healthcare team and the patient or legally authorized representative regarding the appropriateness of providing life-sustaining treatment, every reasonable effort should be made to resolve the conflict promptly. The attending physician should initiate and exhaust the appropriate conflict resolution process.

When there is a disagreement between the medical team and patient or legally authorized representative about withholding or withdrawing life-sustaining interventions, a decision must be made to ensure ethically appropriate medical care. A fair and rational due process must be used.

The following steps outline that process.

- Meet with patient or legally authorized representative and other relevant support persons and healthcare team members for a patient care conference.
- Explore and review treatment options and explain why the requested treatment is non-beneficial and discuss the burdens of the treatment compared to any perceived benefit.
- Explore compromises and solutions such as time limits on particular treatments, no further escalation, or limited escalation of selected treatments.

ETHICS CONSULTATION

Institutional ethics services should be available to all parties.

Ethics consultants or teams may provide guidance and promote additional dialogue, leading to consensus. The ethics consultant does not determine that treatment is non-beneficial, but encourages decision-makers to recognize any underlying conflicts of values that may prevent them from acting together on the patient's behalf.

If the conflict is not resolved, further efforts for dispute resolution may be undertaken.

The patient or legally authorized representative should be informed of the option to transfer the patient to another physician or hospital willing to agree to the request for continued treatment. Finding such a physician or institution is the responsibility of those seeking nonbeneficial treatment. The patient or legally authorized representative will also be informed of the option to retain legal counsel and seek judicial relief. A reasonable amount of time should be provided in either case.

There may be factors that make limited, continued life-sustaining treatments for brief periods desirable as accommodations to the patient and legally authorized representative. Such factors may include family needs or schedules or faith-based goals for ministering to the patient or to allow family members time to travel to the patient before treatment is withdrawn.

NO RESOLUTION

Once conflict resolution processes are complete and if the patient or legally authorized representative does not seek to transfer the patient or if the transfer is not feasible, and if no legal action is taken preventing the implementation of the decision, the physician may order that the specified treatment be withheld or withdrawn without the agreement of the patient or legally authorized representative.

The team will continue to provide comfort care. The patient, legally authorized representative and family members should be aware of the full range of support services, including the palliative care team, chaplains, social work, case management, and the ethics service.

Efforts to minimize pain and provide comfort and quality care are always appropriate. The proper dose of pain medication suffices to relieve pain and suffering, regardless of secondary consequences.

OTHER CONSIDERATIONS

There is no ethical obligation to accept or honor a legally authorized representative's demand for interventions that harm patients; indeed, one ought never intentionally harm a patient without reasonable expectation of therapeutic success. If a legally authorized representative lacks capacity, pursuing a court-appointed guardian maker should be considered.

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