We Have All the Time in the World[1]: The Law and Ethics of Time-Limited Interventions in Clinical Care

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Abstract: The authors consider the legal and ethical considerations of offering a time-limited trial of a potentially non-beneficial intervention in the setting of patient or surrogate requests to pursue aggressive treatment. The likelihood of an intervention's success is rarely a zero-sum game, and an intervention's risk-to-benefit ratio may be indiscernible without further information (often, a matter of time).

I. Introduction

Significant advances in medical technology make it easier to postpone the natural processes of disease and death. "Most of the cases and dilemmas that have shaped the law on end-of-life care have involved patients whose lives could be prolonged by new medical treatments and technologies, but whose health, functioning, quality of life, and even conscious awareness itself could not be restored."[2]

For patients, easy access to medical information online, coupled with the growth of social media, has been both a blessing and a curse. Patients are more informed about conditions and treatments but often lack the medical understanding to interpret that information. Mistrust of the medical community abounds. A patient or a patient's surrogate may not simply take a provider's word that a treatment is inappropriate or ineffective and may request treatments that are both, leading to conflicts. Depictions of critical care in popular media also portray an unrealistically high probability of full recovery from critical illness.[3]

On the provider side, "defensive medicine" and "doing everything" are the responses to fears of litigation. Providers offer inappropriate treatments or interventions — and continue those treatments and interventions without a goal or timeframe in mind — when patients or their families demand aggressive care. Providers often fear that, if they choose not to provide or prolong interventions that a patient or family demands, they will end up embroiled in a costly, long-lasting lawsuit. Instead, providers end up practicing medicine *outside* the standard of care, opening themselves up to moral distress and to additional liability if the interventions are still unsuccessful. It

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is often difficult to cease life-sustaining interventions once they are started, and withdrawal of care may be perceived as patient abandonment by the patient or the patient's surrogate.[4]

In this article, we contend that it should be the clinical standard of care to offer to a patient *any* continuous medical intervention — ventilators, dialysis, chemotherapy, etc. — only on a time-limited basis. A time-limited trial of a medical intervention accomplishes several important legal and ethical goals: (1) promoting shared decision-making among patients and providers; (2) creating a framework for goals of care discussions; (3) providing clinical benchmarks to determine whether the interventions are meeting the agreed-upon goals of care; and (4) creating space for emotional responses to complex medical care decisions.

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II. Case Study

Mr. L.A., a 54-year-old male patient, was admitted for confusion and left-sided weakness. Imaging showed that he suffered a hemorrhagic brain stem stroke. Over the next three days, despite maximal medical and surgical management, the stroke evolved, resulting in likely permanent loss of consciousness and ventilator dependence. Due to the swelling of injured tissue in the brainstem, the normal drainage of cerebrospinal fluid (CSF) to the spinal cord was blocked. The development of hydrocephalus, or the accumulation of CSF in the ventricles of the brain, led to critically high levels of intracranial pressure (ICP), which could progress to brainstem herniation and brain death if left unaddressed. An extraventricular drain (EVD) was placed.

An EVD is a tube placed into one of the ventricles, passing through brain matter and skull, to allow CSF drainage out of the head and thereby reduce brain pressure. EVD placement is normally a temporary measure used to bridge the patient through a critical period of brain swelling. An EVD, like Extracorporeal Membrane Oxygenation (ECMO), is a critical intervention that requires intensive care unit (ICU) monitoring and poses complication risks (e.g. infection, dislodgement) which increase the longer the drain is in place. Often, an EVD may be removed once the window of peak brain swelling has closed and intracranial pressure has normalized. Otherwise, in cases of persistent hydrocephalus, an internalized drain called a ventriculoperitoneal (VP) shunt may be surgically implanted which allows drainage of CSF into the abdominal cavity.

Over the following weeks, Mr. L.A. failed to improve: he did not respond to pain or move any of his extremities, with a slight cough reflex being the only sign of retained brainstem function. The clinical team doubted there was any likelihood for meaningful and functional recovery, and felt he likely had a prognosis of permanent vegetative state at best. Additionally, repeated attempts to wean Mr. L.A.'s EVD were unsuccessful due to the nature of his stroke and location of affected brain tissue; even as tissue swelling subsided, the intrinsic drainage pathway of CSF to the spinal cord proved to be blocked. Removal of the EVD would risk progression to herniation and brain death. Meanwhile, the alternative pathway to EVD discontinuation proved to be unavailable. The consulting Neurosurgical team declined to offer VP shunt placement as the surgery entailed posed serious risks of harm given Mr. L.A.'s history of prior abdominal surgeries, with little expected benefit to offset these risks in the setting of Mr. L.A.'s poor prognosis for recovery.

When the providers met with Mr. L.A.'s family to discuss this quandary of care, his wife became emotional and expressed that she felt backed into a corner:

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without the option of VP shunt, the "decision" she was being asked to make rang false as the only available course of action was to remove the drain and accept that her husband would die. Instead, she refused to make this decision and opted for the unspoken option of leaving the drain in place indefinitely.

III. Legal Framework

The law is clear that "[a] competent person has a liberty interest under the Due Process Clause in refusing unwanted medical treatment."[5] Every state has a similar statement of autonomy. When patients are unable to make decisions for themselves, state laws provide for patients to make their wishes known in advance (via an advance directive, living will, durable power of attorney for healthcare, etc.) or provide that a legally designated surrogate should make decisions under a substituted judgment or best interests standard.[6] Yet a patient (or their surrogate) does not know what clinical decisions should be made until those decisions are presented by a physician or other provider.

In *Causey v. St. Francis Medical Center*, the Louisiana Court of Appeal, Second Circuit, noted the extraordinary powers granted to physicians: "Physicians are professionals and occupy a special place in our community. They are licensed by society to perform this special role. No one else is permitted to use life-prolonging technology, which is considered by many as 'fundamental' health care."[7] That case involved a physician and hospital's decision to withdraw life-sustaining treatment (ventilator and dialysis) from a 31-year-old comatose woman with quadriplegia and end-stage renal disease, despite the patient's family's insistence on aggressive life-sustaining care. Interpreting the Louisiana statute governing the right of a patient to refuse life-sustaining treatment, the Court of Appeal further stated:

> The physician has an obligation to present all medically acceptable treatment options for the patient or her surrogate to consider and either choose or reject; however, this does not compel a physician to provide interventions that in his view would be harmful, without effect or "medically inappropriate." In recognizing a terminal patient's right to refuse care, La. R.S. 40:1299.58.1(A)(4) states that the statute is not to be construed "to require the application of ***medically inappropriate*** treatment or life-sustaining procedures to any patient or to interfere with ***medical judgment*** with respect to the application of medical treatment or life-sustaining procedures." (Emphasis added).
>
> Unfortunately, "medically inappropriate" and "medical judgment" are not defined.[8]

Physicians are not legally or ethically required to provide futile or medically inappropriate care. Unfortunately, what constitutes "futile" or "medically inappropriate" care may vary widely, depending on the patient's condition, the available resources, and the prevailing law of the state where care is taking place. Most states have the word "futile" in statutes involving the right of patients to refuse treatment or defining a patient who is a candidate for non-resuscitation[9], but there is no universal definition of "futile" or "medically inappropriate" care.

"Futility is difficult to quantify ... The concept also may mean different things to physicians than it does to patients and their surrogates. [P]hysicians frequently cite futility in recommending that life-sustaining therapy be foregone [and] some physicians have acknowledged that they have unilaterally withheld or withdrawn life support they considered futile without informing patients or their surrogates or despite their objections."[10]

"Futility" may be a concept that should be informed only by the physician's best medical judgment – the same medical judgment that would be questioned in a medical malpractice action. In a malpractice action, one essential question is whether the physician acted with that degree of care and skill required of a physician under similar conditions and like circumstances.[11] The Court of Appeal in *Causey* recognized that "[a] finding that treatment is 'medically inappropriate' by a consensus of physicians practicing in that speciality [sic] translates into a standard of care."[12] When a physician withholds or withdraws care due to "futility," the question is whether a physician in the same or similar circumstances would have done the same.

However, medical judgment must also be balanced against individual liberties. As stated by the Texas Court of Appeals in *T.L. v. Cook Children's Medical Center*, "while reasonable medical judgment may inform the decision, the deciding factor is ultimately the individual liberty interest of the patient in deciding that a natural death is the best treatment option."[13]

IV. Ethical Framework

Given this legal landscape, the medical ethical principle of Respect for Autonomy is held in high regard and often prioritized in care decisions, especially in Western medicine. However, allowing a patient or their surrogate to wholly drive medical care would be to abdicate treatment decisions to those lacking the expertise, judgment, and clinical context to determine the medi-

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cal appropriateness of intervention. The expression of a patient's autonomy vis-à-vis expressed preferences for treatment should be respected but must be balanced against other relevant considerations. It is in cases of medical futility or potentially nonbeneficial treatment where providers are reminded most acutely that Respect for Autonomy cannot be the sole measure by which complex medical decisions are made.

Following the aforementioned legal cases, the term futility has been limited to an extremely strict scope of application. As clarified in a 2015 multi-society statement on surrogate requests for potentially inappropriate treatments, "The term futile should only be used on the rare circumstance that an intervention simply cannot accomplish the intended physiologic goal. Providers should not provide futile interventions and should carefully explain the rationale for the refusal."[13] The stated goals of a patient or their surrogate may be fundamentally unachievable by way of medical science and thus *cannot* be supported, practically or ethically — for example, indefinite prolongation of life or the indefinite occupation of an ICU bed (which are both legally and ethically inappropriate). In such cases, the care team should assist in recalibrating the goals of care based on more realistic expectations.

On the other hand, potentially nonbeneficial treatments are those that *may* stand to confer some benefit, but medical providers feel that competing ethical considerations justify not providing them.[14] Per the ethical principle of Distributive Justice, which requires the fair allocation of scarce resources, the utilization of ICU care is justified by expected benefit derived from that resource. "The diversion of hospital resources to nonbeneficial care should not occur if there is credible threat to the health of other patients."[15] The Covid-19 pandemic proved a stark reminder of just how scarce the resources of the ICU can be and caused some soul-searching as to the calculus of maximizing benefit among competing individual interests.

Absent competing ethical considerations, it could be ethically supportable to initiate potentially nonbeneficial treatments given that they stand some chance of conferring a desired benefit. However, this treatment pathway may lead to consternation down the road when those benefits fail to be realized or are short lived. While it has been argued theoretically that withholding and withdrawing are ethically equivalent actions, in practice the act of removing supportive treatment can feel very much like causing death versus allowing a natural process to occur unimpeded by withholding intervention. Providers may hesitate to initiate an intervention if they see the treatment's eventual withdrawal as problematic. Alternatively, some interventions may be appropriate when initially offered and implemented, yet conditions may evolve that render the intervention increasingly inappropriate over time as its observed benefits wane and risks of harm increase. In both cases, the continued utilization of nonbeneficial interventions causes unjustifiable harm by only serving to postpone the inevitable and prolong an expected dying process.[16]

V. Current Legal Approaches

Cases involving the right to refuse — or continue — medical treatment when available medical evidence suggests no chance of recovery are dramatic and tragic, and these facts lead to conflicts between patients and physicians. Several states have enacted statutes regarding procedures to be followed when a physician determines that patient care is "futile," "medically ineffective," "medically inappropriate," or "ethically inappropriate." The statutes generally include caveats that determination of whether care is "medically inappropriate" should be based on medical condition only, and not on age, demographics, disability, or other prohibited categories. These statutes require a certain notice to the patient or the patient's surrogate and an opportunity for the patient to be transferred to a different provider. As noted by the Texas Court of Appeals, in reference to the case of an extremely ill minor child (but equally applicable in all cases involving the withdrawal of life-sustaining care): "[T]he decision to withdraw life-sustaining medical care from a desperately ill child is one that should rarely involve the courts … [T]he decision-making process should generally occur in the clinical setting without resort to the courts, but … courts should be available to assist in decision making when an impasse is reached."[17]

A. Historical Precedent for Statutes Addressing the Provision of Medically Inappropriate Care

Often referred to as the first "right to die" case, the New Jersey Supreme Court's opinion in *Matter of Quinlan*[18] set the initial framework for considering whether withdrawing care that was merely prolonging life through artificial means was appropriate. At the time of the case, Karen Ann Quinlan was twenty-two years old, lying in a "debilitated and allegedly moribund state" at a hospital in Danville, New Jersey. She was in a persistent vegetative state, a result of an anoxic brain injury, and her functions were maintained by a ventilator and artificial nutrition and hydration. Her father sought to be appointed as her guardian in order to "authorize the discontinuance of all extraordinary medical procedures … sustaining Karen's vital processes and hence her life, since these measures …

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present no hope of her eventual recovery."[19] Her physicians believed that doing so would amount to murder and had declined to remove these interventions. In describing the dilemma brought before them for adjudication, the New Jersey Supreme Court expressed a preference for ethics committees to assist in the decision-making in complex cases:

> The most appealing factor in the technique suggested by [Dr. Karen Teel] seems to us to be the diffusion of professional responsibility for decision, comparable in a way to the value of multi-judge courts in finally resolving on appeal difficult questions of law. Moreover, such a system would be protective to the hospital as well as the doctor in screening out, so to speak, a case which might be contaminated by less than worthy motivations of family or physician. In the real world and in relationship to the momentous decision contemplated, the value of additional views and diverse knowledge is apparent.[20]

Ultimately, the New Jersey Supreme Court determined that, upon the concurrence of Ms. Quinlan's guardian and family, her case should be referred to the hospital's Ethics Committee (or similar body) if her responsible attending physicians concluded that there is no reasonable possibility of Ms. Quinlan ever emerging from her persistent vegetative state and that life-sustaining interventions should be removed.[21] If the Ethics Committee then agreed with the physicians' determination, life-sustaining interventions could be removed without any civil or criminal liability on the part of anyone involved.[22] The Court further noted in a footnote that this process could be applied in other terminal medical situations that did *not* necessarily involve the "hopeless loss of cognitive or sapient life."[23]

Following *Quinlan*, the United States Supreme Court addressed the question of whether a state could put legal guardrails or standards of evidence around the withdrawal of life-sustaining treatment from a patient in a persistent vegetative state. The Supreme Court held that the State of Missouri's requirement that evidence of a patient's wishes be established by "clear and convincing evidence" was constitutionally supportable, and particularly noted that it was essential in cases of vulnerable patients who may have no surrogate to speak for them.[24]

The choice between life and death is a deeply personal decision of obvious and overwhelming finality. We believe Missouri may legitimately seek to safeguard the personal element of this choice through the imposition of heightened evidentiary requirements. It cannot be disputed that the Due Process Clause protects an interest in life as well as an interest in refusing life-sustaining medical treatment. Not all incompetent patients will have loved ones available to serve as surrogate decisionmakers. And even where family members are present, [t]here will, of course, be some unfortunate situations in which family members will not act to protect a patient. A State is entitled to guard against potential abuses in such situations. Similarly, a State is entitled to consider that a judicial proceeding to make a determination regarding an incompetent's wishes may very well not be an adversarial one, with the added guarantee of accurate factfinding that the adversary process brings with it. Finally, we think a State may properly decline to make judgments about the "quality" of life that a particular individual may enjoy, and simply assert an unqualified interest in the preservation of human life to be weighed against the constitutionally protected interests of the individual.[25]

Quinlan and Cruzan involved incapacitated adult patients. In *Miller v. Hospital Corporation of America*, the Texas Supreme Court considered a case in which the parents of a premature infant sued the hospital and physicians for battery and negligence when the doctors resuscitated the infant at birth.[26] The Texas Supreme Court held that the parents could not assert either claim as (1) the infant could not be fully evaluated for medical treatment until birth and (2) the attending physician was faced with emergent circumstances at birth (the child might survive with treatment but would likely die before either parental consent or a court order overriding the withholding of consent could be obtained).[27] After Karla Miller was admitted to the hospital in premature labor, her physicians discovered that she had an infection that could endanger her life and require them to induce delivery. The physicians explained to the parents that, if the infant was born alive, she would most likely suffer severe impairments including cerebral palsy, brain hemorrhaging, blindness, lung disease, pulmonary infections, and mental retardation. Mark Miller testified at trial that the physicians "told him they had never had such a premature infant live and that anything they did to sustain the infant's life would be guesswork." The Millers requested, prior to the infant's birth, that no heroic measures be performed.[28] The hospital asked Mr. Miller to sign a consent form allowing resuscitation of the infant according to HCA's policy of resuscitating infants over 500 grams, but Mr. Miller refused. All of these discussions happened in a span of hours, without time to seek a court order declaring the parties' rights.[29] At the time, the statutory protections afforded by Texas (see below) did not apply to minor patients.

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When the infant was born, she was emergently resuscitated and in fact suffered all the severe impairments that the physicians opined she would have. However, in finding that the Millers could not bring claims for battery and negligence, the Texas Supreme Court noted that, although parents generally have the right to make medical decisions for their children, those rights are not unfettered and may be subject to intervention by the state. Additionally, "a physician, who is confronted with emergent circumstances and provides life-sustaining treatment to a minor child, is not liable for not first obtaining consent from the parents."[30] The Supreme Court went on to state that, in the circumstances presented in this case, the infant could only be properly evaluated after she was born, and any decision the parents made before birth would be based on speculation, would not be fully informed, and would not be in the infant's best interest.[31] The case demonstrates an extreme conflict between the parents and the physicians, where the physicians made a unilateral decision regarding resuscitation without a collaborative discussion with the parents at the time of the infant's birth.

In other cases, plaintiffs have sought to *prevent* physicians from withholding or withdrawing life-sustaining treatment, particularly in the case of minor patients, even when such treatment may be medically inappropriate or futile. In some cases, even the government itself has attempted to intervene to prevent the withholding or withdrawing of life-sustaining treatment (especially where family members opposed to withdrawal have contacted government officials).[32] In *Matter of Baby K*,[33] the mother of a child born with anencephaly insisted that the child continue to receive mechanical breathing support whenever the infant developed difficulty breathing on her own. Anencephaly, as the Court noted, is a congenital malformation in which a major portion of the brain, skull, and scalp are missing. Baby K had basic brain stem functioning, but she was permanently unconscious due to a lack of a cerebrum. She had no cognitive abilities or awareness, and could not see, hear, or otherwise interact with her environment. Initially, when Baby K had difficulty breathing on her own, the hospital physicians placed her on a ventilator to provide time to confirm the diagnosis and speak to Baby K's mother about her condition. They recommended that Baby K only receive supportive care, noting that aggressive medical treatment would serve no palliative or therapeutic purpose. Unfortunately, the physicians and Baby K's mother did not reach an agreement as to the appropriate care for the infant. The hospital did not seek any court intervention at the time, but rather attempted to transfer Baby K to another hospital. No other hospital with a pediatric intensive care unit would accept the infant and, ultimately, Baby K was discharged to a nursing home.[34] Baby K was readmitted several times due to difficulty in breathing. The hospital sought court intervention to clarify whether it had an obligation under the Emergency Medical Treatment and Labor Act ("EMTALA") to stabilize Baby K every time she returned to the hospital.[35] Stating that "It is beyond the limits of our judicial function to address the moral or ethical propriety of providing emergency stabilizing medical treatment to anencephalic infants," the Fourth Circuit held that, under EMTALA's definitions, the hospital was required to provide stabilizing treatment — including treatment that the physicians believed was medically inappropriate — each time that Baby K presented to the hospital.[36]

B. Statutory Approaches

1. Texas Advance Directive Act

In 1999, Texas codified the Texas Advance Directives Act, a section of which provides that life-sustaining treatment may be withdrawn when the care is "futile." This statute is the most comprehensive of the statues regarding withholding or withdrawing care that is "futile" or "medically inappropriate." Section 166.046 provides a lengthy, involved process when an attending physician refuses to honor an advance directive of, or a healthcare or treatment decision made by or on behalf of, a patient who is incompetent or otherwise mentally or physically capable of communication.[37] Unlike other states that place decisional authority with the treating physician alone, or requiring concurrence of only one other physician, the Texas process culminates in a decision by an ethics or medical committee (of which the attending physician is not a member) as to whether it is "medically inappropriate" to continue life-sustaining treatment.[38] If the committee determines that it is "medically inappropriate," withdrawal of life-sustaining treatment is permitted but the physician and healthcare facility must continue to provide life-sustaining treatment for twenty-five days after the committee's decision is rendered and must make reasonable efforts to aid the patient or the patient's surrogate in transferring the patient to another physician or facility.[39] After those twenty-five days (unless extended further by court order), the physician and health care facility are protected by law from civil or criminal liability when treatment is withdrawn.[40]

When the committee meets to determine whether life-sustaining treatment is "medically inappropriate," the committee shall consider whether the provision of life-sustaining treatment:

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(1) will prolong the natural process of dying or hasten the patient's death;
(2) will result in substantial, irremediable, and objectively measurable physical pain that is not outweighed by the benefit of providing the treatment;
(3) is medically contraindicated such that the provision of the treatment seriously exacerbates life-threatening medical problems not outweighed by the benefit of providing the treatment;
(4) is consistent with the prevailing standard of care; or
(5) is contrary to the patient's clearly documented desires.

The committee shall consider the patient's well-being in conducting the review but may not make any judgment on the patient's quality of life.[41]

The Texas Court of Appeals noted that "medically inappropriate" standard employed by Section 166.046(e) of the Texas Advance Directives Act, "even when informed by reasonable medical judgment, fails to articulate an objective standard by which to decide that the patient's natural death is either [the patient's] chosen or best treatment option." Instead, the "medically inappropriate" standard authorizes the discontinuation of life-sustaining treatment solely upon the authoritative decision of the attending physician. "Stated differently, the statutorily-mandated committee review process decides whether a natural death is the best treatment option for the patient without reference to the opinion of either the unwilling patient or her unwilling designated representative."[42] The opinion of the patient and/or the surrogate is completely left out of the statutory review process, which leads to additional conflict with the providers.

2. Maryland Health Care Decisions Act

Maryland's Health Care Decisions Act contains a provision stating that a physician is not required to prescribe or render medical treatment to a patient that the physician or physician assistant determines to be ethically inappropriate[43] or medically ineffective.[44] To withhold or withdraw as medically ineffective a treatment that, under generally accepted medical practices is life-sustaining, the patient's attending physician and a second physician must certify in writing that the treatment is medically ineffective and the attending physician must inform the patient or the patient's agent or surrogate of the physician's decision. If the patient is being treated in the emergency department of a hospital and only one physician is available, the certification of a second physician is not required.[45]

3. Virginia Health Care Decisions Act

Enacted in 2008, well after the *Baby K* case, the Virginia Health Care Decisions Act contains a provision stating that "Nothing in this article shall be construed to require a physician to prescribe or render health care to a patient that the physician determines to be medically or ethically inappropriate. A determination of the medical or ethical inappropriateness of proposed health care shall be based solely on the patient's medical condition and not on the patient's age or other demographic status, disability, or diagnosis of persistent vegetative state."[46]

If a physician determines that the proposed health care, including life-sustaining treatment,[47] is medically or ethically inappropriate or is contrary to the request of the patient, the terms of a patient's advance directive, the decision of health care agent or legally authorized surrogate, or a Durable Do Not Resuscitate Order, the physician or his designee shall (1) document the physician's determination in the patient's medical record, (2) make a reasonable effort to inform the patient or the patient's agent or surrogate of such determination and the reasons therefor in writing, and (3) provide a copy of the hospital's written policies regarding review of decisions regarding the medical or ethical appropriateness of proposed health care. If the conflict between the physician and the patient or the patient's decision-maker remains unresolved after those efforts, the physician shall make a reasonable effort to transfer the patient to another physician or facility that is willing to comply with the request of the patient, the terms of the advance directive, the decision of an agent or surrogate, or a Durable Do Not Resuscitate Order and shall cooperate in transferring the patient to the physician or facility identified. The physician must provide the patient, their agent or surrogate with a reasonable time of not less than fourteen days after the date of documentation of medical or ethical inappropriateness in the patient's medical record to affect the transfer. During those fourteen days, the physician shall (1) continue to provide any life-sustaining treatment to the patient that is reasonably available to such physician, as requested by the patient or their agent/surrogate, and (2) the hospital in which the patient is receiving life-sustaining treatment shall facilitate prompt access to the patient's medical record (presumably for purposes of the proposed transfer).

If, at the end of the fourteen-day period, the conflict remains unresolved and the physician has been

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unable to transfer the patient after making reasonable efforts, the physician may cease to provide the treatment that the physician has determined to be medically or ethically inappropriate, subject to the right of court review by any party. However, artificial nutrition and hydration may be withdrawn or withheld only if, on the basis of physician's reasonable medical judgment, providing such artificial nutrition and hydration would (a) hasten the patient's death,[48] (b) be medically ineffective in prolonging life, or (c) be contrary to the clearly documented wishes of the patient, the terms of the patient's advance directive, or the decision of an agent or surrogate regarding the withholding of artificial nutrition or hydration. In all cases, care directed toward the patient's pain and comfort shall be provided.

The Virginia statute also considers the possibility of limited resources, or the illegality of providing certain treatments: "Nothing in this section shall require the provision of health care that the physician is physically or legally unable to provide or health care that the physician is physically or legally unable to provide without thereby denying the same health care to another patient."[49]

VI. A New Approach: Time-Limited Trials as the Standard of Care

The statutory approach to addressing withholding or withdrawing of "medically inappropriate" care, as discussed above, creates an almost automatic conflict between patients, surrogates, and medical providers. Such conflicts may be mitigated by time-limited trials: agreements between physicians and patients or families to use certain medical therapies over a defined period of time to see if the patient improves or deteriorates according to prespecified clinical outcomes.[50] The authors posit that interventions that stand to potentially deliver a defined goal or benefit but yield diminishing benefit over time are particularly amenable to being proposed within the framework of a time-limited trial, which allows for collaboration between patients or surrogates and the health care providers.

In a prospective quality improvement study conducted by Chang et al, providers were trained to use time-limited trials in their approach to engaging families in shared decision-making for medical ICU patients.[51] Compared to pre-intervention, use of time-limited trials was found to result in higher incidence and quality of family meetings with more frequent discussion of patient preferences, family values for care, and clinical markers of improvement. Utilizing time-limited trials also resulted in reduced median length of ICU stay and less frequent use of invasive ICU procedures while hospital mortality remained similar to the preintervention period, suggesting that time-limited trials did not lead to a premature withdrawal of care.

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Schenker et al identified that, where the concept of a time-limited trial is utilized, these discussions often failed to include essential components for the effective use of this decision-making model.[52] In their 2022 *Chest* article, Downer, et al. provide an excellent framework that addresses these necessary elements of a time-limited trial: TIME, or Truth about uncertainty in prognosis, Interval of time, Measure of improvement, and End or extend.[53]

The TIME framework allows providers to first communicate uncertainty in a patient's prognosis and potential risks and benefits of a particular intervention. Providers should "be clear and honest about what is known and what is not known, how this patient compares with others, and how this patient is different."[54] Next, providers will determine the medically reasonable amount of time after which one would expect to see improvement in the clinical condition. The provider should inform the patient or surrogate of the specific clinical measures that will be used to

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evaluate the patient's condition and the efficacy of the time-limited trial in the context of the patient's overall goals. Finally, the trial will end or be extended depending on the patient's clinical improvement (or lack thereof). If progress has been made, the trial might be extended; if not, providers should recommend (1) discontinuing the treatment because it will not help the patient reach their goal and (2) transitioning to comfort-focused care with the expectation that the patient will die.

A time-limited trial of a medical intervention accomplishes several important legal and ethical goals: (1) providing an opportunity to elicit the patient's goals of care; (2) promoting shared decision-making among patients and providers; (3) establishing objective clinical benchmarks to determine whether the interventions are meeting the agreed-upon goals of care; and (4) creating space for emotional responses to complex medical care decisions.

A. Time-Limited Trials Provide an Opportunity to Elicit Goals of Care

A time-limited trial requires discussion of the patient's goals and priorities. Patient-centered goals are not just preferences for specific treatments such as code status or initiation of dialysis.[55] Providers should seek to understand from the patient or surrogate what "recovery" would look like to them, in terms of an acceptable resulting quality of life. Downer, et al. note that it is necessary to establish goals initially for three reasons: (1) a time-limited trial may not be needed if the patient and family already perceive that the burdens of treatment outweigh the benefits and wish to shift to comfort-focused care; (2) to establish a common goal for the therapeutic intervention(s) that help to guide later decision-making; and (3) starting with an open conversation about values builds trust and aligns the medical team with the patient and family.[56]

Regarding the case of Mr. L.A., above, providers should learn from his family what his life was like before he came to the hospital. What did he love to do? Did he and his wife travel? Did they have children or grandchildren? Did he have pets? What did he do for employment, and what were his hobbies? Maybe Mr. L.A.'s wife would like him to be able to hike the Appalachian Trail in a few months – a trip they had talked about doing. Determining what recovery he would need to demonstrate to be able to go on that trip leads directly into a discussion about the goals of his care. Many legal disputes arise from a feeling that the provider did not care about the patient. Taking the time to explore who a patient *is* helps to build trust between providers and families.

B. Time-Limited Trials Promote Shared Decision-Making

The model of shared-decision making has come to be held as the gold standard of medical decision-making: the patient's expressed values, preferences, and goals for care are considered in the determination of medically available options and recommendations for treatment which are in turn offered for the patient's consideration. The Agency for Healthcare Research and Quality notes that "[s]hared decision-making occurs when a health care provider and a patient work together to make a health care decision that is best for the patient. The optimal decision takes into account evidence-based information about available options, the provider's knowledge and experience, and the patient's values and preferences."[57]

In cases where there is true uncertainty as to whether an intervention may achieve its goals, it would seem heavy-handed for the clinician to make the unilateral decision not to offer the intervention, especially where this might be against the patient or family's preference. On the other hand, relinquishing the decision fully to the patient or surrogate risks overburdening them with a choice that they lack the knowledge and expertise to make. Time-limited trials and the TIME framework bring together relevant stakeholders to develop a plan of care based on both clinical and humanistic considerations.

C. Time-Limited Trials Establish Objective Clinical Benchmarks

Bruce et al. differentiate between narrow and broad goals for time-limited trials, where narrow goals look at quantitative measures like trends and changes in lab values, level of ventilatory support, and dosing of vasopressor medications, while broad goals are concerned with more qualitative measures related to quality of life, such as levels of consciousness, interaction, and functional mobility.[58] The duration of a time-limited trial should be determined by the average time needed to demonstrate a response to an intervention in setting of a particular injury or illness, e.g., three days may be reasonable to expect demonstrated benefit of ventilation in congestive heart failure, whereas seven to fourteen days may be needed to assess the benefit of mechanical ventilation following a stroke.[59]

At the end of the specified time for a time-limited trial, providers should meet with the patient or surrogate and determine the perception of the results of the trial. If uncertainty remains, the trial may be extended for another specified, clearly defined time period (again, with clinical benchmarks to indicate

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whether the intervention is showing a benefit in line with the patient's goals of care). If the defined markers were not met, providers should shift the discussion to relief of suffering and a peaceful death.[60]

D. Addressing Emotions in Complex Care

Emotions tend to run high in the face of complex uncertainty and potential for death. The urgency often required in decision-making in critical illness and the tendency for decision-making in these contexts to be limited to dichotomous life-or-death options can prompt extreme emotional reactions ranging from outright conflict to decisional paralysis. Time-limited trials afford patients, families, and providers a much-needed pause and opportunity to develop clarity as they grapple with acknowledging the finitude of life, limitations of their moral agency, and the boundaries of medical knowledge.

Even though an expected poor prognosis may be evident to providers, families may have unrealistic expectations for recovery or hold out hope for a miracle. For families struggling with decision-making, allowing time for them to consider what is right for their loved one and thoughtfully weigh the benefits and burdens of treatment may enable them to comprehend the clinical reality and likelihood of dying.[61] Further, the framework of a time-limited trial can provide closure by helping families feel that all options for treatment of their loved one were duly explored. Time-limited trials address the problem of uncertainty by allowing for the patient's condition to further declare itself and can thereby alleviate the burden of decision-making experienced by the family.

Time-limited trials help with moral distress among providers as well. A period of collecting and evaluating serial objective metrics helps to provide clarity about the potential benefit of the intervention and supports more concrete prognostication. An agreed-upon end point is established at the outset of the time-limited trial, mitigating the anxiety and injustice providers may experience with the prospect of open-ended and indefinite provision of questionably beneficial treatment. Lastly, there is time to determine if providers will continue caring for the patient or give the patient time to be transferred to another provider.

VII. Case Study Revisited

In the case of Mr. L.A., the care team found themselves faced with his wife asserting an impossible goal: that of indefinite ICU care as necessitated by the EVD remaining in place. Neither of the apparent two options forward felt appropriate: it would feel wrong to remove the EVD over his wife's objection, and yet leaving it in indefinitely without any prospect of Mr. L.A.'s recovering also seemed to be inappropriate. The team consulted the Ethics Committee and conferred with the Legal Department. The family meetings that followed were heated and contentious. A time-limited trial may have prevented such a standoff from developing at two different points: with the initial placement of the EVD, and later with the failure to wean the EVD when VP shunt was determined not to be an option.

At the time that Mr. L.A. needed the EVD placed to address his critically high ICPs, three days after suffering a severe stroke, there was no question in his wife's mind of whether or not to proceed — she was not ready to lose him and would readily agree to any measure to save his life. Rather than posing EVD placement as an in-the-moment, life-or-death choice, utilizing a time limited trial would have provided the opportunity to clearly convey the uncertainty that the EVD will be effective, elicit Mr. L.A.'s goals of care, and establish objective metrics within a defined timeframe by which EVD placement would be judged as meeting those goals. Most importantly, the time limited trial allows for emotions to settle with the potential for non-recovery having being clearly communicated at the outset.

VIII. Recommendations

The authors acknowledge the difficulty of these conversations. To achieve the best outcome, providers must prepare for these conversations ahead of time.

- Conduct a team meeting, including any consulting specialists, before meeting with the patient and/or surrogate. Have a clear plan of what intervention(s) are medically indicated, who will be managing those intervention(s), and the risks and benefits of those intervention(s). Have a plan for who will act as the spokesperson in the family meeting.
- If a certain intervention requires consent forms to be signed, prepare those consent forms and bring the paperwork with you to the patient/surrogate meeting. Take the time to go over the paperwork and answer any additional questions.
- Use a clear framework for discussion and documentation, such as Downer, et al.'s TIME framework described above. Health care facilities and providers should prepare a form documenting the time-limited trial that the patient or surrogate signs. In the event of a later dispute, such a form may serve as evidence for the agreements reached with the patient or surrogate.

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IX. Conclusion

Any continuous medical intervention — ventilators, dialysis, chemotherapy, etc. — should only be offered on a time-limited basis. Laws related to withholding or withdrawing "futile," "medically inappropriate," or "ethically inappropriate" care (as previously described in this article) often create more uncertainty around the provision of care and put patients and their surrogates in a needlessly adversarial situation with providers. While the courts ultimately remain a potential option for intractable disputes, these disputes are less likely to arise where providers and patients or their surrogates have collaborated on a plan of care. Without understanding a patient's goals and priorities, providers cannot state with certainty that a potential treatment is "futile." At the same time, patients and their surrogates need to understand that there are limits to medical interventions, and that those interventions may not achieve the stated goals. In a time-limited trial, both sides work together toward a common understanding of the patient's situation and the effect that a particular intervention might have.

Note

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4. For the purpose of this paper, a "surrogate" refers to any person who makes decisions on behalf of a patient. A surrogate may be a health care agent designated in an advance directive, a decision-maker defined by statute, or a decision-maker appointed by a court (such as a guardian).
5. Cruzan by *Cruzan v. Dir., Missouri Dep't of Health*, 497 U.S. 261, 262 (1990).
6. Under a "substituted judgment" standard, the surrogate attempts to determine, with as much accuracy as possible, what decision the patient would make if they were able to do so. Under a "best interests" standard, the surrogate considers the decision a reasonable person would make under the patient's circumstances, considering the benefits and burdens of treatment.
7. *Causey v. St. Francis Med. Ctr*., 719 So. 2d 1072, 1075–76 (1998).
8. *Id.* (emphasis in original).
9. See, e.g., O.C.G.A. § 31-39-2(4) (listing a defining characteristic of a "candidate for nonresuscitation" in the context of cardiopulmonary resuscitation as "a person for whom cardiopulmonary resuscitation would be medically futile in that such resuscitation will likely be unsuccessful in restoring cardiac and respiratory function or will only restore cardiac and respiratory function for a brief period of time so that the patient will likely experience repeated need for cardiopulmonary resuscitation over a short period of time or that such resuscitation would be otherwise medically futile.")
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11. See, e.g., *Smith v. Finch*, 285 Ga. 709, 711, 681 S.E.2d 147, 149 (2009) (citations omitted) ("To establish professional medical negligence the evidence presented by the patient must show a violation of the degree of care and skill required of a physician. Such standard of care is that which, under similar conditions and like circumstances, is ordinarily employed by the medical profession generally.").
12. See *Causey*, 719 So. 22d, at 1076.
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25. *Id.*
26. *Miller ex rel. Miller v. HCA, Inc*., 118 S.W.3d 758 (Tex. 2003).
27. *Id.*
28. *Id.* at 762.
29. *Id.*
30. *Id*., at 767–68.
31. *Id*., at 769.
32. See, e.g., *Gilmore v. Finn*, 259 V.A. 448 (2000); *Schiavo ex rel. Schindler v. Schiavo*, 403 F.3d 1289, 1291 (11th Cir. 2005).
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43. MD. CODE ANN. § 5-611(A) (LexisNexis 2023).
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45. *Id.*
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