Beyond the Futility Argument: The Fair Process Approach and Time-Limited Trials for Managing Dialysis Conflict

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Summary
Futility is an ancient concept arising from Greek mythology that was resurrected for its medical application in the 1980s with the proliferation of many lifesaving technologies, including dialysis and renal transplantation. By that time, the domineering medical paternalism that characterized the pre-1960s physician–patient relationship morphed into assertive patient autonomy, and some patients began to claim the right to demand aggressive, high-technology interventions, despite physician disapproval. To counter this power struggle, the establishment of a precise definition of futility offered hope for a futility policy that would allow physicians to justify withholding or withdrawing treatment, despite patient and family objections. This article reviews the various attempts made to define medical futility and describes their limited applicability to dialysis. When futility concerns arise, physicians should recognize the opportunity to address conflict, using best practice communication skills. Physicians would also benefit from understanding the ethical principles of respect for patient autonomy, beneficence, nonmaleficence, justice, and professional integrity that underlie medical decision-making. Also reviewed is the use of a fair process approach or time-limited trial when conflict resolution cannot be achieved. These topics are addressed in the Renal Physician Association’s clinical practice guideline Shared Decision-Making in the Appropriate Initiation and Withdrawal from Dialysis, with which nephrologists should be well versed. A case presentation of intractable calciphylaxis in a new dialysis patient illustrates the pitfalls of physicians not fully appreciating the ethics of medical decision-making and failing to use effective conflict management approaches in the clinical practice guideline.


Case Presentation
Mrs. A, a divorced 57-year-old former nurse, was hospitalized 3 months for treatment of calciphylaxis-induced leg wounds. In the prior 3 months, she had resided in a transitional care unit or smaller community hospital for wound care. Her past medical history included diabetic retinopathy, neuropathy, and nephropathy; hemodialysis initiation 4 months into her illness for acute or chronic kidney failure; obesity despite vertical band gastroplasty; hypertension, hypercholesterolemia, previous myocardial infarction, and stenting; and remote breast cancer. She had never received warfarin, had normal parathyroid hormone and low 25-hydroxy vitamin D levels, and underwent a thorough negative serologic evaluation for an alternative diagnose to calciphylaxis. Extensive calciphylaxis treatments included two surgical debridement procedures, with one complicated by septic shock; daily wound treatments; sodium thiosulfate intravenously postdialysis; hyperbaric treatments complicated by tympanic membrane perforation; and intravenous antibiotics for multiple positive wound cultures, fever, and hypotension. The palliative care service addressed pain management and comfort care, although the patient wished for continuing dialysis, wound care, and cardiopulmonary resuscitation. Her stated goal was to live with and support her granddaughter and daughter, whom she believed to be in an abusive relationship with her son-in-law. Mrs. A’s hospital team sought transfer to a hospital with burn specialists with wound expertise. One hospital refused, stating that additional aggressive care would not benefit her. A second hospital’s burn surgeon accepted her care, unaware of her serum albumin being <1.5 g/dl, her wound extensiveness and intractability, and the prior refusal from another burn center. At the second hospital, the palliative care and nephrology services promptly engaged in pain management and family conferences to readdress goals of care. The patient’s son, her legal agent and only consistently involved family member, acknowledged lack of understanding of his mother’s prior clinical course and poor relationships between the patient and her family. Physicians informed the patient that she was not likely to survive, but she declined their recommendations for hemodialysis discontinuation and aggressive comfort care. All parties agreed to reassess the situation after 2 weeks, although no formal time-limited trial contract was established. After 2 weeks, the burn surgeons concluded that she had an ultimately incurable condition that additional surgery would not help. The nephrologists believed that continued dialysis was not appropriate but wanted Mrs. A to make the decision to discontinue dialysis. Mrs. A repeatedly stated, “I am only 57 and am
not ready to die” and expressed ongoing anger with her circumstances. Dialysis was continued, but all treating physicians agreed to not escalate care if she decompensated and placed a do not resuscitate order. After this 6-week hospitalization, she was transferred to an acute care rehabilitation hospital, where her wounds progressed in the ensuing month. Mrs. A became lethargic and lost decision-making capacity. Her son, acting as her legal agent, agreed to discontinue dialysis, and the patient died days later.

Introduction

The term futility derives from the Latin word futilis, meaning leaky. In Greek mythology, the daughters of Danaus were condemned in Hades to fill a bath with leaky sieves. Likewise, a futile medical intervention is ineffective and serves no meaningful purpose, no matter how often repeated (1,2). Although Hippocrates and Plato clearly denounced futile care in ancient medical writings (3,4), scholarly attention to the long dormant concept of medical futility reemerged in the mid-1980s and waned 10 years later, when it was clear that no universal definition could be established to give physicians the trump card (5) to end patient demands for aggressive medical care that seemed nonbeneficial. This article describes various futility discussions and applies them to dialysis, establishes a futility definition, uses prognostic data to resolve the debate, and addresses the supremacy of patient versus physician autonomy (6). To avoid physician–patient conflict, effective communication strategies are discussed. When these fail, resolving conflict disputes by a due process approach or time-limited trial is reviewed. The ethical principles of autonomy, beneficence, nonmaleficence, justice, and professional integrity underlying medical decision-making are integrated into the discussion.

The Futile Search for a Broadly Accepted and Useful Definition of Futility

Based on presumed common sense notions and widely accepted levels of probability, Schneiderman et al. (7) attempted to define futility both quantitatively and qualitatively. Their quantitative argument proposed that “when physicians conclude (either through personal experience, experiences shared with colleagues, or consideration of reported empiric data) that in the last 100 cases, a medical treatment has been useless, they should regard that treatment as futile” (7). They rationalized that, in most areas of medicine, physicians could attain a personal and literature experience of 100 cases and that a success standard of 1 in 100 is reasonable and consistent with clinical trials that conservatively use a 1 in 100 chance of an observation being clinically significant ($P=0.01$) (7). They also proposed that a medical treatment could be qualitatively futile and nonbeneficial if “it merely preserves permanent unconsciousness or fails to end total dependence on intensive medical care” (7). Examples are maintenance of a persistent vegetative state, constant ventilatory support, and ongoing intensive care nursing (1,7). They, furthermore, argued that, for an intervention to have benefit, an individual needs to have the cognitive capacity to appreciate the effects of treatments and that the goals of medicine are not “to preserve organ function, body parts, and physiologic activity” but to advance the health of the individual as a whole (7).

Under these definitions, physicians then would not be obligated to offer treatments to sustain this existence, and patients and families would have no right to demand them, although the physician may opt to temporarily do so on a compassionate basis to fulfill a short-term patient or family life goal. They believe that futility judgments fulfill a physician’s moral obligation of beneficence by only providing therapeutically beneficial treatments. Furthermore, they enjoin the medical profession to maintain this professional value or risk becoming a commercial business that exists to satisfy patients, families, and insurance companies (1,7).

The quantitative and qualitative approaches by Schneiderman et al. (7) received numerous criticisms. Because futility involves probability, no statistical threshold could be accepted. Even if the course of action is agreed on, physicians have been shown to be highly unreliable in estimating the likelihood of an intervention’s success and make unilateral decisions at 2% or even 5% success threshold (not 1% as was proposed) (2,7). Patients base their decisions on this potentially highly inaccurate information (8,9). Certainly patients or families differ on what constitutes an acceptable qualitative outcome and may believe that a 1% chance of success is worth pursuing in specific circumstances (2).

Numerous mathematical models to predict mortality have been developed, the Acute Physiology and Chronic Health Evaluation (3rd version) scoring system being the most notable. This version reported in 1991 included 17,440 random admissions to intensive care units in 40 hospitals. Unfortunately, the data were highly predictive for groups but not individuals and can only be seen as a tool to discuss futility and not designate a given treatment as being futile for an individual (6,10). Survival research for cardiopulmonary resuscitation, pediatric and neonatal intensive care, and hematologic cancers has improved prognostication accuracy for physicians in these areas, but their use in individual decision-making is still limited (6).

Because of the problems with physicians deciding what constitutes futility, communities or institutions have established their own standards for various circumstances. Defining the community itself can be problematic, and they as well as institutions must accommodate multiple opinions, outline special conditions, and update care approaches (11). Institutions have attempted to proactively define what constitutes futility, most notably for cardiopulmonary resuscitation (12-14).

With no consensus on a broad futility definition, efforts focused on whether patient or physician autonomy reigned, with physician autonomy being the right to refuse to provide medical care that physicians believed to be nonbeneficial. In “The illusion of futility in clinical practice,” Lantos et al. (15) argued that patients are best positioned to decide what is best for them and that futility is most appropriately assessed considering their opinions and goals (15). Others agreed that physicians may be more qualified to make judgments regarding the technical aspects of medical care but not the subjective assessments of futility (16). Echoing the sentiments of Schneiderman et al. (7), opponents voiced concern that physicians would lose their integrity and simply become agents of their patients’ wishes (6,17).
The diversity of values in our culture and the acknowledgment that futility assessments are value-laden have precluded the agreement on a futility definition except in the narrowest of terms (that is, physiologic futility) (2,8,18). Lo (2) describes three distinct conditions (Table 1) that justify physicians making unilateral decisions to withhold or withdraw interventions. According to Lo (2), because such interventions will not achieve their goal, physicians have no ethical obligation to provide them. Moreover, Lo (2) claims physicians have the ethical duty not to provide them.

As applied to the provision of dialysis, the distinction between feasibility and futility can be made. Feasibility addresses technical aspects, whereas futility addresses whether dialysis accomplishes its goal. Dialysis is usually not feasible because of the technical inability to obtain access or provide the treatment safely in the setting of profound hypotension. Unless serious medical comorbidities are present, dialysis usually can improve survival in acute kidney failure and ESRD patients. Dialysis is physiologically futile if the treatment fails to correct a metabolic or volume disorder or will not stave off imminent death (2,19). An example of futile dialysis is intractable hyperkalemia and lactic acidosis from irreparable bowel ischemia. In the case of Mrs. A, calciphylaxis treatments were futile, although dialysis was feasible. Dialysis was discontinued before it became nonfeasible from refractory hypotension.

**Communication Strategies to Understand and Avoid Physician–Patient Conflict**

Rather than invoking a futility argument when patients insist on everything or care that seems burdensome and ineffective, physicians should more closely elicit the patient’s values, life goals, opinion on acceptable quality of life, and understanding of her medical condition (18,20,21). Effective communication strategies have been shown to accomplish this goal and should be used in all shared decision-making discussions (20–24). Nephrologists have often received inadequate communication training. Consequently, CKD stages 3–5 patients have inconsistent preparation for making decisions regarding treatment modalities and had infrequent end-of-life care discussions with their nephrologists (23,25–27). Quill et al. (21) offer a step-wise communication approach (Figure 1) to address requests for burdensome, ineffective care. The first step is to understand the patient’s treatment philosophy—the prioritization of quantity of life versus minimization of suffering. Physicians should also probe for underlying fears of becoming sicker, concerns of physician abandonment or less vigilance if aggressive treatments are foregone, or ignorance of the true prognosis or limited benefit of treatments (21). Step 2 summarizes communication strategies, including permission to initiate the conversation. The ask–tell–ask approach gives information, and wish statements respond to unrealistic goals (20–23). Schell et al. (23) describe a communication skills workshop for nephrology fellows called NephroTalk, which further reviews these discussion strategies for difficult conversations on dialysis initiation and withdrawal. Neglecting to explore ongoing requests for nonbeneficial treatment may reinforce denial of how ill and near death patients are, potentially depriving them from working through the grieving process. They might suffer through treatments otherwise refused had they better understood their burdens and benefits (21,25).

A fair process approach, including its underlying ethical principles, was originally promoted by the Council on Ethical and Judicial Affairs of the American Medical Association (11) to resolve futility cases and has been well summarized (18–20,22,28,29). The Renal Physician Association (RPA) clinical practice guideline (22) adopted the proposal (Figure 2) to resolve conflict between patients and the kidney care team.

<table>
<thead>
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<th>Table 1. Conditions of physiologic futility with examples</th>
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<tr>
<td><strong>Conditions</strong></td>
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<td>No pathophysiological rationale exists for the intervention</td>
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<td>Example: Penicillin for treatment of methicillin-resistant <em>Staph aureus</em></td>
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<td>Refractory hypotension or hypoxemia causes cardiac arrest</td>
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<td>Example: Additional cardiopulmonary resuscitation in a mechanically ventilated patient on maximal vasopressors</td>
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<td>The intervention has previously failed in the patient</td>
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<td>Example: Attempting to declot a thrombosed dialysis fistula despite three attempts in the previous week</td>
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Modified from reference 2.
It specifically excludes the term futility to acknowledge the wide spectrum of opinions that physicians may have regarding what constitutes beneficial and harmful care. Shared decision-making, using previously outlined communication techniques, promotes the ethical principle of respecting patient autonomy. Respecting patient autonomy, however, does not mean that patients may insist on and receive any treatments that they desire. Patients only have a choice among medical options that physicians believe are likely to benefit their condition. The physician’s obligation is to fully inform patients about their medical conditions and prognosis as well as the risks and benefits of possible treatment options and offer only those treatments that have a reasonable expectation of providing benefit and avoiding undue harm. This information addresses the ethical principles of beneficence, nonmaleficence, and shared decision-making.
Families need to know that physicians, not families, are responsible for the dialysis decision when the benefit of dialysis is low and the burdens are high. Consensus does not need to be achieved through this process. Rather, families should feel that they provided meaningful input in the decision-making and had the opportunity to be heard. If the physician ultimately believes that the burden of dialysis outweighs its benefit, then professional integrity requires that physicians not provide it, and the patient and legal agent should be informed that dialysis will be withheld or withdrawn (19,20,22,28,29). The nephrologist may wish to make a comment such as, “While I have strongly considered and respect your wishes and viewpoints, as the ordering doctor, please understand that I must do what I believe is best for the patient. I cannot order dialysis, because it may be harmful, and doctors are obliged first to do

![Systematic approach to resolving conflict between patient and kidney care team](image-url)
A Middle Ground, the Time-Limited Trial

Regardless of whether conflict between physician recommendations and patient requests exists, a time-limited trial (TLT) may provide an acceptable option if a patient’s response to treatments is uncertain or burdensome treatments seems undesirable. To be effective, a TLT should be a written contract signed by both the physician and the patient or legal agent that specifies the duration of time with clear milestones that must be met for dialysis or other aggressive therapies to be continued. If clinical outcomes are achieved, therapy continues. If they are not, then the therapy (in this case, dialysis) is discontinued, and aggressive palliative care is provided (20,22). The typical duration of a TLT for AKI is several days to 2 weeks and 1–3 months for ESRD. At the completion of the TLT, if the treatment’s benefit remains uncertain, then another TLT may be proposed (22,31). Quill and Holloway (31) have summarized strategies for a successful TLT (Table 2).

TLTs have multiple benefits but are challenging to execute. Physicians are forced to develop consensus, set expectations, and speak with a unified voice at the outset. With ongoing care updates, families and patients receive less conflicting information and gain better insight into how physicians respectfully balance the benefits and burdens of treatments (31). TLTs may also be a more effective way of dealing with patients and families who want everything done versus attempting to unilaterally limit treatment (21). However, families also may have internal conflict or may be dysfunctional, making the establishment and eventual adherence to a TLT contract difficult (30). Mutual trust between family and care team members is essential, although it may be difficult to establish with such families (31). Unfortunately, achieving physician consensus can be problematic when many physicians and/or care teams are involved with any complex patient, particularly as physicians rotate within those teams. At the trial’s initiation, a written contract should list the patient’s symptoms, functional status, nutritional parameters, comorbid conditions, and trial outcomes justifying the continuation of dialysis. This documentation gives guidance, perspective, and authority to the new physicians assuming responsibility for the patient’s continuing treatment who are in the position to judge the trial’s success or failure (20). Although recommendation 7 of the RPA clinical practice guideline proposes a TLT of dialysis for patients in whom prognosis is uncertain or care consensus cannot be reached, supportive evidence and experience are lacking (22,31).

The Case of Mrs. A: Lessons Learned

Mrs. A’s medical saga of life-threatening calciphylaxis persisted for 9 months, with dialysis initiation 4 months into her illness. The physicians and medical staff who cared for her agreed that she suffered physical, social, and psychologic pain and did not have a good death. How did this event happen when capable and conscientious physicians, including palliative care teams, cared for her? First, Mrs. A, like the majority of CKD patients, had no advance directive to name and involve her legal agent and explore life goals to guide care decisions, not surprising given her challenging family relationships. Recommendation 4 of the RPA clinical practice guideline stresses the importance of patients with advanced CKD having such planning (22,26,27). After she could articulate her goal of not dying yet, physicians accepted it at face value and either did not probe further to understand Mrs. A’s emotional, spiritual, or social struggles and motivations or Mrs. A was not

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**Table 2. Key elements of time-limited trials (31)**

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<td>Define clinical problems and prognosis</td>
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<td>Achieve consensus among all involved physicians</td>
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<tr>
<td>Set limits on invasive treatments if unlikely to be beneficial</td>
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<tr>
<td>Identify the patient’s goals and life values</td>
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<tr>
<td>Review previous advance care planning decisions</td>
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<tr>
<td>Assess the patient’s competency and identify surrogate decision-maker if necessary</td>
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<tr>
<td>Clarify clinical measures of improvement or treatment failure</td>
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<tr>
<td>Obtain physician consensus for these measures</td>
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<tr>
<td>Link markers to signs readily apparent to patients and families</td>
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<tr>
<td>Provide regular family updates</td>
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<tr>
<td>Make a time frame</td>
</tr>
<tr>
<td>Consider patient’s condition, proposed interventions, and patient/family needs; reassess time frame as patient’s clinical condition changes</td>
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<tr>
<td>Identify possible consequences at the conclusion of the time-limited trial</td>
</tr>
<tr>
<td>Consider a written contract signed by all parties and list symptoms, functional status, nutritional parameters, and comorbid conditions at initiation</td>
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*Recommended by reference 20.*
cognitively able to engage in meaningful discussions because of narcotic use. Thereafter, physicians allowed respect for her autonomy to overrule their responsibility to provide beneficial and nonharmful care that acknowledged a just use of limited resources. Because no conflict of values was verbalized at the referring hospital and nephrologists were notably silent, her physicians concluded that she needed more technical expertise to continue respecting her autonomy. At the accepting hospital, physicians felt duped into agreeing to her transfer and obliged to continue with aggressive care for at least a limited time. The new nephrologists voiced that dialysis was not beneficial, because she would ultimately die from sepsis, but agreed to provide its support until the burn surgeons concluded that their treatments were futile. Unfortunately, no formal TLT was established, the surgeons could not reach consensus to justify stopping dialysis, and the nephrologists failed to realize that they, not the patient, were in charge of withdrawing dialysis in this circumstance. At both hospitals, use of more effective communication strategies to understand conflict as well as knowledge of the shared decision-making guideline recommendations to initiate or withdraw dialysis, resolve conflict with a due process approach, or consider a TLT would have altered Mrs. A’s treatment course considerably (22). At 1–3 months, a TLT could have been invoked when she initiated dialysis, with failure being defined as (1) the need for continued prolonged hospitalization or (2) wound progression despite aggressive treatment. Had the referring hospital pursued the conflict resolution path, then phone calls to tertiary care burn centers might have been made more transparently, knowing that a refusal from those centers still fulfilled their ethical obligation to Mrs. A. Likewise, the second hospital would not have needed to pasture her at an acute rehabilitation hospital. In both instances, Mrs. A would have been given the opportunity to accept her impending death, receive comfort centered care, and conduct life closure conversations with her family and friends.

Nephrologists have the professional responsibility to understand the ethics behind medical decision-making and know intimately the well-defined recommendations for initiating and discontinuing dialysis. They are uniquely poised to the persistence of other nonbeneficial treatments, as they wait for the end point of dialysis to become nonfeasible or futile. When nephrologists voice an alternative solution, caregivers, including nephrologists.

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References

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