



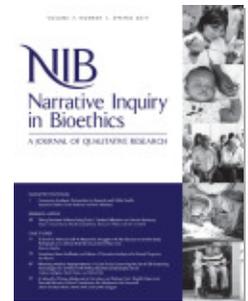
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Reframing Medical Appropriateness: A Case Study Concerning the Use of Life-Sustaining Technologies for a Patient With Profoundly Diminished Quality of Life

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Abstract. This case study considers the clinical ethics issues of medical appropriateness and quality of life for patients who are critically ill. The case involves a terminally ill cancer patient with a profoundly diminished quality of life and an extremely poor prognosis; his spouse desires to bring him home, where she will arrange to keep him alive for as long as possible via life-sustaining interventions. The analysis engages with the complicated notion of medical appropriateness, both in general and as it pertains to life-sustaining interventions in a critical care setting, and considers the ethical implications of the various ways in which one might understand this concept. It also addresses the significance of quality-of-life determinations, emphasizing the role of individualized values in determining the importance of quality of life for clinical decision-making. The discussion concludes with a description of the two strategies employed by the ethics team in helping to alleviate the medical team's concerns about this case.

Keywords. Case Study, Method, Clinical Ethics Focus

Case description

Steven B., a 70-year-old gentleman with Stage IV pancreatic cancer, was hospitalized in the Intensive Care Unit (ICU) for acute ischemic stroke, acute respiratory failure, and gastrointestinal bleeding. He had been intubated and had recently undergone tracheostomy. He was mostly unresponsive, although he did withdraw from painful stimuli on examination. He was receiving artificial nutrition

and hydration via a Dobhoff tube. Since Steven's admission to the ICU, he had been treated for *Klebsiella* bacteremia and atrial fibrillation. Although he had a history of a deep vein thrombosis and pulmonary embolism, prophylaxis was not possible due to thrombocytopenia and severe coagulopathy. He also had a history of vascular disease and cardiac arrhythmia, and he was status post multiple back surgeries to allow for extensive metallic stabilization of his spine. Prior to this admission, he was

receiving chemotherapy as part of a Phase 1 clinical trial. All of the members of Steven's medical team, including his primary oncologist, Phase 1 physician, and the attending ICU physician, agreed that he was exceedingly unlikely to have any meaningful recovery from his most recent neurological events. A transition to end-of-life care had been recommended to Steven's wife, who was at the bedside.

The couple had been married for over 30 years. They had no children, but Steven's wife described a significant support network of close friends, as well as her siblings and their families. They lived in a rural area of a nearby state, operating a highly successful business out of their home. Steven's wife was receptive to the physicians' discussion of her husband's poor prognosis, but she consistently reported that he wished to be kept alive as long as possible, regardless of his quality of life. He had not completed advance directive documents. She was therefore not in agreement with the recommended plan to transition Steven to end-of-life care, and instead expressed a desire to transport him back to their home, where she would arrange for him to be kept alive for as long as possible via life-sustaining technologies. Because they were extremely wealthy, Steven's wife was able to pay the cost of his care without incurring significant financial hardship. However, his medical team had already made arrangements for him to be transported via air ambulance to an ICU nearer to his home, in the hope that he would eventually be stable enough to return there, although most likely still requiring mechanical ventilation and artificial nutrition and hydration.

Several members of the ICU medical team expressed their concerns with Steven's wife's plan to transport him directly home so that he could be kept alive on a ventilator; in their view, attempting to do so would be "ridiculous," "pointless," and "medically inappropriate." They described her as being "in denial" and "not concerned with what's best for him (the patient)." An Ethics consult was requested by the ICU medical team in order to clarify goals of care, to determine whether or not returning to his home and being kept alive via life-sustaining technology would be consistent with the

patient's preferences so far as they were known, and to discuss whether the current plan of care was medically appropriate.

Discussion of ethical issues

This case raises a number of significant ethical issues. First, it allows us to better appreciate the complicated nature of the concept of medical appropriateness, both in general and as it pertains to the use of life-sustaining technologies for critically ill patients. Second, it illustrates the challenges that emerge when a patient's values and those of his or her family regarding quality of life are strongly at odds with the perspective of the medical team. We will begin by discussing the concepts of medical appropriateness and quality of life, as well as their respective ethical significance, both in general and within a critical care setting. The aim of this discussion is to help to illuminate how the Ethics team arrived at a recommendation concerning this case.

Medical appropriateness and life-sustaining interventions in critical care

In this case, the ICU medical team struggled to accept keeping this patient alive for as long as possible, via life-sustaining technology, as a medically appropriate goal of care. Thus one challenge for the Ethics team was to investigate the source of this struggle. We will begin here by discussing the concept of medical appropriateness and explaining its ethical significance.

In a clinical setting, members of a medical team may describe as "medically inappropriate" an intervention, a treatment—or, as in this case, a goal of care—with which they disagree or find objectionable. This term is not well defined, although the literature generally takes it to mean something like "contrary to sound medical judgment" or "inconsistent with the standards of medicine" (Alexander, Werner, & Ubel, 2004; Brook, 1994; Buetow, Sibbald, Cantrill, & Halliwell, 1997; Hicks, 1994; Murphy & Matchar, 1990). Its usage within a clinical setting indicates that it is something of a catch-all for several different, although closely related, claims.

Understanding the ways in which this term is used will help us to understand the sentiments of the medical team that, in this case, prolonging the patient's life indefinitely via life-sustaining interventions was not a medically appropriate goal of care.

Sometimes, the claim that a particular treatment or intervention is not medically appropriate is intended to express the belief that it would not be clinically effective. There are several reasons why a treatment or an intervention might not be clinically effective in a given case. First, it may be that the intervention in question does not alleviate the targeted condition or symptom. For example, one might regard the common practice of giving antibiotics to patients with a viral infection as an instance of medically inappropriate care in this sense, as antibiotics have virtually no clinical effect on viruses. Alternatively, it may be that the intervention in question is disproportionate, such as administering high-dose chemotherapy to a patient with localized melanoma. The risks and potential side effects associated with chemotherapy are not justified in such a case by the benefits that one may receive from the therapy; also, less risky alternatives are both available and known to be effective. In this case, high-dose chemotherapy is disproportionate because it is a clear case of over-treatment. Proportionality considerations can also be relevant in cases of under-treatment, such as when a proposed therapy is not sufficiently potent to achieve the desired results. For our purposes, then, claims about medical inappropriateness can sometimes be understood as claims about clinical effectiveness, which can be rooted in concerns about whether a proposed treatment affects the targeted symptom or condition, or be based on concerns about proportionality.

The claim that a particular intervention is not medically appropriate can also be understood as a claim about medical futility. "Medical futility," much like "medical appropriateness," is a term that is frequently used but not often well defined in a clinical setting (Brody & Halevy, 1995; Callahan, 1991; Cranford & Gostin, 1992; Truog, 2012; Youngner, 1988, 1990). In fact, the use of this term often

conflates two distinct concepts: quantitative versus qualitative futility (Callahan, 1991). A quantitatively futile intervention is one that is exceedingly unlikely to have the desired clinical effect. For example, the above example of providing antibiotics for viral infections is an instance of a quantitatively futile intervention. While the term "medical futility" is often mentioned in end-of-life and critical care situations, most life-sustaining interventions are not quantitatively futile in this setting. For example, a ventilator is often not a quantitatively futile intervention, even for the severely critically ill, because in most cases it does provide ongoing respiratory support. CPR, in contrast, often can be a quantitatively futile intervention in this setting, because it's well established that CPR is exceedingly unlikely to be effective among patients requiring critical care (Manthous, 2007; Murphy & Matchar, 1990; Truog et al., 2008; Truog et al., 2001). Many life-sustaining interventions, however, do continue to be clinically effective even for patients who are severely critically ill, and are therefore not quantitatively futile in such cases. For these reasons, it has been suggested that the term "futile" should only be used in the rare case in which an intervention cannot achieve its physiological goal (Bosslet et al., 2015).

Although many life-sustaining interventions are not *quantitatively* futile even for the severely critically ill, such interventions are often regarded as *qualitatively* futile by the medical team involved. A qualitatively futile intervention is one that is deemed to be of little to no value or worth (Callahan, 1991; Gallagher & Holmes, 2012; Moratti, 2009). Importantly, an intervention may be seen as qualitatively futile even in cases in which it will be clinically effective. For example, ventilator support for a severely critically ill patient is a clinically effective intervention, insofar as it supports respiration. However, ventilator support is often regarded as qualitatively futile for severely critically ill patients. For instance, imagine a patient with multi-organ failure and widespread metastatic cancer, whose breathing is being fully supported by a ventilator. Members of the medical team may regard continued respiratory support via the ventilator to be a qualitatively futile intervention, because the ventilator

does not affect the patient's underlying conditions and will not change the prognosis. As such, it's difficult to identify the value or purpose of this intervention, and as a result it may be regarded as qualitatively futile. Qualitative futility invariably involves a normative judgment that the end which a particular intervention is meant to achieve is of little to no value, and therefore not worth pursuing. Therefore, Bosslet et al. (2015) have recommended that what we are here calling "qualitatively futile" interventions should instead be referred to as "potentially inappropriate," in order to make it clear that such determinations involve an ethical judgment on the part of the clinician. Our intention here is not to recommend any particular semantic strategy regarding these concepts, but rather to describe the myriad ways in which the term "medically inappropriate" may be used in the clinical setting.

The differences between the various uses of the term "medically inappropriate" are not merely semantic—the conceptual distinctions that underlie this variation in usage have ethical significance within the clinical setting. In many cases, the fact that an intervention is medically inappropriate gives rise to an ethically significant reason not to provide it. For example, an intervention that is medically inappropriate in the sense that it does not target the condition for which it is being ordered—such as prescribing antibiotics for a viral infection—gives rise to a reason not to provide this intervention on the grounds that it is both nonbeneficial and potentially harmful, thereby violating two of the core ethical requirements of medicine (Beauchamp, 2007; Jecker, Jonsen, & Pearlman, 2007; Jonsen, Siegler, & Winsdale, 2010). On similar grounds, disproportionate interventions ought not to be provided. Further, there is an established consensus that quantitatively futile interventions are unethical, and should not be provided either, again based on concerns about potential harm and lack of benefit to the patient (Jecker & Pearlman, 1992; Jecker & Schneiderman, 1993; Schneiderman, 1994; Truog, 2012; Veatch, 2013).

However, the same cannot be said of interventions that are regarded as medically inappropriate in the sense of being qualitatively futile. While it is

sometimes claimed that qualitatively futile interventions should not be provided on ethical grounds, it is more frequently argued that clinically effective interventions cannot be justifiably withheld on grounds of qualitative futility, precisely because determinations of qualitative futility require a normative judgment about the value of a particular end, which may conflict with the values of patients and their families (Jox, Schaidler, Marckmann, & Borasio, 2012; Lantos et al., 1989; Lo, 1995; Veatch, 2013; Youngner, 1988, 1990). Withholding an intervention based on concerns about qualitative futility might be regarded as unduly paternalistic, since it places greater weight on the normative judgment of the physician regarding whether the intervention in question is worthwhile. So while many concerns about medical inappropriateness do give rise to a reason not to provide the intervention in question, this cannot be said of clinically effective interventions that are deemed medically inappropriate on the basis of concerns about qualitative futility.

Quality of life and the severely critically ill

As we've noted, part of the ICU team's struggle with the goal of keeping this patient alive as long as possible via life-sustaining technology was rooted in their discomfort with his wife's apparent lack of concern for his quality of life. This presented an additional challenge for the Ethics team. Let's briefly discuss the concept and ethical significance of the term "quality of life," both in general and as it pertains to life-sustaining interventions for patients who are severely critically ill.

Much like medical appropriateness, quality of life is a notoriously difficult concept to characterize. The World Health Organization recently adopted an account whereby quality of life is characterized in terms of one's own perceptions of how one's life is going. This assessment, they continue, is made from the perspective of one's culture and values, in light of one's goals, expectations, and concerns (WHOQOL group, 1995). On this account, to say that someone has a good quality of life is to say that that individual is generally satisfied with his or her life overall. A person who has a bad quality

of life, then, is one who is generally unsatisfied with his or her life overall. An individual's quality of life is therefore a function of that person's attitudes about his or her life. This attitudinal account is problematic in several ways. First, it implies that one cannot be mistaken about one's quality of life: it is good or bad, better or worse, depending on how one feels about it, irrespective of how one appears to be faring from the outside. Second, this account suggests that individuals who lack certain cognitive capacities, such as very young children, people with cognitive disabilities, or those who are either temporarily or permanently unconscious—effectively have no quality of life to speak of, since they lack the requisite capacities for making such an evaluation (Jonsen et al., 2010; Nussbaum & Sen, 1993; WHOQOL group, 1995).

Finally, this definition allows for a problematic degree of cultural variability regarding quality of life determinations. Since it posits that one's level of satisfaction with one's life is situated within one's culture and value systems, it becomes exceedingly difficult to make meaningful cross-cultural comparisons regarding quality of life. It can also lead to highly counter-intuitive conclusions about cases. For example, based solely on their respective attitudes about their lives, a healthy, well-educated individual with extensive opportunities for success may turn out to have a lesser quality of life than someone in comparatively poor health who struggles to meet his or her daily basic needs. Insofar as resources are allocated based on quality of life considerations, such counter-intuitive conclusions may support otherwise unjust resource allocation strategies.

Such concerns have led to the development of more objective, empirically based assessments of quality of life, whereby it's thought to be possible to evaluate a person's quality of life by considering features that tend to be significant for such an assessment. For instance, physical health, the ability to pursue and achieve one's goals, the opportunity to participate in political institutions, and the availability of resources are all empirically evaluable features of one's life, and they generally tend to correlate with one's general level of satisfaction

(Costanza et al., 2007; Jonsen et al., 2010; Nussbaum & Sen, 1993; Nussbaum, 2011; WHOQOL group, 1995). However, the various instruments for evaluating these purportedly objective measures of quality of life tend to be heavily scrutinized, in part because they are seen as biased in favor of certain conceptions of "the good life" as being preferable over others. Nevertheless, this sort of approach does help to address some of the concerns with the strictly attitudinal account discussed previously.

Empirical approaches to quality of life determinations can be especially important in cases involving individuals who are severely critically ill. In these situations, considerations such as prognosis and likelihood of meaningful recovery, ability to communicate and interact with others, ability to make decisions for oneself, ability to pursue meaningful ends, and freedom from pain and suffering are all relevant to evaluating an individual's quality of life (Jonsen et al., 2010). While it remains desirable to seek the patient's own perspective regarding quality of life in such cases, many critically ill patients are unable to communicate in any meaningful or reliable way, and advance care planning documents are often not specific enough to determine whether a particular set of conditions constitutes an unacceptable quality of life for a particular patient. Furthermore, surrogate decision-makers may have little to no knowledge of the patient's preferences regarding quality of life in a critical care setting, and may need to rely on these same objective parameters in determining whether their loved one's quality of life has become unacceptable.

Jonsen, Siegler, and Winslade (2010) offer three different terms for compromised quality of life that are useful in analyzing clinical ethics cases involving such conditions. *Restricted quality of life*, they claim, involves severe physical or mental deficits, which hinder one's ability to perform one or more common human activities. In most cases, they note, persons with a restricted quality of life remain largely satisfied with their lives, and their level of satisfaction can often be increased via relevant medical interventions. *Severely diminished quality of life*, in contrast, involves a serious and irreversible deterioration of one's physical and

mental condition. Persons with severely diminished quality of life frequently experience significant pain and suffering, and their ability to function and communicate is very limited. Such patients are often only minimally able to communicate about how satisfied they are with their lives, and in some cases even this is not possible. Finally, *profoundly diminished quality of life* involves extreme physical debilitation along with complete, irreversible loss of one's sensory and communicative capacities. Patients with profoundly diminished quality of life have no ability to communicate, and so are wholly unable to express whether or not they are satisfied with their lives

As Jonsen et al. point out, it's well known and empirically supported that most people regard severely or profoundly diminished quality of life as undesirable. Absent evidence to the contrary, one can reasonably presume that an individual whose quality of life is severely or profoundly diminished would not be satisfied with that quality of life. What's more, they note that in some cases, severely or profoundly diminished quality of life is a consideration that counts in favor of withholding or withdrawing life-sustaining interventions. Each case is different, as they rightly point out, and considerations such as patient and family preferences are also highly significant for making these decisions. However, it's worth noting that even in cases in which determinations regarding quality of life cannot be made via querying the patient, one can still make reasonable determinations about quality of life that are relevant for deciding whether it's ethically permissible to withhold or withdraw life-sustaining interventions.

Recommendations

As we've noted, the ICU team consulted with the Ethics team about this case because they were concerned that prolonging this patient's life indefinitely via life-sustaining technologies was a medically inappropriate goal of care. How should we interpret the medical inappropriateness claim being made by the medical team in this case? Discussions between various members of the medical team and the Ethics

team did not yield any substantive concerns about the clinical effectiveness of the interventions being provided. In most cases, these interventions were known to be effective in treating the targeted symptoms or conditions, and there were no significant concerns about proportionality. Rather, the prevailing sentiment among the members of the medical team was that the goal of taking this patient home, with life-sustaining technologies squarely in place, for the purpose of keeping him alive for an indefinite period of time was of no value. Therefore, any interventions aimed at helping him to move toward this goal were regarded as medically inappropriate, because the goal itself was deemed to be not worth pursuing.

The ethical significance of the claim that the life-sustaining interventions that this patient received were medically inappropriate, in the sense of being aimed at a qualitatively futile goal, is not immediately clear. On the one hand, because the concerns raised by the medical team are not about the clinical effectiveness of these interventions, but rather the value of providing them, there is no clear ethical directive regarding whether or not these interventions ought to be provided. As we've noted, concerns about qualitative futility do not themselves give rise to an ethical prohibition. Further, one can't plausibly claim that these interventions harm the patient without providing a corresponding benefit. In some cases, such as continued respiratory support via the ventilator, there is relatively little harm or risk for the patient, other than the elevated risk of infection associated with long-term ventilator support. And it would beg the question to insist that prolonging one's life, which the ventilator clearly does do, is not a benefit to the patient, since this presupposes that the goal of sustaining his or her life is not worthwhile. On the other hand, the patient's right to autonomy is not absolute, and does not oblige physicians to provide interventions that they deem to be medically inappropriate. In general, the determination that an intervention is medically inappropriate, in the sense of being qualitatively futile, does not immediately give rise to ethical obligations in either direction. Rather, it indicates a need for the involved parties to

reach a shared decision about the next steps in the patient's care, with a focus on identifying options that respect his or her values regarding being kept alive indefinitely via life-sustaining technologies, without compromising the integrity of the medical team, who feel strongly that the current goal of care for this patient is not worth pursuing.

The Ethics team employed several strategies in an effort to resolve the disagreement surrounding goals of care for Steven B. We focused on two strategies in particular. First, we sought to define more narrowly the goal of care as it pertained to our medical team. Next, we initiated a discussion about hierarchy of values, and pointed out ways in which the persistent disagreement about goals of care for this patient was rooted in differences between his and his spouse's hierarchy of values versus that of the medical team. Let's briefly discuss both of these strategies.

Our first strategy in resolving the conflict between the patient and his wife and the medical team was to define more narrowly, but also more accurately, the goals of care. While the long-term goal for Steven, as identified by his spouse, was to discharge him home with all required life-sustaining interventions firmly in place, this was not the goal of care for our medical team. Rather, they were charged with stabilizing him in preparation for transport via air ambulance to another ICU closer to his home. Setting aside the more long-term goal of discharge home, this is not an uncommon goal of care for many patients in our institution. Further, the claim that the goal of care for this patient was medically inappropriate, in the sense of being qualitatively futile, was undermined to some extent by the fact that he had already been accepted for admission to another ICU. This suggests a difference of medical opinion regarding the qualitative futility of Steven's long-term goal of care. For our purposes, however, the point is that however our medical team may have felt about the long-term goal of discharging him home to be sustained indefinitely via life-sustaining interventions, the goal of care that pertained to them was that of stabilization in preparation for transport. What's more, given the likely availability of additional support

from friends should he be moved closer to home, there was additional value in transporting him to the new ICU, apart from the stated long-term goal of discharge home.

The Ethics team also initiated a discussion with our medical team regarding the concept of "hierarchy of values," which refers to the ways in which individuals rank-order their value commitments. Often this is done informally, as one's hierarchy of values is usually expressed by one's choices rather than via a deliberative process. In this case, the most significant difference between the medical team and the patient and his family regarding hierarchy of values pertained to quality of life. The medical team believed that Steven's quality of life was, and would likely continue to be, profoundly diminished for the remainder of his life. And while his spouse did not disagree with this account, she held a different view regarding the importance of quality of life. While the medical team clearly held that Steven's profoundly diminished quality of life undermined the value of keeping him alive via life-sustaining interventions, quality of life was not a significant consideration for the patient and his spouse. While the medical team's hierarchy of values ranked quality of life as among the most ethically important considerations, it was effectively absent from the hierarchy of values of Steven and his wife.

Disposition

Following an extended stay in the intensive care unit, Steven was successfully transported via air ambulance to the ICU of a hospital closer to where he lived. It is unknown whether he was ever successfully discharged home.

Conclusion

The case presented here highlights the complicated nature of the concept of medical appropriateness, and draws our attention to the various ways in which this term might be used within a critical care setting. However, this discussion also illuminates the importance of clarity concerning our usage of the concept of medical appropriateness,

especially when deployed as a potential justification for withholding or withdrawing life-sustaining care. This case additionally draws our attention to the ethical significance of quality of life determinations in cases of severe, irreversible critical illness. But it also illustrates the need to situate quality of life within a broader narrative about the patient's hierarchy of values, and to remain open to the possibility that some patients may not value quality of life to the extent that we typically expect. By remaining open to the possibility that patients and their medical teams may reasonably disagree about the importance of quality of life, we are better able to accommodate the needs of patients who do not share our perspective. This openness, in turn, can help us to better appreciate why goals of care that seem medically inappropriate to some may not be regarded as such by patients and their families.

Reflection Questions

1. Is the goal of keeping a terminally ill patient, with a profoundly diminished quality of life, alive for as long as possible via life-sustaining technologies a medically appropriate goal of care?
2. Is "medical appropriateness" a useful term for conducting an ethical analysis of a particular case?
3. What is the ethical significance of a profoundly diminished quality of life for determining goals of care for a particular patient?
4. Do quality of life considerations ever outweigh patient or surrogate decision-maker preferences regarding the ethical justifiability of continuing with life-sustaining interventions?

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