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What does it mean to help: Ethics, Mental Health and Addiction in Cardiology Patients

J. Henriksen, K. Hjartardottir, K. Katzung

November 28, 2022

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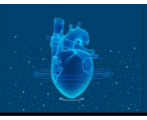

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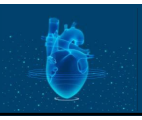

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Learning Objectives:

After this activity, learners should be able to:

- Name values in tension in cases where cardiology, mental health and addition problems intersect.
- Describe ethical considerations when developing plans of care for cardiology patients with complex psychosocial needs.

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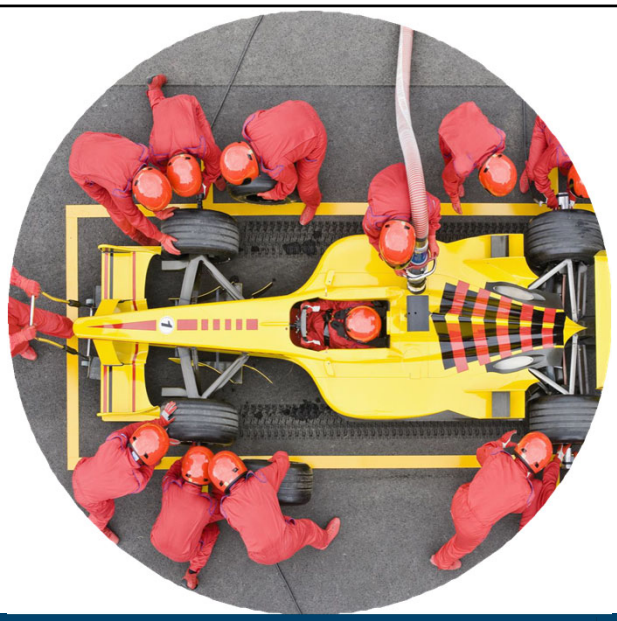
Beneficence

- Healthcare = doing good
- “Helping” can be complicated



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Additional Perspectives

- Scope of work
- Three questions we would ask
- Two traps to avoid
- One thing we might do or suggest

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Case Example

•44 year old male with history of end-stage dilated NICM s/p Heartmate 3 LVAD implantation four years ago.

- DM, HTN, CKD, anxiety and depression.
- chronic driveline infections and multiple surgical debridements.

•Hospitalized now with MSSA bacteremia felt to be incurable without system exchange along with ICD removal and lead extraction.

•Concern raised in AHF rounds about whether exchange should be offered given his poor glycemic control, obesity, recorded lack of adherence, and likely substance use.

- Began drinking in his mid-teens and drank 'on and off' for 20 years. Reported occasional cocaine, cannabis, and methamphetamine use. Denies use in last year. One drug test positive for amphetamines.

•He has continued to live independently in his apartment. His teenage son stays with ex-wife. Parents live nearby and help patient with general household needs.

- Stated consistently that he wants to live and will do whatever is necessary to continue being treated.

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Clinical Ethics

- Reflection on the Intersection of Values in Healthcare

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Work of Clinical Ethics

Identify	values at stake
Focus on	values in *tension*
Weigh	the priority of certain values over others
Highlight	reasons and reasoning

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Three Questions Ethics Will Ask

- What does the patient hold as most important?
- What does the patient see as acceptable quality of life?
- Would we reason the same way for different patient?

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Two Traps to Avoid

- Believing clinical judgments are only objective
- Layering on moral responsibility for behavior

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One thing to try

- Track the reasons and reasoning used in value-heavy decisions

The role of clinical ethics is to encourage clinicians to:
"to think of moral questions about therapeutic decisions as a matter of public analysis rather than a matter of intuition or private conscience protected by professional authority."
~*Margaret Urban Walker*

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Mental Health Impacting Medical Illness and Treatment

- Studies have confirmed that people with mental illness get less quality care than people without
- In some cases, symptoms of mental illnesses can cause difficulties with medical treatments
- Other factors also play a part; education, SUDs, higher risk of psychosocial issues

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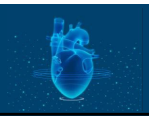

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Mental Health Impacting Adherence

- One of the most challenging feature in all of medicine
- Managing multimorbidity is the focus of most of our patients
- Depression has impact on adherence and rehospitalizations
- Treatment can cause anxiety, depression, and psychosocial issues
- But also, illness perception, physical functioning, social support, and more general health-related attitudes such as self-efficacy impact adherence greatly

Ladwig, et.al. (2022)

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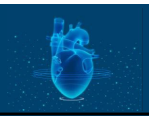

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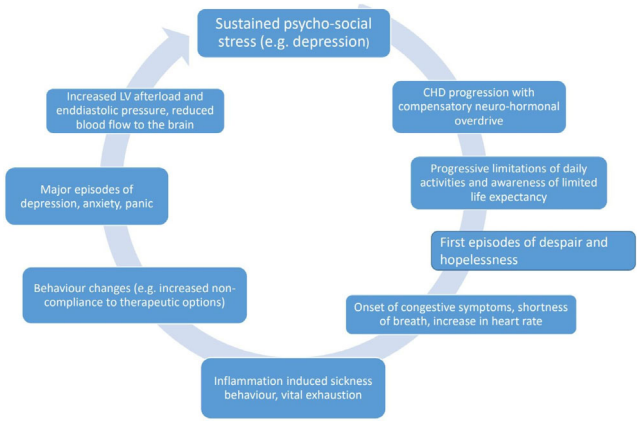

Ladwig, et.al. (2022)

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Other things to consider

- Mental illnesses do not always explain all the variables
- Adjustment following VAD placement is complicated
- Patients and caregivers experience anxiety and depression
- Illness denial not only for people with known mental illnesses
- Coping skills fluctuate with time and severity of illness

- Many heart failure patients are being seen by mental health and addiction medicine for the first time as they are being diagnosed with a life-threatening illness

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What do I do?

Assessment

Medication

Educator

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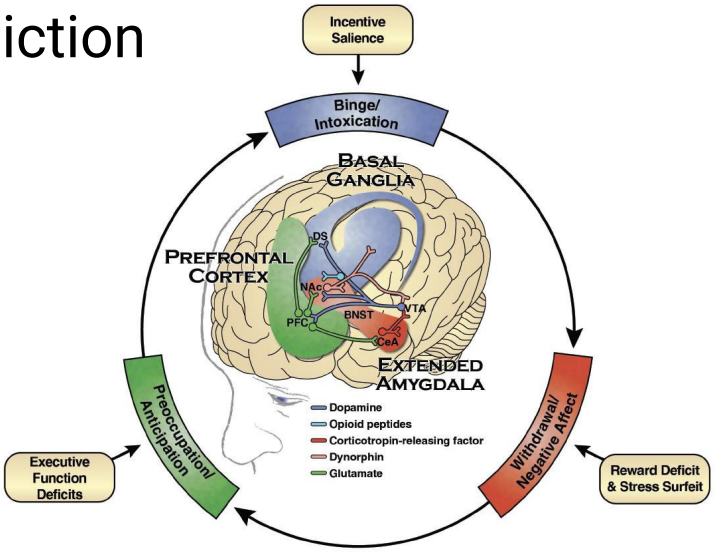
Neurobiology of Addiction

- Drug addiction is NOT a moral failing.
- Chronic, relapsing/remitting, disease with changes in brain structure & function.



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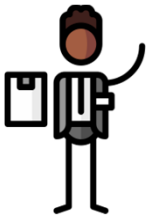
Who Else Do I Need To Help?



Social Work

Licensed Alcohol Drug Counselors (LADC)

Mental Health

Harm Reduction

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What I will ask…

Tell me your story…

Are you ready for change?

What have you tried & what has worked?

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Outcomes in Patients with Opioid Addiction

- Treatment retention rates (6-12 months) for patients on opioid agonist treatment range from 40-75%.
- Methadone maintenance superior to drug detoxification, 71% vs. 20%, for maintaining users in treatment.
- Cohort study of IV drug users with native IE:
  - 91% survival at 4 years, but 82% did not require surgery = less severe cohort.
  - Older studies – 60% mortality at 13 months, 45% mortality at 22 months.

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Traps to Avoid

1. Not treating their withdrawal.
2. Writing them off because they won't go along with the plan you have in mind for them or haven't been successful in the past. Meet them where they are NOW.
3. Minimizing the importance of social determinants of health & adverse childhood experiences on their current situation.
4. Not recognizing how your own biases contribute to the perceived experience.

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Debating Medical Utility, Not Futility: Ethical Dilemmas in Treating Critically Ill People Who Use Injection Drugs

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- Deplorable "Lifestyle Associated Condition" -- unconscious/conscious bias; independent of addiction, voluntary behaviors that lead to harm do not typically affect treatment decisions.
- Treatment Non-Adherance
- Low-Cost Effectiveness: accurately assessing "societal" costs in individual treatment is impractical/impossible.
- Poor Allocation of Scarce Resources: should only be considered *if critical scarcity of resources exists.*

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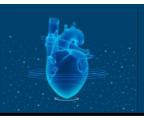

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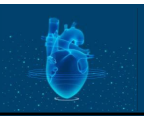

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Debating Medical Utility, Not Futility: Ethical Dilemmas in Treating Critically Ill People Who Use Injection Drugs

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INTRODUCTION

Physicians who care for critically ill opioid users frequently face legal and ethical questions related to the provision of life-saving medical care. A key question that arises for physicians caring for critically ill patients with severe opioid use disorders is whether the patient's condition is such that providing additional care has close to zero probability of being effective. Or very little benefit? Or does the expected outcome preclude any hope of a good quality of life? That is, would further care be "futile"?

The futility question has been considered extensively in the medical profession. Historically, general medical opinion has suggested the propriety of withholding certain medical treatments from people who inject opioids in some settings. For example, 1997 national guidelines for treatment of hepatitis C (HCV) suggested not treating injection drug users with antiviral medications until their "habits" are discontinued for at least six months, citing concerns of toxic treatment effects and non-adherence to therapy.[1] However, it was soon discovered that data supporting this recommendation were lacking,[2] raising the possibility that the guidelines might result in care being inappropriately withheld. More recent guidelines suggest that injection drug use alone should not be seen as a contraindication to provision of HCV treatment.[3] At the same time, however, injection drug use is thought to preclude certain other treatments. For example, recent guidelines for liver transplantation suggest that ongoing injection drug use is a contraindication to receiving an organ, citing concern for "behaviors harmful to health" that would presumably compromise the transplantation.[4]

We revisit a complex medical case[5] that raises important legal, ethical, and philosophical questions regarding the provision of life-saving care in individuals with relapsing injection

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drug use. We will use this case to explore—from medical, legal, and ethical perspectives—the care of critically ill people who use injection drugs and have life-threating conditions. We focus on a specific question: Is *futility* an appropriate and useful standard by which to determine provision of care to such individuals? Our goal is to establish guidance for hospital and legal systems to ensure consistent delivery of high quality, compassionate care for individuals with relapsed opioid use disorder and drug addiction more generally. The case also raises important philosophical questions regarding the fair distribution of scarce healthcare resources and whether futility is an appropriate standard by which to determine action. We conclude that although futility has been historically utilized as a justification for withholding care in certain settings, it is not a useful standard to apply in cases involving people who use injection drugs for non-medical purposes.

CASE PRESENTATION

A 43-year-old man with a history of intravenous heroin use and prior bacterial endocarditis (heart valve infection) requiring heart valve replacement presented to the hospital with complaints of fever and groin pain. Blood cultures grew fungus, and endocarditis was confirmed by echocardiography. Despite appropriate medical therapy with antibiotics, his hospital course was complicated by persistent fungemia (fungus in the blood) and circulatory shock (inadequate oxygen delivery to organs leading to organ failure). Further history revealed that he had returned to injecting opioids since his prior heart valve replacement. The medical intensive care unit (ICU) team determined that the patient's condition was fatal without surgical replacement of the infected heart valve. Two cardiothoracic surgeons were consulted and independently determined that the patient was **not a surgical candidate due to recidivism.** The ICU team consulted the hospital's Ethics Committee, which recommended proceeding with surgery.* Ultimately, the patient underwent heart valve replacement (performed by a third surgeon) and was discharged to a physical rehabilitation facility. The patient left the facility against medical advice and did not adhere to recommended medical treatment. He was re-admitted to the hospital one month later and was diagnosed with bacterial endocarditis. He died one week after hospitalization despite appropriate medical treatment.

[**Final medical decisions are typically made collectively among the patient, family members, physician providers, ethics committee, and hospital administration.]*

This case introduces an ethical dilemma commonly faced by physicians: has the disease progressed too far for further treatment to be effective? Is the treatment worse than the disease? Is effective treatment dependent on documented behavior change? Such dilemmas are encountered throughout medicine and are particularly challenging when they involve people with injection drug use. The decision for the ICU team, considering the patient's immediate condition, is clear; the patient needs surgery to survive and should get it without delay. The surgeons, who are consultants on the case, have a different perspective. The patient has returned to injection drug use despite already receiving a valve replacement for a similar condition. Opioid use disorder is a chronic, relapsing disease, and even if he receives yet another valve replacement, the endocarditis could recur yet again. The surgeons conclude that the patient is not a surgical candidate. Since the patient will certainly die

without the procedure, the surgeons implicitly invoked arguments of futility and non-maleficence to justify withholding care, though they stated that the reason for not offering the treatment was “recidivism.”

AN OVERVIEW OF OPIOID USE AND ADDICTION

Opioids derive from the opium poppy plant and have been consumed by humans for thousands of years.[6] They have been recognized both for their therapeutic potential in the relief of pain as well as their addictive properties. Opioids were first produced synthetically in the late 19th century and have been utilized both therapeutically and recreationally. This class of drugs acts neurologically to stimulate naturally occurring receptor targets in the brain.[7] In addition to blocking pain perception, opioid effects may include euphoria, sedation, and decreased breathing drive. At extremely high doses, opioids lead to loss of consciousness and respiratory failure.

Is Addiction Like Any Other Illness?

Drug addiction has traditionally been viewed as a moral failing, even by some within the medical profession, until relatively recently.[8] The traditional view suggested that drug use was a personal choice and that the activity could be stopped if only the person had sufficient motivation. We now know the neurobiology of addiction is best understood as a chronic disease of the brain, with changes in brain structure and function.[9] Motivation is certainly required to cease drug use, but is almost never sufficient by itself. Long term drug use leads to re-wiring of normal brain circuitry that can lead to persistent cravings. Tolerance quickly develops, requiring that more drug be administered to achieve the desired effect. Withdrawal symptoms that are quite dysphoric occur if the drug is not used after a period of time. Eventually, the addicted individual consumes the drug simply to relieve these symptoms in the absence of pleasurable drug effects

MEDICAL COMPLICATIONS OF OPIOID ADDICTION

Immediately life-threatening infections can occur as a result of non-sterile injection practices that are often connected with persistent injection drug use. Shared needles and syringes can introduce bacteria and fungus into the bloodstream, capable of infecting critical structures such as a *heart valve*, a condition known as *endocarditis*. These infections can cause perforation of the valve, leading to heart failure, respiratory failure, *circulatory shock*, which in turn may cause dangerously low blood pressure and decreased oxygen supply to vital organs. Circulatory shock is an immediately life-threatening condition that can rapidly cause death if inadequately treated. The typical indications for surgery in individuals with valve endocarditis includes heart failure related to valve dysfunction, valve abscess, heart block, infection caused by fungus or other highly resistant organism, and persistent blood stream infection.[10]

Chronic **infections** are another major complication of opioid addiction that occur in individuals who inject opioids. Injection drug use is a major risk factor for development of blood-borne infections such as HCV and the human immunodeficiency virus (HIV).[11] These infections typically progress slowly over time and can lead to devastating health

consequences. HCV can lead to liver failure and death,[12] while HIV destroys the body's immune system and is uniformly fatal if left untreated.

Finally, **respiratory failure** is the most immediate life-threatening complication, not of injection, but of opioid intoxication. Opioids reduce the brain's natural drive to initiate breaths, which can lead to the loss of oxygen delivery to vital organs, increased carbon dioxide blood levels, depressed consciousness, and ultimately death. This condition can be rapidly reversed with the use of naloxone, a drug that blocks the effects of opioids. Individuals who do not receive reversal of acute opioid effects or who fail to respond adequately to naloxone can still be saved by the initiation of mechanical ventilation, which is provided routinely in ICUs.

THE ROLE OF DATA IN CLINICAL DECISION MAKING: OUTCOMES IN PATIENTS WITH OPIOID ADDICTION

Physicians want to provide effective treatments when the patient is likely to receive significant benefit. Treatment plans may be based on experiential evidence, consensus guidelines or, more appropriately, evidence-based best practices. However, in some cases the evidence may be lacking or the physician may be unaware of the evidence or risk/benefit analysis. The key to optimizing medical decision-making is to make use of high quality medical data whenever possible. Unfortunately, when it comes to evaluating expected outcomes in injection drug users with valve infections, strong data are scarce.

Before addressing the case study set forth in the introduction to this article, we must address a broader question: what are typical treatment outcomes of patients with severe opioid use disorder independent of medical illnesses? A recent meta-analysis of 11 randomized clinical trials containing a total of 1,969 participants found that methadone maintenance therapy was superior to non-drug detoxification for maintaining users in treatment (71% vs. 20%) and reducing heroin use as measured by self-report (37% vs. 76%) and urine/hair analysis, but not different with respect to short-term mortality (1.0% vs. 2.4%).[13] Treatment retention rates (6-12 months) among those receiving opioid agonist treatment such as methadone or buprenorphine in clinical trials range from 40-75%.[14] Participants in clinical trials are healthier, of course, than those requiring hospitalization or surgery.

We need but do not have such robust data regarding likely treatment outcomes for sicker patients who inject drugs. Mathew et al.[15] conducted a cohort study of injection drug users from a single US hospital center who developed native valve infective endocarditis. Among 125 cases identified in a 4-year period, 91% survived. However, the vast majority (82%) did not require surgery, indicating their condition was less severe than the case we have presented. Other small case series have indicated relatively (though not uniformly) poor long-term outcomes for injection drug users following cardiac surgery. One older study noted a 60% mortality rate at 13 months,[16] while another study found that 45% had died within 22 months.[17]

The most specific data related to the case presented was reported just recently.[18] From 2001-2015, 41 French and Spanish hospitals identified 46 individuals who had developed

fungal endocarditis of an existing prosthetic heart valve. Nine (20%) of the individuals were using injection drugs. Forty one percent of the patients received surgery, while the remainder were treated with antifungal medical therapy alone. Thirty four percent died within 6 months, and 56% died during the entire follow-up period.

Overall, the quality of the available evidence to determine the likely outcome for a sick person who injects drugs and develops a severe infection is extremely limited by the small number of individuals studied, the design of the studies, and the lack of generalizability to specific populations (particularly those not affiliated with academic medical centers). The lack of evidence complicates decision-making, since there is more room for physicians to disagree about the course of treatment. Nonetheless, it is clear that neither medical outcomes nor treatment retention rates are uniformly negative for individuals with drug addiction (even in severe cases).

KEY LEGAL, MEDICAL AND ETHICAL ISSUES RAISED BY THE CASE

We now consider the legal and ethical issues related to our paradigm case patient, focusing specifically on the standard of medical futility. We conclude that the futility standard does not apply well to ill patients who use injection drugs, regardless of whether their drug use is new or recurrent. Our analysis leads us to embrace a more comprehensive and holistic approach to the management of these complex patients, taking into a consideration also how the likely advancement of addiction treatment will impact clinical decision-making in the future.

Futility : A Relevant Concept?

In the critical care setting especially, it is common for doctors to cite medical futility as a reason for withholding or removing life-sustaining measures such as mechanical ventilation or cardiopulmonary resuscitation (CPR).[19] In such cases, patients are thought to be too sick to benefit from the proposed care. In the case of a person who uses injection drugs, behavior necessarily influences the expected outcome. If the new prosthetic valve is going to become re-infected due to continued drug use, and require another surgery, one might consider the first procedure to be futile. Indeed, we find many instances in the literature discussing futility as a potential reason to withhold valve replacement surgery in these patients. Dating back to the 1980s, we find physicians who identify certain patients as “undesirable” and call for the provider to become a stronger “resource gatekeeper” for health care.[20]

In the literature, the situation of our case study has been called “psychosocial futility,” where the patient’s addiction, drug use, and other maladaptive behaviors threaten to compromise the patient’s physical health.[21] The discussion is not limited to US physicians. Multiple European physicians recently conducted a forum discussion on role that futility plays in our precise type of dilemma, where surgeons sometimes view the surgery as being futile.[22]

Yet on closer examination of our case, the idea of medical futility does not offer much guidance. There are three criteria most often used by bioethicists and state legislatures to define medical futility. Our case fails to fit any of the three, as explained further below and corroborated separately by others.[23] Moreover, our case is different in two crucial ways from

the usual futility situation. As we will demonstrate, futility laws are typically applied to the withdrawal of ongoing care, such as turning off a ventilator, rather than the refusal to initiate care, such as performing a surgery. (An important exception involves the question of the futility of CPR.) The classic patient in a futility dispute is also unconscious with no decision-making ability, while our patient may retain that capacity.

Medical Futility Statutes

Regulation of medical practice is primarily done at the state level. “Medical futility” is defined by the laws of individual states, each of which may define futility differently. The roots of many of these laws can be traced to a piece of model legislation promulgated in 1993 by the Uniform Law Commission, a national organization that drafts model laws for states to consider adopting. The Uniform Health-Care Decisions Act (UHCDA) was an influential piece of model legislation, and included provisions specifically designed to handle futility disputes.[24] In its original form, UHCDA suggested allowing providers to decline to provide care that would be “medically ineffective,” and care that is “contrary to applicable health-care standards.”[6] It defined “medically ineffective” as treatment that would not provide the patient “any significant benefit” but did not elaborate further on what that standard means.[25] The act also said physicians could decline to provide any type of treatment, as long as patients were properly informed of the decisions and associated medical risks.

As often occurs with draft uniform legislation from the Commission, no state has passed legislation identical to the UHCDA; instead, each has made its own modifications. States have restricted the situations in which providers can make decisions unilaterally against patients’ preferences and instituted different procedural requirements. These laws can be generally classified into three groups based on “traffic lights”.[26] “Red light” states forbid providers from ever unilaterally terminating treatment (Oklahoma[27]), while “green light” states expressly allow unilateral termination within certain limitations, and “yellow light” states (e.g., California[28]) provide ambiguous guidance that makes the situation resoundingly unclear. As Texas remains the only green light state in the U.S., most states have laws that do not provide any guarantee of protection to physicians against liability for ending treatment, perhaps causing risk-averse physicians to deliver more care to avoid lawsuits. Some state statutes even explicitly state that the calculus of whether to terminate care should not include how likely patients are to be harmed as a result of continued care, a subject of critical importance that will be re-visited below.

Thus under the regulatory regime in most states, physicians looking for legal guidance on how to handle our example patient will not find clear guidance. The most recent American College of Cardiology and American Heart Association guidelines make no specific recommendation on whether to offer surgery to a person with ongoing injection opioid use.[29] The common statutory command that physicians should adhere to the current accepted standard of care doesn’t settle the matter, as there is no accepted standard in this area. Instead, care is determined by custom and practice, which varies among providers.

Standards of Medical Futility

There is no consensus regarding the definition of futility in the medical community, bioethical community, or the public.[30] Nevertheless, there are three conceptions of futility that are commonly invoked: physiological, quantitative, and qualitative futility. After defining each below, we will explain why each is inapplicable to the facts of the case we are considering.

Physiological futility is a narrow definition that says the intervention is futile because there is a zero probability of it being effective. The determination can be made as a matter of science or empirical observation that the treatment simply does not work. Examples include antibiotic therapy for viral infections or lung transplant for appendicitis. Valve replacement surgery clearly does not satisfy this simplest definition, since the procedure can work as intended to fix the problem, at least temporarily; the infected valve will be removed and replaced with a new, uninfected one.

Quantitative futility relies on medical consensus to determine the likelihood that the intervention brings benefit to the patient. While with physiological futility there is no cogent expectation at all that the intervention will work, with quantitative futility there is some probability of effectiveness, but it is so low that the intervention is virtually futile and should not be tried. Putting this concept in probabilistic terms, it is preferable not to subject 500 patients to a treatment that is expected to work for one. At its core, a quantitative futility argument is one about probability and thresholds. Two questions must be answered: what is the probability of effectiveness for the intervention and how low of a probability is considered futile? The latter question is especially difficult to answer definitively, since any defined threshold risk risks being called arbitrary (and likely is).

In the case of our user of injection drugs, surgical valve replacement might be considered futile if the patient has become too ill to tolerate the procedure (such that he might die on the table or become unstable immediately after the operation). Yet as the data noted above indicate, outcomes for these types of patients are variable and certainly by no means uniformly fatal. Thus, we could not easily invoke quantitative futility in this case.

Qualitative futility is a situation in which even if the intervention works properly to achieve its intended outcome, the outcome or quality of life attained is inherently undesirable. For example, while a patient could be kept alive on artificial support in a persistent vegetative state for years, most providers and patient care advocates do not believe that to be a goal worth pursuing. This is a value judgment that could vary tremendously among providers and patients.

In the case of the user of injection drugs, the goal of the valve replacement is to cure the endocarditis and relieve the life-threatening condition of the patient. It is difficult to imagine that any medical professional would see this outcome as undesirable. It is conceivable that providers may view the status of continuing addiction in conjunction with the patient's overall medical illness as undesirable and might question whether the patient's quality of life following the surgery would be tolerable. It is also possible that the expected duration of the benefit of the surgery might be thought to affect its quality; but the expected duration in this

case is determined by statistical inference from data about how people who use injection drugs have previously done with the procedure, and this expectation applies only probabilistically and hence problematically to the case of a single, identifiable patient. In most cases, the patient's perception of his quality of life—even if that quality might be fleeting—will take precedence over the provider's personal values. Thus, qualitative futility cannot be determined unilaterally by providers. However, a collective determination of life quality might be possible when taking account of the preferences of patients, family members, and providers together.

Scope of Medical Futility Disputes—Few futility cases end up in state or federal court after private mediation processes fail to settle differences between the parties (which in most cases are the medical team, on the one hand, and members of the patient's family, on the other). The cases that are litigated overwhelmingly involve the very specific ICU situation in which 1) the patient is incapacitated, often on life support; 2) a surrogate decision-maker is engaging with providers; and 3) a medical decision was made to withdraw life-sustaining treatment.[31]

One recent lawsuit of this type was filed against our own affiliated academic center, Yale-New Haven Hospital. Helen Marsala, 76, was already on artificial life support when she was transferred to the hospital. Her husband advised that Helen had previously stated her desire to stay alive as long as possible even if on life support. Despite his insistence that the hospital "never pull the plug," the medical team consulted other physicians and an ethics committee, which decided that the care being provided for Marsala's weeks-long multi-organ failure was futile and should be stopped. After Marsala died, the family sued for negligent and intentional infliction of emotional distress, medical malpractice, and wrongful death. A state court struck all but the family's claim for intentional infliction of emotional distress, and the case then settled.[32]

Most discussion of medical futility in the literature involves this type of case. Of course, many cases are resolved in arbitration, or settled and never publicly reported. But the publicly litigated cases are dominated by Marsala-like scenarios. Thus, discussions of "medical futility" in academic journals or print journalism have been informed primarily by this type of scenario.[33] Judges have dismissed plaintiffs' claims on the basis that there was no professional gross negligence, that the emotional distress was inflicted on a bystander rather than directly on the patient, or that the allegations were duplicative in nature. In the context of futility disputes, these judgments make sense. For our valve replacement surgery patient, however, they do not apply so readily.

To our knowledge, there have been no litigated cases involving our paradigm patient scenario. We hypothesize some reasons for this. Difficult end-of-life decisions have had a constant presence in ICUs since life support systems became readily available in the 1960s. Patients who use injection drugs and require multiple surgeries due to recurrent endocarditis represent a relatively new problem in the last decade due to the recent opioid crisis. Since only a fraction of all disputes are ever litigated and each takes years to resolve, this could explain the relative dearth of litigated cases involving our scenario.

The second reason we may not see litigated cases that match our scenario is the growing resort to pre-litigation arbitration, which means that claims on this issue may simply not be public.

A third reason involves access to the legal system. The transactional costs of litigation are tremendously high. Injection drug use impacts people across demographic groups, but disproportionately affects those from lower socioeconomic backgrounds.[34] These individuals and families are among the least likely to pursue litigation due to their weak financial situations and social status. We note that the sheer magnitude of the current opioid addiction crisis could change these dynamics significantly, as there is already a more equal distribution of people across the economic spectrum using injection drugs in 2018 than was true even ten years ago.[35] As the number of people who use injection drugs continues to grow to a previously unseen level across the country, we may see more patients (or their families) capable of pursuing litigation

Do Futility Definitions Matter?—The reader may wonder why it is important to frame the issue as one of the existence *vel non* of medical futility. After all, when physicians say the procedure is "futile," they may only be using the term as a synonym for "useless," rather than invoking the medical definitions described above. Indeed, we do acknowledge that few physicians are literally referring to the existing legal and ethical framework when they speak of futility, whether in hospitals or medical journals. They may be simply stating their belief that the surgery will not "work" for the patient, however effectiveness is defined.

Yet having reviewed the three leading definitions of medical futility, the problems of applying the "useless" or "will not 'work'" standard are evident. Since the immediate outcome of prosthetic valve replacement surgery is known to functionally work (physiologic test), is statistically effective in a large number of cases (quantitative test), and helps the patient achieve a desirable quality of life (qualitative test), one cannot say that the procedure is medically futile.

Of course, most of the case law, like most of the discussion in the literature, deals with withdrawal of treatment (apart from DNR/CPR cases about emergency resuscitation), rather than our situation regarding whether the physician may refuse to initiate treatment. DNR decisions typically reflect a collaboration between the patient and physician in which both parties agree not to pursue resuscitation in the event of a cardiac arrest. In cases where patients and providers disagree on DNR status, providers may choose to provide limited resuscitation (even if felt to be unhelpful) or to involve a hospital ethics committee (e.g., "conscientious objection") to determine appropriate limitations of the care requested by the patient or surrogate decision-maker.

We are left, then, in a situation where even if the physician has a high suspicion that the procedure will not work long for the patient (because, e.g., the new valve will become infected due to subsequent injection drug use), futility is not a medical justification for declining treatment, and should not be presented as such in informing the patient and fellow providers, or in presenting the case in the literature. It is critical to be transparent about the clinical thought process as to why the surgery is medically contraindicated for each

particular patient. Understanding that the argument for medical futility is inapplicable also enables a more robust discussion of the case's ethical considerations, which the next section details.

Ethical Discussion

Though the medical futility framework, is inapplicable here, it has tended to overshadow other analytical perspectives that should be brought to bear on this complicated case. In a clinical scenario where drug addiction, harm reduction, victim blaming, treatment non-compliance, and lack of insurance *might* be relevant, it is somewhat odd that such a large portion of the academic conversation revolves around futility and subjective cost-benefit analyses. We therefore take a systematic approach of hypothesizing alternative justifications or rationales for why our patient might be denied surgery and evaluate whether these are ethically justifiable or contradictory. We have attempted to be comprehensive in our analysis without suggesting that certain reasons might be more relevant to physicians or used more commonly than other reasons.

Deplorable "Lifestyle-Associated Condition"—We start by directing attention to how our patient might differ from the many others whom physicians treat daily and assess whether there may be an inappropriately harsh standard being applied to people who use injection drugs. An ethics discussion about treating a patient who uses injection drugs should not be started de novo if there are significant similarities to settled ethical cases. Rather, if in significantly similar cases, ethical principles require that treatment be provided, then the default position must be that it is also provided to the person who uses injection drugs.

Unconscious and conscious biases against people with injection drug use may remain problematic in the clinical setting.[36] As previously discussed, a bias against this group of patients may be due to the long-held social narrative that drug addiction is a choice rather than a disease. As previously noted, the scientific evidence against this belief is now significant.

Yet ultimately, the clinical manifestation of substance use disorder is maladaptive behavior that causes harm to the individual using the drug. Independent of addiction, voluntary behaviors that lead to harm are ubiquitous and do not typically affect treatment decisions. For example, consider the chronic hiker who spends a lot of time outdoors without her legs, feet, head, and arms properly covered. She often removes ticks from her body. Perhaps she has been treated for tick-borne diseases many times before and now presents with life-threatening Lyme carditis from yet another tick bite. No physician would deny her antibiotic treatment even though she has a recurring infection triggered by her own actions. Similarly, the motorcyclist with recurring fractures is among many others in the realm of lifestyle-associated conditions that are regularly treated without hesitation. Thus, to the extent that outcomes depend on certain behaviors, the person who injects drugs is quite similar to others who are otherwise treated.[37]

It is true that the person who injects drugs is engaged in illegal activity, and this status indicates some socially-shared ethical disapproval of their actions. Hiking and motorcycling

are permitted activities, after all. But it's not clear how any appeal to the legal status of the underlying self-harming actions actually cuts. Hikers and motorcyclists, after all, can stop their self-harming activities at any time, whereas people who inject drugs have neurologic changes that hinder them from doing so. It may be that the person who injects drugs is less to blame for self-harm than the hiker or the motorcyclist.

Treatment Non-Adherence—Treatment non-adherence is a constant challenge for medical providers to navigate. Even the best plans, if not followed, bring no benefits to patients. A potential full treatment plan for our patient is to undergo the valve replacement, receive treatment for drug addiction, and ultimately abstain from injection drug use. Surgeons might refuse to operate on the grounds that recurrent injection drug use constitutes treatment non-adherence (or would make future non-adherence more likely). While non-adherence is certainly a reasonable concern as it pertains to the patient's ability to recover medically, we noted above that the outcome data show that at least not an inconsiderable minority of patients will be successfully retained in addiction treatment when given the opportunity. We cannot precisely predict which patients these will be, but there is certainly some reasonable probability of adherence to treatment and recovery. This might be reason enough to offer the valve replacement and subsequent substance use treatment if it were consistent with the patient's goals and expectations.

Yet even in the situation in which non-adherence is a virtually foregone conclusion, we still cannot justify permitting the patient to die. Just as addiction psychiatrists or internists agree to continue treating those with an inability or unwillingness to take their medications or follow through with other physician recommendations, other providers must do the same. Under the principle of beneficence, doctors do not generally decline to treat patients based on past non-adherence alone (especially in emergency situations), even though future non-adherence potentially compromises the patient's outcome. While we acknowledge that nearly all providers already agree with this sentiment, if physicians refuse prosthetic valve surgery because "the patient will just keep injecting drugs," they are essentially implying post-operation non-adherence itself is sufficient grounds to deny treatment.

Low Cost-Effectiveness—Cost effectiveness of treatment is critical to consider at the societal and policy levels, but not at the level of an individual physician, particularly in cases where care is emergent. Cardiothoracic surgeons have rightfully pointed out that the valves they replace may not last very long if reinfection occurs due to persistent injection drug use.[38] We may reasonably assume that the patient may struggle with his addiction and go through cycles of relapse and recovery. In a world of limited resources where high health care costs are absorbed by society, one could argue that while the procedure may not be quantitatively futile, it may nonetheless be a poor use of money that could be better spent elsewhere. Does the high cost of treatment combined with the potentially short-lasting effect *ethically* justify denial? No, at least not as it pertains to an individual treatment decision made between patients and providers. The physician will simply do what is best for the *patient* in the acute setting, while the costs of this action are distributed among third parties. The latter consideration is of no concern to the physician. We could perhaps imagine the burden imposed on an individual physician if she was asked not only to assess how the cost

of each treatment impacts an individual patient, but how it impacts everyone else ("society"). We quickly realize that accurately assessing "societal" costs in individual treatment decisions is not only impractical, but also impossible. So instead, physicians need only to consider the patient in front of them at that specific moment in time and ask the question: "What is the best thing to do for this patient at the present time." Determining what is "best" for the patient, of course, involves a holistic approach that considers the wishes of the patient, input from family members, and the physician's knowledge of the risks and benefits of the treatment.

We can think about this question theoretically by comparing costs of the surgery in this case to those of modern cancer treatments. The average newly approved cancer pharmaceutical now costs upwards of $200,000 per year[39] and many of these provide only additional weeks of benefit compared with previous treatments. The medical community has embraced and provided the new treatments (while denouncing the extremely high costs) with little debate on whether prescribing the next novel therapy to extend cancer survival by three months is cost-effective. The clinical standard is that individual physicians may prescribe the treatment if the patient is willing to receive it and can benefit.

The decision whether to provide the prosthetic valve procedure is similar. There is no reason for individual medical professionals to embrace one treatment over the other based on cost concerns alone. In fact, to praise one expensive treatment but snub the other could even be seen by the courts as discriminatory on the basis of disease. Willingness to provide only certain persons with some amount of additional time to live at whatever cost is not an ethically defensible position. The cost-effectiveness argument becomes even weaker if we assume our patient does not immediately re-infect the new valve and can benefit from treatment longer than do recipients of well-accepted aggressive cancer therapies.

Poor Allocation of Scarce Resources—Allocation of scarce resources must only be considered by the individual physician *if critical scarcity of the resource exists.* Organ transplantation is a key example of an extremely scarce resource for which patients of all types may never receive access. Those suffering from drug addiction are typically denied organ transplants due to the risk that ongoing drug use poses to the survival of the new organ. This decision typically comes down to a determination of who is most likely to benefit from the transplant. Although one might consider refusal of prosthetic valve surgery as an extension of this same logic, there are key differences between the two situations.

Human transplant organs are extremely scarce, while prosthetic cardiac valves are not. People are listed on waiting lists for common transplants such as kidney, liver, or heart sometimes for many years, while most valve replacement surgeries can be performed at any time. Thus, resource allocation in the transplant instance is immediately more critical. Misuse of a precious organ in an unsuitable recipient almost guarantees that someone else on the waiting list will die before another organ is available. If valves did in fact become immediately scarce or extremely expensive, a strategy to determine who is most likely to benefit from receiving the resource becomes relevant. While the endocarditis patient does require urgent treatment, it does not typically require denial of emergency treatment to someone else.

However, the physician's time itself should be considered a scarce resource that requires protection. In the case where multiple emergencies occurred simultaneously, decisions would be made to provide the needed service to the person most likely to benefit. The key difference between the two situations is the urgency of resource allocation. Organ transplantation typically requires making these decisions routinely, not at the discretion of an individual but rather by a complex process that seeks to reflect social consensus. In conclusion, surgeons have no duty to ration general health care resources, while transplant committees are tasked with the responsibility of distributing extremely rare organs.[40]

CONCLUDING THOUGHTS

While futility has been historically utilized as a justification for withholding care in certain settings, we conclude that it is not a useful standard to apply in cases involving critically ill patients who use injection drugs and require life-saving interventions, including those with repeated or relapsing use. The patient in the case presentation ultimately died despite receiving a second valve replacement. Retrospectively, it might appear that the decision to repeat the operation was ill-advised. The patient ultimately derived little benefit. The surgeon spent time that perhaps could have otherwise been spent caring for another patient. Society paid the cost of the medical care. But we frequently cannot predict outcomes accurately. Suppose the patient had recovered and achieved a remission from drug abuse for the next 30 years and became a productive member of society? If that were the case, we would have a very different conclusion. The repeat operation was life-saving and beneficial. The surgeon's time was put to optimal use. Society invested resources in an individual and it paid off well.

Legally, the case appears relatively clear: the physicians are under no obligation to provide treatments if they determine that the risks of the treatment itself outweigh the benefits. State laws vary as to how they define medical futility, but none compels physicians to do something they think will not help patients. Certainly, surgeons should not be required to provide a service if they believe it will cause more harm than good to the individual patient. Critically, however, "recidivism" alone cannot justify withholding care from a patient who has historically relapsed into injection drug use, because relapse does not render the care futile under any of the legal futility definitions. Ethically, we are ultimately left trying to answer a difficult question: what are the odds that the patient "does well?" Should we treat the patient if there is a 50% chance of improvement? 10%? 0.00001%? These questions link to the "quantitative" definition of futility described previously. At best, we are making an estimate because the available data simply do not tell us the answer. However, there is no room for moral judgments regarding the patient's behavioral patterns. This patient's behavior is due in most significant part to a disease of the brain. We must therefore think of this case just as we would if someone had cancer or a heart attack. The central question is: how likely is this patient to benefit from the proposed intervention? Yet even defining what constitutes a "benefit" is difficult. Is it enough to increase life expectancy by for 1 month? 1 year? 10 years? Must the patient be expected to have a subjectively good quality of life?

We are well advised to explore the patient's situation in a holistic manner. Perhaps the patient and/or a surrogate decision maker (i.e., a family member or close friend) can give us

more insight into the patient's quality of life. We might learn whether the patient has been relatively healthy until now, or whether he has suffered greatly and over a prolonged period as a result of his drug addiction. Family members may also be able to give us insight into the patient's future prospects, his support system, and what he might have to look forward to when he recovers. There is not clearly a "right" or "wrong" decision to make for our patient, but it is critical to recognize the reasoning for the decision. There must be a full consideration of the patient's underlying medical stability and likelihood of benefit from the procedure that involves the patient, family members, and caregivers.

Finally, we can imagine a future when addiction care has improved to the point where we no longer need to provide a second valve replacement. We can only accomplish this if we can definitively improve outcomes in people who use injection drugs. We must work to improve addiction treatment access and quality to help our patients achieve a sustained remission. We must ensure all our patients have access to maintenance medication such as methadone or buprenorphine, as well as adequate psychiatric care. We should significantly expand harm reduction initiatives such as needle-exchange programs, which reduce infection risk for people who use injection drugs. Indeed, widespread availability of clean needles would dramatically improve prognoses for surgical heart-valve replacement in injection drug users. Other novel approaches to be considered include supervised injection facilities, which are being piloted in other cities around the world. Harm reduction strategies are urgently needed in this time of rapidly rising opioid-related deaths. Time will tell whether these novel approaches to reducing the harms of opioid addiction will be successful. But most certainly, we must treat patients with life-threatening medical conditions who use injection drugs as completely and compassionately as we would treat any other illness.

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