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Repeat Valve Surgery in Recurrent Injection Drug Use Associated Infective Endocarditis: A Qualitative Study of Provider Attitudes and Approaches and a Normative Analysis of Relevant Bioethical Concepts

By

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I have reviewed this thesis. It represents work done by the author under my supervision and guidance.

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Abstract

Background: Despite growing awareness of the infectious complications of opioid use disorder there is little consensus on how to best treat injection drug use associated infective endocarditis (IDU-IE), particularly when patients present with recurrent infections that may require multiple valve surgeries. This is the first study to empirically examine differing attitudes and approaches towards this clinical and bioethical dilemma.

Objective: To explore the diversity of attitudes and approaches towards treating patients with recurrent IDU-IE with a focus on surgical decision-making.

Design: Qualitative approach with semi-structured interviews with healthcare providers at a single academic medical center.

Approach: We used an inductive, grounded theory approach to analyze interview data.

Participants: We selected a sample of 19 healthcare providers with experience caring for patients with IDU-IE across a variety of disciplines and departments.

Key Results: Three themes emerged from the interviews: 1) caring for patients with IDU-IE is especially challenging, 2) implicit and explicit bias remain pervasive, and 3) criteria for surgical decision-making are not transparent. When discussing surgical decision-making, participants relied on two predominant bioethical concepts: 1) futility and 2) rationing and the efficient use of resources.

Conclusions: There was a wide divergence of opinions on how to approach repeat valve surgeries, ranging from those who endorsed strict single surgery policies to those who felt patients should be offered as many surgeries as needed. Creating general principles for the care of recurrent IDU-IE may help provide more reliable, equitable and predictable care to these patients. The creation of reasonable guidelines requires input from an interdisciplinary group and should address not only empirical data but also the appropriateness of futility and rationing of care questions. Further normative analysis reveals that futility is unlikely to be a philosophically rigorous concept in these discussions and more thought must be given to how to discuss rationing with physicians and the public and how to apply its principles in these cases.

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Glossary

ACC: American College of Cardiology

AHA: American Heart Association

AMA: American Medical Association

HIV: human immunodeficiency virus

IDU: injection drug use

IDU-IE: injection drug use associated infective endocarditis

IE: infective endocarditis

IVDU: intravenous drug use

MAT: medication-assisted treatment

MRSA: methicillin resistant staph aureus

NHS: National Health Service

OPAT: outpatient parenteral antibiotic therapy

ODU: opioid use disorder

PICC: peripherally inserted central catheter

PWID: persons who inject drugs

Introduction

The opioid crisis continues across the United States. Deaths from unintentional drug overdoses have been increasing dramatically since the 1990s (1). The nature of epidemic has shifted over time: the initial rise of opioid deaths was largely associated with prescription opioid use (2). Beginning in around 2010, due in part to interventions aimed to reduce over-prescribing of opioids, prescription abuse began to fall, but rates of heroin use and overdose deaths increased dramatically (3–6). During this time, the demographics of heroin users also shifted: while historically heroin use has been concentrated in urban, African American populations, new users were more likely to be younger, Caucasian and in rural communities. In addition, new users were more likely to have been introduced to opioids via prescription drugs (7). A third phase of the epidemic began around 2013 as more and more overdose deaths were attributed not to heroin, but to synthetic opioids, particularly illicitly-manufactured fentanyl (see figure 1) (4,8). The crisis has continued despite growing public health attention: in 2017 Americans were more likely to die from an opioid overdose than from a motor vehicle accident for the first time in history (9). In addition to the burden of overdose deaths, infectious diseases are a considerable source of morbidity and mortality secondary to the opioid crisis, especially with the shift from prescription pharmaceuticals to injection drug use.

Injection drug use (IDU) has infectious complications that can largely be grouped into two categories: increased transmission of viruses such as hepatitis C and HIV which is largely linked to the sharing of needles, and increasing incidence of bacterial infections, such as skin abscesses, osteomyelitis and infective endocarditis (IE). Bacterial infections are associated with non-sterile drug preparation and injection practices, as well as the sharing of needles and other drug paraphernalia (10). While the public health implications of increasing incidence of hepatitis C and HIV among persons who inject drugs (PWID) are significant, this thesis will focus on the bacterial complications, particularly IE (11,12). Most bacterial infections in PWID are caused by commensal mouth and skin flora, notable *Staphylococcus aureus* and *Streptococcus* species, although outbreaks of more unusual organisms, such as *Pseudomonas* or *Candida* have been documented as well (10). It is difficult to measure overall infection rates among PWID as

many minor abscesses are self-treated, but the burden is undoubtedly high. A cross-sectional study of PWID in San Francisco found that 32% had had an abscess, cellulitis, or both (13). 36% of a sample of 1000 PWID in England reported an injection site infection in the last year (14). In the United States PWID are estimated to be 16x more likely to develop a methicillin resistant *Staphylococcus aureus* (MRSA) infection than the general population and in some samples, up to 10% of PWID have had a MRSA infection (15,16). Increasing hospital admissions for bacterial infections have been noted as an important consequence of increasing rates of IDU in the United States and United Kingdom (17,18).

Infective endocarditis has garnered particular attention as an increasingly common complication of IDU with considerable morbidity and mortality, as well as high costs of care. Baseline rates of IE in PWID are estimated to be 1.5 to 3.3 cases per 1000 PWID per year (19,20). It is thought that the inadvertent injection of particulate matter along with drugs can cause endothelial damage on the tricuspid valve (and if particulate matter is small enough to cross pulmonary capillaries, damage to mitral or aortic valves) leading to increased susceptibility of infection (21,22). HIV, infection at other sites, colonization with *S. Aureus*, increased frequency of IDU and a history of previous IE increase risk of IE in PWID (10,19,23). Injection drug use associated infective endocarditis (IDU-IE) rates have increased over the last two decades. From 2000 – 2013 the portion of all IE hospitalizations attributable to IDU increased significantly from 7 to 12.1% nationwide (24). This pattern has also been documented statewide using the North Carolina Hospital Discharge database, which showed that the incidence for IDU-IE increased twelvefold between 2010 and 2015, and in rural communities in New York and Southeastern United States where higher rates of IE were linked to increased IDU (25–27). Increasing incidence of IDU-IE has also changed the demographics of surgical practice: in North Carolina, for example, nearly half of all IE valve surgeries were due to IDU-IE between 2007 and 2017 (28).

Typically, IE is treated by a long (usually 6 week) course of intravenous antibiotics as well as valve repair or replacement surgery in indicated cases. The American Heart Association/American College of Cardiology (AHA/ACC) 2014 Guidelines for Management of Patients with Valvular Heart Disease, updated in 2017, strongly recommends early surgery (i.e.

during initial hospitalization, before completion of full antibiotic course) in those cases where patients are presenting with valve dysfunction leading to symptomatic heart failure, in left-sided IE caused by *S. aureus*, fungal, or other highly resistant organisms, in IE cases complicated by heart block, annular or aortic abscess, or destructive penetrating lesions, or in IE cases with persistent bacteremia or fevers despite appropriate microbial therapy (29,30). In-hospital mortality across all cases of IE remains high, between 10- 20% (31–33).

Treatment of IDU-IE is medically and surgically complicated. Medically, many cases of IE are managed with outpatient parenteral antibiotic therapy (OPAT) where patients can receive their intravenous antibiotics at home via a peripherally inserted central catheter (PICC) line. Traditionally PWID have been considered poor candidates for OPAT therapy, out of concern that they may inject drugs using the PICC line (34–37). Surgically, because prosthetic valve endocarditis is a serious complication with high rates of morbidity, physicians may be more hesitant to provide an initial valve replacement surgery in a patient with risks of relapse and reinfection due to IDU (38–40). However, the AHA/ACC guidelines do not make separate recommendations for IDU-IE. The European Society of Cardiology also does not offer explicit guidelines for this population, although it counsels a more conservative surgical approach, citing the higher rate of recurrent infection (41).

Valve surgery (as well as referral to addiction treatment) is associated with reduced mortality in first presentations of IDU-IE (42). Comparing IDU-IE to non IDU-IE patients, a 2018 meta-analysis found no significant difference in in-hospital or 30-day mortality (43). Mortality data is complicated to interpret, however, because in general, IDU-IE patients are younger and have fewer medical comorbidities than non IDU-IE patients (44–46). In retrospective studies comparing surgical outcomes Kim et al. and Kaiser et al. found similar long term mortality rates between IDU-IE and non IDU-IE populations, but higher reinfection rates in the IDU population (when correcting for age and other factors, outcomes were worse for IDUs in Kim et al. study) (44,47). In contrast, in their retrospective cohort, Rabkin et al. found significantly increased risk of mortality (but consequently lower risk of reinfection) among IDU-IE patients (45). Interestingly, Shrestha et al. found in their retrospective cohort of surgically treated IDU-IE patients, that there was a high-risk time of 90-180 days following surgery where IDU was

associated with higher rate of death and reoperation. Outside of that window, however, risks of death or reoperation were not significantly different (46). More research is also needed to characterize rates of reinfection in this population and understand pertinent risks and protective factors. Data on rates and outcomes of repeat operations in recurrent IDU-IE are particularly scarce (see table 1 for summary of available data on surgical outcomes in IDU-IE vs. non IDU-IE patients).

Rising incidence of IDU-IE also has notable financial implications. In general, patients with substance use disorders are more than twice as likely as others to be hospitalized (48). For a variety of reasons, care for IDU-IE can be particularly costly. In the review of North Carolina hospital discharges from 2010 - 2015, researchers found that in addition to the twelvefold increase in incidence of IDU-IE hospitalizations, the hospital costs for those patients increased eighteenfold, from \$1.1 million in 2010 to \$22.2 million in 2015. The median charge for an IDU-IE hospitalization was \$54,281 (25). Another study found that patients with IDU-IE had nearly twice as expensive hospitalizations as those with non IDU-IE (median cost \$47,899 vs. \$26,460) (23). This caused some to label increasing incidence of IDU-IE not just as a public health crisis, but as a “growing health care cost crisis” (49).

Given a lack of consensus guidelines, the scarcity of reliable and consistent outcomes research in this population, and the well documented costs of care, it is not surprising that there is an ongoing debate regarding the indications for surgery, especially in the setting of recurrent infection. Cardiac surgeons have expressed hesitancy to re-operate in this population given perceived risks of surgical complications, recurrent infections, and increased mortality (50–54). Physicians have debated the value of patient contracts at time of initial presentation and the ethical implications of denying patients surgery at re-presentation (55–58). Questions of futility and appropriate allocation of resources are also prevalent (52–54,58). This has thrust IDU-IE not only into a clinical spotlight, but also a bioethical one. There has been no empirical research examining how different healthcare providers understand and approach this ethical dilemma. In Part I of this thesis I will present qualitative research which seeks to elicit the diversity of attitudes regarding repeat surgeries for recurrent IDU-IE to understand the underlying ethical and clinical principles that ultimately guide surgical decision-making. In Part II

of this thesis, I will present an in-depth normative analysis of the major bioethical themes revealed in Part I – namely futility and rationing of care – as they apply to cases of repeat surgery for IDU-IE.

Methods

Study Design and Patient Population: We conducted a qualitative study consisting of 19 semi-structured interviews at a single large, urban, academic, tertiary medical center in Boston, MA. All materials and procedures were approved by the institutional review board of the hospital.

Participant Sampling and Recruitment: We identified and recruited staff members by contacting members of opioid and endocarditis working groups within the institution. We also directly contacted staff members on services that are routinely involved in the care of patients with IVDU-IE. The intention was to sample the diversity of providers involved in these cases, including nurses, social workers, advanced care providers (nurse practitioners and physicians assistants) and physicians from a variety of specialties. All participants provided written consent before participation.

Interview Procedure: We developed a semi-structured interview guide (see Appendix 1) in order to elicit the diversity of attitudes and approaches towards treating patients with recurrent IVDU-IE, with a focus on surgical decision-making. Interviews began with a case presentation of a patient with recurrent IVDU-IE presenting with persistent bacteremia and worsening heart failure. We piloted the interview guide on experts in bioethics and addiction medicine and revised the guide based on feedback. We obtained written consent from all participants prior to the interviews, which were recorded and lasted between 20 and 50 minutes. Participants were recruited and interviews were completed until thematic saturation was reached.

Qualitative Analysis: We transcribed interviews and analyzed them using a grounded theory, inductive approach. Grounded theory allows for the generation of theory from primary data from individual interviews rather than from preconceived notions from the research team or others (59). One author (MH) developed an initial coding book which was refined and revised by a second author (AM). Both authors coded all interviews using qualitative analysis software (NVivo). Coded interviews were discussed together, and final definitions were agreed upon as a

research team. Codes were condensed and consolidated into final emergent themes via an iterative process with input from both study authors (MH and AM).

Results

We interviewed 19 hospital providers from a range of positions (12 physicians, 3 social workers, 2 registered nurses, 2 advanced practice providers) and across a range of primary departmental affiliations (cardiothoracic surgery (4), psychiatry (4), infectious disease (3), hospital medicine (2), internal medicine house staff (2), cardiology (1), nursing (1), transplant surgery (1) and ethics (1)). In discussing the challenges of caring for patients with recurrent IDU-IE, participants described a variety of experiences and moral and ethical frameworks. Attitudes on the appropriateness of repeat surgeries ranged from some participants advocating “one and done” approaches: *“I can put you through this operation, I can do the operation again but ... I’m not doing anybody any favors and so later on I will have a patient who comes in a second time and I say I’m not doing anything, I’m just not going to operate on you”* [19]. Others argued that surgical decision-making should be guided by medical risk alone: *“I don’t think someone should have treatment withheld because they suffer from that disorder even if they are going to continue suffering from it, unless it’s truly a greater risk to them medically to have that surgery done”* [15].

As participants reflected on their own experiences with these cases, three qualitative themes emerged: 1) Caring for patients with IDU-IE presents unique challenges resulting from the addiction and associated psychosocial factors, 2) explicit and implicit bias remain pervasive, and 3) criteria for surgical decision-making are not transparent, consistent, or uniform across providers (table 2). In discussing the underlying values guiding surgical decision-making, two bioethical concepts dominated: 1) futility and 2) rationing (table 3). Differing assessments of these parameters lead to conflicting opinions on the appropriateness of repeated surgery for patients with recurrent IDU-IE (figure 2).

Theme 1: A challenging population

Providers widely endorsed that caring for patients with IDU-IE is especially challenging due to medical and social complexity as well as the associated emotional burden. Debates and disagreements about pain control (e.g. how to treat acute pain in the setting of opioid use disorder (OUD), how to assess if a patient was “drug seeking”) and behavioral issues (e.g.

hostility towards providers, violating hospital rules) contributed to this emotional toll. Some participants struggled to relate to these patients, citing poor eating habits or alcohol use as relatable behaviors but IDU as foreign or “reckless.” These factors led to a lack of trust from the onset of the clinical encounter: a participant spoke of *“the tension of having to walk into the room and start to doubt the relationship ... right out of the gates, to wonder if the person is going to be honest with you”* [16]. For many, OUD was perceived as a deadly force that led to a feeling of impotence: *“they are dying left and right. The stakes are really high and there’s that feeling of helplessness that comes that just makes providers...hate it. They hate feeling helpless”* [1]. Many participants also stated they had had little formal training in treating this population. Together, these factors led feelings of powerlessness and burn out when caring for patients with IDU-IE.

Theme 2: Explicit and implicit bias remain pervasive

Despite universal endorsement of the concept of addiction as a disease, providers acknowledged that PWID have historically been treated differently than other patients: *“I think that people who have drug problems are judged much more harshly and I think that’s just because you’ve been trained that there’s some sort of moral failing”* [8]. Many participants noted improvement in the healthcare system’s ability to respond to and care for these patients over time. Providers acknowledged that regardless of stated beliefs or intentions and progress over time, unconscious or implicit bias was still pervasive.

At times, participants also presented viewpoints which perpetuated the ideas that IDU is the result of a moral failing rather than a treatable medical condition: *“So I think if there is a medical reason why they are failing then do as many medical things as make sense ... that said, if the person is sabotaging their own success... I think we have an ethical responsibility and professional responsibility to say, is this the right thing to do?”* [13]. The addiction as chronic disease model did not preclude participants from viewing personal responsibility as an important factor in OUD: *“It starts out as free will I think. It starts out as a bad habit and then becomes physiological dependence. So it’s a combination of both. So if you didn’t do the first part then the body doesn’t become dependent”* [18].

Theme 3: Criteria for surgical decision making are not transparent

Debate and disagreement about surgical candidacy were common. Conflict was sometimes present between medical teams, who advocated for surgery, and surgical teams who were more reluctant to operate. Despite this, there was acknowledgement of each side's perspective and a sense of respect between providers. Decisions were primarily made by the cardiac surgeon and other members of the care team were largely deferential to these decisions. Participants contrasted this process with decision making around other similarly resource-intensive surgical decisions such as liver transplants or the use of ventricular assist devices, where decision making is more interdisciplinary. Because there were no clear criteria for valve surgery in IDU-IE, surgical decisions were often unpredictable and surgeon-specific. This led one provider to recommend surgical evaluation elsewhere when a surgery was indicated but declined by one surgeon: *"at a certain time where it should no longer be the whim of somebody's decision, it should be based on the medical merits of the case"* [2]. While this uncertainty was a point of frustration, participants were skeptical of the role of strict rules in determining surgery eligibility and felt strongly that decisions should be made on a case-by-case basis.

Key Bioethical Concept 1: Futility

While every repeat valve surgery is a technically challenging case, cases related to recurrent IDU-IE present additional challenges due to questions of futility and a patient's inherent "surgical candidacy" given their underlying OUD: *"Once the decision is made, they are like any patient, whatever needs to be done, we do it ... You give them the best chance possible. The problem is the decision making"* [18]. A "futile" surgery - or one that was destined to fail - could be defined as a surgery where a patient was at significant risk of not surviving the operation or the immediate recovery. Disagreement was less often related to this short-term prognosis, but rather ensued because of differing opinions on the chance of meaningful long-term recovery in the setting of ongoing drug use. For some participants, a surgery was considered successful if it gave patients another opportunity to recover from OUD. Therefore,

some participants gauged futility not by a patient's history of previous surgeries or substance use, but by their present level of hope, engagement and desire for recovery: *"I think sometimes it can be futile ... it's not the number of valves that indicates that, it's where the patient is at, their level of hopelessness"* [1].

For others, a surgery was successful only if the patient survived the immediate intervention and never returned to intravenous drug use. Given this definition of success, any re-presentation proved the prior intervention to be futile. This perspective fueled a "one and done" philosophy: *"It's hard to see patients that have had a valve come back and look so bad and need another valve replacement. I think I've felt the team's frustration and the surgeon's frustration in thinking is this the best thing we are doing? And is this patient ultimately going to die?"* [12]. Participants with this philosophy viewed patients with IDU-IE as unlikely to recover from their addiction and thus surgery would not change the ultimate outcome, even if lifesaving in the short term.

Other participants felt that it was inappropriate to assess these cases on a futility standard, citing that the concept contradicts the idea that recovery can happen at any point and that it's nearly impossible to predict which patients will enter sustained recovery. In addition, some participants were uncomfortable using futility to assess these young, otherwise healthy patients when the concept is more often used to assess the care of the very elderly and given the perception among some that any amount of added time is a benefit. Several participants spoke of a case where the patient died of an overdose only five days after returning home following surgery. The patient's family subsequently expressed gratitude for the surgery and the additional five days at home that resulted. Several providers described how this case had prompted them to rethink their own conceptualizations of futile care.

Key Bioethical Concept 2: Rationing Care

In addition to futility, there was considerable discussion of the costs and value of care: even if the surgery could "work", would it be worth the resources? The discussions of costs and resources were contrasted with organ transplant decisions. With IDU-IE the concern was not that valves are scarce in the way that donated livers are, but a more abstract assessment of the

dollars and time invested in these patients in a system that was already too costly: *“it’s resource intensive, not only for the staff in the operating room doing the operation but also people taking care of him and also the social resources that are involved in trying to get him clean”* [19]. Costs were often considered in the decision-making process: *“I don’t tell the patient that you’re wasting my resources, I can’t tell them that but in the back of my mind that is one factor I consider. Because, you know, my time is better used to operate on someone else who is going to benefit from it”* [18]. For some, awareness of costs conflicted with their sense of being empathetic caregivers: *“I’m supposed to think of finances and length of stay and all this stuff, but...it’s still a human being”* [6].

Others expressed concern that a focus on costs could translate into rationing care unfairly in these patients, rather than in a systematic fashion across the entire system. Some could justify rationing in more resource limited settings, but not in an academic medical center. There was also a critique on the focus on costs in the peri-operative setting when so little money is invested in primary care and harm reduction strategies for PWID.

Discussion

To our knowledge this is the first study examining attitudes and approaches towards repeat valve surgeries in the setting of IDU-IE. Providers expressed a wide variety of opinions on how to approach these cases, ranging from a “one and done” philosophy to multiple operations if indicated and feasible. Implicit and explicit bias remain pervasive. This is consistent with recent work showing that despite the rise of the “addiction as a disease” paradigm, stigma remains a powerful force (60,61). Interestingly, in our study, bias was evident even among providers who were aware of historical mistreatment of patients with OUD. Providers also wrestled with burnout in caring for these patients and recognized a need for further education, training, and support. The combination of implicit and explicit bias and feelings of burnout, in addition to a lack of national or hospital wide guidelines or policy, can lead to unpredictable and inequitable care. This study also illustrates the complexity of making these discussions: cases were rarely black and white and even strong advocates could understand a surgeon’s hesitancy to do repeated risky operations on patients who continue to struggle with OUD. In making surgical decisions, providers grappled not just with assessments of medical risk, but also with ethical considerations around futility and rationing of care.

Given that we understand IDU-IE to be a complication of primary OUD, it’s important to understand this study in the context of OUD care in the United States, as adequate medical treatment has been shown to improve long-term outcomes. Medication-assisted treatment (MAT) leads to reductions in all-cause and overdose mortality among patients dependent on opioids, yet nationwide the rate of opioid dependence was nearly double the maximum treatment capacity for MAT in 2012 (62,63). A recent retrospective study of patients with IDU-IE in a tertiary academic medical center found that less than 10% of patients had a plan for MAT mentioned in their discharge paperwork (64). Beyond MAT, harm reduction techniques (patient education, supervised injection facilities and syringe exchanges) may also reduce rates of IDU-IE and other serious bacterial infections (10). These interventions remain controversial, with no supervised injection facilities nationwide and access to syringe exchanges variable across the country (65). Some providers have argued to “stretch the scope” of traditional practice models in order to increase access to addiction medicine, but overall, access to reliable OUD treatment

remains poor (66). Access to primary OUD treatment should influence the way we think about patient responsibility, futility, and our collective obligation to treat the secondary complications of the disease, such as IDU-IE. If the medical system has failed to appropriately treat the primary disease, it seems unreasonable to talk of blaming the patient for suffering a secondary complication.

Where does this leave us? Hospitals across the country will undoubtedly continue to see cases of IDU-IE as the opioid crisis continues. How do we begin to think about these difficult decisions in a systematic way? Reflecting on the decision-making process, one participant stated, *"It's not my job to [punish]. I can say I'll operate, I may not operate, it's up to you, you know. I'm not here to make judgements, I tell the patient that. I'm not judging your habits or anything like that. I'm not a moral person to make all those judgements. I don't deal with that"* [18]. A first step in addressing repeat surgeries in IDU-IE may be to acknowledge the role of moral and ethical values in decision-making. When providers discuss futility or rationing, they are attempting to define treatment success and evaluate the resources needed to achieve it, which is value-laden. There is danger in using the language of "surgical candidacy" to mask moral and ethical decisions as objective medical facts.

Negative emotions towards hostile or "difficult" patients are common and can lead to bias when treating patients. In addition to anti-stigma campaigns, guidelines can serve a useful role in guarding against prejudice or bias. Given the complexity of factors involved in making a decision for repeat valve surgery, it is difficult to develop a set of criteria that can be applied to all patients. However, a systematic, team-based structure for decision-making including an explicit discussion of potential biases and the moral and ethical components of the decision would be beneficial and may lead to more equitable decision making. Models for this already exist in the allocation of livers to transplant recipients and in the evaluation of patients for ventricular assist devices (67,68). At some institutions, a multidisciplinary workgroup of providers taking care of patients with IDU-IE helps to address these issues however these groups are rarely formalized, do not include all relevant providers and ultimately do not have decision-making power. Guidelines should be developed with input from the range of departments and disciplines who care for IDU-IE patients. We believe guidelines should

consider the view of addiction as a chronic, relapsing disease. Consideration of a patient's own desire for surgery and recovery are important factors. Furthermore, any program to improve the surgical decision-making process would be most effective if it is coupled with interventions to increase access to MAT and harm reduction, as these are the tools that treat the primary disorder of OUD and thus will likely decrease incidence of IDU-IE. It is a hope that healthcare leaders will see this study as impetus to begin to design systems that provide more rational and predictable care to patients with IDU-IE.

The advantages of this study include that it is an innovative empirical exploration of the underlying values guiding a specific difficult, and increasingly relevant clinical and bioethical case. Participants represented a diversity of roles, professional backgrounds, and departments across a single institution. Disadvantages include its limited size, which represent only a single academic medical center. It is difficult to generalize findings to more community based or rural care settings. The sample size is also insufficient to generalize across medical and surgical subspecialties or departments. In addition, no patient perspectives were included. This project was conceived to include patient perspectives, but the recruitment process proved too difficult as patients were often too sick to participate. In the future, whether in further research or in the process of developing clinical guidelines and decision-making structures, patients should have a seat at the table, as not only do they have the most at risk in these decisions, they are experts in the complexities of OUD and recovery. Physicians and healthcare providers have expertise in medical decisions, but cannot claim any particular moral or ethical expertise, and thus patients as well their family members, deserve not only to be heard, but to help lead as we learn to navigate the normative aspects of these decisions.

Recurrent IDU-IE remains a clinical and bioethical dilemma and there is insufficient consensus on the optimal approach to management. This study highlights a diversity of perspectives on management of IDU-IE and also suggests a need for more investment in outpatient OUD care, harm reduction strategies, and education and support for all providers who care for patients with OUD. Now is the time to increase transparency and provide more reliable and equitable care to patients with IDU-IE.

Part II: Normative Analysis

The qualitative study presented in Part I reveals how providers utilize the concepts of futility and rationing of care to grapple with difficult decisions around repeat surgeries in patients with IDU-IE. The above analysis also illustrates the often unstated complexities involved when a healthcare provider chooses not to offer an intervention or advises it is “not clinically indicated.” Evidently, this can mean a variety of things, ranging from this intervention will not help the patient immediately, this intervention will fail to change the patient’s overall life expectancy (both futility arguments) to this intervention is not a reasonable use of societal resources or physician’s time (rationing arguments). These two concepts, futility and rationing, also dominate the growing bioethical literature on repeat valve surgeries in IDU-IE (69–71).

It is worth clarifying terminology with regard to these concepts, as historically they have been applied in a number of ways and can be easy to conflate. The concept of futility came to prominence in the 1980s in response to concerns that patients and families would increasingly demand life-prolonging treatments that providers felt were medically inappropriate. There have been multiple attempts to define futility, either 1) quantitatively, as a percentage chance that the proposed intervention would be useless, 2) qualitatively, in an assessment of the effect intervention would have on a patient’s quality of life, or 3) physiologically, as the ability of an intervention to achieve its physiologic goals (i.e. mechanical ventilation achieving blood gas levels compatible with survival) (72). While these attempts to create universal definitions have largely failed, the concept has remained prominent. Applications have clustered around decisions where there is disagreement about the likelihood of achieving 1) life prolongation, 2) the patient’s goals, 3) a physiologic effect of the body, or 4) a therapeutic benefit or a minimum quality of life for the patient (73). Notably, there is no explicit distributive discussion in these debates: the scope of analysis for any futility question is the individual and discussions involve objective and subjective assessments of what counts as good care for an individual. Assessments of futility do not depend on availability of resources or costs of care.

In contrast, discussions of rationing presuppose scarcity and therefore ask how to best distribute those scarce resources among a population. These are inherently questions of

distributive justice (74). Very inexpensive and plentiful but ineffective resources could theoretically be withheld from patient under grounds of futility, but would be unlikely to be rationed. On the other hand, extremely expensive cancer care, that has been shown to prolong life, may be denied to patients on grounds of rationing, but is unlikely to meet a futility standard. Futility is often a more comfortable term, as it suggests wastefulness, rather than rationing, which suggests denial of care based on cost or other resources. As Jecker and Schneiderman write, “It is easier for a physician to tell a patient that medical care is being withheld because there is nothing that can be done, than it is to say that medical care is unavailable because it is costly” (73). In the following sections, I will examine the futility and rationing arguments that have been made against repeat valve surgeries in IDU-IE and explore, what role, if any, these concepts should play in future discussions.

The Role of Futility in Discussions of Repeat Valve Surgery in IDU-IE

The futility argument against repeat valve surgeries in IDU-IE generally states that if a patient has failed to recover from their OUD after a first major heart surgery, this is unlikely to change with any future surgeries and thus surgery will not change their ultimate outcome. As stated by Stell in a Hasting Center Report on “The Noncompliant Substance Abuser:” “health care professionals have no obligation to offer treatment options that have been proven to be ineffective in a patient. An otherwise effective therapeutic effort can be rendered ineffective by non-compliant patient behavior” (54). Are valve surgeries, even if live-saving or life-prolonging in the short term, rendered ineffective, and therefore futile, by the risk of ongoing injection drug use in these patients?

The answer depends on who gets to define what counts as beneficial or effective care. Classically, futility arguments have been plagued by this particular critique. Imagine the case of a patient who had received a valve replacement for IDU-IE 18 months ago and represents with recurrent IDU-IE now causing symptomatic heart failure. After much uncertainty and debate, surgeons opt to operate again. The surgery is a technical success but patient struggles with ongoing injection drug use in the immediate post-operative period and unfortunately is found to have died of an overdose after only five days at home following the surgery and immediate

recovery period. While many of his physicians felt like this was a failure and the surgery had been in vain, the patient's own family members called repeatedly to profusely thank the doctors for their hard work, stating that the five days at home had been priceless. In this case, who gets to decide what counts as benefit? From the surgeon's point of view, the intervention was a waste. The patient returned to injection drugs almost immediately after the surgery and died soon thereafter. It is unclear how the patient himself assessed the benefit of those additional days of life, but it's clear that to his family, they were of utmost value. Whose assessment of futility matters more? When a futility standard is applied to a case like this, its weakness becomes clear: there is no objective standard by which futility can be assessed. It is a subjective concept, entirely dependent on individual's assessments of their own goals and values (74). Certainly, there are rationing discussions applicable to this case (was this surgery an efficient use of resources given the poor outcome?), but these are different than questions of futility and if the surgery benefitted this individual patient and his family.

In general, the bioethical literature has come to the consensus that patient values and perceptions of risk and benefit must take precedence over those of providers. In a 1986 *New England Journal of Medicine* piece, Brett and McCullough propose futility guidelines that include, "when a patient requests an intervention that has a finite potential for both benefit and harm, the patient's weighing of various possible strategies and outcomes should take precedence" (75). Other bioethicists have agreed, stating that while physicians may be experts in describing technical aspects of treatment, prognosis and its possible effect on quality of life, they hold no special training in subjective assessments of what counts as futile care (74,76). More recent analyses have supported this position, with the understanding that when providers are uncomfortable with care they deem to be futile, the answer may not be in finding ways to override patient and family requests, but rather to understand the rationale behind requests in the first place and to put effort into supporting the emotional needs of the clinical team as they find ways to tolerate these requests and support each other (72,77).

This consensus, that patient perceptions of benefit will generally trump provider's assessments of futility has been legally supported as well. A 1995 legal review stated, "To date, in nearly every known case in which the patient has sought treatment and the doctor has

objected on the grounds that the treatment offers no medical benefits, courts have found in favor of the patient” (78). Given that valve surgery is generally not conceived of as marginally beneficial intervention but is often lifesaving in the short term, it seems difficult to make an objective argument that these surgeries are futile and unlikely to provide benefit to patients. If we take this understanding along with the consensus that patient’s perceptions of benefit will largely trump those of physicians, then there seems to be little ground to make futility argument against a repeated valve surgery. Again, concerns about the cost-effectiveness of such an intervention or the use of limited resources in these cases, are discussions of rationing, rather than futility and will be addressed below.

If valves cannot be denied to patients on the basis of futility, is there still any role for the concept when navigating these difficult concepts? More recent scholarship on futility has focused not on the search for objective definitions, but on the art of communicating and negotiating with patients at the bedside (72). Historically, futility has been used to stop rather than spark discussion. Burt critiques the use of futility because “it’s apparent moral authority can too easily divert physicians from engaging in the time-consuming, emotionally stressful and seeming “unprincipled” business of negotiating about treatment alternatives with frightened, grief-stricken patients or family/surrogates” (79). Perhaps a physician’s assessment of futile care is not a conversation-stopper, but an entry into a deeper conversation with patients, family members, and co-workers. In the setting of IDU-IE, perceptions of futility could also serve as signals not to cease caring for the secondary complications of OUD, such as IDU-IE, but for the medical community at large to greater invest in upstream prevention and primary care resources, such as availability of evidence based MAT like buprenorphine and methadone, as well as harm reduction strategies such as needle exchanges and safe injection facilities. Likewise, if the provision of what is perceived to be futile care causes moral distress among providers, the answer may not be to deny such care on principle, but as Burns and Truog suggest, “to turn our efforts toward tolerating the demands for care we believe to be futile, and finding ways to better support the emotional needs of each other in those rare cases where we are called on to provide this care” (72).

A more nuanced understanding of futility argument clarifies not only that it is of limited use in making determinations about repeat surgery in IDU-IE, but also that there is opportunity to use futility not as a conversation-stopper, but as an entry point into deeper discussions about patient values and beliefs, as well as how the medical system at large can improve the way it cares for patients with OUD.

The Role of Rationing in Discussions of Repeat Valve Surgery in IDU-IE

When examining commentary on the ethics of repeat valve surgery in IDU-IE it is clear that arguments that are framed around futility easily lapse into rationing questions and concerns. In a recent commentary in the American Journal of Bioethics, Kirkpatrick and Smith discuss the case of a patient who presents with recurrent IDU-IE two years after an initial valve surgery. In their discussion of futility, they assume that the operation would not be physiologically futile (i.e. the valve replacement is technically possible), quantitatively futile (i.e. the chance of good results are sufficiently high), or qualitatively futile (i.e. there is good reason to believe that intervention would improve the patient's symptoms and quality of life). It seems, then, that there would be no grounds to deny a surgery on a futility standard. However, the authors go on to state, "there is another aspect that lies between quantitative and qualitative futility – duration of benefit. We must not only ask whether there is a good chance the surgery will produce a good benefit, but also for how long. ... If he is unable to avoid using IV drugs for very long, there may be a valid futility argument against replacing his valve again, as the expected time to reinfection may be short. From a resource utilization perspective, we may question whether the 2 years gained from the first valve was enough time to justify the valve replacement." (69). I will argue that these sorts of objections are not futility objections at all: the authors have made it clear that the surgery would have clear benefits for the patient. When we begin to talk about resource utilization, we have shifted from a futility framework to a rationing framework. This is not to imply that such arguments are unfounded or morally wrong, but they must be evaluated for what they are: questions of how to distribute limited resources fairly across a population and not assessments of what counts as good care for an individual patient.

As with futility, discussions on the proper role of rationing care have a long history in bioethics. The United States has historically been uncomfortable with public rationing debates and there are no unified bodies, similar to National Institute for Health and Care Excellence in the United Kingdom, that are tasked with making decisions about what health technologies will be used in the United States and under what indications (80). This is not to say that rationing decisions are not made perpetually across the United States, but they often done in less formalized ways. Most prominently, given the lack of universal health care in the United States, medical care is rationed on the basis of ability to pay. Rationing discussions in the United States have intensified over the last 30 years as new payment models have shifted financial responsibility onto hospitals and even individual physicians. As early as 1985, when “diagnosis-related groups” (DRGs) for prospective reimbursement were introduced in Medicare (meaning hospitals were reimbursed not in a “fee for service” model but with a flat fee depending on the nature of the patient illness) bioethicists such as E. Haavi Morreim realized this had important implications: “issues that could once be passed off as distant social questions of macroallocation have suddenly become pressing questions of microallocation” (81). Initially, Morreim and others felt it was wrong to make these sorts of rationing decisions at the bedside, but as concern for growing health care costs continued bedside rationing found more advocates. In 1995 Ubel and Arnold wrote that “although bedside rationing raises serious moral problems, these are outweighed by the important social goal of containing health care costs, while providing adequate health care to those who need it” (82). There remains no ultimate consensus: in 2005, the American College of Physicians stated that “resource allocation decisions are policy decisions that are most appropriately made at the system level, not at the bedside” (83) yet others widely agree that stewardship is necessary at multiple levels including the bedside to contain health care costs in order to provide best possible care to all Americans (84). Advocates argue that some form of bedside rationing is essential for physicians to maintain autonomy necessary to specialize care for particular patients, each with their own set unique set of circumstances (80).

Taking a global view of rationing, it is hard to argue that it is not pervasive in our current system, even if rarely acknowledged explicitly. Certain examples, like organ transplants are

widely acknowledged to be rationed and are physically scarce: more patients desperately await liver transplants than there are organs available. However, other rationing decisions happen constantly, more often due to economic rather than physical scarcity. Economic rationing often occurs in more subtle ways: a procedure may never be offered in the first place, rather than explicitly denied to a patient. For example, there are well regarded practice guidelines that limit how MRIs should be used to evaluate headaches and other low-risk complaints and older antibiotics are routinely used rather than newer and more expensive forms. These are decisions that have been rationed for economic reasons in order to curtail overall health care costs but patients and families are likely unaware of them. In addition, providers likely understand these decisions not as ethical rationing determinations, but as high-quality clinical care (80).

With this understanding, it seems obvious that rationing is happening in every sector of healthcare, whether we name it or not. In the case at hand, that of repeat valve surgeries in the IDU-IE, while valves are not physically scarce in the way that livers are, economic constraints apply as they do across all of healthcare. In at least some settings, a surgeon's time and operating room availability are also limited resources and thus are inevitably rationed, whether explicitly acknowledged or not. Similar themes are seen in bioethical literature discussing IDU-IE whether there is concern over "squandering resources" (52) and the fact that "time is not unlimited. ... Expending this limited resource on [the patient] is wasteful" (53) or even questions of "how long must a valve last to make it a good investment?" (85). The concern over resources and questions of investment are not about futility (i.e. would this intervention conceivably benefit the individual patient) but are questions of rationing (i.e. is this a wise or just way to allot societal resources?).

If this rationing is inevitable, how do we proceed? How do we begin to think about distribution of scarce resources (health care dollars, operating room time, hospital beds, etc.) in patients with IDU-IE? A first step is likely to be clear in our thinking and avoid the trap of masking rationing discussions as futility ones or as no decision at all. Dan Brock cites the example of National Health Service's (NHS) policy on hemodialysis in the 1980s, where primary care doctors often told patients older than 55 or 60 with end stage renal disease that "there was nothing more that could be done for them." This was patently false: there is nothing to

suggest that a 55 or 60-year-old could not go on hemodialysis just as a 45-year-old might. Rather this statement reflects the social and political decision the NHS had made to not fund this additional treatment (80). The danger is implicit rationing is this: social decisions are masked as medical facts. As patients trust their physicians to be experts in diagnosis and prognosis, masking a rationing argument as a medical one robs the patient of their ability to debate or reconsider.

In his exploration of the inevitableness of rationing, Dan Brock sets out two broad ethical standards that should guide rationing decisions: 1) resources should be allocated efficiently to maximize health benefits they produce and 2) health benefits derived from limited health care resources should be distributed fairly or equitably (80). He asserts that maximizing efficient allocation generally involves cost-effectiveness analysis. Discussions of equitable allocation have been more controversial, however, without clear agreement on what theories of justice are most applicable. In their review of principles of allocation of scarce medical interventions, Persad, Wertheimer and Emanuel lay out multiple distributive strategies such as: treating people equally, favoring the worst-off, maximizing total benefits, and promoting and rewarding social usefulness. They suggest a system which prioritizes younger people who have yet to live a complete life while also incorporating prognosis, lottery, instrumental value, and a utilitarian goal to save the most lives. They freely acknowledge however, that these are all normative decisions, stating “there is no value-free criteria for medical allocation” (86). This makes rationing an inherently difficult and controversial topic, as there is no general way to ensure broad agreement on values.

In addition, the United States health care system poses additional complexities as it has no explicit distributive justice principles built in to the system. In the NHS, for example, if patients are denied hemodialysis at a certain age (regardless of whether that is morally appropriate), physicians and the public at large can understand the resources from those interventions have been diverted to other patients and diseases. No such guarantee is present in the United States. Norman Daniels notes that in the US system, “saying no to beneficial treatment or procedures carries no assurance that we are saying yes to even more beneficial ones. ... Just as important, the system as a whole is not governed by a principle of distributive

justice, appeal to which is made in questions about disseminating technological advances. It is not closed under constraints of justice” (87). This complicates any rationing decision as it becomes difficult to deny care to one patient if you cannot justify that choice as freeing up for resources for other, potentially more deserving, patients.

Upon final analysis, rationing is certainly a more philosophically defensible (as well as inevitable) rationale for decision-making in cases of repeat valve surgeries in IDU-IE than futility, but complexities abound. Not only is rationing a more uncomfortable concept than futility to discuss with patients and the public, there remains no clear consensus on what values or principles of distributive justice should be used in these cases and how to apply them fairly from within the US healthcare system.

Other Considerations: Determination of “Social Worth”

Before moving on to final conclusions, it is worth briefly touching upon an additional objection, beyond futility and rationing, that is seen in the bioethical literature. Some surgeons may hesitate to offer multiple surgeries in the setting of recurrent IDU-IE because it is seen as encouraging irresponsible behavior. Repeatedly fixing a valve that is infected from IDU may harm society as it encourages individuals to look to others to solve their own problems. As DiMaio writes in *The Annals of Thoracic Surgery*, “the more medicine and society direct individual behavior, the less autonomous, and therefore, the less healthy the individual may become” (53). Similar logic is seen in statements that reference recidivism, which implicitly equates OUD with a crime, despite the fact that addiction is now understood as a chronic disease (51,52,88). While often not worded explicitly, arguments of this nature sound like punishment: patients have failed to behave in the way that was expected of them (i.e. remaining abstinent from IDU) and therefore, despite the fact that an additional surgery would be medically indicated, it will be denied to them given their behavior.

Treatment decisions that hinge on the assessments of the social worth of a patient have no role in modern medicine. Assessment of what care is deserved or undeserved is a moral, rather than medical decision. In these cases, physicians certainly may have a voice, but they have no special expertise in moral determinations, despite the fact that a medical degree gives

them certain power over the clinical encounter at large. This power may be easy to abuse, but history shows us that is unacceptable to factor social worth or moral value into medical decision making. The Seattle hemodialysis committee of the 1960s is now notorious for its use of subjective assessments of patient's social worth in deciding who would get access to the dialysis machines (89). The committee was notoriously critiqued by David Saunders and Jesse Dukeminier, a law professor and psychiatrist respectively at UCLA, who famously wrote: "The Pacific Northwest is no place for a Henry David Thoreau with bad kidneys" and more substantively argued that selection of patients is not on the face of it unjust, but that justice "requires that selection be made by a fairer method than the unbridled consciences, the built-in biases, and the fantasies of omnipotence of a secret committee. Selection by a secret committee operating without explicit criteria is a grotesque conceit worthy of Franz Kafka" (90). Deciding when to perform repeat valve surgeries for IDU-IE based on an individual physician's assessment of a patient's moral worth or contribution to society is an equivalent injustice and abuse of power.

Since the 1960s, thanks in part to the work of Saunders, Dukeminier and other bioethicists, the medical establishment has reached consensus that there is no role for determinations of moral standing in medical decisions. The American Medical Association (AMA) Code of Ethics states clearly that "Non-medical criteria, such as ability to pay, age, social worth, perceived obstacles to treatment, patient contribution to illness or past use of resources should not be considered" when determining allocation of scarce resources (91). While judgements of the deservedness of patients are still present in biomedical literature and perspective pieces in cardiothoracic surgery journals, there is no clear ethical defense for the use of these assessments in clinical decision-making. Such use amounts to punishment for these patients and does not reflect any rational system of distribution of resources or assessment of patient benefit. In addition, this line of reasoning is especially inappropriate given the current state of OUD care, where demand for treatment far outweighs current capacities (62). It is unconscionable to condemn patients for their substance use disorders when the medical system has failed to respond to the growing need of a crisis that it in part fueled.

Conclusions

This paper has engaged three potential objections to the use of repeat surgeries for recurrent IDU-IE: 1) futility arguments, 2) rationing arguments, and 3) social worth arguments. I have worked to show that debate around futility is plagued by definitional critiques (who gets to decide what counts as benefit?) and thus is unlikely to be a fruitful concept in these discussions, especially when valve surgeries are often live-saving. I have also briefly discussed questions of social worth and shown that moral judgements on the deservedness of certain patients is unsupported by mainstream bioethics and inappropriate criteria for allocation of medical resources. A rationing framework, while initially appearing more controversial than a futility framework as they imply not cutting back on wasteful care but withholding care from some groups or patients in order to assure a more overall efficient and equitable distribution of resource, is the only potentially philosophically defensible rationale for withholding valve surgeries in these settings.

Isolating rationing as a potentially more viable rationale, does not, however, address the tangle of questions and uncertainties inherent in this topic. Rationing is philosophically defensible in that healthcare at large is a limited resource and not all interventions can be performed in every patient. Rationing happens in small and large ways every day in every hospital across the country. By what grounds, then, if any could a valve surgery be rationed in a patient with IDU-IE? As an aside, it seems impossible to have this conversation in isolation from rationing decisions that currently happen or should happen elsewhere in medicine. To carefully ration the healthcare costs and interventions associated with injection drug use but not those associated with smoking, sun exposure, sedentary life styles, or any other etiology for that matter seems patently unjust and an example of determinations of social worth masquerading as rationing decisions.

That point notwithstanding, the practical question emerges: how do we create spaces to have conversations about difficult choices, like when valve surgeries in setting of IDU-IE should be performed, in philosophically sound and just ways? Esteemed philosopher and bioethicist Norman Daniels has proposed a framework with which to hold such discussions. He acknowledges that in diverse, pluralistic societies (like the United States) it is unlikely to find

universal agreement on the principles of allocation and priority setting (i.e. giving to sickest first vs. youngest vs. the most likely to benefit etc.). Daniels writes that if given a likely irrevocable disagreement on principles, the decision-making process must take precedence and that it is this process, rather than principles, which is the key to creating general agreement on what counts as legitimate and fair policy. Daniels lays out the key elements of a fair process: “transparency about the grounds for decisions; appeals to rationales that all can accept as relevant to meeting health needs fairly; and procedures for revising decisions in light of challenges to them” (92). Together, these criteria guarantee an “accountability for reasonableness” which is the backbone of Daniels’ framework.

Implementing an accountability for reasonableness framework would surely improve upon current decision making around valves in IDU-IE, which is haphazard, opaque and inconsistent. The first condition, that of publicity or transparency, is notably absent from many valve discussions. The lack of hospital wide or national guidelines also keeps decisions in grey areas, where patients are assessed on an ad-hoc basis and there is no presumptive “standard of care”. Daniels writes that “there must be no secrets where justice is involved, for people should not be expected to accept decisions that affect their well being unless they are aware of the grounds for these decisions” (92). In order to get to this stage for valve surgery in IDU-IE there must be more philosophical clarity regarding the grounds by which decisions are currently made (and such discussions would likely reveal the limitations of social worth and futility determinations) as well as more engagement with healthcare providers outside cardiothoracic surgery teams and the public at large.

Daniels’ second criteria is one of relevance: appeals must be limited to rationales that are “relevant to meeting health needs fairly.” This criterion has been critiqued by others for being too open-ended. If we can never agree on shared priorities, can we expect to agree on what rationales are relevant or not? (93). I would argue here that with the above analysis, it is reasonable to admit that determinations of social worth or deservedness are not relevant criteria in meeting health needs fairly. In addition, futility is unlikely to be a relevant criterion in these situations. This can help to narrow the discussion to the grounds by which we accept rationing in these cases. Finally, Daniels demands that processes have structure to allow for a

revision or appeals mechanism. A more public project of creating guidelines for care in these cases would also provide the transparency and publicity necessary for accommodating revisions or appeals.

Norman Daniels' accountability for reasonableness framework gives us guidance and structure in thinking through what an ideal decision-making framework would look like. Transparency is of utmost importance. While I may disagree with the choice to ration valve surgeries in repeat cases of IDU-IE, I have less problem with that decision if it is made publicly and defended at large, rather than being made privately and couched in language of futility rather than rationing, which gives the unfair impression that individuals patients have nothing to gain from these surgeries. There are calls for interdisciplinary "heart teams" that can address these cases within the hospital (94–96). This is a first step in gaining more transparency. I would argue that in addition to interdisciplinary teams (which would involve not only surgeons, infectious disease and addiction medicine physicians, but also the licensed social workers, nurses, and others who care for these patients), there must be robust patient involvement as well. Medical providers have no special moral authority when making difficult decisions. Ultimately these are societal and political decisions about the allotment of resources: politicians, economists, other social scientists and especially patients also deserve seats at the table. It is also of utmost importance to have clarity with regards to the criteria by which we make decisions. If not, there is a risk, especially in highly stigmatized diseases and populations, such as OUD, that bias will overpower any other reasoning. Demanding clarity and transparency in decision making will hold all of us to higher standards in terms of what rationales we can accept and those we cannot.

This paper, thus, cannot provide the single answer on how to approach this clinically and ethically vexing situation. Bioethics, however, has an important role to play in helping clarify contentious health care debates such as this one. The conversation about whether a patient deserves a valve surgery, whether a patient benefits from a valve surgery, and whether a valve surgery is an efficient and equitable use of resources are three very different questions. I hope this paper has helped to clarify these debates and show that questions of if patients deserve a surgery or will benefit from a surgery are largely inappropriate in these cases. The discussion

about how to allocate healthcare resources remains unsolved. A framework, such as accountability of reasonableness, can ensure a fair process and legitimate outcome even in the face of considerable disagreement about principles and priorities. Clarity in these discussions will guard against further intrusion of bias as we navigate the complexities of caring for patients with opioid use disorder.

Summary

This thesis aims to present a complete view of complex problem: repeat valve surgeries in patients with IDU-IE. In Part I, I present a thorough review of the literature, examining the growing injection drug use trends in the United States, the association between injection drug use and bacterial infections, particularly, infective endocarditis, and the available outcomes research on initial and repeat occurrences of IDU-IE. I also present a review of the bioethical literature and commentaries on the surgical treatment of IDU-IE. Following the literature review, I report on innovative qualitative research, examining attitudes and beliefs towards repeat surgery in IDU-IE among healthcare providers at a single academic institution. Three qualitative themes emerge: 1) caring for patients with IDU-IE is especially challenging, 2) implicit and explicit bias remain pervasive, and 3) criteria for surgical decision-making are not transparent. When discussing surgical decision-making, participants relied on two predominant bioethical concepts: 1) futility and 2) rationing. Following those results, in Part II, I present a normative analysis of bioethical concepts revealed in Part I, concluding that rationing is the only philosophically defensible ground on which to deny or withhold surgeries, although the parameters on which that might be done remain unsolved. A future discussion should involve a fair and transparent decision-making process in order to assure a just and legitimate outcome. IDU-IE is a growing concern and increasingly common complication of OUD. The healthcare system must do a better job in treating these patients with the respect and equitable care they deserve.

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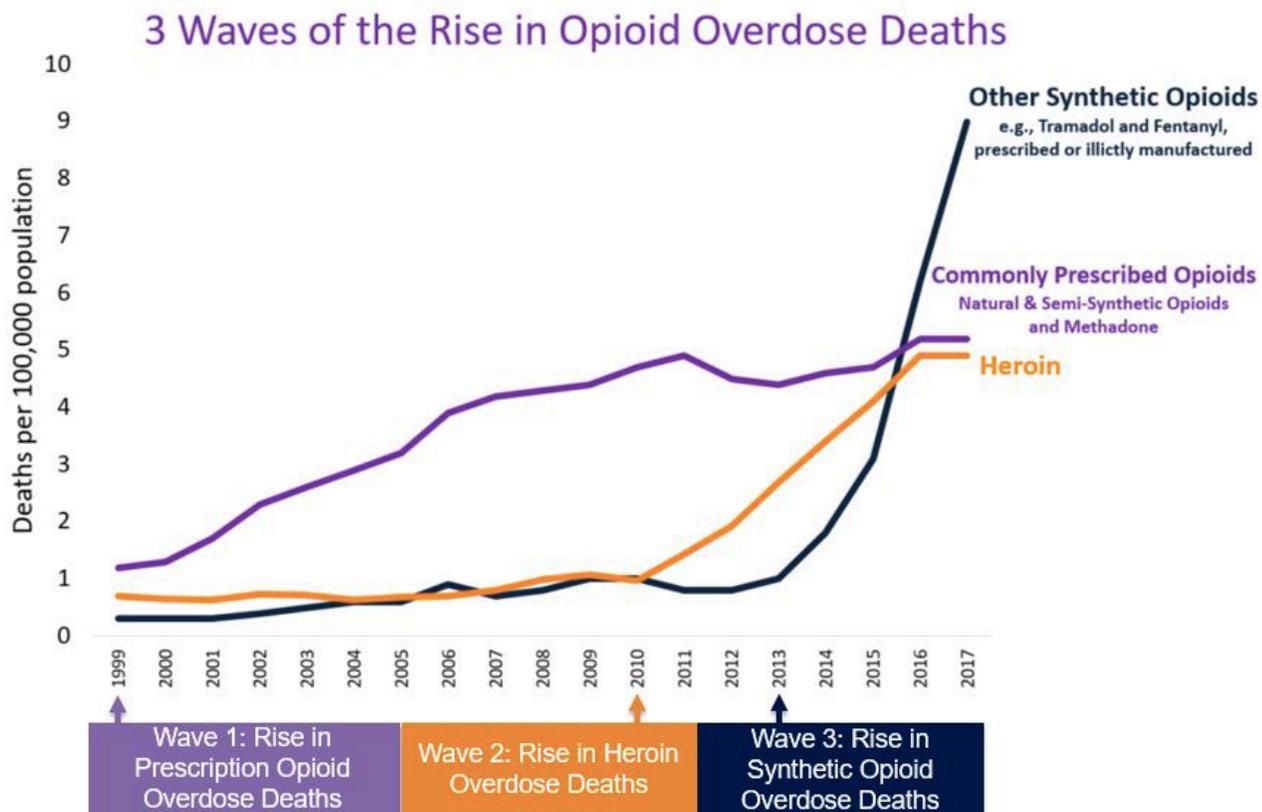
Thank you also to Leslie Bosworth, Dr. Joji Suzuki, and Dr. Tony Brey who reviewed and helped me refine the semi-structured interview protocol.

Importantly, I wish to thank all the participants who made time in their busy days to participate in this project and reflect on these challenging and interesting questions.

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Figures, Tables and Supplementary Materials

Figure 1: Opioid overdose deaths in United States, 1999 – 2017. Source: National Vital Statistics System Mortality File



SOURCE: National Vital Statistics System Mortality File.

Available at: <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

Figure 2: Role of Perceptions of Futility and Rationing in Surgical Decision Making in IDU-IE

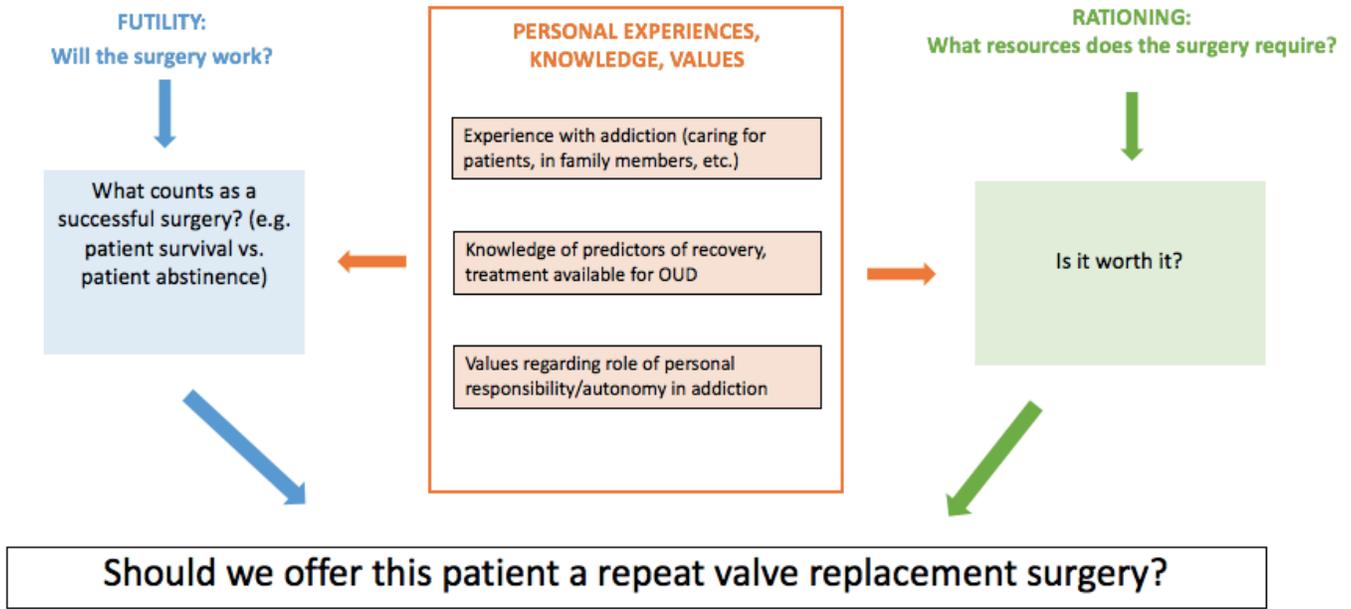


Table 1: Five recent retrospective cohort studies, comparing surgical outcomes in IDU vs non IDU IE

Study	Year, Location	Population	Mortality Outcomes	Reinfection / reoperation rates	Repeat surgery outcomes data
Shrestha et al.	2015, Cleveland Clinic	-536 surgically treated IE Patients, 2007-2017 -41/536 (8%) IDU-IE	-IDU-IE pts had increased hazard ratio of death or reoperation between 90-180 days (HR 9.8, 95% CI 2.7 – 35.3), but prior to 90 days or after 180 days	-Among PWID, reoperation and death contributed equally to outcome, whereas in non IDU-IE cases, reoperation was far less common.	-Not available
Rabkin et al.	2012, University of Washington Medical center	-199 surgically treated IE patients, 1999 – 2010 -64/199 (32.1%) IDU-E	-IDU-IE patients had decreased survival at 30 days, 1 year, 5 years, and 10 years; 91.2 vs. 93.6%, 77.5 vs 83.0%, 46.7 vs 71.1%, 41.1 vs 52.0%, p = .027 -IDU independent risk factor for decreased survival, p = 0.03	-IDU-IE not significantly associated with reoperation (p value = .95)	-16/199 patients had repeat operations, no significant difference between IDU and non IDU-E -Perioperative mortality 12.5%
Kim et al.	2016, Massachusetts General Hospital and Brigham and Women’s Hospital	-436 surgically treated IE patients, 2002 – 2014 -78/436 (17.9%) IDU-IE	-Operative mortality lower in IDU-IE (OR .25, 95% CI .06 - .71) -No difference in overall mortality (HR .78, 95% CI .44 – 1.37)	-Increased risk of valve complication (HR 3.82, 95% CI 1.95 – 7.49) and reinfection (HR 6.20, 95CI 2.56 – 15.00) in IDU-IE -28/75 (37.3%) early IDU survivors had reinfection	-Of 28 IDU-IE patients with reinfection, 14 (50%) underwent surgery -5 year survival rates in recurrent IDU-IE 91.7% in surgically managed group vs. 38.9% in medically managed (p value = .066)

Kaiser et al.	2007, Washington University / Barnes Jewish Hospital, St. Louis, Missouri	-322 surgically treated IE patients, 1986 – 2005 -52/322 (16.1%) IDU-IE	-No significant difference in operative mortality, or 10 or 15 year mortality between groups	-Increased reoperation rates in IDU-IE cases (17% vs. 5%, p value = .03)	-24 reoperations in 23 patients, 9 patients with IDU-IE
Carozza et al.	2006, Second Unity of Naples, V. Monaldi Hospital, Naples, Italy	-39 patients with IVDU referred for surgical treatment for native valve IE between 1980-2004 -85 contemporary non IVDU-IE patients with native valve IE	-No significant difference in hospital or long term survival	-Increased risk of recurrence in IDU-IE at 1, 3, 5, and 10 years (92.4 vs 96.1%, 82.3 vs 96.1%, 76.0 vs 94.2%, 76.0 vs 88.7%, p value .038)	-not available

Table 2: Experiences caring for IDU-IE Patients

THEME 1: A Challenging Population		
Subthemes	Description	Representative quote
<i>Pain Control</i>	Providers feared undertreating and overtreating pain.	“I would just feel manipulated all the time. They’re talking about pain, I don’t know if they’re in pain ... I don’t want to give them something that perpetuates the addiction” [8]
<i>Behavioral Issues</i>	Behavioral issues can make it difficult to provide high-quality care.	“If someone is verbally abusive to me, I would like to forgive them that, but sometimes I am still mad about it” [10]
<i>Relatability</i>	It was difficult to relate to IVDU-IE patients.	“[Injecting yourself] sounds insane. So there’s a level of recklessness that I personally can only try to imagine I just can’t relate to it at all” [1]
<i>Burnout</i>	Providers felt helpless and powerless to address these patients.	“[SUD] is taking an emotional toll on providers in a way that we don’t really talk about ...the tragedy of the heartbreak of it is also something that costs us as providers” [14]
THEME 2: Explicit and implicit bias towards PWID remains pervasive		
<i>Historical mistreatment</i>	SUDs have historically received suboptimal care.	“what I realized is we weren’t treating addiction ... we were basically just saying you are going to withdraw immediately and tough cookies” [18]
<i>Unconscious bias</i>	There is dominant societal messaging that OUD is a moral failing	“This is your fault, this happened to you because of things that you did. You couldn’t abstain. And just because this is baked into a little bit to society and to the news and TV, I carried some of that with me” [11]
<i>Explicit bias</i>	Some participants continue to endorse views that PWID are less deserving of care.	“The people eating burgers and smoking... are productive members of society ... they’re normal people doing a little bit of bad things whereas here drug addiction I don’t envision them being in a fruitful job or good for society” [18]
THEME 3: Criteria for surgical decision making are not transparent		

<i>Disagreement</i>	Disagreement about the surgical candidacy of an IVDU-IE patient is common.	“Surgical team say no. Medical team is pushing. Yeah that happens all the time ... infectious diseases they will say the same thing, he’s going to die if you don’t operate ... and then surgical team sees an obvious drug abuser, why are you operating? They are going to die” [18]
<i>Lack of interdisciplinary decision making</i>	Surgical decisions were largely made unilaterally.	“I think at the end of the day it’s the surgeon who makes the case and there’s not a whole lot of opportunity to really sit down and debate or go over pros and cons” [1]
<i>Unpredictable judgments</i>	Surgical decisions can appear to be random or unpredictable.	“I mean there are certain surgeons who said I will do one valve but don’t do a second. And then there are other surgeons who ... just didn’t feel comfortable saying to a young person I’m not going to give you a chance ... it was kind of random” [8]

Table 3: Ethical thinking in surgical decisions

Key Concept 1: Futility		
Viewpoint	Rationale	Representative quote
<i>Repeat surgeries for IVDU-IE are often futile</i>	The first surgery already failed and repeating it will not lead to different solution.	“heart surgery is life changing and if you do such a big operation ... and that doesn't make them change, stop the drug habit, what is going to change? And the next time you operate the same thing” [18]
<i>Repeat surgeries for IVDU are not necessarily futile</i>	If addiction is a chronic, relapsing disease, recurrence is an expected outcome and recovery can still happen at any time.	“I wouldn't be asking for any sort of promises that they were going to remain in remission for the rest of their lives ... but I would want them to be engaged in wanting treatment” [16]
<i>Futility is an inappropriate paradigm</i>	These are young, otherwise healthy patients who stand to live long, healthy lives if they recover from their SUD.	“Saying that it's futile gives the impression that you are giving up on a patient” [15]
Key Concept 2: Rationing Care		
<i>Rationing IVDU-IE valve surgeries is appropriate</i>	Additional surgeries for IVDU-IE should be rationed because they are an inefficient use of resources.	“maybe it's an inappropriate allocation of resources to do major surgeries in particular patients who haven't shown a great promise for recovery” [15]
<i>Rationing IVDU-IE valve surgeries is an example of discrimination</i>	If the US healthcare system does not ration other resource intensive procedures, it is wrong to do so in this case.	“We should be more cost conscious and it seems like that's being applied to this case more unfairly and I'm not seeing that discussion happen as much with let's say heart failure patients or other near fatal diseases that need lots of procedures and hospitalizations” [11]
<i>Rationing IVDU-IE valve surgeries is an inappropriate paradigm</i>	Given the lack of investment in primary and outpatient care for OUD it is inappropriate to debate costs of surgical treatment for its complications.	“Until you are going to start talking ...about the costs of not providing better care and prevention and support to the thousands and thousands ... of people out there struggling with opioid use disorder then I don't want to start hearing about how expensive their surgeries” [16]

Supplementary Material: Semi Structured Interview Protocol

Introduction: You have agreed to take part in a research project which is examining different attitudes and thoughts to a specific ethical problem: when patients with a history of infective endocarditis and a previous valve replacement surgery present with a second (or third) case of endocarditis that may require an additional surgery. There is little consensus in the medical literature about what is the best way to approach these difficult cases. The goal of this project is to elucidate some of the diversity of approaches to these cases.

[For hospital staff]

To start, I'm going to present a brief case that presents the type of patients I'm interested in: a patient with a history of opioid use disorder who presented to hospital in 2016 with infective endocarditis, had a successful valve replacement and completed a course of antibiotics, but now ~2 years later has re-presented with fevers and malaise and found to have a second case of infective endocarditis after using injection drugs again. The patient has persistent bacteremia and worsening heart failure. There is discussion about if this patient is a surgical candidate.

- Have you had personal experience caring for a patient in a similar situation?
- Have you developed a personal approach for these situations (when a patient presents with recurrent endocarditis and may require another valve replacement)?
 - How does a patient's drug use influence your decision? What variables are part of your personal decision-making algorithm? Patient age, outpatient providers, trust, a patient contract, a gut feeling, etc.?
 - Are your attitudes the product of past experiences you've had in the hospital or during your training?
 - Are there broader abstract ethical principles that also guide your decision making process?
 - If uncertain, will prompt with: for example, theories such as utilitarianism or consequentialism vs. deontology or 4 key bioethical principles (respect for autonomy, non-maleficence, beneficence, and justice). Do you rely on these principles in your daily decision making?
- Do you think there should be rules that limit how many surgeries an individual should be able to receive? Why or why not?
- Once it has been established that a case of endocarditis is from IV drug use (as opposed to a dental procedure, or another blood stream infection, etc.) does that change your approach to the patient's medical needs? If yes, how does it change your approach?
- What are your concerns about treating individuals with IV drug use?
- What is your understanding of addiction?
 - For clarification: how much do you see it as a medical disease? How much free choice or will is involved?
 - Is there effective treatment available for opioid use disorder? How does the presence or absence of that change your decision making progress with regards to multiple valve replacement surgeries?

- Do you think about IV drug use differently than alcoholism or unhealthy eating habits?
 - If further prompting needed, ask question about role of personal responsibility and free choice? Ethical duty of medical team to continue to provide care?
- Many people make comparisons between valve replacements in the setting of infective endocarditis and liver transplants in the setting of alcoholism? How do you see these examples as similar or different?
- Is there a role for doctors and other health care professionals to punish behavior that we, as the medical community, or you as an individual care provider, think is wrong? Do you see denying a valve surgery as a potential form of punishment?
- Do you have a definition of “futile care? Do you believe there comes a time at which further care for sick patients crosses that line? If yes, how do you tell where that is?
- What is your sense about how your approach differs from others in the hospital? Have you experienced any conflict between other staff (either within your service or on other services) when caring for these patients?
- To close, do you have any other comments or thoughts on this subject that you haven’t had a chance to voice until now? Is there anything else that is important about this topic that we haven’t discussed?

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