

Principlist approach to multiple heart valve replacements for patients with intravenous drug use-induced endocarditis

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ABSTRACT

Medical professionals often deny patients who inject opioids a second or third heart valve replacement, even if such a surgery is medically indicated. However, such a position is not well defended. As this paper demonstrates, the ethical literature on the topic too often fails to develop and apply an ethical lens to analyse the issue of multiple valve replacements. This paper addresses this lacuna by analysing the case of Mr Walsh, a composite case which protects the identity of any one patient, through the principlist approach of Beauchamp and Childress. It argues that the hospital should offer Mr Walsh, a second valve replacement because the procedure is: medically indicated, autonomously requested, non-maleficent, beneficent and does not violate a formal account of justice. The paper concludes with clinical ethical guidelines for valve surgery for patients with opioid use disorder.

Repeated transplants of the same heart valve for persons who suffer from intravenous drug use (IVDU)-induced endocarditis have emerged as an ethical issue over the past decade. Some providers refuse to offer a second or third valve to such patients out of fear that the patient will 'waste' the surgery by reinfecting the valve after continued IVDU. Currently, there are no industry ethical standards that prohibit providers from holding and implementing such a position. The American College of Cardiology, for instance, has not provided guidelines regarding the repeated replacement of a heart valve due to IVDU.¹ As a result, many medical institutions allow these patients to die of endocarditis instead of providing a second or third transplanted valve.

The opioid crisis has been exacerbated by the COVID-19 pandemic. Opioid use and overdose deaths spiked during the COVID-related lockdowns of 2020.² Tragically, it appears that IVDU use-induced endocarditis will remain an issue for years to come.

This paper argues that it is unethical for providers in the American medical context to allow patients to die because the providers fear that the patient will return to IVDU. Such a practice stigmatises and unjustly treats patients who have a clinically verifiable mental disorder—opioid use disorder (OUD). Therefore, this paper's first task is to construct an argument against blanket exclusions of patients suffering from OUD who are indicated for a valve replacement. Patients should be offered heart valve transplants, even second and third transplants, as medically indicated. However, medically indicated

surgery can be withheld from a patient if the procedure limits other patients' access to beneficial treatment. Second, the paper offers ethical guidelines regarding offering valve surgery to patients suffering from OUD. The paper also intends to correct a deficiency in the literature on this issue. As I demonstrate below, previous articles have been long on description but short on argumentation and prescription. This paper substantively engages with an ethical methodology, principlism and uses it to guide the issue's normative analysis.

ENDOCARDITIS: DEFINED, CAUSES, TREATMENTS

Endocarditis is an infection of the inner lining of the heart. Such infections often develop on the heart's aortic and mitral valves. Infective growths, or vegetations, inhibit these valves' proper functioning and prevent the normal circulation of blood throughout the body. If untreated, endocarditis can be deadly. Individuals who inject recreational drugs expose themselves to the risk of endocarditis if they use unsterilised needles. Such needles introduce bacteria into the bloodstream, subverting the body's natural immune defenses. The bacteria often settle on the valves of the heart, causing vegetations to develop.

While it is probable that IVDU is the cause of endocarditis in patients with OUD, clinicians cannot make such a claim with epidemiological certitude. Endocarditis can be caused by teeth brushing, inflammatory bowel disease and tattooing, for example. Furthermore, it is even more challenging to identify the cause of an infection of a replacement (prosthetic) heart valve. Prosthetic valves are highly susceptible to bacterial and fungal growths. Such growths can be caused by latent bacteria and fungi from a previous infection that settles on the new valve and creates a new vegetation. Patients, then, can develop a growth *even if* they did not inject drugs after receiving a replacement valve. Thus, the chain of events that cause a second episode of endocarditis is not well known.

Providers prescribe antibiotics to cure and control vegetations. However, medical treatments cannot eliminate large vegetations or vegetations on prosthetic valves. Because most of this patient population is under the age of 60, they typically receive mechanical prosthetic valves.³ Mechanical valves are more durable than bioprosthetic valves, which use bovine tissue and require replacement after 15 years.⁴ Because each of these valves is non-cadaveric, there is no more threat of scarcity in the American context than for standard medical



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procedures. Studies have suggested the rates of hospitalisation and heart valve transplantation due to IVDU-induced endocarditis continues to rise in the USA.⁵

THE CASE OF MR WALSH

In January, a middle-aged man, Mr Walsh, was admitted at a hospital in New England in the USA.⁶ He was experiencing extreme fatigue, dyspnoea and a fever of 104°F. Mr Walsh's left arm was covered with intravenous tracks, and he admitted to injecting fentanyl. Tests revealed that the patient had bacteraemia and aortic valve endocarditis. Providers gave Mr Walsh antibiotic treatment for his condition. In late February, an echocardiogram indicated that the aortic regurgitation worsened and that the aortic vegetation had grown. The patient's condition was grave, and an aortic valve replacement was indicated. Prior to the procedure, Mr Walsh signed a contract, indicating that he would refrain from injecting drugs after the surgery and enrol in an addiction therapy programme. The patient received an aortic valve repair for his IVDU-induced endocarditis in early March.

Ten months later, Mr Walsh returned to the hospital with a second case of aortic valve endocarditis. The endocarditis recurred after Mr Walsh relapsed and returned to IVDU. Six weeks of in-hospital antibiotic therapy was unsuccessful in treating the disease. The cardiothoracic team determined that a second replacement of the aortic valve was indicated. Studies demonstrate that a second valve replacement is a medically effective,⁷ low-risk surgery, as 'the risk of reoperative aortic valve replacement is similar to that for primary aortic valve replacement'.⁸

Should the hospital offer this patient a second valve replacement? After all, Mr Walsh had violated the agreement to remain sober after the first valve replacement.

THE STATE OF THE QUESTION IN CLINICAL ETHICS

Patients seeking a second or third replacement valve due to IVDU often encounter providers who are unwilling to offer the surgery. A past president of the American College of Cardiology noted that 'when the prosthetic valve gets infected because of continued drug use...some surgeons...say they won't re-operate on these patients'.⁹ The scholarly literature on the topic also reflects this perspective.

Khung-Keong Yeo argues that 'The recidivist abuser (of opioids) with demonstrable non-compliance who sustains a second episode of endocarditis need not be offered another valve', because the patient 'bears the responsibility for the consequences of her actions'.¹⁰ Yeo also notes that such decisions also maximise a society's overall health utility. Along these lines, Sarah Hull and Farid Jadbabaie argue that medical institutions should not offer a patient a third replacement valve to 'establish a futility threshold in an effort to balance our obligations to individual patients versus society'.¹¹ Aultman et al maintain that if 'the patient is unwilling to commit to a comprehensive treatment programme after thorough guidance by the healthcare team, then it is ethically justifiable to refuse surgery'.¹²

Some of these positions hold that a second or third valve replacement is psychosocially futile. Psychosocial futility exists if a 'patient's addiction, drug use and other maladaptive behaviours threaten to compromise the patient's physical health'.¹ Determining this form of futility assumes that providers can predict future patient behaviour based on past action and statistical probabilities.

DiMaio uses libertarian and utilitarian lenses to argue that second valve replacements are not obligatory. Medical professionals are not responsible for the health of persons with OUD because 'individuals need to accept responsibility for their own health'.¹³ Furthermore, surgeons should consider 'the good of many others' when deciding to operate for a second time. Expending medical and monetary resources on such patients is 'wasteful'. Crucially, each of these articles fails to control ethical terms such as utility, beneficence and responsible stewardship, rendering impossible an in-depth ethical analysis the issue.

Stephen Baldassarri *et al* represent the opposing position. They suggest that valve surgery should be offered to patients if it is likely to provide a benefit. They emphatically reject arguments from the futility of treating such patients: "'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 definition".¹ Also, they note that because prosthetic heart valves are abundant, arguments regarding the rationing of scarce resources do not apply to this issue.

The *American Journal of Bioethics* dedicated a section of its January 2018 issue to the case of John; a case which is similar to that of Mr Walsh. Each of the three articles argued that John should receive a second valve. Kirkpatrick and Smith focus on the risk of recidivism. Because they believe there are 'favourable signs' that John will not relapse postsurgery, they argue that he should be offered a second surgery.¹⁴ Daniel Buchman and Marie-Josée Lynch turn to the structural factors that affect persons with OUD and the stigma that such persons carry in medical settings. They maintain that John should be offered a second valve replacement 'if it is clinically indicated'. Withholding the procedure 'intensifies his structural disadvantage and leaves him worse off'.¹⁵ Mishra notes that DiMaio's 'patient-blaming' approach is inconsistently applied.¹⁶ Many patients are responsible for their medical conditions and still receive lifesaving treatment. Furthermore, she argues that bedside rationing is inappropriate and that public policies should address the responsibility of medical professionals to provide limited and expensive therapies to patients whose lifestyles cause their diseases.

The work of Baldassarri, Buchman and Lynch and Mishra is promising but in need of further development. Drawing on their insights, I argue that a principlist approach to the issue supports the provision of a second valve transplant to patients with IVDU-induced aortic valve endocarditis.

PRINCIPLISM

Patients and providers need a best, current, methodological approach to medical ethical decision-making in a pluralistic context. The best candidate for such an account is Beauchamp's and Childress's *Principles of Biomedical Ethics*, now in its eighth edition. Although principlism is not without its problems,^{17–19} it does provide viable a set of principles that are widely held by medical ethicists and which guide and inform the work of ethics committees at many secular medical facilities.

Beauchamp and Childress contend that each principle 'must be specified in order to achieve more concrete guidance'.²⁰ Below I offer action-guiding specifications for the principles of autonomy, non-maleficence and beneficence. Due to the fact that I draw on their formal account of justice I do not offer a specification of this principle.

The principle of respect for patient autonomy *prima facie* requires medical professionals to 'acknowledge (patients') right to hold views, to make choices and to take actions based on their

values and beliefs²¹ Specified for the purpose of analysing this case, medical professionals should respect autonomous requests for lifesaving treatment except when such treatment violates another's autonomy or violates one or more of the three other principles such that the violation of one or more of the former principles outweighs the respect for patient autonomy. The principle of non-maleficence *prima facie* obligates medical professionals to avoid 'thwarting, defeating or setting back of some party's interest'.²² This account of non-maleficence focuses on the bodily and mental harms that patients suffer at the hands of medical professionals. More specifically, this principle guides medical professionals to provide lifesaving treatment unless such treatment is more probable than not to kill or to seriously disable the patient. Medical professionals undertake specific obligations of beneficence 'through entering a profession and taking on professional roles' to promote the well-being of their patients.²³ The principle of beneficence directs providers to attempt to preserve a patient's life and to improve a patient's health, if possible. When specified, this principle guides medical professionals to provide surgeries that have a reasonable probability to save the lives of patients who suffer from deadly medical conditions. Finally, the principle of formal justice states 'that no matter what respects are under consideration, if persons are equal in those respects, then they must be treated equally', and 'that no person should be treated unequally, despite all differences with other persons, unless it has been shown that there is a difference between them relevant to the treatment at stake'.²⁴ Although this formal notion of justice is devoid of ethical content, it does aid in comparing cases to ensure that patients are not victims of unfair discrimination.

CASE ANALYSIS

Recall that Mr Walsh is autonomously requesting an aortic valve replacement—a lifesaving treatment. The medical providers have no reason to believe that Mr Walsh's decision does not satisfy the threshold for autonomous choice. Medical providers should respect a patient's autonomous choice to pursue medically indicated treatments unless 'competing moral considerations override' autonomy.²⁵ Drawing on the specification of autonomy presented above, because Mr Walsh has autonomously requested a medically indicated, lifesaving treatment, his request should be fulfilled unless the valve replacement significantly violates another's autonomy or one or more of the three remaining principles.

The repeat aortic valve surgery for Mr Walsh is non-maleficent. First, the surgery does not expose Mr Walsh to a substantial risk of harm. As demonstrated above, second valve replacements are as safe as initial replacements. Second, the surgery is not medically or physiologically futile for Mr Walsh. The surgery is medically indicated and has a low probability that it will kill or permanently disable Mr Walsh. In sum, the surgery does not set back Mr Walsh's interests.

Next, the surgery is beneficent for Mr Walsh. The surgical team has determined that Mr Walsh's valve replacement is medically indicated and has a high probability of saving his life. In this case, the medical team has the duty to rescue. They can reasonably expect to save the patient's life without exposing neither the Mr Walsh nor themselves to risks of harm or unreasonable burdens.

Finally, a comparison of cases demonstrates that patients with OUD, such as Mr Walsh, are equals who often are treated unequally. Baldassarri *et al* invite us to consider the cases of the irresponsible hiker and the irresponsible motorcyclist. The hiker is a woman who regularly walks in the woods without proper

protection from ticks. As a result, she has acquired Lyme disease many times. They note that 'no physician would deny her antibiotic treatment even though she has a recurring infection triggered by her own actions'.¹ The 'irresponsible hiker' case is the paradigm case, which shares relevant similarities with Mr Walsh's case. Both the hiker and Mr Walsh causally contributed to their diseases. Both required the same medical interventions multiple times to restore their health. The only significant differences between these cases are the level of resources required and the procedures' costs. However, altering the paradigm case addresses this difference. Imagine a young man, helmetless, sustained cranial fractures and brain injuries on multiple occasions. Physicians repeatedly would operate to fix the cranial and brain injuries, all at a substantial cost to the hospital and the public. There is no substantive difference between the 'irresponsible motorcyclist' and Mr Walsh because they are equal in morally relevant respects. Each has caused life-threatening harm to his health that requires expensive life-saving interventions. These equals should be treated equally.

This section proves that the provision of a second aortic valve surgery for Mr Walsh is recommended in light of an application of the principles of the respect for patient autonomy, non-maleficence, beneficence and justice. The lifesaving procedure has been autonomously requested by Mr Walsh, does not set back his interests, offers a high probability of restoring his health and is consistent with how contemporary medical practice treats patients with self-inflicted health problems. Those who disagree with this conclusion must demonstrate how the valve surgery violates one of the four principles.

GUIDELINES FOR LIMITING REPEAT VALVE REPLACEMENTS FOR PATIENTS WITH LIKELY IVDU-INDUCED ENDOCARDITIS

As argued above, autonomous patient requests for medically indicated, lifesaving treatment typically should be respected by medical providers. However, it is ethically justifiable to deny a patient a second or third valve replacement in certain circumstances.

Providers can deny a repeat valve replacement if:

1. The surgery is deemed maleficent. This applies to surgeries in which the risk of harm far outweighs the expected benefit of the surgery to the patient as well as situations in which the surgery is medically non-beneficial (physiologically futile).
2. The surgery violates a community adopted material theory of justice. Such a community will advance ethical reasons, derived from its account of material justice, for limiting valve surgeries for patients with OUD. For example, a hospital may decide, as a matter of policy, to limit patients to a single-valve replacement if the community intends to focus on promoting an egalitarian distribution of its medical resources (prioritising numerical lives over identifiable lives, broadening access to medical care for the poor, starting an outreach service to persons suffering from homelessness, etc). The adoption of a material account of justice should emerge from an open public conversation among all community stakeholders.

Providers cannot justifiably deny a valve replacement to a patient suffering from OUD for reasons of psychosocial futility or qualitative futility. Medical professionals can and should distribute medical treatments based on the probability that the treatment will be medically effective. However, such reasoning fails when dealing with patients who are 'likely' or 'unlikely' to remain sober. Although statistics regarding recidivism postvalve replacement provide insight regarding past patients' behaviours, such data are not predictive of whether *this* patient will return

to IVDU. Patients have moral agency, and, thus, their actions do not emerge in a mechanistic fashion, unlike medicines that have ‘mechanisms of action’ which are probabilistically efficacious. Qualitative futility raises philosophical, not medical, questions. Whether a human person will enjoy sufficient quality of life after a medical intervention cannot be answered by medical providers *qua* medical providers. Medical providers who attempt to determine psychosocial and qualitative futility commit the error of generalising their expertise.²⁶

CONCLUSION

In the absence of a material theory of justice that would exclude such provision, medical providers should provide medically indicated repeat heart valve replacements for patients with IVDU-induced endocarditis. The refusal to do so violates the principles of respect for autonomy, non-maleficence, beneficence and justice. Persons suffering from OUD have a clinically verifiable brain disease and should be treated as such.²⁷ They are as deserving of treatment as those other patients whose lifestyle decisions causally contributed to their diseases. Stigmatising and refusing to save the lives of persons with OUD is a grave violation of the common medical morality.

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