

# One Pulsatile Heart Pump Size Does Not Fit All Patients



*In recent years, the medical device industry has grappled with a fundamental challenge in cardiac care: the standardization of ventricular assist devices (VADs).*

While mass production and standardization have made these life-saving devices more accessible, the one-size-fits-all approach increasingly conflicts with the principles of personalized medicine.

This tension between standardization and personalization has sparked crucial debates among healthcare providers, manufacturers, and patient advocates.

## BACKGROUND

The first-generation ventricular assist devices (VAD) systems for adult patients relied on volume displacement pumps with one constant stroke volume for all sizes of patients. The concept of one size of the medical device for all patients goes against the principle of personalized medicine. Personalized medicine emphasizes the importance of tailoring the size and design of these devices to the individual needs of patients. The using a one standard size of a pump can lead to suboptimal outcomes. Factors such as body size, and specific medical conditions must be considered when

selecting a heart pump.

The mismatch between the device size and the patient's physiological requirements can occur and result in complications such as non-physiological blood flows and pressure or inefficient circulatory support. The issues are particularly critical in patients with unique anatomical features or extreme body sizes. By adopting a personalized approach, clinicians can improve the effectiveness and safety of treatment while reducing the risk of complications.



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## Cleveland Clinics'

## Medical Device Mismatch

***To explore the ethical complexities of standardized medical devices in modern healthcare, consider the case at Cleveland Clinic's cardiac unit. In this high-stakes situation, a critical decision had to be made regarding the use of a standard-sized ventricular assist device (VAD) for a patient whose physical dimensions fell well outside the typical range, highlighting the tension between standardized medical solutions and personalized patient care.***

Dr. Olivia Park faced an ethical dilemma in Lakeside Medical Center's cardiac unit. Her patient, Thomas Jenkins, needed an urgent VAD implant, but at 6'7" with an unusually large chest cavity, the standard device seemed inadequate. As she reviewed his case file late into the evening, the weight of the decision pressed heavily on her mind. Thomas's condition was deteriorating rapidly, and time was not on their side.

"We can't delay any longer," urged Dr. Victor Patel, head of cardiology, during an emergency staff meeting. "The standard VAD is FDA-approved and insurance-covered. Custom solutions would take weeks we don't have." His voice carried the authority of years of experience, but also the pragmatism that came from working within a complex healthcare system.

"But forcing a standard-sized device could cause complications," Olivia countered, pulling up Thomas's scans on the conference room display. "The blood flow patterns would be non-physiological. We'd be knowingly using a suboptimal solution." She pointed to specific areas of concern on the imaging, highlighting the potential risks.

The hospital's ethics committee was split. Dr. Elena Rivera, representing patient advocacy, supported Olivia's concerns: "We're ignoring individual patient needs for the sake of standardization. How is this patient-centered care?" Her passionate defense of personalized medicine resonated with many committee members who had seen similar cases before. Meanwhile, Dr. Benjamin Foster from hospital administration emphasized practical constraints: "Custom devices mean higher costs, longer waiting times, and complex regulatory approvals. How many patients could we help with those extra resources?" His arguments reflected the broader challenges of resource allocation in modern healthcare.

The debate touched on core issues in modern medicine: standardization versus personalization, immediate access versus optimal outcomes, cost efficiency versus individualized care. For Thomas Jenkins and thousands of other patients, the stakes couldn't be higher. The resolution would not only impact Thomas's immediate health outcomes but also set a precedent for how the medical community balances standardization with personalized care in critical situations. As the committee deliberated, the clock kept ticking, and somewhere in the cardiac unit, Thomas Jenkins waited for a decision that would determine his future.



# Ethical Considerations

## 1. Patient Safety at Risk

The use of standardized heart pumps for patients with non-standard anatomies poses significant safety concerns. When medical devices don't match a patient's physical requirements, it can lead to improper blood flow, tissue damage, and potentially life-threatening complications. This is particularly concerning for patients who fall outside the "average" size range, where using standardized devices essentially forces their bodies to adapt to the device rather than the other way around.

## 2. Compromised Medical Decision-Making

The pressure to use standardized devices due to cost, availability, and insurance coverage can force healthcare providers to compromise their medical judgment. Doctors may find themselves in situations where they must choose between using a suboptimal device immediately or waiting for a better-suited option while the patient's condition deteriorates. This creates a profound ethical conflict between immediate intervention and optimal care.

## 3. Economic Discrimination

The high costs associated with personalized medical devices effectively create a two-tiered healthcare system. Wealthy patients might be able to access custom solutions, while others must accept standard devices regardless of fit. This raises serious concerns about healthcare equity and access to appropriate medical care based on financial status.

## 4. Bias in Research and Development

The development and testing of heart pumps predominantly focuses on average-sized patients, effectively discriminating against those who fall outside these parameters. This systematic bias in medical device research and development means that certain patient populations are consistently underserved, raising questions about the ethics of current medical device development practices.

# Ethical Considerations



## Mitigating Risks

### 1. Preoperative Assessment

Advanced imaging and computational modeling are essential for patients with non-standard anatomies. Comprehensive 3D cardiac mapping and fluid dynamics simulations can predict how devices will function in atypical chest cavities, quantifying specific risks and providing evidence for alternative approaches.

### 2. Personalized Device Selection

Modern approaches include modular VAD systems with interchangeable components that accommodate anatomical variations. Adjustable flow rates and positioning options can partially compensate for size mismatches. Emergency exemptions for modified devices may be pursued when standard options are clearly inadequate.

### 3. Postoperative Monitoring and Follow-up

Enhanced monitoring protocols should specifically target complications most likely in non-standard cases: abnormal flow dynamics, device migration, or unusual mechanical strain. This includes more frequent echocardiograms, specialized flow measurements, and adjusted intervention thresholds.

### 4. Optimize Anticoagulation Therapy

Non-physiological blood flow patterns require carefully tailored anticoagulation regimens. This may involve sophisticated coagulation marker monitoring, personalized dosing algorithms, and modified target ranges to account for unique flow dynamics in larger cardiac chambers.

### 5. Interdisciplinary Care Team

Cases involving device-patient mismatches benefit from teams including specialists experienced with atypical patients, biomedical engineers familiar with device limitations, ethics consultants, and patient advocates. Such collaboration helps develop protocols for similar future situations.

### 6. Patient Education and Engagement

Transparent communication about anatomical challenges, device limitations, and potential trade-offs between immediate intervention and customization is crucial. Patients should understand the specific complications to watch for and participate meaningfully in difficult decisions.

### 7. Early Detection of Complications

Specialized monitoring algorithms can detect unique warning signs that emerge with size mismatches. Predictive analytics comparing post-implant data with historical information from similar atypical cases can identify concerning patterns before clinical symptoms develop.

### 8. Clinical Trials and Research

Device trials must include patients with diverse body sizes and anatomies. Research should specifically evaluate performance in patients outside standard parameters, with findings documented to inform future designs and clinical protocols.

### 9. Ethical Resource Allocation

Healthcare institutions should develop transparent frameworks for deciding when customized solutions are justified. These frameworks must balance immediate needs, long-term outcomes, resource constraints, and equity considerations while avoiding discrimination against patients with non-standard anatomies.

# Questions for Reflection

1. Was the patient's specific anatomy and physiology adequately considered in selecting the heart pump?
2. How did the chosen device impact the patient's quality of life and long-term health outcomes?
3. Were the risks and benefits of the device communicated effectively to the patient and their family?
4. Were there alternative options (e.g., different device types or surgical interventions) that should have been considered?
5. How did the multidisciplinary team contribute to the decision-making process, and were there any gaps in communication?
6. Were potential risks such as thrombosis, tissue damage, or device failure adequately anticipated and mitigated?
7. How was anticoagulation therapy individualized for the patient's needs, and were there any complications related to this approach?
8. Were ethical principles like beneficence, non-maleficence, and equity upheld in the patient's care?
9. Was the patient treated fairly in terms of access to advanced or personalized devices?
10. Could advancements in materials or customization have improved the patient's outcomes?
11. What lessons were learned from this case that could improve future device selection and implantation?

