Clarification of the intent of ventricular assist devices before patient consent

Courtenay R. Bruce, JD, MA,[a,b] Martin L. Smith, STD,[c,d] and Laurence B. McCullough, PhD[a]

Moazami and Feldman[1] recently proposed a single indication for mechanical circulatory support (MCS). This indication, ''end-stage heart failure refractory to medical therapy,''[1] similar to the tripartite nomenclature (''destination therapy,'' ''bridge to transplant,'' and ''bridge to recovery'') by the Centers for Medicare and Medicaid Services (CMS),[2] is clinically and ethically incomplete. In this article, we describe how the CMS tripartite nomenclature unintentionally increases the risk of ethical problems characterized by misalignments in expectations and goals among heart failure teams, patients, and surrogates, and thus increases the risk of an inadequate informed consent process for MCS. Similar to Moazami and Feldman,[1] we assert that the current tripartite nomenclature is problematic because of its emphasis on intended use. However, in providing only the single indication of MCS, the proposal by Moazami and Feldman[1] does not address the nature of MCS, its short- and long-term goals, or outcomes. As a result, their proposal does not fully address the ethical problems with the CMS nomenclature.

We address this ethical challenge with an ethically justified, clinically practical framework for describing ventricular assist device (VAD) implantation. Although this framework is particularly relevant for VADs, it is likely equally applicable for most other types of MCS devices.

As clinical ethicists at 3 high-volume VAD programs, we often participate in informed consent processes with VAD candidates to elucidate patients' and surrogates' understanding and expectations of the device, trajectories, and outcomes, and to document advance care planning preferences before device implantation. We also conduct ethics consultations for VAD patients who already have the device implanted, typically for the purpose of mediating conflicts between surrogates or between surrogates and health care professionals about device deactivation and withdrawal of other life-sustaining treatments. Through this experience, we believe that many such ethics consultations are generated unnecessarily by misalignments in expectations and goals among heart failure clinicians, patients, and surrogates that originate in an exclusive focus on the intended use of VADs and the current CMS nomenclature.

The categorization of purposes and patients within CMS nomenclature is not hard and fast. Patients move from one category to another as clinical factors change, a reality acknowledged in an often-used fourth category, ''bridge to decision.''[3] Some bridge to transplant patients who do not perform as well as expected or intended on a device do not receive a heart transplant (eg, a patient who suffers from a disabling stroke). They then shift to the category of ''destination therapy.''[3] Approximately 17% of destination therapy patients receive a transplant after correcting psychosocial or medical contraindications to transplantation, for example, kidney dysfunction or a lack of supportive networks.[4] We refer to this shift from one intended use of a device (eg, bridge to transplant) to another (eg, destination therapy), as risk of drift.

There are 2 significant components of the informed consent process that need special attention for that process to be adequate: transparent disclosure and patient comprehension and understanding.[5] These components of the informed consent process are undermined by reliance on the CMS nomenclature because it masks the risk of drift. For instance, the phrase ''destination therapy'' masks the reality that there are at least 4 possible destinations, as follows: (1) permanent implantation with disease-related and iatrogenic morbidity but with an acceptable quality of life; (2) permanent implantation and prolonged intensive care unit admission, with disease-related and iatrogenic morbidity and loss of functional status resulting in an unacceptable quality of life; (3) permanent implantation followed by explantation and transplantation, with disease-related and iatrogenic morbidity and an acceptable quality of life; and (4) permanent implantation followed by explantation, transplantation, and prolonged intensive care unit admission, resulting in disease-related and iatrogenic morbidity and loss of functional status resulting in an unacceptable quality of life.

Essential to adequate patient comprehension and evaluation of such outcomes is that patients can reason from present events to future consequences and have a sense of the probability that disclosed potential consequences may indeed occur.[5] Unfortunately, the CMS categories invite unwary clinicians to focus almost exclusively on the use or

From the Center for Medical Ethics and Health Policy,[a] Baylor College of Medicine, Houston, Tex; The Methodist Hospital System,[b] Houston, Tex; Department of Bioethics,[c] and Center for Ethics, Humanities and Spiritual Care,[d] Cleveland Clinic, Cleveland, Ohio.

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Address for reprints: Courtenay R. Bruce, JD, MA, One Baylor Plaza, MS: BCM 420, Houston, TX 77030 (E-mail: crbruce@bcm.edu).

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intended purposes of the device. As a result, patients are put at increased risk of failing to grasp the nature and likelihood of future consequences attendant upon each of the therapeutic options available or the possible outcomes that may be experienced. The options experienced by or available to patients are unjustifiably limited.

Although the nature, purpose, and possible outcomes of an intervention are distinct concepts and requisites for informed consent, within the CMS nomenclature these distinct concepts are fused and therefore can create confusion, which increases the risk of unintentional but real and potent preventable ethical conflict. Consider the following preventable ethical problems characterized by misalignments in expectations and goals among clinicians, patients, and surrogates.

First, because of the tripartite nomenclature, patients may not grasp the nature and likelihood of possible trajectories and outcomes that they may experience. As a result, they may not be able to account for why some patients receive transplants and others do not.[4] Second, of greater concern with the nomenclature and its focus on intended purposes is the likelihood that patients and surrogates are not prepared for outcomes deviating from the originally intended purpose of the device. Consider a case involving a patient who initially is considered a bridge to transplant candidate for whom a series of complications develop after VAD implantation, perhaps a stroke or renal, hepatic, and respiratory failure.[3] The surrogate may resist discussions about medical futility and forgoing life-sustaining therapies, citing pre-intervention discussions focused on transplantation and the term ''bridge to transplant.''

Third, reliance on CMS nomenclature and intended purposes may preclude conducting advance care planning. Some VAD programs integrate palliative medicine consultations for patients receiving VADs as destination therapy, for the purpose of elucidating quality-of-life preferences before device implantation.[6,7] However, if only destination therapy patients receive such consultations before implantation, patients for whom the intended purpose of the device shifts may not receive such referrals or, alternatively, receive them too late for palliative medicine to be fully helpful.

In recognition of the unintentional but preventable ethical problems resulting from the CMS nomenclature, we call for abandoning it and propose an alternative framework. Although a few points mentioned within the framework have been advanced by other investigators, for example, the value of proactive advance care planning,[7,8] we believe this framework is unique in that it is a step-wise approach that defines the nature, purpose, short- and long-term goals of VAD implantation, and responsible management of outcomes, thereby distinguishing specific, essential elements of informed consent that currently are fused within the CMS nomenclature. The framework also provides some of the necessary components for shared decision making between the patient and clinician.[8,9]

STEP 1: USE A NEW DESCRIPTION OF THE NATURE AND PURPOSE OF VAD

When addressing the nature and purpose of a VAD in the informed consent process, the following description should be used: VAD implantation is a surgical introduction of a life-sustaining intervention (nature) that is designed to prolong life with the goal of an acceptable outcome from continued clinical care (purpose), secondary to (as Moazami and Feldman[1] have proposed) end-stage heart failure refractory to medical therapy.

STEP 2: DESCRIBE SHORT- AND LONG-TERM GOALS

The use of a life-sustaining treatment, such as a VAD, is justified as long as both its short-term goal (prolonging life) and long-term goal (preserving for the patient some interactive capacity and an acceptable quality of life) are being achieved.[10] Patients need to understand the centrality of clinical judgments about resulting functional status and patients' own judgments about acceptable quality of life. Patients need to understand that VAD placement as an ongoing life-sustaining treatment frequently does not lead to device removal because the heart may not recover and transplantation may not be possible. Clinicians should caution that the probability of transplant may evolve over time (because of risk of drift), which may necessitate multidisciplinary reviews concerning candidacy for transplantation.

STEP 3: NEGOTIATE STOPPING RULES TO MANAGE OUTCOMES

The objective of initial conversations about stopping rules is to assist patients, in advance of the need for them, to deliberate about the quality of life associated with outcomes. Clinicians should discuss with patients the possible scenarios that can affect quality of life adversely such as debilitative comorbid conditions and VAD-associated complications.[6] More detailed conversations can take place after VAD placement if there is a negative shift in a patient's performance status. Patients should be encouraged to make advance decisions as explicit as possible and communicate those decisions to their surrogate decision makers.

We believe that abandoning the current CMS tripartite nomenclature in favor of a new, more informative framework will help mitigate or prevent the ethical problems we identified.

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