

Decisional Considerations in Left Ventricular Assist Device for Destination  
Therapy

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**Abstract**

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End-stage heart failure is a growing problem in the United States as well as world-wide. The definitive treatment in heart failure that is refractory to medical treatment is a heart transplant. But there are a limited numbers of hearts available for transplant and a growing number of patients in need. There has recently been tremendous development in the area of mechanical circulatory support. One of these developments is the left ventricular assist device (LVAD). The LVAD is a pump that assists the failing left ventricle of the heart. The LVAD has proven to increase survival and improve symptoms of end-stage heart failure.

Initially the LVAD was used to support patients with heart failure to survive to either recovery or heart transplant, thus termed a bridge therapy. But eventually these devices would be implanted without the intent of heart transplant or recovery, becoming known as destination therapy. A third category of LVAD designation is called bridge to candidacy. In this category

patients undergo the implantation of the LVAD and then are later determined whether they are appropriate for heart transplant.

For all patients and families who undertake LVAD therapy, there are risks, uncertainty, and benefits of the treatment. All categories of patients are making high-stakes decisions for their care while living under the threat of a life threatening condition. As is often the case in highly technological devices that prolong and sustain life, LVADs come with very serious and complex ethical challenges as well as psychosocial demands on patients and families.

The first paper in this manuscript addresses the ethical principle of prospective autonomy. The paper uses Walker and Avant's method of concept analysis to come to an operational definition of the concept of prospective autonomy. The definition achieved is: *Exerting current values, life experiences, and perspective to decide the course of one's future*. The defining attributes of the concept are identified as: oriented to the future and events that have not yet happened, independence in that the individual is choosing their course, competency in that the individual meets a threshold for ability to make a rational and prudent choice, authenticity in that it must reflect the individual's true self, knowledge that the person must have the pertinent information that is available, and lastly, self-determination.

The second paper describes original research investigating the process of decision-making in LVAD for destination therapy. The study was conducted with 11 participants with LVADs for destination therapy. The research found that the core process in decision-making was "no choice". This core process was sub-divided into two supporting processes: (a) being in a system of care and (b) having already invested so much in the LVAD. Additional interacting process themes were: (a) personal bias, (b) reacting, (c) perceiving what clinicians thought the

participant should do, (d) unclear goals and hopes, (e) isolation, and (f) severely constrained planning for the future.

The third paper is a secondary analysis from the above mentioned study on decision-making. This manuscript was generated from the unexpected finding of grief around the loss of hope for heart transplant in the participants. The themes identified in this analysis were: (a) taking it in, (b) heart transplant is not perfect, (c) jumping through hoops, (d) mistrust, (e) thinking about the hypothetical, and (f) hope.

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**Dedication**

To my sons: Aidan, Andersen, and Quentin.

My greatest teachers. My beloved.

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I am in awe and deeply grateful to my research participants. To the participant who died before I would complete the writing of this dissertation - I was reminded how valuable and sacred the time was that each participant gave me.

Lastly, For Stu:

He said it doesn't look good  
He said it looks bad in fact real bad  
He said I counted thirty-two of them on one lung before  
I quit counting them  
I said I'm glad I wouldn't want to know  
About anymore being there than that  
He said are you a religious man do you kneel down  
In forest groves and let yourself ask for help  
when you come to a waterfall  
mist blowing against your face and arms  
do you stop and ask for understanding at those moments  
I said not yet but I intend to start today  
He said I'm real sorry he said  
I wish I had some other kind of news to give you  
I said Amen and he said something else  
I didn't catch and not knowing what else to do  
And not wanting him to have to repeat it  
And me have to fully digest it  
I just looked at him  
For a minute and he looked back it was then  
I jumped up and shook hands with this man who'd just given me  
Something no one else on earth had ever given me  
I may have even thanked him habit being so strong

- Raymond Carver  
"What the Doctor Said"

## CHAPTER ONE: The Introduction

### **Heart Failure**

Heart failure is a progressive disease where the pumping action of the heart becomes increasingly compromised. It often begins with vague symptoms, but eventually declares itself as a deadly disease that begins to affect all the other organs of the body. The failure of the heart is a complex process of physiological, cellular, and biochemical changes. Optimal medical management of heart failure has the goal of staving off the neurohumoral compensatory actions that lead to worsening pump failure. The most common causes of heart failure are: ischemic heart disease, hypertension, valvular heart disease, adult congenital heart disease, and an assortment of cardiomyopathies (e.g. alcohol related, obesity, familial, etc.). Failure of the left ventricle leads to venous congestion in the lungs causing breathlessness that worsens when laying down. Additional associated symptoms include sleep disorders, mood disturbances, and changes in cognitive functioning (Jenkins, 2016).

### **The Left Ventricular Assist Device**

Up to 300,000 adults in the United States are estimated to have end-stage heart failure (ACC/AHA Stage D or NYHA Class IV). When heart failure has progressed to the point of not being responsive to conventional therapies, there are two options; heart transplant and left ventricular assist devices (LVAD). However, heart transplant may not be an option for a patient due to advanced age or other illnesses (Vader & Joseph, 2015). Even if the patient is deemed a good candidate for a transplant the next issue is for the person to survive to when a donor heart becomes available. Originally, LVADs were used for the purpose of keeping the transplant candidate alive while they waited. But eventually LVAD use spread to patient who were not heart

transplant candidates, which is called destination therapy. The third use for LVADs is to bridge the patient to see if they can become a candidate for transplant (Fang & Stehlik, 2013).

LVADs continuously propel blood from the apex of the left ventricle to the aorta through either a centrifugal or axial pumping mechanism (Moazemi et al., 2013). The pump itself is implanted in the chest with a percutaneous lead that is connected to the controller and battery packs. The controller and battery packs are worn by the patient. The most common complications of LVAD therapy are: right ventricular failure, bleeding complications, device malfunctions, neurological events, infections, arrhythmias, and renal failure (Vader & Joseph, 2015). The majority of patients with an LVAD will suffer a complication within two years of getting the device.

### **Ethics and the LVAD**

For the majority of patients, deactivating an LVAD will lead to imminent death. This of course leads to ethical considerations of patient autonomy and the clinically perplexing line between living and dying that life supportive technologies produce. But LVADs are associated with continued high stakes decisions throughout treatment due to the frequency and often severity of device-associated complications. For these reasons, informed consent in LVAD therapy has been of major concern for both ethicists and researchers (Edlund, Edlund, & Carey, 2015; Rizzieri, Verheijde, Rady & McGregor, 2008).

In Guletz, Papadimos, & Toevs' (2014) ethical assessment of an LVAD case study the ethical issue of informed consent is identified as having multiple components (a) the necessary medical information must be conveyed to the patient in a way that is understandable including alternative treatment options and (b) an assessment that the information has in fact been received

by the patient. Other ethical considerations are autonomy and that autonomy is both a positive right and negative right, meaning that an autonomous decision can be both to pursue treatment or decline. This dissertation will tackle one ethical concern highly associated with LVADs, prospective autonomy, or making autonomous decisions for future care.

### **Decisional Support**

There has widely been a call for improving the informed consent process in LVAD therapy and also how to best support patients and families in decision-making. One idea that is being developed and tested are decisional aids for LVAD. For example, Thompson and colleagues (2015) have developed decisional aid specific for LVAD destination therapy that is both on paper (also online) and video. The decisional aid is designed to attend to both cognitive and emotional needs of patients and families deciding on implantation of the LVAD. Typically, emotional needs are not addressed in decisional aids. But as the reader of this dissertation will see in Chapter 4, there are very significant emotional concerns associated with this population.

Another promising development has been preparedness planning (Swetz et al., 2014). This is a rather lengthy and in-depth written plan for both after LVAD implantation and in the event that a complication should occur, how would the patient want it treated. This document address; goals/expectations, hemodialysis, intracranial hemorrhage or embolic stroke, device failure, device associated infections, artificial nutrition/hydration, blood transfusions, organ donation, mechanical ventilation, postoperative rehabilitative plans, health care power of attorney, psychosocial assessment, social support, post-LVAD morbidity and mortality information, and spiritual/religious preferences. Having a patient consider all of this is ideal, but in Chapter 2 important questions will be raised about *how* patients with LVAD for destination therapy may be approaching this long list of decisions.

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## CHAPTER TWO:

## Making Care Decision for the Future with Prospective Autonomy: A Concept Analysis

**ABSTRACT**

**Purpose:** The aim of this conceptual analysis is to identify attributes around prospective autonomy that are important in considering the nuanced conceptual difference between real-time autonomy and autonomy for situations that have not yet happened.

**Method:** Using the systematic approach of Walker and Avant's methodology of concept analysis, the concept *prospective autonomy* is analyzed by way of (1) usage of the concept (2) defining attributes (3) three case presentations (4) antecedents and consequences of prospective autonomy and (5) empirical referents.

**Results:** The definition achieved through this analysis of the concept prospective autonomy is: *exerting current values, life experiences and perspective to decide the course of one's future.*

**Conclusion:** Prospective autonomy is an important ethical concept in advance directives and end-of-life care. Conceptual understanding of prospective autonomy is a roadmap for clinical care, communication, and research that moves away from just choosing therapies and towards care that would be acceptable to the patient even when the individual can no longer participate in the decision-making.

## Background

In 1975, a young American woman named Karen Ann Quinlan would become the center of a highly publicized court battle that would lay the legal grounds for patients, or their surrogates on their behalf, to refuse life sustaining interventions in the U.S. (Olick, 2001). Ms. Quinlan was 21 years old when she suffered a cardiac arrest and was subsequently left in a persistent vegetative state. Six months into her care, her parents acting as Ms. Quinlan's surrogate decision-makers, requested that mechanical ventilation be stopped. The hospital and the attending physician refused to follow the parent's wishes and what ensued was a legal battle that was heard all the way to the New Jersey State Supreme Court. The court sided with Ms. Quinlan's parents and mechanical ventilation was stopped, although Ms. Quinlan did not pass away for another ten years (Quinlan & Quinlan, 1977).

Two decades later, in Italy, the case of another young woman, Eluana Englaro, would grip that country as her family requested that life prolonging treatment for their daughter be stopped. Ms. Englaro suffered life changing injuries from a motor vehicle collision in 1992 which left her in a persistent vegetative state. Her father was appointed her surrogate decision-maker four years after the crash and he would go on to litigate for the next thirteen years for the right to stop life-sustaining treatments. Eventually her father won the right to stop artificial hydration and nutrition and Ms. Englaro passed away February, 2009 (Luchetti, 2009). Much like Ms. Quinlan, this case has opened the discussion on right to die and has prompted a movement towards legally recognized advance directives in Italy (Gristina, Martin, & Ranieri, 2012).

Ethically and politically charged end-of-life cases are often cited as the catalysts that yield legal and health care reforms that shift ethical norms into new directions. Where once the paternalistic model of medicine was widely accepted, things have moved towards the principle of patient autonomy (Quill & Brody, 1996, p.763; Woodward, 1998, p. 1047). Respect for patient autonomy means acknowledging another's right to make choices. Autonomy is a fundamental respect of another's person-specific values and beliefs and that they can rightfully determine their own destiny.

In viewing autonomy, it is important to note the historical tradition of paternalism in healthcare. In paternalism, it is often the physician who is the decider, who is thought to know what is best for the patient. Paternalism is over-riding another's power to make decisions for themselves by preventing them from doing what they have decided on, substituting your own judgement for theirs, or interfering with their process of decision-making (Buchanan, 2007).

Medical ethics dating to the Hippocratic Oath were focused on the physician deciding on acts that were for the benefit of the patient. These acts were concerned with the removing, preventing, or mitigating of harms. In the *Corpus Hippocraticum* it says to "reveal nothing of the patient's future or present condition" (Faden & Beauchamp, 1986), and perhaps back when there were very limited options to truly prolong life or cure illness, this may have arguably been the humane route. But with modern healthcare and technology the ability to sustain and prolong life has increased, however these advancements are sometimes at the cost of life quality and at great burden to the patient and family. Thus, paternalism has become a rather

untenable ethic to maintain.

The tension between quality and quantity of life has led to a greater voice for the patients themselves. The weighing of quality versus quantity of life is coming to be seen as a person-specific value. Patients and families are expected to engage in the process of decision-making with clinicians by knowing what they value, what they prefer in their healthcare, and when treatments are too burdensome as weighed against benefit. This patient engagement has also required greater transparency and disclosure of health conditions. But often the point when a person needs to make such important decisions, such as in the case of Ms. Englaro, occurs when they have reached a condition where they can no longer express their wishes for their care due to advanced illness or injury.

Efforts to allow for those who have become voiceless or lost the capacity to make decisions for themselves to retain some control over their care led to the creation of documents that gave instructions for future healthcare. These documents and designations are called many things including surrogate decision makers, power of attorney, proxy decision maker, living wills, healthcare directives, advance directives, advance care planning, etc. For the purpose of this article, I will refer to this very broadly as advance directives. But the reader should be aware that these terms can mean many different things that are not recognized in all nations and even differ in meaning and recognition between states/territories within nations.

An advance directive is a document that can designate a person to act as a surrogate decision-maker and give either substitutive judgement or the instruction to act in the best interest of the person if they should be unable to state their own

wishes. The document can also give instructions about whether the person wants specific therapies and treatments or not. An advance directive can include both a surrogate decision-maker designation and specific instructions for care, or it may just be one or the other (Schneiderman, Pearlman, Kaplan, Anderson, & Rosenberg, 1992).

An example of implementation of these documents in the United States was the 1976 California state law, "The Natural Death Act." This law was one of many state laws that were influenced by the case of Ms. Quinlan. One purpose, as stated in the California law, is to "Protect individual autonomy" (State of California, 1991). This law gave Californians the empowerment to write down instructions today for what healthcare they desire for themselves in the future. In the United States, these state laws would be followed many years later by a nation-wide law, The Patient Self-Determination Act of 1990 provides all Americans with these same healthcare decision-making rights.

Since the advent of these laws regarding advance directives, Americans are showing a trend of increasing numbers of people writing down their wishes for future care. In Silveira et al. (2014) retrospective survey after death, they found that 72% of participants had some type of advance directive, while in 2000 that proportion was 47%. In Italy, where there is not yet an advance directive law, but there is growing interest, following the case of Ms. Englaro, a survey of physicians revealed that 66% of the respondents felt Italy needed specific laws about advance directives (Solarino, Bruno, Frati, Dell'Erba, & Frati, 2011).

While the legal definition of advance directive may be very concrete and

pertinent to the practice of nursing, nursing must also be versed in the ethics behind these documents; autonomy and autonomy for the future. Nurses must educate patients and families on advance directives and end-of-life care and are often called upon to follow an advance directive when the patient no longer has capacity to let their wishes be known. But these concepts and their common usage can be rather abstract and fluid. This paper seeks to consider the nuances and depth of meaning of prospective autonomy for both clinicians and researchers.

Chinn and Kramer (2008) address the fluidity of conceptual meaning as: "...most concepts carry a certain degree of ambiguity, and your meanings will alter as context for use change" (Chinn & Kramer, 2008, p. 194). This is especially true when we are talking about the critically ill and the degree of complexity in decision-making often required in end-of-life care. Additionally, advance directives have been drawn up for circumstances the person may have not yet experienced or even an illness, disease, or traumatic event that they would not know they would face.

The purpose of this paper is to take these two words, *prospective* and *autonomy*, and combine them for a solitary meaning (Chinn & Kramer, 2008). Walker and Avant's model for concept analysis (Walker & Avant, 2010) will be used to analyze and illustrate usage of the ethical term 'prospective autonomy.'

### **Selection of the concept**

Professional nursing is the largest discipline within healthcare and is often the profession that has the most direct and often rather intimate professional relationships with patients and families. Nursing is a moral endeavor, because at the

core of nursing is ‘good care.’ But what constitutes good care can change over the life span such as when health transitions into an incurable disease or unrecoverable injury. Nurses inevitably face clinical situations that require ethical decision-making and awareness, this requires expertise in both the language we use to name and describe the circumstances and a depth of understanding of the ethical tensions in play. Rarely is this more acutely felt than in end-of-life care.

An aging population (Joint Commission on Accreditation of Health Care Organizations, 2003) combined with new technology, new interventions, and better pharmacology (Altmann & Collins, 2007) have created the perfect storm of people living longer lives but often with chronic illness. Suffering may be caused by both the illness and the treatment thereof. There has also been simultaneous growth in technology and access to information. This access has allowed communities to at times be more informed and sometimes misinformed about health, healthcare, and technological limitations.

Analyzing autonomy and considering the imperfect process of exerting it for an uncertain future, that the person has not experienced yet, is pertinent to the clinical practice and the research of good nursing care, particularly in end-of-life care.

## **Analysis**

### *Aims of the analysis*

Using a methodical approach, an analysis of *prospective autonomy* will be developed and further the dialogue of this phrase so that it may be used in the future with some certainty so that the meaning is clear.

*Uses of the concept*

There is a good deal of literature that defines autonomy. In Merriam-Webster's Third New International Dictionary (1993, p.148) autonomy is defined as, "the quality or state of being independent, free, and self-directing; having the right and power of self-government: morally self-legislating." From this definition there is a very obvious ability to apply the word, autonomy, to both individuals and groups. This concept analysis will focus on individual autonomy.

For a person to have autonomy, they must have the capacity to make decisions (Keenan 1999). Intricately woven into capacity is having and understanding information (Faden & Beauchamp, 1986; Beauchamp & Childress, 1994). The presentation and comprehension of that information is the underpinning of informed consent. But autonomy is not only concerned with medical or biological knowledge, Keenan (1999, p.558) describes the base of knowledge needed for autonomy as coming from "...scientific, personal, professional, or experiential" realms. This is the unique quality of knowledge, which encompasses many other dimensions of personhood including the religious, spiritual, and existential realms.

Proot et al. (1998) describes autonomy as giving individuals the ability to live "rational lives". But it is the "rational life" as that individual defines it. Supporting this, from Mill's (1859) work on liberty, he stressed that societal norms should not be imposed on autonomy. Meaning that in order for each person to live autonomously they must be able to make authentic decisions for themselves. Outsiders cannot therefore identify another's autonomy using their own sense of rationality.

Deliberate action is often cited when defining autonomy (Abramson, 1985; Gillon, 1995). But going deeper than autonomy just being an action, Beauchamp and Childress (1994) point out that an autonomous person can make a non-autonomous decision. This means that a person can, free of being controlled by anyone or anything, make a treatment choice that sets aside autonomy (such as choosing care where they will be dependent).

This is particularly important when defining prospective autonomy because it leaves the door wide open for each autonomous person to make their own authentic choices. Schermer (2002, p.2) says autonomy is global and not, "a characteristic of specific actions or choices." Meaning that autonomy cannot be defined by a laundry list of isolated deeds. Autonomy also is not constrained by time, one can say; it was an autonomous decision, it is an autonomous decision, it will be an autonomous decision.

Prospective is the possibility and anticipation of something in the future. In Merriam-Webster's Third New International Dictionary (1993, p.1821) prospective is defined as "commanding an extensive view; foresighted, forward-looking; concerned with or relating to the future: effective in the future." To combine the Merriam Webster definition of autonomy (given above) with prospective creates a combined definition of 'future independence and freedom'.

In health and wellness, the future is not always so clear or predictable. Certainly we know that death is inevitable, but the trajectory to get there is idiosyncratic. It is also questionable if one has never been through the benefits and burdens of a treatment to imagine what it would be like and what they would truly want. It is also quite difficult to predict the condition of one's health or lack thereof when the treatment

decision would need to be made. Prospective is a time that has not come and a situation that has not yet arisen.

Prospective autonomy is a plan now for this future. It is based on the deepest core beliefs and values of the person in the present time and past. Kuczewski (1999, p. 33) says, "People are their stories, not just their psychological states or their biological sensations." Prospective autonomy allows for life to be finished in a way that is congruent with how the person chose to live the majority of their life (Kuczewski, 1999, p.33). This addresses authenticity in autonomy, meaning that the true moral compass or character of the person is directly connected to autonomy (Feinberg, 1986, p.27-51).

Authenticity speaks to who the person is, what they value and what guides them. It is the essence of *the person*. Quante (1999, p. 366) says, "We are mainly concerned with our values and our personality when we plan for our own future." These core issues that drive prospective autonomy and are as unique as a fingerprint. The uniqueness is built upon throughout an individual's lifespan.

Olick (2001, p. xv) defines prospective autonomy as meaning "...having a view now toward what will happen in the future." He identifies two key steps; planning and action. This planning and action in the present tense is for what is yet to exist. Post (1995, p.309) describes the concept prospective autonomy in a way that almost breaks the individual into two parts; the now self and the then self.

Another aspect of future planning means not plotting the course, but rather choosing someone who will. Norman Cantor (1992) illustrates this with the following, "By formulating instructions regarding future medical intervention, the declarant (directive-maker) seeks to shape medical handling

according to his personal preferences." Cantor speaks to appointing someone to make decisions based on one's wishes as a means for communicating current values into the future (Cantor, 1992, p.34). In this situation, an individual is essentially making themselves dependent on another person's ability to predict what they would want done.

### *Defining Attributes*

Defining attributes are a cluster of terms used most commonly in explaining a concept. These are the attributes that one relies on to identify if what they are seeing truly can be described as the concept of interest.

- *Future*: Prospective autonomy addresses events in the future. It is not real-time.
- *Independence*: The individual has chosen their own course of action.
- *Competency*. At the time of decision, the person must meet a threshold for capability to make a rational and prudent decision.
- *Authenticity*: The decision must be a reflection of the individual's true values, character, and life experiences.
- *Knowledge*: An autonomous decision is dependent on the decider having all the information available.
- *Self-determination*: This is the action part of autonomy. This is an expression of one's liberty. It is a phrase that is used quite often when defining all forms of autonomy.

### **Constructed Cases**

Constructed cases help illustrate the conceptual phenomena through a model case, borderline case, and contrary case (Walker & Avant, 2011).

### *Model Case*

This is an illustrative of use of a case where all defining attributes will be present.

A seventy-six-year-old patient, Mrs. Kim, is seen by her primary care physician at the urging of her husband and children who are concerned at her memory loss. Her examination is suspicious for early stages of dementia. The patient undergoes further laboratory testing which reveals no other potential cause for her memory loss. She is referred to a specialist who confirms a diagnosis of Alzheimer's dementia. She begins on medication and returns to her primary care provider for a follow-up appointment.

Mrs. Kim has found her new diagnosis of dementia to be devastating. She wants full information on her prognosis and what to expect with this new diagnosis. Mrs. Kim brings her husband and daughter with her to the appointment. During this very serious discussion with her physician and her family, the fact that she has an incurable and progressive disease is discussed, but also that she can continue to thrive and live well with the disease. Mrs. Kim expresses that she wants to lessen the burden to her family as much as possible, and her physician suggests that she does her advance care planning now, while she able.

Mrs. Kim discusses with her physician and her family her desires for a natural death that is peaceful. She reflects on what quality of life makes her life worth living, and decides that she would not want life prolonging therapies if she

could not recognize and interact with her family. The physician explains the risks and benefits of artificial nutrition and hydration. Mrs. Kim and her family ask a few clarifying questions, which are answered. With this information, Mrs. Kim feels that she would prefer in the later stages of her disease to forego those therapies and instead would want the focus her care on promoting her quality of life and not to lengthen the end-stages of her disease. Mrs. Kim expresses a desire to be treated for pain and suffering. She values her privacy and dignity, so her hope is to spend her final months to days in her own home with her loved ones.

Next, Mrs. Kim considers who should make decisions for her if she cannot. Mrs. Kim explains that her husband has in the past had trouble making difficult decisions. Mrs. Kim decides that her daughter would be better be able to carry out her wishes as her surrogate decision-maker. The physician offers legal forms, but Mrs. Kim declines and instead arranges to have a family member, who happens to be a lawyer, draw up the documents for her.

Mrs. Kim is addressing the possibility of being incapacitated in the future. She is independent in her decision making, although seeking counsel from those she prefers to by including her physician, family, and lawyer. She currently has capacity to make decisions for herself, although she is aware that she likely will lose that capacity. She is making authentic decisions that represent her past experiences and her authentic values. She has chosen to be fully informed by a health professional who is clinically knowledgeable about her specific health circumstances. Lastly, she has taken action on her decision by instituting an advance directive and choosing a surrogate decision-maker that she has determined to be capable of carrying out her wishes.

*Borderline Case*

This is an illustration of a situation where some, but not all of the defining attributes are present.

Mrs. Kim and her husband make an appointment with her attorney to discuss her advance care planning. Mrs. Kim arrives with a summary of what she had discussed at her doctor's appointment. While drawing up her surrogate decision-maker documents, her attorney asks her if she is sure that she does not want her husband to make decisions for her. The attorney tells her that usually it is the spouse that makes decisions. Mrs. Kim feels uncomfortable talking about this in front of her husband, as she worries this could make her husband feel like she does not trust him to make these decisions and he will be hurt by this. So Mrs. Kim instructs to have her husband as her surrogate decision-maker.

Mrs. Kim has lost her authenticity in this decision. She is still making the decision and is still very competent. It is true that often spouses make decisions for their loved ones, but prospective autonomy is a reflection of the individual's life experiences and liberty to choose in their own best interest based on that. A discussion of *why* Mrs. Kim wanted her daughter to make decisions for her would have led the attorney to see that Mrs. Kim had prior experiences, which under thoughtful consideration, had led her to choose her daughter as the person she thought best to carry out her wishes.

*Contrary case*

In the contrary case, the reader will see none of the defining attributes. This is illustrative of what prospective autonomy is not.

Over the next seven years, Mrs. Kim's dementia progresses and she eventually loses the ability to recognize her family, her speech becomes very limited, and she is spending her days in her bed incontinent of urine and stool. Her family continues to honor her wishes of being at home and surrounded by her loved ones. She is able to eat pureed food that is hand fed to her. But one day she becomes more lethargic and stops swallowing the pureed food. Her husband calls for an ambulance and she is taken to the hospital.

Once in the emergency room, she undergoes a battery of tests and begins intravenous antibiotic treatment for pneumonia. Mrs. Kim develops difficulty breathing and is placed on high flow oxygen. She is transferred to the critical care unit. Once in the critical care unit, her breathing worsens and her husband is asked if she would want a breathing tube. He thinks she would because she is not yet at the end of her life. Mrs. Kim is placed on a ventilator. The next day, the critical care team places a feeding tube in her nose for short-term artificial nutrition.

The critical care team holds a meeting with Mr. Kim and the children. The children voice concern that Mrs. Kim did not want this treatment and Mr. Kim feels strongly that Mrs. Kim never said she would not want pneumonia treated. Mrs. Kim is treated with minimal pain medication and no sedation, in hopes of her being awake enough to successfully breathe on her own. But after two weeks without medical improvement, Mr. Kim and the family decide to not have a tracheostomy placed for long term mechanical ventilation and instead ask that Mrs. Kim be extubated. Mrs. Kim

is removed from the breathing machine and dies in the intensive care unit.

Mrs. Kim's prospective autonomy has unfortunately had minimal impact on her end-of-life care. Her desire was to focus treatment on her quality of life, minimize suffering and pain, to be at home, and to have privacy. The condition under which she did not want life prolonging treatment was when she could no longer recognize and speak with her family, which had unfortunately happened. Her husband, perhaps through grief, did not recognize that she had reached the end of life in dementia, displaying a lack of knowledge as her surrogate. This death did not reflect her values, what she had self-determined, and her independence in those decisions was over-ridden by her husband.

### **Antecedents and Consequences**

Identifying what must happen prior to a concept and then the results of the concept are integral to evaluating the greater framework that the concept is practicing within.

#### *Antecedents*

When looking at prospective autonomy it goes without saying that prior to looking to the future, an individual must be dealing with their autonomy in real time. William Littlewood (1999) identifies two autonomies; proactive (the individual is plotting their course) and reactive (the individual is making autonomous decisions within the confines of what has already been chosen for them). Littlewood surmises that the reactive may be a pre-requisite (or a destination within itself) to a more proactive autonomy (Littlewood, 1999, p. 75). Viewing current autonomy as being an

individual's learning grounds for making future decisions addresses Keenan's (1999, p.560) identification that knowledge is indeed an antecedent to autonomy.

Prior to exercising autonomy there is a tremendous amount of work on the behalf of the patient. Insight into the self is essential for identifying one's own moral compass and values. This is the complex process described by Brody (1985, p.383) as, "In moral reflection, one carefully reviews one's core values and ideals and either revises or reaffirms one's commitment to them." The individual must also identify their liberty to be important enough to take current action.

### *Consequences*

It is frequently mentioned in the literature that all types of autonomy result in accountability (Keenan, 1999, p.561; Wade, 1999, p.314). Being the decider of one's own fate, means that the individual bears the burden of successful decision making, failure, and all that lies in between. There are also a number of positive results from autonomy, "personal satisfaction, freedom, increased productivity, positive self-concept, and competent decision-making" (Spear & Kulbok, 2004, p. 148).

### **Empirical referents**

Walker and Avant (2011) distinguish empirical referents as the tangible and definable observation that a phenomenon has in fact happened. It is a way to diagnose the presence of the phenomena in question.

The principle behind advance directives and surrogate decision makers is the

preservation of autonomy for the future (Chan, 2004). What makes advance directives more complicated than just blindly assuming that it is a direct representation of prospective autonomy is that to truly identify the defining attributes of autonomy, one would have to be privy to the process of making the document. But typically, advance directives are not examined until after the person has lost the ability to demonstrate that the antecedents and defining attributes of prospective autonomy were the foundation of the document.

In Dunlay, Swetz, Mueller, and Roger's (2012) longitudinal study of community dwelling patients with heart failure, only 41% of patients with end stage heart failure had an advance directive. These researchers found that while most of these advance directives specified a surrogate decision-maker, they frequently did not address specific pertinent therapies, such as hemodialysis. Of course, it is possible that the patients spoke in specifics about therapies to the people they appointed to make decisions for them. But with a retrospective view it is very difficult to discern whether the patient had the information needed to make informed decisions for future care.

Beyond limited clinician involvement that may happen when a patient creates an advance health directive, verbal advance directives and instructions to family are typically not done in the presence of a health care worker. If clinicians speak with their patients about their wishes at the end of life and it is not written down, they too may find themselves in the potentially difficult position of having to recall and represent the wishes of a patient. However recalling these verbal directives may be, it is not uncommon in clinical practice to ask a family member of a gravely ill patient, "did they ever express what they would want done if they were in this

situation?”

Verbal communication in advance directive is addressed in Black et al.'s (2009) study that interviewed 34 surrogate decision makers of dementia patients who were eligible for hospice care. The surrogates reported that 59% of the patients had written advance directives, 56% had discussed their wishes, and 38% had done both. The non- formalized verbal advance directive group may be more elusive and difficult to identify and enumerate, but this is an area that warrants investigation.

With more contemplation about prospective autonomy, it should not be taken for granted that an advanced directive automatically meets the criteria for prospective autonomy. It has been identified in the literature that large numbers of patients create advance directives without their physician's input (Vermani et al 1994), making it questionable how and what information the individual is using to make informed end-of-life care decisions for the future.

In Calvin and Erikson's (2006, p. 169) Advanced Care Planning Readiness Instrument (ACPRI), knowledge is taken into account. The tool uses 30 questions in a Likert-type scale, it addresses an understanding of mortality, individuality, and personal preservation (which includes taking responsibility). A key point is that the ACPRI is a tool that was developed specifically for patients in end-stage kidney disease, and it was designed to help the health care-practitioner identify if a patient was ready to discuss end-of-life planning.

A commonly used autonomy scale, the Autonomy Preference Index (API) addresses two components of autonomy; information seeking and decision making (Ende, J. et al., 1989). The API was not designed for *prospective* autonomy, nor does it

assess authenticity in autonomy.

Future investigation that focuses on how an individual perceives their prospective autonomy may cast greater light on what truly motivates some to provide formal advance directive. One can only wonder if there is variation in how people would rank the importance of the defining attributes of prospective autonomy. Keeping in mind that an autonomous person can make a non-autonomous decision, there are many confounding principles that need to be looked at before a truly unbiased, patient-focused tool can be developed that expresses an individual's autonomy for future use.

### **Definition of 'Prospective Autonomy'**

This concept analysis has shown the relationship between autonomy and future decision making of prospective autonomy. Based on this concept analysis, the following definition is proposed: *Exerting current values, life experiences, and perspective to decide the course of one's future.*

### **Conclusion**

This analysis has illustrated the link and the divergence of autonomy and prospective autonomy. It will hopefully facilitate the dialogue of addressing prospective autonomy with patients in a timely manner, which would clearly be prior to them becoming incapacitated. This conceptual analysis should also sensitize clinicians to the ethical significance of following an advance directive. Finally, this is somewhat of a cautionary tale to researchers to look deeper into advance directives in measuring “good deaths.” This clarity of concept is important so that healthcare practitioners and researchers can be intentional in how we view and analyze advance directives as an

instrument of bioethics and law. The ethical principle of autonomy, disclosure of health information, and planning for end-of-life care is of global importance.

There is growing scholarly and scientific writing representing diverse nations and cultures that involves prospective autonomy. Some examples of this growing body of literature includes; a study of factors that influence Taiwanese families in using an advance directive (Yang, Chiu, Hsiung, & Hu, 2011), Korean healthcare workers perception of advance directives (Kim, Kim, Hong, Hong, & Kim, 2014), compliance with advance directives in Germany (Evans et al., 2011), the acceptability of advance directives in oncology patients in Brazil (Campos, Bonamigo, Steffani, Piccini, Caron, 2012), and a critical analysis of truth-telling to promote patient autonomy in Turkey (Guvan & Sert, 2010).

From a global perspective, it is also important to note the role of cultural norms in disclosure of diagnosis, how cultural norms affect death and dying, and planning or not for dying (Turner, 2005). Further investigation into cultural influences will likely be a very complex variable in prospective autonomy.

Cultural variance will not likely be easily simply categorized, as generational differences, socio-economic variance, and cultural assimilation will likely have effects. For example, in Bito and colleagues' (2007) study on Japanese and Japanese-Americans views on advance directives and end-of-life issues there were common themes, but there were also key differences in how the groups perceived autonomy and advance directives based on degree cultural assimilation. We need more culturally sensitive work in disclosure of health conditions, autonomy, and willingness to write down wishes.

Even with these pitfalls and difficulties, prospective autonomy is the key to providing care that is congruent with who an individual is and has been throughout their lives. Prospective autonomy is a voice for the voiceless. Used correctly and with intentionality, it can guide clinicians to give care that is true to the person's values, at a time when they are arguably at their most vulnerable.

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## CHAPTER THREE:

## Going Over the Waterfall: Decision-Making after LVAD for Destination Therapy

## Abstract

**Background:** Heart failure is a leading cause of death in the United States. Left ventricular assist devices (LVADs) for destination therapy (DT) can prolong life and improve quality of life in end-stage heart failure, but LVADs require complex on-going medical care and come with significant treatment burdens and risks. LVADs that are not expected to bridge the patient to a heart transplant or full recovery are termed DT. This study investigated how patients with LVADs for DT make decisions.

**Methods:** A qualitative design where semi-structured interviews were conducted between June 2015 and December 2015 with 11 participants who had LVADs for DT. The average age of the participants was 67, with 10 males and one female participant. The median time from implantation of the LVAD to date of interview was 3.7 years (range: 1.17-7.25). Participants were recruited from a large, academic medical center in the Pacific Northwest. Interviews were audiotaped, professionally transcribed, and coded. Participants were asked about how they make decisions concerning their healthcare.

**Results:** The core process of decision-making was having “no choice.” This core process was subdivided into supporting processes of being in a system of care and having already invested so much in the LVAD. Other interacting processes were (a) personal bias, (b) reacting, (c) perceiving what clinicians thought the participant should do, (d) unclear goals and hopes, (e) isolation, and (f) severely constrained planning for the future.

**Conclusions:** The participants typically saw themselves as having no choice in their care. They relied heavily on the healthcare system to automatically provide care with the goal of life prolongation. There was little discussion about end-of-life care, but when it was mentioned the participants seemed to have little realistic information about their options.

## Introduction

Cardiovascular disease is the leading cause of death world-wide (World Health Organization, 2014). Heart failure (HF) has higher mortality than some cancers (Caldwell, McArthur, & Demers, 2007). For individuals who have inotrope dependent Stage D heart failure the one year survival rate is a mere 25% (Long, Swain, & Mangi, 2014). For patients whose HF has progressed to the end-stage, a rapidly growing treatment option is cardiac circulatory support. A left ventricular assist device (LVAD), the most common type of circulatory support, can be surgically implanted to palliate symptoms and prolong or sustain life as the final therapeutic option in HF when the patient is not expected to transition to heart transplant or recovery. When not bridging to transplant or recovery that is independent of the device, LVAD therapy is termed destination therapy (DT).

Survival with LVAD for DT is 76% at year 1 and 57% at year 3 (Kirklin et al., 2015), with elderly patients having higher risk for mortality (Slaughter, Meyer, & Birks, 2011). The most commonly reported adverse events are: bleeding, cardiac/vascular events (e.g. right heart failure, cardiac arrhythmias, venous thrombotic events, etc.), infection, stroke, renal dysfunction, hepatic dysfunction, respiratory failure, wound dehiscence, and psychiatric episodes (Kirklin et al., 2015). Additionally, the device itself has specific burdens that include requiring carrying and maintaining a power source, care of the driveline, special precautions for showering, and considerations for caregiving and placement if the patient needs residential care.

LVADs come with special considerations of treatment benefit, burden, risks, and end-of-life options. These unique features of LVAD therapy make clinical and patient decisions around the device some of the most complex in heart failure care (Allen et al., 2012). Current recommendations are for shared decision-making (Allen et al., 2012), where the clinician and the

patient both provide information in order to reach a decision in care that is tailored to the patient's specific goals, values, and preferences. The shared decision-making model is a relational process between the clinician and the patient.

Not much is known about how patients make decisions in their healthcare and particularly in advanced heart failure therapies. Accordingly, there has been a call to develop decision aids, programs of shared decision making, and metrics to evaluate the quality of decision-making in healthcare (The Patient Protection and Affordable Care Act, 2010). These developments need to be guided by an understanding of the complex nature of the decision-making process by patients in high-stakes health situations.

Patients and families require more decisional support from clinicians as health becomes more uncertain and good or acceptable outcomes become more difficult to ensure (Goldstein, Back, & Morrison, 2008). The cascading effect of decisions on future decisions requires that patients have foresight as well as an ability to weigh competing factors. Clinicians must also be able to elicit important person-specific information from patients about their goals and what information they need in order to engage in the decision making process.

Patients and their families often do not have the experiential knowledge to predict future complications and do not always approach decision-making having already considered what they value most in their healthcare. Clinicians bring specific knowledge and skills to the table, as well as the ability to help patients identify and consider their values and goals. But in order to help in decision-making, clinicians and researchers must refine their knowledge and learning specifically about how people with LVAD's for DT make decisions. Ideally, complex medical decisions will be well-considered, vetted, and contemplated; however, this is not always the case.

This study seeks to understand how patients who have chosen to undergo LVAD for DT make decisions in their healthcare in order to help clinicians hone their knowledge and skills in this very complex domain of clinical practice.

## **Methods**

### **Design**

This study used a qualitative design of in-depth semi-structured interviews with participants who had undergone LVAD for DT. By the time of the study group selection, all participants had been determined to be “destination therapy”, though some participants had, at the time of implantation, been considered “bridge to transplant candidate” and had subsequently been determined destination therapy.

A descriptive qualitative design was chosen for the ability to represent the data in a clinically identifiable and relevant way (Sandalowski 2000, 2010) for a topic that has not been well studied. The qualitative design allowed for both new discovery and greater depth of understanding of how participants make decisions. This study was IRB approved by the Human Subjects Division of the University of Washington.

### **Sample and Recruitment**

Purposive sampling was done as part of an iterative process of data collection, coding the data, data analysis, and subsequent sampling until no new patterns or concepts could be culled from the interviews. Redundancy of data was achieved at interview seven by the key investigator and senior advisors. Over-sampling continued through 11 interviews to assure completeness.

All participants were recruited from a large academic hospital in the Pacific Northwest. All participants had their LVADs implanted at the same academic medical center between the years of 2008-2014. Potential participant names were obtained from a recruitment list of 657 people being followed in the advanced heart failure clinic. Chart reviews were done to assess for an LVAD for DT. Additionally, heart failure or mechanical circulatory support clinicians referred potential participants for screening. After initial chart review, a recruitment brochure was sent to potential participants and a follow-up telephone phone call was made if the individual did not respond within 14 days. Only one person who received the brochure called the number provided, the rest were contacted after the mailing by the researcher by phone.

Twenty-six recruitment brochures were sent. Eleven participants enrolled and completed the screening and interview. Table 1 lists the inclusion and exclusion criteria. Of the 15 who did not enroll: 4 died, 1 received a heart transplant, 1 became too ill to participate, 2 were unreachable by phone and never responded to the recruitment mailing, 3 were too busy to participate, and 4 declined without specifying a reason. One of the enrolled participants died within 30 days after completion of their interview.

The post-chart review screening process was done over the phone or in person. It took an average of 15 minutes to complete. The consent and screening protocol is provided in Appendix A. All participants who went through the screening met the criteria, and went through informed consent, and chose to enroll.

Recruitment	
Inclusion	Exclusion
18 years or older	Unable to communicate in English
Diagnosed with heart failure	Has progressed to heart transplant
Have undergone an LVAD for the purpose of destination therapy	Are cognitively impaired; Short Blessed >10
Are interested in discussing decision making and their LVAD	Medically unable to participate

## Procedures

After screening and informed consent was obtained, an appointment for an interview with the investigator was made. The interviews were semi-structured and designed to take approximately 60 minutes. The interview guide is provided in Appendix B. Interviews were conducted over the phone, in a private space in the clinic, in homes, and in skilled nursing facilities. Each interview was audio-taped and professionally transcribed. The average length of the interviews was 73 minutes (range: 44-110). Data was managed in a MS Excel spreadsheet.

### **Qualitative Analysis**

Initially, for analysis, the researcher broke the interview transcripts into broad categories of incidents, ideas, and events through open coding. Data was broken into manageable chunks of three to four lines until conceptual emergence made this small-scale coding redundant due to the researcher's recognition and awareness of patterns of concepts and categories within the transcripts. Constant comparative analysis continued both within transcripts and between transcripts, until a recognizable and cohesive pattern of conceptual categories emerged from the data and a code book was developed (Birks & Mills, 2011).

The next phase of analysis was intermediate coding, which was informed by Strauss and Corbin's (1990) axial coding. Axial coding is essentially the reassembling of data that has been broken down to manageable pieces into a newly assembled system. An important milestone during this phase of the analysis is determining the pattern that connects the various parts of the process of decision making. A core category or central theme that holds other categories together and serves as the central link will be noted for its frequent and consistent appearance in the data (Glaser, 1978).

Notes were recorded during interviews and following each interview; field notes were taken to include an evaluation and re-structuring of the questions as new data emerged from

interviews. For trustworthiness of the research, an audit trail (Koch, 1994; Rodgers & Cowles, 1993; Wolf, 2003) was maintained through managing raw data (Lincoln & Guba, 1985), condensing field notes (Wolfinger, 2002), documenting the structure of categories, maintaining methodological notes (Lincoln & Guba, 1985), and memoing (Birks & Mills, 2011; Montgomery & Bailey, 2007).

## **Results**

### **Overview**

The average age of the participants was 67 (range: 53-79). Ten participants identified as White, non-Hispanic, and only one woman participated. The median length of time from implantation of LVAD to interview was 3.7 years (range: 1.17-7.25). Table 2 provides an overview of participant demographic information. There was fairly wide distribution of educational backgrounds; none of the participants were currently working. Some participants identified themselves as retired and others as being on disability. The income levels were fairly diverse, with no participants reporting a < \$ 9,999 annual income. One participant was not sure how much their income was and did not answer the question.

Although all of the 11 participants received their initial LVAD at the same center, two were receiving their subsequent care at other facilities out of state. Of the nine participants for whom the researcher had complete medical records all were found, by chart review, to have had at least one complication from their LVAD. Complication was defined as post-LVAD cerebrovascular accident, device-related infection, or a post-LVAD bleeding episode. Only one participant did not have an in-patient hospitalization during the 13 month study-defined span (March 2015-March 2016). These 9 participants had a total of 26 separate admissions to the hospital over this time, with a median length of stay of 13 days (range: 0-65), with one stay right censored due to death.

## **Findings**

The data showed a group who made their decision for implantation of the device in an automatic or quick way and generally this continued to be the dominant process in their subsequent decisions-making after LVAD. Although the researcher had theorized a priori that things would change in the decision-making process as patients lived with devices and learned through their experiences, this was not borne out in data.

**Table 2****Demographic Information**

Age in years, mean (range)	67 (53-79)
Woman	1
Non-white	1
Some High School	1
High School Graduate/GED	4
Some College/Vocational Training	1
4-Year College	3
More than 4-Year Degree	2
Lives: Alone	3
Lives: With Partner/Spouse	8
Lives in: Home, Apartment, Trailer	9
Lives in: Skilled Nursing Facility	2
Employment: Retired	7
Employment: Disabled	4
Prior Employment: Craftsman	1
Prior Employment: Laborer	2
Prior Employment: Proprietor/Business Owner	2
Prior Employment: Military	1
Prior Employment: Professional	1
Prior Employment: Sales	1
Prior Employment: Manager	1
Prior Employment: Technical	2
Income Level: 10,000-29,999/annually	2
Income Level: 30,000-49,999/annually	2
Income Level: 50,000-69,999/annually	2
Income Level: 70,000-89,999/annually	3
Income Level: $\geq$ 90,000/annually	1
Days from LVAD to Interview, median (range)	1390 (429-2661)
Years from LVAD to Interview, median (range)	3.75 years (1.17 – 7.25)

### **Core Process: “No choice”**

All participants discussed their initial decision to have the LVAD implanted as a result of their having “no choice.” Typically, they were told that if they did not get the LVAD, they would soon be dead; hence they believed that their only choice was between LVAD and imminent death. As one participant said, “I would’ve been pushing up daisies if I didn’t try something like that, because I was at the end.” Not one participant spoke about the LVAD as postponing death.

Although the theme of “no choice” was carried over into the participants’ current decision-making, the rationale for *why* they felt they had no choice did change as the patient’s longevity increased, with death being less often cited as the explicit motivator. Two rationales were identified for why they had no choice: going along with the system and not wanting to give up after having already invested so much effort to living with the LVAD. But beneath these rationales, the distal driving factor was still avoiding death.

#### *No Choice: The System*

When I passed through the portals, the doors in the hospital, I gave myself up to the fact that I no longer have dignity, [*I thought:*] I am going to be poked and prodded and in pain, and be scared. I gave myself up to that. It's like all I could do was—well, it's like going over a waterfall in a barrel. It's not the most pleasant thing. All you can do is hold on. When I enter the hospital, that's what I do. I just bear it. What else am I going to do?

*- Participant, 4.16 years with device*

Many participants attributed their status of *no choice* to a system that functions without their input. The participants described just “going along” with the care. As one participant said who has been living with their device for 7.25 years, “Oddly I see myself, here I am, the end user of all this stuff, but most of the time I don’t really see myself as having a decision in the process.” The process that they were going along with became an external force that was not well defined in the participant interviews. It was also not clearly related to any one clinician who may have been caring for them but rather the system of care as a whole. One participant, in talking about a recent hospitalization for a driveline infection, said, “Oh no, I didn't have to make any decisions. I had the infection. *They* had to deal with it.”

*No Choice: Already invested so much*

The other rationale for no choice, was that the participants sensed they had already committed so many resources and been through so much with their LVAD as a reason to “keep going.” “Pushing forward” was a common theme. Said one participant, “Now it works. I’ve made a decision. I’m here, so I have to make the best of it whether good or bad.” Many participants stated that because their families had been through so much with their worsening health before the LVAD, that they needed “to do something.” Which meant agreeing to more treatments that were being offered.

No participant said that any family member or friend told them what to do. But rather, they relay the story of “looking at her [wife] face” and knowing that they must “keep on” because of everything they had been through and put others through as well. Explained one participant, “It was my family. [*They*] had given so much of their time that I figured I needed to do something.”

## **Interacting Themes in the Process: Sources**

### *Personal Biases and Intuition*

A number of participants brought up that they had biases that led them to ignore certain kinds of information, such as negative risk, that was presented to them. One participant who had his LVAD for 2.9 years explained his experience of disregarding information that is not in favor of what he has chosen to do, “Once you decide to go [*with a treatment course*], all these things that they say you have a chance of happening, you know they’re not going happen to you. Sometimes they do, but you know they’re not going to.” Many described themselves as “wildly optimistic” and even acknowledged that they can be difficult to sway.

Many decisions were related to intuition, which could be why none of the participants said that knowing risks and prognosis affected their decision-making. Said one participant, “If I make a decision, the decision’s made unless I get [*a*] really strong feeling other ways. Let’s say I make a decision to buy something, I’m going buy it, unless something really steps in front of me that tells me no, you’re going to be in deep hockey if you buy it.”

### *Reacting*

Participants described “dealing with things as they happen” or “taking things as they come.” This state of “being in the moment” seemed to limit both reflective thinking and contemplation of the future. Said one participant in talking about managing his increasingly serious health decisions: “Usually what I’ve done, it’s all been fairly short-term- [*is to not*] worry about it.” Participants who had recurrent problems, like driveline infections or bleeding did not express concerns about future episodes and described even lengthy hospitalizations in rather

unaffected ways. One participant said, in talking about his difficulties with gastrointestinal bleeding, "...you adjust to it because it is what it is. You live with it. That's just how it is."

Many felt that they had not been told about the challenges that they would have to face in living with their devices, while others acknowledged that they had not really engaged in finding out things ahead of time and instead relied heavily on their own assumptions of facts. "You just kind of—things pop into your mind— and you jump to conclusions. And you just accept them. I didn't even ask."

When talking about death from medical treatment not working, death was mentioned in a rather unaffected way, as illustrated by a participant: "Oh yeah, I don't look at it as a risk. If I was to die tomorrow, today, or whatever, it's okay" but this same participant went on to explain, "The other choice is just not to do anything and then you are gone." Death was not discussed in terms of an option. Risk was talked about in terms of survival with no mention of quality of life. "I figured, well, if I survive, I'll be ahead." Said one participant about a very critical hospitalization they had recently had.

*Doctors wouldn't bring it up if they did not think I should do it*

Interviewees revealed a significant amount of trust in clinicians. If a treatment was brought up, the participants often had the impression that the physician was recommending it. "With regards to all my medical decisions, I kind of just automatically go for everything that's suggested nowadays." Some participants even felt that their doctors were obligated to tell them what to do. "I didn't go to school to be a doctor. They did. Why should I—why should I make the decision when he knows what the problem is?"

A participant explained how they felt that their own medically complex and fragile condition would automatically lead to physicians recommending only absolutely necessary things: “I think I’ve reached the point with my body and with the LVAD and all of that, and come to trust the doctors, that if they’re going to say you need this, you need this because they’re not going to want to touch me if I don’t.” A number of participants talked about how these same clinicians did not really know what life is like with an LVAD. “They have no concept.” Said one participant who has had an LVAD for 4.2 years. But participants still relied on physicians to choose therapies and interventions for them as the medical experts.

### *Hopes and Goals*

There was a surprising awareness among participants about a lack of clear and obtainable goals for their LVAD therapy beyond mere survival. “I’m not even sure if I talked to myself about what I was hoping for, just get what I got,” said one, “It wasn’t a big decision. If I didn’t know [*what I was hoping for*], I don’t think [*clinicians*] knew exactly what I was thinking.” Almost all participants discussed some aspect of heart transplant, even though each participant was fully aware that it “was not in the cards.” What typically appeared when a participant talked about transplant were two narratives: pragmatic (“I’m not getting one”) and hypothetical (“What would I do if they called me today with a heart?”).

Most participants talked about initially hoping to return to their pre-heart failure lifestyle with their LVAD. Many talked about setting physical new stamina goals for themselves, and as they did so they often saw themselves as having achieved quite a bit. But a number of participants acknowledged that they really just hoped to return to their level of health prior to their decline from heart failure. “My goal was to be back and do what I used to do, which that never—I mean I don’t know when it really came to me that, *well, this is what it is.*” None

discussed adapting their goals or hopes to these changes associated with chronic illness, but instead addressed it as acceptance: “I never was a marathon runner” or “I wasn’t a great swimmer anyways.”

### *The Isolated Decider and Their Support System*

Common responses to the question “Who do you talk to?” included: “nobody”, “it’s all internalized”, and “myself”. Most participants were men and a few mentioned that their lives had changed so much due to their worsening health and LVAD that many of their usual activities had been curbed. From having to give up cherished recreational activities to having to stop work. Many cited these activities as having been central to their social relationships and noted that having to stop doing them led to social isolation. Additionally, because this group of participants represented many years of survival, there were also the predictable unplanned life changes; divorces, deaths, family conflicts, and moving which also contributed to the feeling of isolation.

When they were asked about what to tell others about life after LVAD, interviewees often suggested something about how the LVAD clinical team will “always be there for you.” “They’re not going to turn you loose until they’re sure that you can exist on your own. Even after you are on your own,” said one participant, “for any little things, any little question, big or small, they’re there.” But these LVAD patients also talked about losing access to clinicians they had developed relationships with over time. One long-term survivor said, “Anyways, even when I was going back into clinic, I would find myself wanting one of the original team. It was like I’d be sitting there going oh, it’s you [*to the new clinician*]. There’s absolutely nothing wrong with them, it’s just I’m familiar with the others.”

### *The Future: Dichotomous Takes*

There was significant divergence in thinking about the future. There were no explicit questions about end of life in the interview guide, but some participants did talk about end of life. A little over half responded to the question about what they see coming up in their future with: “keep on keeping on”, “I’m going to live a long time, yes I am”, or “just the same-old same-old, just sort of in a routine now.”

But there were also comments like this: “Early on I think, even though I really didn’t want the transplant, at least there was a little bit of hope that something could improve beyond the LVAD. Then when that was taken away, it was just I got into a position of just hoping for living as long as I can. I’m sorry, this has gone on pretty long. Now it’s just I’d like to finish and go comfortably.” But how they thought about “finishing” was variable and sometimes extreme with vague thoughts of their end-of-life including things like choosing to not eat or even taking their own life were among the outcomes some of participants could imagine for themselves.

It was rare to hear of feelings or emotions, but one participant explained, “I’ll tell you. I am not the same person I was when I was going through the hospital ER trips every week. I’m not that person anymore. I’m not thinking that I’m brave enough to go through all that, that I don’t want to have all kind of unpleasant procedures.” Another participant expressed “I don’t want to go through shit when there’s no hope.” But much like their earlier depiction of internalizing their life with the LVAD, the participants had not talked about end of life care with anyone and none brought up options such as hospice or comfort focused care.

## **Discussion**

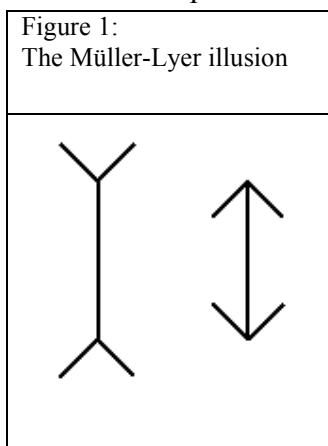
LVAD for DT is a promising and evolving therapy for those in the end-stages of an incurable disease. It has the ability to both prolong life and palliate symptoms of end-stage heart failure, but it also comes with significant treatment burden and high health risks. Patients who undergo this treatment will face health decisions that are likely to become more complicated over time. This study found that decision-making after LVAD for DT occurs in a mostly automatic or reflexive decision-making process, where the patient feels they must accept the direction of clinicians, since they have “no choice”.

The results of this inquiry were similar to what McIlvennan and colleagues (2014) found in a qualitative study in which they compared the decision-making process at the time of implant for those who decided for the LVAD versus those who chose against it. For most of those who chose to have the LVAD for DT, they made fast decisions and the sole focus of the decisions was survival. The opt-for deciders stated that they had “no choice” and did not want to hear about negative aspects of the LVAD. This finding was upheld in our study, where many participants could not think of any reason why someone would opt against the LVAD, even though every participant in this current study had themselves gone through at least one significant post-implantation complication related to their LVAD. This signals that living with the LVAD and experiencing it, had not necessarily made a significant impact on patient motivation to consider negative risks of the therapy.

In McIlvennan and colleagues’ (2014) inquiry on decision making at time of LVAD implantation, the opt-out deciders were found to have a more reflective approach to decision-making that weighed life prolongation in context of their life narrative. To the opt-out deciders, death was a viable option to be weighed against other options. As LVAD therapy is trending to implantation earlier in the disease course, there likely will be more opportunities in future

research to include the opt-out group in longer term research on decision-making. But due to their limited survival expectancy, they were not included in this current study.

These two styles of decision-making have collectively been termed dual process. The fast or automatic decision-making is termed System I by Kahneman (2011). System I requires minimal cognitive effort and is not associated with voluntary control. For most routine decisions, System I is a very reliable decision making-system. An example of this is to look at two lines and estimate whether they are the same length or not, which typically can be assessed quickly and without much attention to the task. But system I is also prone to bias and is not capable of handling multiple competing inputs in a decision-making process. So System I runs into trouble when judging the equal length of simple lines becomes more complicated by optical illusions, such as the famous Müller-Lyer illusion (see figure 1) with two equal lines but fins pointing in opposing directions. It is System II that will look closer at the lines or perhaps even measure them, and see that they are in fact equal.



System II is the slower, more effortful, and reflective style of decision-making. It is associated with deliberate choices between two or more options. This system takes energy for attentive cognitive processes. System II has the capability to over-ride thinking biases and to contemplate the future. System II engagement will correct visual illusions as mentioned above as well as cognitive illusions (Kahneman, 2011).

It could be argued that it is ethical for a patient to ask their physician or clinical team to make decisions for them to achieve the goal of survival. But that is only feasible when life

prolongation is possible and/or the balance between quality of life and life prolongation has not become less clearly balanced or life prolongation simply becomes unsupportable by modern medicine. In this group of participants, the sole focus on survival would leave clinicians with very little person-specific insight on what the patient would find an acceptable quality of life, if the patient themselves has only considered survival.

Decisional support, for these reasons, in this group is very challenging. Approaching the topics of an acceptable level of improvement, and quantity-versus-quality of life with patients who might not understand that even with the LVAD they are still facing death is a difficult bridge to cross. Initially it was the a priori hypothesis of the researcher that patients with LVAD for DT would learn through experience and time about the complexities of LVAD therapy and worsening co-morbidities. However, it should be remembered that these patients having lived through many critical events, and surviving these event may have led to the cognitive illusion that surviving prior health crises means they will survive future events.

Future work should focus on encouraging reflective thought and establishing coping mechanisms for those patients who may be receiving negative information or bad news. Interventions like meaning-centered psychotherapy (Brietbart et al., 2015) have been found to reduce the emotional and spiritual suffering in patients with advanced cancer as well as improving quality of life and symptom burden. But meaning-centered psychotherapy interventions have not been tested in other diseases such as heart failure.

### *Limitations*

Limitations of this study include the use of only one site and a homogenous group of participants. Another limitation is the reliance on recall of the participants. It would be preferable

to assess for change in decision-making process over time in a longitudinal study. This would likely require a larger sample due to the high morbidity and mortality of this population. This study was also limited in that it did not include anyone who decided to not have an LVAD or who was considering deactivation or moving to hospice/comfort measures. A strength of this study is the relatively long average time the participants had been living with their LVADs. The median time from implant to interview was 3.7 years, which represents significant time and experience with their devices.

### *Implications for clinical practice*

This study reveals important information for patient care. For clinicians it is important to be aware that they may think they are doing a thorough job of going through the medical options available to the patient as well as the risks and benefits for informed consent. But the patients themselves may be receiving the communication differently and may come away from the discussion with the perception of “I have no choice”, whether this was said or intended by the clinician or not. This can be clarified by simply asking the patient what their understanding of the discussion was. Clinicians may not be able to change how patients perceive their situation, but they can clarify communication and make sure that both parties come out of these discussions with better mutual understanding.

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## CHAPTER FOUR:

## Grieving or Getting Stuck: Left Ventricular Assist Device Therapy Without the Hope of Transplant

## Abstract

**Background:** There are a limited number donor hearts available for transplant. But there is a growing number of patients who would benefit from heart transplantation due to their medically refractory end-stage heart failure. Left ventricular assist devices (LVADs) were initially used for bridging a patient to heart transplant. But later, LVADs were transitioned into use with patients not expected to undergo heart transplant. A third goal of LVAD implantation is to bridge to evaluation for transplant candidacy. Today, patients with LVAD are known to transition between these classifications and some unexpectedly find themselves with an LVAD for the remainder of their life when heart transplant is deemed not an option after LVAD implantation.

**Methods:** This study used secondary analysis of a qualitative study on decision-making after implantation of LVAD for destination therapy. This study was undertaken in response to the unexpected finding of grief in loss around loss of hope for heart transplant. Eleven participants were interviewed with 10 men and one woman representing an average of 3.7 years with their LVAD devices. Three lived alone, the remaining lived with their spouses. All were recruited from a large Pacific Northwest Medical Center, although at the time of the interview, some participants had transferred their care to other centers.

**Results:** Six themes identified in this study include: (a) taking it in, (b) heart transplant is not perfect, (c) jumping through hoops, (d) mistrust, (e) thinking about the hypothetical, and (f) hope. The theme of hope was a complex theme with both loss and transcendence.

**Conclusion:** Loss and subsequently grief was consistently found in these participants in regards to loss of hope for heart transplant and the imagined life they would have. This grief should be

recognized and normalized by clinicians. Empathetic responses to this loss and therapeutic presence by clinicians can support patients who are grieving the loss of the possibility of heart transplant.

## Introduction

The definitive treatment in heart failure, for those who qualify, is heart transplantation. For those patients who make it through the first year after transplantation, 63% will survive to ten years (Stehlick et al., 2012). But the limiting factor in the number of heart transplants performed is the finite number of donor organs available. Currently, approximately 2,200 heart transplants occur annually in the United States. This number has remained largely stagnant since 1998 (Vega et al., 2009). But the number of individuals who would benefit from transplant is rising (Wilkins et al., 2012).

A major advancement in heart transplantation care was the development of the left ventricular assist device (LVAD). Originally used as a bridge to heart transplant, the LVAD eventually became a viable final therapy for refractory heart failure even when heart transplant was not the goal or an option for the patient (Fang & Stehlik, 2013). For taxonomical purposes three goals or strategies of LVAD implantation are identified; bridge to transplant, bridge to candidacy for transplant, or destination therapy. Bridge to candidacy for transplant allows for transplant teams to further investigate whether conditions such as pulmonary hypertension or lack of social support may resolve after LVAD implantation and allow for transplant listing. But the categorization of LVAD strategy does not remain stagnant over time.

Some bridge to candidacy patients will progress to transplant, just as some patients listed for transplant will have changes in circumstances that result in them being delisted, and a patient who was identified as destination therapy may, with time, become an excellent heart transplant candidate. Between June 2006 and March 2011 out of a total of 2,775 primary LVAD recipients registered in INTERMACS, 41.8% of those were identified as bridge to candidacy at the time of LVAD implantation. This number was further broken down into likelihood of transplant with

68.5% as transplant likely, 24.3% moderate, and 7.2% transplant was unlikely. Bridge to candidacy was the largest group, with 37.6% representing bridge to transplant and only 19.6% of the LVAD recipients identified as destination therapy. But over the next 12 to 24 months, for those still on LVAD therapy, there were observed changes in classification. For those who were still on the device and had been listed as bridge to transplant at time of implantation, 25.8% were no longer classified as bridge to transplant and by 24 months this number increased to 43.5%. Within the bridge to candidacy-low likelihood group, at 12 months 39.1% had been changed to destination therapy (Teuteberg, et al. 2013).

This signals that not only are the patients dealing with the uncertainty of the device itself and end-stage heart failure, they are also often having clinical reclassification of the intent of their device. In prior work with patients in need of a heart transplant, managing uncertainty and coping have been identified as important themes in their care (Haugh & Salyer, 2007). In spouses of heart transplant candidates, the coping strategy of planning was associated with lower levels of depression (Burker et al., 2005).

In Jalowiec and colleagues' (2007) study on coping effectiveness of patients who were listed for heart transplant, it was found that better coping was associated with using optimistic coping behavior and minimizing the use of emotive, evasive, and fatalistic coping strategies. Optimistic is defined as thinking about positive things, emotive is releasing emotions on another person, evasive coping is putting the problem out of your mind, and fatalistic is resigning to hopelessness. Similar results have been found in kidney transplant (Lidqvist, Carlsson, & Sjoden, 2004) and lung transplant candidates (Myaskovsky et al., 2003).

Less is known about coping styles when patients do not successfully go through the work-up process and therefore do not get listed for organ transplant. Heyink and Tymstra's (1990) study

on bereaved family members included 16 participants whose family member had been rejected for a liver transplant listing. Their results revealed that participants felt that their loved one had been dealt a death sentence when they found out that they would not be listed for a transplant. The families also viewed the transplant candidacy work up process as a waste of emotional, physical, and financial resources. The families tended to blame not getting the liver on healthcare system errors and waiting too long. The researchers observed emotional reactions including resignation, bitter spite, and a distrust in the medical community.

In Yorke and Cameron-Taube's (2006) qualitative study on the perceived care needs of patients on heart and/or lung transplant list, most participants were looking forward to post-transplant life. But for the participants who were either "put on hold" or de-listed, the participant reported a loss of hope. The researchers recommended extra compassion centered on communication to support patients through the experience.

This paper came from an unintended finding from a qualitative study on the process of patient decision making in left ventricular assist devices when destination therapy is the goal of treatment. Although the participants in that study were not asked about heart transplant, participants consistently brought up transplant. All participants understood that they were not expected to be listed for transplant and had been living with their LVADs for relatively long periods of time (average 3.7 years). It was a surprise to the researcher to see patients who had been living with their LVADs and still harboring thoughts and feelings about heart transplant.

## **Methods**

### **Design**

This paper is a secondary analysis of a primary study on the process of decision making after implantation of LVAD for destination therapy. This current work best fits the classification

of secondary analysis described by Heaton (2008) as supplementary analysis. In supplementary analysis, there is some convergence with the primary study, but undertaking secondary analysis allows for the emergent finding to be more fully addressed.

The design of the primary study is described in detail in Chapter 3. But briefly, a qualitative design with semi-structured interviews of 11 participants who were living with an LVAD for end-stage heart failure was undertaken. All participants had been declared destination therapy by their clinical team, meaning that they were not expected to recover heart function, be evaluated for possible listing for a heart transplant, or progress to a heart transplant. This study was IRB approved by the Human Subjects Division of the University of Washington.

### **Sample and Recruitment**

Participants were recruited from a large Pacific Northwest medical center. Every participant had their device implanted at the same center, but at the time of the interviews, their geographical locations varied from Southeastern United States to Alaska. Four inclusion criteria for participation were employed: (a) have an LVAD with the goal of destination therapy; (b) 18 years of age or older; (c) diagnosed with heart failure; (d) interested in discussing their decision making process. A patient was excluded if they were unable to communicate in English or had a serious cognitive deficit or medical issue that prevented them from participating in an interview.

The participants were composed of 10 men and 1 woman, with an average age of 67. The median time from transplant to interview was 3.7 years (range 1.7-7.25). Two participants resided in skilled nursing facilities. Three were not married at the time of the interview, otherwise all participants resided with their spouses. None of the participants were employed, with all identifying as either disabled or retired.

### **Procedures**

Potential participants were mailed study information and received a follow-up phone call from the researcher if they had not called within two weeks of receiving the research information. If interested in participating in the study, an appointment was set-up for screening. All participants who agreed to the screening met the study requirements and, after informed consent, agreed to participate. An appointment was made with the researcher for an interview that was designed to take approximately one hour. These interviews happened over the phone, in homes, skilled nursing facilities, the hospital, and in a private room in a library. All participants had one interview and one participant had a follow-up for some clarifications. All interviews were tape recorded and professional transcribed.

### **Qualitative Analysis**

An inductive content analysis (Elo & Kyngas, 2008) approach was employed, as there is little known about the phenomenon of interest. Transcribed data was hand coded and then managed in an MS Excel spreadsheet. Coding is a process of breaking down large sections of text into manageable and purposeful portions. This breakdown can be to the level of words, sentences, or longer text. These segments were coded and then sub-coded by the researcher. Debriefing was carried out throughout the analysis with senior advisors who have extensive experience in qualitative research.

## **Results**

### **Overview**

The themes identified in the interviews were: (a) taking it in, (b) heart transplant is not perfect, (c) jumping through hoops, (d) mistrust, (e) the hypothetical transplant, and (f) hope. There was some labeling of emotions done by patients, but many of the stories were palpable with feelings like frustration, resignation, and anger. A number of participants expressed their

satisfaction with their LVAD but also spoke of wishing they did not have to carry around the device and do all the other LVAD management chores like driveline site care.

### **Taking it in**

Participants often spoke about receiving the news of not getting a transplant not just in terms of hearing it, but rather processing it. Said one participant, “I had to hear that [*not getting a heart transplant*] and let it get in me. To know that you stay on this [*the LVAD*].” This quote also illustrates not only the processing of not getting a transplant, but also realizing that the LVAD therapy is permanent for them. Some described the process as initially being “shocked”.

One participant said, “It’s like those stages of grief- I can’t remember all of them. But I think that’s what I am going through [*since heart transplant would be the next step*].” This particular participant has had their LVAD for 3.7 years and had been aware that they would not be progressing to listing for a heart transplant for the past year. It was interesting that this participant described themselves as going through stages of grief after getting the news of not being listed for heart transplant.

### **Heart transplant is not perfect**

A number of participants brought up negative aspects or imperfection of heart transplant. This was not brought up in the context of explaining how they chose to not undergo heart transplant, but typically was presented in the interview as informing the interviewer of the drawbacks. Said one participant with almost 4 years with their LVAD, “that [*heart transplant*] wasn’t a definite fix either, you know?”

Others talked about people they had met who had been transplanted and had difficulties post-transplant. “But you know, talking to a lot of people in here, a lot of people that have had transplants have had more problems than people that have [*the LVAD*].” Some participants did

talk about heart transplant survival prognosis being longer than with the LVAD. Although the participants did not talk about risk around LVAD, a number did discuss that heart transplant has significant risk associated with it.

### **Jumping through hoops**

Participants described with lingering frustration and even anger of going through the difficult process of transplant evaluation. Said one participant who has had their LVAD for 3.6 years, “I was always on the cusp [*of heart transplant*], there was always just one more hoop. Then I got frustrated because it felt like an endless loop.”

“I was told I was going to get one [*heart transplant*] and then there’s a lot of—you gotta make this point—and then this point. And I made that point and then that point and that point. And finally, it’s just like, well, I’m living with it [*the LVAD*]. I’m not giving up on it [*heart transplant*], it just isn’t—it’s just not going to happen.”

*- Participant, 3.75 years with device*

Another issues that came up regarding the demands of hoping to be listed for transplant, was the pressure to be adherent or a “a good patient” so as not to hurt their chances of being listed. There were also stories that after being told that they would not be listed for transplant, that the participants chose to sometimes not follow all the suggestions of the LVAD team. For example, one participant chose to stay at a family event rather than rushing to the medical center for what the patient perceived as a non-urgent matter, even though the LVAD coordinator had recommended that they immediately be seen at the clinic.

## **Mistrust**

Mistrust came in two forms; towards a system of perceived inequity and the perception that clinicians did not fully disclose everything they knew. There was a feeling of unfairness in who gets listed for heart transplant, “It seemed unfair that younger people who hadn’t taken care of themselves and were overweight and they were eligible.” Another participant felt that they were at a geographical disadvantage, and that if they lived in a different part of the country there would be more donor hearts available.

One participant who was not listed due to their age, spoke about Dick Cheney, “The only person I know who has had a heart transplant is the ex-vice president. He had an LVAD for about a year and half. Then he got a heart, but he's not much younger [*than me*], but he qualified probably because of his stature or status.”

Some participants felt that there was information withheld from them from their clinicians; “I think [the physician] and probably everyone else knew that I wasn’t going to be on the transplant list. They waited the full year before telling me.” This was often talked about with lingering anger and resentment. One participant expressed anger at themselves for not asking better questions for their own clarity.

## **The Hypothetical: What I would I do if...**

There was quite a bit of hypothetical discussion around, ‘what would I do if a transplant was offered now?’ Participants split their comments between whether they would accept a heart transplant or to just stay with their LVAD. Even within the same interview participants sometimes gave conflicting statements about whether they would today undergo a heart transplant, if it was offered. There were also times where the participants revealed what they

imagined what it would be like to live without an LVAD, these tended to be very poignant moments in the interviews.

If the phone were to ring right now and they say, “We have a match,” I really don’t know what I would say. I’d probably say no, I mean if I had the choice. I would probably say no, but then I would think, “Huh, you know I’d get rid of all this stuff [*the LVAD*].”

- *Participant, device for 4.3 years*

Some participants talked about options they had to still try and pursue heart transplant at other transplant centers, but they tended to mention this as “I could” and none of the participants seemed to be actively pursuing this. This ambivalence was quite common.

### **On hope**

Many participants talked about loss of hope for transplant with one participant saying: “then hope for that [*transplant*] was taken off the table.” Another participant who had his LVAD for five years explained, “In the beginning, I was looking for a transplant. My mind was telling I’m going to the hospital for a transplant, and that’s what they got me prepped and everything [*for*]. I’m thinking I’m going to be on this for a few weeks then go to a transplant.”

However, loss of hope for heart transplant also meant loss of hope for no longer having to carry their LVAD and manage the device. Some described that with a heart transplant, they would be “normal” again. Said one participant, “I knew that I didn’t want to have this thing [*LVAD*] in me for the rest of my—well, the rest of my life.” A few participants expressed a hope that the device would improve and be smaller or that there would be advances in pharmaceutical management of heart failure so they would no longer need an LVAD.

One participant expressed regret that they had not pursued their hope for heart transplant more saying, “I wish I had knocked on that door a little more [*heart transplant*].” But some participants felt that accepting that they were not going to be transitioning to heart transplant was a relief. One participant explained that it was better than living on “pins and needles” of not knowing. Many expressed satisfaction and gratitude for their LVAD and had hopes for a long life ahead of them with the LVAD.

But most of the participants had both loss and still had hopes. Some discussed the multi-dimensionality of hope and the intersection with spirituality and existential transcendence.

You will always have hopes. Even in your darkest moments you’ll have hopes and you talk about miracles, I’ve asked God to take this out of me [*the LVAD*]. If He does, He does. If He doesn’t, He didn’t want to. But that would be a miracle.

– *Participant, device for 2.9 years*

### **Discussion**

Loss is associated with both on-going conditions without predictable end-points such as chronic illness and also with clearly defined events such as the death of a family member. From the work of Eakes and colleagues (1998), “Disparity is created by loss experiences when the individual’s current reality differs markedly from the idealized.” Participants in this study describe a lot of loss. On the one hand there is the defined loss of not progressing to a heart transplant, but the loss of transplant also yields a chronic loss for this group of not returning to a “normal” body and having to carry and manage the LVAD for the duration of their lives.

Grief is the result of loss (Pomeroy, 2011) and is a normal reaction to the loss of something significant that the person has bonded to. These losses are both tangible and also can be intangible such as an “imagined future” as described in Gill and Lowes’ (2009) longitudinal work of graft failure after a kidney transplant. One participant in this study openly self-identified that they thought they were going through the stages of grief as described by Kubler-Ross, but for most participants it was their stories that described loss, grief, and even transcendence.

Grief has been associated with emotional manifestations such as anger, guilt, anxiety, sense of helplessness, sadness, yearning, numbness, self-blame, and relief (Corless, 2015). But grief also affects cognitive, spiritual and physical functioning (Doka, 2002). A number of grief associated emotions came up the interview, such as frustration and relief. But some statements such as, “I should have knocked on that door more” can be interpreted as self-blame or regret.

As mentioned earlier, these findings of transplant and grief were unexpected. This researcher had not initially thought to ask about transplant, because all of the participants had their LVADs for greater than a year and in most cases, multiple years. It was an assumption of the researcher that the issues of transplant would have been resolved for these participants by the time of the interviews. But typical grieving is an idiosyncratic process of integrating loss into the mental system and the life of the person (Wakefield, 2012). Uncomplicated grieving is a progression of improvement in symptoms that can go on for years (Corless, 2015).

When grief is not recognized or the loss must be kept hidden it is termed disenfranchised grief. This type of grief is not publically and socially recognized and validated (Doka, 2002). The term empathetic failure has been coined to describe the inability to understand the meaning and loss experience of another person (Neimeyer & Jordan, 2002). It is thought that this empathetic failure can lead to unresolved grief or chronic sorrow. Chronic sorrow has been found in patients

with chronic disease. Some of the most commonly found losses are loss of bodily function, loss of imagined life, loss of relationships, and loss of identity (Ahlstrom, 2005).

### *Limitations*

This study has several of limitations. There are inherent limitations to secondary analysis in qualitative research including that the interviews were conducted to explore decision-making in LVAD for destination and not to explore grief or any other phenomena in regards to heart transplant. This means that important themes may not have been explored sufficiently or even discovered.

Some important information was not collected, such as the amount of time that had transpired since the participant found out that they would not be progressing to heart transplant or the story of how the participant was told. Also analysis for this study is limited to that which was already collected and did not allow for an iterative process of sampling to conceptual saturation. Although the interviews did provide rich quotes and unexpected findings, grief in LVAD therapy requires future work that explores the topic and themes uncovered here in greater depth. This study adds new and interesting findings of grief in a small group of patients with LVADs who will not be progressing to heart transplant.

### *Clinical Implications*

For clinicians, it has been recommended in other studies with different populations to allow patients to talk about loss, grief, and the entailing emotions. Clinicians have the ability to normalize these emotions and the personal process of grief. In Gill and Lowe's (2013) study of grief after kidney transplant failure, the lack of clinician observance and recognition was described as leading to disenfranchised grief. Often support of coping in difficult circumstances

is perceived as “doing something for the patient”, while in fact that greatest need may be for clinician awareness and recognition of loss and grief.

Therapeutic presence and mindfulness in encounters with patients who are grieving has been described as being completely present with the patient on all levels of being: physically, emotionally, cognitively, and spiritually (Geller & Greenberg, 2012). Clinicians should also be aware and that they are not obliged or called upon to fix the grief. But rather, clinicians can bear witness to the journey and validate it as real. This was illustrated during one of the interviews for this study when a participant seemed surprised at himself at the amount he talked about heart transplant during the interview saying “I haven’t thought this much about it [*heart transplant*] in a long time” but then he went on to say, “It’s actually nice to talk about it.”

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## CHAPTER FIVE:

### Conclusion

This dissertation explored key considerations in decision making in regards to left ventricular assist devices for destination therapy. This included (a) an analysis of the ethical principle of prospective autonomy (b) the process of decision-making in left ventricular assist devices for destination therapy (c) the experience of grief in this population. The overall goal of this research is to add to the support the growth of inquiry into decisional support for this very complex population from a holistic perspective of care.

Ethical difficulties are part of clinical practice and they occur from conception to the end-of-life. Nurses face these ethical dilemmas on a regular basis. However, often ethics is not directly discussed. This can lead to limited vocabulary in ethics and stunt the ability of nurses to ethically analyze and decide on a course of action. The simple task of reading and following an advance directive can quickly become not so simple when a family member wants something very different than what is written or following the advance directive does not seem appropriate given the clinical context.

An advance directive is a series of decisions, hopefully informed, that the patient has made. The third chapter in this dissertation raises some interesting questions about how patients with LVADs make decisions. It also highlights some concerning findings that this decision-making process, of fast decision-making, might lead to patients not fully processing what clinicians are telling them about choices, risks, and burdens of LVAD therapy. This can lead to end-of-life situations that can become very difficult and often morally distressing for all involved, including the families.

The final chapter highlights an unexpected finding of grief in this group. This finding is interesting in light of the finding that this group largely used a fast decision-making style that requires less mental effort and concentration. Grief itself alters cognitive processes including the ability to concentrate, which raises a question for further inquiry about whether unprocessed grief is hindering cognitive attention to making health decisions.

Future research should be guided to (a) Further understanding of the emotional and spiritual well-being of patients with LVAD for destination therapy, (b) Interventions that will promote decisions that are a reflection of the goals and values of the patient, (c) viewing advance directives as a process and not just a destination.

## Appendix A

**UNIVERSITY OF WASHINGTON  
CONSENT SCRIPT TO SCREEN FOR RESEARCH**

The process of decision making following left-ventricular assist device implantation in advance heart failure

Thank you for calling regarding the study on decision-making following left-ventricular assist device implantation in advance heart failure.

I need to ask you a few questions in order to determine whether you may be eligible for the research. I will ask you about your recent medical history, some demographic questions like who you live with. Before I begin I would like to tell you a little bit about the research.

**About Me**

My name is Megan Morrison, I am doctoral student in the school of nursing. I have many years working in cardiovascular nursing in addition to being a palliative care nurse practitioner.

**Purpose**

What I am going to read now is the purpose of the study. The purpose of this study is to gain insight into how people who have a left ventricular assist device make decisions in their healthcare. The study involves meeting with me for about an hour, which can be divided up or done in one session. We will meet in person at a place that is comfortable for you, such as me coming to your home or meeting after a clinic visit. It is also possible to have the session over the phone, if you are most comfortable with that. During our meeting, what I am interested in is you telling me what decisions you make or you think you will need to make in your healthcare and how you go about making your health related decisions. I am interested in finding out what you have learned and what you know about making health decisions since you had the left ventricular assist device implanted. There is no right or wrong information, just your journey. I may call you with a further question to clarify something and of course you can always call me if you think there is something more that I need to know. But this study is expected to only have one meeting.

Would you like to continue with the screening?

The screening will take about 20-30 minutes. You may feel uncomfortable answering questions about your medical history or personal life. You do not have to answer any questions you do not wish to answer and you may stop at any time. Your participation in the screening is voluntary. A decision whether or not to participate in the screening will not affect your relationship with UW or any of your providers. You will not directly benefit from the screening.

Your answers will be confidential. No one will know the answers except for the research team. If you decide to not participate, your screening information will be assigned a random number for data management reasons, but your name will not be kept. If you decide to participate, you will also be assigned a random number. This number will be used to identify you within the study. There will be a master list that links names of those participating to study identification numbers. These numbers will link the screening information you give me to our interview that is all kept securely with our study data. But once the study is completed and I have finished the analysis of the data and written the results, the file that links your name to the random number you were assigned will be destroyed. There will be no lasting record of which number you were.

Would you like to continue with the screening?

<If NO>, For study purposes may I ask you three demographic questions before we hang up?

<If yes> May I ask you a few demographic questions?

<If YES>, ask: What is your (3 demographic questions that follow)

Gender:  1. Male  2. Female      Age: \_\_\_\_\_

I will read a list of categories describing different ethnic backgrounds. Let me know when I read the category appropriate for yours..

- |  |   |
|--|---|
| <input type="checkbox"/> 1. Caucasian              | <input type="checkbox"/> 4. Black/African   |
| <input type="checkbox"/> 2. American Indian/Alaska | <input type="checkbox"/> 5. Hispanic/Latino |
| <input type="checkbox"/> 3. Asian/Pacific Islander |   |

<If not enrolling> Thank you for your time and consideration of our study.

#### HIPAA

In the Informational Statement that we sent you, it states that as part of this study we will be reviewing your medical record. Do you have any questions about that?

<After answering any questions>

→ Do you give permission for review of your medical record?

→<If patient says YES>

I appreciate you giving me your permission.

→<If the patient says NO>

You are still able to participate in the study, even if you do not give us permission to review your medical record.

**PROCEED WITH NEXT PORTION ONLY IF INTERESTED IN PARTICIPATION.**

Okay, let's continue. I would like to ask you some questions now about your background and personal health. If you are uncomfortable answering any of these questions over the phone, you can come for an in-person appointment to answer them instead. You do not have to answer any questions that you don't want to answer.

### 1. Inclusion/Exclusion

#### 12. Inclusion criteria

- |  |                                  |                                 |
|--|----------------------------------|---------------------------------|
| 1. Are you able to read, write, and speak English?   | <input type="checkbox"/> Yes (1) | <input type="checkbox"/> No (0) |
| 2. Will you have access to a telephone and/or able to meet for at least one hour in the next 6 months? | <input type="checkbox"/> Yes (1) | <input type="checkbox"/> No (0) |
| 3. <b>(Don't ask patient, from EMR)</b> age 21 and over?   | <input type="checkbox"/> Yes (1) | <input type="checkbox"/> No (0) |
| 4. <b>(Don't ask patient, from EMR)</b> Diagnosed with Heart Failure?                                  | <input type="checkbox"/> Yes (1) | <input type="checkbox"/> No (0) |
| 5. <b>(Don't ask patient, from EMR)</b> Left ventricular assist device for <u>destination therapy</u>  | <input type="checkbox"/> Yes (1) | <input type="checkbox"/> No (0) |

#### 13. Exclusion criteria

- |   |                                  |                                 |
|---|----------------------------------|---------------------------------|
| 1. Have you needed to be hospitalized for any psychiatric problems in the past year?  | <input type="checkbox"/> Yes (1) | <input type="checkbox"/> No (0) |
| 2. <b>(Don't ask patient, from EMR)</b> Age less than 21 years  | <input type="checkbox"/> Yes (1) | <input type="checkbox"/> No (0) |
| 3. <b>(Don't ask patient)</b> Short BLESSED score > 10  | <input type="checkbox"/> Yes (1) | <input type="checkbox"/> No (0) |
| 4. <b>(Don't ask patient, from EMR)</b> Diagnosis of any additional terminal illness with life expectancy of $\leq 1$ year not related to heart disease | <input type="checkbox"/> Yes (1) | <input type="checkbox"/> No (0) |

### 2. SHORT BLESSED (Scores greater than 10 exclude the participant)

I'm going to ask you some questions that may sound silly to you, but they are necessary to ask just one time. These questions are not meant to trick you in any way. I have to ask you for the purpose of the study.

ITEMS	Score	Maximum Error	Weight	Total
1. What year is it now?		1	X 4=	
2. What month is it now?		1	X 3=	
<b>Memory Phrase:</b> Repeat this phrase after me: "John Brown, 42 Market Street, Chicago." Now hold this phrase in your memory until I ask you to repeat it.				
3. About what time is it? (within 1 hour)		1	X 3=	
4. Count backwards 20 to 1		2	X 2=	



- |                          |                              |                          |                        |
|--------------------------|------------------------------|--------------------------|------------------------|
| <input type="checkbox"/> | 1. Full-time                 | <input type="checkbox"/> | 4. Retired             |
| <input type="checkbox"/> | 2. Part-time                 | <input type="checkbox"/> | 5. Full-time Homemaker |
| <input type="checkbox"/> | 3. Not employed/disabled (if | <input type="checkbox"/> | 6. Other               |
|                          |                              |                          | (specify) _____        |

**What is your job? And tell me what you do at your job (describe) If not working now, what was the last job you worked?**

---

*[Interviewer determines job category after talking about the job with the person. Do not ask each category on the list].*

- |                          |  |
|--------------------------|--|
| <input type="checkbox"/> | 1. Clerical (bank teller, bookkeeper, secretary, typist, mail carrier, ticket agent)                             |
| <input type="checkbox"/> | 2. Craftsman (baker, automobile mechanic, machinist, painter, plumber, carpenter)                                |
| <input type="checkbox"/> | 3. Farmer or farm manager  |
| <input type="checkbox"/> | 4. Homemaker (full time without another job)   |
| <input type="checkbox"/> | 5. Laborer (construction worker, car washer, sanitary worker, farm laborer)                                      |
| <input type="checkbox"/> | 6. Manager-Administrator (sales manager, office manager, school administrator, buyer, government official)       |
| <input type="checkbox"/> | 7. Military (career officer, enlisted person in the Armed Forces)  |
| <input type="checkbox"/> | 8. Operative (meat cutter, assembler, machine operator, welder, taxicab or bus driver)                           |
| <input type="checkbox"/> | 9. Professional (accountant, artist, RN, engineer, librarian, writer, social worker, actor, athlete, politician) |
| <input type="checkbox"/> | 10. Proprietor-Owner (owner of small business, contractor, restaurant owner)                                     |
| <input type="checkbox"/> | 11. Protective Service (police officer, detective, guard, sheriff, fire fighter)                                 |
| <input type="checkbox"/> | 12. Sales (salesperson, advertising or insurance agent, real estate broker)                                      |
| <input type="checkbox"/> | 13. School Teacher (elementary or secondary school)  |
| <input type="checkbox"/> | 14. Service (barber, beautician, practical nurse, janitor, waiter, housecleaner)                                 |
| <input type="checkbox"/> | 15. Technical (draftsperson, medical or dental technician, computer programmer)                                  |

**Annual household income (combined subject, partner, retirement, disability)**

- |                          |                     |
|--------------------------|---------------------|
| <input type="checkbox"/> | 1. less than 10,000 |
| <input type="checkbox"/> | 2. 10,000-29,999    |
| <input type="checkbox"/> | 3. 30,000-49,999    |
| <input type="checkbox"/> | 4. 50,000-69,999    |
| <input type="checkbox"/> | 5. 70,000-89,999    |
| <input type="checkbox"/> | 6. 90,000 or more   |

**Is there a most convenient time for me to contact you?**

- Day of the week \_\_\_\_\_  
 Morning between \_\_\_\_\_ a.m. and \_\_\_\_\_ a.m.  
 Afternoons between \_\_\_\_\_ p.m. and \_\_\_\_\_ p.m.  
 Evenings between \_\_\_\_\_ p.m. and \_\_\_\_\_ p.m.

**Do you use email?**  Yes  No

Would you prefer that I contact you through email?

Email address: \_\_\_\_\_

Thank you for answering the screening questions. *[Indicate whether the person is eligible, requires additional screening at the clinic, or is not eligible and explain why.]*

Do you have any questions about the screening or the research? I am going to give you a couple of telephone numbers to call if you have any questions later. Do you have a pen? If you have questions about the research screening, you may call Megan Morrison and I will answer your questions.

If you have questions about your rights as a research subject, please call the UW Human Subjects Division office at 206-543-0098

Thank you again for your time and consideration.

## Appendix B: Interview guide over-view

THE PROCESS BY WHICH PATIENTS WHO HAVE ADVANCED HF & WHO HAVE UNDERGONE DT LVAD THERAPY NAVIGATE & COME TO DECISIONS IN THEIR CARE & HOW THEY CONTEXTUALIZE THOSE DECISIONS WITHIN THE TRAJECTORY OF THEIR DISEASE PROCESS	
1. Context/History Automatic v. Reflective decision-making Goals for LVAD	Can you tell me about being diagnosed with heart failure?
	Tell me about the first time you heard about an LVAD.
	How was the decision to get your LVAD made?
	Some patients describe an automatic decision or that they had no choice but to get the LVAD. Others describe reflecting on their options. Do you identify with either of those decision-making styles?
	In what ways has your decision-making style stayed the same since then? In what ways has it changed? (6)
	Can you tell me about a time that you have had to make a medical decision since you had your LVAD implanted?
	Reflecting back on all that you have learned and lived with your LVAD, did you go into this with a goal of why you got the LVAD? What do you think about setting goals for therapy? What would be helpful/unhelpful about it?
2. Relationship Conflict v. Support Family/friends Clinician Media	When you are worried about something related to your heart care, what do you do? {Talk to partner/friend, talk to clinician, get information from other sources.
	When making decisions about your heart care, are there places that you get information from other than your healthcare provider (on-line discussion boards, etc.)
	How important are your clinicians in your decision-making? Do clinicians ever seem to conflict in what they advise you? What has been the least/most helpful thing a clinician has said/done to aid decision-making?
3. Spirituality Hope & Miracles	Sometime patients with serious illness will find support and guidance through their religion or spiritual beliefs, have you? If so, can you give me an example of when you used your religion or spirituality to aid or guide you in a decision you needed to make?
	When making big decisions in your health care, do miracles play any part of your decision-making?
4. Uncertainty Prognosis: mortality Prognosis: QoL, symptoms, mental, emotion, social, physical functioning, goals	In healthcare, there is a big emphasis on prognosticating how long someone may have to live. But some patient say they do not want or need this information for their decisions, what do you think about this? Do you think knowing this can change hope?
	Would you be interested in prognostic information about things like quality of life, symptoms, or physical/mental functioning in your decision-making? What do you think would be the most helpful information a healthcare provider

	could give you when you need to make serious decisions about your LVAD?
	As you have adapted to your LVAD, has your idea of quality of life changed? Have there been things you adapted to that you thought you couldn't? Were there things you weren't prepared to adapt to?
	Have you had any major complications or incidents from having an LVAD? Would be willing to tell me about them? Were you prepared for the event? Do you think you could have been prepared better and how?
5. Costs/Burdens Direct/indirect medical costs Lost opportunities- Role functioning Caregiver burden	Sometimes people say that they weigh burdens in their decision-making, like burdens on their family or losing their role – what are your thoughts on this in your decision-making?
	Have you thought about the financial – both direct & indirect cost- of healthcare in your decision-making? Has anyone ever talked to you about it?
6. Time	Some research we have with people with LVAD talks about an initial, intermediate, and then a later “new normal” phases of adjusting to living with an LVAD? Have you experienced anything similar to these transitions? <i>{if yes, has it changed how you approach decision-making}</i>
7. Closing questions	What should people know who are just or about to get an LVAD for DT?
	What decisions do you see yourself having to make in the next months or next years?
	What have learned about making decisions about your care from having an LVAD?