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A Conceptual Definition of Quality of Life for People Living with an Implanted, Destination Therapy Left Ventricular Assist Device

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A CONCEPTUAL DEFINITION OF QUALITY OF LIFE FOR PEOPLE LIVING WITH AN IMPLANTED,
DESTINATION THERAPY LEFT VENTRICULAR ASSIST DEVICE

by

David Edward Dwyer

A Dissertation Submitted in
Partial Fulfillment of the
Requirements for the Degree of

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in Nursing

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ABSTRACT

A CONCEPTUAL DEFINITION OF QUALITY OF LIFE FOR PEOPLE LIVING WITH AN IMPLANTED, DESTINATION THERAPY LEFT VENTRICULAR ASSIST DEVICE

by

David Edward Dwyer

The University of Wisconsin-Milwaukee, 2020
Under the Supervision of Professor Jennifer Doering

BACKGROUND: People with advanced heart failure experience persistently severe symptoms with increasingly impaired capacity and quality of life. Treatment options beyond palliative care are limited to heart transplantation or implantation with a mechanical pump that replaces the weakened heart's function. The left ventricular assist device (LVAD) serves as a temporary bridge to transplant or bridge to recovery, or a permanent replacement as destination therapy (DT). While DT-LVAD recipients initially accept the device to extend life, there is a gap in understanding how DT-LVAD recipients define a life worth living, and how nursing and the health care team can help reach that goal.

PURPOSE: This study's purpose is to determine the conceptual definition of "quality of life" in people with a DT-LVAD.

METHODS: A grounded theory study was conducted using a theoretical sample and open, selected and theoretical coding processes within the constant comparison method. Theoretical saturation was reached with 11 participants (age 32-79 years).

RESULTS: *Normalizing* emerged as the basic social process. Participants reported that a life supported by battery-powered equipment is still a normal, human experience. A process of acceptance and adjustment occurred to *Normalize* a machine-dependent life. Although extending life was the original LVAD objective, recipient goals and needs evolved over time. Dependence on a machine to extend life did not replace the need for a life worth living. The conceptual definition of quality of life when living with a DT-LVAD emerged as: *I am able to live my life and do what I want, with some adjustments.*

CONCLUSION: This conceptual definition of quality of life from the DT-LVAD recipient perspective enhances the health care team's understanding and ability to improve DT-LVAD recipient lives. Life with an LVAD is not simply about survival; it is survival of quality that makes a difference and defines success.

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Chapter One

Introduction

Approximately 5.7 million Americans over the age of 20 years have been diagnosed with heart failure and one in nine deaths in the United States includes heart failure as a contributing cause. As a chronic and progressive condition, half of people who develop heart failure die within five years of diagnosis. There are 915,000 new cases of heart failure annually, and projections show that the number of people with heart failure is projected to increase by 46 percent resulting in over 8 million Americans over the age of 18 years with heart failure by 2030 (Mozaffarian et al., 2016).

Heart failure is a clinical syndrome resulting from an impairment of ventricular filling or ejection of blood (Yancy et al., 2013). It results in dyspnea and fatigue, exercise intolerance and fluid retention that may lead to pulmonary congestion and/or peripheral edema. Symptom presentation is individual-specific but most people with heart failure have symptoms due to impaired left ventricular myocardial function. However, clinical symptoms may result from disorders of the pericardium, myocardium, endocardium, heart valves, great vessels or metabolic abnormalities. Thus, heart failure is a clinical diagnosis based on a health history and physical examination. Stated another way, there is no single diagnostic test (Yancy et al., 2013).

There are many risk factors for the development of heart failure. Hypertension, which afflicts almost 25 percent of the American population and has a greater than 75 percent lifetime risk of development in the United States, is a key risk factor. Diabetes, obesity and insulin resistance, metabolic syndrome, atherosclerotic disease, and familial cardiomyopathies

are also among significant risk factors. Less common causes of heart failure include toxic cardiomyopathies from chronic alcohol or cocaine use, tachycardia-induced cardiomyopathy, myocarditis and rheumatological disorders, peripartum cardiomyopathy, amyloidosis and cardiac sarcoidosis. Stress cardiomyopathy, triggered by emotional or physical stress, has also been recognized as a cause of heart failure that most often affects post-menopausal women (Yancy et al., 2013).

In the United States, heart failure is classified using two main staging tools. The American College of Cardiology Foundation/American Heart Association (ACCF/AHA) stages emphasize the development and progression of disease. Once a patient moves to a higher (more acute) stage, they are unable to return to a lower classification. The New York Heart Association (NYHA) functional classifications are focused on the severity of symptoms in those with structural heart disease. Classifications are based on subjective clinician assessment and can change frequently over time (Yancy et al., 2013).

Initial actions to prevent heart failure include recognition and treatment of hypertension and lipid disorders and control of obesity, diabetes, and tobacco use to lower developmental risk of this disease. As heart failure progresses, pharmacological therapies and possible placement of an implantable cardioverter defibrillator (ICD) may be recommended for patients in addition to dietary restrictions on sodium. The use of continuous positive airway pressure (CPAP) to increase left ventricular function along with cardiac rehabilitation/exercise training to improve functional status may be prescribed. Cardiac resynchronization therapy

(CRT), also called biventricular pacing, may also be initiated for patients with a left ventricular ejection fraction of 35 percent or less (Yancy et al., 2013).

Advanced heart failure, also known as end-stage heart failure or refractory heart failure, is a subset of patients who have persistently severe symptoms that continue to worsen despite all available interventions (Yancy et al., 2013). Patients with advanced heart failure display objective evidence of severe cardiac dysfunction and severe impairment of functional capacity, which may include dyspnea or fatigue at rest or with minimal exertion (Jessup et al., 2009; Metra et al., 2007). Following diagnosis, patients with advanced heart failure have a limited survival expectation with median survival under three years, and equally impaired capacity and quality of life (Miller, 2011).

There are limited options for treatment of advanced heart failure. Palliative approaches include intravenous inotropic agents for selected patients that may improve symptoms but will also shorten life. For those who desire advanced therapies, cardiac transplantation is currently the optimal treatment, but is self-limited by the fixed number of heart donors compared to those on the waiting list (Peura et al., 2012). According to the United Network for Organ Sharing (2018), there were 3,960 heart transplant candidates on the waiting list as of January 29, 2018 and during the 2017 calendar year, 3,244 heart transplants were performed. Additionally, heart transplants are limited by physiological exclusion requirements, finite graft survival, and long-term considerations of immunosuppressive therapy (Peura et al., 2012).

Mechanical Circulatory Support (MCS) devices provide temporary and permanent options for advanced heart failure patients. MCS devices can be extracorporeal, percutaneous

or implantable depending on the required therapy. The development of smaller and more reliable ventricular assist devices (VADs) have enabled longer-term use as a bridge to transplant until a heart is available for transplantation-eligible patients and as a bridge to recovery or bridge to decision if it is not possible to determine transplant candidacy until the patient's condition has stabilized. Although patients who have multisystem organ failure may not benefit from MCS therapy, other patients who are not eligible for transplant can benefit from an implanted Left Ventricular Assist Device (LVAD) (Peura et al., 2012).

The LVAD is a mechanical pump that assumes the function of a weakened ventricle to continue blood flow. The device is surgically attached directly to the vessels of the heart. A cable connects an electronic controller carried outside of the body that supplies power through rechargeable batteries and regulates device function (Goldstein et al., 1998). Once considered a last resort, LVAD technology has dramatically improved over time and may eventually challenge heart transplantation as the best viable option of permanent therapy (Kirklin et al., 2012; Miller, Guglin, & Rogers, 2013).

Destination therapy (DT) is an implant of an LVAD that is designed to restore cardiac output, organ perfusion and improve the heart failure patient's clinical condition, quality of life and life expectancy (Kirklin et al., 2012; Tozzi & Hullin, 2016). Unlike other forms of temporary MCS therapy, DT is planned as lifelong support for those who do not qualify or do not desire heart transplantation (Kirklin et al., 2012; Porepa & Starling, 2014). With the continued improvement in device technology, the focus on LVAD implantation has expanded from simply extending life to include the improvement in the recipient's quality of life. Quality of life (QOL)

is an overall appraisal of how satisfied and happy an individual is with life. As a multidimensional concept, quality of life includes physical, mental and social domains (Maciver & Ross, 2012).

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), a national registry of all non-incarcerated adult patients who receive FDA-approved MCS devices in the United States since 2005, did not routinely collect quality of life measures until May, 2012 (Arnold et al., 2016). At present, there is no disease-specific quality of life measurement for people with implanted LVADS (Sandau et al., 2014). INTERMACS uses the Kansas City Cardiomyopathy Questionnaire (KCCQ), designed for heart failure patients, to report QOL status in the first 24-months after implantation. Approximately 80% of responding recipients report they are “glad to have a VAD” (Arnold et al., 2016; Kirklin et al., 2017). However, the KCCQ measures health-related quality of life by focusing on physical and role function for patients with heart failure and is not specifically designed to measure LVAD recipient concerns such as drive-line infection risks, reliance on batteries to survive, burdens of equipment, and dressing changes. Although the KCCQ is robustly validated for heart failure patients, it may not be as sensitive or specific as an LVAD-specific measure would be to measure quality of life with an LVAD (Sandau et al., 2014).

Defining Quality of Life

A conceptual definition facilitates understanding by clarifying an abstract concept into a set of meaningful words, while an operational definition explains how to measure or quantify the term (Bernard, 2013). A conceptual definition of quality of life for a specific patient group

can increase validity for operationalized measurement in research. Studies measuring QOL are often reported without common terminology, which may result in poor validity and a lack of comprehensiveness when measuring QOL in new populations (Bernard, 2013; Sandau et al., 2014). Before we can measure quality of life in LVAD recipients, we must first understand the conceptual definition of quality of life as applied to this population.

There has been only one study focusing on the conceptual definition of quality of life from the perspective of the LVAD recipient (Sandau et al., 2014). Using established and recognized domains, the study conceptualizes QOL factors unique to the experience of an LVAD recipient. Additionally, it advances the case that measurement of QOL in LVAD recipients is unique. While LVAD recipients may share commonalities with other populations including heart failure or heart transplant, they have special attributes that require independent consideration (Sandau et al., 2014).

Prior studies of quality of life in LVAD recipients have grouped all recipient types into a single group containing DT-LVAD with bridge to transplant and bridge to recovery LVAD recipients. The permanent nature of DT-LVAD implantation may create different concerns and perspectives than temporary bridge to transplant or bridge to recovery MCS strategies. The time horizon for destination therapy is considerably longer with no anticipation or expectation of heart recovery or explant/transplant (Patel, Nicholson, Cassidy, & Wong, 2016). This alone is significant, as the recipient has accepted the implanted device as a permanent solution and will keep it for the rest of their lives. Correspondingly, it is reasonable to suggest that this

distinction could also change the overt or subtle dynamics of psychosocial adaptation to the implanted technology and QOL with an LVAD.

Human responses result from interactions with others and thoughtful interaction within the individual themselves. Symbolic interactionism, as a philosophical foundation for grounded theory, focuses on the present, allowing the person to define the world they live in. Objects, like the LVAD, acquire a special meaning that may be unique to the individual and lead to specific responses based on the impact of those objects on the person. This unique and personal approach to reality defines living with an LVAD “as it exists” and interprets a response based on the realities of living with an implanted machine for life (Charon, 1995).

This study will use grounded theory to gain a better understanding of DT-LVAD recipients by discovering a conceptual definition of quality of life when living with an implanted destination therapy LVAD.

Significance

Heart failure is common and increasing in nearly all regions of the world. Although most cardiovascular disease-related death rates have declined, the prevalence and incidence of heart failure is increasing with poor long-term prognosis (Cook et al., 2014). Prevalence of heart failure has been estimated at 1-2 percent of the general population, rising to 10 percent among people over age 70 years, but this may underestimate the true scale of the disease as overall lifetime risk of developing heart failure has been estimated at 33 percent for men and 28 percent for women (Kurmani & Squire, 2017).

There is significant economic impact related to heart failure. Economic burden includes spending on hospital services, medications, physician or provider costs, and primary care costs in addition to indirect costs of lost productivity, sickness benefit and welfare support. In 2012, total global health costs from heart failure was estimated at \$108 Billion per year (Cook et al., 2014).

In the United States, 2.4 percent of Americans have heart failure, but almost 12 percent of men and women over age 80 years have heart failure. More than 8 million Americans will have heart failure by 2030 as the prevalence of heart failure is expected to increase by 23 percent. The total number of Americans living with heart failure will increase 46 percent over this time period (Heidenreich et al., 2013).

Direct medical costs for heart failure in the United States are projected to increase from \$20.9 Billion per year in 2012 to \$53.1 Billion per year in 2030. Total costs of heart failure include an estimate of lost productivity from morbidity and premature mortality, and are estimated to increase from \$30.7 Billion in 2012 to \$69.8 Billion in 2030 (Heidenreich et al., 2013).

Although patients with advanced heart failure have limited therapeutic options, improvements in LVAD therapy devices present a viable option for survival. Following increases in longevity, functionality, and quality of life measurements, DT-LVAD therapy compares favorably with heart transplantation as a long-term solution for end-stage heart failure (Miller et al., 2013). DT-LVAD therapy is increasingly being implanted in advanced heart failure patients who are less ill, improving outcomes while also reducing costs (Boyle et al., 2011;

Kirklin et al., 2012). Reflecting these advances, LVADs became reimbursable in 2004 using the same diagnosis group as heart transplantation, and continued advancements in technology and outcomes have prompted continued growth in the number of implanted LVADs and centers doing the implants. If criteria for implantation is further relaxed, estimates of potential recipients in the United States may be as high as 250,000 (Miller, 2011; Miller et al., 2013).

The continued emergence of new device technology will further reduce adverse events and improve clinical outcomes (Peura et al., 2012). Understanding the physical, mental and social domains that impact quality of life specifically in DT-LVAD recipients is essential to advance health outcomes, including improvements in quality of life. The emotional response of the DT-LVAD recipient, over time, continues to evolve as technology becomes more reliable and expected life-span increases. Uncovering a conceptual definition of quality of life from the perspective of the DT-LVAD recipient is necessary to develop effective interventions to improve outcomes after implantation, but also to assist in decision-making pre-implant to maximize satisfaction and quality of life following the implantation decision.

Problem Statement

More Americans are hospitalized for heart failure than any other medical condition. As a chronic and progressive disease, heart failure is expected to increase the burden and cost of healthcare expenditures substantially over the next 10 years. Advancements in treatment have increased life expectancy, but options are limited to heart transplantation, mechanical circulatory support or palliative care for those who progress to an advanced stage of the disease (Heidenreich et al., 2013; Patel et al., 2016).

The effectiveness of the LVAD as mechanical circulatory support continues to improve. DT-LVAD implantation is being used with recipients who are less ill, improving outcomes and reducing costs of device use. Destination therapy, once used as a last resort to improve end-stage symptoms, now compares favorably with heart transplantation and is being used as a permanent treatment solution (Miller, 2011; Miller et al., 2013).

There has been limited research on quality of life from the perspective of the LVAD recipient. This gap may contribute to a misunderstanding of the concerns and needs of this vulnerable population and challenges that exist for those living with an implanted LVAD. Such misunderstandings may increase costs, prolong psychological adjustment or negatively affect decision-making and quality of life. Individuals with a destination therapy LVAD may share similar experiences with other LVAD recipients, but it is reasonable to believe there are unique attributes that arise when one accepts implantation of a mechanical device for life without expectation of explant after heart recovery or transplantation. Machines which must function at all times for survival place the recipient in a vulnerable position that is often unrecognized by the recipient until after the implantation has occurred (Dwyer & Casida, 2016).

Nurses provide primary care of DT-LVAD recipients in the acute and outpatient environments. LVAD coordinators, in particular, are specially trained nurses or advanced practice nurses who assess, care and educate patients before and after LVAD implantation. The relationship between the nurse and DT-LVAD recipient offers a direct opportunity to assess, intervene and impact the physical and psychological status of the recipient and optimize the DT-LVAD experience. Discovering a conceptual definition of quality of life from the perspective

of the DT-LVAD recipient is a crucial step toward understanding their journey and promoting their needs.

Purpose of the Study

The purpose of this study is to determine the conceptual definition of “quality of life” in people living with an implanted destination therapy left ventricular assist device (DT-LVAD).

Specific Aims

The specific aim of this study is to generate a grounded theory of living with a DT-LVAD.

Sub-aims of this study are:

1. Determine how patients conceptualize life when living with a DT-LVAD.
2. Determine how patients conceptualize quality of life when living with a DT-LVAD.

Definitions

New York Heart Association (NYHA) Functional Classification of Heart Failure

Patients are categorized based on limitation of physical activity and severity of symptoms.

Class I: No limitation of physical ability. Ordinary physical activity does not cause symptoms of HF.

Class II: Slight limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.

Class III: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes symptoms of HF.

Class IV: Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest.

(Yancy et al., 2013)

American College of Cardiology Foundation/American Heart Association (ACCF/AHA)

Functional Classifications of Heart Failure

Patients are categorized based on progression of heart failure. Once symptoms develop, patients are unable to move backwards to prior stages.

Stage A: At high risk for HF but without structural heart disease or symptoms of HF.

Stage B: Structural heart disease but without signs or symptoms of HF.

Stage C: Structural heart disease with prior or current symptoms of HF.

Stage D: Refractory HF requiring specialized interventions.

(Yancy et al., 2013)

Chapter Two

Review of Literature

This chapter reviews the literature related to the development of a conceptual definition of quality of life when living with an implanted destination therapy LVAD. To provide background and insight into this phenomenon, this review will examine psychosocial factors connected with heart failure, the impact of technological advancement on outcomes, psychosocial factors associated with LVAD implantation, and existing quality of life information for LVAD recipients. The chapter concludes with an explanation of how the proposed study will advance nursing science within the population of destination therapy LVAD recipients.

Heart Failure

Heart failure is a complex clinical syndrome that can lead to pulmonary and peripheral edema and exercise intolerance. As a clinical diagnosis based on multiple criteria, there is no single diagnostic test for heart failure. Natriuretic peptide biomarkers are being increasingly used to establish the presence and severity of heart failure, but there is not yet sufficient data available for agreement on specific guidelines (Yancy et al., 2013, 2017). The New York Heart Association (NYHA) and American College of Cardiology Foundation/American Heart Association (ACCF/AHA) provide widely used functional classifications about the presence and severity of heart failure. The NYHA classification is the most commonly used system to describe the impact of heart failure and is an established predictor of heart failure outcomes (Holland et al., 2010).

Psychometrics of Commonly Used Instruments

Heart failure research has used multiple quantitative tools to examine how the disease impacts patients. In this section, the psychometrics of the most common tools used in studies included in this chapter will be reviewed, but this list is not inclusive of all quantitative tools used. In studies discussed in this chapter, over 30 different quantitative tools were used to expand understanding of the impact of heart failure on patients. This extraordinary number of tools is not unique in this literature. A literature review by Grady et al. (2015a) from January 1990 to June 2014 identified over 35 different tools measuring health related quality of life in patients with advanced heart failure and health related quality of life before or after mechanical circulatory support interventions. Although studies use multiple instruments to cover generic and heart-failure specific measurements, there is no specific quantitative tool yet developed that covers the unique burdens associated with living with an LVAD (Grady, et al., 2015b). The most common tools used in studies relevant to this review include the Minnesota Living with Heart Failure Questionnaire, the Kansas City Cardiomyopathy Questionnaire, the Hospital Anxiety and Depression Scale and the EuroQual Instrument.

The Minnesota Living with Heart Failure Questionnaire (MLHFQ) is designed to measure the adverse effect of heart failure on patient lives. Twenty-one items assess the perceived impact of physical symptoms, depression, and effects on common life functions over the prior month, resulting in a numeric score. The tool is based on a traditional clinimetric perspective and reports high internal consistency (Cronbach alphas 0.91 to 0.96). Retest reliability has been shown by correlation between repeated measurements ($r=0.80$ to $r=0.93$) and intraclass

correlation coefficient (icc=0.84 to icc=0.89). The tool's validity has been measured by a number of studies correlating scores with measures of heart failure symptoms or other effects on daily exercise, and it has been strongly correlated with generic Short Form Health Survey (SF-36) scores, psychological measures, and heart specific measures (Rector, 2017; Rector, 2006). In absence of a comprehensive assessment tool for LVAD patients, the MLHFQ has been used in conjunction with other specific and generic measures to assess quality of life of LVAD recipients. Used as part of a multi-tool plan, the MLHFQ has provided the best approach to measure quality of life until a specific tool focused on LVAD recipients is created (Allen et al., 2010).

The Kansas City Cardiomyopathy Questionnaire (KCCQ) examines physical limitations, symptoms, self-efficacy, social interference and quality of life in patients with heart failure. The 23-item questionnaire results in a numeric score that independently quantifies symptoms (frequency, severity and stability), social limitations, and quality of life. The KCCQ demonstrated high internal consistency (Cronbach alphas 0.78 to 0.95) in all domains other than self-efficacy (0.62) and was shown to have validity in all domains. Additionally, the KCCQ showed an increased sensitivity to clinical change almost three times larger than corresponding domains of comparison tools, including the frequently used SF-36. Specifically, the KCCQ was substantially more sensitive to changes related to exacerbations of congestive heart failure as compared to baseline variability in stable patients. The increased sensitivity may help show more subtle indicators of quality of life that are tied to other clinical markers (Green, et al., 2000).

The Hospital Anxiety and Depression Scale (HADS) assesses for anxiety disorders and depression using separate subscales for anxiety (HADS-A) and depression (HADS-D). A review of 747 identified papers using HADS found Cronbach alpha for HADS-A varied from 0.40 to 0.76 (mean 0.56) and HADS-D from 0.67 to 0.92 (mean 0.82). Sensitivity and specificity for both subscales was 0.80, similar to the General Health Questionnaire. Correlations with other common questionnaires were 0.49 to 0.83. Additionally, HADS was found to have the same properties when applied to samples from the general population, general practice and psychiatric patients (Bjelland et al., 2002).

The EuroQual instrument (EQ-5D) is a five-dimensional generic tool to measure and value health status in five dimensions across disease areas. Respondents rate overall health in addition to Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression. The tool has been widely tested and used in general populations and within specific areas (Herdman et al., 2011). A review of 66 studies using the EQ-5D with patients having cardiovascular disease found support for the validity and reliability of the tool within this specific patient population. Evidence of construct and convergent reliability was reported, along with responsiveness measured by test-retest statistics, intra-class correlation coefficients, and effect size. However, studies reviewed were often too small to detect treatment effects, and calculation of pooled means across studies was not appropriate given a high level of heterogeneity of study design. The EQ-5D was less able to detect clinical changes than disease-specific tools such as the KCCQ, but the EQ-5D did show good responsiveness compared to other generic measures such as the SF-12 (Dyer et al., 2010).

Past studies have made reasonable progress in taking the first steps towards understanding mechanical circulatory support patients with the use of these tools. However, the unique burdens of LVAD life cannot be fully measured by tools that are non-specific to mechanical circulatory support recipients. The development of the MLHFQ and KCCQ have improved understanding of heart failure and cardiomyopathy, but the sensitivity and precision required of these tools for their specific foci highlights the need for a new tool that is LVAD-specific. This paper addresses this critical gap by studying the destination therapy LVAD population specifically, to determine a conceptual definition of quality of life as a starting point towards further condition-specific tool development.

Psychosocial Factors and Heart Failure

Heart failure is associated with a lower quality of life and increased depressive symptoms than the population at-large. In a study of 781 people with heart failure and 781 age and gender-matched community dwelling people without heart failure, data were analyzed using the Medical Outcome Study 36-Item General Health Survey (RAND-36) measuring quality of life, Cantril's Ladder of life measuring well-being, and the Center for Epidemiological Studies Depression Scale (CES-D) assessing depressive symptoms. People with heart failure had significant quality of life impairment and lower well-being compared to the matched group in both genders, and the risk for depressive symptoms was also more than doubled. Heart failure participants scored lower in physical functioning, role limitations and vitality, and people with heart failure and comorbidities were worse off than comparable populations with comorbidities (Lesman-Leegte et al., 2009).

The Lesman-Leegte et al. (2009) study supported earlier work showing heart failure patients had an increased impairment of quality of life than the general population. The study had broad selection criteria and recruited from 17 hospitals but focused on conditions likely to have substantial comorbidity. While the study sorts effects of comorbid conditions, it may still underestimate total disease burden for heart failure patients. Women were underrepresented (36% of sample) which may further distort results.

Cline, et al. (1999) used the self-administered generic and disease-specific instruments Nottingham Health Profile, Quality of Life Questionnaire in Heart Failure and Patient's Global Self-Assessment to measure quality of life in patients aged 65-84 years ($n=191$, mean age 75.4) who were hospitalized with a primary heart failure diagnosis. Health related quality of life was impaired in heart failure patients compared to age and sex matched reference populations ($p<0.001$). As the patient's New York Heart Association (NYHA) functional classification declined, quality of life decreased ($p<0.001$). There were no significant differences between age groups, but quality of life was significantly reduced in women compared to men ($p<0.001$). Women reported higher disturbances in sleep, energy, pain and mobility. Additionally, women (47% of the sample) experienced a reduction of perceived physical capacity compared to men (Cline et al, 1999). Ekman et al. (2002) administered the Short Form Health Survey (SF-36) and Sense of Coherence to patients ($n=94$) with a mean age of 81 years hospitalized with NYHA functional class III and IV heart failure (mean 3.2). The SF-36 measures a personal evaluation of health and well-being, and scores significantly indicated higher quality of life for the control group in all domains ($p<0.0001$ with exception of bodily pain $p<0.001$). Patients suffered from considerable functional losses with lower levels of health-related quality of life and scored

particularly low on physical dimension items such as physical function, general health and vitality. Women (45% of the sample) had lower scores than men in physical function. The Sense of Coherence scores did not differ between control and patient groups (Ekman, et al., 2002).

Differences in perceived physical function between women and men illuminate the complexity of heart failure and its effect on different groups of patients. Although it is important to identify broad quality of life reductions, we are unable to understand the causes or develop solutions without recognizing that each measured dimension has a different level of importance for different subgroups of patients. The Cline et al. (1999) and Ekman et al. (2002) studies present a mixed gender sample, but participants are all hospitalized patients which may not reflect overall quality of life scores when not experiencing an acute exacerbation or when living outside the hospital.

Juenger et al. (2002) also administered the SF-36 to patients ($n=205$) with heart failure and systolic dysfunction finding a significant quality of life decrease with NYHA functional class decline. In NYHA class III ($n=83$), quality of life domain scores including physical functioning, physical role functioning, bodily pain, general health, vitality and emotional role functioning were reduced to approximately one-third of the general population's scores. Interestingly, this pattern of reduction was unique to heart failure patients measured by NYHA functional class as compared with other chronic conditions including hepatitis C and hemodialysis. Heart failure patients in NYHA class III also had similar quality of life impairment as control group patients with major depression ($n=502$, $p<0.05$), indicating mental distress in addition to reduced

physical capacity (Juenger et al., 2002). Koenig (1998) screened admitted patients for depression ($n=542$) using the Center for Epidemiologic Studies Depression Scale and Mini-Mental State Exam in addition to an interview with a psychiatrist and medical record review. Independent of past individual or family psychiatric history, heart failure patients ($n=107$) were more likely than other cardiac patients without heart failure to have a major depressive disorder ($p=0.002$). Severity of illness ($p=0.032$) and impaired ADLs ($p=0.017$) were predictors of major or minor depression in heart failure patients (Koenig, 1998).

Psychosocial factors have been shown to increase negative outcomes and mortality rates. A systematic review of depression and anxiety in heart failure patients reviewed 26 articles meeting criteria on depression ($n=80,627$) and six articles meeting criteria on anxiety ($n=17,214$). The unadjusted risk of death among heart failure patients with depression was 1.57 times higher than heart failure patients without depression (Sokoreli et al., 2016). Even so, similar reviews have found an even higher risk of mortality (Fan et al., 2014; Rutledge et al., 2006). Anxiety was not found to increase risk of mortality, but it is a covariate to factors such as depression and had a similar prevalence to depression in patients with heart failure (Sokoreli et al., 2016).

Changing the patient's negative beliefs about living with heart failure may improve psychological well-being and quality of life. Hallas et al. (2011) used the Illness Perceptions Questionnaire-Revised (IPQ), Hospital Anxiety and Depression questionnaire, COPE inventory, World Health Organization Quality of Life Brief Assessment, and Minnesota Living with Heart Failure Questionnaire to assess the relationship between advanced heart failure patient

($n=146$) psychological and clinical variables related to quality of life and mood. Patients scoring as anxious and depressed showed higher amounts of maladaptive coping (behavioral disengagement, $p<0.001$, coping and venting emotions $p<0.05$) and negative perceptions about symptoms, heart failure, and their ability to control the disease (IPQ sub-scales $p\geq 0.05$). Depression, anxiety, and COPE behavioral engagement were significant predictors of psychological quality of life in their final stepwise regression model ($R^2=0.66$) with depression explaining the largest proportion of this relationship ($\beta=-0.45$, $R^2 \Delta 0.45$). (Hallas et al., 2011).

The Hallas et al. (2011) findings supported prior research showing depression and anxiety as significant influences on quality of life. Personality traits and psychosocial conditions may also alter perception of the symptoms associated with heart failure. Specifically, actual physiological function has only a partial impact on perceived outcomes. Obieglo et al. (2016) used the generic Nottingham Health Profile and Acceptance of Illness Scale to examine the relationship between quality of life and acceptance of illness in heart failure patients ($n=100$) with six months of clinical symptoms corresponding to NYHA class II, III or IV. Patients with a low acceptance of illness had significantly higher pain, emotional reaction, sleep, social isolation and mobility domain scores, indicating greater functional impairment ($p<0.001$). Additionally, persons over age 60 years scored significantly higher on social isolation, mobility and emotional reaction scales, while women of all ages had significantly higher scores on energy and mobility. Acceptance of illness was an independent predictor of quality of life ($p<0.001$) in all measured domains (Obieglo et al., 2016).

Poor quality of life generally increases risk of mortality. The change in self-assessed

health status as measured by the Kansas City Cardiomyopathy Questionnaire for heart failure patients ($n=459$) was independently associated with five-year mortality (Hazard ratio 0.87, CI: 0.80, 0.94, $p=0.0007$) in a predominantly male population of veterans (Subramanian, Eckert, Yeung, & Tierney, 2007). Additionally, health-related quality of life as measured over seven years ($n=416$, 30.3% survival) by SF-36 and the Minnesota Living with Heart Failure Questionnaire predicted long-term mortality in heart failure patients. Controlling for biomedical, healthcare and social variables, a poor mental component summary on SF-36 (hazard ratio 1.38, 95% CI 1.06-1.76) or poor physical summary on Minnesota Living with Heart Failure Questionnaire (hazard ratio 1.31, 95% CI 1.01-1.70) predicted higher mortality (Zuluaga et al., 2010). Further, a cohort of heart failure patients ($n=661$) was followed for three years assessing quality of life through questionnaires (Ladder of Life, RAND36 and Minnesota Living with Heart Failure Questionnaire) and brain natriuretic peptide (BNP) levels following any heart failure hospital admission. Poor quality of life scores predicted higher mortality independent of BNP levels or demographical and clinical variables on RAND36 physical functioning dimensions (hazard ratio 1.08, 95% CI 1.02-1.14) and general health dimensions (hazard ratio 1.08, 95% CI 1.01-1.16). Baseline measurements showed survivors at three years (57.6%) rated quality of life better than non-survivors on Minnesota Living with Heart Failure total score ($p=0.01$) and physical subscales ($p=0.001$). Emotional subscale scores at baseline did not differ between survivor and non-survivors (Hoekstra et al., 2013).

Better Measurement Needed

The variety of instruments used in heart failure research present a number of strengths,

as generic instrument scores combined with results from specific tools like the Kansas City Cardiomyopathy Questionnaire (KCCQ) or Minnesota Living with Heart Failure Questionnaire (MLHFQ) capture different elements of life with heart failure. Comparisons can be made between control/healthy participants and study/heart failure participants. As shown earlier, both KCCQ and MLHFQ have good reliability and specificity for heart failure. Over time, larger sample sizes across multiple locations have helped improve generalizability, and studies looking at mortality have compared longevity with a variety of factors in studies stretching up to seven years.

However, the use of generic tools can miss subtle or long-term changes in a progressive disease like heart failure. Many studies providing insight into this complex phenomenon have been completed in a single medical center and/or are focused exclusively on hospitalized patients. Individuals undergoing an illness exacerbation may have different feelings about their current quality of life that may not be reflective of feelings when living at home or feeling better. If we are interested in understanding the patient's quality of life to improve it, we must conduct research based on where the patient lives most of the time.

Many studies control for the impact of medication or treatments, but these elements are a central part of the heart failure patient's life and this variable control may cause underreporting of symptoms or disease burden that eventually impact quality of life. Unfortunately, most studies have a majority of male participants, even though studies have shown female heart failure patients experienced lower levels of quality of life in select areas including physical function, fatigue, and emotional domains when compared with male

patients. Those particular domains have also been shown to predict mortality. Clearly, women must be included in more heart failure research opportunities.

Quantitative tools examine the patient experience from the perspective of the clinician or researcher. The tools used are valid and reliable but may overlook the smaller elements of daily life that dramatically impact the patient experience. Since psychosocial variables have been shown to amplify symptoms even if physiological criteria are absent in heart failure patients, it is vital to examine the patient experience from their perspective to ensure understanding. Since DT-LVAD recipients are also advanced heart failure patients, use of the heart failure literature as a starting point is certainly an advantage. However, applying these studies or instruments as a custom fit for LVAD patients is not possible. A disease and condition-specific examination into the complexities of living with an implanted DT-LVAD is required to understand quality of life in this unique population.

The Left Ventricular Assist Device (LVAD)

There are limited treatment options available for advanced heart failure patients. For people who want an alternative to palliative care, heart transplantation remains the gold standard (Yancy et al., 2013). However, an inadequate supply of donor hearts coupled with patient contraindications to transplantation created the need for additional long-term options to replace failing hearts. Mechanical circulatory support (MCS) through implantation of a left ventricular assist device (LVAD) has become an effective and durable alternative to heart transplantation (Peura et al., 2012).

First Generation LVADs

First generation LVADs were bulky, noisy devices with limited durability. These pulsatile devices had a high risk of mechanical failure and device-related complications (Peura et al., 2012). However, the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial ($n=129$ from 20 cardiac transplant centers) showed that patients not eligible to receive a heart transplant improved one-year survival from 25 percent to 52 percent ($p=0.002$) by receiving an implanted LVAD instead of medical management alone. Two-year survival improved from 8 percent in the medical management group to 23 percent ($p=0.09$) in the LVAD group. Median survival was 408 days in the LVAD group and 150 days in the medical management group. Quality of life, as measured by the SF-36, showed significant improvement in physical function ($p=0.01$) and emotional role ($p=0.03$) in the LVAD group and depression was also lower ($p=0.04$) than the medical management group as measured by the Beck Depression Inventory. The NYHA classification was also reduced for the LVAD group ($p=0.001$). Minnesota Living with Heart Failure scores were reported as improved but not significant. The frequency of serious adverse effects in the LVAD group was 2.35 times that of the medically managed group (95% CI 1.86-2.95) with a predominance of infection, bleeding and device malfunction (Rose et al., 2001).

Following the REMATCH study, the United States Food and Drug Administration approved long-term LVAD use in 2002 enabling widespread use as destination therapy or bridge-to-transplant options for advanced heart failure patients (Shah et al., 2016).

The relatively low number of LVAD implantations challenged researchers to find adequate

sample sizes. The REMATCH trial, as an example, required 20 different cardiac transplant centers to achieve the required sample size of 129. Although quantitative tools were still used, the use of qualitative methods became more prevalent over time.

Dew et al. (1999, 2000) recognized a quality of life and mental health advantage for heart transplant candidates with left ventricular assist systems who could live out of the hospital ($n=10$) as compared to those who remained hospitalized ($n=25$). Additionally, quality of life for the non-hospitalized LVAD patients improved from their own pre-implant measurement and was also better than other non-hospitalized transplant candidates who did not require an LVAD. The non-hospitalized LVAD group more closely resembled a demographically similar group of non-hospitalized transplant recipients ($n=97$) instead of transplant candidates ($n=55$). Semi-structured interviews were used with the Sickness Impact Profile, Symptom Checklist-90, Index of General Affect, Index of Life Satisfaction and a survey of primary caregiver responsibilities and perception of burden. The sample was overwhelmingly male (Dew et al., 1999, 2000).

Grady et al. (2001) examined quality of life outcomes in first generation bridge-to-transplant LVAD patients 1 to 2 weeks after implantation. Patients completed questionnaires before ($n=30$) and after ($n=81$) implant, reporting more satisfaction with health and functioning ($p=0.001$) and greater quality of life ($p=0.002$) following implant. Additionally, patients reported less exertional shortness of breath ($p<0.0001$) and weakness ($p=0.008$) following implant. However, patients also reported insomnia, fatigue, gastrointestinal distress and incisional pain (Grady et al., 2001). One month following implantation, recipient satisfaction with quality of life as measured by the Quality of Life Index continued to improve ($n=92$)

although the most positive scores were obtained following heart transplantation. The least positive ratings were related to quality of life and stress level. Patients thought the LVAD saved their lives (53 percent) or thought they had no alternative but to accept the LVAD (17 percent). Seventy-nine percent of patients would “definitely have” the surgery again and 12 percent would “probably have” it again. Almost half of participants originally enrolled ($n=150$) were too ill to complete the questionnaires, and one-third of patients that were recruited but not-enrolled died. The sample was 92 percent male (Grady et al., 2002).

After one year, a booklet of six quality of life instruments were selected based on the study team’s definition of quality of life and the domains they felt were important to measure. Quality of life outcomes remained largely stable after LVAD implantation ($n=78$), although Satisfaction with Life subscale Health/functioning improved ($p=0.01$) and symptom distress declined in cardiopulmonary ($p<0.05$), neurologic ($p=0.007$), psychological ($p=0.0003$) and physical ($p=0.02$) scales over one year. Additionally, Sickness Impact Profile functional disability subscales also significantly improved in work, home management, social interaction, self-care and physical disability over one year. However, participants continued to experience anxiety, helplessness, and depressive feelings including weakness, difficulty sleeping, feeling sad or helpless, and having trouble concentrating or remembering things. Selected items from the physical domain, including the ability to walk or dress oneself, were significantly associated with the risk of dying after LVAD implantation. Focusing on quality of life, including physical and psychosocial interventions while monitoring symptom distress and physical disability was suggested to improve survival (Grady et al., 2004).

The studies by Dew et al. (1999, 2000) and Grady et al. (2001, 2002, 2004) broke new ground looking at LVAD recipient quality of life. The studies examined changes in quality of life and presented new information on life as an LVAD recipient. The importance of caring for the physical and emotional elements of the patient were again highlighted, and challenges of having the life-saving device were identified. Perhaps most importantly, the studies provided hope for extended life for those suffering with advanced heart failure and supported continued development of new technology to improve the LVAD experience for patients.

The exclusion of LVAD recipients that were too ill to complete the questionnaires seems to introduce selection bias as it eliminates the participants that would be most likely to report a negative experience with the device. A difficult experience, whether it is an extended recovery or adverse complication at one month or one year, must certainly influence overall quality of life. LVAD recipients have already chosen to accept the LVAD instead of selecting a palliative care option, as it is the only way for them to remain alive. Yet, 12 percent of those well enough to be surveyed stated they would “probably have” the surgery again, 6 percent were not certain, and 2 percent would not do it again. Indeed, 79 percent of recipients stated they would “definitely have” the surgery again, but if continuing life is the patient’s priority, simply stating they would have the surgery again may not indicate anything about quality of life or overall satisfaction with the procedure. If the LVAD presents the only available way to stay alive, agreeing to have the surgery again may simply indicate the patient has retained their desire for life.

Selecting tools based on the research team’s perception of quality of life following LVAD

implantation could miss vital information that is important to the recipients themselves. Tools selected were carefully chosen based on the characteristics of the LVAD population. However, this seems to imply that research teams or clinical experts can substitute their knowledge for that of the actual patient. Instead, allowing the patient to determine what is important to them may lead to better understanding of what it means to actually live with the burdens and benefits of a mechanical circulatory support device.

Continuous Flow LVADs

In 2008, continuous flow LVADs were approved for use in the United States. These non-pulsatile devices are smaller and have fewer device-related complications. Subsequently, third generation, continuous flow devices that produce a centrifugal blood flow without any contact bearings were introduced. The improved design reduces hemolysis and continues to improve outcomes. Since 2008, continuous flow LVAD overall survival is 81 percent at 12 months and 70 percent at 24 months. Significantly, with technology improvements, destination therapy implantation has continued to increase and now account for almost 50 percent of LVADs, outpacing bridge-to-transplant (26 percent) and bridge-to-candidacy (23 percent) (Bonacchi, et al., 2015; Kirklin et al., 2017; Shah et al., 2016). Since 2010, all DT-LVAD implantations have been continuous flow devices (Kirklin et al., 2014).

There was no significant difference in mortality, infection, bleeding or device malfunction between men ($n=1535$, 402 were pulsatile devices) and women ($n=401$, 78 were pulsatile devices) receiving LVAD support between June 2006 and March 2010, although women had a statistically significant higher rate of neurological events ($p=0.020$). However, this may be

related to body surface area and not gender, as patients with smaller body surface areas had a higher incidence of neurological events than patients with larger body surface areas. Body surface area may also account for the overwhelming numbers of men compared to women who received LVADs, as larger first-generation pulsatile devices may have been too big to physically fit into the chest. Additionally, there is a higher percentage of male heart donors in the United States and sex differences in transplantation may reflect the higher likelihood that a male heart based on size may simply fit better in a male recipient (Hsieh et al., 2012). As LVAD technology continues to improve and device size becomes smaller, women will make up an increasing number of LVAD implantations. Whenever possible, women recipients of LVADs must be included in the research now to determine possible differences in the LVAD experience between men and women.

Despite improvements in device technology, significant physiological and psychological adjustments are needed to accept a new LVAD. Fatigue, anxiety, depression and sleep disturbance have all been reported within the first six months of implantation (Casida, et al., 2011; Casida & Parker, 2012). A cross-sectional, grounded theory study with current and former LVAD recipients ($n=11$) identified perceived control as a central category related to successful adjustment, as recipients constantly attempted to gain or regain control of their lives. Control was important to achieve mental well-being, make sense of the situation and prognosis, and understand the changes that have caused dependency on medical staff and family/caregivers. Changes in environmental circumstances, like hospitalization, directly impacted their ability to reduce uncertainty, feel normal in appearance and remain in control of daily routines (Hallas, Banner, & Wray, 2009).

In a phenomenological study, long-term LVAD recipients ($n=9$) described early adjustments following implant as a basic change to physical, psychological and environmental aspects of everyday life combined with an uncertainty of what that life was going to be. Later adjustments included acceptance of the LVAD as an integral component of the recipient's body and life. The overarching theme "adjustment takes time" highlighted the recipient's early and later acceptance of the device and the changes necessary to survive (Casida et al., 2011).

Sleep disturbances with accompanying daytime dysfunction have also been related to advanced stage heart failure and LVAD implantation. A descriptive exploratory research design ($n=12$) using the Pittsburgh Sleep Quality Index, Epworth Sleepiness Scale, and Minnesota Living with Heart Failure Questionnaire found patients had significant sleep disturbances before and 6 months after LVAD implantation. Although patients had poor quality of life and sleep quality at baseline, physical and emotional domains of quality of life and global quality of life domains showed significant improvement at 6-months after LVAD implantation (Casida, Brewer, Smith, & Davis, 2012).

Sexual dysfunction has also been noted in recipients of an LVAD. A validated questionnaire and visual analogue scale were used to compare people with an LVAD ($n=14$) and heart transplant recipients ($n=17$). Participants had comparable recall of satisfaction pre-transplant or pre-implant, but pleasure or satisfaction with sex was significantly lower for LVAD patients than heart transplant recipients ($p=0.017$). A majority (82 percent) of heart transplant recipients reported full pleasure or satisfaction with sex compared with only 14 percent of LVAD recipients. Additionally, 50 percent of LVAD recipients reported mild or significant

disturbance and 36 percent reported no pleasure or satisfaction with sex (Hasin et al., 2014). A sexual and psychosocial survey ($n=26$) sent to individuals who received implanted LVADs between January 2010 and July 2014 found steady improvement in physical activity and quality of life but a decrease in satisfaction with sexual life following implantation ($p=0.05$). A trend toward limited desire and frequency was observed, but a majority of participants reported the main reason that sexual activity was limited was the concern about satisfying one's partner. Other concerns included possibilities of device failure and cardiac arrest. Interestingly, only one patient discussed their concerns about sexual activity with their primary physician (Merle et al., 2015).

The perception of sexual activity and its impact on quality of life in LVAD recipients ($n=72$) and their partners ($n=48$) were studied using a cross-sectional observational design. The Psychosocial Adjustment to Illness Scale, Short Form Health Survey (SF-36), Hospital Anxiety and Depression Scale, Work Performance Index, and the Sexual Activities in Left Ventricular Device Patients or Partners Scale (specifically developed for this study) found that perceived illness-related changes disturbed the quality of sexuality in both patients (58.3 percent) and partners (52.1 percent). The device itself created sexual activity disturbances due to battery pockets ($p=0.006$) and driveline ($p=0.033$) leading to significantly higher levels of distress in patients and partners. These disturbances were independently associated with higher rates of depression ($p=0.001$) in patients and lower mental quality of life ($p=0.036$) in partners. Compared to their partners, LVAD recipients reported significantly impaired quality of life scores in four of eight domains including physical functioning ($p<0.001$), role physical ($p<0.001$), general health perceptions ($p=0.001$) and physical component ($p=0.034$) despite being

considered medically stable and fully recovered from the implantation surgery (Kugler et al., 2017).

The important findings around adjustment, sleep and sexual function with an LVAD point to the complexity of individual needs when living with MCS therapy. There is a gap in understanding which factors most influence LVAD patients and how those factors can be corrected or modified. Without communicating with LVAD recipients, we could miss important elements affecting life satisfaction or quality. Although these early studies have small sample sizes, they are the beginnings of research that help us understand what makes a difference for LVAD recipients.

Psychosocial characteristics are also connected with increased readmissions following DT-LVAD implantation. Six years of data from medical records of DT-LVAD patients ($n=136$, includes 16 patients who did not survive following implant until discharge) were reviewed finding illegal drug use (HR 1.55, 95% CI 1.01-2.35) and depression (HR 1.77, 95% CI 1.40-2.22) were both associated with higher readmission risk (Snipelisky et al., 2015). Minimizing readmissions is important to reduce costs and improve quality of life. Almost seventy percent of LVAD recipients are readmitted during the first year of having the device (Rossing et al., 2015) with an average length of stay of 5 (Forest et al., 2013) to 9.7 days (Patel et al., 2015) and a median direct cost per readmission of \$7546 (Akhter et al., 2015).

There is also a gap in understanding how length of time with an LVAD affects patient quality of life. As device technology continues to improve, median survival times improve. Two year LVAD survival rates are just over 70 percent with four year survival reported just under 50

percent (Dunlay et al., 2016; Morgan et al., 2016; Tsiouris et al., 2015).

Predictors of health status over 12 months following LVAD implantation were examined using the Kansas City Cardiomyopathy Questionnaire, Patient Health Questionnaire-9, Generalized Anxiety Disorder-7, and Short Form Health Survey (SF-12) to determine that patients ($n=54$) experienced a moderate to large improvement in health status after 3 months ($p<0.001$) following LVAD implantation. These improvements were maintained, as scores were not statistically different between 3-month and 12-month measurements. Over time, higher scores on depression were associated with lower self-perceived health status ($p<0.001$). Interestingly, within-patient variance in health status scores over time was explained by scores on depression and anxiety, not clinical factors (Brouwers et al., 2014).

Casida et al. (2018) measured psychological distress at less than 12 months, 13-24 months and greater than 25 months following LVAD implant for bridge-to-transplant, bridge-to-recovery and destination therapy. The study ($n=100$) used the Patient Reported Outcomes Measurement Information System (PROMIS) Short Form instruments to measure depression and anxiety, and the World Health Organization QOL-BREF questionnaire to measure quality of life. Anxiety ($p=0.033$) and depression ($p=0.001$) were significant predictors of quality of life and were correlated with physical health, psychological, social relationships, environment and global domains ($p<0.0001$). Interestingly, patients with LVADs greater than 13 months had lower scores on the quality of life social relationship measure ($p<0.01$) and global quality of life measure ($p=0.04$) than those with LVADs 12 months or less. Over 30 percent of respondents reported anxiety or depression with psychological distress occurring across all measurement

windows. Perhaps reflecting the increasing availability of smaller LVADs, 30 percent of study participants were female (Casida, et al., 2018) .

As LVAD recipient life expectancy increases, further studies examining quality of life beyond 24 months are needed to assess continued adjustment to the device. Studies using bridge-to-transplant LVAD patients may be subject to selection bias as transplanted patients are removed from the sample reducing validity of comparisons between earlier and later periods. It is likely that the percentage of patients using destination therapy as a device strategy compared to bridge-to-transplant will continue to increase over time. Additionally, examination of quality of life variables within and between different time points are needed to determine if living with the device over longer periods of time affects quality of life.

From the perspective of the recipient, the LVAD extends life but requires significant sacrifice. A qualitative content analysis ($n=90$) showed that pre-implant expectations of LVAD recipients may not fully account for the difficulties of life following implantation. Adjustment to the LVAD only becomes real after implantation, with equipment burden and restrictions on water activities (like showering or swimming) identified as key physical limitations. Psychosocial elements of life with the LVAD included having fear, a need to be cautious, and feeling vulnerable. LVAD implantation both improved and decreased the quality of recipient's lives, and chance (of infection, malfunction or random error) was seen as an ever-present threat to continued recovery (Dwyer & Casida, 2015, 2016).

Measuring Quality of Life

LVAD therapy has expanded from extending life to include the improvement in recipient

quality of life (Emin et al., 2016; Krishnamani et al., 2010). Quality of life (QOL) is an overall appraisal of how satisfied and happy an individual is with life. As a multidimensional concept, quality of life is a personal perception that includes physical, mental and social domains (Maciver & Ross, 2012; Rector, 2005).

A retrospective chart review was conducted to compare quality of life between bridge-to-transplant ($n=17$) and destination therapy ($n=5$) LVAD recipients. Scores from the Minnesota Living with Heart Failure Questionnaire was obtained from 3-month and 6-month post-implant time points, finding both groups improved but DT-LVAD recipient scores improved to a greater degree ($p=0.16$) over the full measurement period (Milley et al., 2016). A larger study collected data of DT-LVAD patients ($n=1470$) retrospectively to determine if age was a determinant in health-related quality of life changes. Patients were divided into age groups of 60 years or less ($n=457$), 60-69 years ($n=520$), and 70 years or more ($n=493$). The study used the EuroQuol (EQ-5D) questionnaire to find that older patients reported better health related quality of life than younger patients ($p<0.0001$), but all age groups showed improvements in overall health related quality of life from before implant to 1 year after implant. The 60 years and under group differed from the other two groups demographically, having the highest proportion of unmarried subjects, more non-white subjects, more women (25 percent of sample), more people with less than a high school education and more reports of substance abuse. Importantly, this younger group is more commonly offered bridge-to-transplant therapy than older groups, so accepting a destination therapy LVAD may have quality of life implications (Grady, et al., 2015a)

As discussed earlier, 87 percent of early generation LVAD recipients answered “yes” when asked if they would still have decided to have an LVAD based on their experience after living with the device for one month (Grady et al., 2002). Interestingly, a variation of this question is still asked of LVAD recipients as a measure of quality of life. Eighty percent of responding patients ($n=17,633$) stated yes when asked “Are you glad to have a VAD?” after 24 months with the device. Although other quality of life data is collected using the Kansas City Cardiomyopathy Questionnaire and EuroQuol instrument (EQ-5D), this question has been presented as a “favorable impression” of the patient LVAD experience (Kirklin et al., 2017).

However, implantation of an LVAD is a treatment, not a cure (Maciver & Ross, 2012). Being “glad to have a VAD” may address more about being physically alive than actual quality of life. LVAD-eligible patients who declined the device had a 1-year survival rate of 25 percent and a 2-year survival rate of 10 percent (Rose et al., 2001). A sizable number of those who accept LVAD therapy do not view DT-LVAD implantation as a choice because they value life above risks or device burdens. Regardless of life’s quality, these “immediate acceptors” of LVAD-therapy would not consider palliative options if other ways to stay alive were possible (Dwyer & Casida, 2015, 2016; McIlvennan et al., 2014; Ottenberg et al., 2014).

A retrospective review of data collected 30 days prior to implantation ($n=1190$) and 3, 6 and 12 months after implantation ($n=1559$) used the EQ-5D-3L, a generic, self-reported health related quality of life survey. Advanced heart failure patients had poor health related quality of life prior to transplant, but recipients were satisfied with overall health related quality of life at 6 months and one year after implant regardless of heart failure severity prior to receiving the

device. However, before and after implant, recipients have worse overall health related quality of life than the general population, showing the effect of advanced heart failure on health-related quality of life even with steady improvements following LVAD implantation. Patients that were too ill to complete the questionnaire were included by entering the lowest possible scores on their behalf. Destination therapy was less than 8 percent of the sample (Grady et al., 2014).

LVAD recipient quality of life has generally been assessed using quantitative tools that include a heart failure specific tool and a generic instrument. Heart failure specific tools, like the Kansas City Cardiomyopathy Questionnaire, effectively capture the patient response to physiological improvements from heart failure. However, if quality of life is affected by more global factors (post-implant complications or a lack of partner support, as examples), heart failure tools may report an increase in heart-failure specific symptom relief but miss the general decline in overall quality of life (Nassif et al., 2017). Generic tools, like the EuroQol and SF-36, lack sensitivity to detect changes in LVAD-specific areas but can provide a gross comparison across populations (Sandau et al., 2014). Studies of patients using generic and heart-failure specific quality of life instruments lack sensitivity and precision as they do not address unique elements of LVAD life including changing power sources, driveline exit site dressing changes, water immersion restrictions, driving or traveling precautions, trouble-shooting device alarms and equipment and supply maintenance (Grady, et al., 2015b; Sandau et al., 2014).

Although LVADs have been used for more than 20 years (Petty & Bauman, 2015), LVAD-specific quality of life studies are often reported without use of consistent terminology and lack

a conceptual definition of quality of life. Thus, measurements of quality of life may have poor validity and a lack of comprehensive understanding of the major dimensions being evaluated, especially if readers are required to ascertain the conceptual definition from the tools being used (Grady et al., 2015b; Sandau et al., 2014). Additionally, understanding the factors affecting quality of life in LVAD recipients may also help address patient-generated concerns that lead to effective patient care (Maciver & Ross, 2012).

In prior studies, qualitative methodology has been used with heart transplant patients to identify themes that were not observed following quantitative testing (Abbey et al., 2011). Additionally, qualitative methodology can provide a baseline validity for the development of disease-specific quantitative measures (Sandau et al., 2014).

Sandau et al. (2014) used grounded theory methodology to develop the first known conceptual definition of quality of life with an LVAD. Adult, outpatient, continuous flow LVAD recipients ($n=11$) participated in two separate individual or paired interviews. The participant sample included bridge-to-transplant ($n=6$), destination therapy ($n=4$) and bridge-to-recovery ($n=1$) patients. Participants averaged 19-weeks post-implant at the time of the first interview, and 25-weeks post-implant at time of the second interview (Sandau et al., 2014).

Recipients initially described quality of life as being independent or “normal” in most routine life activities. Goals that influence quality of life are congruent with one’s developmental stage. Initial vs. long-term physical responses included postoperative complications, healing and pain, and an adjustment to a “new rhythm for daily activities.” Five domains were important to LVAD recipients, but the physical domain was essential due to the

interface between the human recipient and the implanted machine keeping them alive (Sandau et al., 2014).

The Sandau et al. (2014) conceptual definition of quality of life with an LVAD emerged as “Being well enough to do and enjoy the day-to-day activities that are important to me.” With this definition, the gap of defining quality of life from the perspective of the LVAD recipient has narrowed. Sandau et al. (2014) used established quality of life domains to guide the study but also allowed participants to identify unique areas needing further exploration. The study identifies aspects of life with an LVAD that are not generally identified by generic or heart failure specific instruments, and again demonstrates the need for an LVAD-specific tool to capture the unique experience of living with a mechanical circulatory support device. Additionally, study participants were outpatients who might better reflect the daily quality of life when stressors from hospitalization are not present. This is especially important since the average LVAD recipient spent more than 92 percent of their time out of the hospital (Akhter et al., 2015). Further, this study focused on a conceptual definition of quality of life seeking to clarify terminology and explain the experience from the perspective of those living it. This is an essential element before operational definitions are developed to measure the concept.

As would be expected in grounded theory research, a purposeful, theoretical sampling of LVAD recipients from one implantation center was described. The study’s sample of 27 percent female and 91 percent white was fairly representative of the registry tracking all LVAD implants in the United States (Sandau et al., 2014). However, it was unclear why the study selected participants based on three distinct device strategies (bridge to transplant, destination therapy,

bridge to recovery) as each has a different long-term goal and could lead to difference in patient outlook. The authors explain that each group had consistency in responses, but the examination of each group did not end in data saturation, only data saturation of the mixed sample as a whole. There was also a wide variance of time that each subject had the LVAD. This was appropriate for the Sandau et al. (2014) study as it was focused broadly on quality of life for LVAD patients; however, as LVAD device advancement and quality of life research continues, it will be important to examine gaps in the literature regarding change in LVAD recipient perspective over time.

To further explore the adjustment to living with mechanical circulatory support (MCS) and health related quality of life, Grady et al. (2015b) also used a grounded theory approach to create a conceptual model of adjustment to MCS, leading to a set of 239 items having evidence of content validity to assess adjustment to MCS and health related quality of life. Expert clinicians ($n=15$) included cardiac surgeons, cardiologists, MCS coordinators, social workers and psychologists were interviewed. In addition, interviews were conducted with advanced heart failure patients ($n=16$) scheduled for MCS implantation and current MCS patients ($n=48$) including bridge-to-transplant (48%) and destination therapy (52%). One-half of the sample's current MCS recipients were less than six months post-implant (Grady, et al., 2015b).

Recipients were generally positive and grateful after implant, although they were bothered by MCS-specific limitations and self-care. Some heart failure symptoms abated soon after implant while others remained. Caregivers were pivotal suppliers of information and emotional support. Overall, MCS patients noted an improvement in physical function, although

depression and anxiety were reported in the early phases following implantation. Over time, most recipients had adjusted to MCS therapy and reported less anxiety and depression (Grady, et al., 2015b).

Importantly, the device strategy affected satisfaction with MCS therapy and health related quality of life. Bridge to transplant patients had uncertainty about the waiting period and were eager to “get on with life.” Destination therapy patients were uncertain about life expectancy and concerned about the experience of dying while on a VAD (Grady, et al., 2015b).

The purpose of LVAD implantation is crucial to understanding the recipient experience. Each device strategy has different outcome expectations. There continues to be a critical gap in knowledge regarding patient expectations based on the specific device strategy they have received. As destination therapy is the most common device strategy and continues to become more popular, this study is focused on examining quality of life exclusively from the destination therapy LVAD recipient’s perspective.

The Grady et al. (2015b) conceptual model indicates that the effect of disease and treatment encompasses satisfaction with MCS, potential signs and symptoms, and self-efficacy in self-care. Caregiver support and the reason for implant (or implant strategy) is causally related to effect of disease and treatment, leading to overall health related quality of life in physical, mental and social domains.

The advancement toward development of an MCS-specific measurement instrument is an exciting step forward. The Grady et al. (2015b) study employed a grounded theory approach to involve patients in the development of items to assess adjustment and quality of life following

LVAD implantation. The model incorporated an NIH-supported initiative to standardize patient outcomes and expert clinicians were interviewed to develop interview guides later used by the study team with patients. It is interesting that these developmental clinicians were divided into physician and non-physician groups, as sharing of perspective may have broadened the comprehensiveness of the guides. As interviews with patients progressed, the guides were modified by adding new questions until theoretical saturation was received.

As mentioned previously, there is a gap in studying the female LVAD recipient experience. The Grady et al. (2015b) study sample contained 17 percent female participants. However, it was also one of the most diverse studies in this review with the sample containing non-Caucasian participation of 45 percent. Interestingly, the sample characteristics cited “married” as a demographic (50 percent of sample) but did not list “partner” or other term that may have indicated a permanent support relationship.

The Grady et al. (2015) study was centered on adjustment to the MCS experience and the sample reflected this focus as half of participants were less than 6 months post-implant. The study also presented a model on quality of life with a mechanical circulatory support device. As stated earlier, the gap in the literature demands investigation of individual sub-sets of this area (i.e. destination therapy LVAD). Expanding the study by including all MCS devices and not specifically focusing on DT-LVADs could introduce further terminology confusion in this area.

Destination Therapy

As health technology continues to advance, we are able to postpone death through efficacy of new clinical tools for specific populations and conditions. The technical ability to

reduce mortality can take priority over quality of life. These “ironic technologies” address the purpose of extending life but, in the process, actively create a new set of challenges. An ethnographic case study of patients with advanced health care technology (Kaufman et al., 2011) shows that goals change over time and may differ significantly from those desired at time of implementation. The patient’s dependence on technology produces the sense of losing control as one is immersed in the health care system, the feeling that technology has saved life but changed life, the need to accept the technology and adapt to the fear of death, and the ability to find value in a “second chance” at life (Kaufman et al., 2011).

Destination therapy LVAD implantation changes the definition about who is “terminal” and who can still be “saved” through sophisticated technology. Using a grounded theory study, Barg et al. (2017) investigated how unforeseen dilemmas challenge how DT-LVAD recipients integrate the device into their daily lives. Open-ended, structured interviews were conducted with patients ($n=39$) and caregivers ($n=42$). Fifty-nine percent of patients were less than 2 years post-implant (Barg et al., 2017).

Patients and caregivers described a moral obligation to accept the DT-LVAD, as the machine created the opportunity to continue “the miracle of life” though a “second chance.” However, recipients entered a liminal space following the implant where they viewed themselves as both sick and well. While some “normal” activities were again possible, they were also dependent on a machine for existence. The LVAD, viewed as a heroic and life-saving device pre-implantation, was changed into a disability caused by a needy machine after discharge from the hospital (Barg et al., 2017).

DT-LVAD patients more than 2 years following implant were more likely to feel uncertainty about the future. Recipients disclosed a notable shift when they and their families realized the machine will eventually reach the “destination, life-end,” and that the machine would be part of their bodies for the rest of their lives. The permanence of the DT-LVAD as the terminal biomedical solution reinforces this existence between well and ill. The DT-LVAD experience may not have been as good as expected, but it was often “better than the alternative” (Barg et al., 2017).

There is a critical gap in understanding how recipients of a destination therapy LVAD conceptually define quality of life. This conceptual definition, from the perspective of the DT-LVAD recipient, will help to standardize terminology and assist measurement of quality of life in this specific group.

Chapter Summary

This chapter addressed the pertinent literature related to the quality of life when living with an implanted destination therapy LVAD. Clearly, there have been significant advances in LVAD technology and overall survival of patients with continuous flow LVADs is now close to heart transplant survival rates at 24 months (Kirklin et al., 2015). Cost of initial hospitalization for implant has declined 50 percent over the past decade due to lower post-operative costs and reduced length of stay. As DT-LVAD outcomes improve, an expanded pool of healthier patients are choosing destination therapy which further reduces length of stay, improves overall outcomes and reduces implantation costs (Miller et al., 2013). The total first-year cost of LVAD implantation and care was \$369,519, not significantly different from heart transplantation. A

continual shortage of donor hearts and potential for further cost savings from reduced length of stay and device technology advancements indicates that the need for LVAD implantations will continue to expand (Patel et al., 2015).

To understand this growing population, several instruments are commonly used in heart failure and LVAD research. Over 30 different tools were used in research presented in this review alone, but there remains a gap because no tool precisely measures quality of life when living with a mechanical circulatory support device in general, or examines impact of device strategy (like destination therapy) in specific. While current strategies of using generic and heart failure specific tools in combination to measure quality of life and impact of disease has been effective, smaller changes that affect the patient experience may be missed without a disease and device strategy specific tool.

The lack of conceptual clarity around the definition of “quality of life” when living with an implanted LVAD may hinder efforts to explain the phenomenon, which may impede development of effective interventions to optimize quality of life. Additionally, by fully understanding quality of life from the perspective of the LVAD recipient, decision-making prior to device implantation can be optimized, leading to higher quality of life and satisfaction post-implantation. Initial efforts to define “quality of life” have focused on the LVAD or MCS population as a whole, but destination therapy is significantly different from other LVAD interventions. The permanent nature of DT-LVAD implantation has a longer time horizon with no hope of explant from recovery or transplantation. Recipients recognize they will eventually reach the “destination, life-end” and that the machine will be with them for the rest of their

lives (Barg et al., 2017). Accordingly, it is reasonable to suggest that this distinction also changes the overt or subtle dynamics of psychosocial adaptation to this implanted machine, and there is a gap in understanding the human response to the differences in device strategy. There are two known tools in development to understand LVAD quality of life and MCS adjustment (Sandau et al., 2014; Grady et al., 2015b) but neither focus on specific device strategy. While these tools will advance the science, further development of tools for each unique reason for implantation (destination therapy, bridge to transplant) is required.

Despite improvements in technology, significant adjustments are still required to accept a new LVAD. The first months of implantation are particularly difficult physically and emotionally, and LVAD recipients experience higher rates of psychosocial distress including depression and anxiety. However, health related quality of life appears to increase over time. Notably, there are few quality of life measurements beyond 24 months post-implantation. As the time horizon for life with DT-LVAD therapy continues to expand, this gap in understanding how quality of life is affected over longer time periods requires further study.

Subjects represented in LVAD research have been predominantly white males. Early devices were bulkier than current models requiring a larger body cavity to fit the device. However, as the device becomes smaller, more women with advanced heart failure are eligible and electing LVAD support. Additionally, studies ($n=79$, $n=88$) comparing African American and white survival rates following LVAD implantation found no significant differences in mortality (Aggarwal et al., 2012; Tsiouris et al., 2015). Going forward, inclusion of a more diverse sample is clearly necessary.

It has been reported that LVAD recipients experience quality of life improvements in the first three months following LVAD implant, and are overwhelmingly satisfied with their decision to accept LVAD therapy over the first two years post-implant (Kirklin et al., 2017). However, LVAD recipients may not view implantation as a choice, because they may value being alive over device burden or risks. Advanced heart failure patients who are eligible for mechanical circulatory support but decline the therapy have a 2-year survival rate of 10 percent (Rose et al., 2001). LVAD recipients may change their definitions of “sick” or “well” as the device becomes familiar and they are more able to complete physical tasks, and this may also increase expectations leading to quality of life changes. When asked, LVAD recipients are willing to identify positive and negative elements of living with an implanted device (Dwyer & Casida, 2016). A more robust definition of quality of life when living with an LVAD is needed to clarify the difference of being alive and quality of life.

Considering the unique nature of the DT-LVAD, it is crucial to study this subset of MCS therapy as a separate entity. This study will help promote common terminology about quality of life in DT-LVAD recipients from their perspective. This advancement in knowledge may help development of tools for operational measurement of this concept and improve informed decision-making before implantation, enhancing efforts to maximize quality of life post-implantation. As the median survival for DT-LVAD recipients continues to climb, more patients with advanced heart failure will have the opportunity to select DT-LVAD therapy as a life-saving option. Understanding the DT-LVAD experience, starting with a conceptual definition of quality of life when living with an LVAD, is the first step in this process.

Chapter Three

Methods

This chapter describes the methods used to create a conceptual definition of quality of life when living with a destination therapy left ventricular assist device. The philosophical underpinnings of the grounded theory research method will be discussed and a detailed description of this study's sample and setting, measures, protection of human subjects, data collection, data analysis and criteria for establishing rigor and trustworthiness will be provided.

Prior studies of LVAD recipients have been conducted quantitatively and qualitatively, although only two studies to date have conceptualized a definition of quality of life from the perspective of LVAD recipients (Grady et al., 2015b; Sandau et al., 2014). This study advanced those research efforts by focusing on the destination therapy LVAD recipient, a select population of LVAD recipients who may have unique differences that influence quality of life outcomes.

A grounded theory methodological design was used. Grounded theory is designed to generate a theory from the data, follows a rigorous and systemic method of discovery, and emphasizes openness to data that allows emergence of pattern (Glaser, 2014). Grounded theory was an ideal methodology for the expansion and exploration of emerging themes related to this specific population.

Grounded theory, as created and originally published by Glaser and Strauss (1967) and later refined by Glaser (1978), is a research methodology that is designed to uncover the core

categories that lead toward a basic social process that explains a pattern of social behavior over time. The basic social process is developed through analysis of core categories that arise from the coding of data. Throughout the systematic process, constant comparison is used to ensure understanding of what is happening in the data and relevance is established through emergence of the core categories or central, frequently recurring problems (Glaser, 1978; Simmons, 2011). To reflect the specific scope of nursing research, physiological and psychological elements must also be included as part of an expanded basic social process that explains the patterns of human-environment health and wellness studied by nursing (Reed & Runquist, 2007).

Grounded theory is designed to go beyond preconception and empirically explain substantive concepts that are generated from the data. It identifies the main concern of the research participants and prevents preconceived assumptions from masking the core variable. In grounded theory, patterns emerge from the data as opposed to deducing, testing or verifying a hypothesis. This keeps the focus on the participants and ensures the researcher will conceptualize data and discover latent patterns and relationships between data that can be verified (Glaser, 1998).

Grounded theory has been used successfully in prior LVAD research, including both studies presenting a conceptual definition of quality of life from the experience of all types of LVAD recipients (Grady, et al., 2015b; Sandau et al., 2014). Other studies have compared quality of life and psychological adjustment of LVAD recipients to heart transplant recipients (Hallas et al., 2009), investigated how cultural meanings inform acceptance of the LVAD as

destination therapy (Barg et al., 2017), and explored how relatives of LVAD recipients used coping strategies during the bridge to transplant experience (Egerod & Overgaard, 2012).

Living with a destination therapy LVAD stretches the boundaries of understanding and challenges the accepted definitions of life itself. This grounded theory study generated categories that emerged from data and are grounded in the experience of the phenomena, instead of seeking to verify an existing theory. Thus, the true concerns of destination therapy LVAD recipients are explained using data that was derived directly from their experiences.

Philosophical Underpinnings

Symbolic interactionism, the most often associated theoretical perspective underpinning the grounded theory method, believes that individual actions are a specific response to the view held of the current situation (Charmaz, 2014). Interactions are a symbolic process where subjective meanings are obtained from shared spoken and unspoken language that occurs within the historical, social and cultural perspective of the individual. Interpretation of these symbols depend on this interaction and are constantly changing, shaped by the past, present and even the imagined future. Meanings are developed from what the individual does with the symbol and how that symbol impacts their life (Blumer, 1969).

Human responses are formed based on individual interactions with others and can be modified or ignored as the situation evolves. Interpretations are based on individual socialization within environment or culture, and people respond to life with reflexive interactions that are purposive and unique (Wuest, 2007). Thus, human actions and responses are based on meaningful symbols that are uniquely defined for each person. Symbols may

include words, actions or concepts that represent an object or feeling and cause an individual response (Charmaz, 2014).

For destination therapy LVAD recipients, life with implanted technology presented a need to potentially redefine common terms that may have unique interpretations. When a machine replaces a beating heart, the terms life, health, and quality may have vastly different meanings for those living with this technology (Dwyer & Casida, 2016). Grounded theory, using the philosophical perspective of symbolic interactionism, is concerned with the systematic generation of theory through an intertwined method focused on the subjects themselves and their experiences. The discovery of conceptual categories from the original data was a necessary step toward understanding complex phenomena such as quality of life (Glaser & Strauss, 1967).

Sample and Setting

The participants for this study were found using a purposeful theoretical sampling of destination therapy LVAD recipients who were either affiliated with one or more online support group that catered to LVAD recipients or were seen by a provider of a participating LVAD/Heart Failure clinic. Participants met inclusion criteria if they were community dwelling adults (over age 18) with an implanted, continuous flow, destination therapy LVAD and resided within the United States. Participants were excluded if they had been implanted less than 90 days, could not communicate their thoughts independently in English, were hospitalized in an acute care setting, or were living in a temporary sub-acute or rehabilitation setting.

Participants were interviewed by telephone and interviews were scheduled at a time acceptable to the participant. Although online videoconference was also offered as an interview option (Scott, 2011), it was not selected by any participants.

Recruitment occurred through introduction of the study to LVAD-specific online support group forums and a participating LVAD/Heart Failure clinic by supplying a flyer (Appendix E) that identified the study opportunity, supplied a brief summary of the study and provided options to contact the researcher if they were interested in participating or wanted to learn more about the study. Potential participants who contacted the researcher received more detail and had an opportunity to ask questions before an interview was scheduled. The participants were informed that approximately 60 to 90 minutes would be required for the interview. All participants who completed the interview received a \$20 gift card.

Measures

Demographic information (Appendix A) collected included age in years, gender, race, ethnicity, education level, caregiver type, employment status, marital/partner status, household member count, date of DT-LVAD implant, duration of hospitalization for initial implant, device type/manufacture, and original device strategy. In addition, data was collected regarding readmissions and complications experienced by the participant following LVAD implantation. A semi-structured interview guide that aligns with techniques appropriate for a grounded theory study as described by Glaser and Strauss (1967) and Glaser (1978) was used. The original guide was revised as the study progressed (Appendix B).

Protection of Human Subjects

Approval to conduct the study was obtained from the University of Wisconsin Milwaukee Institutional Review Board (Appendix C). The study was approved as a minimal risk study with few risks or direct benefits to the participants. An informed consent waiver for research participation was also approved (Appendix D). Prior to beginning each interview, the researcher reviewed the study with participants and answered any questions. The informed consent document was provided in advance of the interview and read to the participant before verbal consent was obtained. The participant was informed that a recording device was used to digitally record the interview. Participants were also informed that telephone calls could be vulnerable to unauthorized discovery.

Procedures to ensure confidentiality of participants during analysis, transcription and dissemination of results were implemented. Participants were assigned a numeric ID number to de-identify transcripts. A single file linking the participant name with the ID number was maintained. This file was destroyed following the completion of data analysis. As soon as possible following the participant's interview, the digital audio file and all other electronic data were backed up and transferred to the university's password protected and encrypted storage system (OneDrive). Non-electronic data was secured in a locked cabinet within the researcher's office.

Data Collection

Although grounded theory studies are eligible to use all data obtained from any relevant and available source, most grounded theory studies rely on qualitative data and interviews as

primary sources of data collection. Observation, document examination and interviews occurred simultaneously. In the early phases of the research, interview questions were broad and open-ended to encourage the participant to direct the conversation towards those experiences that are most salient to the participant's perspective of quality of life (Holton & Walsh, 2017). The semi-structured interview guide (Appendix B) was revised as the study progressed.

Field notes. Field notes were used during and after the interview to capture relevant content (called incidents) that could lead toward the uncovering of a concept. Field notes are brief, momentary reminders of the incidents that occur during an interview or interaction. Field notes included verbal or non-verbal observations of the participant along with initial thoughts of the researcher including key phrases, interpreted meanings, interview setting and interactions between the participant and researcher. Following the interview or interaction, field notes were used to help elaborate ideas by creating memos (Glaser, 1992; Glaser, 1978, 1998; Holton & Walsh, 2017).

Theoretical sampling. The purpose of grounded theory data collection is to elicit codes from raw data that help direct future collection efforts. Thus, data collection was guided by the emerging data analysis and, eventually, the emerging theory. The complete system that constructs tentative ideas about the data is called theoretical sampling (Glaser, 1998) which is defined as "the process of data collection for generating theory whereby the analyst jointly collects, codes and analyses his data and decides what to collect next and where to find them, in order to develop his theory as it emerges" (Glaser & Strauss, 1967, p. 45).

Theoretical sampling was designed to allow the researcher to select participants who would inform the study and provide diversity of experiences. Sampling decisions were made by using predetermined criteria, called purposive sampling. Participants were selected who enhanced the understanding of the phenomenon through their diversity and experiences. The process began by selecting participants that had a shared knowledge or experience and met all inclusion criteria. As the study progressed, gaps were identified, and new participants were selected that provided additional understanding of the phenomenon through their perspective. The researcher provided rationale for participant selections, and sampling continued in this manner for the remainder of the study (Glaser, 1978).

Data Analysis

Every interview was transcribed then reviewed by listening to each recording while comparing with the transcription. Transcripts were read multiple times with key phrases noted and coded. The grounded theory methodology is comprised of several methods that generate a substantive theory that is “grounded” in the data. The individual methods that enable the generation of the theory will be defined and followed by a brief discussion of how the method was operationalized in this study.

The Constant Comparison Method. The constant comparison method is the foundation of data analysis in grounded theory. In this method, the collection of data and analysis occurred simultaneously. The method required explicit coding and analytic procedures to convert data into a quantifiable form (codes) that allowed comparisons between codes, categories, incidents, participants, experiences and all other data elements. These comparisons

determined the direction of the data collection and were continued throughout the study. The constant comparison method allowed disciplined creativity to suggest plausible hypotheses about general questions that led toward the generation of a theory (Glaser, 1978; Glaser & Strauss, 1967; Holton & Walsh, 2017).

Open coding. Open coding is used to break data into separate pieces of information that can help increase understanding. Open coding was completed line-by-line and by phrase cluster, and one-word or two-word labels or “codes” were created that represented specific words, phrases, or meaningful statements. During open coding, each element was coded into as many categories as possible, and new codes were continuously compared with older codes to help begin the understanding of the concept (Glaser, 1978; Glaser & Strauss, 1967). Close reading of the data ensured that important concepts were not missed and that concepts earned relevance instead of being included because of an assumed importance (Charmaz, 2014). Through this constant comparison of data, conceptual indicators allowed patterns to emerge across the data (Glaser, 1978, 1998; Holton & Walsh, 2017).

Selective coding. Following the effort to fracture data and identify codes in open coding, selective coding made connections between codes and formed categories. The constant comparative process was used to examine the codes and identify how categories related to each other. Patterns were reviewed and examined to avoid the inclusion of single incident codes. The conceptual strength of each code was assessed by comparing with other codes and determining which ones had greater analytical power. Comparisons were made across wider

spans of open coded data and tentative categories were refined by grouping related data together into categories (Charmaz, 2014).

As codes were placed into groups, the number of open coding categories was naturally reduced. This category reduction led toward a natural limitation of the study. Codes which were not selected as central to this analysis remained valid and can still be used in other efforts (Glaser, 1978; Glaser & Strauss, 1967; Holton & Walsh, 2017).

Theoretical coding. Theoretical coding is the final coding step that led toward theory formation by identifying the core (or central) category. By reviewing the coded data again, the researcher was able to see an overall pattern that verified the relationships among concepts and explained the integration of the individual codes. Through the examination of the relationships, the researcher also identified gaps within the data. A deliberate, focused sampling was done to complete saturation of the categories and enabled the building of a theory based on the relationships of the data. The theoretical coding process, like open and selective coding, was an iterative process that emerged from the data. However, theoretical coding also provided the process that helped to consider unique frameworks and alternative meanings of the phenomenon when it returned the data to a meaningful whole (Charmaz, 2014; Glaser, 1978; Holton & Walsh, 2017).

Memoing. The completion of the theoretical development of ideas and their relationship to existing codes in a sortable format was accomplished through memos. Memos are the thoughts of the researcher as the data was collected and analyzed (Glaser, 1978, 1998). By writing memos on developed codes, the descriptive data was reviewed while coding boundaries

were defined that included the conditions of emergence and significance to the theoretical theme. The freedom of memo writing allowed recording of ideas that were modified as concepts emerged and allowed the researcher to take risks by suggesting new directions of exploration without expending crucial resources. In addition to service as an analytical tool, memos also created a “bank” of ideas for the current study or for future studies within the same area. Thus, each memo was labeled with a date, time and title so that they could be sorted and remain easily searchable. Memo subjects were reduced and combined as the theory developed and concepts that once seemed appropriately specific became too global for consideration (Glaser, 1978, 1998; Glaser & Strauss, 1967; Thomas, 2011).

During data collection, conflicts and confusion historically develop around the central theme of the research and direction of the study. Memos provided an outlet to record theoretical ideas and reflections that allowed logical conclusions. Memos detailed the conceptual connection between categories and were part of the continual process of the constant comparison system. Memos stimulated and captured conceptual ideas that emerged; as such, they were freely written simultaneously as coding was done without regard for grammar or syntax (Glaser, 1978, 1992; Glaser & Strauss, 1967).

Theoretical saturation. Data collection ended when analysis from the constant comparison method indicated theoretical categories were robust and saturated with data. Relationships between categories were defined, checked and explained. Additionally, new data collection did not reveal any new core theoretical categories or generate new theoretical insights (Charmaz, 2014). However, saturation was more than simply seeing the same stories appear; saturation

was the conceptualization of incidents that yielded different properties of the pattern. This abstraction preserved the connection to the data and determined sample size. The grounded theory method resulted in a small sample size, which is appropriate for the research objective (Charmaz, 2014; Glaser, 1978; 1992). Out of an abundance of caution against ending data collection prematurely, this study collected data from two participants beyond the point at which the researcher believed theoretical saturation was achieved.

Writing the theory. The iterative nature of grounded theory and the constant comparative method began with the first data collected and continued until theoretical codes were developed and the emerging theory was written. In fact, the writing of results was part of the discovery process. Researchers are often overwhelmed and in a state of ideational overload. The preparation to write helped finalize the sorting of data and the development of the theory (Holton & Walsh, 2017). As each draft was completed, further insights were gained and the output was advanced. “Each successive draft grows more theoretical and comprehensive” (Charmaz, 2014, p. 289). Like the rest of grounded theory, the writing process was interconnected and almost impossible to separate from the other stages.

Establishing Rigor/Trustworthiness

Research findings are more accepted when the integrity, competence and legitimacy of the process is validated. Qualitative research has often relied on the seminal work of Lincoln and Guba (1985) to examine rigor or trustworthiness of the study. The four criteria for use recommended by Lincoln & Guba include credibility, transferability, dependability, and confirmability. As another tool to enhance trustworthiness, reflexivity will also be addressed.

Credibility. Credibility describes the level of confidence present in the data and study. Several measures were used to increase credibility and enhance the believability of the study's findings. First, the grounded theory method required hands-on researcher involvement in data collection and analysis. The "prolonged engagement" with the study enhanced the credibility of the researcher, who was in contact with the participants and directly performed the work needed to obtain results. Prolonged engagement enabled the researcher to obtain sufficient "persistent observation" that ensured the depth needed to advance knowledge using grounded theory's theoretical sampling and constant comparison method of analysis (Lincoln & Guba, 1985).

To facilitate credibility, study participants had direct access to the researcher as opposed to a data collector. Participants were also offered the opportunity to discuss any topic that they felt was relevant to the phenomenon or was not covered by the interview questions. "Member checking" asked the participant to provide reactions to the researcher's interpretation as the interview continued, ensuring ambiguous items were clarified and subjects felt comfortable with the researcher's understanding of their experience. Member checking also included adding questions during the interview to clarify statements (Lincoln & Guba, 1985).

A study gains credibility when vivid, faithful descriptions can be recognized by people that have already experienced that phenomenon. As part of member checking, two of the study participants were asked to review the emerging theory to determine if it captured the DT-LVAD recipient experience. Participants were selected from mid and late stages of the study to

ensure variety of opinion (Lincoln & Guba, 1985) and direct quotes from participants were used to prevent distortion and misrepresentation (Beck, 1993).

“Peer debriefing” helped to examine the questions of the semi-structured interview in addition to analysis techniques that were used (Lincoln & Guba, 1985). This study was fortunate to have the researcher’s major professor and dissertation committee available for debriefing before the study began and during the study’s course. Updates on progress along with examples of coded data were discussed every two weeks during the collection and analysis period.

Finally, the credibility of the researcher also helps increase credibility for this study (Lincoln & Guba, 1985). The researcher has extensive experience in cardiothoracic surgery and heart/lung transplant, heart failure, and ventricular assist devices, and maintains professional connections with researchers, surgeons, LVAD coordinators, clinical nurse specialists, nurse administrators and nurse clinicians who have additional expertise in this area.

Transferability. The burden of accepting a study’s transferability in qualitative research is largely left to the reader. Thus, thick description was provided to ensure the reader has enough information to make a transferability decision (Lincoln & Guba, 1985). In this study, faithful following of the grounded theory method ensured that theory was generated from the data and was able to be traced back to the data. Direct quotations and vivid writing that captured the essence of the participant’s meaning in relation to the theory were used to help the reader understand the findings (Glaser & Strauss, 1967).

Dependability. The stability of data over time and across conditions is called dependability. Techniques of “overlap methods” and “stepwise replication” were not applicable to this study, but study data including investigation elements and record keeping were examined by an independent auditor to ensure dependability (Lincoln & Guba, 1985). Accurate records of collected data, memos, and decision-making strategies throughout the study were required to ensure dependability and were also required for audit purposes as part of confirmability. The researcher communicated activities and procedures with the major professor throughout the study to ensure decision processes were clear and logical (Lincoln & Guba, 1985). Additionally, as part of grounded theory, highly descriptive field notes and memos were used as a source of data for conceptual development (Glaser, 1978, 1992, 1998). The availability of the recorded transcript of the interview was used to enhance trustworthiness through the inquiry audit, leading to increased dependability (Holton & Walsh, 2017).

Confirmability. To ensure the research was objective, an audit trail that detailed data collection and analysis procedures was used to review the study (Lincoln & Guba, 1985). In this study, these materials included field notes, memos, transcriptions, decision-making records and written results. An independent auditor examined the audit trail and verified accuracy based on collected records (Cooney, 2011). The auditor had familiarity and comfort with qualitative research and was asked to randomly select concepts in the theory and trace them from the original data. Additionally, several randomly selected open codes were chosen and traced from the original interviews to see how decisions were made that resulted in the concepts that emerged in the theory. Through this interpretative rigor, trustworthiness was enhanced through examination of the analytical process and methodological rigor (Cooney, 2011). The

auditor was given full access to all data and analysis of the study, and questions were answered by the researcher as needed. The auditor submitted a summary statement of audit findings (Appendix F).

Reflexivity. In any study, the researcher must be aware of their influence on the participants and results. In grounded theory as discussed by Glaser (1998, 2014), the researcher acts as an objective participant-observer that presents the emerging data. In other forms of research (including other forms of grounded theory), the data may be influenced or adjusted by the researcher's own experiences (Hall & Callery, 2001). In this study, the researcher remained objective and allowed the data to speak for itself. Thus, a journal of events and perspectives was maintained as an additional tool that raised awareness of role and prevented personal bias from undue influence on the results of the study. In addition, the audit of memos and review of audio transcription helped to ensure awareness of possible bias while it also improved the interview questions and analysis techniques.

Chapter Summary

The purpose of this research study was to develop a conceptual definition of quality of life from the perspective of the permanently implanted, destination therapy LVAD recipient. This chapter discussed the methods of using grounded theory for this goal. Grounded theory is designed to generate a conceptual theory from participant data and is an appropriate research method for this study. Through the grounded theory method of research, a systematic process was used to allow emerging themes from destination therapy LVAD recipients that created a conceptual definition specific to this population. A target population of destination therapy

LVAD recipients were selected based on inclusion and exclusion criteria, and sample size was determined based on theoretical sampling and theoretical saturation derived through the constant comparison method of data analysis. Rigor and trustworthiness were enhanced by following a classical approach of grounded theory as described by Glaser and Strauss (1967) and later refined by Glaser (1978). Additionally, the study was guided by the seminal work of Lincoln and Guba (1985) and included reflexivity tools to help ensure researcher objectivity was maintained throughout the study.

Chapter Four

Results

This chapter presents the results obtained from interviews of 11 men and women with implanted destination therapy left-ventricular assist devices (DT-LVAD). The purpose of this study was to determine the conceptual definition of “quality of life” in people living with a DT-LVAD. The specific aim of this study was to generate a grounded theory of living with a DT-LVAD. Sub-aims of the study were:

Sub-Aim One: Determine how patients conceptualize life when living with a DT-LVAD.

Sub-Aim Two: Determine how patients conceptualize quality of life when living with a DT-LVAD.

The first section of this chapter will summarize the characteristics of the study group and provide an individual synopsis of each participant. The second section will describe the grounded theory of living with a DT-LVAD. The last section will consider how grounded theory addresses the aims of this study and explore the conceptual definition.

Sample Characteristics

A total of 11 participants (8 men and 3 women) were recruited for the study. The participants' range in age was 32 to 79 years ($M=64.7$ years, $SD 17.05$). Three participants were below 50 years of age while 7 participants were age 70 or above. Nine participants self-identified their race as white, while two participants self-identified as African American. Eight participants were married, two were divorced, and one was single. Highest educational

attainment was split between high school graduate (n=3), some college (n=4), bachelor's degree (n=3) and PhD (n=1). Six participants reported their employment status as retired, three reported as disabled, one reported as partially retired, and one reported having two jobs and working more than full time.

Table 1: Participant Demographics		
Demographic n=11	Number n (%)	Mean (SD), Range
Age		64.7 (17.05), 32-79
Sex (Female)	3 (27%)	
Self-Identified Race		
African American	2 (18%)	
White	9 (82%)	
Highest Educational Attainment		
HS Diploma	3 (27%)	
Some College	4 (37%)	
College Degree	3 (27%)	
Terminal Degree	1 (9%)	
Marital Status		
Single	1 (9%)	
Married	8 (73%)	
Divorced	1 (9%)	
Widowed	1 (9%)	
Geographical Region		
East	1 (9%)	
Midwest	7 (64%)	
South	2 (18%)	
West	1 (9%)	
Household Members (including participant)		2.36 (1.63), 1-6

Participants had lived with a DT-LVAD from 7 months to 96 months (M=48.45 months, SD=31.38) at time of interview. Five participants had a DT-LVAD for more than 60 months while three had their device for less than 24 months. Three participants had been explanted and re-implanted for various reasons; two had emergent issues with their DT-LVADs and were immediately re-implanted (blood clot, drive line electrical short) and one participant had recovered from heart failure sufficiently to be explanted from his bridge to recovery LVAD for 76 months until requiring implant of a new destination therapy LVAD.

Table 2: LVAD Demographics

Demographic n=11	Number n (%)
Device Type	
Heartmate 2™	7 (64%)
Heartmate 3™	4 (36%)
Original Device Strategy	
Destination Therapy	9 (82%)
Bridge to Transplant	1 (9%)
Bridge to Recovery	1 (9%)
Length of Time with an LVAD	
<24 months	3 (27%)
24-60 months	3 (27%)
>60 months	5 (46%)
First LVAD was Explanted and Re-Implanted with second device	3 (27%)

Summary of Participant Interviews

Before the interview began, participants were provided additional information about informed consent, the interview process, and were offered time to ask questions. After the

interview ended, participants were again asked if they had any questions or concerns and demographic data was collected. Each interview, not including the pre and post information/question periods, lasted between 31 and 61 minutes ($M=44.18$, $SD=8.02$).

This section will provide a synopsis of each participant's interview. Each participant interview was assigned a number for confidentiality.

Participant One. Participant One is a married, white male in his late 70s who received his DT-LVAD 81 months before the date of the interview. He lives with his wife in the Eastern United States and reports he is retired. He has had one LVAD. He describes an active life, serving in the armed forces before opening and operating a successful business for over 30 years. He considered himself a successful business owner and provider for his family. Due to episodes of pulmonary edema, he was forced to step away from the business but found it necessary to return when the business was failing. Eventually, his heart failure made it impossible to continue working and he was forced to declare bankruptcy. He accepted a DT-LVAD because he had never known his grandparents and wanted to be around for his grandchildren. He was removed from the heart transplant list because tobacco appeared in his lab results after smoking a cigarette. At the time of implant, he projected the device would allow him to live two more years. Almost seven years later, he reported feeling extremely sedate and isolated. As a business owner, he was required to be socially active, but as his health declined, he welcomed the chance to become a more private person. He states his biggest stress is the need for financial assistance that he receives from his children. The LVAD equipment is heavy, omnipresent, and a constant reminder that it could fail without warning

and he would die. Nevertheless, he considers the LVAD to be a miracle of technology and is grateful to be alive and free of infection for the entire time he has had the device. He feels that the inconveniences of the LVAD are minor compared to the symptoms of heart failure. While he would make the same decision about his own implantation, he feels it is a private matter for the individual and their family and he has no interest in counseling anyone about their decision.

Participant Two. Participant Two is a married, white male in his mid-70s who lived with his DT-LVAD for over six years until a blood clot within the device forced a complete LVAD replacement just over three months ago. He lives with his wife in the Midwest and states he has been retired for over 20 years. He reports that he has never been an athletic or active person; in early retirement, he would tend to fall behind during more vigorous recreational activities although just walking was fine. A heart attack essentially destroyed the function of his heart causing him to require an LVAD, since he was not eligible for a heart transplant because of his age. Without the LVAD, it was estimated he would live only three months; with the LVAD, he expected to live two more years. At the time of the interview, he considered himself to be recovering from the second implantation and states his recovery could take six months.

Although the nuisance of connecting to batteries each morning and night along with the weight and bulk of the equipment are the greatest drawbacks of having an LVAD, he states that one becomes used to those issues and can achieve some control. He states that it is upsetting when physical therapists demand he wear a standardized vest during his clinic visits because it removes that control. In general, he prefers to hide the LVAD and selects clothing (including specialty-made vests) that conceal the cords and equipment. While he states the LVAD inhibits some activities, he feels that he had a fairly sedentary life before the implant, and they aren't

activities he would want to do anyway. He doesn't feel the LVAD has reduced his general activity level. He is uncertain how to respond to questionnaires grading his health since his heart is essentially non-functional, yet he reports feeling positive about his overall health status. He says that he accepted a second LVAD because he was not ready to die, just as he wanted to live six years ago. The LVAD provides that option, and he hopes that his new device will last as long as his first one.

Participant Three. Participant Three is in his late 70s and has had an LVAD for 5 ½ years. He is a married white male living in the Midwest and is retired. He became weak after acquiring a respiratory illness when working on a home project during a cold and rainy day. After multiple visits to his physician over several months, it was determined he had a blood clot in his lung that was followed by a heart attack a few months later. At that time, it was estimated he would live three weeks. He had no expectations of the LVAD except to extend his life. His recovery from the implantation surgery was difficult, as he needed to regain strength and learn to walk and swallow again. His recovery continued at home with physical therapy visits where he learned to avoid tangling his lines in the equipment being used. Over five years later, he has had no infections or complications. He cares for the device very carefully, avoiding risky behaviors like showering, and taking care to protect his drive line from entanglements. At first, he thought having the LVAD in public was strange, but that feeling has long been erased. He wears a custom-made vest to carry his LVAD equipment and has been asked if his batteries are handguns. He has explained the LVAD to those with questions and to others considering an LVAD implant. Although some activity has been limited (hot tubs and pools, as examples), he feels able to do most things and life has continued as it was before his original illness. He reads

the obituaries and marvels that he is still alive when so many others his age are passing away. In some respects, he has discovered other joys because of the LVAD including mowing the lawn on his automatic tractor or sitting back and enjoying the day. He has accepted that many people are unable to live a normal life because of health, but he isn't one of them. He states that he had a choice, and he accepted and embraced the LVAD opportunity.

Participant Four. Participant Four is a single, white male who states he is disabled but works on independent projects usually related to living with an LVAD. He is about 60 years of age, lives in the Western United States, and has had two different LVADs. Nine years ago, he was implanted with a bridge to recovery LVAD for 15 months following a rapid, unexpected occurrence of heart failure. The cause has been attributed to a virus, but it is impossible to confirm. Thus, when a second, permanent health decline occurred, he felt that a heart transplant could be susceptible to the same virus that originally weakened his heart. With his prior experience living with a bridge to recovery LVAD, he felt confident in selecting a destination therapy LVAD instead of heart transplantation to avoid the uncertainty of the transplant waiting list. Additionally, he was given a life expectation of 10 years with transplantation or LVAD implantation. He determined that he did not want to take the anti-rejection medications needed with a heart transplant that would also prevent him from eating the foods he loves. He has had the DT-LVAD for about one year and reports that he has adapted as he expected. He was not surprised at the annoyance of the equipment, including the weight on the neck and shoulders and the caution needed when maneuvering around a table, out of a car, or into bed. He feels the equipment burden is the largest drawback of having the device. Unfortunately, because of the LVAD, he is no longer able to swim or enjoy water

activities which had been an important part of his life. That said, the DT-LVAD has enabled him to avoid hospitalizations and erased his fatigue. He states that he feels healthy every day and filled with energy. He often counsels others who are considering an LVAD by saying the device will allow them to stop feeling sick and exhausted, but it will become a constant presence. For example, the LVAD limits his clothing choices and makes it very difficult to dress for formal events as he wishes. That said, his health prevented him from even attending events prior to the LVAD, so he says the tradeoff has been worth it. He is hopeful that new equipment will be lighter and smaller, but he recognizes that may happen after he is gone. He feels that he has a limited amount of time remaining and chose to accept the DT-LVAD to help him recreate his life, continue forward, live independently and to the full.

Participant Five. Participant Five has had his DT-LVAD for three years. He is a married, African American male in his mid-40s who lives in the Southern United States. He states he is disabled and unable to work. As his health declined, he rejected the LVAD for over a year, largely because he was worried about how it would affect quality of life. In addition, the nearest LVAD provider was three hours away. He accepted the device when learning he had only six months to live. He was not eligible for a heart transplant because of end stage renal disease and because he gained too much weight as his health declined. The implantation surgery was very difficult, leaving him physically and emotionally compromised. He was unable to breathe on his own and was ventilator dependent with a tracheostomy. He was unable to walk or write and couldn't go outside for 10 weeks. He required a stay in a rehab facility and nursing home, acquiring an infection that needed expensive IV medications that could only be given in certain facilities. He received constant phone and text encouragement but being the

youngest person at the care home and celebrating his wedding anniversary there was demoralizing. During this period, he regretted accepting the LVAD.

Once home, he agreed to gastric sleeve surgery to lose weight. This surgery also had complications, including an unexpected week on the ventilator and another hospital acquired infection. Despite the complications, he lost 85 pounds which enables him to be listed for transplant, but he can't fathom undergoing such an extensive surgery again.

He has few expectations beyond staying alive. He misses being active and working at his job. As a music lover and former DJ, he feels unable to fully participate in clubs or events because he wouldn't be able to hear the warning alarms from the LVAD. Yet, he also states that he is alive because of his decision to accept implantation and work through the complications. He feels a responsibility to smile and make life better for others by using his experience to help those having difficult times. He believes that various degrees of complications are present throughout life, but how you respond defines who you are. He feels that he has responded to the best of his ability and is still the same happy person, but his habits have dramatically changed. He is less social, but still participates in his church and a fraternal group. He considers the LVAD is a gift, and that he was blessed to receive it.

Participant Six. Participant Six is an almost 80-year-old widowed, white woman from the Midwest who has had her DT-LVAD for three and one-half years. Her husband passed away eight years ago. She has always been active with exercise classes and played tennis until four months before implantation. Her weakened heart was a side-effect of a cancer medication.

When she was given about one year to live, her medical team encouraged her to accept the

LVAD before it was medically necessary. She hoped the device would extend her life beyond one year and improve its quality, so she feels any expectations have been far surpassed. She is again attending exercise classes, volunteers, and has traveled to visit family across the country numerous times. She believes that receiving the LVAD before she became seriously ill has speeded her recovery and has helped her maintain good health since then.

About nine months after implant, an electrical short was discovered in her LVAD driveline. This requires her to take an additional battery charger when traveling or far away from home. The extra equipment weighs about 40 pounds; she must ask for assistance in carrying it. She notes her LVAD equipment seems noisy when she is in a quiet place like a church or at a play, and she hopes the alarms don't ring and bother other people. She often wears a vest or fanny pack to carry the controller and manage the wires. On the day of the interview, she reported wearing the fanny pack since she was scrubbing her floors before our conversation. She would like to be able to connect with other LVAD recipients in her area to obtain positive feedback since she has experienced negative attitudes in online support groups. She has met with others considering an implant but rarely receives any updates after their meetings. She is aware the last two people she spoke with have died, and this causes her to think about her own mortality. Yet, she feels that the LVAD is part of the daily reality of her life and is not that unusual. She plugs in her LVAD, but others also plug in hearing aids, diabetes pumps, and even phones. She states that she feels as healthy, perhaps healthier, than others at her age and is thankful every day to lead an independent, normal life.

Participant Seven. Participant Seven is a white female who has been divorced for many years and is now in her mid-70s living in the Midwest. After years of atrial fibrillation, she began to retain fluids as her heart and kidney function declined. At first, she refused the LVAD because of the equipment burden and extent of the surgery. As her condition intensified, she was told that she would die in two months, but the LVAD could extend her life ten years. At that moment, the LVAD became a viable option to her and it was implanted just over two years ago. Although the LVAD implant was a challenge, she states that having a knee replacement was worse, because the recovery period was longer and more difficult.

Almost immediately after implant, she realized that she was not short of breath, her color improved, and she had more energy. She doesn't feel limited by the LVAD but does by the normal aspects of aging: she doesn't drive at night because of eyesight and she finds it difficult to move around because of her knees. She is not considering another knee replacement. Her kidney medications tire her, so she uses motorized carts at the store to retain energy so she can attend potlucks and play cards at night with others in her building. She recently flew across the country to attend a relative's funeral and is planning a vacation with her daughter near the ocean. She recognizes that she can't go into the water or do water aerobics because of the LVAD, but she feels that is a minor sacrifice for being able to do almost everything else and live a normal life. She says the LVAD equipment is hot, heavy and bulky but is no different than people who carry an oxygen tank with them. She doesn't try to hide the device in public. Her apartment design allows her to connect the 20-foot cord of the charging device to wall power and reach every room, permitting her to be free to move where she wishes. She is extremely careful to follow instructions and reduce risk, including having her

daughter change laundry loads so water does not touch her by accident. She feels many stories about infections and other problems with the LVAD that she heard about in support groups could be avoided by being more careful and following the medical team's instructions. She states the LVAD has given her the opportunity for a normal life and has improved her ability to live it. She asserts that having an LVAD means she is always connected, to batteries and to her family, and the connections allow a very nice life.

Participant Eight. Participant Eight is a married, African American woman who has had the LVAD just over six months. She is in her early 40s and a mother of four from the Southern United States who says she was a molecular biology researcher but is now disabled because of an unexpected onset of post-partum cardiomyopathy. Because her heart failure developed so rapidly, the decision to accept the LVAD was also made quickly and there were few expectations about living with the device. She would have accepted it regardless of any risks or challenges, because it was the only way to give her more time with her family. She is not considering a transplant because no one can be certain the antibodies in her system would not reject the new heart.

She describes herself as being in an adjustment period that is centered around living with the LVAD safely and determining her limitations. She is trying different ways to carry the equipment and also hold her 1-year old baby. She recently completed cardiac rehabilitation but feels full control of her life has been taken away because of the LVAD restrictions on things like swimming or bathing her child. Additionally, she recognizes that she will be unable to have another child because of her heart. For her, the device has created an emotional challenge that

is a constant reminder of her own mortality and that life is temporary. A simple mistake, like catching her LVAD cords on a door handle or an accidental grab by a child, could end her life. Her spouse has been very supportive, but she worries about being unable to recover fast enough to provide what her family needs. So far, she doesn't understand how her children are adapting to the new reality or how they will look at life in general after seeing their mother living with an LVAD. Nevertheless, she also feels that life is worth living and is savoring any extra time with her children. During the interview, she spoke more about her children than the device and held her 1-year old throughout the conversation. She states that she must keep going day-by-day, just as her batteries and LVAD must also keep going.

Participant Nine. Participant Nine is a married white male from the Midwest in his early 30s who has had an LVAD for six years. His first device lasted for two years but needed replacement due to a short in the driveline; there have been no issues with the second device. He has an extensive medical history dating from a childhood illness that caused three heart attacks at age one. However, he made an unexpected recovery and had an active life, participating in college dance teams, exercising and his work. His fourth heart attack, this one in his 20s, occurred soon after finding out he was going to be a father and caused irreparable heart damage resulting in an emergent LVAD implantation. With no preparation about the device, he felt overwhelmed and unprepared to learn that the device could never be removed. He says that he hated the LVAD at first because it turned him into someone else. However, he eventually realized that without the LVAD, his baby would never know her father. He described that the LVAD was no longer about him; it was about his family.

His first daughter, now age five, has never known him without the LVAD and can change the batteries on his device. His second daughter was conceived after his implant and born without issue. Although he qualified for disability benefits, he determined they would not be enough to support his growing family. He obtained a full-time job and later added an additional part-time job. He plans to keep both jobs until the children start school and his wife begins working outside the home. He states he can do almost everything with an LVAD that he did before; he has developed innovative ways to secure the device to his clothing and to protect the wires when he holds his youngest child. He described several daily routines that he has created to charge batteries, do dressing changes by himself and live with his LVAD as a parent. He now hides the device in public to shield his family from bystander intrusions. He described how a bank security guard thought he was wired with a bomb and how a woman at Disney World exclaimed that he looked “so normal” with an LVAD and was “actually out in public.” He is hopeful for the future, as he has seen LVAD technology improvements occur and average lifespan increase; he counsels other younger device candidates to look forward to the possibilities and the developing technologies. For him, life with or without an LVAD is about adaptation. He feels that he is living a normal life, but he has an LVAD, too.

Participant Ten. Participant Ten has had an LVAD for about 1 ½ years. He is a married white male in his early 70s from the Midwest who considered himself to be actively retired (fishing, golfing, walking) for five years until the medicine treating his congestive heart failure stopped working. He required an LVAD shortly after that and had few expectations of the device beyond extending his life. Following the implantation surgery, he experienced a difficult recovery due to a lingering effect from anesthesia. He was unsure of the clarity of his thinking

and asked his son to remove the gun from his home. He requested to visit with a psychiatrist and his pastor, and this helped him move forward. He reports that there was little physical pain after the LVAD surgery, but people also need psychological support to make a successful recovery.

Once at home, he began to adjust. He states the LVAD is restrictive and limits some of his favorite activities. He does not feel able to do many physical projects around the house like cleaning gutters or raking the yard. He no longer golfs and finds it difficult to walk up hills, partly because diabetic neuropathy makes him unstable on his feet and he is concerned about falling and damaging the LVAD. The device is heavy and is hot, especially in the summer; he has adapted a fishing vest to carry the equipment and does not try to hide it. He greatly misses the simple pleasure of taking a shower. That said, he would make the same decision to accept the LVAD again because there was no alternative but death. He feels he has made many necessary compromises but could not agree to give up his fishing boat. Instead, he states that he compromised again by trading it for a more stable pontoon boat that would still allow him to keep fishing. He recognizes that there is a risk he will be killed by falling into the water, but he has accepted it. He believes that any candidate for an LVAD must consider whether they can accept the compromises and changes the device will cause, and that a certain personality is needed to have success. He feels he was a good candidate and, thus far, remains able to adapt to the changes.

Participant Eleven. Participant Eleven was celebrating the eighth anniversary of his LVAD implant during the week of the interview. He is a married white male about 70 years old,

lives in the Midwest, and considers himself partially retired. He was an active hunter until becoming fatigued in the woods, leading to a discovery that he had a congenital heart defect and onset of heart failure. Four years later, he agreed to the LVAD with a hope of seeing his youngest grandson begin high school. Now, eight years after the implant, he looked forward to the grandson's graduation from high school one week after the interview.

The initial recovery after implant was challenging, but he is now back in the woods hunting and feels limited only by the 10-hour life of his batteries; he takes replacement batteries so he can stay out longer. He still uses a chainsaw despite the fears of his medical team, and reports that his life has improved dramatically since implant. He has more energy and wants to be part of family activities instead of resting. That said, he also recognizes there is danger. His drive line is somewhat frayed, and his controller has unexpectedly stopped two different times; in one case, he became extremely dizzy, his vision had lost color, and light was fading by the time he connected to the wall power console. He is certain that death was only seconds away; once reconnected to a working energy source, things returned to normal within a minute. He has participated in a support group but found little value as the discussion about LVAD problems often pointed back to a lack of basic preparation, like failing to charge batteries or keep a spare battery pack nearby. He has developed a monthly routine that includes cleaning and testing his equipment, and a daily routine focused on recharging and preparing for the next day. His biggest fear is not another unexpected mechanical failure, but simply falling at home or in the woods and damaging the equipment. Yet, he also recognizes that he must accept additional risk if he is to live life the way he wishes. He feels that he can do almost

everything he did before implant. By planning ahead, he believes the LVAD has treated him well.

Description of the Grounded Theory

The explication of the conceptual definition of quality of life for people living with an implanted, destination therapy left ventricular assist device was possible through the creation of a grounded theory. In summary, six core categories were identified: *Normalizing*, *Staying alive*, *Accepting the equipment*, *Making adjustments*, *Managing risk*, and *Living life* (see Figure 1).

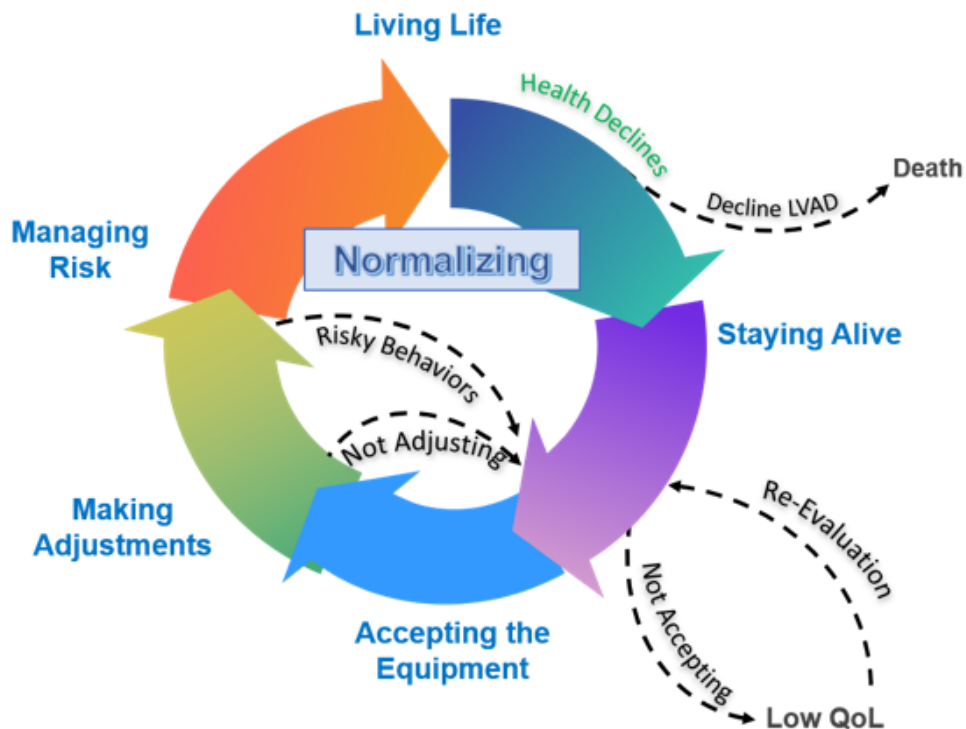


Figure 1
Quality of Life with an Implanted DT-LVAD

Normalizing is an essential component that touches all other categories and is this grounded theory's Basic Social Process. It defines life with a DT-LVAD as a normal human experience that includes a continual process of adjustment that occurs to integrate the demands of the device with the varied experiences of human living. *Staying alive* is the decision to accept the option of DT-LVAD implantation to continue life. *Accepting the equipment* is a choice the recipient makes to embrace their DT-LVAD and the related processes that are essential for life that is dependent on a machine. *Making adjustments* are the alterations that are made in thought and action that determine how one perceives oneself and is perceived by others. *Managing risk* refers to the decisions made to care for the equipment, practices to prevent infection, and compromises made that balance safety with things the recipient needs to have a normal life. *Living life* is the goal of living with a DT-LVAD; the ability to remain alive and do activities that are desired by the recipient without struggle or suffering. In many cases, this category represents the ability to do most of the same things that were done before the DT-LVAD was required.

Each of these core categories will be examined individually. Data excerpts labeled by participant number will be provided to demonstrate relationships and facilitate the reader's evaluation of dependability, transferability and confirmability.

Normalizing Life with a DT-LVAD

Normalizing emerged as the basic social process of this grounded theory study. Considering one's life that is dependent on a machine is normal, or adapting one's equipment dependence into a normal, routine process allows for recognition that a life supported by

battery-powered equipment is still a human experience. “Normalize” is defined by the Oxford University Press (2019) as “to bring or return to a normal condition or state, where normal is usual, typical or expected” (para. 1). *Normalizing* was a consistent theme with all participants and is connected to all other categories as a defining element impacting quality of life when living with an LVAD.

“Normal with the LVAD is, you can still do certain things. You just have to do it in moderation, and slow yourself down, and be careful” (Participant Five, 372-373).

“A normal life with an LVAD? It looks exactly how it is now. I go to work, kiss my wife and say goodbye to the kids, and I come home from work. It looks no different than having a reg—than not having an LVAD” (Participant Nine, 590-592).

Evidence of *Normalizing* is demonstrated by how recipients of the LVAD have incorporated the care of the device into their daily routines, as in the extended quotes below.

“You develop that routine according to the way you live. I just have my controller laying right next to me in bed and it’s hooked up to wall power. My apartment is a two-bedroom apartment, but it’s compact enough so that I have my wall power plugged into a plug, by the kitchen. It’s got a 20-foot cord on it, so I can reach to the chair or watch television or go into my kitchen or go to the bathroom or go to bed, and I don’t have to move my wall power cord. It gives me that freedom to be walking around” (Participant Seven, 251-252, 261-267).

“I put new batteries in so when I start the morning, I have fresh batteries, or in case there was a problem in the middle of the night that the power would go out. I’ve had that happen because we live in the country and so I have that plus a backup generator in case the power would go out, which we’ve had several times where the power’s out for maybe half a day to a day” (Participant Eleven, 157-162).

Although participants recognized some limitations due to the LVAD, they still felt that they were living normal lives.

“I’m as normal as you can possibly be, except I’m limited in what physical activities I can do” (Participant One, 428-429).

“You know, I can live my life normally now, and I just have this bag that I’m dragging around everywhere I go” (Participant Four, 120-121).

Additionally, participants felt that having implanted equipment and “plugging in” was quite common and not unique to the LVAD.

“I think I live a very normal life, the only thing is I carry some baggage around with me, but I also know that one of the fellas in the exercise class has an implanted pump or something for diabetes, and I see a lot of people my age with, oh my gosh, they all plug-in at night. Hearing aids and all, they’re plugging in all kinds of things, so my life is normal” (Participant Six, 336-341).

Other LVAD recipients used humor to describe normal lives that are dependent on technology. In one case, the recipient responded to a Facebook meme sent by his mother that showed a picture of a person lying under the Christmas tree with the caption ‘I hope you’ll realize what a gift I am.’ He stated:

“Mom, that’s a great gift but I’m probably a better gift than you.... Cause I come with batteries” (Participant Nine, 386-388).

Staying Alive

To understand the importance of the concept of *Normalizing* and place it within a relevant context, the processes driving quality of life from the recipient perspective that emerged from the data will be examined. Making a decision to accept the implanted DT-LVAD and, therefore, continue life (*Staying Alive*) was the beginning. Some participants felt as if the LVAD was a beacon of hope.

“Grab onto the ring, because the merry-go-round goes around once for most people. For some of us, it’s went around twice” (Participant Three, 415-417).

“And I know we all gotta go some day. I’m just not ready yet. I’m thinking, (God is) keeping me here, to teach other people some stuff” (Participant Five, 347-348).

Nevertheless, the LVAD was also viewed as an extension of time that some relatives or friends didn't receive, and would someday end.

"I'm sitting here wondering how I was picked for this, how the series of coincidences happened that I ended up with an LVAD and other people I see in the paper, the 65, 70 year old, you know, if you just thumb through the paper and the obituaries come up and you think, holy shit!" (Participant Three, 219-223).

"Well, you're running out of someday. So what are you gonna do with the rest of your time? And I don't mean that to sound morose or depressing, it's just fact. You know, the sun is gonna set tonight and it's gonna come up tomorrow morning. I know that my time is running out... Your grandparents, your parents have died. Now your cousins and your friends are dying. I'm up against that ultimatum as well. It's, it's coming" (Participant Four, 247-251; 372-375).

"It's like having life on borrowed time" (Participant Eight, 61-62).

Some recipients initially declined the LVAD but changed their mind as they became more ill and death became imminent, while others received the device emergently and had no input in the decision to be implanted with the device.

"I thought there was no way anybody is gonna put something like that in my body, I'm just gonna let Mother Nature be. Don't mess with Mother Nature! But I changed my mind after, you know, getting opinions of other people and thinking about it" (Participant Six, 124-126).

"So, it was kind of no preparation. Kind of just get thrown into it and the decisions were made for me. I had no control over any of it. It was very scary. So, before the LVAD, yeah, my life was amazing, very active, involved with dance and multiple activities including theater.... But, leading up to the LVAD it was like, we're gonna change gears in your life here, and everything is about to drastically change, so buckle up" (Participant Nine, 56-62).

Without exception, those who received the LVAD recognized that they had a chance to live a longer life. It was also clearly understood that those who didn't accept the LVAD died.

"It was either pushing up daisies or get an LVAD. So, this is not an option. This is the option" (Participant Ten, 552-553).

Accepting the Equipment

Once the LVAD implant was complete, recipients needed to learn how to live with the mechanical device that would keep them alive. The first step was initially accepting the equipment that was now part of their bodies.

“It scared the hell out of me because of the equipment that you had to carry, and I felt like the mechanical man” (Participant One, 55-57).

“(The equipment) reminds us of our own mortality” (Participant Eight, 50).

Although initially accepting the LVAD was essential, the study participants all cited the burden of the equipment as a lifelong, continual problem.

“You gotta wear this gear which, listen, in the Marine Corps my M1 rifle was nine pounds. If you basically carried it all day long, it became fifty pounds. So, when you put the (LVAD) bag on for the first hour or so, it’s no problem. When you gotta wear it all day long.... I feel like I need a new hip because I’ve been wearing this thing for almost seven years now. It, basically, really draws on your lower back” (Participant One, 206-213).

“I tend to carry the equipment for the most part in a messenger bag at my side. It’s roughly ten pounds so it’s always tugging at my neck. I keep the strap across my body on my shoulder. Any place you’re maneuvering, into a car, out of a car, you go to bed and you unplug from a battery on the base unit, and you still have this tail coming from you. If you wake up in the middle of the night and you need something in another room, you can’t just get up and get it. You’ve gotta unplug, plug back the batteries, go out and, it’s just irritating and awkward” (Participant Four, 98-106).

“The experience is you live with it every day, it’s not something that you can take off on weekends or holidays. You wanna go swimming? You can’t take it off to go swimming. It’s part of your life, just like eating. And, you can either decide you’re gonna fight with it or you’re gonna work with it” (Participant Ten, 568-573).

One participant reflected on how a mechanical issue with the LVAD instantly became a logistical issue, making life even more difficult.

“I have to carry the medical suitcase with me because I’m ungrounded. I had one problem about nine months after I got the LVAD, there was a short in the driveline and it’s inside my body, so I have an ungrounded, my cord is ungrounded, so I have a large battery charger. So I have that and all the batteries, and I put that all in one suitcase, and then I usually have a backpack with my batteries that I carry with me all the time, and then I also have a carryon, so it’s cumbersome (Participant Six, 204-210).

Despite these problems, however, study participants universally agreed that continuing their life was worth the equipment burden. They expressed hope for smaller batteries or for the entire LVAD unit to be implanted even as they admitted the new technology would probably not reach them in time.

“My hope now is I can keep the LVAD, but they just make it smaller. The batteries are so big” (Participant Five, 244-245).

“(The LVAD manufacturer) might be coming out with new equipment and it’s gonna be lighter and smaller. And I’m very much looking forward to that. I mean, I know they’re working on a fully implantable device, but the reality is that, you know, one or two decades away and I’ll be gone by then” (Participant Four, 200-204).

Making Adjustments

Once the LVAD had been accepted by the recipient, continual adjustments were required to balance the needs of the mechanical device with the needs of the human spirit.

“If that breaks down, I’m gonna break down. So, it’s on your mind even though I don’t dwell on it, is that you never know if I’m gonna see tomorrow.... I think I’m probably closer to death than I am basically closer to life, but I’m not afraid of it because I’ve already been there” (Participant One, 218-220, 272-273).

“I don’t worry about that much, because you know, what’s going to happen is going to happen. You try, you take good care of yourself and try to keep it from happening, but I don’t worry about it too much” (Participant Three, 307-309).

“I’ve decided to not let myself stress out. I’m not gonna think about what happens when it fails or why it fails. So, I try not to be stressed out. The cold probably stresses me out more than anything!” (Participant Seven, 353-355).

One participant felt that the LVAD was really an emotional challenge and not a physical one. She described the need to be “a superhero” for her family and make adjustments that changed her life. She felt that her batteries made her “invincible” but she also felt “breakable” because machines can fail.

“VAD life, as we call it... figure out my limitations.... It’s a struggle to accept that I may not participate in the process (of determining she can’t swim or do other activities)” (Participant Eight, 26-30).

In addition to adjusting to the physical and emotional challenges of having the device, participants also reported having to adjust to others who were curious about the equipment they needed to carry.

“How other people react to you, and it used to be that people came out of the hospital wearing the (battery) holsters out on top of everything else, and you know they look like some kind of robot or a terrorist” (Participant Two, 222-225).

“We went to a funeral and you could see the people looking at me and one of the guys comes over and he says, ‘Are we packing heat today?’” (Participant Three, 153-155).

“I took a break to go to the bank. And I didn’t think anything of it, but the security guard in the bank walked in and said hello and greeted everyone. But when he saw me come in, he immediately put his hand on the gun. He’s like, ‘Wait right there.’ And he saw the cables and the wires and the, the bulge in my pocket from the pocket controller and batteries on the back. So, it made him a little uneasy. I said, ‘It’s a heart pump, the LVAD is going into my stomach here, and it’s what’s keeping me alive’” (Participant Nine, 330-337).

“You go into a restaurant, you know people are looking at you. I’ve become kind of immune to it, you know? And some people say, ‘Oh, you going fishing? You been fishing?’ I’d say no, you know, I’d tell them the truth, what it is” (Participant Eleven, 189-192).

Some recipients saw the implant as a moment for reflection and a call to action.

“When he woke me up and gave me a transparent idea of what it was going to be; do you have complications? Yeah, complications all through your life. But the complications, that’s when you rise to the occasion. And I rose to the occasion” (Participant Five, 281-285).

“I just came to the realization. Look, I can’t change what happened, I can just move forward. So that’s what I did. I started taking better care of myself. I started doing things for myself where (his wife) would do ‘em all for me. I started to be more independent (Participant Nine, 185-188).

Managing Risk

Although the LVAD can remove the symptoms of heart failure and extend life, being dependent on a machine for life also introduces a new set of vulnerabilities. In addition to an unexpected mechanical failure of the machine, participants were also mindful of their responsibilities to do what they could to live safely and protect their equipment.

“My biggest fear was getting my driveline, my battery lines, tangled up in the equipment for physical therapy, the bicycles and the treadmill and things like that. All them things have very big and hairy hooks and handles on them that you’ve never noticed before unless you got things hanging out” (Participant Three, 123-127).

The risk of infection and machine malfunction was mentioned by all study participants as a concern. Most participants spent a considerable amount of time reviewing their own daily routine. Some believe that the risk of infections or problems may be increased by risky behaviors.

“I worry a little bit about getting a driveline infection. And, something happening with the mechanical bearing, goes out in the pump. You know, I’m up the creek without a paddle in that case. Like today, wife would come home and find me sitting here in my chair, you know, staring blankly into nothing” (Participant Three, 300-305).

“I have never had an infection, knock on wood. But my daughter and I change the dressing every week. We both wear a mask when we do that. We use the sterile gloves. We do what we’re supposed to do. We’re careful about it because I don’t want an infection. I think, sometimes, I see people on (a support group website) posting and they’ll say, ‘I wanted to go swimming with my kid, so I wrapped myself in plastic wrap and tried to do it.’ Well, I’m not supposed to get this equipment wet, so I don’t. I’m not gonna take a chance. So, I think sometimes people abuse, but they’re younger so maybe they need to do that, to live or be happy” (Participant Seven, 286-294).

“You know, it’s kind of funny how these people, they would actually leave home without their backup and then the alarms would go off, and they had to drive like hell to get home to switch batteries. And that, they’re not using any common sense here” (Participant Eleven, 184-187).

One participant summarized the risks and consequences of not caring for the LVAD.

“Not to fall, not to get bruises, make sure the line is not cut, make sure you get your batteries checked, make sure your batteries are changed, all the time. Make sure you’re taking your medication... If you just do half of what they say, you’ll be OK, but if you don’t do nothing they say? We gonna be putting dirt over you” (Participant Five, 236-238; 461-463).

Living Life

Despite the challenges and risks of living with an LVAD, the device extended the lives of the study participants and improved the quality of their lives by taking away the debilitating symptoms of heart failure. Without exception, participants recommended the LVAD for someone in a similar condition.

“I’d rather have the LVAD rather than the symptoms of heart failure” (Participant One, 257-259).

“It gives me the quality of life to still be who I still, who I was. I just have to watch what I do, and it still makes me smile” (Participant Five, 255-256).

“It’s given me eight more years and it allows me to basically do all the things I did before I developed heart problems. You may be limited to some degree, but I can still enjoy going to a football game, watching my grandson go fishing, I can go hunting, going to a wedding or whatever, so it’s treated me pretty well” (Participant Eleven, 355-360).

The LVAD gave participants with younger children the chance to live longer and to be part of their children’s lives.

“Not being here vs. being with my one year old” (Participant Eight, 16).

“My daughter is five years old, but she’s never known me without the LVAD, and it’s pretty cool. She knows what it is. She knows how to change my battery. She knows just the basic stuff that any person should know. And she, I think the coolest thing in the world is, she doesn’t treat me

any different than if I didn't have the LVAD. I'm still her hero, and that is amazing to me" (Participant Nine, 207-212).

Most participants stated that living with an LVAD required some compromises, but each person would determine how to apply them to their daily life. Decisions were often tied to the type of lifestyle present before the LVAD implantation, or the level of activity that was considered "normal" before the symptoms of heart failure appeared.

"I had to recreate myself, and this is what I've chosen to do" (Participant Four, 302-303).

"Look, I'm gonna compromise. I'm gonna sell my fishing boat and I'm gonna buy a pontoon boat. And I'm going out on the lake in my pontoon boat, and that's it. If I fall in, I fall in with a smile on my face and maybe I'll drown or whatever, but I don't really care. I didn't wanna die in a nursing home, just sitting in a wheelchair drooling on myself...It's not likely I'll fall in the lake, but if I do, c'est la vie, you know?" (Participant Ten, 232-236; 240-241).

"If I go hunting, I get limited by the battery's life. It's usually around ten hours so if I go out in the woods I have to be considerate that I've only got so many hours to be out there, and you always have to remember to bring your backup batteries" (Participant Eleven, 107-110).

Specific Aims of the Research Study and the Conceptual Definition

This section will address the specific aim and sub-aims that were proposed for this study and the development and presentation of a conceptual definition of quality of life with an implanted DT-LVAD. In grounded theory, initial research questions provide a basis for discovery and exploration of the topic. As this study evolved, interview questions (Appendix B) were added, changed or removed to reflect the emergence of data.

The specific aim of the study was to generate a grounded theory of living with a DT-LVAD. The grounded theory that emerged highlighted the basic social process of *Normalizing* when living with a DT-LVAD. Although there were individual variances in how each LVAD

recipient approached their daily life, all shared common connections that linked their experiences with one another. As the participants described their experiences, six core categories emerged that allowed discovery of the conceptual definition of quality of life, from the DT-LVAD recipient's perspective.

Sub-Aim One. The first sub-aim of the study was: *Determine how patients conceptualize life when living with a DT-LVAD.* Participants agreed that being dependent on a machine for life did not reduce or change the importance of being alive or living at this moment in time. In fact, the LVAD was a tool to continue living.

"I got the LVAD. I'm talking to you. I'm breathing. What little, little time I have, basically, to see my grandchildren, at least I can still see them. I can talk to them basically on the phone" (Participant One, 361-364).

"Use (the LVAD). It's a tool to get you through to somewhere" (Participant Three, 426).

"I'm (talking) to you right now. If I didn't have the LVAD, I'd be six feet under" (Participant Five, 254-255).

One participant clarified that, with an LVAD, she has no pulse and is at higher risk of bleeding due to anti-coagulation medications she is taking. She will be unable to have another child, even if she wanted to (Participant Eight, 57-60). Nevertheless, she states:

"I'm still here.... life is worth living" (Participant Eight, 59; 80).

Another participant educated the local emergency room and EMT rescue squad to ensure they understood he was alive, even without a pulse or blood pressure.

"The first thing they do when they come is take your blood pressure and if they can't find any then what they do is start pumping your chest. Well, they can't do that either! So, you have to have a special kind of doppler reader to read the blood pressure, and it's only a single number,

it's not systolic, diastolic reading, it's one reading. That's because of the action of the pump. So, if they took my blood pressure with a regular cuff, they'd think I'd died" (Participant Ten, 262-268).

In summary, LVAD recipients conceptualize life when living with an LVAD as a normal process that can be mechanically assisted but is not replaced. Life remains a human experience; the LVAD is a tool to help continue that life.

"I'm still here on Earth!" (Participant One, 259).

"I'm alive!" (Participant Seven, 319).

Sub-Aim Two. The second sub-aim of the study was: *Determine how patients conceptualize quality of life when living with a DT-LVAD.* Participants agreed that the initial goal of the implanted LVAD was to save their lives. While that central objective is key to the duration of life, the quality of life is determined by connecting the new normal of LVAD dependence to the life they had before the implant or before the symptoms of heart failure became severe.

"I think a normal life for somebody with a positive outlook is that they can go on and do most of what they could do before" (Participant Ten, 506-507).

"Our grandkids are in (location), so we check in with the hospital down there when we go take a trip. And, I carry a black bag with me, with extra batteries, extra controller, wiring and fresh batteries. So, other than that, not too much has changed" (Participant Three, 208-211).

"I'm as normal as you can possibly be, except I'm limited in what physical activities I can do" (Participant One, 428-429).

Participants described the freedom of doing what they wanted to do as an important component that determined the quality of their lives.

“Um, being able to do what I want to do, without feeling pain or sickness” (Participant Two, 164).

“I think I have a good quality of life. I’m happy, and I pretty much do what I wanna do when I wanna do it” (Participant Seven, 200-201).

The restriction on water activities (including bathing, showering or swimming) was mentioned by every participant as a significant loss. Yet, they also balanced that loss with the knowledge that the machine has saved their life.

“I get around, do pretty much what I want to do, except take a shower. I sure miss that. Showers and the electronic batteries and wiring don’t go really good together” (Participant Three, 85-87).

“I like to swim, and I also enjoy going to spas. And, of course, I can’t do either of those things anymore. But, other than that, pretty much anything that I want to do, I can do. So, you know, I can’t sit here and be upset about that when pretty much the alternative would be if I didn’t do this, I’d be dead” (Participant Four, 125-129).

Participants also acknowledged that life with an LVAD required some adjustments.

“Life with an LVAD, just one word comes to mind. Adaptation. You learn to change things. You learn to roll with things” (Participant Nine, 597-598).

“I never went back to playing tennis. But I can do a lot of things. I can travel, I can walk, hike. I don’t run, but I can walk. So, it’s made a huge difference for me in life” (Participant Six, 474-476).

“You can have an LVAD, then you could do what you want to do, but in moderation” (Participant Five, 231-232).

The Conceptual Definition

The purpose of this study was to develop a conceptual definition of “quality of life” in people living with an implanted destination therapy left ventricular assist device. The emergence of *Normalizing* as the basic social process allows one to recognize that life supported by battery-powered equipment remains a human experience. This core category

was a consistent theme with all participants and is connected to all other core categories in the study. The conceptual model (Figure 1) shows a process of *Normalizing* the dependence on a machine for life. The decision to allow the device implant (*Staying alive*) was a first step toward extending life through LVAD machine technology. For some, it was a beacon of hope while others were overwhelmed and only knew they would either be implanted or die. Once implanted, recipients needed to learn how to live with the machine and accept that the equipment burden would now be part of their life (*Accepting the equipment*). Continual monitoring and adjustments (*Making adjustments*) were required to support the emotional needs of the recipient in addition to the necessary mechanical needs of the machine. The dependence on a machine introduced new vulnerabilities to the recipient. The risk of device failure or infection required continual evaluation and choices to control the risk associated with having an implanted LVAD (*Managing risk*). As the LVAD extended the duration of the recipient's life, the freedom to live without symptoms of heart failure and live "normally" in a way they were used to living improved the quality of their life (*Living life*). All recipients in the study would recommend an LVAD to another heart failure patient, and—now knowing what they know about life with an LVAD—all would have made the same decision to accept an LVAD when they did.

Certainly, each participant in the study displayed unique attributes and individuality. However, the common experience of living with an LVAD allowed similar themes to be developed among this diverse group and the conceptual definition to emerge. Thus, supported by data from this grounded theory study, the conceptual definition of quality of life for people

living with an implanted DT-LVAD is: *I am able to live my life and do what I want, with some adjustments.*

Chapter Summary

This chapter presents a conceptual definition of quality of life for 11 people living with an implanted DT-LVAD which emerged from this grounded theory study. The basic social process has been identified and each core category has been explained. Characteristics of the sample and a synopsis of each participant were provided. Additionally, this chapter discussed how the data addressed the study's specific aim and sub-aims.

Chapter Five

Discussion

This grounded theory study was completed to determine a conceptual definition of quality of life in people living with a DT-LVAD. The study discovered three central findings about LVAD recipient perspectives of being dependent on a machine for life: 1) Emergence of the basic social process of *Normalizing*; 2) That LVAD recipients conceptualize life as a normal human process that can be mechanically assisted but is not replaced; and 3) That LVAD recipients conceptualize quality of life as the ability to live their life and do what they want with some adjustments. This chapter will discuss the study's findings and conceptual definition in relation to the literature. Then, strengths and limitations of the study will be discussed along with recommendations for future practice, policy and research.

Integration with the Literature

Normalizing emerged as the basic social process and was an essential component involved with all other elements of the study. Six core categories, reported in Chapter Four, were identified that describe a necessary process to accept and adapt to living with an implanted machine required for life. This process changed and continued over time. As recipients recovered from the LVAD implantation, accepted the device, and made adjustments to new routines that managed risk and equipment burden, they were able to do more activities central to their lives. The ability to do what they wanted to do with some adjustments continued to increase over time.

These findings support earlier research by Casida et al. (2011) which reported that “adjustment takes time” and was a significant part of the recipient’s ability to fully accept the implanted LVAD. Additional research found that fatigue, anxiety and depression were reported during the first six months of implantation (Casida & Parker, 2012) and remained clinically relevant even longer, although perceived quality of life also continued to improve as time passed (Modica et al., 2015).

The current study’s findings were consistent with research by Adams and Wrightson, (2018) who used Sandelowski’s steps for meta-summary to analyze the literature published since 2007 on the impact of LVAD implantation on quality of life. They found that emotional and physical adaptation involves learning to manage the LVAD over time, but physiological distress and functional limitations still exist after implantation.

An observational cross-sectional study by Casida et al. (2018) found that anxiety and depression exist in LVAD-recipients (n=100) after implantation. However, this study also found that quality of life did not improve over time. Recipients who were implanted less than one year had higher global quality of life scores than those who had the device longer (p=0.001). There were no significant differences in anxiety or depression based on time with the device. This is supported by research from Cowger et al. (2019) who administered surveys (n=146) at mean 82 weeks post-implant and compared QOLVAD tool results with the Kansas City Cardiomyopathy Questionnaire, Patient Health Questionnaire-9, and Patient Reported Outcomes Measurement Information System (PROMIS) tools, finding time-dependent differences in selected domains. Physical wellbeing (p=0.048) was lower for those who had just

received the device compared with those who had the device longer, but recipients who had the device longer had lower emotional ($p=0.009$), social ($p=0.007$), and cognitive ($p=0.003$) wellbeing compared with earlier implants.

The current study found that participants required a process of physical and emotional acceptance to the device over time, and psychological support was an important component of recovery. This finding complimented results of a meta-synthesis by Abshire et al. (2016) who found that a process of coping and adaptation over time included the successful assimilation of normal routines to care for the equipment. Importantly, physical routines caring for the device were reported to be relatively easy to adopt, but emotional adaptation was more difficult and could present a long-term struggle.

These findings were congruent to the research of Kaufman et al. (2011) who found that dependence on health care technology can seem like life has been saved but is fundamentally changed. This is coupled with a feeling that there is a loss of control unless the technology is accepted and the recipient adjusts to living with the risks and benefits of the new circumstance.

Acceptance of the equipment and adjustment to the LVAD, which included dealing with the significant equipment burden and making clothing choices to carry the equipment, was an important step toward better quality of life for the participants of the current study. This is similar to findings by Tosto et al., (2019) which showed that acceptance of the LVAD was associated with better quality of life including lower depression and anxiety. A cross-sectional study ($n=101$) found a strong correlation between device acceptance and psychological distress ($p<.001$) and quality of life ($p<.001$). While participants had significant body image concerns,

their perceived return to a normal state along with distress about the LVAD equipment were main drivers of this correlation.

The current study differs from research by Standing et al. (2017) who found that machine-induced limitations on LVAD recipient lives can precipitate a loss of identity, and that the LVAD is a liminal experience that increases the struggle to develop a new normality around the device. The LVAD is positioned as a temporary extension of life instead of an 'answer' to the condition, and those eligible for transplant may believe that obtaining a new heart will allow them an even greater approximation to their pre-illness self. This is similar to findings by Barg et al. (2017) that the LVAD device created a state of being neither sick nor healthy, and there was no culturally scripted role for living with a device. Participants in the current study did not describe this feeling, but two participants who were eligible to be listed for heart transplantation discussed organ transplant as a potential option for themselves or for others, and encouraged younger LVAD-candidates to accept the device if needed to extend their lives.

This has congruence with research from Barg et al. (2017) that found LVAD recipients felt an obligation to accept the device to extend life. All participants in the current study, transplant-eligible or not eligible, viewed the LVAD as the only true option, although some delayed the implantation surgery as long as possible. Additionally, all participants in the current study stated they would still make the same decision and accept the LVAD today. This is consistent with other studies showing that a sizable number of those who accept LVAD therapy would not consider palliative options as long as other means to stay alive were possible (Dwyer & Casida, 2015, 2016; McIlvennan et al., 2014).

As discussed in Chapter Two, a quantitative tool specifically designed for LVAD recipients has not previously been available. However, a new quantitative tool (QOLVAD) has recently been introduced as an LVAD-specific measure based on qualitative research including five identified quality of life domains (physical, emotional, social, cognitive, and spiritual/meaning). These domains are integrated in the current study's core categories and within the new conceptual definition. Sandau et al. (2018) reported preliminary psychometrics from a prospective, multi-site, cross-sectional study which showed internal consistency reliability and construct validity. Surveys (n=113) were completed at median time of 48 weeks from implant showing the 46-item tool had internal consistency reliability and construct validity. An additional study by Sandau et al. (2019) reported second stage preliminary psychometrics using a prospective, cross-sectional study at seven sites. Participants (82.7% male, 77.3% white, 50% bridge to transplant) completed surveys (n=186) at median time of 44 weeks post-implant. Scores were standardized to range from 0 to 100 (higher equals better quality of life scores). Findings were significant when comparing overall score ($p<0.001$) and specific domain scores (physical, $p<0.001$; emotional, $p<0.001$; social, $p<0.001$; meaning, $p<0.001$) with other tools, including the Kansas City Cardiomyopathy Questionnaire, Patient Health Questionnaire-9, Patient Reported Outcomes Measurement Information System (PROMIS), and Functional Assessment of Chronic Illness Therapy (FACIT), showing the tool is a valid, reliable measure of quality of life with an LVAD in these domains.

The Conceptual Definition

This study theorized that the permanent nature of DT-LVAD implantation may create different concerns than temporary bridge to transplant (BTT) or bridge to recovery options. Accepting an implanted device as a permanent solution may change the dynamics of how one perceives quality of life compared to others who view LVAD therapy as a temporary situation. This is consistent with research conducted by Milley et al. (2016) who found that LVAD recipients with destination therapy and bridge to transplant device strategies had similar scores on the Minnesota Living with Heart Failure Questionnaire prior to implant. While sample sizes are small, scores improved for both groups after implant but DT-LVAD recipient scores (n=5) improved to a greater degree than BTT-LVAD recipient scores (n=17) over the 6 months following implant. This is congruent with research by Katz et al. (2015) showing higher scores for DT-LVAD recipients at three and six months (n=61, n=50) compared to BTT-LVAD recipients (n=48, n=26). At 12-months, scores slightly declined for both groups, but DT-LVAD recipient scores (n=16) decreased less than bridge-to-transplant recipient scores (n=14).

The current study's grounded theory allowed the emergence of the conceptual definition for quality of life with a DT-LVAD as: *I am able to live my life and do what I want, with some adjustments*. This finding is congruent with research by Sandau et al. (2014) who used grounded theory to establish a conceptual definition of quality of life with an LVAD (including destination therapy, bridge-to-transplant, and bridge-to-recovery participants) as "Being well enough to do and enjoy day-to-day activities that are important to me." Participants described quality of life as being "normal" while doing most routine things. Additionally, perceived

quality of life may adjust depending on the individual's stage of life. Over time, the initial trauma of implant was replaced with a longer-term period of adjustment including emotional, social and cognitive domains.

Of interest, the current study did not discover a conceptual definition that was significantly different from the earlier Sandau et al. (2014) study that contained participants with differing device strategies. The conceptual definition of quality of life for DT-LVAD recipients was largely the same as for LVAD recipients as a whole. Of note, a conceptual definition that is exclusive for bridge to recovery or bridge to decision recipients has not been published.

Finally, if desired now or in the future, four participants in the current study might be eligible to change from a destination therapy device strategy to a bridge to transplant strategy because they were younger than the transplant age limit. In these cases, the "permanent" nature of the LVAD decision would no longer exist; the LVAD might be viewed as a temporary measure that could be changed later. These participants were at different stages of decision-making, but the hurdles in being approved for the transplant list and obtaining a donor heart along with limitations following heart transplantation were all discussed in relation to their current health status and satisfaction with their current DT-LVAD. Regardless, the ability to change device strategies remained an option that was unavailable to other DT-LVAD participants and could affect quality of life for younger recipients. This is supported by research from Grady et al. (2015a) finding that quality of life after implantation improved for all groups, but older recipients (over age 70) reported higher quality of life scores than younger recipients

(60-70 years of age and under 60 years of age) during the first year following LVAD implantation.

Additional Findings

There are several other findings that emerged from this study and deserve additional discussion and further exploration.

Caregivers. Participants from the current study frequently discussed caregivers as an essential component of recovery from LVAD implantation and support at home. Some recipients continued to rely on their caregivers for routine support long after the initial recovery period, while others returned to a more independent life. While the caregiver relationship in the LVAD context has been studied, more research is needed to determine how to best support LVAD recipients while reducing the burden of the caregiver role. This is supported by research of Bidwell et al. (2018) who found that early LVAD recipient outcomes could be improved by selection of a properly matched caregiver, and that caregiver strain never resolved, although it did worsen during the first 6-months following implant. This is also congruent with research by Bruce et al. (2017) who found that LVAD recipient mortality was reduced by having a caregiver who understood the severity of the illness, identified a backup plan, and was able to provide logistical support. Additionally, risk of death was more likely among recipients who lived alone.

Although most LVAD recipients in the current study acknowledged the important role of caregivers in their recovery, it was not universal. One participant stated he had a caregiver after initial implant but was now his own caregiver, and another participant reported selecting

the LVAD over transplantation because they could avoid burdening someone to be a caregiver with that choice. This is consistent with research from Koeckert et al. (2017) who found that carefully selected recipients implanted without a designated caregiver had comparable outcomes to those who retained their original caregivers. Recipients with caregivers were most likely to retain the original caregiver if they were a spouse and lived at the same residence. Thirty-day readmission rates were highest for recipients who did not retain their original caregiver (Koeckert et al., 2017).

Pre-implant counseling. Participants in the current study often reported waiting as long as possible before accepting the implantation of the LVAD. The amount of information to consider about living with an LVAD was called overwhelming. While participants knew they needed to make a timely decision, they stated it was difficult or impossible to rationally consider the complexities of the implantation. Participants commonly stated that the decision to accept LVAD therapy was made because there were no other options but death. Further research is needed to ensure LVAD candidates fully understand the obligations that come with the implantation and ensure that LVAD implantation is the correct choice for each individual who is experiencing the strain of this decision. This is supported by research from Kitko et al. (2016) who found that most LVAD recipients (n=15) did not recall the information provided during the pre-implant period. Recipients felt they had no choice but to accept the device. This could present ethical issues as patients had a loss of autonomy over their decision. However, this research also differs from the current study by finding that recipients, particularly those with destination therapy device strategies (n=5), felt their experience living with the LVAD did not meet their pre-implant expectations.

Research by Swetz et al. (2011) found that proactive palliative care consultation for patients considering LVAD implantation can result in creation of a person preparedness plan, which includes an expanded advance directive used to help develop patient-centered outcomes. This is consistent with research from Nakagawa et al. (2017) who found that pre-implant intervention by palliative care teams were able to help LVAD candidates identify benefits and concerns about LVAD therapy and also explain what makes their life meaningful. This research agreed with findings by Salomon et al. (2018) showing palliative care consultations can be integrated into the LVAD evaluation process to provide care coordination without delaying LVAD placement.

Emotional and psychological support. Participants in the current study reported feeling emotionally challenged by aspects of adjusting to the LVAD after implementation. Over time, participants stated they became more comfortable with the equipment, which reduced their concerns. While some participants stated they refused to worry about things out of their control (like device malfunction), others stated they were worried about dying, infections or unexpected equipment breakdown. One recipient stated they were on medication to relieve the anxiety over living with the device. Many participants stated additional support or professional assistance was needed to manage the stress and uncertainties of living with an LVAD. The existence of physiological and psychological symptoms, including sleep quality, perceived stress, anxiety, and depression in patients with an LVAD has been well established and was previously reviewed in Chapter Two. This was supported by research from Jaganathan et al. (2019) who reported findings using the QOLVAD tool consisting of ten items in the emotional subset that were compared with the Patient Health Questionnaire (PHQ-9), Patient

Reported Outcomes Measurement Information System (PROMIS), and Euroqual 5 dimensions (EQ-5D). Surveys of LVAD recipients (n=186) were completed at a median time of 44 weeks post implantation. Destination therapy recipients were found to have higher levels of social functioning and emotional scoring with less anxiety compared to bridge-to-transplant recipients.

Differing from the current study, research from Weerahandi et al. (2017) found that increased functional capacity and improved quality of life may be reducing other mental health symptoms commonly reported with LVAD implantation. The depression and anxiety modules of the Patient Reported Outcomes Measurement Information System (PROMIS) Short Form 8A and panic disorder, acute stress disorder and PTSD modules of the Structured Clinical Interview for the DSM (SCID) to LVAD patients (n=87) were administered during six periods over a forty-eight week span following LVAD placement. Depression and anxiety were found to decrease over time and may have been present initially due to the significance of the impending procedure. None of the patients in the study met the criteria for PTSD or acute stress disorder. While some patients met the criteria for panic disorder (2.8%), it was less than the lifetime prevalence of panic disorder in the United States (4.7%). The study reported high non-response rates at certain times, likely due to participants not feeling well enough to answer the questions. Additionally, questionnaires were completed by nurse practitioners in the peri-implant period who were also required to teach the patient about LVAD care, making survey completion a lower priority.

Functional status. Participants in the current study often discussed their physical abilities and functional status living with an LVAD compared to their physical abilities and functional status pre-implant or pre-heart failure exacerbation. Some participants reported they were never physically active before implant, so a sedentary life with the LVAD felt normal to them. Others reported that they had improved their ability to participate in physical activities but still felt limited when climbing hills or walking for longer periods. Still other participants reported they felt health improvements due to LVAD implantation allowed them to again attend formal events or exercise classes, scrub floors, or hunt in the woods for extended periods. This self-comparison of current functional status to past functional status may have important quality of life implications. Further research is needed in this area since functional status (and LVAD recovery) may be partially determined by pre-implant or pre-exacerbation lifestyle in addition to current physical status. This is consistent with research from Klompstra et al. (2018) who found that motivation to engage heart failure patients in physical activity was not sufficient unless a high degree of self-efficacy was also present. Higher levels of motivation led patients to a higher level of self-efficacy that includes an ability to overcome barriers to physical activity. This is analogous to findings from a systematic review by Rajati et al. (2014) that reported exercise interventions integrating strategies of exercise self-efficacy can improve confidence and ability to initiate exercise and recover from heart failure symptoms. Research by Jakovljevic et al. (2014) found initial improvements in physical activity measures for LVAD and heart transplant recipients at 3 months post-surgery, but LVAD recipients had a lower activity level than those with heart transplants over a 12-month period despite both groups completing in-hospital mobility and rehabilitation programs. This is similar to research by

Moreno-Suarez et al. (2020) who found LVAD recipients had a higher level of daily physical activity than advanced heart failure patients. Self-efficacy scores showed a modest positive correlation approaching statistical significance ($p=0.055$).

Intimacy and Sex. Although this study did not originally intend to explore the relationship of intimacy and/or sexual activity on LVAD recipient quality of life, two male participants requested during the interview process that information about this topic was brought forward. According to one participant, sexual activity had naturally stopped due to the normal aging process before implantation of the LVAD was required, but that intimacy including holding hands, kissing and being together was still an active and important part of life. Another recipient stated that many people considering the LVAD ask about sexual activity. He disclosed that sexual activity was possible with a little planning, and he fathered two of the couple's three children while supported by the LVAD. The role of intimacy and sexual activity on perceived quality of life in LVAD recipients remains understudied, including the perspectives of women living with an LVAD. As LVAD therapy continues to become a more viable option for younger and healthier heart failure patients, this important quality of life dynamic will need further attention as a normal part of life. This is supported by research by Kato et al. (2018) who found a positive relationship between the level of sexual life satisfaction and quality of life in LVAD recipients ($n=44$). Most participants (55%) reported no change in satisfaction compared to pre-implant levels, but 13% reported a satisfaction increase and 32% reported a satisfaction decrease in sexual activity after implant. A majority of participants (57%) reported some disturbances in sexual activity due to the driveline, batteries, fear of injuring their own health, or feeling depressed. This is congruent with research by Hasin et al. (2014) who found that

sexual dysfunction commonly occurs in male and female patients with LVAD support (n=14) or heart transplantation (n=17). Possible contributors to this dysfunction include physiological issues that may be tied to organ transplantation in general, LVAD equipment burden, and psychosocial elements including depression, fear, altered self-image and concerns of their partners.

This finding differs from research by Marcuccilli et al. (2011) who found that LVAD recipients (n=11) reported an improved state of sexual relations following LVAD implantation compared to pre-implant levels. A period of sexual adjustment was required to promote satisfaction and maintain a sense of normalcy, including developing self-care behaviors such-as device positioning, driveline protection and acceptance of the uncertainty of the experience. Nonsexual intimacy was an important element even if sexual intercourse was not possible. Participants reported an increased sense of connectedness including holding hands or performing intimate behaviors such-as snuggling in bed or sitting together.

Lifespan Considerations. Participants in the current study shared some goals and expectations but also revealed some differences that seemed to be linked to the participant's age and life experience. All participants reported an appreciation of time with family; younger participants (defined as those who could be eligible for heart transplant listing) discussed being routinely present with their own children while older participants (defined as those not eligible for heart transplantation) stated they enjoyed the times when children or grandchildren were together. Younger participants expressed hope that technical advancements might arrive in their lifetime and reduce the weight of the device and equipment burden or expand the

functionality of the batteries required to provide LVAD power. One younger participant has requested to be included in any new trial to advance LVAD technology, while another participant stated that the device strategy selected can be temporary and a transplant option could always be pursued at a later time. However, another younger participant stated that he was hopeful for the future but uninterested in considering any additional interventions due to the difficult course of treatment already experienced. He stated that being alive was enough.

Older participants reported they had completed their “bucket list” and were content with the LVAD’s ability to extend life and reduce symptoms of heart failure. Participants stated wonderment at attending funerals of relatives and friends while they remained alive due to an implanted machine. Participants had difficulty imagining they would be able to accept the sacrifices of the LVAD if they had not already completed certain important events or milestones in their lives. Some older participants mentioned the importance of having a full career or watching their children become adults. One younger participant couldn’t imagine living with an LVAD without the memories of being active and playing contact sports. Other younger participants reported a more day-to-day approach by working in a job or taking care of their children. There is a difference in the experience of living with an LVAD based on the recipient’s age or life experience. The lifespan considerations of living with an LVAD deserve additional attention to better understand the impact of age and experience on quality of life. This is supported by research by Hoffman et al. (2019) who used the QOLVAD tool to find that younger LVAD recipients (defined as age 55 or younger, n=68) had a lower social domain score than older LVAD recipients (n=118), suggesting that younger LVAD recipients struggle more socially after implantation. This is congruent with research by Mudigonda et al. (2019) who also used

the QOLVAD tool (n=186) to find that LVAD recipients less than 55 years of age had lower Emotional Domain ($p=0.007$) and Meaning/Spiritual Domain scores ($p=0.031$) compared to older recipients. This is also consistent with research from Tosto et al. (2019) who used the Kansas City Cardiomyopathy Questionnaire quality of life subscale, the Generalized Anxiety Disorder (GAD-7), Patient Health Questionnaire (PHQ-9), and Florida Patient Acceptance Survey (FPAS) to find a strong correlation between LVAD recipient (n=101) device acceptance and both quality of life ($p<0.001$) and psychological distress ($p<0.001$), with younger age associated with lower device acceptance ($p<0.001$) and lower quality of life ($p<0.001$). Importantly, lifespan considerations for younger and older recipients alike may become even more important, as research by Sajgalik et al. (2016) shows an increased trend toward use of LVADs in younger, less sick patients with heart failure while complimentary research by Rali et al. (2017) shows the maximum age of potential candidacy for an LVAD continues to increase and candidates having multiple co-morbidities are being implanted with improved survival outcomes.

Water restrictions. Restrictions that prohibit water from contacting the LVAD equipment are well documented. Yet, without specifically being asked about water restrictions, every participant in the current study discussed their disappointment in the inability to connect with water by showering, bathing, swimming, or doing other activities alone or with their families related to water. Participants stated they understood the rationale for this restriction but still missed the contact with water more than they expected. None of the participants in this study chose to utilize “body wraps” due to the risk of driveline infection or leakage which could ruin the LVAD equipment. Some recipients stated that others who did use those options were at higher risk of infection or problems. The impact of water restrictions on LVAD recipient

quality of life is a continuing issue that retains an important status for those living with these devices. This is supported by research from Bogar et al. (2016) who found that the top two requested quality of life improvements by LVAD recipients (n=113) were the ability to submerge in water and unrestricted showering. This is supported by research by Dwyer & Casida (2015, 2016) who found that the impact of adjustment to the LVAD only becomes real for device recipients (n=90) after implantation, when the importance of water restrictions including showering and swimming were recognized as a key physical limitation.

Strengths and Limitations of the Study

This is the only known study focusing on the conceptual definition of quality of life from the perspective of destination therapy LVAD recipients. The study presented a rich sample that included participants who had been recently implanted and those who had been implanted for many years. Some participants were living with their second LVAD following replacement for mechanical issues while others had their original LVAD. The sample had a wide variance of age, educational level and geographical location. Additionally, the sample was racially diverse and included participants at different stages of their lives; some participants were raising children, some had grandchildren and others were not parents. Some participants had completed their working lives and were retired before LVAD implantation, some were disabled but hoped to return to work, while others were employed in full or part-time positions. Most participants had designated caregivers, but some did not. Finally, two participants reviewed the proposed conceptual definition and provided feedback and agreement that it reflected an accurate definition of quality of life when living with a DT-LVAD.

This study has several limitations. The study had only eleven participants limiting generalizability, although data saturation to generate the grounded theory was achieved. In addition, the study sample was recruited from various online LVAD support groups and only one LVAD/Heart Failure clinic. Participants willing to participate in online support groups and contact the researcher to discuss their experience may not be reflective of DT-LVAD recipients as a whole. While the sample does include participants that had experienced mechanical or infection-related issues, it does not include participants with recurring hospitalizations after the initial implantation period, which can dramatically reduce quality of life. Finally, the interviews of participants in this dissertation study became more focused over time as the experience of the researcher with the grounded theory method increased. Grounded theory presents a wealth of opportunity to capture participant insight, based on the ability to elicit that data from a participant's experience.

Implications for Nursing Practice

This study provides nurses and the health care team at large with a better understanding of how DT-LVAD recipients view quality of life, which may lead to more knowledge about the needs of this specific patient population. Nursing and the health care team must begin to embrace the perspective of those with artificial organs, including the LVAD, to develop common strategies that will help clinical teams deliver consistent, relevant care based on the recipient's needs. Living with an LVAD is a continual process of acceptance, modification and adjustment. Supporting the LVAD-recipient and their family through these stages while providing individualized interventions to assist them in being successful with the

device is an essential part of nursing's role. In addition, nursing must support LVAD-recipients who agree to share their stories with others. Multiple participants in this study agreed to speak to LVAD candidates or were interested in helping other new recipients adjust to living with the LVAD, but some of them were never contacted again while others were left wondering how things turned out. One participant stated he felt responsible after two people he spoke with died pursuing LVAD-therapy. Nursing care should be provided to the recipient after these visits to assess if additional support is needed for the candidate or recipient, and to conduct a debrief that also provides an update on the candidate. It is possible to protect the privacy of the candidate and also respect the needs of those willing to help others while reducing the potential for anguish as a result of providing advice to a person who subsequently dies. Additionally, numerous participants in this study reported their support groups were more focused on people making risky behavior decisions, not on those who took care to avoid placing themselves at risk. Because of this, several participants stated they stopped attending support groups, losing this sense of community and the ability to influence others toward more healthy behaviors. Additional support groups, designed from the LVAD-recipient perspective, that encourage community and build on success is needed. Nurses and other providers may be unintentionally focusing on LVAD recipients who are having difficulties while ignoring those with positive outcomes. In addition, nursing and other disciplines represented on the health care team should understand that the regional availability of LVAD-provider care may influence decisions on treatment strategies. Improving tele-health options for DT-LVAD recipients who do not live near LVAD provider clinics is a reasonable step toward provision of competent care. For all LVAD recipients, nurses must actively work to screen psychosocial symptoms including

depression, anxiety and stress pre- and post-implant, and ensure the appropriate intervention and support is provided to reduce these issues and promote quality of life. Finally, health care providers must have respect for the informed decision of the LVAD-recipient to choose the treatment strategy that is best suited for them, including destination therapy, bridge to transplant or palliative care. This is a tremendously difficult decision and nurses can provide information, support, resources and connections to other professionals as required to ensure the needs of the patient remain at the center of our care.

Implications for Policy

The progressive, debilitating effects of advanced heart failure that leads to LVAD implantation results in numerous, devastating changes in the individual's life and the lives of their family. Participants in the current study reported having financial stress over reliance on their children to pay their medical bills and expenses. Assessing costs of LVAD-care was cited by multiple recipients as a factor in determining whether to accept this life-saving treatment. One recipient reported that he was fortunate to be enrolled in a study paying all his medical bills; without the study, he may not have thought the LVAD was a viable option to save his life. Government policy can mandate clear language on health care coverage options as well as accurate out-of-pocket costs of LVAD therapy. Reasonable coverage models, including affordable co-payment rates, must be available to ensure coverage is available for all. In addition, government policy must require a reasonable time for response to questions and appeals of coverage. One participant in the current study reported his Medicaid eligibility was revoked due to a calculation error and was told the appeal process would take over six months

to resolve. During the appeal, his Medicaid benefits would be suspended. He stated he could not survive without income or health coverage for that long; it forced him to seek full-time employment to receive money and benefits to live. When the Medicaid error was finally resolved in his favor, he was asked to either stop working or reject benefit assistance.

Government must respond promptly and establish easy to understand rules that can encourage work while recognizing the danger overwork places on this fragile population. Finally, multiple participants in this study discussed the need of psychological and emotional counseling during the pre- and post-implant periods, particularly as a new LVAD recipient. Government policy must encourage access and support funding for pre-implant and post-implant psychological and emotional counseling to ensure appropriate assistance is available and obtainable for LVAD recipients.

Recommendations for Research

There are numerous opportunities for expanding research in this area. Symbolic interactionism, as discussed earlier in this study, believes that individual actions are a specific response to the view held of the current situation (Blumer, 1969; Charmaz, 2014). The complexity of the phenomena “quality of life with an LVAD” requires clarity to understand terms and ensure health care providers are measuring appropriate elements that define “success” of the treatment from the perspective of the recipient. The importance of normalizing life when dependent on a machine by accepting and adapting the technology and living life are important meanings created by the LVAD recipient that emerge over time. Decisions to leave the LVAD visible or hide it in public, accept additional risk by using a body

wrap to take a shower or swim in a pool, or follow a consistent battery-charging routine are all choices made that shape the recipient's future, created from the context in which they exist. This work extends the science by providing a conceptual definition to better understand these meanings from the recipient's perspective, allowing the health care team to help improve the DT-LVAD recipient's life. Destination therapy LVAD recipients accepted the LVAD to extend their lives; going beyond the extension of life to become a life worth living as the participant defines it should be the health care team's goal.

As LVAD technology continues to evolve and offer life-extending opportunities to a wider variety of people, it becomes even more important to add the perspectives of the destination therapy LVAD recipient in specific, and all LVAD recipients in general, to the body of knowledge. This specific list of recommendations for further investigation only covers a small sample of needed research.

1. Further advancement and validation of the model presented in this study, including the impact of "normalizing" or "being normal" on quality of life when living with an LVAD.
2. Specific studies on the unique perspectives of destination therapy LVAD recipient, bridge to transplant LVAD recipients, and bridge to recovery LVAD recipients on factors that improve and hinder quality of life, recognizing the unique attributes and shared elements of each treatment strategy.
3. Further exploration of the recently introduced VADQOL quantitative tool to expand knowledge about LVAD recipient quality of life.

4. Creation of interventions and strategies across various artificial organs that can be personalized for and applicable to recipients.
5. Continued study of LVAD-recipient caregivers, including best practices to select and retain qualified caregivers and methods to reduce caregiver burden, stress and anxiety.
6. Effective ways to deliver pre-implantation information to overwhelmed and stressed LVAD candidates, and provide emotional and psychological support during the pre-implant, peri-implant and post-implant periods for LVAD recipients.
7. Further exploration of the immediate and longer-term needs of LVAD recipients who were emergently implanted and had no decision-making involvement with the decision to accept an implanted device.
8. Elements of functional status as it relates to exercise self-efficacy, including perceptions on LVAD effectiveness/quality of life based on pre-implantation lifestyle.
9. Continued exploration of the impact of intimacy and sex on quality of life for LVAD recipients and their partners.
10. An understanding of lifespan considerations, including gender differences and the specific needs of younger and older LVAD-recipients.
11. An understanding how children of LVAD recipients view life or mortality and how they are impacted by having a parent dependent on mechanical technology for life.
12. The impact of water restrictions on quality of life and development of safe methods to ease this burden for LVAD-recipients.

Conclusions

The conceptual definition of quality of life for people living with an implanted, destination therapy left ventricular assist device emerged as: *I am able to live my life and do what I want, with some adjustments.* DT-LVAD recipients *Normalize* their experience over time, from deciding to accept an implanted LVAD, adjusting to the physical and emotional challenges of the implant while managing risk of infection and device malfunction, to enable living in a normal way that improves the quality of their lives. While this study supports findings of the minimal conceptual work existing for LVAD recipients as a whole, it extends the body of knowledge by introducing a process of *Normalizing* and a conceptual definition that defines quality of life exclusively from the DT-LVAD recipient's perspective. Although extending life was the original objective of the DT-LVAD recipient when the device was first accepted, their goals of this therapy advanced over time. From the LVAD recipient's perspective, life with an LVAD is not simply about survival; it is the survival of quality that makes a difference and defines success.

Chapter Summary

This chapter discussed the study's findings and conceptual definition in relation to the literature. In addition, strengths and limitations of the study were discussed. Finally, implications and recommendations for nursing practice, policy and research were provided.

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Appendix A
Demographics Data Sheet

Demographic Information

Participant #

Age in Years:

Gender Code

Unknown, Male, Female, Not specified

Race USA category

American Indian or Alaskan Native, White, Asian, Unknown, Black or African-American, Not reported, Native Hawaiian or Other Pacific Islander

Ethnicity USA category

Hispanic or Latino, Not Hispanic or Latino, Unknown, Not reported

Education level USA type

Never attended/Kindergarten only, 1st grade, 2nd grade, 3rd grade, 4th grade, 5th grade, 6th grade, 7th grade, 8th grade, 9th grade, 10th grade, 11th grade, 12th grade no diploma, High School Graduate, GED or equivalent, Some college no degree, Associate degree occupational/technical/vocational program, Associate degree academic program; Bachelor's degree eg BA AB BS BBA; Master's degree eg MA MS MEng, MEd, MBA; Professional school degree eg MD DDS DVM JD; Doctoral degree eg PhD EdD; Unknown

Caregiver primary type

Self, spouse or partner, parent or legal guardian, child, sibling, home aide, long-term care/nursing facility staff, other, unknown

Employment Status

Working now, Only temporarily laid off/sick leave/maternity leave, looking for work/unemployed, retired, disabled/permanently or temporarily, keeping house, student, other (specify), unknown

Marital or partner status

Never married, married, domestic partnership, divorced, widowed

Household member total count:

Date of DT-LVAD implantation:

Duration of hospitalization for initial implant:

Device type/manufacturer:

Original device strategy:

Other/observations:

Appendix B

Semi-structured Interview Guide

Interview Guide

IRB Approval: December 14, 2018

Study Title: **Living with a Destination Therapy LVAD**

1. Tell me how long you've had your VAD.
2. Tell me about your life before you received the LVAD.
3. Why did you choose destination therapy?
4. What were your expectations when you decided to get an LVAD?
 - a. Has the LVAD lived up to those expectations?
5. Tell me about the first couple of weeks after the LVAD surgery.
 - a. What was it like? How did you feel during this time, physically and emotionally?
 - b. Did you feel prepared for it? What helped the most/should have been done?
What surprised you in the first couple of weeks?
6. Tell me about your life now.
 - a. How has the LVAD changed your life?
7. Let's change gears a bit. What is the first thing that comes to mind when say "Quality of Life" right now?
8. How would you describe your quality of life right now?
9. How has your quality of life changed since getting the LVAD?
 - a. Were there surprises? What was affected? Were there areas not affected?
10. Tell me something positive about having the LVAD.
 - a. Tell me something positive about daily life with the LVAD.
11. What causes you the most worry or stress right now?
12. If you had 1 minute to talk with someone who would think about having an LVAD, what would you say?
 - a. Did anyone talk with you?
 - b. If you could do it over again, would you have the LVAD placed?
13. We've talked a lot today. What do you think we have missed about quality of life for someone with an LVAD?

Interview Guide **REVISED**

IRB Approval: January 31, 2019

Study Title: **Living with a Destination Therapy LVAD**

1. Tell me how long you've had your VAD.
2. Tell me about your life before you received the LVAD.
3. Did you have a choice between destination therapy and bridge-to- transplant?
4. Why did you choose destination therapy?
5. What were your expectations when you decided to get an LVAD?
 - a. Has the LVAD lived up to those expectations?
6. Tell me about the first couple of weeks after the LVAD surgery.
 - a. What was it like? How did you feel during this time, physically and emotionally?
 - b. Did you feel prepared for it? What helped the most/should have been done?
What surprised you in the first couple of weeks?
7. Before you made your decision to accept the LVAD, did you talk with someone that already had an LVAD?
 - a. Have you talked with potential LVAD candidates and shared your experience?
8. Tell me about your life now.
 - a. How has the LVAD changed your life?
 - b. *What was your activity level before the LVAD? What is it now? (prompt)*
9. Let's change gears a bit. What is the first thing that comes to mind when I ask you to describe your "Quality of Life" right now?
10. How has your life changed since getting the LVAD?
 - a. Were there surprises? What was affected? Were there areas not affected?
11. Do you try to hide the LVAD in public?
 - a. Have you made any clothing choices that help you carry or hide the LVAD?
 - b. Have you had any conversations with people after they see your LVAD?
 - c. Have any of your friends or other people you know stopped connecting with you because of the LVAD?
12. Do you follow a routine, with connections, disconnections or daily life?
 - a. Did you develop the routine?
13. Do you participate in LVAD support groups? How has that gone?
 - a. Have you encountered people that have had a negative experience with the LVAD in support groups or outside of the support groups?
14. Do you think a person's age makes a difference with satisfaction with an LVAD?
 - a. Do you think a person's gender makes a difference?
15. Tell me something positive about having the LVAD.

- a. What is the biggest negative thing about having the LVAD?
16. What causes you the most worry or stress right now?
17. Do you think about the possibility of future technology and the LVAD?
18. When I say “normal life with an LVAD,” what does that look like?
19. If you had 1 minute to talk with someone who would think about having an LVAD, what would you say?
 - a. If you could do it over again, would you have the LVAD placed?
20. This has been very helpful, thank you for sharing your experiences. What else do I need to know, or what have we missed about quality of life or the experience of living with an LVAD?

Appendix C

Protection of Human Subjects



Melissa Spadanuda
IRB Manager
Institutional Review Board
Engelmann 270
P. O. Box 413
Milwaukee, WI 53201-0413
(414) 229-3173 phone
(414) 229-6729 fax

New Study - Notice of IRB Expedited Approval

<http://www.irb.uwm.edu>
spadamid@uwm.edu

Date: December 14, 2018

To: Jennifer Doering, PhD
Dept: College of Nursing

Cc: David Dwyer

IRB#: 19.125
Title: Living with a Destination Therapy LVAD

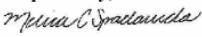
After review of your research protocol by the University of Wisconsin – Milwaukee Institutional Review Board, your protocol has been approved as minimal risk Expedited under **Category 6 and 7** as governed by 45 CFR 46.110. Your protocol has been granted approval to waive documentation of informed consent as governed by 45 CFR 46.117 (c).

This protocol has been approved on **December 14, 2018** for one year. IRB approval will expire on **December 13, 2019**. If you plan to continue any research related activities (e.g., enrollment of subjects, study interventions, data analysis, etc.) past the date of IRB expiration, a continuation for IRB approval must be filed by the submission deadline. If the study is closed or completed before the IRB expiration date, please notify the IRB by completing and submitting the Continuing Review form found in IRBManager.

Any proposed changes to the protocol must be reviewed by the IRB before implementation, unless the change is specifically necessary to eliminate apparent immediate hazards to the subjects. It is the principal investigator's responsibility to adhere to the policies and guidelines set forth by the UWM IRB, maintain proper documentation of study records and promptly report to the IRB any adverse events which require reporting. The principal investigator is also responsible for ensuring that all study staff receive appropriate training in the ethical guidelines of conducting human subjects research.

As Principal Investigator, it is your responsibility to adhere to UWM and UW System Policies, and any applicable state and federal laws governing activities which are independent of IRB review/approval (e.g., [FERPA](#), [Radiation Safety](#), [UWM Data Security](#), [UW System policy on Prizes, Awards and Gifts](#), state gambling laws, etc.). When conducting research at institutions outside of UWM, be sure to obtain permission and/or approval as required by their policies.

Contact the IRB office if you have any further questions. Thank you for your cooperation and best wishes for a successful project.

Respectfully,

Melissa C. Spadanuda
IRB Manager



Department of University Safety & Assurances

Leah Stoiber
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Amendment – Notice of IRB Expedited Approval

Date: January 31, 2019

To: Jennifer Doering, PhD
Dept: Nursing

CC: David Dwyer

IRB#: 19.125
Title: Living with a Destination Therapy LVAD

After review of your research protocol by the University of Wisconsin – Milwaukee Institutional Review Board, your protocol has received modification/amendment approval for:

- Adding and revising interview questions.

IRB approval will expire on **December 13, 2019**. If you plan to continue any research related activities (e.g., enrollment of subjects, study interventions, data analysis, etc.) past the date of IRB expiration, a Continuation for IRB Approval must be filed by the submission deadline. If the study is closed or completed before the IRB expiration date, please notify the IRB by completing and submitting the Continuing Review form in IRBManager.

Any proposed changes to the protocol must be reviewed by the IRB before implementation, unless the change is specifically necessary to eliminate apparent immediate hazards to the subjects. The principal investigator is responsible for adhering to the policies and guidelines set forth by the UWM IRB, maintaining proper documentation of study records and promptly reporting to the IRB any adverse events which require reporting. The principal investigator is also responsible for ensuring that all study staff receive appropriate training in the ethical guidelines of conducting human subjects research.

As Principal Investigator, it is also your responsibility to adhere to UWM and UW System Policies, and any applicable state and federal laws governing activities which are independent of IRB review/approval (e.g., [FERPA](#), [Radiation Safety](#), [UWM Data Security](#), [UW System policy on Prizes, Awards and Gifts](#), state gambling laws, etc.). When conducting research at institutions outside of UWM, be sure to obtain permission and/or approval as required by their policies.

Contact the IRB office if you have any further questions. Thank you for your cooperation, and best wishes for a successful project.

Respectfully,

Leah Stoiber
IRB Administrator



Department of University Safety & Assurances

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Continuing Review – Notice of IRB Expedited Approval

Date: December 10, 2019

To: Jennifer Doering, PhD
Dept: Nursing

CC: David Dwyer

IRB#: 19.125
Title: Living with a Destination Therapy LVAD

After review of your research protocol by the University of Wisconsin – Milwaukee Institutional Review Board, your protocol has been approved as minimal risk Expedited under **Category 6 and 7** as governed by 45 CFR 46.110.

This protocol has been approved on **December 10, 2019** for one year. IRB approval will expire on **December 9, 2020**. If you plan to continue any research related activities (e.g., enrollment of subjects, study interventions, data analysis, etc.) past the date of IRB expiration, a Continuation for IRB Approval must be filed by the submission deadline. If the study is closed or completed before the IRB expiration date, please notify the IRB by completing and submitting the Continuing Review form found in IRBManager.

Any proposed changes to the protocol must be reviewed by the IRB before implementation, unless the change is specifically necessary to eliminate apparent immediate hazards to the subjects. The principal investigator is responsible for adhering to the policies and guidelines set forth by the UWM IRB, maintaining proper documentation of study records, and promptly reporting to the IRB any adverse events which require reporting. The Principal Investigator is also responsible for ensuring that all study staff receive appropriate training in the ethical guidelines of conducting human subjects research.

As Principal Investigator, it is also your responsibility to adhere to UWM and UW System Policies, and any applicable state and federal laws governing activities which are independent of IRB review/approval (e.g., [FERPA](#), [Radiation Safety](#), [UWM Data Security](#), [UW System policy on Prizes, Awards and Gifts](#), state gambling laws, etc.). When conducting research at institutions outside of UWM, be sure to obtain permission and/or approval as required by their policies.

Contact the IRB office if you have any further questions. Thank you for your cooperation, and best wishes for a successful project.

Respectfully,

Leah Stoiber
IRB Administrator

Appendix D

Informed Consent Waiver

Study title	Living with a Destination Therapy LVAD
Researcher[s]	David Dwyer MSN, RN (PhD Candidate) dedwyer@uwm.edu (414) 436-5690 Jennifer Doering, PhD, RN (Student Advisor/Professor) doering@uwm.edu (414) 229-5146

I am inviting you to participate in a research study. Participation is completely voluntary. If you agree to participate now, you can always change your mind later. There are no negative consequences, no matter what you decide.

What is the purpose of this study?

I want to understand what it is like to live with a destination therapy left ventricular assist device (DT-LVAD).

What will I do?

While we know what life is like with some chronic illnesses, little is known about the challenges faced by people living with a destination therapy LVAD. I want to understand what it is like to live with a destination therapy LVAD in your own words. What we learn may help the health care team better care for people with a DT-LVAD.

Risks

Possible risks	How we're minimizing these risks
<ul style="list-style-type: none"> Breach of confidentiality (your data being seen by someone who shouldn't have access to it) Online data being hacked or intercepted: This is a risk you experience any time you provide information online. 	<ul style="list-style-type: none"> We're using a secure system to collect this data but we can't completely eliminate this risk. All identifying information (such as your name) is removed and replaced with an ID number after the interview. I will store all electronic data on a password-protected, encrypted computer. This includes all recorded interviews. I will store all paper data in a locked filing cabinet in a locked office. I will keep your identifying information separate from your research data, but we will be able to link it to you by using a study ID. We will destroy this link after we finish collecting and analyzing the data. Some questions may be personal or upsetting. You may choose to skip any questions that you wish not to answer. I will provide resources to you if you need to contact someone. These resources will include your personal physician or LVAD support network/group. I will be willing to contact the appropriate resources for you.

There may be risks that I am unaware of. Throughout the study, I will tell you if I learn anything that might affect your decision to participate.

Other Study Information

Possible benefits	<ul style="list-style-type: none"> Contribute to individual or personal understanding of what it means to live with a destination therapy LVAD. Contribute to the medical and nursing profession for better patient care for people with destination therapy LVADs. Possibly contribute to other health care professions understanding what it means to live with a destination therapy LVAD.
Estimated number of participants	Up to 40 participants are needed for this study.
How long will it take?	Each interview should take about 1 hour and 30 minutes
Costs	None
Compensation	To thank you for talking to us, you will receive a \$20 gift card.
Future research	All identifying information will be removed (de-identified), Interviews may be shared with other researchers. You won't be told specific details about these future research studies.
Recordings / Photographs	I will record your voice. The recordings will be used for transcription, data analysis, and coding. This helps me to hear everything you say.
Funding source	None.

Confidentiality and Data Security

I will collect the following identifying information for the research: Your name and email address.

This information is necessary because I may want to share my findings with you at a later date in order to verify that what I am discovering actually represents your experience.

Where will data be stored?	On a password protected computer and locked filing cabinet.
How long will it be kept?	Interviews (data) will be kept for 5 years after the completion of this study.

Who can see my data?	Why?	Type of data
The researchers	To analyze the data and conduct the study	Identifiable: your name, phone number, and email for contact purposes. Coded: names removed and labeled with a study ID (recordings, demographic data, data transcripts).
The IRB (Institutional Review Board) at UWM The Office for Human Research Protections (OHRP) or other federal agencies	To ensure I am following laws and ethical guidelines	Identifiable: your name, phone number, and email for contact purposes. Coded: names removed and labeled with a study ID (recordings, demographic data, data transcripts).

Anyone (public)	If I share my findings in publications or presentations	De-identified (no names, birthdate, address, etc.) If I quote you, I will use a pseudonym (fake name)
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Contact information:

For questions about the research	David Dwyer, MSN, RN	(414) 436-5690 Email: dedwyer@uwm.edu
For questions about your rights as a research participant	IRB (Institutional Review Board; provides ethics oversight)	414-229-3173 / irbinfo@uwm.edu
For complaints or problems	David Dwyer, MSN, RN	(414) 436-5690 dedwyer@uwm.edu
	Jennifer Doering, PhD, RN	(414) 229-5098 Email: doering@uwm.edu
	IRB	(414) 229-3173 irbinfo@uwm.edu

If you agree to participate...

The researcher will ask you these questions after explaining the study.

- Have you had all of your questions answered?
- Would you like to participate in the study?
- Remember, **you can skip any question that you don't want to answer** and can stop participating or withdraw from the study at any time.

Name of Participant (print)

Date/Time

Name of Researcher obtaining consent (print)

Signature of Researcher obtaining consent

Date/Time

Appendix E

Recruitment Flyer

Life with an LVAD

I want to hear about your experience with an LVAD.

“Have
your
say”

What: I am a nurse interested in your destination therapy LVAD experience. I want to hear what you have to say.

Why: We know an LVAD can change a person’s life. Hearing about your unique experience living with a DT-LVAD will help us care for others with an LVAD.

How: To join in this study, you must:

- Be 18 years of age or older
- Have a destination therapy left ventricular assist device (DT-LVAD).

What happens if I join?

Meet with me *in person or online* (using your computer or phone) to talk about your experience living with a DT-LVAD.

We will meet at a convenient time and place for you.

The meeting will last about 60-90 minutes.

To thank you for sharing your thoughts, you will receive a \$20 gift card.

Interested? It is easy to join.

Call me at: 414-436-5690

Email me: dedwyer@uwm.edu or LVADstudy@gmail.com



Researcher: David Dwyer, MSN, RN (PhD Candidate) 414-436-5690
University of Wisconsin-Milwaukee, College of Nursing

Appendix F

Confirmability Study

Confirmability Study Summary

A CONCEPTUAL DEFINITION OF QUALITY OF LIFE FOR PEOPLE LIVING WITH AN IMPLANTED, DESTINATION THERAPY LEFT VENTRICULAR ASSIST DEVICE

I completed an examination of this grounded theory study on February 18, 2020, to review the process that uncovered the concepts and theories presented in this study. I had access to all original study documents, including interview transcripts, coding documents and researcher notes, and traced the process of discovery from the interview through the coding process to emergence of core concepts. Questions were answered by the researcher as needed about decision processes that included field notes, memos and written findings.

The discovery of "Normalizing" as the basic social process is supported by the emergence of the study's core categories and can be traced to the original data. Examples of categories that were relevant but did not reach the strength needed for inclusion of a core category were found and reviewed. There is a visible audit trail showing core category and concept development that is directly from the experiences of the participants. There does not appear to be mixing of methods or compromises made to the grounded theory method or procedures.

It is my opinion, based on data reviewed, that the study followed a planned analytical process and was completed using a high degree of methodological rigor that resulted in a conceptual definition that emerged from the grounded theory.

Sincerely,

Donald Miller

Donald Miller, MSN, RN

March 1, 2020

Curriculum Vitae

David Edward Dwyer

Academic Degrees

- 2020 University of Wisconsin-Milwaukee
Doctor of Philosophy in Nursing
Dissertation: *A Conceptual Definition of Quality of Life for People Living with an Implanted, Destination Therapy Left Ventricular Assist Device*
- 2008 Marquette University, Milwaukee, Wisconsin
Master of Science in Nursing
Emphasis: Strategic Health Systems Leadership
- 1997 Marquette University, Milwaukee, Wisconsin
Bachelor of Science in Nursing
- 1989 University of Wisconsin-Oshkosh
Bachelor of Science
Major: Political Science

Professional Nursing Experience

- 2016-Present Clinical Associate Professor, School of Nursing
University of Wisconsin-Madison
- 2015-2016 Clinical Assistant Professor, School of Nursing
University of Wisconsin-Madison
- 2008-2015 Nurse Manager, Cardiac and Thoracic Surgery/Heart and Lung Transplant
University of Wisconsin Hospital and Clinics, Madison, WI
- 2007-2008 Nurse Manager, Cardiology and Cardiac ICU (Interim)
University of Wisconsin Hospital and Clinics, Madison, WI
- 2005-2006 Nurse Manager, Burn Unit (Interim)
University of Wisconsin Hospital and Clinics, Madison, WI
- 2004-2009 Nurse Manager, Heart and Vascular Progressive Care
University of Wisconsin Hospital and Clinics, Madison, WI

- 2001-2004 Nursing Supervisor/House Supervisor
University of Wisconsin Hospital and Clinics, Madison, WI
- 1998-2001 Nurse Clinician, Intensive Care, Intermediate Care, and General Care Units
University of Wisconsin Hospital and Clinics, Madison, WI
- 1997-1999 District Nurse, Verona Area School District, Verona, WI

Nursing Licenses and Certifications

- 2010-Present Nurse Executive, American Nurses Credentialing Center
- 1997-Present Registered Nurse, State of Wisconsin

Abstracts/Publications (Peer Reviewed)

- Dwyer, D. E., Doering, J., Casida, J. (2019). A Conceptual Definition of Quality of Life for Left Ventricular Assist Device Destination Therapy, Preliminary Results. *ASAIO Journal*, 65(S1), 110.
- Dwyer, D. E., & Casida, J., (2016). Implantation of a Left Ventricular Assist Device (LVAD) from the Recipient's Perspective: Then It Becomes Real. *Heart & Lung: The Journal of Acute and Critical Care*. 35(4S), 344-345.
- Dwyer, D., Casida, J. (2015). Discovery of the importance of the quality of life among ventricular assist device (VAD) recipients from their perspective. *Heart & Lung: The Journal of Acute and Critical Care*. 44(6), 550-551.
- Abshire, M., Dwyer, D. (2015). *Need for Palliative Care for VAD Patients Continues to Grow*. (44th Ed., pp. 19-20). AAHFN Connection.

National Podium Presentations

- Dwyer, D. E., (2019). A Conceptual Definition of Quality of Life for Left Ventricular Assist Device Destination Therapy, Preliminary Results. *ASAIO National Conference, American Society of Artificial Internal Organs. San Francisco, CA.*
- Dwyer, D. E., & Casida, J., (2016). Implantation of a Left Ventricular Assist Device (LVAD) from the Recipient's Perspective: Then It Becomes Real., *National Conference, American Association of Heart Failure Nurses, Scottsdale, AZ.*

Poster Presentations

- Solheim, K., Dwyer, D., Norsby, H., Pavek, K. (2016). Transitioning to a Concept-Based Curriculum; Insights and Innovation from the University of Wisconsin-Madison. *American Association of Colleges of Nursing. Atlanta, GA.*
- Dwyer, D., Casida, J. (2015). Discovery of the importance of the quality of life among ventricular assist device (VAD) recipients from their perspective. *National Conference, American Association of Heart Failure Nurses. New Orleans, LA.*
- LaFrancois, K., Kunde, A., Klinkner, G., Dwyer, D., Murray, M. (2012). Postop Cardiac Surgery Blood Sugar Control. *University of Wisconsin Health Sciences Research Fair. Madison, WI.*

Teaching Awards and Honors

- 2017-2020 Invited Presenter, Successful Online Discussions, UW Academic Technology
2017 Honored Instructor, University Housing, University of Wisconsin-Madison
2016 Graduate Student Scholarship, American Assembly for Men in Nursing

Teaching Experience

- NUR 105, Health Care Systems, 9 semesters
NUR 306, Transitions—Professional and Personal, 7 semesters
NUR 313, Foundations of Nursing Practice, 1 semester
NUR 446, Nursing Research and Evidence Based Practice, 4 semesters
NUR 219, Clinical Nursing I, 1 semester
NUR 301, Health History and Patient Assessment, 1 semester
NUR 319, Nursing Care in the Inpatient Setting, 2 semesters
NUR 422, Advanced Concepts of Nursing Practice, 1 semester
NUR 299, Directed Study/Independent Study, 3 semesters
EDPSY 125, Wisconsin Experience Seminar, 1 semester

Service (University of Wisconsin School of Nursing)

- 2019-Present BSN@Home Program Coordinator
2019-Present BSN@Home Statewide Steering Committee
2016-2018 Concept Based Curriculum Task Force
2016-2018 College of Nursing Admissions and Progression Committee
2017-2018 Supervisor of Instructional Academic Staff/Clinical Faculty
2016-2017 Faculty Workload Policy Committee
2015-2016 Accelerated Program Development Task Force

Committee Memberships

American Association of Heart Failure Nurses
2014-2018 Research Committee, Member

Council for the Advancement of Nursing Science
2015-2017 Operating Guidelines, Policies and Procedures Committee, Member

Midwest Nursing Research Society
2013-2016 Research Interest Group, Acute and Critical Care Across the Lifespan, Member
2014-2015 Research Interest Group, Acute and Critical Care Across the Lifespan, Chair
2012-2014 Communications Committee, Member

Professional Memberships

2019-Present American Society for Artificial Internal Organs
2013-Present American Assembly for Men in Nursing
1997-Present Sigma Theta Tau International
2015-2017 Council for the Advancement of Nursing Science
2012-2016 Midwest Nursing Research Society