DNP Portfolio Table of Contents

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Curriculum Vitae

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Heart Failure, Cardiac Transplantation, Mechanical Circulatory Support Devices, Patient and Family Education, Staff Development, Palliative Care, Multidisciplinary Care, Self-Care

Licensure & Certifications:
Oregon State Board of Nursing, 2008 – Current
Acute Care Nurse Practitioner, Prescriptive Privileges,
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The University of the State of New York Education Department, 2005 – Current
Registered Professional Nurse, License # 562194
American Association of Critical Care Nurses Certification Corporation, 2006 – Current
Certified Critical Care Nurse, CCRN # 0689398
American Heart Association
Basic Life Support for Healthcare Providers
Advanced Cardiac Life Support
American Burn Association
Advanced Burn Life Support
Society of Trauma Nurses
Advanced Trauma Care for Nurses

Education:
DNP, Nursing, Oregon Health & Science University School of Nursing, anticipated June 2011
MS, Acute Care Nurse Practitioner, University of Rochester School of Nursing, May 2008
BS, Nursing, University of Colorado at Colorado Springs, May 2005
Nursing Pre-requisites, Scottsdale Community College, May 2002

Professional Experience:

June 2008 – Current
Mechanical Circulatory Support Program Manager
Acute Care Nurse Practitioner, Instructor
Oregon Health & Science University, Portland, Oregon
Department of Cardiovascular Services

March 2011 – Current
Ventricular Assist Device Disease-Specific Care Reviewer
Advanced Disease-Specific Care Certification Division
Joint Commission, Chicago, Illinois

August 2007 – May 13, 2008
Nurse Leader
Surgical Intensive & Intermediate Care Units
University of Rochester Medical Center
Strong Memorial Hospital, Rochester, New York

July 11, 2005 – August 2007
Staff Nurse
Kessler Family Burn & Trauma Intensive Care Unit
University of Rochester Medical Center
Strong Memorial Hospital, Rochester, New York

August 29, 2004 – May 22, 2005
Student Assistant
University of Colorado at Colorado Springs, Colorado Springs, Colorado

Abstracts, Posters, Publications:

F. McNeil, J. Gelow, J. Mudd, E. Adler, H. Song, A. Kim. (2011). Limited correlation between cardiac output and displayed device flow in patients with heartmate II LVAS. The Journal of Heart and Lung Transplant, *30(4S),* p. S163.

K. Song, B. Diggs, **F. McNeil**, K. Caddell, M. Slater, F. Tibayan, S. Guyton, E. Adler, A. Kim. (2010). Impact of ventricular assist device (VAD) implantation on clinical and economic outcomes of heart transplantation (HT) in the United States from 2001-2006. *29(2S),* p. S125.

J. Richardson, L. Staul, J. Cloud, K. Goodbole, V. Gowan, T. Loudon, K. Lum, **F. McNeil**, C. Myers, S. Norman, C. Perez. Supporting professional development throughout a nursing career. National Teaching Institute, Washington, DC. May, 2010.

McNeil, F.M. (2008) Joint commission visits the mechanical circulatory support program. *Nursing News to Peruse, December,* pg. 4. Retrieved December 3, 2008, from www.ohsu.edu.

Research Projects:

IRB # 6873: Hemodynamic Assessment of Continuous Flow Ventricular Assist Devices
IRB # 7165: Atrial and Ventricular Arrhythmias after Left Ventricular Assist Device Therapy vs. Valvular or Bypass Surgery
IRB # 7146: Economic, Clinical, and Humanistic Outcomes in Patients Implanted with HM II LVAS: A Single Center Experience
IRB # 6941: Biventricular Pacing in LVAD Patients
IRB # 6903: HeartWare Ventricular Assist System
IRB #: 6827 Altered Thromboresistance in the Endocardium of the Failing Heart
IRB # 6714: Caregiver Burden in Post-Ventricular Assist Device Patients
IRB # 2598: InterAgency Registry for Mechanically Assisted Circulatory Support (INTERMACS)

Professional Presentations

June 2011, Patient & Family Education and Assessing Patients with Non-Pulsatile Flow, American Association of Heart Failure Nurses, Seattle, Washington.
March 2011, Community Outreach, The Shared Care Concept, Thoratec Destination Life User's Meeting, Orlando. Florida.
January 2011, Mechanical Circulatory Support in the Community, State of Jefferson County EMS Conference, Medford, Oregon.
December 2010, Mechanical Circulatory Support in the Community, Multnomah County EMS Education Series, Portland. Oregon.
October 2010, Building a Financially Sustainable VAD Program, Thoratec Corporation National Economic Summit, Dallas, TX.
January 2010, Introduction to HeartMate II LVAD, Oregon Health & Science University, Cardiac Surgical ICU & Cardiac & Vascular Progressive Care Unit, Portland, Oregon.
November 2009, Introduction to HeartMate II, Crestview Skilled Nursing Facility, Portland, OR.
November 2009, Rapid Response & VADs, Oregon Health & Science University, Cardiac & Surgical ICU, Portland, Oregon.
October 2009, Rapid Response & VADs, Oregon Health & Science University, Cardiac & Surgical ICU, Portland, Oregon.
October 2009, HeartMate II Clinical Operation & Patient Management, Oregon Health & Science University, Cardiac & Vascular Progressive Care Unit, Portland, Oregon.
July 2009, TLC-II VAD Operation & Patient Management, Crestview Skilled Nursing Facility, Portland, OR.
June 2009, HeartMate II Clinical Operation & Patient Management, Oregon Health & Science University, Cardiac & Vascular Progressive Care Unit & Cardiac Surgical ICU
January 2009, HeartMate XVE Outpatient Emergency Response, Tuality Cardiac Rehab, Hillsboro, OR.
Spring 2009, OHSU MCS Program & VAD Theory, Cardiothoracic Surgery Education Day, Oregon Health & Science University, Portland, Oregon.
Fall 2008, HeartMate XVE Emergency Response, Tillamook County General Hospital, Tillamook, OR.
Fall 2008, HeartMate XVE Clinical Operation & Patient Management, Oregon Health & Science University, Portland, Oregon.

Fall 2008, Thoratec PVAD/IVAD Clinical Operation & Patient Management, Oregon Health & Science University, Portland, Oregon.
August 2008, Thoratec BiVAD Heart Series, Television Interview, NBC Medford Affiliate
Summer 2008, VAD as a Bridge-to-Transplant, Oregon Health & Science University, Portland, Oregon.
Fall 2007, Outcomes Management Project: Identification of Sepsis, University of Rochester, Rochester, New York.
Fall 2007, Bioethical Decision Making: A Case Study, University of Rochester, Rochester, New York.
Spring 2007, Policy Implementation: Organ Donation for the Non-Resident Citizen, University of Rochester, Rochester, New York.

Honors & Awards:
2010, Advanced Practice Nurse of the Year, Oregon Health & Science University
2008-2011, Nurse Faculty Loan Program, Oregon Health & Science University
2008-2011, Nurse Faculty Traineeship Grant, Oregon Health & Science University
2008-Current, Faculty Appointment, Oregon Health & Science University School of Nursing
2006, Friends of Strong Educational Scholar
2005, Closing Response Convocation Speaker, University of Colorado at Colorado Springs
2002-2004, Chancellors Scholar, University of Colorado at Colorado Springs
2003-2005, Memorial Hospital Nursing Scholar
2002-2003, Alexander Foundation Scholar

Professional Organizations:
2011-Current, American Heart Association
2008-Current, International Society for Heart & Lung Transplantation
2005-Current, American Association of Critical Care Nurses
2008-Current, Greater Portland Chapter, American Association of Critical Care Nurses
2008-Current, American Heart Association, Heart Walk Team Captain

Hospital Committee Service:
Advanced Practice Nursing Council
Cardiac Best Practice
Coordinating Council
Heart Failure, VAD, & Transplant Selection Committee
Heart Failure Best Practice
Advanced Heart Failure & Cardiac Transplant Program Review Committee

DNP Portfolio Executive Summary

Frederick M. McNeil, MS, ACNP, CCRN
Doctor of Nursing Practice Candidate, OHSU School of Nursing
Instructor, Division of Cardiovascular Services, OHSU Healthcare

May 31, 2011

The Doctor of Nursing Practice (DNP) program at Oregon Health & Science University (OHSU) prepares nurses to practice at the highest level of nursing practice. There are three major program competencies that are highlighted throughout my professional portfolio:

1) Practice within an advanced-practice nursing specialty in a professional, evidence-based, skilled and ethical manner
2) Influence health and health outcomes of individuals, groups, and populations through clinical inquiry
3) Influence health policy and systems of healthcare in the local, regional, state, and international forums.

I currently practice as an Acute Care Nurse Practitioner at OHSU caring for patients and their families who are implanted with mechanical circulatory support devices as a bridge-to-transplantation, bridge-to-recovery, or as destination therapy. I entered the DNP program in the summer of 2009 as a post-masters graduate. I completed elective course work in nursing education in efforts to increase my knowledge and awareness of nursing education issues in today's rapidly changing healthcare education environment.

Within the major components of my DNP portfolio you will find the clinical inquiry project titled "Economic, Clinical and Humanistic Outcomes in Patients Implanted with the HeartMate II LVAS: A Single Center Experience". The goal of this project was to independently conduct a clinical inquiry project within my advanced practice specialty area. In the final report you will find the results, discussion, and conclusions associated with this work. You will also find several exemplars of scholarly work that include case reports of patients that I cared for during my clinical residency and several examples of manuscripts prepared for courses such as ethics in clinical practice, equities in health and healthcare, and nursing education.

The DNP program at OHSU has provided the platform to gain a thorough understanding of complex organizational structures and systems while simultaneously providing a venue for enhanced clinical practice within my specialty area during the clinical residency. I have developed a comprehensive understanding of healthcare economics and disparities that affect the advanced heart failure population at OHSU and beyond. I have been able to present and publish abstracts at the national and international level. Additionally, I have gained an advanced set of leadership skills that has served me well as I have been an invited speaker to local and national venues.

My strengths as a DNP prepared nurse have also put OHSU's Advanced Heart Failure and Cardiac Transplant program on the national map with specific regard to the Mechanical Circulatory Support program. We will continue to grow as a team and I look forward to continued professional growth in academics, education, leadership and practice.

Economic, Clinical, and Humanistic Outcomes in Patients Implanted with the HeartMate II LVAS: A Single Center Experience

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A document submitted in partial fulfillment

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Description & Significance of the Clinical Problem

Heart failure (HF) is a complex clinical syndrome rather than a disease and can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood (Hunt et al., 2005; Barkley, 2008). Although the cardinal manifestations of HF are dyspnea and fatigue that limit exercise tolerance, and fluid retention that leads to pulmonary congestion and peripheral edema (Hunt et al., 2005), physical manifestations of HF are heterogeneous. For example, patients with dyspnea and fatigue may not present with signs and symptoms of fluid overload and pulmonary congestion and those with fluid overload may not present with fatigue and dyspnea (Hunt et al., 2005).

According to the American Heart Association (AHA), HF affects nearly 6 million Americans with approximately 550,000 new cases annually. Direct and indirect costs associated with HF and the treatments thereof are approximately $40 billion dollars (Lloyd, et al., 2010). The incidence of HF approaches 10 per 1000 population after the age of 65 and at age 40, the lifetime risk of developing HF is 1 in 5. At 80 years of age, remaining lifetime risk for developing HF remains at 20%, even in the face of a much shorter life expectancy (Lloyd, et al., 2010). 250,000 patients die each year as a result of HF and it is estimated that between 300,000 and 800,000 patients have advanced HF, as defined by the American College of Cardiology (ACC) and AHA (Russell, Miller, and Pagani, (2008). Table 1 contains data on incidence, prevalence, mortality, hospital discharges, and costs for HF.

HF is classified into four stages as depicted in Figure 1. The stages of HF highlight the progressive nature of the worsening syndrome. For example, Stage A places the patient at high risk for HF without structural heart disease or symptoms of heart failure (Hunt et al., 2005).

Stage B designates patients with structural heart disease but without prior or current signs or symptoms of HF. Stage C includes patients with structural heart disease and prior or current symptoms of HF (Hunt et al., 2005). Stage D describes the patient with refractory HF requiring specialized interventions such as permanent mechanical circulatory support devices, chronic inotropic agents, heart transplantation, experimental surgical or medical interventions, and/or end-of-life care (Hunt et al., 2005). This staging guideline is endorsed by the ACC and AHA and is often used in conjunction with the New York Heart Association (NYHA) Functional Classification system, which is an assessment of current functional limitations secondary to HF symptoms.

Patients with advanced HF can be in either stage C or D. Patients often move back and forth between these two stages as HF progresses. This patient population is a high consumer of healthcare resources often requiring complex chronic disease management with multiple multidisciplinary teams such as the Advanced HF and Transplant Program at Oregon Health & Science University (OHSU). As discussed above, mechanical assistance and cardiac transplant are viable treatment options for eligible end-stage HF patients.

Ventricular assist devices (VAD) have three major indications: bridge-to-transplantation (BTT); destination therapy (DT); and bridge-to-recovery or determination. For patients who are not candidates for cardiac transplantation the term destination therapy has been coined (Rose et al., 2001; Slaughter et al., 2010). Investigators for the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial concluded that the use of a left ventricular assist device in patients with advanced heart failure resulted in a clinically meaningful survival benefit and improved quality of life (QOL) (Rose et al., 2001). The device used in the REMATCH trail was the HeartMate E**x**tended Lead **V**ented **E**lectric

(XVE) (see Figure 2). Since the REMATCH trial the HeartMate II left ventricular assist system (LVAS) has also been approved by the Food and Drug Administration (FDA) for both BTT and DT see (Figure 3). Both of these devices are manufactured and marketed by Thoratec Corporation in Pleasanton, California.

The HeartMate II LVAS has three major components: 1) an implanted blood pump that is connected to the left ventricular apex with an outflow graft sewn to the ascending aorta and a percutaneous electric lead that is tunneled to an exit site in the right upper quadrant of the abdomen; 2) system controller; and 3) power sources either 14 volt lithium ion batteries or alternating current (AC) electric power from a wall outlet (Thoratec Corporation, 2010). The HeartMate II LVAS is an axial flow blood pump design in which there is only one moving part, the internal rotor. An electromagnetic motor surrounds the rotor and allows for greater durability, smaller implant size and decreased adverse event rates (Slaughter et al., 2010).

Relative indications for VAD implantation include but are not limited to: assessment of severity of illness and ability to undergo a successful implant procedure, absence of end-organ dysfunction as evidenced by serum creatinine <2.5 mg/dl, INR <1.2, pre-albumin >15 mg/dl, and total bilirubin < 2.5 mg/dl, anticipated survival benefit in patients with NYHA functional class III & IV heart failure symptoms who have failed to response to optimal medical therapy during the last 45 of the 60 days preceding implantation, objective functional limitations with a peak oxygen consumptions of $\leq$ 14 ml/kg/min, use of inotropic agents, being evaluated for heart transplantation or were not selected as candidates (Slaughter et al., 2010; Joint Commission, 2008). Absolute indications for implantation are based on the treatment strategies for example BTT or DT. The majority of the above mentioned indications are based on recommended guidelines for the care of patients implanted with assist devices.

Currently, OHSU is the only Joint Commission DT certified program in the state of Oregon. OHSU received its initial certification for DT in November of 2008 and has completed one intra-cycle review. The next site visit is expected in the fall of 2010. This certification process is important because it is directly linked to Centers for Medicare and Medicaid Services (CMS) reimbursement. Without certification implanting centers would not be reimbursed for the procedure or hospitalization by CMS.

An additional requirement of the Joint Commission certification is participation in a nationally audited registry and program performance improvement initiatives. The most widely used registry in the field of mechanical circulatory support is known as the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS). This registry was devised as a joint effort for the National Heart, Lung, and Blood Institute, the Centers for Medicare and Medicaid Services (CMS), FDA, clinicians, scientist, and industry representatives in conjunction with the University of Alabama at Birmingham, and the United Network for Organ Sharing (INTERMACS, 2010).

All patients implanted with FDA approved devices are consented for the INTERMACS registry so that clinical outcomes, adverse events, and duration of support can be tracked at the national level. This allows investigators to query a larger patient sample rather than just their own specific center. Additionally, these data are used in post market research efforts and for the development of clinical practice guidelines and patient management strategies. Participating centers are able to query the database for center specific outcomes. In the near future, site-specific reports may be available for performance improvement initiatives and program reporting purposes.

Advanced practice nurses (APNs) are capable of managing patients with HF and VADs. The Doctor of Nursing Practice (DNP) prepared nurse will be well positioned to develop disease management programs as well as assist in the clinical management of patients with various disease processes such as advanced HF. The Advanced HF and Transplant Program at OHSU currently employs three VAD coordinators. One of these coordinators is an APN who has been trained as an Acute Care Nurse Practitioner (ACNP). The ACNP role is designed to assist with complex care coordination across the acute care hospital setting. In addition, program performance and quality improvement initiatives are also imperative to this role. With DNP education and training the ACNP will be able to conduct scholarly clinical inquiry and program improvement initiatives at the local, state, and national level.

Clinical outcomes and QOL have been measured in various VAD studies. However, the QOL and the financial impact of VAD support have not been addressed widely in the literature or at OHSU. The purpose of this clinical inquiry project (CIP) is to assess how the implantation of a VAD influences economic, clinical and humanistic outcomes in persons with advanced HF at OHSU. OHSU gained access to the HeartMate II LVAS in June of 2009. From June 2009 through current the VAD program has implanted approximately 50 HeartMate II LVAS. The HeartMate II program as well as various other performance improvement initiatives has positively influenced the economic standing of the current VAD program at OHSU. It is suspected that new technology can greatly impact the economic viability of a program. This project provides a venue to test this hypothesis. This project will use the economic, clinical and humanistic (ECHO) model to guide clinical inquiry and performance improvement (Gunter, 1999). The economic, clinical and humanistic questions to be answered in the project are: 1) what are the hospital costs associated with patients implanted with the HeartMate II LVAS at

OHSU, 2) what clinical variables play a role in the increased cost of the implant admission, and 3) what is the QOL of patients implanted with HeartMate II LVAS at OHSU.

Synthesis of Evidence

There are a handful of papers published regarding economic, clinical and humanistic outcomes in the setting of VAD therapy. In the following section, a critical synthesis of literature is presented that supports this CIP. For example: what QOL assessments are used and reported in the literature; what cost metrics and analysis are presented and discussed for financial consideration, policy development, program implementation or evaluation. Last, the knowledge gaps and recommendations for improvement will be explored.

Economic Evidence

There are very few reports in the literature that address the impact of economics on programs that are implanting continuous flow devices such as the HeartMate II LVAS. According to cost data provided by Thoratec's North American Price List, the cost of the HeartMate II LVAS implant kit is approximately $87,500.00 and associated patient support equipment is $12,325.00 (Thoratec, 2009, p. 4). OHSU started the HeartMate II program in June of 2009 and has implanted 38 devices as of July 2010. The total estimated programmatic impact for the implant and associated equipment cost for one year is approximately $3.8 million. This cost does not include operational cost, capital equipment needs, or individualized patient care cost due to complications or additional patient care needs. This is of significant importance because local healthcare systems turn to OHSU for guidance and assistance with regard to starting VAD programs, such as, the Portland Providence System, Good Samaritan (Corvallis, Oregon), and Kaiser Permanente (Clackamas County Oregon).

Hernandez et al., 2008, completed a retrospective analysis of inpatient claims from CMS from 2000-2006. There were two patient groupings in this analysis, the primary therapy device group and the postcardiotomy device therapy group. Survival for the primary and postcardiotomy group at one year was 52 percent and 31 percent respectively (Hernandez et al., 2008). Many of these patients were also discharged from the hospital with an implanted device and nearly one half of the patients were readmitted to the hospital in both groupings (Hernandez et al., 2008). The mean one-year Medicare payments for inpatient care in 2000-2005 were $178,714 (standard deviation (SD) $142, 549) in the primary device group and $111,769 (SD $95, 413) in the postcardiotomy device group. The specific device types were not discussed in this manuscript because the authors used "International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes" to pull CMS claims (Hernandez et al., 2008, p. 2399). However, device specific cost should be considered when performing single center program evaluations such as the one being proposed for this project. This is important because there is a wide range for device costs with in a single company, for example, $12,000 to $87,500.00 (Thoratec, 2009).

Sharple and colleagues conducted a program evaluation on 70 VAD implants and 71 inotrope dependent transplant candidates at several United Kingdom hospital systems for the BTT patient population. The devices used in this analysis were the HeartMate vented electric (VE), Thoratec paracorporeal and implantable VAD (PVAD/IVAD), Jarvik 2000, and the HeartMate II LVAS (Sharple et al., 2006). However, there was only one patient implanted with the HeartMate II LVAS, therefore these financial metrics may not be directly applicable to this project. The researchers also used the EQ-5D to measure patient health status within one month of implant and then every three months thereafter. Cost for intensive care unit (ICU), cardiac

step-down, implant device, heart transplant procedure were all collected and reported. The mean quality-adjusted life years (QALY) for a VAD patient were 3.27 at a lifetime cost of $316,078 United States (US) dollars and £173,841 Euro dollars (Sharple et al., 2006). The majority of these costs were related to the device implant procedure, initial hospital stay in the ICU and the cardiac step-down unit. The inotrope dependent group QALY was 4.99 at a lifetime cost of $238,011 US dollars (Sharples et al., 2006). The incremental cost-effectiveness ratios (ICERs) were also reported. For example, the mean ICERs for the VAD vs. inotrope-dependent group was -£37,160 (-$67,564 US dollars) (SD £22,080). Negative values indicate that the inotrope-dependent group is cheaper and has greater survival than the VAD group. However, when comparing VAD vs. worst-case scenario, the VAD costs are more favorable. Based on these findings the VAD group had significant QALY over those in the inotrope dependent group, however, the VAD was considered expensive for the risks associated with the implant procedure. This analysis was a mixture of first generation and second-generation devices. This study should be replicated using one specific device such as the HeartMate II LVAS in a single center or integrated health system. A targeted program evaluation such as this will be very beneficial to start-up programs in the near future.

The healthcare climate is rapidly changing with regard to measuring high quality economic and clinical outcomes. OHSU has targeted ICU LOS as a performance measure for the VAD DT Disease Specific Care Certification for the Joint Commission. This project will allow the DNP student and colleagues to evaluate a rejuvenated program. An additional hypothesis for the project includes: does increasing the number of patients who are discharged on durable devices such as the HeartMate II, in a safe, organized and timely manner decrease the LOS and economic burden associated with VAD therapy at OHSU?

Anecdotally we have seen a reduction in LOS at OHSU, however, it has yet to be demonstrated that the reduction in LOS has an economic impact. The OHSU program needs focused attention on economic, clinical, and humanistic outcomes to determine if program growth should continue at its current rate. However attention to readmission rates is also warranted. The previous generations of VAD devices made it difficult to discharge patients safely, thus with new, smaller, and reliable technology such as the HeartMate II LVAS discharging patients is more feasible and safer. Additionally, this allows the patient and family to be at home while waiting for transplant where they can participate in cardiac rehabilitation, physical and occupational therapy, and family life.

Clinical Evidence

There are several types of FDA approved VADs for commercial use for BTT and DT. For example, the HeartMate XVE and HeartMate II LVAS (Thoratec Corporation, 2010). The HeartMate XVE is considered a first generation device and has a pulsatile mechanism of action while the HeartMate II LVAS is axial flow and runs continuously over the cardiac cycle. The HeartMate II LVAS is considered a second-generation device and was approved for BTT in 2008 and for DT in 2009 (Thoratec Corporation, 2010). For the purposes of this CIP the economic, clinical and humanistic evidence for the HeartMate XVE and HeartMate II will be presented.

Several trails have documented that the HeartMate II LVAS out performs the HeartMate XVE with increased patient support times. During the REMATCH trial the survival at one year for patients implanted with the HeartMate XVE compared to the optimal medical therapy group was 52 percent and 25 percent respectively (Rose et al., 2001). Adverse events related to the HeartMate XVE pump include bleeding, infection, and device failure (Rose et al., 2001). The

HeartMate XVE has an internal pumping chamber and motor system that is prone to failure after prolonged use. The pump failure is largely related to bearing wear and degradation. However, no HeartMate XVE system failed by 12 months, but the probability of device failure was 35 percent at 24 months (Rose et al., 2001). During the REMATCH trail the device was replaced in 10 patients (Rose et al., 2001). In 2007, Lietz and colleagues reported that the median time on the first HeartMate XVE pump was 18.6 months with a range of 1 day to 3.6 years. They also reported that during follow up 69 patients (24.6%) either required device replacement or died as a result of pump failure or associated complications (Lietz et al., 2007).

Between January 2003 and December 2004, 42 consecutive patients were implanted with the Thoratec HeartMate XVE LVAS and were evaluated at four high volume centers based on data from the Thoratec DT registry. The data from these 42 patients was then compared to the REMATCH trial data. This evaluation is known as the post-REMATCH trial.

In the post-REMATCH trial researchers found that DT patients had a 40% lower rate of death (0.49 vs. 0.84 deaths per patient year) than those patients originally studied in the REMATCH trial. The mean duration of support was approximately 232 days with a range of 15-699 days (Long et al., 2005). The researchers concluded that although this was not a randomized clinical trial, it did show that higher volume implant centers have a reduced risk for adverse events and death during the immediate post operative period. A “high volume” center was defined as a center that implanted eight to 18 devices (Long et al., 2005). This is likely due to increased experience with patient selection, pre-implant optimization of patient hemodynamics, implantation techniques, and post-operative management. The survival at 1 year for both the DT and REMATCH group was 60 percent and 52 percent respectively (Long et al., 2005). A similar phenomenon occurred with cardiac transplantation in centers that had a greater volume of cases

and better-reported clinical outcomes. This pattern has led to regionalized transplant centers such as OHSU. A similar pattern is already occurring with VAD therapies and will likely be solidified by initiatives associated with healthcare reform and outcomes reporting.

In 2009, Slaughter et al., published a randomized comparison of the HeartMate II LVAS and the HeartMate XVE. In this trial 200 patients were randomized in a 2:1 ratio to undergo implantation of a continuous flow device (HeartMate II LVAS) or a pulsatile device (the HeartMate XVE). In this trial, adverse events and survival were better in the continuous flow LVAS group. The primary composite end-point was achieved in more patients with continuous flow devices than with pulsatile-flow devices (62 of 134 [46%] vs. 7 of 66 [11%]; p=<0.001; hazard ratio, 0.38; 95% CI, 0.27-0.54; p=<0.001), and patients with continuous flow devices had superior actuarial survival rates at 2 years (58% vs. 24%. p=0.008). Additionally, the QOL was significantly better in the continuous flow group. In 2007, Frazier et al., reported their single center experience with the first 43 HeartMate II LVAS patients and reported that the average duration of support was 258 days with a cumulative duration of support of more than 31 patient years. Frazier and colleagues report their one-year survival as 80 percent.

Slaughter, et al., assessed QOL with the Minnesota Living with Heart Failure Questionnaire (MLHFQ) and the Kansas City Cardiomyopathy Questionnaire (KCCQ). QOL assessments were obtained at baseline, three months, 12 months, and 24 months and will be discussed in later sections of this text. OHSU does not currently measure QOL due to availability of resources. Therefore, this project will provide a venue for such measurements.

In a prospective multicenter trial, 281 subjects underwent implantation of the HeartMate II as a BTT (Pagani et al., 2009). In this cohort the median time to transplant was 118 days with a range of 10-545 days. The median duration of support was 155 days with a range of 0-1,026

(Pagani et al., 2009). Overall survival was 82 percent at 6 months, 73% and one year, and 72% at 18 months (Pagani et al., 2009). Seventy eight percent of these patients were discharged from the hospital with a LVAS. The median length of stay (LOS) was 25 days (range 8-180). One hundred forty nine patients (68%) required readmission to the hospital, the mean time out of the hospital before transplant, readmission or death was 55.5 days (Pagani et al., 2009).

As one can see the clinical evidence presented on devices has continuously improved over the years since the initial REMATCH and post REMATCH era. Continuous flow blood pumps such as the HeartMate II LVAS are smaller innovative technologies that substantially improve the overall QOL and survival for those patients with advanced HF. The smaller blood pump and driveline contributes to lower rates of complications such as pump failure and infection. These improved outcomes have led to an increase in patient implant volumes across the country. In a recent communication with Thoratec industry personnel, there are now over 5000 HeartMate II LVAS implants worldwide (J.B., personal communication, July 2010). Industry leaders feel that favorable clinical outcomes, longer durations of support, and economic efficiency will lead to increased implant volumes in the next one to two years.

Humanistic Evidence

Many HF intervention studies utilize QOL metrics as an outcome variable, yet how QOL is measured varies across studies. Many of the studies used in this evidence review utilize one or more of the following instruments to assess QOL, symptoms, or health utility. Two of the most common assessment instruments are the MLHFQ and the KCCQ. However, Sharples et al., and INTERMACS utilize the EuroQoL (EQ-5D). The EQ-5D is applicable to a wide range of health conditions and treatments. It provides a simple descriptive profile and single index value for

health status (EQ-5D, 2010). Examples of the MLHFQ and the EQ-5D are located in the appendix.

In 2010, Rogers and colleagues analyzed data on 281 BTT and 374 DT patients from previous clinical trials to study the impact of continuous flow devices on functional capacity and heart failure related QOL. Data from Rogers et al., (2010) demonstrates that patients implanted with the HeartMate II LVAS have improved and sustained functional status and QOL. Most patients had NYHA functional class IV symptoms at baseline. However, following implant 82 percent (BTT) and 80 percent (DT) patients at six months and 79 percent (DT) at 24 months improved to NYHA functional class I or II. Additionally, six-minute walk distance in DT patients was 204 meters in patients able to ambulate at baseline, which improved to 350 and 360 meters at six and 24 months respectively (Rogers et al., 2010). There were also significant and sustained improvements from baseline in both the BTT and DT patient groups with median MLHFQ scores (Rogers et al., 2010). The MLHF scores decreased over time, indicating an improvement in QOL. When compared with baseline scores in patients with paired comparisons, highly significant ($p<0.001$) mean, SD, and median scores were seen -12 ± 27 and -17 ± 31, -10 and -13 points were seen at one month in the BTT and DT groups respectively. In Addition, there were continued improvements at six months of support (Rogers et al., 2010). Although there is statistical significance, there is a wide range in variability in the SD. This is clinically meaningful and should be assessed in the OHSU patient population. Last, improvements were also seen in the KCCQ scores at one and six months post implantation.

Methods

Clinical Inquiry Design & Program Evaluation

The purpose of this project is to conduct a program evaluation of the OHSU experience with the HeartMate II LVAS in patients with advanced HF to date. OHSU gained access to the HeartMate II LVAS in June of 2009. From June 2009 through current the VAD program has implanted approximately 50 HeartMate II LVAS. The questions to be answered in the project are: 1) what are the hospital costs associated with patients implanted with the HeartMate II LVAS at OHSU, 2) what clinical variables play a role in the increased cost of the implant admission, and 3) what is the QOL of patients implanted with HeartMate II LVAS at OHSU. The inquiry design is a cross-sectional descriptive exploratory analysis of economic, clinical and humanistic outcomes.

Setting

OHSU has a comprehensive Advanced HF and Transplant Program that has a long-standing reputation for clinical excellence in patient care and research. The Advanced HF and Transplant Program have performed over 500 heart transplants and over 100 VAD implantations. The team is comprised of Cardiologist, Cardiothoracic Surgeons, Nurse Practitioners, Nurses, Transplant Coordinators and a Social Worker. This multidisciplinary team approach to patient care ensures that patients receive comprehensive and efficient care. The majority of this project will take place within the Cardiovascular Service Line within OHSU. Patients will be surveyed via face-to-face interviews at the Center for Health and Healing in Portland, Oregon. Patients who cannot be interviewed in clinic will be contacted by phone and mail to ensure good understanding of the QOL instruments. Additionally, the following patient care environments

will be considered: Cardiac Medical Intensive Care Unit (CMICU), Cardiac Surgical ICU (CSICU), Cardiac and Vascular Progressive Care Unit, outpatient ambulatory clinic for Advanced HF and Transplant, and outpatient ambulatory clinic for Cardiothoracic Surgery.

Study Sample

All patients will be invited to participate in this project who are living with a HeartMate II LVAS that was implanted at OHSU. They will be asked to participate in an assessment of QOL with the MLHFQ and the EQ-5D at a single point in time post implantation. Consent will be obtained after institutional review board (IRB) submission and approval. Currently all patients are accessible through the OHSU Advanced Heart Failure and Transplant Program.

Measures & Data Collection Procedures

Demographics

Demographic data will be collected on all subjects included in this project. Data will be collected after consent is obtained. The following elements are proposed for collection: age, gender, ethnicity, race, marital status, education level, employment status, and payor type (primary and secondary). Subjects will be given a demographic questionnaire at the time that consent is obtained.

Clinical

Clinical data will be abstracted from the electronic medical record (EMR) after consent is obtained. Data will include: survival status at 30 days post implant; duration of support; admission, implant and discharge dates (to calculate time from implantation to assessment of QOL); pre-operative, post-operative ICU, and step-down unit LOS; number of re-operations for

bleeding; readmissions to the hospital within 30 days of implant discharge date, and other associated data points requested from the project committee. Data will be abstracted from EPIC, the EMR used at OHSU. Clinical data collection methods will be retrospective in nature.

MLHFQ

QOL will be assessed using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) and the EQ-5D. The MLHFQ was designed in 1984 to measure the effects of HF and the treatments of HF on an individual's QOL (Rector, 2005). The content of the questionnaire was selected to be representative of the ways HF and treatments can affect key physical, emotional, social, and mental dimensions of QOL without being too long to administer in the clinical or research environment (Rector, 2005). The questionnaire asks each person to indicate using a 6-point Likert scale how much each of the 21 facets prevented them from living their life as they desired (Rector, 2005, para, 2). The questionnaire is one page in length and can be completed in less than 5 minutes (see appendix). There will be minimal subject burden associated with the MLHFQ. Higher scores (range 0 to 105) on the MLHFQ indicate worse HF health-related QOL; Cronbach's α is 0.92. (Rector, 2005; 2009) Summary scores include a total score as well as a physical and an emotional health-related QOL index.

EQ-5D

The EQ-5D was developed by the EuroQol group that is a network of international multidisciplinary researchers devoted to the measurement of health related QOL (Cheung, Oemar, Oppe, & Rabin, 2009). The EQ-5D is a standardized measure of health status that provides a simple, generic measure of health for clinical and economic assessment (as cited in Cheung, et al., 2009). The EQ-5D is designed for self-completion by the subject and is well

suited for postal surveys, in clinics, and face-to-face interviews (Cheung et al., 2009). Although the EQ-5D has been used in recall health status situations, the EuroQol group recommends using the health status tool as an immediate situation measure.

The EQ5D provides data that is complementary to MLHFQ data, in that the EQ5D is an index of general QOL, not merely the influence of HF and its treatment on QOL. The EQ5D asks respondents to rate their health state today with respect to 5 items: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each item is ranked from 1-3 generating a 5-digit health state classification. The health state is a descriptive system and may be converted into a single summary index by applying a formula that attaches values, also known as weights (Cheung et al., 2009). A general population-normalized health index (ranging from approximately 0 to 1 similar to a health utility) is calculated by normalizing each 5-digit health state to established U.S. population data. Eurol-QOL provides value sets so that patient populations can be assessed versus general populations, for example, the same patient population being evaluated across different countries (Cheung et al., 2009). The EQ5D also includes a visual analogue scale on which respondents rate their general health state (ranging from 0-100). The 5-digit health state and visual analogue scale are used in combination to reflect clinical and economic evaluation of health as well as population health (Cheung et al., 2009). QALY can be calculated with the EQ-5D and may be useful in future projects.

Cost

Cost data will be obtained through OHSU hospital financial services after approval from hospital administration. For the purposes of the project a detailed itemization of inpatient and outpatient direct and indirect costs, from a cost accounting perspective, total charges,

adjustments, and reimbursement will be requested, see Table 2. Data will be analyzed and presented after all patient identifiers have been removed. Cost data will not be shared without permission from OHSU hospital administration. Data will be presented from a payer/institutional perspective.

Analytic Methods

Descriptive statistics will be used for this project. Frequencies and measures of central tendency such as the mean, median, and mode will be useful in the interpretation of demographic and clinical data. For example, mean, range, standard deviation, duration of support, and LOS can be calculated using SPSS version 18 Software. A specific costs accounting analysis will also be performed with data obtained from hospital financial services; variances will be assessed. Additionally, advanced statistical support will be required with regard to costs and QOL data points for a more sophisticated analysis. Statistical consultation will be sought after a preliminary dataset is created. Once data are obtained it will be entered into SPSS, de-identified, and password protected. Data will be presented in table, graphic, and text format according to American Psychological Association (APA) format. Data may also be presented to public and academic audiences in power point format. See variable definitions in Table 3.

Protection of Human Subjects

This project will require submittal to and approval by the (IRB). All patient identifier information will be removed from the data prior to analysis and presentation. Data will be stored in a locked filling cabinet at OHSU in a locked office not accessible to the public. Electronic data will be de-identified and stored in a password-protected file. Only the project advisor and DNP student will have access to the identifiable data. Additionally, financial information will not be

disclosed without permission from OHSU administration or committee members. If institutionally mandated, cost data will be presented in proportions, rather than whole U.S. dollars. The knowledge gained from this project will likely enhance program performance and future growth with regard to VAD therapy at OHSU as well as regionally and nationally.

Plan for Dissemination to Stakeholders

Pending completion of the finalized CIP proposal the following OHSU staff will review and comment on the project: Anne Rosenfeld, Christopher Lee, Kristin Ellison, Howard Song, Antony Kim, and Steven Scott. All information discovered throughout the course of this project will be shared and disclosed to the project stakeholders in an executive summary, oral defense, and public presentation. Any additional requests for dissemination will be provided upon request and with permission from the key stakeholders, primarily the project advisor.

Project Timeline

September	• **Complete draft of CIP proposal – completed** • **Review IRB processes – in process** • **Meet with advisor to finalize CIP proposal – completed**
October	• **Submit CIP proposal to committee – completed November 23, 2010** • **Prepare for IRB submission – in process** • **Meet with clinical agency stakeholders, form committee – completed** • **Obtain letter of support – completed**
November **December**	• **Make required edits to proposal after committee reads – completed** • **Defend proposal – completed November 23, 2010** • **Obtain letter of support – completed and on file** • **Submit to IRB – in process** • **Begin data collection for QOL, cost, and clinical data** • **Data entry** • **Monitor progress**
January **February**	• **Analyze data** • **Describe findings** • **Meet with project team** • **Begin writing phase**
March **April** **May**	• **Continue with writing phase of project** • **Submit final reports to portfolio, clinical agency, and committee** • **Prepare for oral defense** • **Prepare executive summary** • **Revise report as needed and resubmit** • **Submit project title to commencement program booklet**

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Appendix

Tables

Table 1. Adapted from Lloyd-Jones et al., 2010, p. e132

Population Group	Prevalence, 2006 Age ≥ 20 y	Incidence New Cases Age ≥ 45 y	Mortality (Any Mention), 2006 All Ages	Hospital Discharges, 2006 All Ages	Cost, 2010
Both sexes	5,800,000 (2.6%)	670,000	282,754	1,106,000	$39.2 billion
Males	3,100,000 (3.1%)	350,000	123,600 (43.7%)	523,000	…
Females	2,700,000 (2.1%)	320,000	159,167 (56.3%)	583,000	…

(…) indicates missing data

Table 2. Costs Variables Data Collection Form

Cost Variable Data Collection Form	**Data**
Date of Admission	
Date of Discharge	
Diagnostic Codes (Admitting and Discharge)	
Principal Procedure Codes	
Length of Stay Data	
Total LOS	
Pre-VAD LOS	
Post-VAD LOS	
ICU LOS (pre-post if applicable)	
Intermediate LOS	
Economic Data	
Device type	
Device cost	
Cannulae cost	
Total VAD charges	
Total Hospital Charges	
Direct Hospital Charges	
Indirect Hospital Charges	
Total Pre implant Charges	
Total Post-VAD Charges	
Average Charge per day	
Average Charge per ICU day	
Average Charge per intermediate care day	
Total Hospital Expense	
Direct Hospital Expense	
Indirect Hospital Expense	
Primary Payer	
Secondary Payer	
Percent of Charges Recovered	
Profit/Loss	
Revenue Categories (for sub-analysis of direct and indirect charges)	
Clinic	
Emergency Department	
Imaging	
Lab/Blood	
OR/Anesthesia	
Organs	
Other	
Other Services	
Pharmacy	
Pro Fees	
Room & Board	
Supplies	
Trauma	

Table 3. Variable Definition Table

Domain	Variable	Conceptual & Operational Definitions
Economic	Principal procedure codes	The International Classification of Diseases and Related Health Problems is most commonly known as ICD-9. It provides codes to classify diseases and a wide variety of signs, symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or disease (e.g.; 37.66 – implant of an implantable heart assist system).
	Cost	Costs are the monetary value of expenditures for supplies, services, labor, products, equipment and other items purchased for use by a business or other accounting entity (e.g.; cost of the HeartMate II LVAS system and components).
	Direct cost	Costs that can easily be associated with a particular cost object.
	Indirect cost	Costs that is not directly accountable to a cost object such as a particular function or product. Indirect costs may be either fixed or variable. Indirect costs include taxes, administration, personnel and security costs, and are also known as overhead.
	Incremental Cost-Effectiveness Ratio (ICER)	The ICER is a term used in cost-effectiveness analysis in health economics. It is defined as the difference in costs of a therapeutic intervention compared to the alternative, such as doing nothing or using the best available alternative treatment, to the difference in effectiveness of the intervention compared to the alternative.
Clinical	Survival at 30 days	The patient's ability to survive 30 days post-implantation, a common clinical and quality metric.
	Duration of Support	Length of time from implant to transplant, explant, replacement or death.
	Number of re-operations for bleeding	The number of reoperations for bleeding (e.g.; washouts, re-exploration, massive blood transfusion, cardiac tamponade, or sternal closure).
	Readmission	Readmission to the hospital after initial implant hospitalization discharge. Emergency room admissions are excluded.
Humanistic	Disease-specific quality of life (QOL)	Minnesota Living with Heart Failure Questionnaire (MLHFQ) The MLHFQ was designed to measure the effects of heart failure and treatments on physical, emotional, social, and mental dimensions of QOL. It is a disease specific measure of QOL.
	Health-related (QOL)	The EuroQOL (EQ-5D) measures health-related QOLas a single index, normalized to the general U.S. population. As such, the EQ-5D index reflects the influence of altered health on QOL adjusting for a social tariff. The EQ-5D also includes a single visual analog scale that represents the individual's rating for their current health-related QOL (not adjusted for a social tariff).
	Quality of Life Adjusted Year (QALY)	The most common measurement of health benefit. QALYs offer a way to integrate changes in both length and quality of life produced by an intervention; they are calculated as the product of life expectancy and health utility (EQ-5D health index).

DNP Clinical Inquiry Project Executive Summary

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Instructor, Division of Cardiovascular Services, OHSU Healthcare

May 31, 2011

The Doctor of Nursing Practice (DNP) program at Oregon Health & Science University (OHSU) prepares nurses to practice at the highest level of nursing practice. During the course of my studies at OHSU I have completed a clinical inquiry project (CIP) that highlights my capabilities as a DNP prepared nurse.

My practice population includes patients who are implanted with mechanical circulatory support devices as a bridge-to-transplantation (BTT), bridge-to-recovery, or as destination therapy (DT). Currently OHSU uses approximately seven different types of devices for the treatment of advanced heart failure and mechanical unloading of the heart. Our most widely used device is the HeartMate II left ventricular assist system (LVAS) which can support patients as BTT or DT for months to years.

CIP Title: Economic, Clinical and Humanistic Outcomes in Patients Implanted with the HeartMate II LVAS: A Single Center Experience

Design: Cross-sectional descriptive design of economic, clinical and humanistic outcomes

Methods: This study was approved by the OHSU institutional review board #7146. Data were collected on 29 participants (78% of the currently supported patient population at OHSU). Implant dates ranged from September 2009-February 2011. Economic data was obtained from hospital financial services; clinical data from EPIC the electronic health record, and humanistic data from the Minnesota Living with Heart Failure Questionnaire (MLHFQ) and the European Quality of Life Dimensions (EQ-5D).

Results: The average age of the sample was 55±16 years, and the majority of subjects were male (78%), Caucasian (93%), and implanted as BTT (65%, n=19). The mean duration of support was 268±146 days. A majority of subjects (63%) had non-ischemic heart failure as a primary etiology. Total hospital charges were $497,616±$115,620. Supplies accounted for approximately 60-75% of minimum and maximum hospital expenditures respectfully. Total length of stay was 24.24±12.05 days and 30-day readmissions were 21% for BTT and 0% for DT patients. MLHFQ physical, emotional, and total scores were 17±12, 10±9, and 44±21 respectively; EQ5D summary heath index and VAS scores were 0.76±0.21 and 64±21 respectively. Although comparable QOL was reported in most domains between groups, DT patients reported better QOL on the EQ-5D VAS compared with BTT patients (77±10 vs. 57±22; p =0.002). There were moderate-to-strong correlations among the EQ-5D calculated and VAS scores and emotional, physical, and total MLHFQ scores (rho = ±0.45-0.92; all p<.01). Interestingly, QOL did not vary by duration of LVAS support in any domain.

Conclusions: This study serves as the foundation for future outcomes research with regard to the mechanical circulatory support patient population at OHSU. Additionally, we will continue to collect economic, clinical, and humanistic outcomes data on this patient population to further advanced the field. Our findings suggest that quality of life is higher in DT patients than BTT patients following implantation with HeartMate II LVAS and QOL does not differ by duration of support. Further studies are justified to explore the basis for differences in QOL based on device strategy and to develop tailored interventions to improve each group's outcomes.

Interdisciplinary Committee:

- Dr. Anne Rosenfeld, PhD, RN, OHSU School of Nursing (Committee Chair, Academic Advisor)
- Dr. Christopher Lee, PhD, RN, OHSU School of Nursing (Committee Member)
- Dr. Antony Kim, MD, OHSU School of Medicine (Committee Member)

Economic, Clinical and Humanistic Outcomes in Patients Implanted with the HeartMate II LVAS: A Single Center Experience

Clinical Inquiry Final Report

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Spring, 2011

Clinical Inquiry Report of Findings

Clinical, economic, and humanistic outcomes research is in early development within the emerging field of ventricular assist device (VAD) therapy. This cross-sectional, exploratory, descriptive analysis of patients implanted with the HeartMate II left ventricular assist system (LVAS) is a single center pilot study that will serve as the foundation to expand future outcomes research in the VAD population and the economic impact of this emerging therapy. This report describes the findings of the following three specific aims; discussed previously in the clinical inquiry proposal: 1) what are the hospital costs associated with patients implanted with the HeartMate II LVAS, 2) what clinical variables play a role in the increased cost of the implant admission, and 3) what is the quality of life (QOL) of patients implanted with HeartMate II LVAS using the European Quality of Life 5 Dimensions (EQ-5D) and the Minnesota Living with Heart Failure Questionnaire (MLHFQ). This study has been reviewed and approved by the OHSU institutional review board (IRB #7146) for the protection of human subjects.

Methods

Patients who were implanted with a HeartMate II LVAS were asked to participate in the study. A copy of informed consent and health insurance portability and accountability act (HIPAA) authorization can be found in the appendices. Subjects were consented during routine inpatient or outpatient post-operative care. Our program currently supports 37 patients on HeartMate II LVAS.

Database functions and analyses were performed using IBM SPSS Statistics version 19 Graduate Pack. Standard descriptive and comparative statistics were used to describe the findings including rates and measures of central tendency and dispersion, as well as Fisher's exact test, Spearman's correlations (rho), and student's *t*-test where appropriate. Patterns and differences in means also were displayed graphically.

Results

Sample

Twenty-nine subjects were enrolled in this study (78% of the currently supported patient population). Four subjects declined either because they did not want their personal information accessed by the research team or due to insufficient time in our clinic. Three subjects were not consented and enrolled by the final cut off date and one subject died prior to consent and enrollment.

Findings

The mean age of the sample was 55 ± 16 years, and the majority of subjects were male (78%), Caucasian (93%), and implanted as bridge-to-transplantation (BTT) (65%). The mean duration of support was 268 ± 146 days. A majority of subjects (63%) had non-ischemic heart failure (HF) as a primary etiology. Additional subject characteristics are summarized in table 1. The term destination therapy (DT) is used for those patients who are non-candidates for cardiac transplantation who have been implanted with a VAD.

Hospital expenditures were summarized using 2010-2011 U.S. dollars and relative proportions. Total hospital charges for the VAD implant hospitalization ranged from $349,946 to $818,214; the mean was $497,616 ± $115,620. Hospital expenses also were stratified by the following categories: imaging, lab/blood, operating room (OR)/anesthesia, other services, pharmacy, room and board, and supplies (Tables 2 and 3). The majority of expenditures were attributed to the cost of supplies, which comprised 60.6% (best case) and 75.7% (worst case) of overall hospital expenditures. Additionally room and board comprised a significant proportion of hospital expenditures as well.

Pre-VAD, post-VAD and total lengths of stay (LOS) and readmission rates were examined as clinical outcomes of VAD implantation (Table 4). The mean total LOS for the implant hospitalization was 24 ± 12 days. Readmission rates within 30 days of post implantation hospital discharge were stratified by device strategy (Table 5). BTT patients had a 30-day readmission rate of 21% while none of the 10 DT patients were readmitted within 30 days of the implant hospitalization (Exact p=0.163) (Table 5).

QOL was measured with the MLHFQ and the EQ-5D (Table 6). MLHFQ scores were analyzed at three levels physical, emotional, and total scores. Reference ranges for the MLHFQ are as follows: emotional (0-25), physical (0-40), and total (0-105), higher scores indicate worse QOL (University of Minnesota, 2011). Reference ranges for the EQ-5D range from 0-100 with the higher scores indicating better QOL (EQ-5D, 2009). Although comparable QOL was reported in most domains between groups, DT patients reported better QOL on the EQ-5D visual analog scale (VAS) compared with BTT patients (77 ± 10 vs. 57 ± 22; p = 0.002) (Table 7). There were moderate non-parametric correlations between the EQ-5D calculated and VAS scores and physical, emotional, and total MLHFQ scores (Table 8). Correlations between QOL and the duration of VAD support also are presented in Table 8; QOL was not influenced significantly by duration of support.

Situational Analysis

As discussed in the proposal and study protocol, subjects were surveyed with the EQ-5D and MLHFQ after informed consent and HIPAA authorization were obtained. Collecting QOL assessments for research posed unique challenges. The majority of subjects (78%) were willing to participate and have welcomed the addition of QOL assessments into the outpatient clinic appointment. In these subjects, QOL assessments facilitated expanded discussion around clinical and QOL care.

Collecting this data in the outpatient clinic added an additional time burden (5-10 minutes). This time commitment should be accounted for if further QOL data will be collected as part of routine standards of care (e.g. including the QOL assessments as part of the pre-clinic check-in process). However, the time can skillfully be integrated into the appointment. Careful attention to clinician/investigator bias must be closely monitored and discussed amongst the research team.

Discussion

Interpretation

The most interesting clinical observational perspective is how well very ill subjects rate their QOL on both the EQ-5D and the MLHFQ. From a clinicians perspective, one can abstract that the subject is pleased to be alive and recovering from surgery rather than severely ill from HF symptoms with decreased functional capacity. Additionally, these subjects are recovering at home rather than the hospital or skilled nursing facility. Many of the subjects expressed that their QOL increased by being able to go home, take a shower, and be with their family members.

Recent data from Starling, et al. (2011), reports comparable patient characteristics to our study sample with a higher duration of support of 306 $\pm$ 173 days and higher percentage of non-Caucasian participants (26%). QOL was measured with the EQ-5D VAS and was significantly improved at 3 months post implant of the device. VAS scores were between 60 and 70 during the 6 and 12 month follow up period for both groups (Starling, et al. (2011). This data is comparable to what we found in our results with mean scores for the BTT group of 56 $\pm$ 22 and 77 $\pm$ 10 for DT.

The lack of significant correlation between the QOL assessments and the duration of support in this study was striking as we hypothesized that QOL scores would improve with increasing duration of device support. The findings displayed in table 8 provide evidence to refute our hypothesis but are consistent with current research published in the VAD and HF literature. Rogers and colleagues (2010), indicate that HeartMate II LVAD support in both

the BTT and DT therapy groups showed early, sustained, and clinically meaningful improvements in functional capacity and HF-related QOL. Rogers et al., utilized the MLHFQ and the Kansas City Cardiomyopathy Questionnaire (KCCQ) to measure disease-specific QOL.

Between BTT and DT groups, scores for the MLHFQ were found to be comparable in the domains of physical, emotional, and total QOL. However, the perceived QOL was better in the DT than BTT patients when using the EQ-5D VAS. One hypothesis is that patients in the BTT therapy group view the assist device as a barrier to cardiac transplantation and thus report lower health-related QOL. Additionally, psychological factors before and after VAD implantation as discussed by Grady and colleagues may play a significant role in this phenomenon. The difference in QOL between these two device strategies should be explored in future analyses and possibly via a mixed methods approach.

Our readmission and LOS data is also less than what has been previously reported in the literature. Pagani, et al. (2009), reported a median LOS of 25 days with a range of (8-180) and readmission rate of (68%). Pagani and colleagues did not specify the time period for their hospital readmissions, for example, all cause versus 30-day. In contrast, we only examined readmission within 30 days of the post implantation hospitalization. LOS and readmission data will be useful in the future as we start to benchmark our outcomes with other comparable centers, published data from the literature, or the INTERMACS Registry.

There was significant heterogeneity in total hospital charges in this study sample. Supplies and room and board make up the majority of these hospital expenditures. There are multiple factors such as multiple procedures being performed within the same hospital admission, as well as repeat trips to the operating room for re-exploration for hemorrhage or thoracic washout and clot removal. Close attention to these details will be required if a financially sustainable program will be expanded upon. Last, attention to LOS is mandatory as this also accounts for a large proportion of total hospital expenditures.

Context

QOL has been measured as an outcome in many of the VAD studies published in the literature. For example, Rogers and colleagues sough to explore the differences in QOL between device strategies over a 24-month period of time using the MLHFQ and the KCCQ. This group found that MLHFQ scores decreased over time, indicating improved QOL when compared with baselines scores in patients with paired comparisons. While we cannot demonstrate changes in QOL over time, we have found significant differences in perceived QOL between device strategy groups using the EQ-5D VAS.

Grady and colleagues (2002), reported that patients with LVADs who are awaiting cardiac transplantation indicate that almost half the variability in satisfaction with overall QOL at one month after LVAD implantation was explained by psychological factors and a single demographic factor (race). While Grady and colleagues used alternative methods for the evaluation of QOL, than those used in this study, they determined that psychological factors may play a significant role in the perception of QOL and that targeted interventions may improve the QOL of those patients implanted with LVADs who are awaiting cardiac transplantation. One of the major limitations in comparing these findings to ours was the device type being implanted during this era, (e.g. pulsatile versus continuous flow). While this is a significant limitation, the underlying themes have yet to be explored in the VAD patient population.

The economics and costs effectiveness regarding VAD therapy is currently underdeveloped in the research community and literature. Future research and collaboration with industry, payors, institutions, and the public sectors will be necessary to develop a better understanding with regard this innovative treatment for advanced HF.

Limitations

The cross-sectional design of this study has intrinsic limitations. Additionally, the study is representative of a single centers experience with a device. All subjects enrolled in this study are at various phases of recovery and the QOL assessments are a single snapshot in time. QOL assessments were performed at random, meaning there was no specified interval for measurement. Additionally, the sample size is small and the majority of subjects are male and Caucasian. Prior to the study being approved by the IRB several patients who were on LVAD support were transplanted thus decreasing the availability of patients on VAD support who could have potentially contributed to the sample size.

Conducting research while providing clinical care to the patient population posed significant challenges; some of the most burdensome challenges were the lack of time available to complete the study documents, answer questions in a timely and thorough manner, facilitation of clinical care, and providing appropriate patient instructions at the conclusion of the clinic visit. The VAD clinics are multidisciplinary; involving care from social workers, physicians, nurse coordinators, and nurse practitioners. The appointments are generally one hour in length and this amount of time is needed for direct patient care. As discussed in the sample section, four patients (11%) declined to participate in the study due to insufficient time during the clinic appointment. Several of these patients were approached a second time and they declined again.

Conclusions

One of the major goals of performing this clinical inquiry project was to assess the feasibility of performing an economic, clinical and humanistic pilot study of patients implanted with VADs. Data collection from various sources such as the hospital financial services, the electronic health record, and from subjects posed significant challenges. However, these challenges can be overcome with the proper education and knowledge of key resources. The INTERMACS Registry utilizes the EQ-5D to measure health related QOL. This study proves that QOL assessments can be performed in our clinical practice. The VAD community at large views these assessments along with various other disease-specific QOL assessment tools as a standard of care with regard to the HF population; however they are underutilized in practice.

We believe that it will be feasible to perform assessments of QOL with two measurement tools during routine patient follow up. The QOL tools used in this study are simple enough to be placed in check-in clinic paperwork and can be filled out prior to being seen by a provider. Additionally, these tools can be used to facilitate patient care with regard to asking pertinent questions around the patients perceived QOL. For example, many subjects throughout the study period used the QOL assessments to bring up pertinent health related questions such as "when is it safe for me to have sex" and "is it normal to feel like a burden to my friends and family".

Evaluation of economic, readmission and LOS data is imperative for the financial performance of this complex and ever changing HF specialty area. Continued exploration of these variables will allow for an increased understanding and benchmarking against comparable programs and the INTERMACS Registry. Pricing agreements and the development of streamlined patient care pathways may decrease hospital expenditures with regard to supplies and room and board expenditures. For example, use of a skilled nursing facility trained to care for the VAD population to decrease the acute care unit LOS.

We would propose the addition of two QOL assessments into routine clinical care for the VAD population at our center. This study not only demonstrates the feasibility but also the significance of assessing QOL for the larger contribution to the growing body of VAD literature. While the MLHFQ has been routinely used in the VAD literature, in this study it was used as a single assessment of QOL. This clinical inquiry project has allowed us to document our patients QOL per MLHFQ and the EQ-5D. We propose continued use of the EQ-5D and MLHFQ in our practice at pre-determined intervals such as pre-implant, 1-, 3-,

and 6-months post implantation. The addition of the KCCQ may also be considered as well due to its responsiveness over time.

VADs are innovative technologies that can be used for the treatment of refractory HF in patients who are no longer responding to traditional treatment modalities. There are an estimated 300,000 to 800,000 patients with advanced HF who could potentially benefit from this type of advanced therapy (Russell, Miller, & Pagani, 2008). This research serves as the beginning framework for future provocative hypothesis generation as well as expanded resource utilization within our VAD program and externally via multicenter collaborations.

The clinical inquiry project has provided a venue to explore hypothesis generation, develop pertinent clinical questions, design, develop and evaluate a clinical project in entirety. Clinical assumptions that were based on observation were disproven with scientific rigor, additionally, new information has been generated. Examples include our hypothesis that QOL would improve as the duration of support was increased and the difference in QOL between device strategy groups. Additionally, information from this study will serve as the basic framework form which future scholarly work and collaboration can develop.

The Doctor of Nursing Practice curriculum has provided the foundation for independent clinical investigation, program improvement, and advanced nursing practice at the highest level.

Acknowledgements

Drs. Anne Rosenfeld, Christopher Lee, Antony Kim, Howard Song, and Jill Gelow have provided academic and clinical mentorship throughout this clinical inquiry project and over the course of the Doctor of Nursing Practice program. Their devotion and passion for improved heart failure care is profound.

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Tables

Table 1. Subject Characteristics (N=29)

Variables	**Data**
Age	
Mean	55.03
Range	18-74
Duration of Support (Days)	
Mean	268
Median	244
Range	45-579

	N	**(%)**
Sex		
Male	21	(72.4%)
Female	8	(27.6%)
Ethnicity		
Caucasian	27	(93.1%)
Non-Caucasian	2	(6.8%)
Etiology		
Ischemic	11	(37.9%)
Non-ischemic	18	(62%)
Device Strategy		
BTT	19	(65.5%)
DT	10	(34.5%)
Primary Payor		
Private	8	(27.3%)
Public	17	(58.4%)
Secondary Payor		
Private	9	(30.8%)
Public	5	(17%)
None	11	(37.9%)
Smoking History		
Ex-smoker	22	(75.9%)
Never smoked	7	(24.1%)
Main Activity		
Employed	2	(6.9%)
Retired	18	(62.1%)
Keeping House	2	(6.9%)
Student	2	(6.9%)
Other	5	(17.2%)
Education Level		
High School or Less	4	(13.8%)
High School / GED	6	(20.7%)
College degree	17	(58.6%)
Graduate degree	2	(6.9%)

Table 2. Total Hospital Charges (N=25)

	Charges in US dollars
Mean ± SD	$497,616 ± $115,620
Median	$484,788
Range	$349,946 - $818,214

Table 3. Proportion of Hospital Expenditures

Variables	**Minimum**		**Maximum**	
	Proportion	**Expenses**	**Proportion**	**Expenses**
Imaging	0.91%	$455	1.21%	$6,082
Lab/Blood	4.76%	$4,335	5.71%	$28,700
OR/Anesthesia	4.97%	$6,912	6.71%	$33,728
Other Services	3.14%	$3,109	4.94%	$24,829
Pharmacy	7.23%	$4,255	11.53%	$57,960
Room & Board	19.75%	$18,776	23.30%	$117,122
Supplies	60.58%	$26,399	75.68%	$380,435

Table 4. Length of Stay (N=25)

Length of Stay	**Mean ± SD**	**Median**	**Range**
Pre-VAD	3.92 ± 5.99	0	0-20
Post-VAD	20.32 ± 10.91	18	10-55
Total-VAD LOS	24.24 ± 12.056	20	11-58

Note. VAD = Ventricular Assist Device, LOS = Length of Stay

Table 5. Readmission Rates (N=29)

30 Day Readmission	**Yes**	**No**
BTT	21%	79%
DT	0%	100%

Note. BTT = Bridge-to-transplant, DT = Destination therapy
$\chi 2 = 2.44$, Fisher's Exact test = 0.163

Table 6. Quality of Life (N=29)

Variables	**Mean ± SD**	**Median**	**Measured Ranges**
MLHFQ			
Physical (0-40)	16.97 ± 11.74	19	0-36
Emotional (0-25)	10.00 ± 8.59	6	0-25
Total (0-105)	43.89 ± 28.04	44	4-89
EQ5D			
VAS (0-100)	63.86 ± 21.47	70	20-90
Pop Norm (0-100)	75.57 ± 20.57	81	29-100

Note. MLHFQ = Minnesota Living with Heart Failure Questionnaire, VAS = Visual analog scale

Table 7. Differences in QOL between Device Strategies

	BTT (N=19)	DT (N=10)		
	Mean ± SD	**Mean ± SD**	**t-test**	***p* value**
MLHFQ Physical	18.21 ± 11.54	14.60 ± 12.36	.765	.455
MLHFQ Emotional	11.26 ± 8.81	7.60 ± 8.05	1.126	.273
MLHFQ Total Score	47.47 ± 27.36	37.10 ± 29.50	.922	.369
EQ-5D VAS	56.58 ± 22.48	77.70 ± 9.92	-3.498	.002
EQ-5D Calculated	71 ± 21.66	83.55 ±16.62	-.758	.456

Table 8. Non-Parametric Correlations between QOL Assessments

Spearman's ρ	**EQ-5D VAS**	**EQ-5D Calculated**	**MLHFQ Physical Domain**	**MLHFQ Emotional Domain**	**MLHFQ Total Score**
EQ-5D Calculated					
Correlation	.525**				
p value	.003				
MLHFQ Physical Domain					
Correlation	-.494**	-.513**			
p value	.006	.004			
MLHFQ Emotional Domain					
Correlation	-.466*	-.451*	.690**		
p value	.011	.014	<.001		
MLHFQ Total Score					
Correlation	-.548**	-.515	.922**	.859**	
p value	.002	.004	<.001	<.001	
Time Since VAD in Days					
Correlation	.362	.292	-.259	-.150	-.314
p value	.053	.125	.174	.438	.097
Time Since VAD in Weeks					
Correlation	.360	.293	-.264	-.153	-.318
p value	.055	.123	.166	.427	.093

Note. ** Correlation (Spearman's rho) is significant at the 0.01 level (2-tailed), * correlation (Spearman's rho) is significant at the 0.05 level (2-tailed)

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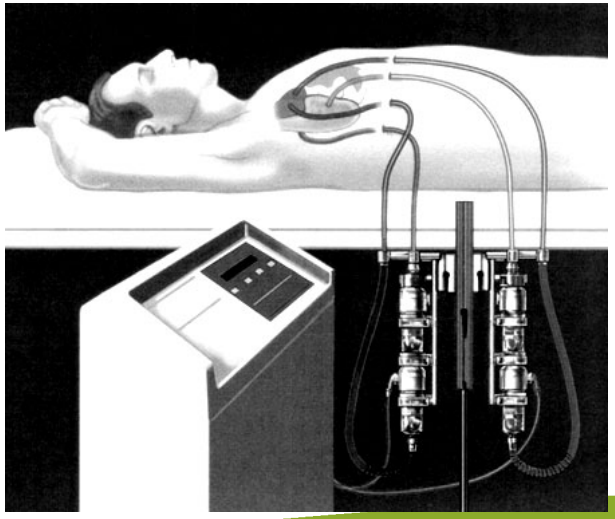

Frederick Michael McNeil, DNPc, ACNP, CCRN
Doctor of Nursing Practice Candidate, OHSU School of Nursing
Instructor, Division of Cardiovascular Services
Mechanical Circulatory Support Program Manager
Oregon Health & Science University
Spring, 2011

DNP Entry Goals

- Develop expert skills as an Advance Practice Nurse in the field of Mechanical Circulatory Support
- Gain a thorough understanding of complex organizational structures and systems
- Develop a comprehensive understanding of healthcare economics and disparities
- Gain advanced leadership skills

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Background on Advanced Heart Failure (HF)

Description & Significance

- HF affects nearly 5 million Americans with 550,000 new cases annually
- Direct and indirect costs are approximately $40 billion dollars annually
- Approximately 250,000 patients die each year from HF
- It is estimated that between 300,000 to 800,000 individuals have advanced HF

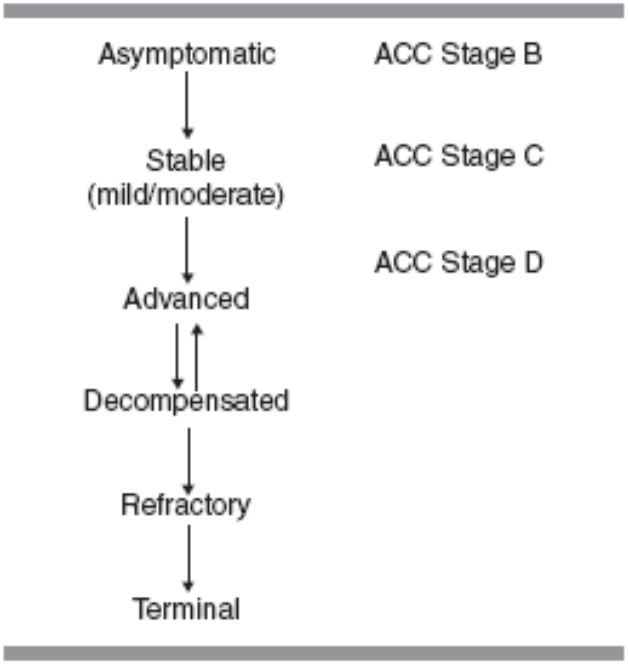

Table I. ACC/AHA–Recommended Therapy for Heart Failure Patients by Stage[6]

Stage A	ACE inhibitor or ARB in appropriate patients	
Stage B	ACE inhibitor or ARB in appropriate patients. β-Blockers in appropriate patients	
Stage C	Routine Diuretics if fluid retention ACE inhibitors β-Blockers	Select patients Digitalis Hydralazine/nitrates Biventricular pacing Implantable defibrillators
Stage D	Hospice Heart transplant Chronic inotropes Permanent mechanical support Experimental surgery or drugs	

Abbreviations: ACC, American College of Cardiology; ACE, angiotensin-converting enzyme; AHA, American Heart Association; ARB, angiotensin receptor blocker.

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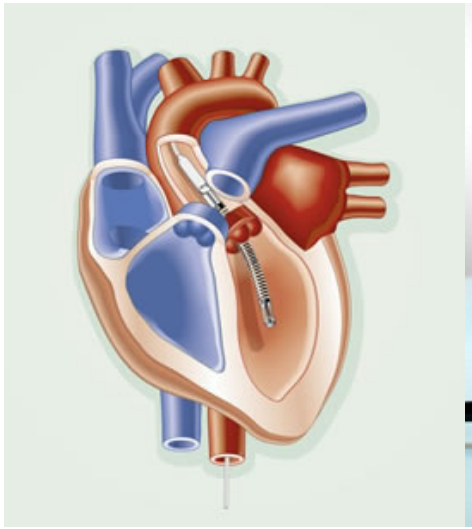
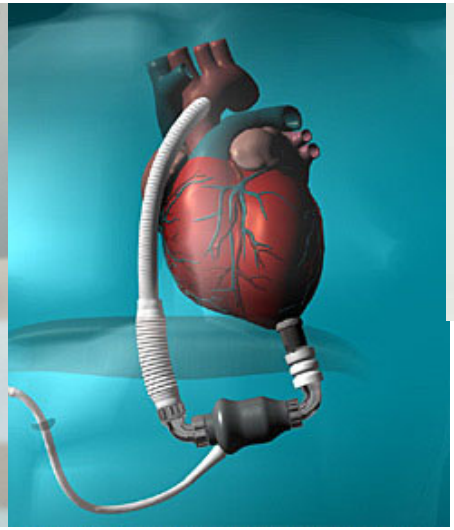
Practice Population

- Advanced heart failure and cardiac transplantation
- Acute and chronic mechanical circulatory support devices





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Advanced HF & Cardiac Transplant at OHSU

Brief Program History

- **1985**: cardiac transplant program, > 500 heart transplants performed
- **1995**: first outpatient support with continuous inotropes
- **1997**: first VAD implant (HeartMate implanted pneumatic)

Major VAD Indications

- Bridge-to-transplantation (BTT)
- Bridge-to-recovery or determination (BTR/BTD)
- Destination therapy (DT)

VAD Volume

- **2008**: 9 devices implanted
- **2009**: 20 devices implanted
- **2010**: 49 devices implanted
- **2011-2012**: 50-60 device implants projected

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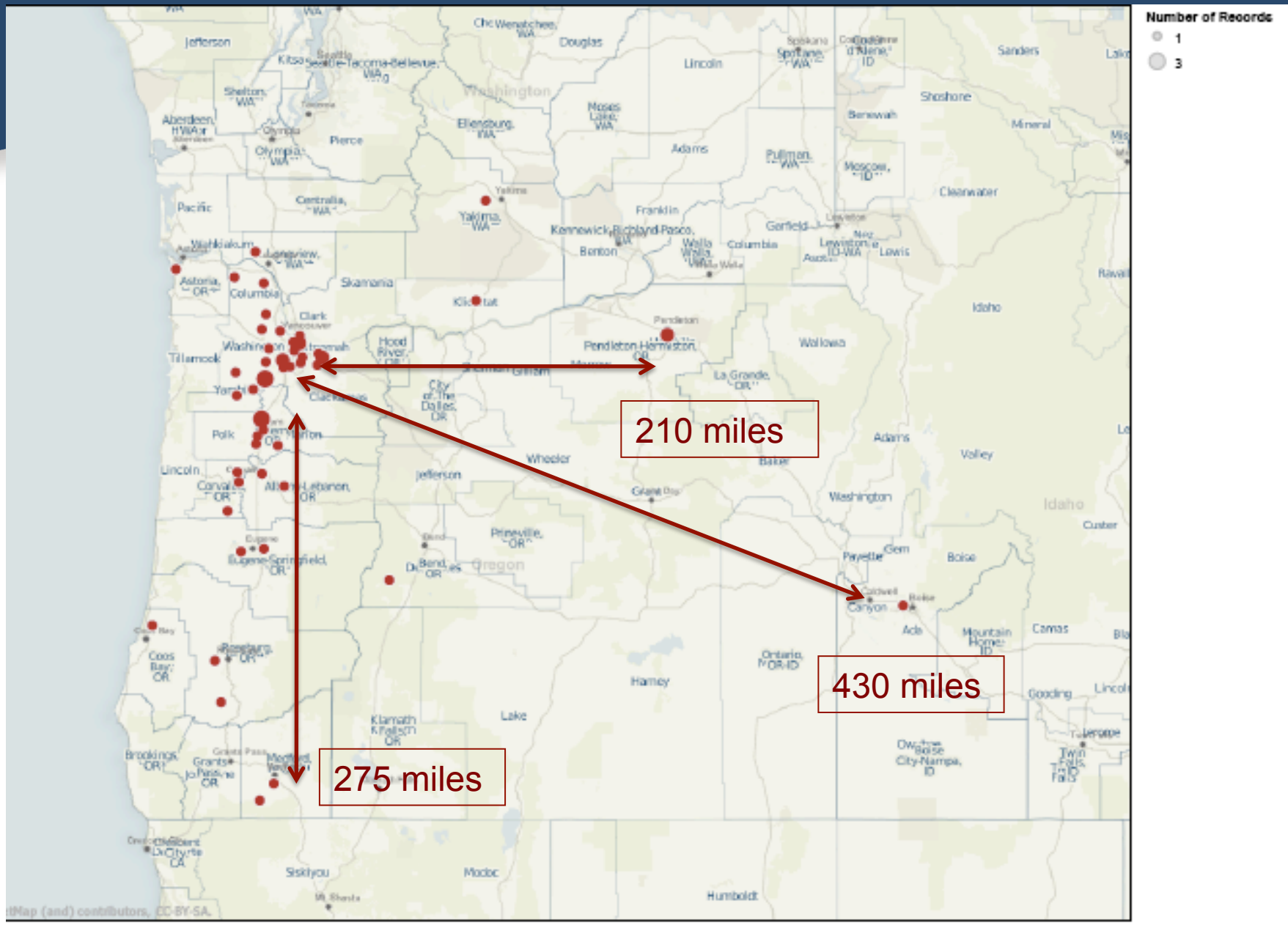
Region Served



Clinical Inquiry Project Committee & Influential Faculty

Committee Members

- Dr. Anne Rosenfeld, Ph.D, RN, CNS
  - Professor, Committee Chair, Academic Advisor
- Dr. Christopher Lee, Ph.D, RN
  - Assistant Professor, Academic Mentor, Committee Member
- Dr. Antony Kim, MD
  - Associate Professor, Clinical Mentor, Committee Member

Professional Mentors

- Dr. Howard Song, MD, Ph.D
  - Surgical Director for Advanced HF & Cardiac Transplant
- Dr. Eric Adler, MD
  - Heart Failure Cardiologist
- Dr. Jill Gelow, MD, MPH
  - Heart Failure Fellow

Clinical Inquiry Project

Clinical Questions & Design

Questions

1. What are the hospital costs associated with patients implanted with the HeartMate II LVAS
2. What clinical variables play a role in the increased cost of the implant admission
3. What is the quality-of-life (QOL) of patients implanted with the HeartMate II LVAS using the European Quality of Life Dimensions (EQ-5D) and the Minnesota Living with Heart Failure Questionnaire (MLHFQ)

Design

- Cross-sectional descriptive design of economic, clinical and humanistic outcomes

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Clinical Inquiry Project
Methods

- Study was approved by the OHSU IRB # 7146
  - Enrollment criteria
    - Age 18 or older
    - Able to read and understand English
    - Able to be reached by telephone
    - Have been implanted with a VAD
- Subjects were consented during routine inpatient or outpatient post-operative care
- Data were collected on 29 subjects (78% of the currently supported patient population at OHSU)
- SPSS version 19 Graduate Pack was used for the database and statistical analysis

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Clinical Inquiry Project
Methods, Cont.

- Implant dates ranged from Sept 2009 – Feb 2011
- Economic Data
  - Obtained from hospital financial services
- Clinical Data
  - Abstracted from EPIC the electronic health record
- Humanistic Data
  - Collected from QOL surveys
    - MLHFQ
    - EQ – 5D

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Clinical Inquiry Project
Results – Demographics
(N=29)

Age: mean 55 ± 16, range 18 – 74
Sex: 72% male
Ethnicity: 93% Caucasian

Etiology of HF: 62% non-ischemic
Device Strategy: 65% bridge-to-transplantation
Duration of Support (days): mean 268 ± 146, range 45 – 579

Primary Payor: 58% public
Secondary Payor: 30% private, 37% none

Smoking History: 75% ex-smokers
Main Activity: 62% retired, 17% other (disability/unable to work d/t illness)
Education Level: 58% college degree, 20% high school / GED

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Clinical Inquiry Project Results – Economic

Total Hospital Charges (N = 25)	
	Charges in US dollars
Mean ± SD	$497,616 ± $115,620
Median	$484,788
Range	$349,946 - $818,214

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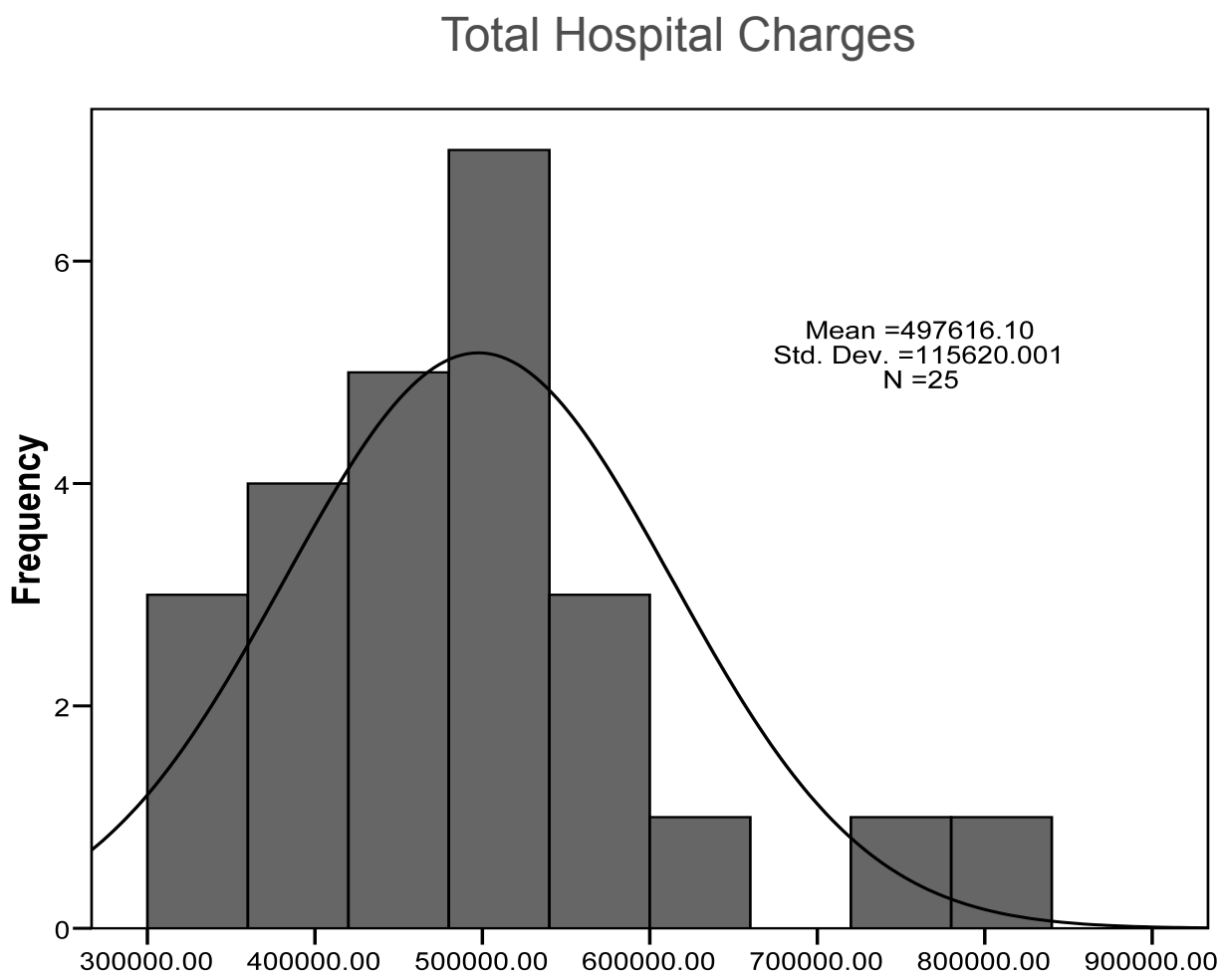
Clinical Inquiry Project Results – Economic



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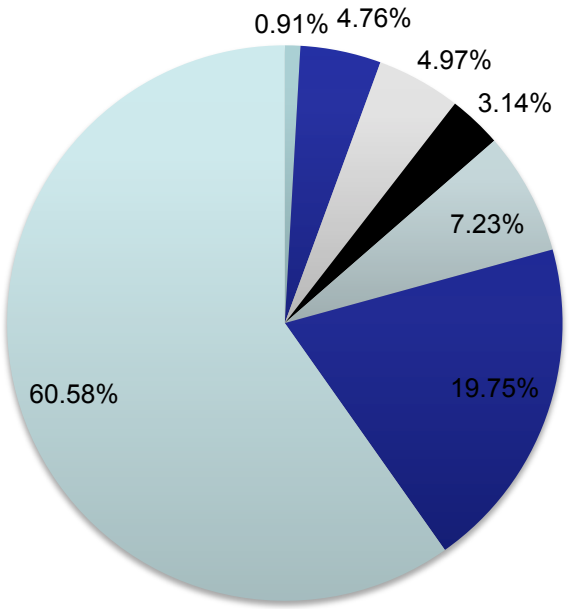
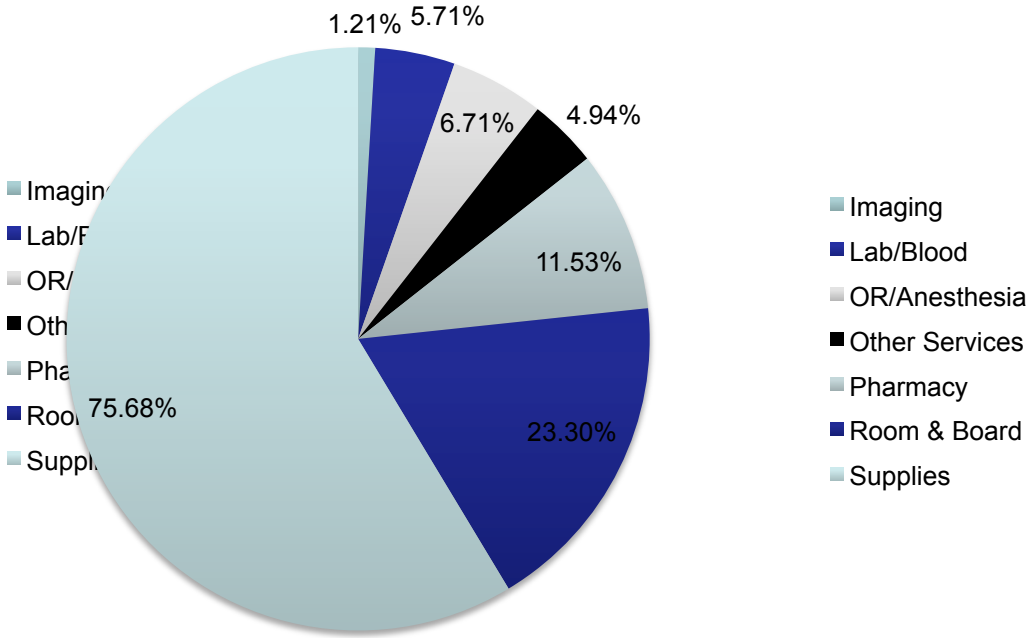
Clinical Inquiry Project Results – Economic

Minimum Proportion of Hospital Expenditures



Maximum Proportion of Hospital Expenditures



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Clinical Inquiry Project
Results – Clinical

Length of Stay		
	Mean ± SD	Range
Pre – VAD	3.92 ± 5.99	0 – 20
Post – VAD	20.32 ± 10.91	10 – 55
Total – VAD	24. 24 ± 12. 05	11 – 58

30 Day Readmission (All Cause)	Yes	No
BTT	21%	79%
DT		100%

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Clinical Inquiry Project Results – Humanistic

QOL Scores

Variables	Mean ± SD	Median	Measured Ranges
MLHFQ			
Physical (0-40)	16.97 ± 11.74	19	0-36
Emotional (0-25)	10.00 ± 8.59	6	0-25
Total (0-105)	43.89 ± 28.04	44	4-89
EQ5D			
VAS (0-100)	63.86 ± 21.47	70	20-90
Pop Norm (0-100)	75.57 ± 20.57	81	29-100

Note. MLHFQ = Minnesota Living with Heart Failure Questionnaire, VAS = Visual analog scale

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Clinical Inquiry Project
Results – Humanistic

Differences in QOL between Device Strategies

	BTT (N=19)	DT (N=10)		
	Mean ± SD	Mean ± SD	t-test	*p* value
MLHFQ Physical	18.21 ± 11.54	14.60 ± 12.36	.765	.455
MLHFQ Emotional	11.26 ± 8.81	7.60 ± 8.05	1.126	.273
MLHFQ Total Score	47.47 ± 27.36	37.10 ± 29.50	.922	.369
EQ-5D VAS	56.58 ± 22.48	77.70 ± 9.92	-3.498	.002
EQ-5D Calculated	71 ± 21.66	83.55 ±16.62	-.758	.456

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Clinical Inquiry Report
Results – Humanistic

Non-parametric Correlation between QOL Assessments (Spearman's rho)

- Moderate significant correlations between the MLHFQ and the EQ-5D
- No significant correlations between QOL assessments and the time since VAD implantation (days)

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Clinical Inquiry Project Discussion

- Cardiac mechanical device economics is under-reported in the literature
- Our LOS and readmission rates are less than what has been reported in the literature or by our colleagues at other centers
- By my perception, subjects rated their QOL rather high
- There was significantly higher perceived QOL using the EQ-5D VAS in the DT vs. the BTT group
- There was no statistically significant correlation between QOL and the time spent on VAD support

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Clinical Inquiry Project
Limitations

- Cross-sectional design
- Single center experience
- Small sample size, rather homogeneous
- Clinical and student bias
- Lack of time

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Clinical Inquiry Project

Learned Lessons

- Designing a research project is difficult
- It takes a long time
- It requires a lot of critical thinking about thinking
- The current QOL tools may not adequately address the VAD populations needs
- You need academic, clinical, and research mentors to flourish

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Clinical Inquiry Project Conclusions

- Economic monitoring of the program is imperative for financial success or demise
- Clinical outcomes are also being scrutinized
- Feasibility to collect QOL data
- Benchmarking capability

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Accomplishments

1. Practice within an advanced practice nursing specialty in a professional, evidenced-based, skilled, and ethical manner.

- Developed NP VAD clinic at the Center for Health and Healing
- Able to see acute patients with Tony Kim
- Developing shared care concept with high referring providers
- Expanding end-of-life care for the advanced HF population at OHSU and beyond

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Accomplishments

2. Influence health and health outcomes of individuals, groups, and populations through clinical inquiry.

- Completion of clinical inquiry project, which has a repository component
- Involved with multiple clinical and investigational research projects
- Multiple opportunities to sit on clinical and scientific councils at the national and international level

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Accomplishments

3. Influence health policy and systems of healthcare in the local, regional, state, national, and international forums.

Speaking Engagements

- Thoratec Corporation National Economic Summit, Dallas, TX. October, 2010
- Multnomah County EMS Education Series, Portland, Oregon. Dec, 2010
- State of Jefferson County EMS Conference, Medford, OR. January 2011
- Thoratec Destination Life User's Meeting, Orlando, FL. March 2011
- 7th Annual Heart Failure Nursing Conference, Seattle, WA. June 2011

Secondary Appointment

- Joint Commission Disease-Specific Care Reviewer

Abstracts & Posters

F. McNeil, J. Gelow, J. Mudd, E. Adler, H. Song, A. Kim. (2011). Limited correlation between cardiac output and displayed device flow in patients with heartmate II LVAS. The Journal of Heart and Lung Transplant, *30(4S),* p. S163.

K. Song, B. Diggs, F. McNeil, K. Caddell, M. Slater, F. Tibayan, S. Guyton, E. Adler, A. Kim. (2010). Impact of ventricular assist device (VAD) implantation on clinical and economic outcomes of heart transplantation (HT) in the United States from 2001-2006. *29(2S),* p. S125.

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OREGON HEALTH & SCIENCE UNIVERSITY OHSU

Post Graduation Goals

- Submit abstracts and manuscripts for publication
- Continued collaboration between the SON, SOM, and OHSU healthcare faculty and staff
- Post CIP analysis of programmatic data for hospital system
- Continued hypothesis generation and testing with faculty and staff
- Industry collaboration
- Referring provider collaboration
- Complete post-master's certificate in nursing education
- Complete ethics fellowship

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Figures

Figure 1. Adapted from Hunt et al., 2005, p. e161

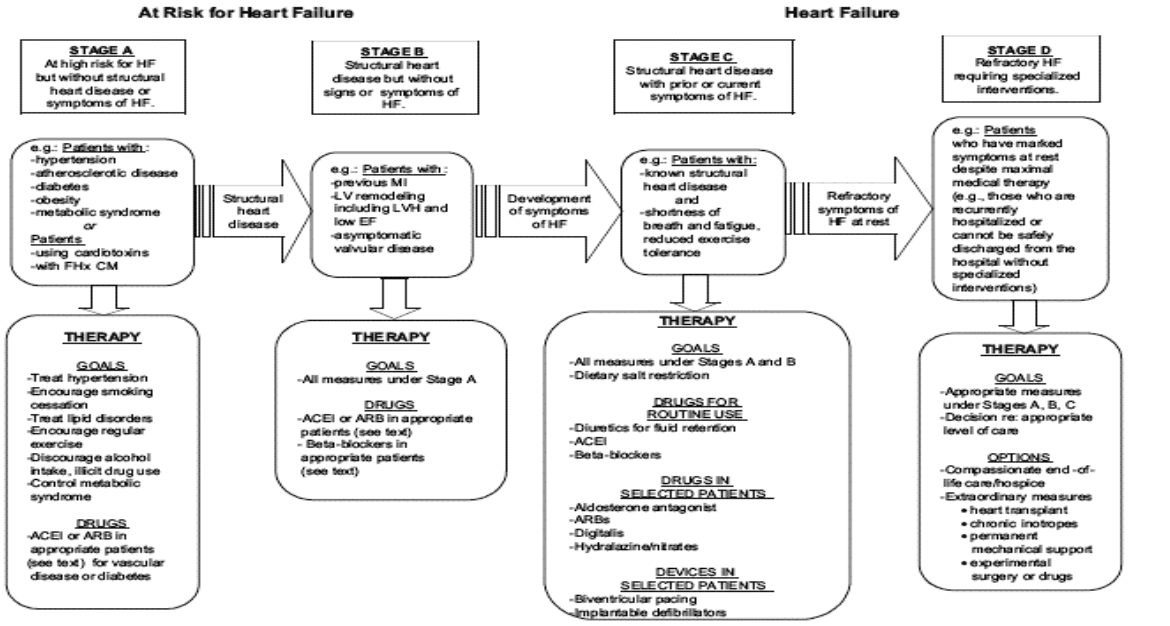


Figure 1. Stages in the development of heart failure/recommended therapy by stage. FHx CM indicates family history of cardiomyopathy; ACEI, angiotensin converting enzyme inhibitors; and ARB, angiotensin receptor blocker.

Figure 2. Components of the HeartMate XVE, reprinted with permission from Thoratec Corporation.

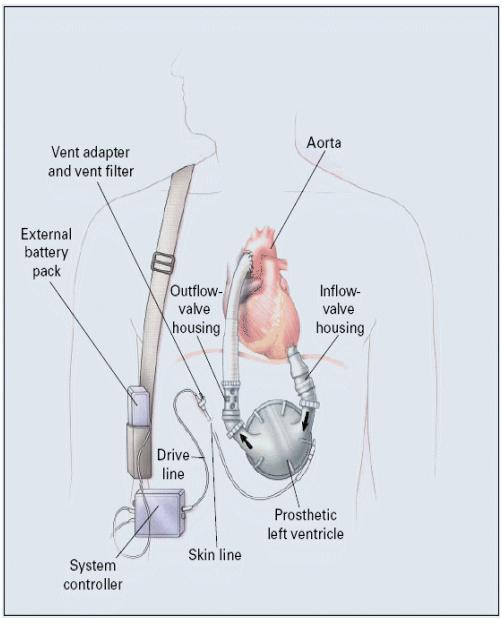
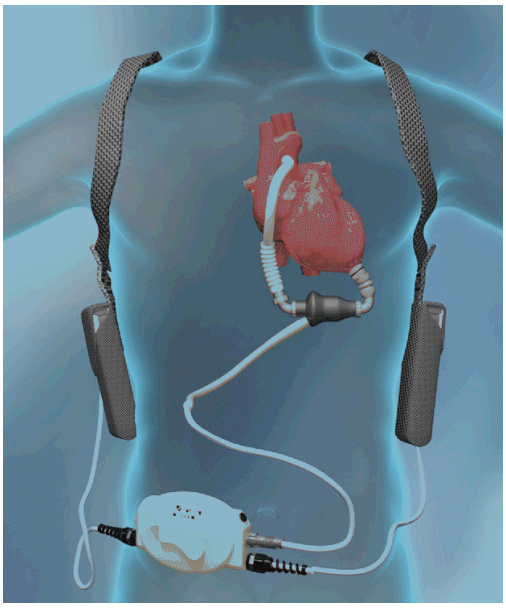


Figure 3. Components of the HeartMate II LVAS, reprinted with permission from Thoratec Corporation



MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -	**No**			**Very Little**			**Very Much**
1. causing swelling in your ankles or legs?	0	1	2	3	4	5	
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5	
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5	
4. making your working around the house or yard difficult?	0	1	2	3	4	5	
5. making your going places away from home difficult?	0	1	2	3	4	5	
6. making your sleeping well at night difficult?	0	1	2	3	4	5	
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5	
8. making your working to earn a living difficult?	0	1	2	3	4	5	
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5	
10. making your sexual activities difficult?	0	1	2	3	4	5	
11. making you eat less of the foods you like?	0	1	2	3	4	5	
12. making you short of breath?	0	1	2	3	4	5	
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5	
14. making you stay in a hospital?	0	1	2	3	4	5	
15. costing you money for medical care?	0	1	2	3	4	5	
16. giving you side effects from treatments?	0	1	2	3	4	5	
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5	
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5	
19. making you worry?	0	1	2	3	4	5	
20. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5	
21. making you feel depressed?	0	1	2	3	4	5	

Health Questionnaire EQ-5D
(English version for the US)

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

Self-Care

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

Pain/Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

Anxiety/Depression

I am not anxious or depressed ❑

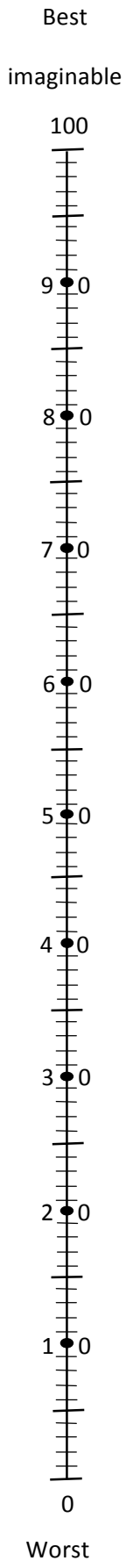
I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state



OREGON HEALTH & SCIENCE UNIVERSITY

Consent Form

TITLE: Outcomes in Patients Implanted with Ventricular Assist Devices

PRINCIPAL INVESTIGATOR: **Anne Rosenfeld**, PhD, RN (503) 494-0133

CO-INVESTIGATORS: **Antony Kim**, MD (503) 494-3201
Christopher Lee, PhD, RN (503) 278-9073
Frederick McNeil, MS, ACNP (503) 494-7097

SPONSOR: Unfunded

This form contains important information about the study in which you are being invited to participate. Please read the form carefully, ask questions of the investigators or others who are obtaining your consent to participate in the study, and take time to think about your participation. You may want to discuss the study with your family or friends before agreeing to be in the study.

What is the purpose of this study?

The purpose of this study is to learn about the clinical, economic, and quality of life outcomes in patients who are implanted with ventricular assist devices (VADs) at Oregon Health and Science University (OHSU). You have been invited to be in this research study because you have been implanted with a VAD.

What is required to participate in this study?

To qualify for this study, you must meet the following criteria:

1. Age 18 years or older
2. Able to read and understand English
3. Able to be reached by telephone
4. Have been implanted with a VAD

Table Template for Evidence

Citation	Subjects	Variables & Measurement	Design	Findings	Clinical Significance

Citation	Subjects	Variables & Measurement	Design	Findings	Clinical Significance
Frazier, O.H., et al. (2007). Initial clinical experience with the heartmate II axial-flow left ventricular assist device. *Texas Heart Institute Journal, (34)3,* 275-281.	43 patients implanted with HeartMate II LVAS 26 as bridge-to-transplant and 17 as destination therapy.	Demographic data Duration of support Hemodynamic function Ejection fraction Previous type of support Outcome	Single center experience with the newly designed HM II LVAS. They completed the feasibility phase of the clinical trial and then started enrolling patients in the phase II pivotal trial.	The average duration of support was 258 days with a cumulative duration of support for more than 31 patient years. Hemodynamic function improved. By 48 hours cardiac index increased from 1.9 $\pm$ 0.27 to 3.5 $\pm$ 0.8 L/(min-m^2), pulmonary capillary wedge pressure had also decrased. 35 out of 43 patients were discharged. Support is ongoing longest is >700 days. Nine patients died during support. Four patients underwent explantation due to recovery. Three underwent transplantation. One device replacement due to accidental driveline trauma. One explantation due to pump pocket infection after 749 days of support.	10 HM II LVADs replaced HeartMate XVE, 8 were discharged from the hospital. The authors have seen tremendous improvement in the HM II LVAS with regard to hemodynamics, functional capacity, QOL, with improved perioperative survival. This article is a good exemplar of single center experience with the HM II LVAS. It should be used as an exemplar for my CIP.

Clinical Evidence

Citation	Subjects	Variables & Measurement	Design	Findings	Clinical Significance
Long, J.W., et al. (2005). Long-term destination therapy with the HeartMate XVE left ventricular assist device: improved outcomes since the rematch study. *Congestive Heart Failure, May – June,* 133-138.	Between Jan 2003 and Dec 2004: 42 consecutive patients were implanted with the Thoratec HeartMate XVE left ventricular assist device for destination therapy (DT). These patients were evaluated at four high volume centers in the US Thoratec DT registry The DT group was compared to the REMATCH group (a previous study) The baseline study participants were (REMATCH N=68) and the (DT group N=42).	Demographics Duration of support Survival at: 6 mo, 12 mo, 18 mo, and 24 mo. Cause of Death Adverse Events	The hypothesis was that higher volume centers would most likely demonstrate better outcomes than the registry alone. The number of implants at each center ranged from 8-18 and represented 28% of the DT registry patients. Inclusion criteria included the US FDA approval indications for implantation of the HeartMate XVE DT LVAD. CMS implant criteria is as follows: 1) NYHA class IV heart failure, 2) patients being on optimal medical management for at least 60 of the last 90 days, 3) life expectancy less than 2 years, 4) left ventricular ejection fraction ≤ 25%, 5) peak oxygen consumption <12 ml/kg/min, 6) ineligible for cardiac transplantation.	Survival at 30 days, DT = 90.4%, RM = 80.9%. Survival at 1 year, DT =60.5%, RM = 51.5%. There was a 40% decreased rate of death (rate 0.49 vs. 0.84 per patient year) from any cause in the DT group. The mean duration of support through Dec 2004 was 232 days (range 15-699 days). 69% 29/42 patients were ongoing and 31% 13/42 had died by the primary end-point. 9 patients 21% had more than 300 days of support vs. The REMATCH group having 366 mean days of support. Overall, DT patients were 2.1 times less likely than REMATCH patients to experience an adverse event (RR, 0.47; 95% CI, 0.35-0.63). Incidence of death (per patient year) for REMATCH was 0.837 vs. 0.487 for DT (RR, 0.58, 95% CI, 0.32-1.06).	Although this is not a randomized clinical trial it does show that higher volume centers have a reduced risk for adverse events and death during the immediate perioperative period. Higher volume centers have more experience with patient selection, implant techniques, and post-operative care management. Clinical phenomenon and the limitations associated with randomized clinical trials can be missed in the pioneering-stages of new device therapy. A similar phenomenon occurred with cardiac transplantation. Centers with greater volumes of cases had better clinical outcomes thus leading to regionalized transplant centers. A similar concept may be required with implanting VAD centers.

Citation	Subjects	Variables & Measurement	Design	Findings	Clinical Significance
Lietz, K., et al. (2007). Outcomes of left ventricular assist device implantation as destination therapy in the post-rematch era implications for patient selection. *Circulation, (116),* 497-505. doi: 10.1161/CIRCULATIONAHA.107.691972	280 patients who underwent HeartMate XVE LVAD implantation between Nov 2001 and Dec 2005. A total of 309 patients underwent LVAD implantation as DT in the US between Nov 2002 and Dec 2005 at 66 US hospitals after completion of the REMATCH trial and US FDA approval for the modified HeartMate XVE LVAD. Data was obtained from the US FDA mandated DT registry maintained by the LVAD manufacturer, Thoratec Corporation	Preoperative risk scores 1-year Survival In hospital mortality Causes of death Patients were also stratified into low, medium, high risk, and very high risk categories.	This study is a retrospective analysis of a data registry. CMS implant criteria was based on the rematch trail data. And includes: 1) NYHA Class IV heart failure symptoms for the last 60 days despite maximized oral therapy or requirement of inotropic support, 2) left ventricular ejection fraction $\leq$ 25%, 3) peak oxygen consumption of < 12ml/kg/min or documented inability to wean from inotropes, 4) contraindication for heart transplantation because of age > 65 y/o or comorbidities such as diabetes, renal failure, or weight.	Most patients were white men> 60 y/o with ischemic cardiomyopathy. 1 year survival after implant was 56%. Intrahospital mortality post surgery was 27%. Main causes of death included sepsis, right heart failure, and multiorgan failure. Most important determinates of intrahospital mortality were poor nutrition, hematological abnormalities, markers of end-organ or right ventricular dysfunction, and lack of inotropic support. Stratification of DT candidates was low (N=65) medium (N=111) high (N=28) very high (N=18). Based on the calculated risk scores these predictors corresponded with 1 year survival rates of 81%, 62%, 28%, and 11%, respectively. 155/280 patients (55%) died during the mean support time of 10.4 months (range was 1day to 3.6 years)	The median time on first pump was 18.6 months (range 1 day to 3.6 years). During the follow up period 69 patients (24.6%) either required device replacement or died as a result of pump failure or complications. 17% of patients underwent heart transplantation after a mean mechanical support time of 1.8 to 28.4 months. The change in transplant eligibility was due to reversal of pulmonary hypertension, recovery of renal function, weight loss, 5-year cancer free survival, and infection. HeartMate XVE has a defined life span of approximately 18.6 months. This is an important consideration especially when considering this pump for patients who are not candidates for cardiac transplantation such as the Destination Therapy (DT) population. Additionally, proper patient selection can play a significant role in immediate post-implant mortality, post-hospital survival, and long-term mechanical circulatory support. Patient laboratory values such as platelet counts, serum albumin and right ventricular function can play a significant role in patient prognosis and survival to hospital discharge. Risk stratifying patients can also help provide more information to patients and family's risks and burdens in decision-making especially around the decision to implant.

Citation	Subjects	Variables & Measurement	Design	Findings	Clinical Significance
Pagani, F.D., et al. (2009). Extended mechanical circulatory support with a continuous-flow rotary left ventricular assist device. *Journal of the American College of Cardiology, (54)4,* 312-321. doi: 10.1016/j.jacc.2009.03.055	The study was conducted at 33 centers in the U.S. between 3/2005 – 4/2008. 469 subjects met study criteria and were enrolled as of 4/2008 and received a continuous-flow LVAD as BTT. 281 subjects have at least 18 months of follow-up with ongoing support. 133 subjects received additional follow-up because they were part of a primary cohort. Most subjects were men with a median age of 54 years. The most frequent etiology was nonischemic cardiomyopathy.	Survival and transplant rates were assessed at 18 months. Adverse events included: bleeding, stroke, right heart failure, percutaneous lead infections, and pump thrombosis.	In a prospective, multicenter trial, 281 subjects underwent implantation of a continuous-flow LVAD as BTT. Subjects with NYHA functional class IV heart failure who were eligible for cardiac transplantation	222 (79%) either received cardiac transplantation, removal of the device, or remained alive with ongoing LVAD support at 18-month follow-up. At 18 months, 157 (55.8%) subjects had received a heart transplant, 58 (20.6%) remained alive with ongoing LVAD support, 56 (19.9%) died, 7 (2.5%) recovered cardiac function and underwent device removal. The median time to transplantation was 118 days (range 10-545 days). The median time to death was 64 days (range 0-797days) The median duration of support for all subjects was 155 days (range 0-1,026 days). Overall survival was 82% (95% CI: 77%-87%) at 6 months, 73% (95% CI: 66%-80%) at 1 year, and 72% (95% CI 65%-79%) at 18 months. 220 (78%) of subjects were discharged from the hospital with an LVAD, with a median LOS of 25 days (range 8-180 days). 149 (68%) required readmission to the hospital.	Continuous-flow blood pumps are innovative designs, especially the HeartMate II axial flow blood pump. The smaller implant size along with the smaller driveline contributes to lower rates of adverse events with better outcomes with regard to long-term survival. Significant adverse events are still a consideration. For example, bleeding requiring re-operation and/or $\geq$ 2 U PRBCs, ventricular arrhythmias, localized infections, and percutaneous lead infections. 78% percent of these subjects were also discharged from the hospital with a median LOS of 25 days. This increase in discharge rates, as well as, decrease in LOS should significantly reduce the overall financial burdens associated with this innovative heart failure therapy.

Citation	Subjects	Variables & Measurement	Design	Findings	Clinical Significance
Rose, E.A., et al. (2001). Long-term use of a left ventricular assist device for end-stage heart failure. *The New England Journal of Medicine, (345)20,* 1435-1443	129 patients with end-stage HF who were ineligible for cardiac transplantation to receive a LVAD (68 patients) or optimal medical therapy (OMM) (61 patients)	**Demographics** **Survival:** Measured at 6,12,18, 24, 30 months **QOL:** SF-36, MLWHF, Beck Depression Inventory, NYHA Functional Capacity	Patients were randomly assigned in a 1:1 ratio to receive either a vented electric LVAD or optimal medical therapy. Randomization was done in a block design to ensure continued equivalence of group size according to center. Eligibility was determined by each sites investigator and they acted as gatekeepers. The surgical risks prevented this trial from being a double-blind design.	Survival analysis showed a reduction of 48 percent in the risk of death from any cause in the group that received LVAD as compared to the medical therapy group (RR 0.52; 95% CI, 0.34 to 0.78, p = 0.001). Survival at one year: 52% in the device group 25% in the medical group Survival at two years: 23% in the device group 8% in the medical group Adverse events were: infection, bleeding, and pump malfuction. MLWHF scores were improved in the device group. However, they were not significance. MLWHF LVAD group 23/24 patients were assessed (96%) scores were 41 $\pm$ 22 vs.the medical therapy group 6/11 patients (55%) 58 $\pm$ 58 21 (p=0.11).	This was a landmark study (REMATCH) in that the use of LVADs in patients with advanced HF resulted in clinically meaningful survival benefit than those treated with optimal medical therapy. Additionally, the QOL was improved over the OMM group. From this study the LVAD HeartMate XVE became FDA approved for Destination Therapy (DT)

Citation	Subjects	Variables & Measurement	Design	Findings	Clinical Significance
Slaughter, M.S., et al. (2009). Advanced heart failure treated with continuous-flow left ventricular assist device. *The New England Journal of Medicine, (361)23,* 2241-2251. doi: 10.1056/NEJMoa0909938	200 patients randomly assigned (133 patients were continuous flow) (59 patients were pulsatile-flow). There were more women in the continuous flow group. Devices used were the HeartMate II LVAS (Continuous flow LVAD) and the HeartMate XVE (pulsatile-flow (LVAD) QOL was measured with MLWHFQ and KCCQ.	Baseline Demographics Survival free from disabling stroke and reoperation to repair or replace the device. First event that prevented the patient from reaching the primary end point. Adverse events: pump failure, stroke, LVAD related infection, local infection, sepsis, bleeding, other neurological event, right heart failure, cardiac arrhythmia, respiratory failure, hepatic dysfunction, thrombosis, and rehospitalization. Functional capacity was measured using NYHA Functional Class and 6-minute walk test. QOL was measured using MLWHF and the KCCQ.	In this randomized clinical trial patients were enrolled in a 2:1 ratio, to undergo implantation of a continuous flow device or the currently approved pulsatile-flow device The primary composite end point was at 2 years, survival free from disabling stroke and reoperation to repair or replace the device. Secondary endpoints include: survival, frequency of adverse events, quality of life, and functional capacity. Enrolled patients met the following criteria: 1) LVEF $\leq$ 25%, 2) peak oxygen consumption < 14 ml/kg/min, 3) NYHA functional class IIIb or IV for at least 45 of the 60 days before enrollment or dependence on an IABP or inotropes for a period of 14 days before enrollment, 4) ineligible for cardiac transplantation.	Mean age of 64 years (range, 26-81). Mean LVEF17%, nearly 80% of patients were receiving inotropic agents. The primary composite end-point was achieved in more patients with continuous flow devices than with pulsatile-flow devices (62 of 134 [46%] vs. 7 of 66 [11%]; p=<0.001; hazard ratio, 0.38; 95% CI, 0.27-0.54; p=<0.001, and patients with continuous flow devices had superior actuarial survival rates at 2 years (58% vs. 24%. P=0.008). Quality of life was also significantly better in the continuous flow LVAD group vs. the pulsatile flow LVAD group. For continuous flow at baseline, 3 mo, 12 mo, 24 mo, scores were 75.4 $\pm$ 17.7, 37.4 $\pm$ 22.2, 74.1 $\pm$ 22.4, 29.6 $\pm$ 22.4; and for the pulsatile flow group: 76.1 $\pm$ 18.0, 42.1 $\pm$ 23.3, 42.1, 44.4 $\pm$ 23.2, 61. The p value for both groups (p=<0.001) Cont. Flow Devices Survival at 1 year, 68%(95% CI, 60-76), Survival at 2 years 58%(95% CI, 49-67), Pulsatile-flow Devices, 1 year 55%(95% CI, 42-69), 2 years 24%(95% CI, 1-46).	This study demonstrates that survival at 2 years is better in patients implanted with continuous flow LVAD devices specifically the HeartMate II LVAD. The HeartMate II LVAD shows improved probability in pump performance and the decreased need for pump change outs due to life span issues seen with the HeartMate XVE. In addition, due to pump size, length of surgery, and ease of use the pump has decrease risks for adverse events and thus increased quality of life and functional capacity. Patients returned to NYHA functional class II or I within 3 months, 12 months, and 24 months. The percentage of those patients with the HeartMate II is shown here 75%, 76%, and 80% respectively. Of those patients 75% started at NYHA functional class IV and 21% at functional class IIIb.

QOL Evidence

Citation	Subjects	Variables & Measurement	Design	Findings	Clinical Significance
Opasich, C., Gualco, A., De Feo, S., Barbieri, M., Cioffi, G., Giardini, A., & Majani, G. (2008) Physical and emotional symptom burden of patients with end-stage heart failure: what to measure, how and why. *Italian Federation of Cardiology, (9)11,* 1104-1108	46 patients with end-stage HF	Symptoms: Edmonton Symptom Assessment Scale (ESAS) and Kansas City Cardiomyopathy Questionnaire (KCCQ)	Patients completed the ESAS and KCCQ twice daily during their hospital stay, therefore a relatively stable condition was achieved.	Most distressing symptoms were general discomfort and tiredness followed by anorexia and dyspnea. The KCCQ summary scores were highly correlated with ESAS (r=-0.78; p=0.0001) Among the domains explored by the KCCQ, social functioning and self-efficacy showed the lowest correlation coefficients With multiple regression analysis of ESAS and KCCQ scores, general discomfort, depression, and anxiety were the symptoms that were mostly related with the results in the domains explored by KCCQ. No independent predictor was found among symptoms and quality-of-life.	General discomfort together with depression and anxiety were the symptoms mostly related with the physical limitations of health status but did not influence social functioning and self-efficacy domains. When the ESAS is used together with the KCCQ, comprehensive and quanitiative information on the patiens physcial, emotional, and social distress is provided. Combining multiple tools in a single clinical environment may be helpful to clinicians assessing quality-of-life in patients with HF. QOL assessment tools may assess different domains of patient perceptions

Citation	Subjects	Measurement/Variables	Design	Findings	Clinical Significance
Rogers, J.G., et al. (2010). Continuous flow left ventricular assist device improves functional capacity and quality of life of advanced heart failure patients. *Journal of the American College of Cardiology, (55)17,* 1826-1834. doi: 10.1016/j.jacc.2009.12.052	Advanced HF patients enrolled in the HeartMate II LVAD BTT (n=281) and DT (n=374) trials were analyzed	**Functional Status:** NYHA Functional Status, 6-min walk, patient activity scores **QOL:** (Minnesota Living with Heart Failure (MLWHF) and Kansas City Cardiomyopathy Questionnaires (KCCQ).	Data was collected before and after LVAD implantation.	LVAD patients demonstrated and sustained early improvement in functional status and quality of life. Most patients had NYHA FC IV symptoms at baseline. Following implant 82% (BTT) and 80% (DT) of patients at 6 months and 79% (DT) at 24 months improved to NYHA FC I or II. For patients who performed the test, average baseline 6 min walk distance was 214 ± 125 m (BTT) and 204 ± 150 m (DT), which increased significantly at 6, 12, 18, 24 months ($p=<0.05$). MLWHF scores decreased over time, indicating an improvement in QOL. When compared with baseline scores in patients with paired comparisons, highly significant ($p<0.001$) median improvement in scores of -10 and -13 points were seen at 1 month in the BTT and DT groups, followed by continued improvements of -29 and -40 points at 6 months of support.	Use of continuous flow LVAD in advanced HF patients results in clinically relevant improvements in functional capacity and HF related QOL. Additionally two QOL assessment tools were used in the evaluation of QOL for this study.

Citation	Subjects	Variables & Measurement	Design	Findings	Clinical Significance
Green, C.P., et al. (2000). Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: a new health status measure for heart failure. *Journal of the American College of Cardiology, (35)5,* 1245-1255.	70 stable and 59 decompensated HF patients with an EF <40%	**Physical limitations, symptoms, QOL, Social limitations, & capacity:** Kansas City Cardiomyopathy Questionnaire (KCCQ) Minnesota Living with Heart Failure Questionnaire (MLWHF) Short-Form -36	Upon entry into the study subjects were administered the KCCQ and MLWHF and Short-Form-36. Questionnaires were repeated three months later.	Convergent validity of each KCCQ domain was documented by comparison with available criterion standards (r = 0.46 to 0.74; p = < 0.001 for all). Among those with stable CHF who remiained stable by the pre-defined criteria (n=39), minimal changes were deteced over the three months of observation. Larges changes occured in those patients who had decompensated HF and improved 3 months later. (n=39; mean change = 15.4 to 40.4 points, p<0.01 for all). The sensitivity for the KCCQ was substantially greater than that of the MLWHF and SF-36.	The KCCQ is a valid, reliable and responsive health status measure for patients with HF and may server as a clinically meaningful outcome in cardiovascular research, patient management, and quality assessment.

Cost Evidence

Citation	Subjects	Variables & Measurement	Design	Findings	Clinical Significance
Hernandez, A.F, et al. (2008). Long-term outcomes and costs of ventricular assist devices among medicare beneficiaries. *Journal of the American Medical Association, (300)20,* 2398-2406.	Primary therapy device group (1476) post cardiotomy group (1467)	**Demographics:** **Survival:** **Device replacement:** **Outcomes:** Heart transplantation Device removal Death Discharged alive LOS (median)	Retrospective analysis: Analysis of inpatient claims from the Centers of Medicare and Medicaid Services for the period of 2000-2006.	1 year survival was 51.6% (n=669) in the primary device group. 55.2% discharged alive with a device. 55% readmitted within 6 months and 73.2% were alive at 1 year. 33.6% of postcardiotomy patients discharged alive with a device. 48% were readmitted within 6 months and 76% were alive at 1 year. The mean 1 year medicare payments for inpatient care in 2000-2005 were $178,714 in the primary device group and $111,769 in the post cardiotomy device group.	Although the authors completed a retrospective analysis for intpatient claims processed by the Centers of Medicare and Medicaid, the findings are very important when assessing cost and outcomes related to VAD implantation. The specific device types were not discussed because the authors used ICD-9 codes to pull CMS claims. However, device specific costs should be considered when advancing single center VAD programs.

Citation	Subjects	Variables & Measurement	Design	Findings	Clinical Significance
Sharple, L.D., et al. (2006). Cost-effectiveness of ventricular assist device use in the United Kingdom: results from the evaluation of ventricular assist device programme in the UK (EVAD-UK). *The Journal of Heart and Lung Transplantation, (25)11,* 1136-1343. doi: 10.1016/j.healun.2006.09.011	70 VAD implants for BTT and a consecutive cohort of 71 inotrope dependent transplant candidates between 4/2002 and 12/2004	**Survival time** **Outcome:** Transplant, explantion, or death **QOL:** Euro-QoL (EQ-5D) to measure patient utility within one month of implant and then every 3 months thereafter **Cost:** ICU, cardiac ward, implant costs, heart transplant procedure, and associated ICU and ward costs	Patients were prospectively monitored for survival transplantation, QOL, and resource use. **Devices used:** HeartMate VE (n=14) Thoratec PVAD/IVAD (n=42) Jarkikk 2000 (n=13) HeartMate II (n=1)	Only 13 of the 71inotrope-dependent patients could complete the EQ-5D, there was no different between the VAD and inotrope group with regard to EQ-5D. Mean quality-adjusted life years for a VAD patient was 3.27 at a lifetime cost of £173,841 ($US316,078). The majority of costs were related to the device implant, initial hospital stay ICU and ward. The inotrope-dependent patients QALY of 4.99 at a lifetime cost of £130,905 ($US 238,011)	Based on these findings the VAD group had significant QALY over those in the intrope-dependent group and the VAD was considered expnsive for the risks associated with the implant procedure. These were older devices and only included one HeartMate II LVAD. The study needs to be repeated with only one device such as the HeartMate II LVAD. There should have been a table with costs associated to the type of devices used.

What can I expect as a study participant?

We will complete two short quality of life assessments called the Minnesota Living with Heart Failure Questionnaire and the Euro-QOL EQ-5D. This will involve answering questions and drawing lines through a visual scale on paper.

The survey will ask you questions about:

1. You and your general health,
2. Your activity level,
3. Symptoms you may have, like feeling short of breath or fatigue, or feeling depressed, sleepy, or anxious.

You can complete the survey in the clinic. You can complete the survey at home and return it to us using envelopes we will give to you. If you prefer, we can make arrangements to call you at a time that is convenient for you, and ask you the survey questions over the phone.

We will review your medical and hospital financial records during the study period. We will collect information on diagnostic and laboratory tests, medical conditions and procedures, cardiac medications and other treatments, visits to the emergency room, and visits to the hospital. Your involvement in the study will be primarily focused around the quality of life assessments. All other data will be collected from OHSU medical and financial databases.

Approximately 75 participants will be enrolled at OHSU.

If you have any questions regarding this study now or in the future, contact Anne Rosenfeld at (503) 494-0133 or Frederick McNeil at 503-494-7097.

What effect will this study have on my care?

Being in this study will not affect any care that you might receive at OHSU.

What are the possible risks of participating in this study?

Some of these questions may seem personal or you may become fatigued when answering them. You may refuse to answer any of the questions that you do not wish to answer or delay completing the questions until a later time. During the study, we may become aware of previously unknown or undiagnosed depression. In that case, we will refer you to available services at OHSU or in your community, and we will talk with you about notifying your primary care provider. Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality.

What are the possible benefits of participating in the study?

You will not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients and healthcare policy in the future.

What are the alternatives to participating in the study?
You may choose not to be in this study.

Confidentiality:
We will not use your name or your identity for publication or publicity purposes.

Research records may be reviewed and copied by the supporter, the OHSU Institutional Review Board and the Office for Human Research Protections (OHRP).

Under Oregon Law, suspected child or elder abuse must be reported to appropriate authorities.

How will my privacy be protected?

We will protect your privacy in the following ways:

1. We will keep your name, address, and telephone number in a separate and protected file that does not contain any other protected health information.
2. Your name or other protected information will not be used in any other way. Instead, we will identify you by unique study codes.
3. Only the four researchers (Christopher Lee, Antony Kim, Anne Rosenfeld, and Frederick McNeil) will be able to access your information.

The specific health information we will collect from you will be limited to your responses to the study survey, and limited information from your existing health record, including demographics, diagnostic and laboratory tests, other medical conditions or procedures, current cardiac medications and other treatments, and visits to the office, emergency room, and hospital. The purposes of our use and disclosure of this health information are described in the **Purpose** section of this Consent & Authorization Form.

The persons who are authorized to use and disclose your health information are all of the investigators who are listed on page one of this form and the OHSU Institutional Review Board.

This authorization will not expire and we will keep protected health information that we collect from you in this study indefinitely. You have the right to revoke this authorization and can withdraw your permission for us to use your information for this research by sending a written request to the Principal Investigator listed on page one of the research consent form.

Will it cost anything to participate?

There are no costs or compensation related to this research study.

What if I am harmed or injured in this study?

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact Anne Rosenfeld at 503-494-0133 or Frederick McNeil at 503-494-7097.

You have not waived your legal rights by signing this form. If you are harmed by the study procedures, you will be treated. Oregon Health & Science University does not offer to pay for the cost of the treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

What are my rights as a participant?

If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (503) 494-7887.

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

You have the right to revoke this authorization and can withdraw your permission for us to use your information for this research by sending a written request to the principal investigator listed on page one of this form. If you do send a letter to the principal investigator, the use and disclosure of your protected health information will stop as of the date he/she receives your request. However, the principal investigator is allowed to use information collected before the date of the letter or collected in good faith before your letter arrives. Revoking this authorization will not affect your health care or your relationship with OHSU.

If the researchers publish the results of this research, they will do so in a way that does not identify you unless you allow this in writing.

Your health care provider may be one of the investigator*s* of this research study, and as an investigator is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

You may be removed from the study if the investigators stop the study, if the sponsor stops the study, or if we cannot contact you by phone.

You may choose to withdraw from this study. You will not be asked to complete any additional study procedures.

To participate in this study, you must read and sign this consent and authorization form. If you withdraw your authorization for us to use and disclose your information as described above, will be withdrawn from the study.

We will give you a copy of this form.

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

OREGON HEALTH & SCIENCE UNIVERSITY

INSTITUTIONAL REVIEW BOARD

PHONE NUMBER (503) 494-7887

CONSENT/AUTHORIZATION FORM APPROVAL DATE

Mar. 7, 2011

Do not sign this form after the Expiration date of: 03-06-2012

Signature of Participant	Print Name	Date

Signature of Person Obtaining Consent	Print Name	Date

OHSU Oregon Health & Science University

HIPAA RESEARCH AUTHORIZATION

AUTHORIZATION FOR THE CREATION, USE, AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR INSTITUTIONAL REVIEW BOARD APPROVED RESEARCH

Instructions: This authorization should be attached to each Consent Form. Investigators please complete information fields below and questions 2-4, 8, 9. If applicable, modify question 6 to match the consent form. Leave subject name and signature areas blank.

Title of Study:	Outcomes in Patients Implanted with Ventricular Assist Devices
Name of Investigator:	Anne Rosenfeld, PhD, RN
Phone Number:	503-494-0133
Sponsor:	Unfunded
IRB Number:	7146
Protocol Approval Date:	03.07.2011
Consent Form Approval Date:	03.07.2011

This authorization is voluntary, and you may refuse to sign this authorization. If you refuse to sign this authorization, your health care and relationship with OHSU will not be affected. However, you will not be able to enter this research study.

1. This form authorizes Oregon Health & Science University (OHSU) to use and disclose (release) certain protected health information about _____ (name of subject) that we will collect and create in this research study. The description of the information to be used or disclosed and the purposes of the requested use or disclosure are indicated in item number 8 of the authorization form.

2. The persons who are authorized to use and disclose your protected health information are:
   - ☒ All investigators listed on page one of the Research Consent Form and others at OHSU who are participating in the conduct of the research protocol
   - ☒ The OHSU Institutional Review Board
   - ☐ Others: _____

3. The persons who are authorized to receive this information are:
   - ☐ The sponsor of this study: _____
   - ☒ Federal or other governmental agencies as required for their research oversight and public health reporting in connection with this research study:
     ☒ OHRP ☒ FDA ☐ NIH ☐ Other: _____
   - ☐ Others: _____

4. We may continue to use and disclose protected health information that we collect from you in this study until:
   - ☐ HIPAA Research Authorization expiration date _____

   -OR-
   - ☐ The study is completed _____
   - ☒ Indefinitely
   - ☐ Other: _____

5. While this study is still in progress, you may not be given access to medical information about you that is related to the study until after the research is complete. After the study is completed and the results have been analyzed, you will be permitted access to any medical information collected about you in the study that OHSU maintains in your medical record.

6. You have the right to revoke this authorization and can withdraw your permission for us to use your information and/or tissue or blood sample that identifies you for this research by sending a written request to the Principal Investigator listed on page one of the research consent form. If you do send a letter to the Principal Investigator, the use and disclosure of your protected health information and/or tissue or blood sample that identifies you for this research will stop as of the date he/she receives your request. However, the use and disclosure of information collected before the date of the letter or collected in good faith before your letter arrives is allowed to continue. If you withdraw permission for use of any tissue or blood samples that were collected from you for a genetic research study, they either will be destroyed or stored without any information that identifies you. Revoking this authorization will not affect your health care or your relationship with OHSU.

7. The information about you that is used or disclosed in this study may be re-disclosed and no longer protected under federal law. However, Oregon law restricts re-disclosure of HIV/AIDS information; mental health information; genetic information; and drug/alcohol diagnosis, treatment, or referral information.

8. Description of the information to be used or disclosed and the purposes of the requested use or disclosure:

HEALTH INFORMATION *(Check as applicable)*	**PURPOSE(S)** *(Enter corresponding letter(s) from Purpose Categories)*
☒ Your complete existing health record **	A, B, D, E
☐ Limited information from your existing health record** (specify):	
_____	_____
** If we are requesting existing health records that are located outside of OHSU, you will need to complete an additional authorization to release these records to OHSU.	
THE FOLLOWING CHECKED ITEM(S) WILL BE GENERATED/COLLECTED DURING THE COURSE OF THIS STUDY:	
☒ History and physical examinations	A, B, D, E
Reports: ☒ Laboratory ☒ Operative ☒ Discharge ☒ Progress	A, B, D, E
☐ Photographs, videotapes, or digital or other images	_____
☐ Diagnostic images/X-ray/MRI/CT	_____
☐ Bioelectric Output (e.g., EEG, EKG)	_____
☒ Questionnaires, interview results, focus group survey, psychology survey, behavioral performance tests (e.g., memory & attention)	A, B, D, E
☐ Tissue and/or blood specimens	_____
☒ Other: Minnesota Living with Heart Failure Questionnaire and the EURO-QOL EQ-5D	A, B, D, E

PURPOSE CATEGORIES

a. To learn more about the condition/disease being studied
b. To facilitate treatment, payment, and operations related to the study
c. To comply with federal or other governmental agency regulations
d. For teaching purposes
e. To place in a repository or information/tissue "bank."
f. Other _____

Document Control No.: IRB-HRA-01-10
Original Date: 03/25/2003; Revision Date: 08/24/2005

9. If the information to be used or disclosed contains any of the types of records or information listed just below, additional laws relating to use and disclosure of the information may apply. You understand and agree that this information will be used and disclosed only if you **place your INITIALS** in the applicable space next to the type of information.

N/A Acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV) infection information
N/A Drug/alcohol diagnosis, treatment, or referral information/
N/A Mental or behavioral health or psychiatric care
N/A Genetic testing information

You will receive a copy of this authorization form after you sign it.

OREGON HEALTH & SCIENCE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
PHONE NUMBER (503) 494-7887
CONSENT/AUTHORIZATION FORM APPROVAL DATE

Mar. 7, 2011

Do not sign this form after the
Expiration date of: 03.06.2012

Printed name of Research Subject

Signature of Subject Date

-OR-

Printed name of Subject's Legally Authorized Representative

Signature of Subject's Legally Authorized Representative Date

Description of Relationship to Subject:

Document Control No.: IRB-HRA-01-10
Original Date: 03/25/2003; Revision Date: 08/24/2005

OREGON HEALTH&SCIENCE UNIVERSITY

Research Integrity Office, L106-RI
3181 SW Sam Jackson Park Road
Portland, OR 97239-3098
(503) 494-7887

Memo

Date: March 7, 2011

To: Anne Rosenfeld,

Susan B. Bankowski, M.S., J.D., Chair, Institutional Review Board
Elizabeth Steiner, M.D., F.A.A.F.P., Co-Chair, Institutional Review Board
Gary T. Chiodo, D.M.D., F.A.C.D., Director, OHSU Research Integrity Office

From: Kara Manning Drolet, Ph.D., Associate Director, OHSU Research Integrity Office
Mindy Roberts, M.A., C.I.P., Assistant Director, OHSU Research Integrity Office

Subject: IRB00007146, Outcomes in Patients Implanted with Ventricular Assist Devices (VADs)

Initial Study Review
Protocol/Consent Form Approval

This study is approved for 75 subjects.

The protocol was reviewed and approved for one year effective __03/7/2011____.

Items reviewed and approved include:

- Consent Form
- Questionnaire- Euro-QOL EQ-5D
- HIPAA Authorization Form
- Lay Language Summary
- MLHFQ
- PPQ

This study met the criteria for EXPEDITED IRB review based on Expedited Category # 5 where research involves materials (data, documents, records) that have been collected, or will be collected, solely for non-research purposes and Expedited Category # 7 where research on individual or group characteristics or behavior.

Subjects must receive a copy of OHSU's Notice of Privacy Practices.

Accounting for disclosures is not needed because all subjects will sign a consent and HIPAA authorization form.

This approval may be revoked if the investigators fail to conduct the research in accordance with the guidelines found in the Roles and Responsibilities document (http://www.ohsu.edu/research/rda/rgc/randr.pdf). Please note that any proposed changes in key personnel must be submitted to the IRB via a Modification Request and approved prior to initiating the change. If you plan to discontinue your role as PI on this study or leave OHSU, you must arrange either (a) to terminate the study by so notifying the IRB and your department head, or (b) propose to transfer the responsibility of the PI to a new faculty member using a Modification Request.

Investigators must provide subjects with a copy of the consent form, keep a copy of the signed consent form with the research records, and place a signed copy in the patient's hospital/clinical medical record (if applicable).

This memo also serves as confirmation that the OHSU IRB (FWA00000161) is in compliance with ICH-GCP codes 3.1-3.4 which outline: Responsibilities, Composition, Functions, and Operations, Procedures, and Records of the IRB.

Genomics Case Study

Frederick M. McNeil

Oregon Health & Science University

School of Nursing

A paper submitted in partial fulfillment

of NURS. 721 Genomics in Healthcare

Fall, 2009

Genomics Case Study

"Heart Failure (HF) is a syndrome, rather than a disease, caused by a variety of pathophysiologic processes in which the heart is unable to pump an adequate amount of blood to meet the metabolic demands of tissues" (Barkley & Myers, 2008, p.169). Risk factors include hypertension, coronary aretery disease, myocaridal infarction, family history, obseity, smoking, exessive alcohol intake, and chemotherapeutic agents (Barkley & Myers, 2008). According to the American Heart Asscoiation (AHA), prevelence for adults 20 and older is approximately 5.7 million with 3.2 million males and 2.5 million females (American Heart Association, 2009). "The estimated direct and indirect cost of HF in the United States for 2009 is $37.2 billion" (American Heart Association, 2009, p.20).

Doxorubicin (Adriamycin) is a well know chemotherapeutic agent used to treat certain types of lymphoma as well as breat cancer. However, doxorubicin is also cardiotoxic. In this case presentation we will dicuss a 53 year old woman with doxorubicin induced cardiomyopathy on bi-ventricular mechanical support as a bridge-to-cardiac transplantation. This case presenation allows for a boarder understanding of doxorubicin induced cardiomyopathy in heart failure patients who are bridging to transplantation with mechanical support. This pateint has been selected because of her complex medical and surgical course. The case study provides and excellent opportunity to reflect apon Advanced Practice Nursing (APN) interventions needed to coordinate the complex and expert care for this patient.

Case Presentation

The patient is a 53 year old woman who is established with the Oregon Health & Science University advanced heart failure and cardiac transplantation practice. She was admitted to the cardiac and vascular progressive care unit on March 12, 2009 for persistent cough and chest

pressure after receiving a seven-day course of levofloxacin for acute bronchitis. She completed the course and felt '*okay*' for a couple of days, but started to feel unwell and experienced intermittent chest pressure and cough. She described the pain to be better when she leaned forward with no chest pressure radiation. Her cough was mostly dry with no signs of infection and a myocardial infarction was ruled out.

Her past medical history includes: doxorubicin induced cardiomyopathy, breast cancer, diabetes mellitus, asthma, depression, and ventricular dysrhythmia. The patient is single and has been divorced twice with three children from her first marriage. One child lives on the east coast, another in California, and the third is in the Portland metro area. However, he has severe bouts of depression and uses illicit drugs. The patient denies alcohol, tobacco, and illicit drug use.

The patient was admitted for evaluation and management of possible acute viral pericarditis given her recent illness of bronchitis. Over the course of the following week she continued to decompensate and required intravenous inotropes and continuous cardiac monitoring. A computed tomography (CT) scan was performed to assess for infectious processes. During the scan a beta-blocker was administered and she suffered a bradycardic arrest. She was intubated and resuscitated in radiology and transferred to the cardiac and medical intensive care unit (ICU).

After the bradycardic arrest she never fully recovered her cardiac function and was neurologically intact. She was continuously dialyzed for several weeks for acute renal failure. She ultimately was able to tolerate conventional dialysis and her renal function did return to baseline after several weeks. During this time, she was worked up for transplant and listed status 1A. Status 1A is the highest listing status; this status usually denotes inpatient status waiting on inotropes or ventricular assist device (VAD) support.

On April 17, 2009 she was implanted with Thoratec paracorporeal bi-ventricular assist devices for worsening HF despite maximal medical therapy. See (Figures 1 and 2) for visual depictions of the paracorporeal ventricular assist device (PVAD) system. Her aortic valve was sutured closed for moderate aortic insufficiency. Aortic insufficiency must be corrected prior to the initiation of VAD support, otherwise retrograde flow will occur. The patient was transferred to the ICU for recovery.

Due to multiple post surgical complications such as bleeding, infection, thrombosis, and stroke the patient was not able to successfully discharge from the hospital on VAD support. Additionally, her panel reactive antibody (PRA) was extremely high post surgery upwards of 55%. The treatment team proposed a desensitization protocol to the transplant committee to potentially assist with lowering her PRA and increasing her chance for a prospective donor cross-match. The treatment team, patient, and family agreed to the desensitization protocol and treatment was initiated. The protocol duration was two weeks and the patient was changed to a status 7 on the regional transplant list. Status 7 is equivalent to delisting except that they still accumulate waitlist time.

Shortly after the desensitization protocol was completed the patient began to have severe headaches. The treatment team suspected sinusitis and consulted with multiple other specialist including otolaryngology and neurology. A head CT scan was obtained and a large posterior nasal pharyngeal mass with erosion into the skull base was found. This mass was predicted to be a fast growing tumor, as it was not visible on prior head CTs. A posterior nasal pharyngeal biopsy was completed and pathology deemed the tissue as an aggressive b-cell lymphoma. Referrals to oncology and palliative care were made. Multiple family meetings were planned with the treatment team and consultants. In the following sections, the case will be analyzed with

evidence from the literature. Social, ethical, and economic implications will also be discussed in the reflection.

Case Analysis

The mechanisms of doxorubicin-induced cardiomyopathy are being investigated at many levels. According to Singal, Li, Kumar, Danelisen, and Illiskovic (2000) extensive basic science research is being conducted on the inhibition of nucleic acid and protein synthesis, release of vasoactive amines, changes in adrenergic function, abnormalities on the mitochondria, lysosomal alterations, altered sarcolemmeal Ca^{2+} transport, imbalances in the myocardial electrolytes, free radical formation, reduction in antioxidant enzyme activities, and lipid peroxidation. The list is long and will probably reveal multifactorial etiologies. However, the majority of changes can probably be contributed to free oxygen radicals and lipid peroxidation (as cited in Singal, et al., 2000, p. 79).

In a study published by Tallaj, et al. (2005) twenty-five patients (20 women, 5 men) with a diagnosis of doxorubicin-induced cardiomyopathy were reviewed from 1990 to 2003. The study's aim was to evaluate modern treatment modalities in patients with doxorubicin-induced cardiomyopathy. HF was assessed using left ventricular ejection fraction (LVEF) and the New York Heart Association (NYHA) functional classification system. The most common types of cancers were breast and lymphoma (12 and 7) respectively.

The mortality rates cited in this article are as high as 61%. Patients who received both angiotensin-converting enzyme (ACE) inhibitors and beta-blockers showed significant improvement over the ACE only group. Limitations included a small sample size, lack of control group, and retrospective trial design. The results indicated that patients with early diagnosis, treatment, and invasive surgical modalities such as transplantation or VAD support improved

survival time. The authors report their mean survival time was 14 years with a 10-year survival of greater than 60 percent (Tallaj, et al., 2005, p. 2200).

An additional article published by Mehra & Ventura (2004) states that small dosages of doxorubicin could contribute to increased risk for HF. For example, a dosage of 300 mg/m^2 can result in a 1% incidence of HF. That percentage increases to 7% after the administration of 550 mg/m^2, and to 35% after 700 mg/m^2 (Mehra & Ventura, 2004, p. 197). Additionally, the authors cite a mortality rate ranging from 28%-70% with doxorubicin-induced cardiomyopathy. Mehra and Ventura also support the use of diuretics, beta-blockers, ACE inhibitors, and inotropic agents as treatment modalities. However, when patients continue to decline despite optimal medical management transplantation and VADs should be considered.

The type of device used for mechanical support is varied depending on the patient's needs and surgeon's preference. Patients who are experiencing cardiogenic shock refractory to medical therapy are candidates for bi-ventricular support. If the patient demonstrates signs of myocardial recovery, then the device may be explanted (Mehra & Ventura, 2004).

Use of VADs as a bridge-to-recovery is a challenging and complex treatment strategy. In a study conducted by Hall et al. (2004) 19 patients were implanted with left ventricular assist devices (LVADs) as a bridge-to-transplant. In this unbiased gene discovery trail the authors discovered that many genes were down regulated and up regulated with mechanical unloading of the left ventricle. The authors found two very significant findings: 1) the down regulation of GATA-4 a binding protein which may serve as a specific marker for cardiomyocyte remodeling and 2) a clustering of genes that govern vascular reorganization and migration (Hall et al., 2004). These findings are very preliminary and warrant further investigation. Last, the human heart may

need interval training with intermittent increases in workload and stretch and explanting devices may be trickier than previously thought.

If the patient does not demonstrate recovery then a transplant or VAD as destination therapy should be considered. Destination therapy is another term used for long-term mechanical support for patients not eligible of cardiac transplantation due to conditions such as malignancy, obesity, or pulmonary hypertension.

VADs as a bridge-to-transplant in patients with a previous history of malignancy should be free from reoccurrence for approximately 5 years before listing. According to providers at Duke University, longer waiting periods should be considered for patients with a history of aggressive tumors (Simsir, Lin, Blue, Gockerman, Russell, & Milano, 2005, p. 718). Recent Food and Drug Administration (FDA) approvals for VADs as destination therapy have proven to be viable options for this patient population. However, at this time there are no FDA approved devices for bi-ventricular support.

Reflection on Practice

Epigenetics is a relatively new specialty within the field of genomics. "The term has evolved to include any process that alters gene activity without changing the DNA sequence, and leads to modifications that can be transmitted to daughter cells" (Weinhold, 2006, p. A163). According to evidence cited by Weinhold (2006) epigenetic considerations are one of the five most important considerations in the cancer field today. Doxorubicin-induced cardiomyopathy is a perfect example of an epigenetic consideration that has had tremendous effect on the patient presented in this case study. Additional epigenetic considerations to be accounted for include exposure to vasoactive medications, mechanical circulatory support, radiation, and lack of

physical activity from severe illness. Weinhold (2006) suggests that certain conditions may be reversed when the environmental condition is changed, removed, or altered.

The profession of nursing has also been charged with recognizing the importance of genetics and genomics. According to Jenkins (2008), Forty-nine professional nursing organizations have embraced the *Essential Nursing Competencies and Curricula Guidelines for Genetics and Genomics*. This charge encourages nursing faculties and students to search out educational, research, and practice opportunities that investigate the genetic contributions to health and illness. This paper is one of those opportunities for the Doctor of Nursing Practice (DNP) student to apply knowledge and newly acquired skills to nursing practice in a reflective learning process. DNP prepared nurses will uniquely be able to conduct practice oriented clinical inquiry projects specifically aimed at assessing stressors, costs, effectiveness, and other outcomes associated with clinical genomics practice (Jenkins, 2008, p. 2).

Ethical, financial, and social implications are also important considerations. For example, with a new diagnosis of aggressive b-cell lymphoma, should aggressive VAD therapy be continued even though cardiac transplantation is not an option due to malignancy? The Thoratec PVAD is not designed for long-term use. Explanting the Bi-VAD and inserting a LVAD is likely to result in an extremely poor prognosis or death.

The financial impact for this hospitalization from March 2009 to present is approximately 1.9 million dollars with an estimated reimbursement of approximately $200,000 dollars. The 1.7 million dollar deficit will severely impact the cardiac service line's financial performance. Last, the family must relocated to care for the patient if there is any inclination that she will want to have palliative care treatment provided in her home, as she is not functionally capable of providing self-care.

Conclusion

The patient presented in this case study is extremely complex with multiple post surgical complications. The epigenetic impact of doxorubicin and mechanical unloading of both the right and left ventricle is of particular interest in this reflective learning process. One could argue that this patient is too intensive for an APN to manage as either an inpatient or outpatient, and that statement is largely true. However, the patient presented in this case study is the prime rationale for our multidisciplinary team approach to patient care. The advanced heart failure and cardiac transplant program at Oregon Health & Science University consists of cardiothoracic surgeons, heart failure cardiologist, social workers, nursing, transplant coordinators, a VAD coordinator, and various other disciplines.

The APN specifically a DNP prepared APN brings the tools such as leadership, collaboration, and coordination to complex patient and system management. This case has provided the opportunity to evaluate the literature on doxorubicin-induced cardiomyopathy and genetic alterations to the myocardium with mechanical unloading of the heart. In addition, the course has provided a basic entry-level understanding of genetics and genomics which promotes further intellectual curiosity.

Because this case is still unfolding in reality the outcome is not known at this time. The patient is currently undergoing palliative radiation and is considering additional chemotherapeutic agents which will hopefully slow tumor growth and metastasis. Heart failure, cardiothoracic surgery, and palliative care are working on placement options including a skilled nursing facility and hospice home. However, there are several financial barriers that need to be addressed with regard to who will fund this transitional period. Last, end-of-life dilemmas are now being discussed with regard to code status. When is the right time to turn off the VAD?

Figures

Figure 1. Thoratec paracorporeal ventricular assist device (PVAD) system. A) left atrial position; B) bi-ventricular option with left ventricular cannulation; C) bi-ventricular option with left atrial cannulation. Courtesy of Thoratec Corporation.

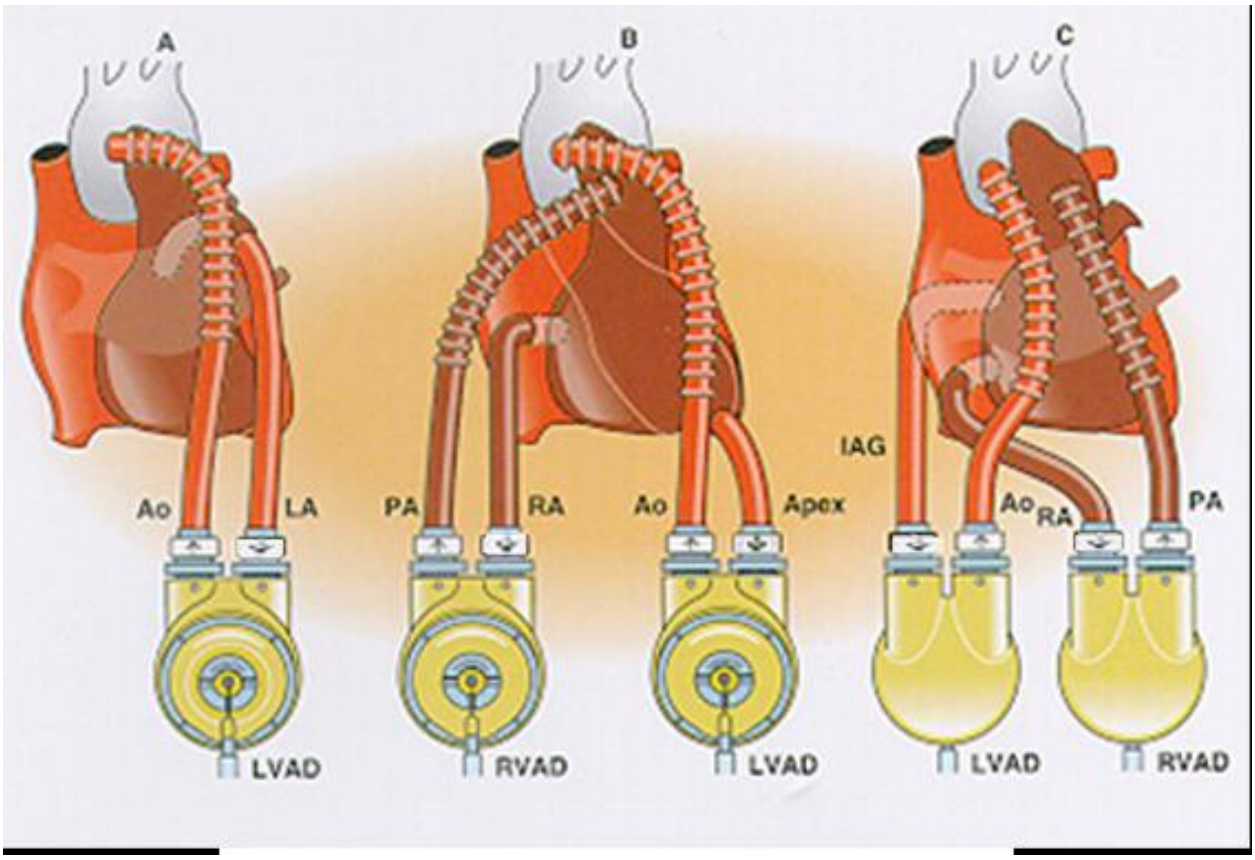
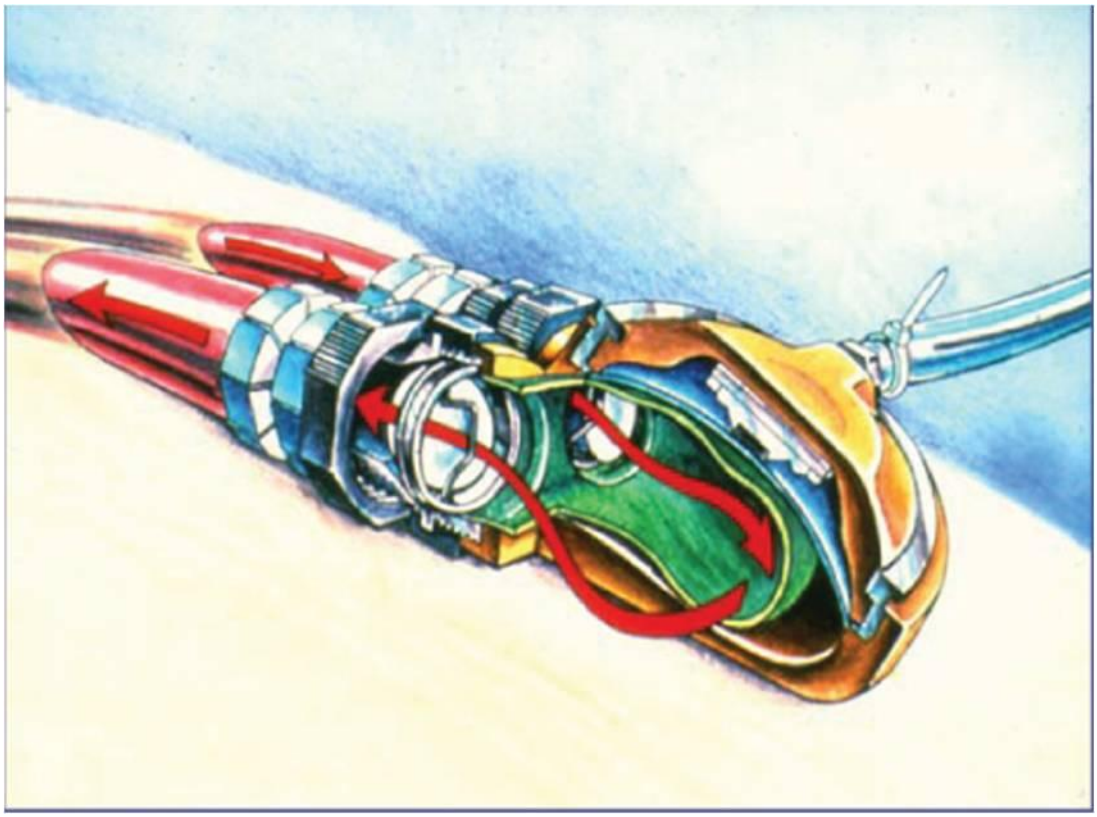


Figure 2. Path of blood flow through the PVAD. Courtesy of Thoratec Corporation.



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Implantation of a Long-Term Mechanical Circulatory Support Device in a HIV Infected Patient as Destination Therapy

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Purpose & Background

The purpose of this case study is to review the literature surrounding implantation of mechanical circulatory support devices in patients with human immunodeficiency virus (HIV) and anthracycline induced cardiomyopathy for destination therapy; to review the case of a patient at our center who underwent the implantation of a HeartMate II left ventricular assist device (LVAD); and discuss the implications for practice from a multidisciplinary and nurse practitioner perspective with regard patient management and end-of-life (EOL) planning.

LVADs are increasingly being utilized in the treatment of advanced HF as a bridge-to-transplantation (BTT) and as destination therapy (DT) in patients who are not candidates for cardiac transplantation (Slaughter, et al. 2010). Currently the HeartMate II LVAD is the most widely used axial flow device approved for use in both the BTT and DT patient populations. There are currently 6000 implants worldwide at this point in time (Thoratec, personal communication, March 2011).

Chemotherapy induced cardiomyopathy has been described in the literature as rapidly evolving interest due to the growing number of long-term cancer survivors. The most common clinical presentation of cardiotoxicity is a dose dependent cardiomyopathy leading to chronic HF frequently occurring after administration of chemotherapy agents including anthracyclines (as cited in Cardinale, et al., 2010). Data from oncology literature indicates that more than half of all patients exposed to anthracyclines will show some degree of cardiac dysfunction within 10 to 20 years after chemotherapy administration. Researchers estimate that five percent of patients receiving anthracyclines will develop overt HF and more than 60,000 patients are treated with anthracyclines every year (Cardinale, et al., 2010). Recent malignancy within the past five years preceding transplant evaluation will likely exclude patients from being considered for cardiac

transplant. In most cases, these patients will be referred for other advanced therapies such as inotropes, palliative care, and mechanical assist devices as destination therapy.

There are currently no publications in the literature describing patients who have been implanted with assist devices as destination therapy who also have concomitant HIV or acquired immunodeficiency syndrome (AIDS). We conducted on online Ovid Medline search from 1996 to 2011 using the following terms: mechanical circulatory support, heart failure, human immunodeficiency virus, HIV, acquired immunodeficiency syndrome, AIDS, ventricular assist devices, VAD, heart pump, cardiomyopathy, and cardiac transplantation. Two case studies describing a known HIV positive patient who underwent successful cardiac transplantation and one editorial perspective was located as a result of multiple searches, filtering, and reviews of abstracts. All three articles are extremely brief in nature, two of the articles describe the same patient and the other was a letter to the editor of the New England Journal of Medicine. Calabrese and colleagues (2003) report that their article is the only case report published in the literature regarding the controversial treatment option of performing cardiac transplantation in patients with HIV or AIDS. The letter to the editor stated that Columbia University had also performed a cardiac transplant in a patient with stable HIV infection. There was no discussion on the use of assist devices in any of these articles. Dr. Morgan and colleagues (2003) stated that further case reports and evaluation of patient outcomes were needed prior to making definitive statements regarding the outcomes and the allocation of scarce resources.

Our case report potentially describes the first patient with HIV who was implanted with a HeartMate II LVAD as destination therapy. Although he has multiple comorbid conditions that potentially could affect his long-term outcomes, our team felt that he was an appropriate candidate for destination therapy. The patient and family decided to proceed with LVAD

implantation after having multiple consultations with our program, infectious diseases, and another HeartMate II implanting center in the Pacific Northwest.

Case Review

Patient A is a 42 year-old male admitted in September 2010 for elective HeartMate II LVAD insertion due to anthracycline induced cardiomyopathy. His past medical and surgical history includes: HIV, hepatitis B, B cell lymphoma, implantation of an internal cardiac defibrillator (ICD), depression, hyperlipidemia, and mesenteric adenitis. The patient was optimized with home milrinone via a peripherally inserted central catheter. His ejection fraction upon admission was 20 percent with severe tricuspid regurgitation. The patient uses medical marijuana, smokes three cigarettes a day, and has been in a monogamous same sex relationship for several years. His biological parents live in Spokane, Washington. His partner has been designated as the primary caregiver for the immediate postoperative discharge recovery. However, he also works and will need to return to work after 30 days of family medical leave. At that time the patients mother will assist with recovery and caregiver support. The patient and family were appropriately concerned about their health status. There was no concern for inadequate psychosocial support systems.

Home medications upon hospital admission include: abacavir-lamivudine 600-300 mg daily, darunavir 600 mg twice daily, ritonavir 100 mg twice daily, ferrous sulfate 325 mg twice daily, furosemide 80 mg daily, Lisinopril 2.5 mg twice daily, milrinone 0.5 mcg/kg/min, pravastain 20 mg daily, spironolactone 25 mg daily, lorazepam 0.5 mg twice daily, nicotine replacement therapy 7 mg/24 hours, ondansetron 4 mg every four hours as needed, ranitidine 75 mg twice daily, senna-docusate 8.6-50 mg once daily, and sertaline 150 mg once daily. Multiple physical exams have been documented in the medical record and are consistent with advanced

HF findings that would be expected for this patient population. According to medical records the patient has been classified as New York Heart Association functional class four and American College of Cardiology stage D HF.

Admission labs: sodium 135 mmol/L, potassium 3.3 mmol/L, chloride 99 mmol/L, bicarbonate 29 mmol/L, creatinine 0.89 mg/dl, glucose 87 mg/dl, calcium 9.2 mg/dl, phosphorus 3.4 mg/dl, albumin 3.7 g/dl, white blood cells 5.2 K/cu mm, hematocrit 27.8 %, hemoglobin 9.7 g/dl, platelets 149 K/cu mm, international normalized ratio (INR) 1.16, prothrombin time 32. 6 seconds. All electrolyte abnormalities were corrected upon admission to the intensive care unit.

The patient tolerated surgical implantation without complications and was recovered in the intensive care unit. The postoperative course was uneventful and he could be weaned from inotropic support during the hospitalization. The patient and family underwent routine LVAD education with the nurse coordinator and was initiated on warfarin and aspirin for anticoagulation prophylaxis with a goal INR of 1.5-2. The patients total hospital length of stay was 16 days and he was discharged to home in stable condition. Postoperative follow up for LVAD care includes weekly clinic visits with HF cardiology for four weeks and then biweekly visits for another month. Once stabilized, he will be transferred to the nurse practitioner assist device clinic for follow up. Follow up with his infectious disease, primary care physician, and oncologist was scheduled within one month of hospital discharge following the VAD implant.

Discussion & Application to Practice

At this point in time, pre-implant education and consultation at our program does not include robust EOL care or planning. Often times, patients have been living with advanced HF for long periods of time, most often years. Patients presenting to our program have decompensated HF and diminished quality-of-life. In most circumstances, patients are being

referred for advanced therapies late due to lack of education in the community regarding heart assist technologies and advances in the field within the past five years. As a last resort, patients and families have been told by their referring cardiologist that there are no longer any available medical management modalities that will increase their functional capacity and quality-of-life. However, despite all of those factors and nationally recognized guidelines for the treatment of chronic HF, hospice and palliative care are not routinely considered as potential treatment pathways for this population.

The patient presented in this case study has now been on support for approximately six months with a few minor complications such as a urinary tract infection and an ICD firing for hypokalemia. However, as one could imagine there are numerous complications that could arise with assist device therapy such as arrhythmias, bleeding, and infection. Complications are routinely addressed with the patient and family during preoperative education and during consultation with cardiothoracic surgery. However, more in depth conversations around chronic intensive care unit stays, disabling stokes, and renal failure from cardiogenic shock have been minimized due to low risks and improved outcomes with regard to the therapy. Minimization of these risks could be a reason that EOL care and the introduction of palliative care are absent from the care plan.

Interviewing patients and disclosing full risks such as disabling stoke and prolonged intensive care unit stays should be discussed. Hypothetical situations should also be presented to the patient and family. For example, what if you fail to be weaned from the ventilator, would you want to have a tracheotomy and what if you suffered a stoke, would you want to remain on life support? When is enough, enough? These questions are difficult to ask especially by members of the team who may have cared for the patient and family for several weeks. Additionally, what

biases do we as advanced HF and transplant clinicians bring to the table? We know that VADs and cardiac transplant are proven successful therapies, but in what circumstances do patients and families fully understand the gravity of what will occur while under our care during their most vulnerable times.

Moulton and King (2010), suggest that in today's medical practice, patients and families frequently receive too little medical information to make an informed decision or too little physician opinion to feel confident in their choice of medical therapy. Moulton and King also suggest that systems should be put into place that support shared decision-making, beneficence, autonomy, and respect for informed patient choice.

One way of fully supporting the patient and family while decreasing provider bias could come in the form of a palliative care consultation prior to the implant consultation with the VAD coordinators, HF and transplant, and cardiothoracic surgery providers. Due to the nature of advanced HF these consultations would need to be expedited to ensure that patients do not decline while waiting for care. Full integration between our advanced HF and transplant and palliative care teams could be initiated and could take several months to years to fully examine the details, idiosyncrasies of complex team dynamics, and potential benefits. There are several academic medical centers that anecdotally report integrated HF and palliative care teams for the benefit of patient care and informed decision-making. While these teams report that integration and consultation take many years of development, refinement, and constructive criticism, the payoff has been worth the effort.

Palliative care teams have numerous areas of expertise to offer to specialist such as HF and transplant clinicians, oncologist, and many other specialty providers. One area in particular where the palliative care team can be immediately deployed is in the topic of delivering bad

news. Timothy Quill and colleagues (2003), suggest that many physicians find it challenging to convey "bad news" especially when it involves life-threatening illness. The authors suggests that providers often feel ill prepared, inexperienced, and struggle with the desire to provide hope while being honest and realistic. In many circumstances, palliative care and be consulted to assist in delivering bad news. Quill and colleagues (2003) site Robert Buckman's *How to Break Bad News: A Guide for Healthcare Professionals* six-step process for communicating bad news: 1) preparation and planning, 2) finding out what the patient and family already know, 3) finding out how much the patient wants to know, 4) sharing the information, 5) responding to emotions, and 6) planning and follow up. Expertise with communication around severity of illness, death and dying, pain management and patient desires and wishes makes the palliative care team an invaluable colleague and collaborative medical partner.

There are many projects underway at Oregon Health and Science University. However, incorporating the palliative care team into our advanced HF and transplant program is a strategic goal for the next calendar year. We have begun preliminary discussions with their team and we will be spending clinical time with the palliative care clinical nurses specialists in which we hope there will be mutual benefit and gain from integrated practice. Our clinicians can teach them about HF management and we can learn about palliative care. One current barrier for the advanced HF and transplant program is that there are no trained inpatient or residential care hospice facilities that are trained on VADs. We recently had a patient who wished to die at home with his family, however, due to the logistics surrounding the discontinuation of VAD support and lack of family support systems the patient was unable to go home and subsequently died while arrangements were being made to transfer him to an inpatient hospice unit. While this was not ideal, it serves and another example of why our programs should be closely integrated.

Although the patient presented in the case above is clinically stable and doing well, the palliative care team should be introduced so that relationship building, planning, and long-term EOL care discussions can occur.

The Doctor of Nursing Practice (DNP) prepared nurse practitioner is the ideal change agent who can assist in integrating the advanced HF and transplant program with the palliative care and hospice team. Integrating services may lead to increase communication and trust between providers. The creation and utilization of EOL protocols and patient care pathways can assist with streamlining the patient experience for those patients who are implanted with assist devices as both BTT and DT. In the future, a dedicated facility in the Portland metro region and perhaps in various regions throughout the state will be properly educated to care for this complex and innovative patient population. The DNP has been provided with the education, experience, and expertise in setting up these individualized programs. The future is promising for this new group of providers entering the healthcare workforce with a specific interest in advanced hear failure.

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Shared Care: Refining the Concept

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Background

Over the past several months the Advanced Heart Failure (HF) and Transplant Program have been working on the concept of "shared care". In a previous case report submitted to the Oregon Health & Science University (OHSU) School of Nursing; shared care was defined as the combination of multiple disciplines or specialist caring for a patient or population; also known as the mixed management approach to patient care and is designed to optimize the care of patients with chronic diseases or syndromes such as cancer and HF as cited in (Aggarwal, Glare, Clarke, & Chapuis, 2006). The OHSU Advanced HF and Transplant Program have grown rapidly, over the past two years, approximately four hundred percent. Due to this growth we have examined ways to decant patients from our program back into the care of the referring cardiologist. This concept is known as shared care in our program. Over the course of this quarter we have examined various components of this approach to care and have been asked to share our experiences with other HeartMate II left ventricular assist system (LVAS) users at the Thoratec HeartMate II Users Meeting in Orlando, Florida. This case report will provide a brief venue for concept exploration, program reflection, and next steps in building a successful outpatient ventricular assist device (VAD) program with specific aims to care for the destination therapy patient population.

The American College of Cardiology (ACC) and American Heart Association (AHA) estimate 500,000 incident cases and 6 million prevalent cases of HF in the United States (Hunt, et al. 2009). It is estimated that between 300,000 and 800,000 patients have advanced HF (Russell, Miller, & Pagani, 2008). 300,000 to 800,000 patients with advanced HF may be eligible for VAD implantation and could result in extreme programmatic growth. Many cardiologists at the users meeting inquired whether or not programs would be able to manage an extreme influx

of patient referrals as well as supporting up to 100-200 patients at any given center. Most programs currently support 20-60 patients and that growth would significantly impact the hospitals fiscal, operational and quality resources. OHSU has implanted nine HeartMate II LVAS in 2009 and 44 in 2010, we currently project anywhere from 60-100 implants in 2011. The majority of OHSU implants are as bridge-to-transplantation while many other centers have much larger destination therapy patient populations. Destination therapy refers to patients who are not candidates for cardiac transplant and will be supported on the VAD for the remainder of their lives.

OHSU obtained the HeartMate II LVAS in 2009 and has implanted 55 devices to date. Forty-one were implanted as bridge-to-transplant, nine as destination therapy, six died due to late complications, and one patient transferred from the University of Washington post implantation so that he could be cared for by our program. Our thirty-day all cause readmission rate for fiscal year 2010 is 19.1% and our mean duration of support is currently 216 days. Many of our patients live up and down the I-5 corridor in cites such as Salem, Eugene, Roseburg, and Medford. Our closest patients reside in Portland, Oregon and our farthest patient lives in Boise, Idaho.

Defining the Concepts

Over the course of several weeks team members met to discuss the advanced heart failure and transplant shared care concept. We used the core OHSU outreach mission as the foundation for our work. The OHSU outreach mission is as follows:

> Through a network of partnerships, OHSU is enhancing community-based care, serving Oregon's most vulnerable citizens, increasing access to healthcare education, and bringing groundbreaking health research to rural communities. With more than 200

community service programs already in place, OHSU is improving the well-being of people across Oregon and throughout the region (OHSU, 2011).

Figure 1, depicts the original diagram of the key stakeholders that we believed would be involved in the shared care concept. While the stakeholders remain integral factors in the success of the shared care concept, we have consolidated the diagram to include patients and families, providers, nurse coordinators, social workers, pharmacy services, referring community cardiologists, home health and cardiovascular rehabilitation services, shown in Figure 2. This outpatient care delivery model is not original; it has been adapted from the Park City Work Group, (2004) in which numerous experts gathered in Park City, Utah to discuss the general requirements for successful VAD programs. They developed numerous models for VAD healthcare delivery. Our model is an example of what we believe will make a successful outpatient VAD program with specific regard to the destination therapy population, but this has not been tested and remains in development.

Our hypothesis is that our outpatient care delivery model and collaboration with referring providers will: 1) return patients and families to their community sooner, 2) increase trust and communication between the implanting center and the community cardiologists, 3) develop robust partnerships with outlying community hospitals and private practice groups, and 4) provide targeted community education and support in those communities where patients implanted with VADs are currently living.

We also hypothesize that our patients will have: 1) increased patient and family satisfaction, 2) increased access to care via knowledgeable community providers, 3) decreased cost due to less travel burden, and 4) patients and families will feel safe and comforted by being cared for in their local community.

The VAD Coordinators Perspective

The VAD Coordinators at OHSU play an integral role in the multidisciplinary care of patients implanted VADs. OHSU currently employs two bachelor's prepared nurse VAD Coordinators and one Advanced Practice Nurse (APN) VAD Coordinator. In fiscal year 2012 we plan on adding an additional Nurse Practitioner and a database coordinator. The VAD Coordinators utilize EPIC an electronic medical record (EMR) for documentation purposes with regard to coordinating inpatient and outpatient care. We currently have a VAD specific department within EPIC that can track documentation encounters such as telephonic, outpatient clinic, refill requests, pre and post-operative education and evaluation, and letter writing capability for communication with non-OHSU community resources such as cardiac rehabilitation. During our last Joint Commission disease specific care certification for the VAD program in early 2011, the reviewer remarked that she had never observed better use of an EMR to coordinate care. Patient A and B serve as exemplars for care coordination and the data that can be obtained from the EMR that facilitates programmatic growth.

Patient A

Patient A, is a 58-year-old male with ischemic cardiomyopathy, ventricular tachycardia, implanted cardiac defibrillator, and HeartMate II placement on March 23, 2010 for destination therapy. His past medical history includes: atrial fibrillation, acute on chronic kidney disease, chronic hypokalemia, pulmonary hypertension, obstructive sleep apnea, hypothyroidism, Barrett's esophagus, and restless leg syndrome. He was readmitted to OHSU three times due to bowel obstructions, with multiple explorations resulting in a laparoscopic bowel resection during the last surgery. His post hospital discharge includes twenty-eight documented telephone

encounters with the patient or referring cardiologist office to coordinate care and discharge follow up.

Patient B

Patient B, is a 68 year-old male implanted with HeartMate II as destination therapy with a primary etiology of ischemic cardiomyopathy; his implant date was February 12, 2010. His past medical history includes: coronary artery disease, coronary artery bypass grafting (three vessels) in 2000, hyperlipidemia, benign prostatic hypertrophy, basal cell carcinoma, cerebral vascular accident, obstructive sleep apnea, chronic pulmonary edema secondary to heart failure, type two diabetes mellitus, acute on chronic kidney disease, marijuana use from 1965 to1968, and methamphetamine use from 1970 to 2005. He experienced one hospital readmission due to a transient ischemic attack and a low international normalized ratio. There were eighteen documented telephone encounters with the patient or referring cardiologist office to facilitate readmission and to coordinate care post hospital discharge.

While these telephone encounters may seem rather insignificant there are numerous considerations to take into account. For example, what was the duration of the call, how many calls were merged into one encounter, and what were the follow up instructions given to the patient. A good example of a common call includes symptom management, five prescription refills, and instructions to have the patient's labs checked at a local facility and to have these labs faxed back to OHSU for review. Not all calls were that intensive, however, perhaps the provider was not reached and multiple rounds of voice messaging took place. Tracking telephonic encounter follow up care is critical because it solidifies the VAD coordinators relationship with the patient and community providers. We have also used the number of encounters and time

spent to justify additional VAD coordinator resources. This work is time intensive and requires superb customer service, interviewing and assessment skills.

The OHSU Advanced HF & Transplant Program has invested a significant amount of time into training and education, which has largely been organized by the programs leaders. We have committed to providing regionalized education at least once per quarter. We have approached training and education in a variety of ways such as peer-to-peer communication, for example, provider-to-provider and nurse-to-nurse. We have participated in grand rounds, emergency department and emergency medical services education days, utilized educational technologies, such as, Adobe Connect, webinars, community publications, and through collaboration with vendors such as Thoratec the manufacturer and marketer for the HeartMate II LVAS. Additional resources are also required for travel and transportation. We have used the office of provider relations to assist in setting up travel plans and education venues. They assist with setting up grand rounds in various outlying community hospital systems. As a team we have decided that any travel requiring driving greater than two hours may require air transport and in those cases the office of provider relations should be brought into the planning and coordination of the educational event. Use of these internal resources has also significantly removed burden from the VAD coordinator group. The VAD coordinators can now focus on preparation of educational materials, coordinating with patients and families so that they can also attend the event. We have found that incorporating patients and families into the education session brings a sense of realism into the discussion, provides a venue for individual case presentations, and provides the patients and families with the full spectrum of coordinated care efforts. Patients and families routinely inform our program that they enjoy being asked to participate.

Our team has identified several resources to provide the shared care concept throughout the region of Oregon and furthermore the Pacific Northwest region. Many of the resources have been discussed in the preceding paragraphs. However, we have organized them into the following categories. Programs should identify and seek assistance from outreach offices if they are available. Provider relations and outreach coordinators can decrease VAD coordinator burden and enhance customer satisfaction. Utilization of vendor support can also be extremely helpful as well. However, programs should be advised to avoid conflicts of interest and should seek consultation from the compliance office. In our circumstance, OHSU prefers our program to utilize the provider relation's office whenever possible, however, there may be budgetary restrictions associated with this department and assistance from vendors may be needed in some circumstances. Last, identification of existing community resources and presenting a standardized message is also necessary. Our program has spent a considerable amount of time developing a standard educational power point so that we all deliver as consistent message.

There are several barriers to sharing care with referring providers, as well as, being able to provide in depth community education across wide expanses of the region. One of the most challenging barriers is call coverage. When we first started this endeavor, three team members from cardiothoracic surgery, heart failure and transplant, and nursing traveled together; granted that we did this with relatively low frequency it created a significant gap in the call coverage plan. Inadequate call coverage could potentially place the program at risk for the inability to provide adequate care for the patient during a complication or adverse event. Time for travel was another concern and provider relation's has assisted us significantly with this barrier. Risk management also is another concern. We found that in outlying cardiology clinics, we were participating patient care and interacting with patients in a more informal manner. After

discussions with risk management, off campus authorizations were obtained so that we could perform provider-based functions in the community setting under the auspices of outreach and community education. These efforts take a tremendous amount of time, attention to quality, and follow up. When providers ask for information, it is imperative to provide a timely response with specific attention to customer service and patient care.

Presenting to a National Audience

During routine programmatic meetings, Thoratec staff inquired about what we were doing in Oregon. During these meetings we explained the shared care concept and our outpatient care delivery model. They asked us for several examples of successful collaboration with referring providers. After providing examples, they referred our program on to the meeting organizers as a recommendation to present at their national meeting. The charge was to present our program structures, processes, and the shared care concept. This opportunity provided us the venue to get our ideas out on paper and to discuss the strategies for success and the barriers to implementation. Even though we were going through the process of doing the work, it was not formally organized in a manner that was understandable to anyone outside the program. Two of the three presentations are attached in the appendix of this paper in hyperlink format.

Personal Reflection

It was a phenomenal experience presenting at this level in front of a wide range of peers. The Doctor of Nursing Practice curriculum and clinical residency time has assisted with the development of leadership, organizational, and a higher level of advanced practice skills. This was evident from a personal and programmatic perspective. Our presentations were well-received and inspired conversation and exploration of future and potential collaboration at the

regional and national level. Our work on the concept of shared care was well supported and contributes to the field of advanced heart failure, specifically VAD therapy.

Next Steps

Further development of our outpatient care delivery model, hospital to home and the shared care concepts need to be further refined, vetted with hospital administration and formally implemented. Working on this project over the course of two quarters has provided us with more depth and breadth as to the amount of time, energy, and effort that is required to maintain healthy and robust community partnerships. We look forward to developing an additional Nurse Practitioner to assist with running the advanced heart failure and transplant program in collaboration with our medical leadership, and the Schools of Medicine and Nursing. Communicating our plan for the future organizational structures to support continued program growth is required. Last, laser like focus will be required with regard to patient and family centered care; facilitating relationships with community cardiologists; infrastructural support to the existing program at OHSU; and quality and timely follow up. This is what we call shared care.

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Figure 1. Original diagram of the key stakeholders involved with shared care

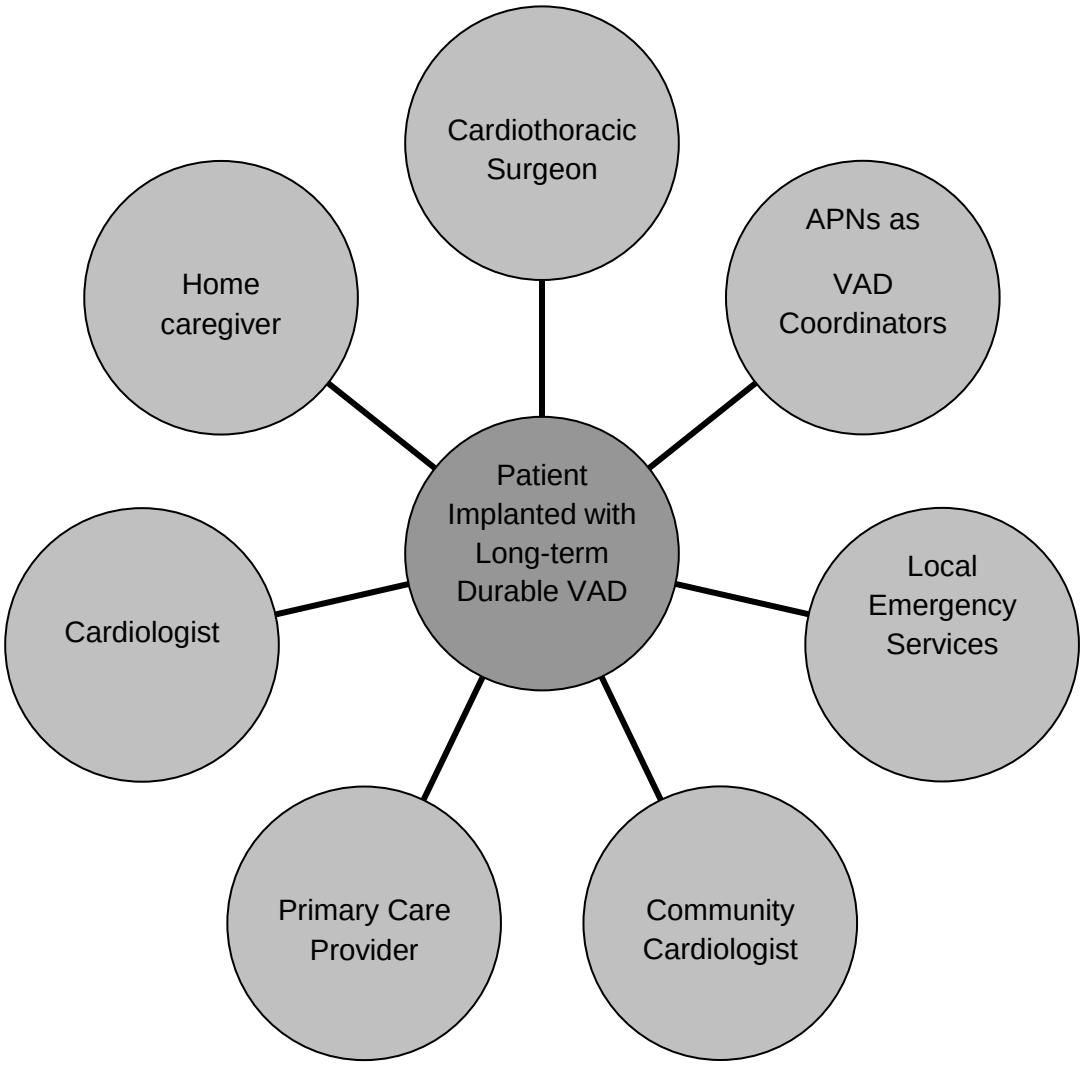
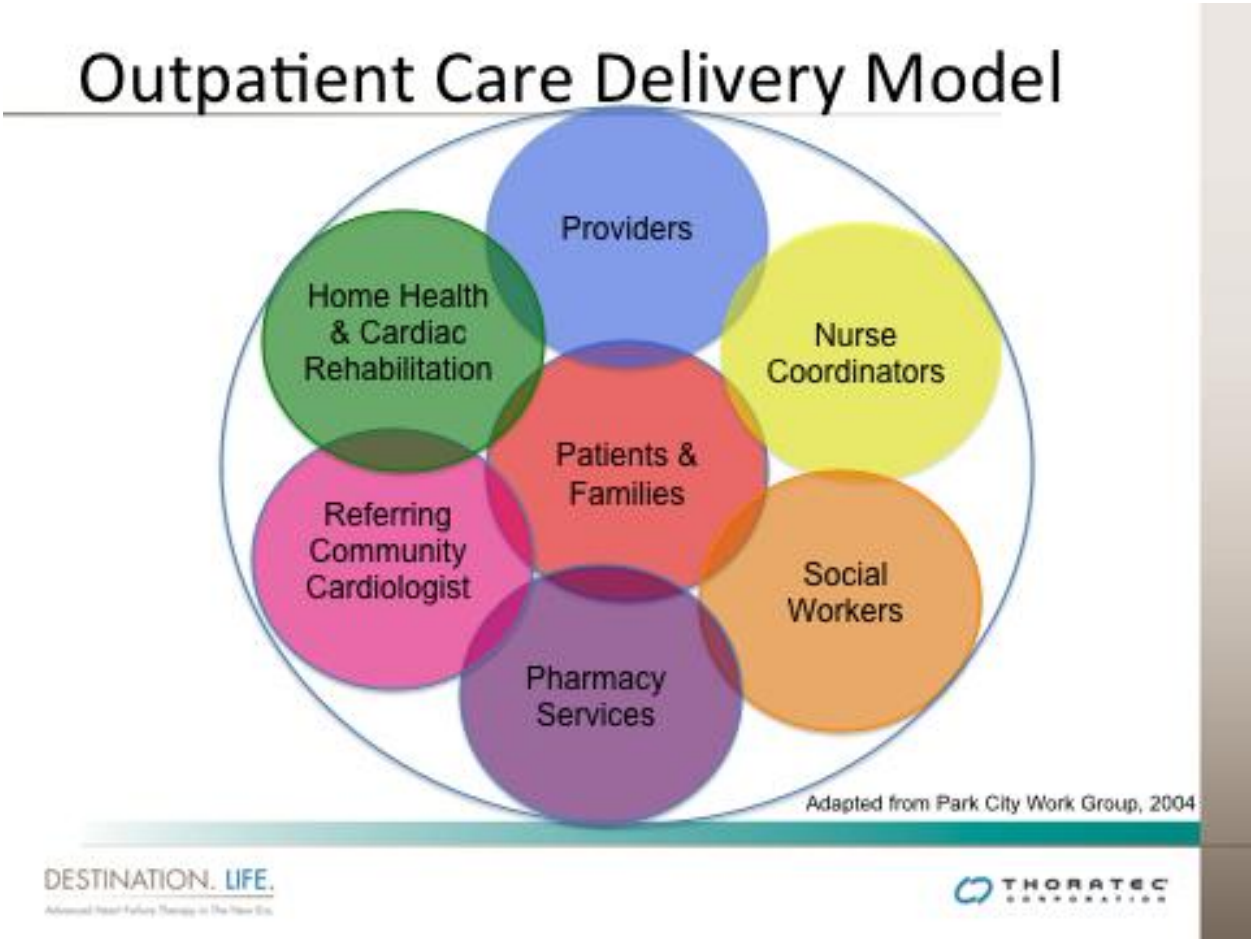


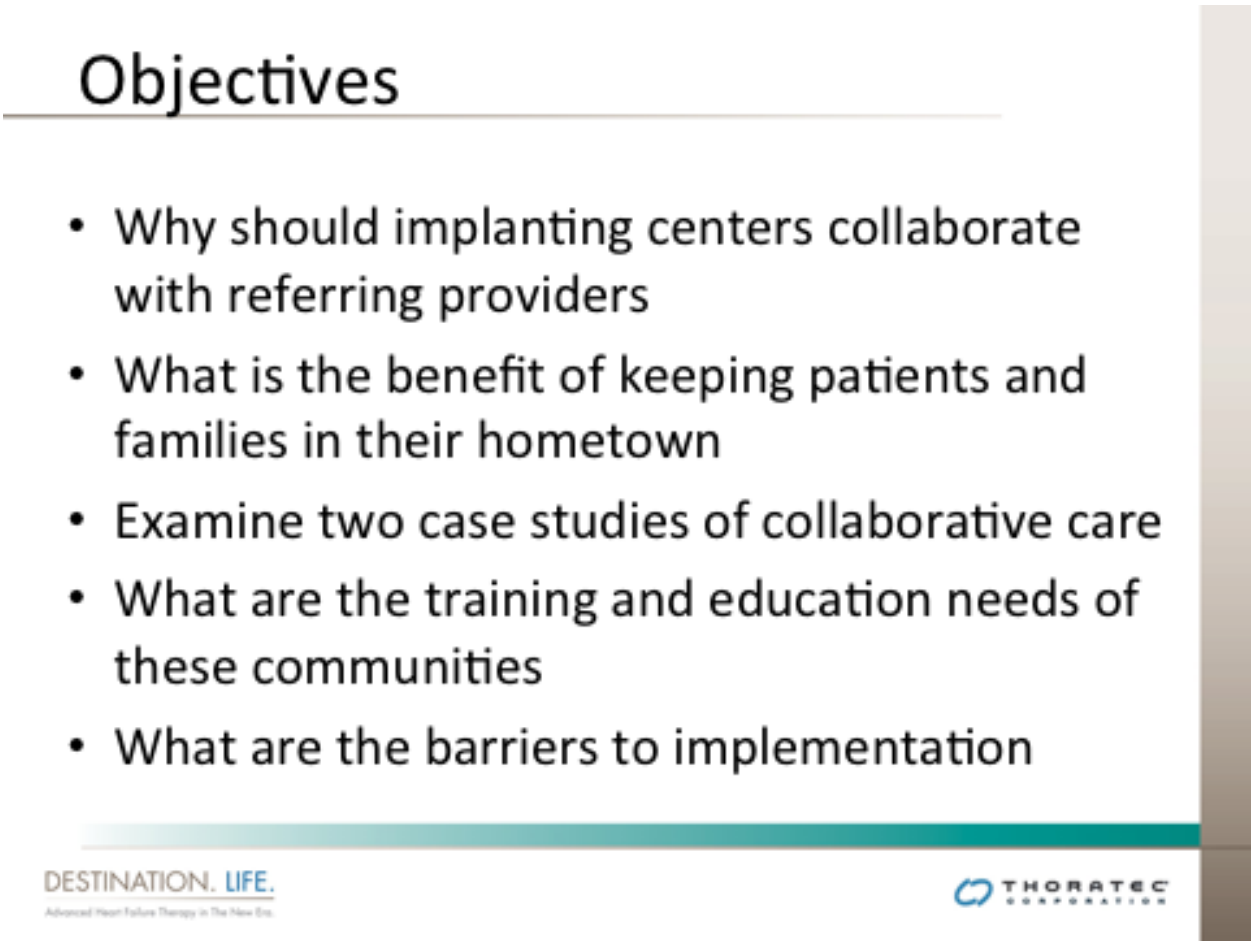
Figure 2. Refined diagram of OHSU outpatient care delivery model



Appendix: Collaborative Care with Referring Providers: Power Point Presentation, Thoratec HeartMate II LVAS Destination Life Users Meeting, Orlando, Florida. March 4, 2011.

Clinical Residency/Winter 2011/Thoratec Users Meeting. Fred McNeil.2.26.ppt

Breakout session 5 overview.ppt


Objectives
• Why should implanting centers collaborate with referring providers
• What is the benefit of keeping patients and families in their hometown
• Examine two case studies of collaborative care
• What are the training and education needs of these communities
• What are the barriers to implementation
DESTINATION. LIFE.
THORATEC


Background
• Oregon Health & Science University
– Only academic medical center in Oregon
– Outreach Mission
"Through a network of partnerships, OHSU is enhancing community-based care, serving Oregon's most vulnerable citizens, increasing access to healthcare education, and bringing groundbreaking health research to rural communities. With more than 200 community service programs already in place, OHSU is improving the well-being of people across Oregon and throughout the region" (OHSU, 2011) .
DESTINATION. LIFE.
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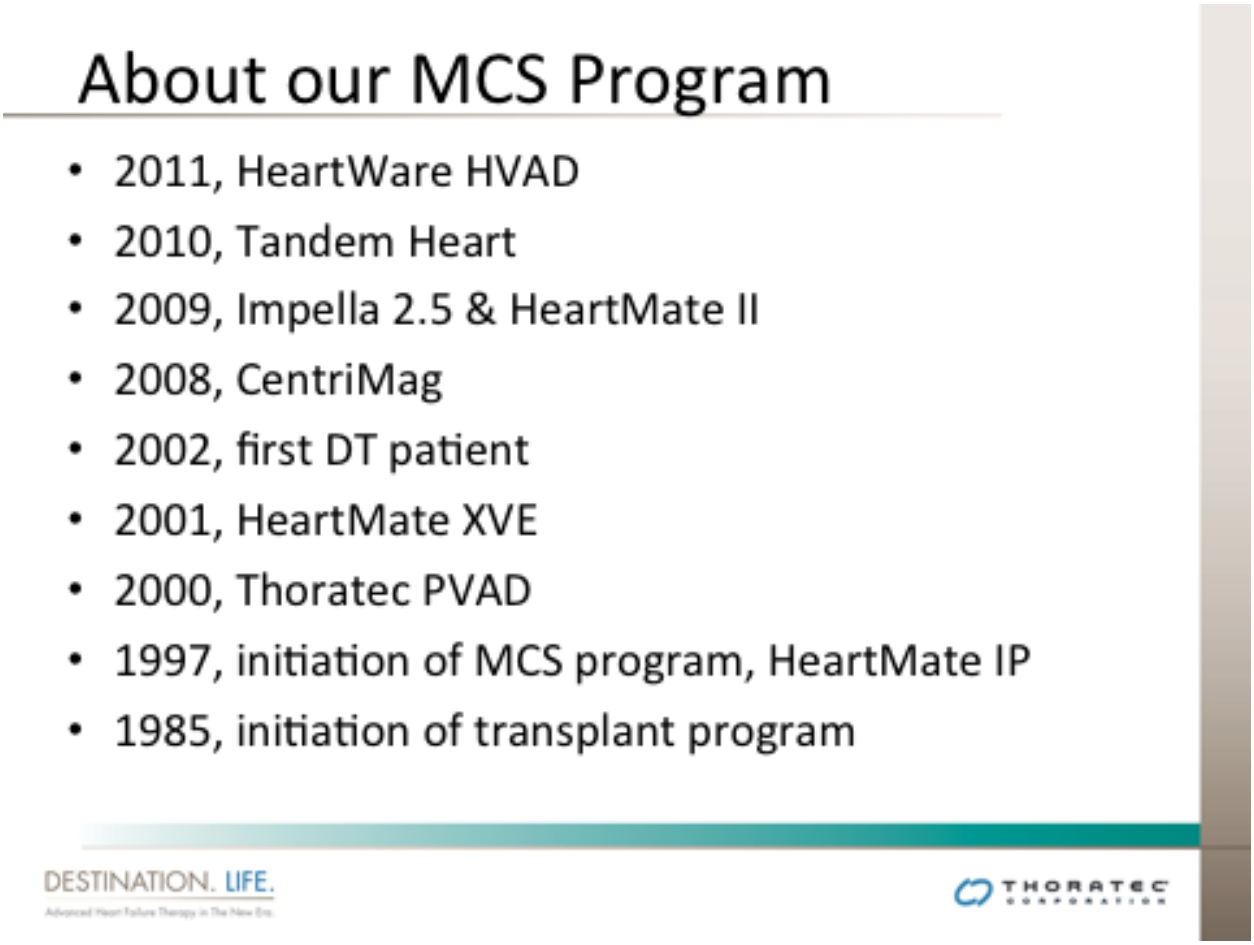
About our MCS Program
• 2011, HeartWare HVAD
• 2010, Tandem Heart
• 2009, Impella 2.5 & HeartMate II
• 2008, CentriMag
• 2002, first DT patient
• 2001, HeartMate XVE
• 2000, Thoratec PVAD
• 1997, initiation of MCS program, HeartMate IP
• 1985, initiation of transplant program
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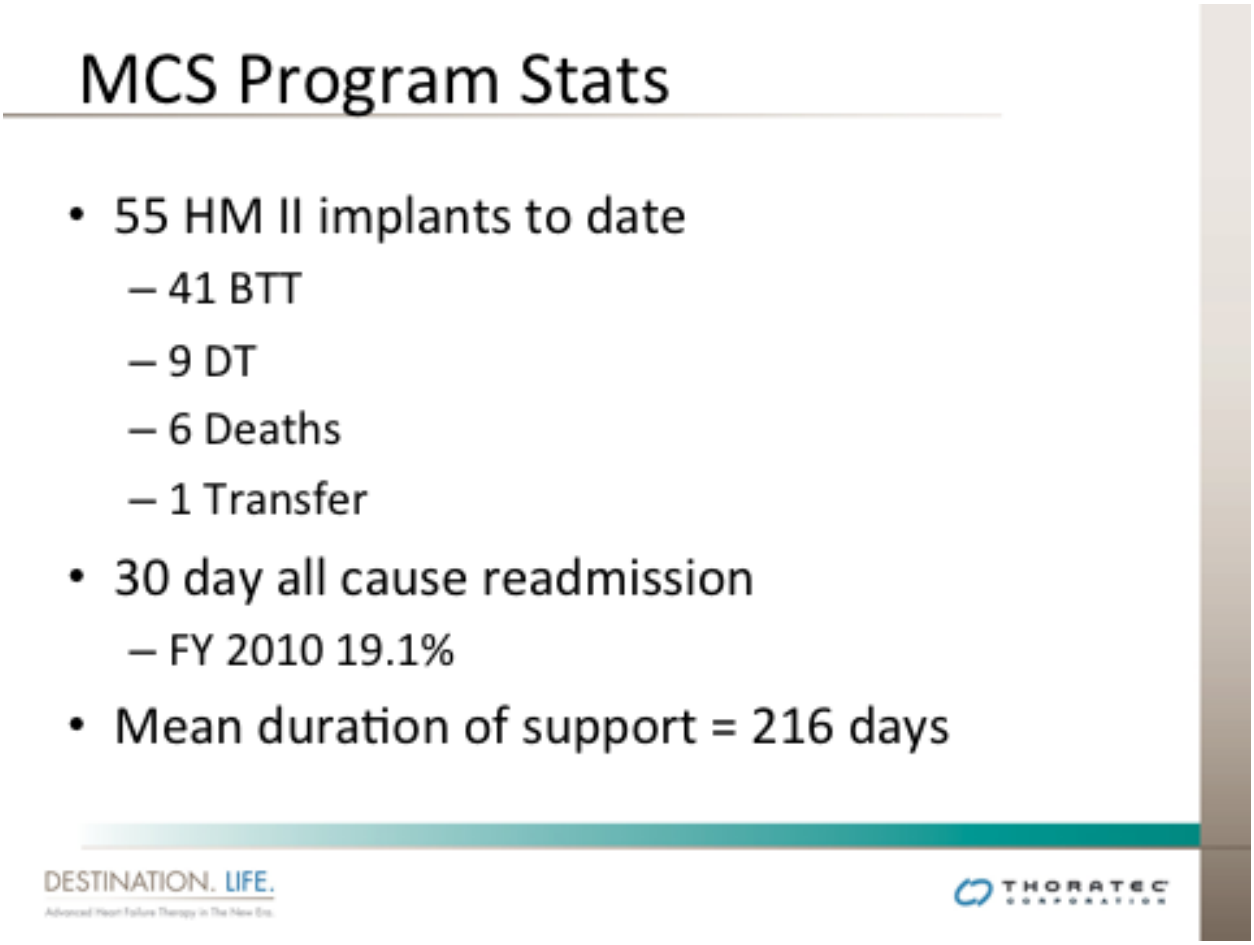
MCS Program Stats
• 55 HM II implants to date
– 41 BTT
– 9 DT
– 6 Deaths
– 1 Transfer
• 30 day all cause readmission
– FY 2010 19.1%
• Mean duration of support = 216 days
DESTINATION. LIFE.
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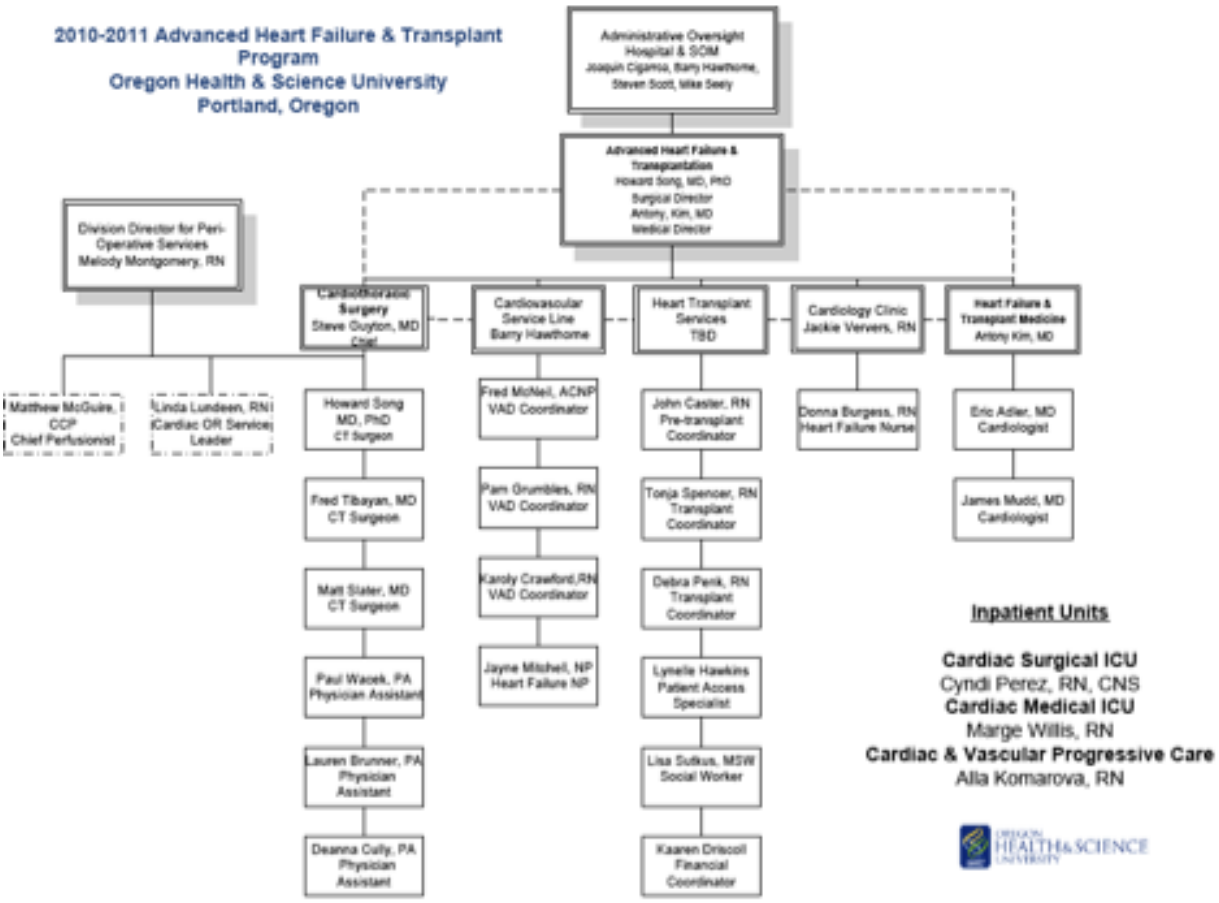
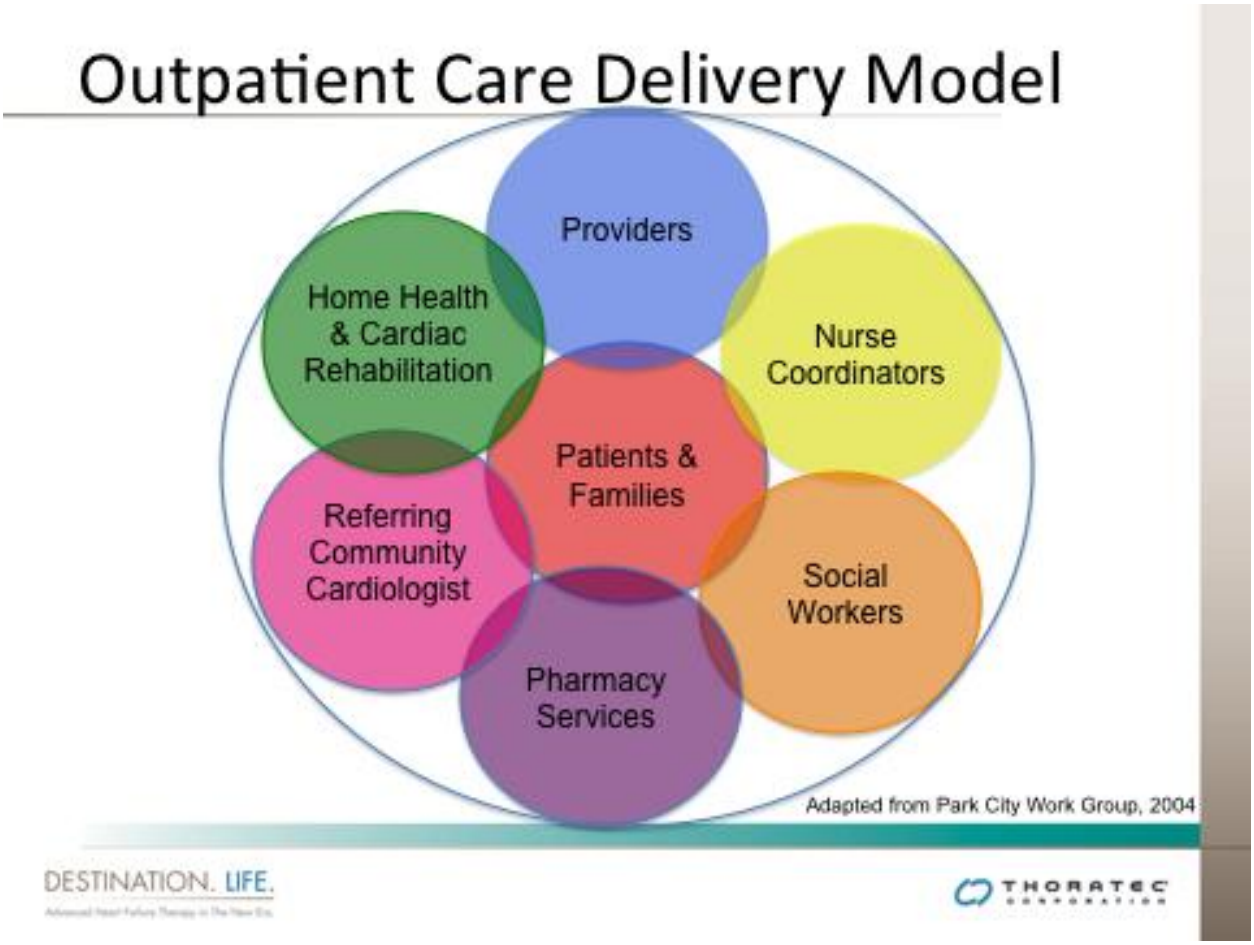

2010-2011 Advanced Heart Failure & Transplant Program
Oregon Health & Science University
Portland, Oregon
Administrative Oversight
Hospital & SOM
Joaquin Cigarroa, Barry Hawthorne, Steven Scott, Mike Seely
Advanced Heart Failure & Transplantation
Howard Song, MD, PhD
Surgical Director
Antony, Kim, MD
Medical Director
Division Director for Peri-Operative Services
Melody Montgomery, RN
Cardiothoracic Surgery
Steve Guyton, MD
Chief
Cardiovascular Service Line
Barry Hawthorne
Heart Transplant Services
TBD
Cardiology Clinic
Jackie Ververs, RN
Heart Failure & Transplant Medicine
Antony Kim, MD
Matthew McGuire, CCP
Chief Perfusionist
Linda Lundeen, RN
Cardiac OR Service Leader
Howard Song MD, PhD
CT Surgeon
Fred Tibayan, MD
CT Surgeon
Matt Slater, MD
CT Surgeon
Paul Wacek, PA
Physician Assistant
Lauren Brunner, PA
Physician Assistant
Deanna Cully, PA
Physician Assistant
Fred McNeil, ACNP
VAD Coordinator
Pam Grumbles, RN
VAD Coordinator
Karoly Crawford,RN
VAD Coordinator
Jayne Mitchell, NP
Heart Failure NP
John Caster, RN
Pre-transplant Coordinator
Tonja Spencer, RN
Transplant Coordinator
Debra Penk, RN
Transplant Coordinator
Lynelle Hawkins
Patient Access Specialist
Lisa Sutkus, MSW
Social Worker
Kaaren Driscoll
Financial Coordinator
Donna Burgess, RN
Heart Failure Nurse
Eric Adler, MD
Cardiologist
James Mudd, MD
Cardiologist
Inpatient Units
Cardiac Surgical ICU
Cyndi Perez, RN, CNS
Cardiac Medical ICU
Marge Willis, RN
Cardiac & Vascular Progressive Care
Alla Komarova, RN
OREGON HEALTH & SCIENCE UNIVERSITY


Outpatient Care Delivery Model
Providers
Home Health & Cardiac Rehabilitation
Nurse Coordinators
Patients & Families
Referring Community Cardiologist
Social Workers
Pharmacy Services
Adapted from Park City Work Group, 2004
DESTINATION. LIFE.
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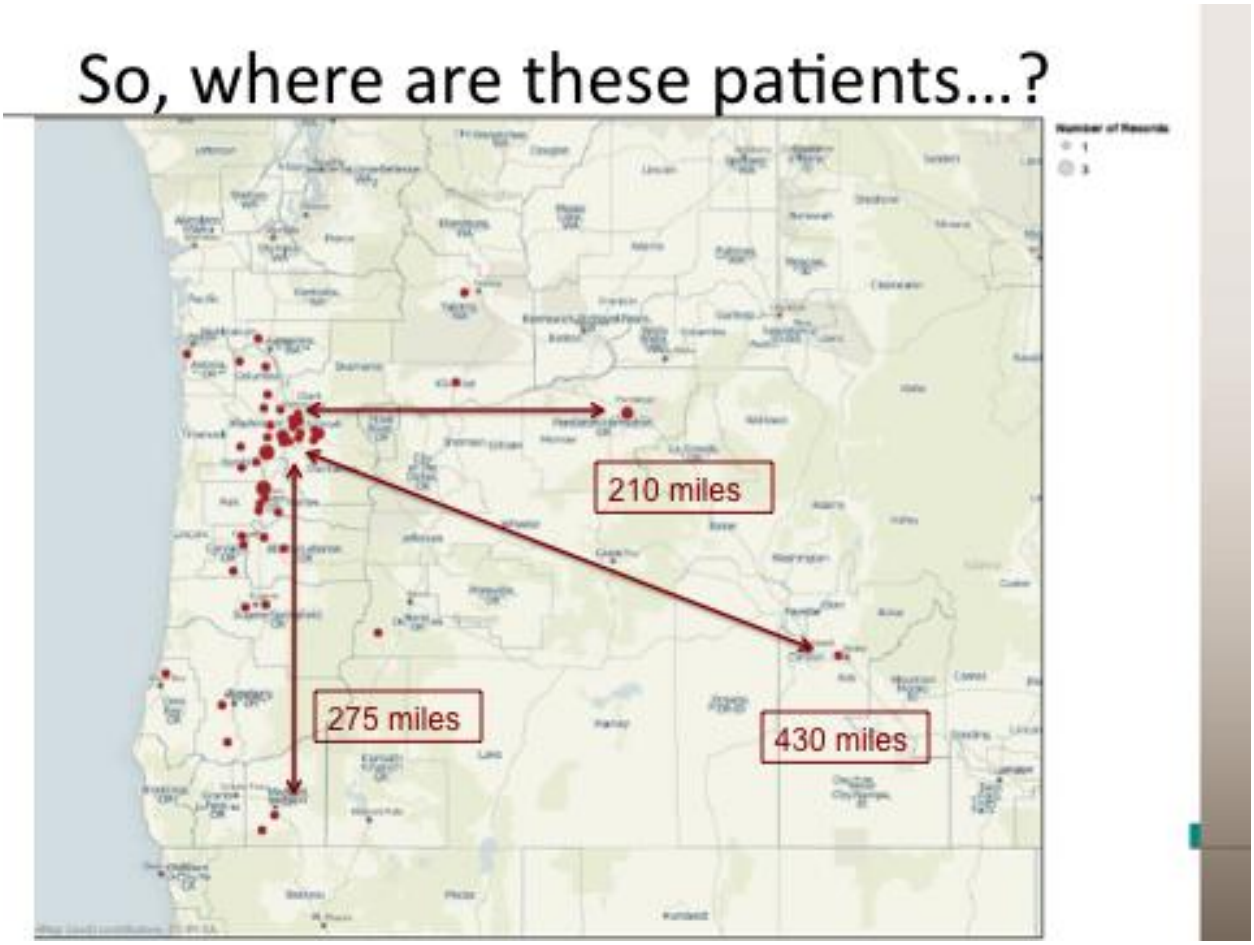
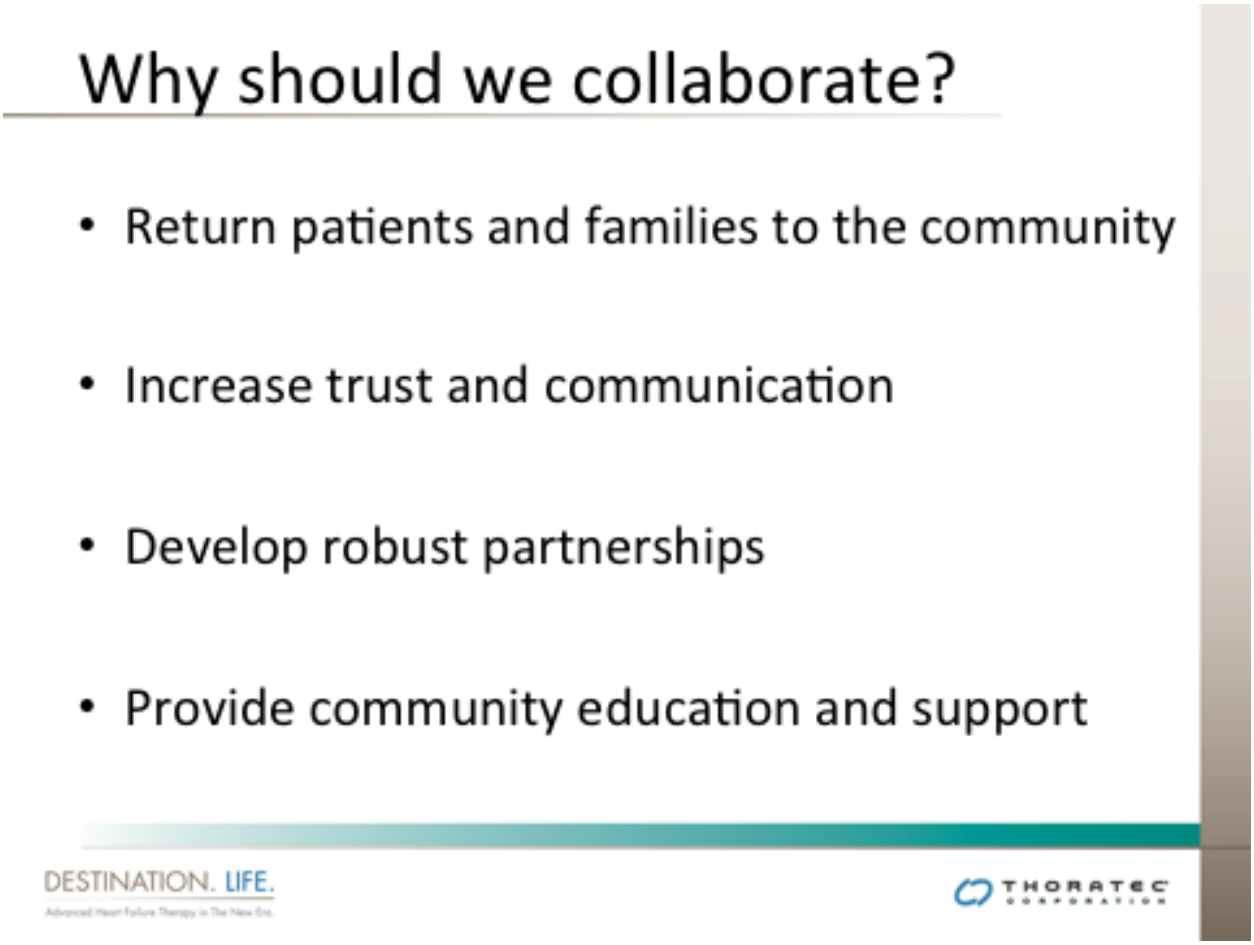

So, where are these patients…?
210 miles
275 miles
430 miles


Why should we collaborate?
• Return patients and families to the community
• Increase trust and communication
• Develop robust partnerships
• Provide community education and support
DESTINATION. LIFE.
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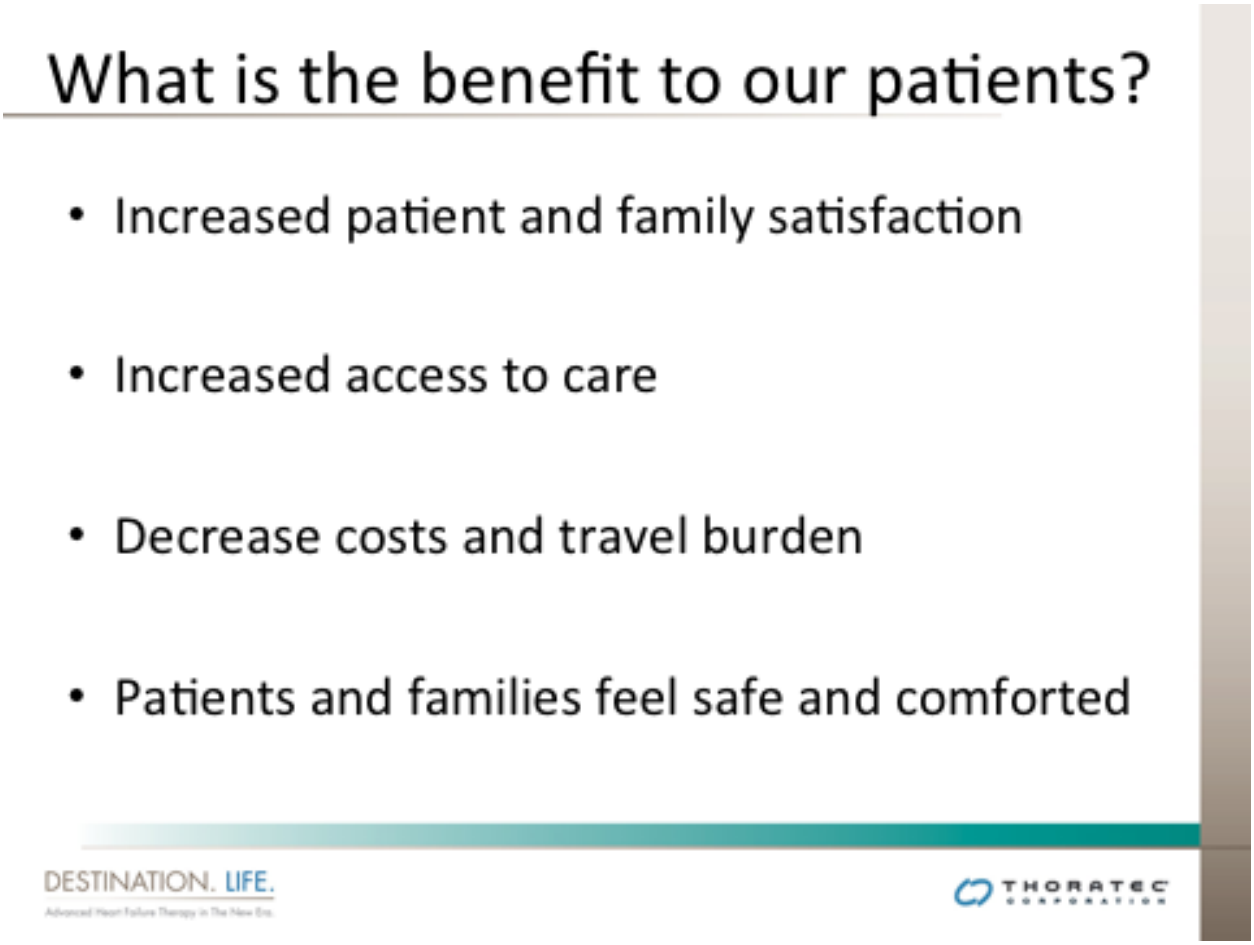
What is the benefit to our patients?
• Increased patient and family satisfaction
• Increased access to care
• Decrease costs and travel burden
• Patients and families feel safe and comforted
DESTINATION. LIFE.
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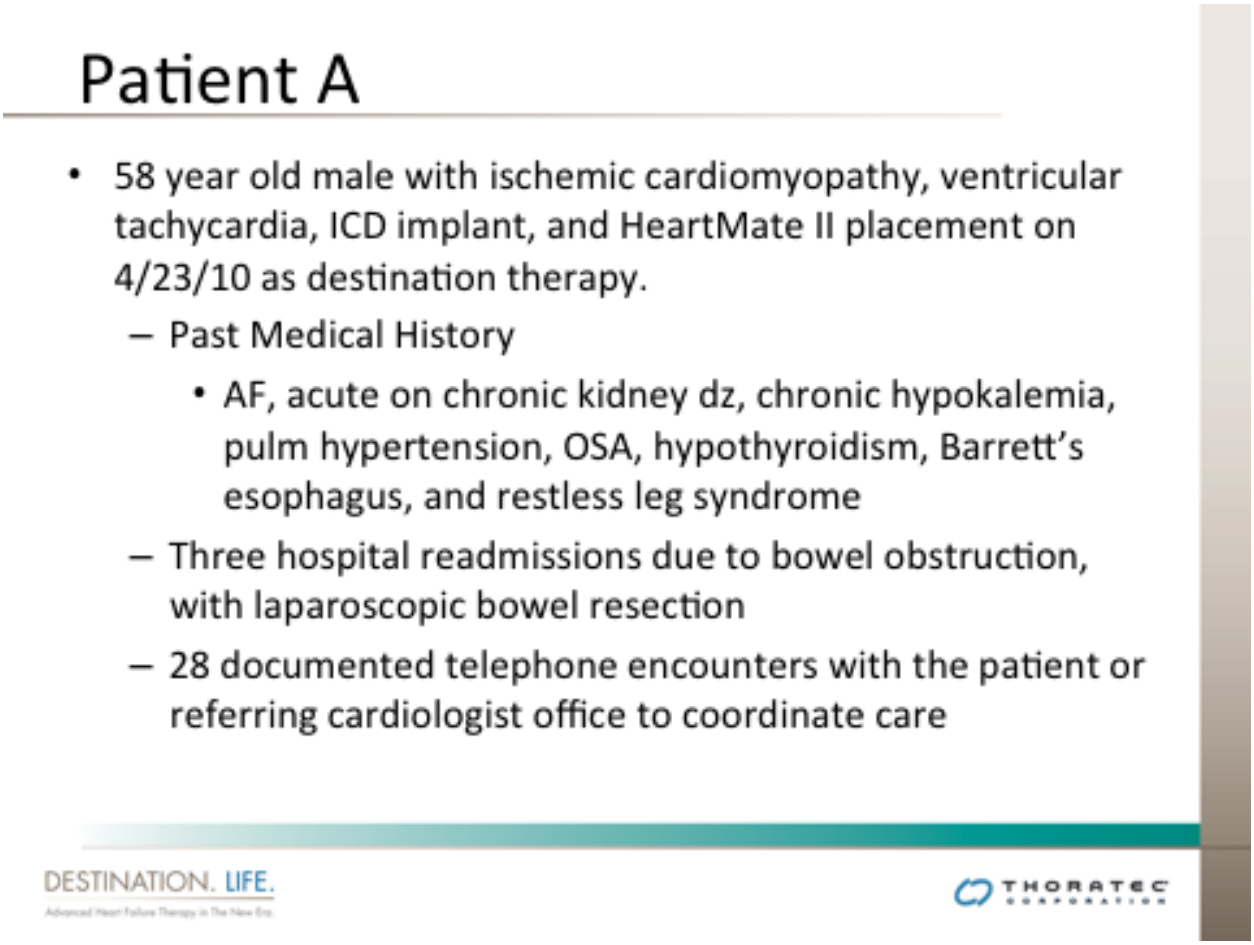
Patient A
58 year old male with ischemic cardiomyopathy, ventricular tachycardia, ICD implant, and HeartMate II placement on 4/23/10 as destination therapy.
Past Medical History
AF, acute on chronic kidney dz, chronic hypokalemia, pulm hypertension, OSA, hypothyroidism, Barrett's esophagus, and restless leg syndrome
Three hospital readmissions due to bowel obstruction, with laparoscopic bowel resection
28 documented telephone encounters with the patient or referring cardiologist office to coordinate care
DESTINATION. LIFE.
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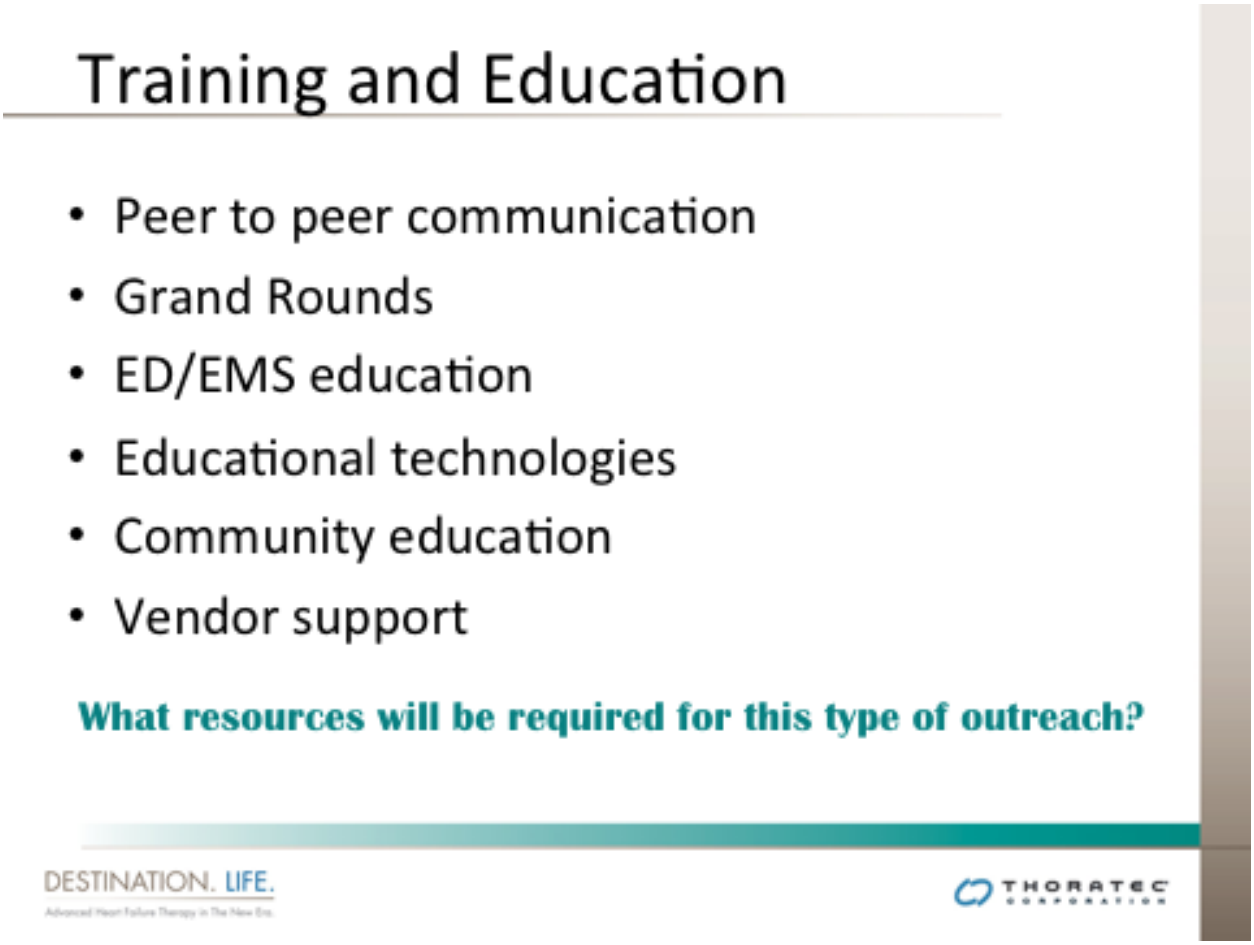
Patient B

- 68 year old male implanted with HeartMate II as destination therapy, primary etiology of ischemic cardiomyopathy, implanted on 2/12/2010.
  - Past Medical/Social History
    - CAD, CABG x 3 in 2000, hyperlipidemia, BPH, basal cell carcinoma, CVA, OSA, chronic pulm edema, DM type 2, acute on chronic renal failure, marijuana use from 1965-1968, methamphetamine from 1970 to 2005
  - One hospital readmission due to TIA and low INR
  - 18 documented telephone encounters with the patient or referring provider to coordinate care

DESTINATION. LIFE.
Advanced Heart Failure Therapy in The New Era.

THORATEC CORPORATION


Training and Education
• Peer to peer communication
• Grand Rounds
• ED/EMS education
• Educational technologies
• Community education
• Vendor support
What resources will be required for this type of outreach?
DESTINATION. LIFE.
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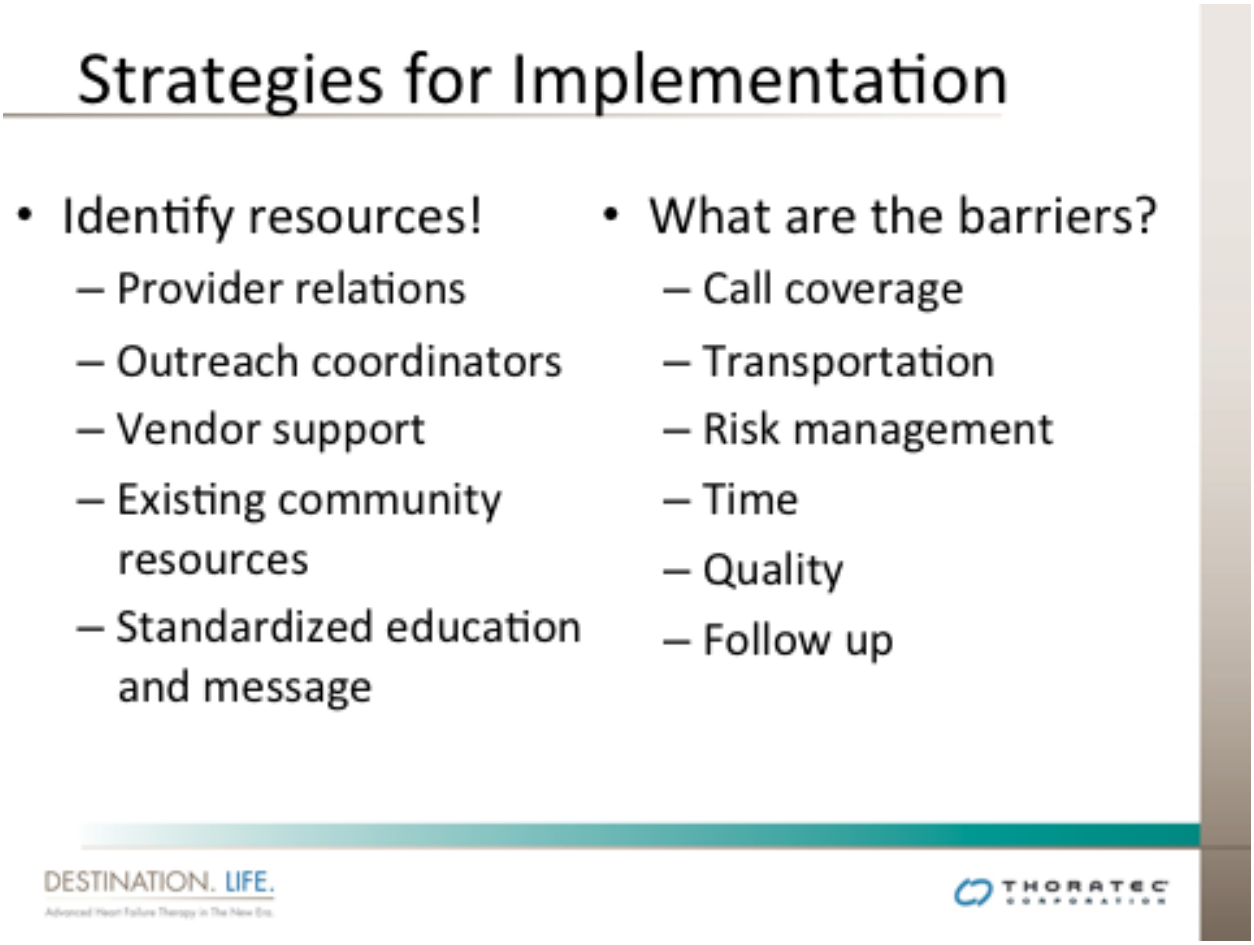
Strategies for Implementation
• Identify resources!
– Provider relations
– Outreach coordinators
– Vendor support
– Existing community resources
– Standardized education and message
• What are the barriers?
– Call coverage
– Transportation
– Risk management
– Time
– Quality
– Follow up
DESTINATION. LIFE.
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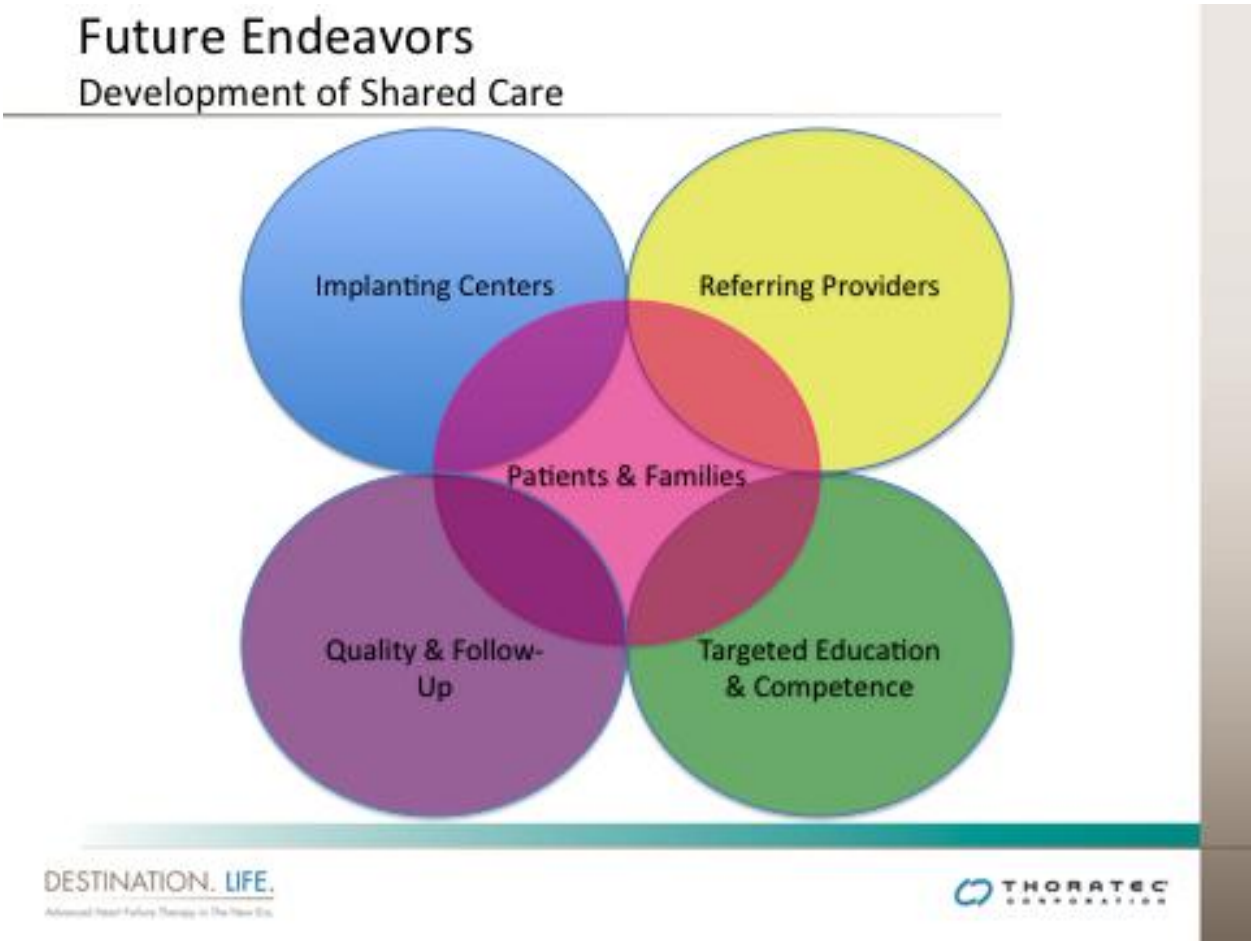
Future Endeavors
Development of Shared Care
Implanting Centers
Referring Providers
Patients & Families
Quality & Follow-Up
Targeted Education & Competence
DESTINATION. LIFE.
THORATEC

Successful Outpatient Dialysis in Patients with Implanted Left Ventricular Assist Devices: A Case Report

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Keywords: heart failure, dialysis, ventricular assist device, heart assist device

Fall, 2010

Abstract

Heart failure is a significant problem, with an estimated 6 million prevalent cases and 550,000 incident cases annually. One complication of heart failure is cardiorenal syndrome (CRS), one manifestation of which is changes in renal function in response to the hemodynamic changes associated with cardiac dysfunction. Patients with severe cardiac dysfunction may require implantation of a left ventricular assist device (LVAD) as bridge to transplantation, bridge to determination/recovery, or as destination therapy. Rates of renal failure associated with LVAD implantation range from 10-50%. Until recently, any patient with an LVAD device who needed dialysis had to remain hospitalized. The process of transitioning an LVAD patient to outpatient dialysis status requires multiple steps and education for the patient's outpatient physician, community emergency services, and dialysis providers, and has historically been difficult to arrange and maintain. This case report describes a patient who received a LVAD device at Oregon Health and Sciences University (OHSU), and who was able to transition to long-term outpatient renal replacement therapy in their local community dialysis units. Examination of these cases may lead to better understanding of the steps necessary to safely provide outpatient dialysis to LVAD patients in the future.

Introduction

The American College of Cardiology and American Heart Association estimate 500,000 incident cases and 6 million prevalent cases of heart failure in the United States.[1] Patients with heart failure are at risk of developing cardiorenal syndrome (CRS). Some patients with severe cardiac dysfunction may also require implantation of a left ventricular assist device (LVAD) as either a bridge to transplantation, bridge to determination/recovery, or as destination therapy. Use of LVADs has been shown to improve both survival to transplantation and post-transplantation mortality, but implantation of LVADs is associated with renal failure in 10-50% of patients.[2-4] Patients on dialysis who also have an LVAD have been historically relegated to in-hospital care, due to the complexity of having both the LVAD and dialysis care provided in their local communities. The following case describes the experience of a LVAD-implanted patient who successfully transitioned to an outpatient dialysis unit. OHSU has experience facilitating outpatient dialysis in two patients implanted with LVADs.

Case 1

A 28 year old man with a 14 year history of dilated cardiomyopathy (ejection fraction of <10%), was admitted for acute treatment of ventricular tachycardia and decompensated heart failure. Creatinine on admission was 4.2 mg/dL, up from a baseline of 3 mg/dL. LVAD was implanted as a bridge to transplantation 10 days after admission, after failure of aggressive medical management of arrhythmia and heart failure. The device implanted was a HeartMate XVE (E**x**tended Lead **V**ented **E**lectric Left Ventricular Assist System) manufactured by Thoratec Corporation. The patient was started on continuous venovenous hemodiafiltration (CVVHDF) two days after LVAD

implantation due to persistently elevated BUN, creatinine, and potassium as well as volume overload. He remained on CVVHDF for one month before transitioning to intermittent hemodialysis. The patient was discharged 4 months after admission, with both LVAD and tunneled dialysis catheter in place, to await cardiac transplantation. Of significant note, OHSU did not have a VAD coordinator in place at the time of implantation and one was hired three months into this patient's hospitalization.

This patient received dialysis in the community for 8 months prior to readmission for transplantation. During that time he experienced two readmissions for tunneled dialysis catheter infections with coagulase negative staphylococcus aureus. The patient received cardiac transplantation 12 months after his initial admission for ventricular tachycardia, decompensated heart failure, and device malfunction. Hemodynamic instability at the time of transplant precluded simultaneous kidney transplantation. This patient remains on dialysis and is awaiting kidney transplantation at this time.

Discussion

Cardiorenal Syndrome

Healthcare providers caring for patients with both cardiac and renal dysfunction witness first hand the delicate balance that exists between these body systems, and the true complexity of the problems that can occur when that balance is disturbed.

Fulminant heart failure, or acute decompensation of known heart failure, is a dramatic and serious condition that carries high rates of hospital admission, cost, and mortality. Acute kidney injury (AKI) is a common complication in acute heart failure patients, likely resultant from hemodynamic instability.[5] The incidence of AKI in patients with acute heart failure and left ventricular dysfunction has been found to be as high as

70%.[6] Chronic heart failure can also lead to acute and chronic kidney dysfunction over time. Studies have demonstrated that patients with chronic heart failure have increased production of vasoconstrictors, (epinephrine, angiotensin, and endothelin), as well as decreased production or sensitivity to vasodilators (natriuretic peptides, nitric oxide), which may affect renal perfusion.[5] Diminished renal function in heart failure patients is associated with poor prognosis, including increased duration of hospital admission and increased in-hospital mortality. [1, 7]

The Role of therapy for Left Ventricular Assist Devices

The American College of Cardiology (ACC) estimates there to be 6 million prevalent cases of heart failure in the United States, with 550,000 incident cases annually.[1] In patients with severe end-stage heart disease and no contraindications, transplantation is a listed therapy per the ACC/American Heart Association (AHA) guidelines.[1] Use of LVADs has been shown to improve both survival and medical status at the time of transplantation.[4, 8] Bank and colleagues[8] conducted a retrospective review of 40 patients who received either left ventricular assist devices (LVADs) or maximal inotropic support for severe heart failure. In their study, those patients who received LVADs had both improved clinical function at the time of transplantation as well as improved survival at six months compared to those patients on inotropic support alone. Frazier and colleagues[4] conducted a prospective trial of patients who were treated with LVADs after lack of response to inotropic drugs or intra-aortic balloon counterpulsation compared to similar controls who did not receive an LVAD; their study demonstrated improved survival to transplant, improved organ function at the time of transplant, and improved survival at one year after transplantation with the use of the LVAD.

Additionally, studies have demonstrated successful use of LVADs in the outpatient setting, with no evidence of increased outpatient mortality.[9, 10] The FDA has now approved use of LVADs as outpatient therapy as bridge to transplantation and destination therapy.[2, 11] Implantation of the LVAD, however, has been associated with significant rates of renal dysfunction, ranging from 10-50%.[2-4] Until recently, for those patients with renal dysfunction severe enough to require dialysis, transition to outpatient LVAD status has been an impossibility.

Our local experience

The ventricular assist device (VAD) program at OHSU has implanted more than 100 VAD devices, including reimplantation for pump failure or second implants. Of those 100, 20 (20%) experienced acute renal failure with approximately 13 (13%) requiring renal replacement therapy. The above patient case described represents the first patient to be discharged with both LVAD and renal replacement therapy requirements from OHSU. Close coordination between cardiology and nephrology as well as new organizational methods made it possible for these patients to transition to the outpatient dialysis setting. A structured discharge plan is required for these patients. Figure 1 illustrates the broad range and complexity of the different teams required to care for these patients in an inpatient versus outpatient setting – highlighting the importance of ongoing coordination to achieve success in this arena. Although long-term outcomes were imperfect for a combined cardiorenal transplant, the patient was able to enjoy some outpatient time – an experience that was previously impossible. The hospital system was also able to optimize cost via reduction in inpatient days. We are hopeful that this initial

experience can provide a positive example and some new organizational methods to help transition LVAD patients to outpatient dialysis in the near future.

The Role of the VAD Coordinator

The role of the VAD coordinator has not been well defined in the literature and varies significantly from hospital system to hospital system. OHSU employs three VAD coordinators, two who are bachelors prepared nurses and one Advanced Practice Nurse (APN) who functions as the program coordinator and as an Acute Care Nurse Practitioner (ACNP). The VAD coordinators at OHSU assist with complex coordination of care and services across the acute hospitalization and assist with discharging patients safely and competently back into their community post implantation.

In preparation for hospital discharge, the VAD coordinator arranged for the patient to be taken to the inpatient dialysis unit rather than being dialyzed in the acute care unit. This internal patient excursion to the dialysis unit allowed the dialysis nurses to function within their own unit, enabling them to care for more than one patient at a time. Additionally, it provided the dialysis nurses with more confidence and experience in preparing the patient for discharge. For example, once the dialysis nurses realized that they were competent to take care of the patient, the assist device, and provide safe and effective care they were less likely to discriminate against the discharge plan. Training and education was provided to nephrology, nursing, and the patient and family with regard to device function, pathophysiology, device troubleshooting, and alterations in assessment and patient care routines.

A contingency plan for hypotension was made with the dialysis nurses, cardiology, nephrology, and the VAD coordinators. After the patient had several

successful inpatient “off unit” dialysis runs the patient was then escorted by a VAD coordinator to the community nephrologists who assumed primary outpatient dialysis responsibility. This off campus excursion allowed one additional observed opportunity for self-care and independence and provided the patient and staff with the ability to complete a “test run”. Upon discharge, the patient was referred to outpatient dialysis three times weekly. The VAD coordinator accompanied the patient to dialysis for the first two runs to ensure a smooth transition, provide just in time education and training, and to assist with emergency medical services (EMS) education and training while in the community. Emergency contact information and a device specific educational manual were provided to the outpatient dialysis center and the responding EMS agency.

Future Implications

The HeartMate XVE is considered a first generation pulsatile device. It is approved for use as a bridge-to-transplantation (BTT) and as destination therapy (DT). More recently the HeartMate II left ventricular assist system (LVAS) has also been approved for BTT and DT. Due to the superiority of the HeartMate II LVAS, there has been much wider use of the device as well as increased patient discharges due to safety and efficacy. The HeartMate II LVAS runs continuously over the cardiac cycle and may dramatically decrease the pulse pressure due to continuous flow dynamics. Due to decreases in pulse pressure, it may be difficult to palpate a pulse or obtain traditional blood pressure measurements. For this reason, Doppler pressure measurements must be obtained at the brachial artery. Newer continuous flow technologies may pose a significant burden on training and education with regard to outpatient dialysis centers. Further exploration will be required and should be discussed in the literature.

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(7) Krumholz HM, Chen YT, Vaccarino V et al. Correlates and impact on outcomes of worsening renal function in patients > or =65 years of age with heart failure. *Am J Cardiol* 2000 May 1;85(9):1110-3.

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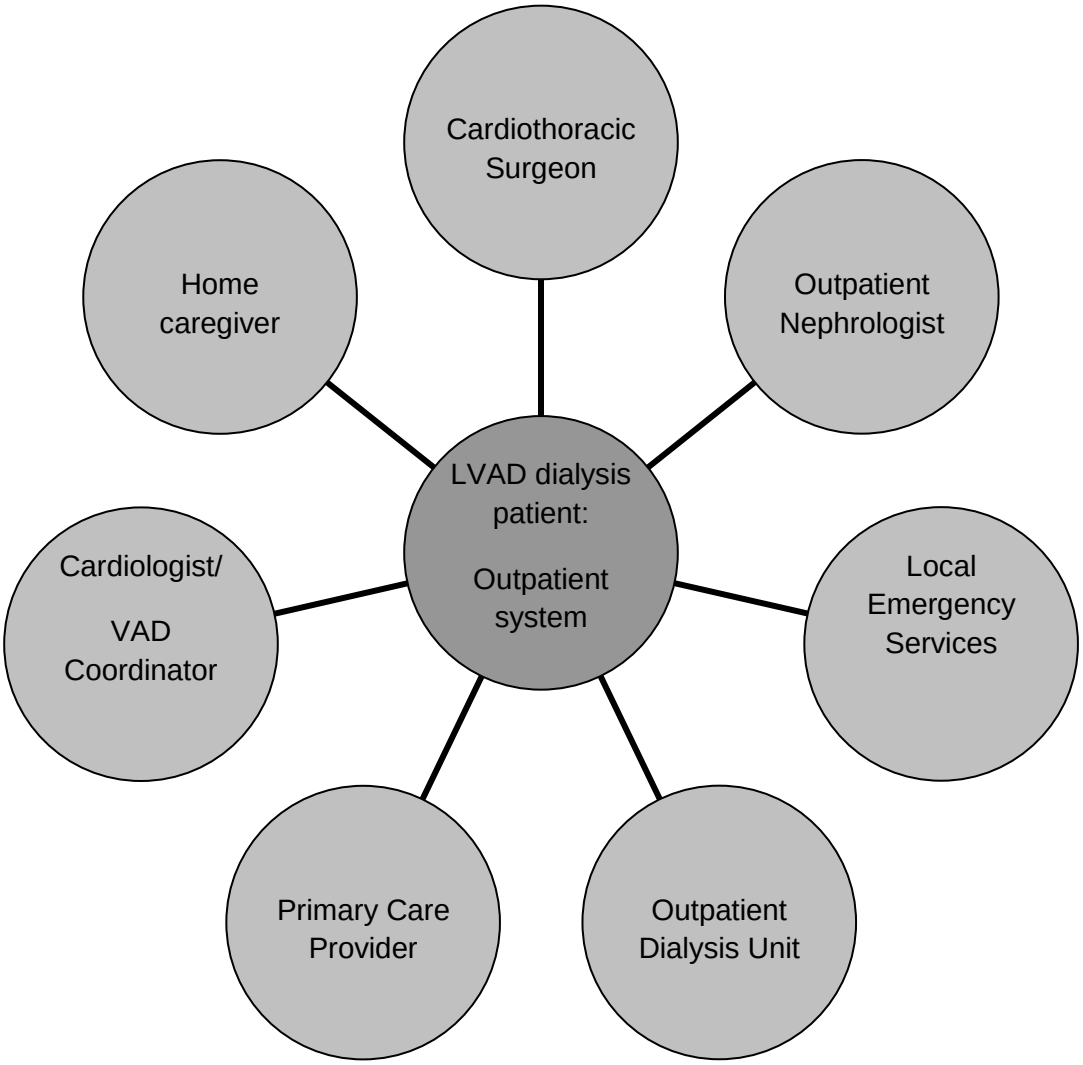

Figure 1: Diagram of the outpatient team for the LVAD dialysis patient

Mechanical Circulatory Support in the Older Adult: A Case Report

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Oregon Health & Science University

School of Nursing

A paper submitted in partial fulfillment of the

requirements for the degree of Doctor of Nursing Practice

Spring, 2011

Russell, Miller, and Pagani (2008), estimate that between 300,000 and 800,000 patients may have advanced heart failure (HF). These patients range from advanced inotrope dependent to terminally ill and will ultimately require palliative care services at some point in their syndrome progression. Patients who are often referred on to advanced therapies such as mechanical circulatory support (MCS) devices and transplantation have often had documented end-of-life discussions with their providers, specifically their primary care providers or their referring cardiologist. However, in our program we have not routinely offered palliative care consults to our patients and families prior to consideration for advanced therapies such as MCS device implantation or cardiac transplantation.

Introduction

MCS is increasingly being used as a treatment modality for advanced HF in patients who may be candidates for cardiac transplantation. Additionally, patients who are not candidates for cardiac transplantation may also be considered, these terms have been described in the literature as bridge-to-transplantation (BTT) and destination therapy (DT) respectively. Caring for the DT patient population poses significant challenges for example: complex medical problems and comorbid conditions; adverse events related to device therapy such as infection, stroke and multisystem organ failure; caregiver burden and logistical challenges such as providing long-distance care and coordination of health related services.

There are numerous recommendations published in the literature that recommend palliative care consultations prior to implantation of MCS devices to assist with advanced care planning and setting goals of care. Recently the term DT

has been called "*destination nowhere*" because at times there can be no real exit plan for either the patient nor the treatment team (Swetz, et al. 2011). This feeling of going nowhere can create a flurry of unwarranted strife between all involved including the patient, family or caregivers, and providers. This case report provides an exemplar in which advanced care planning and consultation of the palliative care team can assist with end-of-life planning, goal setting, and potentially an improved patient perception of quality-of-life (QOL) and experience with the healthcare team.

Patient Case Presentation

For the purposes of patient confidentiality, the patient presented in this case report will be called patient A. Patient A is a 70 year old male with a complex history of ischemic HF, coronary artery disease, coronary artery bypass grafting (CABG) in 2000 where three vessels where grafted, hypertension, hyperlipidemia, ventricular arrhythmia with an implantation of cardiac defibrillator in 2007, begin prostatic hypertrophy, basal cell carcinoma, cerebral vascular accident 6 weeks post CABG, obstructive sleep apnea, flash pulmonary edema secondary to arrhythmias, type two diabetes mellitus, acute renal failure secondary to HF exacerbations, and long-term use of anticoagulants.

The patient has been married for 42 years and has three children, two of which are from a previous marriage. The patient lives with his wife in a small town approximately five hours from the implanting center. Of significant note, he has to drive over several mountain passes covered with snow to get to his HF/MCS outpatient follow up appointments. He has a 50-pack year history of smoking

tobacco and used marijuana and methamphetamines for several years before quitting on his own.

The patient was considered a complex cardiac transplant candidate and decided to proceed with HeartMate II left ventricular assist device (LVAD) implantation on February 12, 2010 for decreasing functional capacity, diminishing QOL, failure to respond to optimal medical therapy, and multiple hospital admissions for acute HF exacerbations and pulmonary edema. During the operative procedure, the patient's aortic valve was over-sewn for aortic insufficiency. Over sewing the aortic valve is an additional routine clinical practice seen with the use of continuous flow LVADs.

Post operatively the patient received aggressive occupational and physical therapy for severe deconditioning. The patient and family received consultation and education from nutrition, pharmacists, and ventricular assist device (VAD) coordinators to ensure a successful hospital discharge. He spent 19 days in the hospital and did not have any significant events during the implant admission.

Approximately five months after the implant hospitalization the patient was readmitted for 24-hours for sudden loss of consciousness while in his home, this loss of consciousness lasted approximately 5 minutes. Prior to this event the patient felt lightheaded and dizzy. He denied fevers, chills, palpitations, seizure activity, incontinence, tongue biting, confusion, or paralysis. He did not report an aura or firing of his defibrillator. A computed tomography scan of the head was completed and revealed lacunar infarcts that were likely age related; there was no evidence of acute hemorrhagic or ischemic stroke. The patient was discharged with stroke

warning signs education, 75 mg of clopidogrel, 40 mg of pantoprazole for gastrointestinal prophylaxis, discontinuation of aspirin, and an increase in Coumadin dosing for a target INR of 2.0-2.5.

The patient has had no subsequent hospital admissions and has been following up in our outpatient nurse practitioner run clinic every 6-8 weeks. Overall, he has expressed that he is able to do everything that he enjoys such as hunting, fishing, trailer camping, and participating in community festivals with his wife and family. His current medications include: atorvastatin 20 mg once daily, carvedilol 12.5 mg once daily, clopidogrel 75 mg once daily, finasteride 5 mg once daily, furosemide 40 mg once daily, glimepiride 1mg once daily, hydralazine 100 mg three times daily, potassium chloride 40 mEq two times daily, vitamin E 400 units once daily, and Coumadin 2 mg once daily.

Recent labs from his primary care physicians offices are: sodium 140 mmol/L, potassium 3.7 mmol/L, chloride 106 mmol/L, bicarbonate 25 mmol/L, creatinine 0.9 mg/dl, glucose 96 mg/dl, calcium 9.4 mg/dl, white blood cells 4.6 K/cu mm, hemoglobin 14.4 g/dl, hematocrit 42.3%, and platelets 196 K/cu mm. His physical and LVAD assessment revealed a compromised LVAD driveline that was repaired via a clamshell repair. There were no LVAD system operations issues noted in the clinical history screen. This is fairly common problem seen with the HeartMate II LVAD in which the silastic driveline becomes detached from the metal housing where the driveline plugs into the system controller. Figure 1 depicts a compromised driveline. Figure 2 depicts a clamshell repair.

Most recently over the past several months the patient has expressed that his preference is not to proceed with cardiac transplantation because he does not want to experience another surgical procedure and prolonged recovery. Additionally, he has brought up several end-of-life questions such as "how long can I stay on this device before I start having problems with it" and "if something major happens to me, can I be cared for in my community?" The patient does not currently have advanced directives and would like to talk with someone about staying in his community should there be a catastrophic event such as stroke or pump malfunction. As we discussed his concerns he asked, "do you think my community is prepared to take care of a malfunctioning LVAD?"

Review of Literature

Results from the post United States (US) Food and Drug Administration approval study of continuous flow LVADs (n=169 HeartMate II patients) indicates that survival with the HeartMate II LVAD is 91% at 6 months and 85% at 1 year (Starling, et al. 2011). Additionally infection 46% (n=78), bleeding 44% (n=75), and cardiac arrhythmia 27% (n=46) comprise of the bulk of adverse events related to HeartMate II LVAD therapy (Starling, et al. 2011). Hemorrhagic and embolic stroke remain in the single percentages, 1.2% (n=2) and 4.7% (n=8) respectively (Starling et al. 2011). Device replacement was significantly lower in the HeartMate II group 1.2% (n=2) as compared to other devices evaluated in the study 7.7% (n=13); p=0.0005 (Starling, et al. 2011). This data is demonstrates that excellent clinical outcomes are being seen despite the confines of a controlled clinical trial. The authors conclude that these results indicate patients are less-ill prior to receiving a

device and that approximately 35% of patients undergoing cardiac transplantation in the US are receiving some type of MCS device prior to transplantation.

Swetz and colleagues (2011), sought to assess the benefit of proactive palliative care medicine consultation for the delineation of goals of care and QOL preference before implantation of LVAD for DT. In their study, they retrospectively reviewed the cases of patients who received a LVAD for DT between January 15, 2009 and January 1, 2010. Of the 19 patients identified, 13 (68%) received proactive palliative care medicine consultations (Swetz, et al. 2011). The mean time of palliative care consultation was 1 day before DT implantation (range, 5-16 days before or after) (Swetz, et al. 2011). Thirteen patients 68% completed advanced directives. The implantation team and families reported that pre-implantation discussions and goals of care planning made the post operative care more clear and that adverse events were handled more effectively (Swetz, et al. 2011). The authors conclude that proactive palliative care medicine consultation for patients being considered or being treated with MCS devices for DT improves advanced care planning and contributes to better overall care of this complex patient population.

Another unique aspect that this paper brings to the MCS community is the development of a preparedness plan for the patient, family or caregiver, and treatment teams. The preparedness plan can be described as the central component to advanced care planning and four additional concepts encompass this plan. These four concepts include: 1) inadequate quality-of-life after implantation of the LVAD, 2) event of device failure, 3) catastrophic complications due to LVAD associated factors, and 4) debilitative comorbid conditions. Using the major components of the

preparedness plan the palliative medicine team was able to explore hypothetical situations and complications that might occur with device therapy. Along with social workers expectations and aggregate documentation from the team was incorporated into the advanced directives and the patient's electronic health record. Swetz and colleagues view DT as permanent palliative therapy for the incurable heart–one that improves QOL and reduces symptom burden. Their experience with incorporation of the palliative medicine team into advanced HF allows for higher rates of advanced directives completion and the establishment of preparedness plans that may help patients and families cope with unexpected complications or changes in the care pathway. Additionally, the sharing of this type of information can only strengthen the patients and families education about their health and illness. Swetz's experience and model may greatly enhance other programs performance with regard to destination therapy and the patients perceived experience and QOL.

Adler and colleagues (2009), have developed a palliative care integrative model. In this model, palliative care is initiated when patients are diagnosed with any serious or advanced chronic illness. As illness progresses, the ratio of palliative care to life-prolonging care gradually increases. Ultimately, life-prolonging care is discontinued according to patient's wishes or when the harm of treatment outweighs its benefits. It is at this point in time when the transition to hospice care is made. After death, palliative care services continue and help the family members with bereavement. Adler and colleagues also stress the importance that machines continue to work even after the patient is clinically brain dead, or they may prolong

the dying process. “It is critical that the patient establish advance directives before implantation that outline the conditions under which he or she desires the device to be turned off” (Adler, et al. 2009).

Discussion

Patient A was known to our clinical practice for several months prior to implantation of LVAD as a BTT. As discussed throughout this case report there have been multiple opportunities to incorporate the use of palliative medicine into the care of this patient and family unit. One of the most recent examples was upon readmission to the hospital for loss of consciousness another was at an outpatient clinic appointment where the discussion of staying on LVAD support rather than proceeding with cardiac transplantation occurred. These are unique opportunities where the cardiovascular specialist can impact the patients experience in a dramatic way. The conversations highlighted in this case report are examples where the topic of palliative medicine can be explored with the patient and family members. Our patient is currently in the process of being referred to the palliative medicine team for advanced care planning with a specific interest of being appropriately cared for in his local community should an adverse event or complications occur.

The models discussed by Swetz, Adler, and colleagues are not routinely used in our advanced HF program unless the patient is not an ideal candidate for MCS devices or cardiac transplantation. As discussed by Swetz and colleagues, DT is a form of palliative medicine and can significantly relieve symptom burden while increasing the patient’s functional capacity and QOL. A strong recommendation to create a pathway in which all patients are seen by the palliative medicine team is

clearly indicated so that advanced care planning, advanced directives, and goals setting and expectations of care can occur. Cardiovascular specialists are generally too busy to take the time to ensure that all these important topic areas are covered in great depth and breadth. Therefore coordination and collaboration with the palliative medicine team is truly indicated for the evaluation and management of these patients.

The integrative palliative care model and the preparedness plan are simple enough for both cardiovascular providers and patients and family members to understand and appear to be an excellent working model for the delivery of complex healthcare. The palliative care medicine team can be incorporated into the pre-implantation process especially in those patients who are known to our program. As discussed in the review of literature, the range of time prior to palliative care consultation was approximately 5-16 days before or after implantation of the assist device. Often times, we have 14 days on either side of the implant where patients are actively being managed by our team. This allows for time to call the consult, have the patient and family seen, and perhaps discuss the patient and family via a combined multidisciplinary team meeting.

Additionally, for both the cardiovascular and the palliative care teams to ensure a good sense of communication, transparency, and coordination of care between the two teams, the VAD coordinators and social workers can be a shared resource. The use of shared resources will decrease the overhead required by the palliative care team and may enhance the skill mix on the advanced heart failure and transplant team as well. Last, combined education will be needed to support

communities who feel ill prepared to care for this complicated patient population as questioned by the patient presented in this case report.

Conclusion

There is limited information published in the advanced HF and cardiac transplant literature on the integration of palliative medicine with specific regard to MCS device therapies. Our program recognizes that there is a need for a more integrated approach to this complex and diverse specialty area of MCS device therapy. We also realize that this tremendously important work cannot be completed without other experts such as palliative medicine providers. Several simple yet intelligent models of healthcare delivery have been presented in this case report and by those cited in this paper. It is our current mission to develop a more robust process to care for our advanced HF patient population in a way that meets their needs in a comprehensive and holistic manner.

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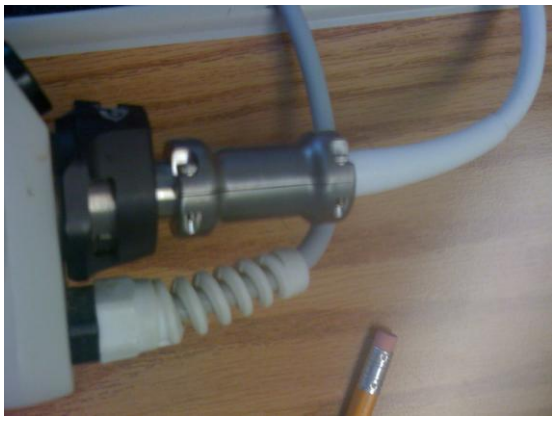
Figures

Figure 1. Compromised HeartMate II LVAD Driveline Before Repair

Figure 2. Completed Clamshell Repair



Health Disparities in African Americans with Heart Failure

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Abstract

Disparities in health and healthcare have become increasingly hot topics since the Institute of Medicine's report Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare. The purpose of this paper is to explore health disparities in African Americans with heart failure (HF) and the implications to health disparity research and future practice.

Cardiovascular diseases such as HF affect approximately 5.7 million adults over the age of 20. Estimated costs for HF in 2009 exceed $37 billion. According to the American Heart Association (AHA), hypertension is considered one of the major risk factors for HF and is increased in the African American population. This article will provide a historical perspective into population based research such as the African-American Heart Failure Trial (A-HeFT), Vasodilator-Heart Failure Trial (V-HeFT), potential gender variations, treatment with BiDil, and issues surrounding cardiac transplantation and organ donation in minority populations. In summary, future implications and proposals for change will be suggested.

Health Disparities in African Americans with Heart Failure

The purpose of this paper is to explore health disparities in African Americans with heart failure and the implications to health dispartiy research and future practice. **"**Heart Failure (HF) is a syndrome, rather than a disease, caused by a variety of pathophysiologic processes in which the heart is unable to pump an adequate amount of blood to meet the metabolic demands of tissues" (Barkley & Myers, 2008, p.169). Risk factors include hypertension, coronary aretery disease, myocaridal infarction, family history, obseity, smoking, exessive alcohol intake, and chemotherapeutic agents (Barkley & Myers, 2008). According to the American Heart Asscoiation (AHA), prevelence for adults 20 and older is approximately 5.7 million with 3.2 million males and 2.5 million females (American Heart Association, 2009). "The estimated direct and indirect cost of HF in the United States for 2009 is $37.2 billion" (American Heart Association, 2009, p.20).

Hypertenstion is considered one of the major risk factors for HF in the United States (American Heart Association, 2009). Hypertension is defined as a systolic blood pressure 140 mmHg or greater and/or diastolic pressure of 90 mmHg or greater (American Heart Association, 2009). AHA states that the prevelence for hypertension in African Americans is amoung the highest in the world and is continuing to rise. Prevelence for hypertension has increased from 35.8 percent to 41.4 percent in African Americans and is particulary high in African American women (American Heart Association, 2009). Lastly, hypertension is increasing amoung young African Americans and places them at higher risk for stroke, HF, and kidney disease than Caucasians.

Because mutilple racial identifiers have been used in the literature, the terms African American, Caucasion, Black, and White will be interchanged throughout the paper. A discussion of this finding will be addressed in later sections.

Editorials and research in disparities in health and healthcare have become increasily hot topics in both private and public health sectors. In the following sections, a review of literature will be performed on the following topics: African-American Heart Failure Trial (A-HeFT), Vasodilator-Heart Failure Trial (V-HeFT), gender variations, treatment modalities, and barriers to transplantation and organ donation within minorty populations.

Review of Literature

A-HeFT

According to evidence cited by Franciosa, et al., (2002) African Americans are at higher risk for HF and death and may respond differently to medications and healthcare management. The A-HeFT trial was designed in response to the V-HeFT I and V-HeFT II trials which demonstrated that Whites and Blacks repsonded differenently to medications such as agiotension-converting enzyme inhibitors (ACEI) and hydralazine-isosorbide dinitrate (H-ISDN) (Carson, Ziesche, Johnson, & Cohn, 1999; see also Taylor, 2003). In analyis of other studies such as the Studies of Left Ventricular Dysfucntion (SOLVD), the researchers found excessive dealths and hospitalizations in African Americans with HF and less effecacy with enalapril an ACEI (Franciosa, et al., 2002).

BiDil is a combination drug consiting of hydralazine hydrocholride/isosrobide dinitrate and is indicated for the treatment of HF in self-identified Black patients (NitroMed, Inc., 2009). As cited in Franciosa, et al. (2002), several physiological theories suggest that African Americans may suffer from impaired nitirc oxide (NO) mediated vasodilitation in the

microvasculature. When hydralazine hydrocholride and isosorbide dinitrate are combined they appear to have a significant synergistic affect on NO diffeciencies and vasodilitation (Franciosa, et al., 2002). Both the A-HeFT and V-HeFT I and II trials have documented their findings specific to the African American population.

Endpoints for th A-HeFT trial inculde a composite score for clinical outcomes including death, first hospitalization for HF, and quailty of life measured at 6 months (Franciosa, et al., 2002). Quailty of life was meansured by the Minnesota Living with Heart Failure Questionaire. The questionaire asseses for subjective HF symptoms, functional capacity, emotional distress, clinicians perceptions, physical assessments, and ejection fraction (Rector, 2009).

The A-HeFT trial enrolled 1050 African American patients who were randomized to fixed dose H-ISDN or placebo and found a striking reduction in mortality and improved outcomes in the H-ISDN group (Taylor, et al., 2007). This study contributes considerible new evidence to the field of cardiology specific to HF management in African Americans. Additionally, it is the first landmark study to assess specifc HF therapies in a racial group. It should be noted that this trial specifically enrolled patients who were self-identified African Americans with New York Heart Association (NYHA) class III or IV HF.

V-HeFT

The V-HeFT I and II trials were designed to assess comparisons between African Americans and Caucasians with HF and their response to vasodilator therapy. Additionally, the V-HeFT trials precede the A-HeFT trail. In the V-HeFT I, baseline characteristics and responses to therapy were the primary outcomes. However, in the V-HeFT II, researchers screened for the presence or absence of hypertension (Carson, et al., 1999). The V-HeFT I enrolled 180 Black male patients compared to 450 White male patients, while, the V-HeFT II enrolled 215 Black

and 574 White male patients (Carson, et al., 1999). Enrollment numbers for the A-HeFT and V-HeFT I and II are displayed in Figure 1.

When looking at mortality data presented by Carson, et al. (1999) White patients had lower mortailty rates with enalapril with or without a previous hypertensive history. However, Black patients with a hypertensive history had higher mortality rates with enalapril than those without a hypertension. Additionally, Black patients with hpertension had reductions in mortality if taking a H-ISDN. Additional data in the V-HeFT trials support the findings cited by the AHA in 2009. Although the enrollment numbers are small, they can be ajudicated by later studies assessing the African American population for hypertension and the effect on morbidity and mortality. For example, the Framingham Study as cited in the AHA Heart Disease and Stroke Statistics.

Data presented in the V-HeFT trials is exciting in that it represents investigation into racial and population based health research and taps into the notion that, *not all should be treated the same*. Additionally, the research teams strived to increase enrollment amoung self-identified African Americans. In the following sections, gender differences, treatment modalities, transplantation and ogran donation will be assessed. In the final section future proposals for health disparies research will be discussed.

Gender

Women account for a large portion of HF patients in the US, approximately 2.5 million. Women are generally underrepresented in clinical trials. For example, no women were included in the V-HeFT trials. However, “40% of the A-HeFT cohort (n = 420) were women” (Taylor, et al., 2006). Authors from the original trials completed an additional analysis of outcomes specific to gender and responses to nitric oxide enhancing therapy (Taylor, et al., 2006). Trial endpoints

were similar including mortality, first hospitalization for HF, and quality of life. Women had a higher prevalence of body mass index, diabetes, and systolic hypertension (Taylor, et al., 2006).

Survival was slightly higher for H-ISDN females than females receiving placebo when looking at Kaplan-Meier survival curves. However, females also had a higher percentage of hypertension compared to the male treatment group. The time to first hospitalization was nearly equal in both treatment groups. However, the event-free survival time was best in women receiving treatment (Taylor, et al., 2006). As discussed by the authors, the A-HeFT trial is unique in that it assesses for responsiveness to fixed-dose H-ISDN within a single racial group. Additionally, it was the largest single study of African American women with HF. The results of this trial show that fixed-dose H-ISDN improves outcomes for both men and women (Taylor, et al., 2006).

An additional study conducted by Dunlap, Mallemala, Sueta, Schwartz, and Adams (2003) evaluated survival rates between African Americans and Whites with HF and found no significant disparities with regard to mortality. The study included a gender analysis, which also found no statistical significance with regard to mortality, race, or gender. However, they did find statistical significance with regard to clinical characteristics and symptoms between the two races within their clinical environment (Dunlap, et al., 2003). The authors encourage further investigation into this area.

Treatment Modalities

BiDil has come under moral scrutiny in the past several years in large part because the Food and Drug Administration (FDA) approved it for use in self-identified Black patients with HF (NitroMed, Inc., 2009). Carlson (2005) discusses the challenges faced in health research with regard to race and genetics. In Carlson's writing, he summarizes that it is unclear as to why the

FDA approved this drug for use. For example, he states, "the FDA is supposed to help move, not just approve, product" (Carlson, 2005, p.W5-467). He goes on to suggest that multiple variables play a role in the development, testing, and approval of products such as BiDil. He does promote the use of biological science; however, he states that social science plays a key role in health research, product development, and marketing.

As discussed previously BiDil is a fixed dose H-ISDN, which was approved for use after the release of A-HeFT trial results. According to NitroMed Inc, blood plasma concentrations for BiDil are more stable than combination dosing for hydralazine hydrochloride and isosorbide dinitrate. The A-HeFT trial did not incorporate pharmacokenetics into the trial results. However, the researchers did provide pharmacologic rationale for effectiveness. According to Taylor et al. (2004), when comparing "endothelial cells from healthy white women, endothelial cells from healthy black women has deminished bioavailability of nitric oxide as a result of increased oxidative stress". Isosorbide dinitrate exterts vasodilitory effects by releasing nitric oxide and dilating arteries and veins, while hydralazine minimizes tolerance to nitrates (NitroMed, Inc., 2009; see also Taylor, et al., 2006; Taylor, et al., 2004). BiDil tablets contain 20 mg of isosorbide dinitrate and 37.5 mg of hydralazine hydrocholride (NitroMed, Inc., 2009).

Transplantation

Cardiac transplantation remains a gold standard for those eligible with end-stage HF. In a study conducted by Park, Tolman, and Kimball (1997), "survival rates for Caucasian recipients at one, three, five, and nine years were 83%, 73%, 63% and 46%, respectively. The transplant survival rates for African American recipients were lower across the board, at 70%, 58%, 51% and 32% respectively" (as cited in Flattery & Baker, 2004). Many factors may contribute to these findings such as socioeconomic status, education, immunological differences, and health

management by the treatment team. Flattery and Baker (2004) acknowledge that studies on race and cardiac transplant outcomes are limited and are often based on single center experience. Additionally, they remark that the findings are often contradictory.

The human leukocyte antigen (HLA) "refers to at least six separate polymorphic genetic loci produced by plasma cells and clustered together in a single area on the human leukocyte" (Flattery & Baker, 2004, p.27). Flattery and Baker suggest that an individual's profile can be ethnically and racially identified, however, they cite that there has been no multicenter trial as of 2004. Additionally, they report that approximately 64% of African Americans receive a poorly matched allograft. Although this information seems disturbing, Flattery and Baker (2004) report that the sample size is too small to determine statistical significance and that larger clinical trials will be needed.

In another study by Pamboukian, et al. (2003), African American and Caucasian patients with HF underwent cardiac transplantation or implantation with a left ventricular assist device (LVAD) and their mortality outcomes evaluated. The survival rates in this study were similar for both groups with no difference at five years. However, the etiologies of HF were statistically significant with idiopathic cardiomyopathy/nonischemic being significantly higher in the African American population. This finding may be suggestive of hypertension or another physiological pathology not detected in the study. In summary, the authors conclude that a comprehensive multidisciplinary team approach may be of greater impact than race with patients experiencing HF and cardiac transplantation.

Organ Donation

Discussion of solid organ donation in the context of racial and ethnic considerations is also an important factor to evaluate in HF disparities within the African American population.

Without organ donation, there would not be solid organ transplantation. According to First (1997), "signing an organ donor card is not enough. It is important for individuals to talk with family members so that their wishes will be carried out". Additionally, education and outreach should be focused toward specific ethnic and racial populations to assist with familiarity. Religion and culture can also have huge implications for organ donation. If Organ Procurement Agencies (OPO) are not aware of these factors then recruitment may be difficult or impossible in the critical care setting.

The American Society of Minority Health Related Transplant Professionals and the National Minority Organ Tissue Transplant Education Program have made significant strides in the area of organ donation education (First, 1997). For example, the organization has put forth the initiative to hire minority health educators. This initiative has resulted in a 77% increase in referrals in some areas; however, there has been no impact on consents for donation (First, 1997). The second phase of the initiative is to hire minority organ requestors, this initiative my increase the number of consents for organ donation. These findings are significant and studies should be completed as to why these initiatives make a difference in referrals and consent for organ donation. One thought is the level of mistrust between providers and patients, an area in need of further investigation.

Future Implications

Recent attention has been placed on the need for health disparities research. According to Powers and Faden (2003), "racial and ethnic disparities in health outcomes from various health services, including screening, diagnosis, and treatment for specific diseases or medical conditions have been noted". Additionally, they ask, when do racial and ethnic disparities matter morally. In the article, they discuss two theses, the neutrality and anti-discrimination theses. The

neutrality thesis stats that “disparities in health outcomes amoung patient groups with presumptively similar medial conditions should trigger moral scrutiny” (Powers & Faden, 2003, p.722). In the second thesis, antidiscrimination thesis, “is that disparities in receipt of healthcare or adverse health outcomes amoung racial, ethnic, or other disadvantaged patient groups should trigger heightened moral scrutiny” (Powers & Faden, 2003, p.722). A good example of health disparities within the African Amercian population is the lack of representation in clinical trials, for example, the V-HeFT I and II. One could argue that underrepresentation in clincal trials is a marker of care or access to healthcare. Furthermore, survival rates post cardiac transplantation are worse in African Amercian than in Caucasians. This data should be cause for moral discomfort, thus, triggering the desire to conduct further research in the area.

According to Carlson and Chamberlain (2004), perceptions of racism vary amoung races. For example, the White reality “ applaud the civil rights movement and congradulate ourselves on moving toward becoming a color-blind society”. While the Black perception is that we have not traveled far from our original racist roots (Carlson & Chamberlain, 2004). The authors also discuss an important phenomenon known as aversion racisim. Aversion racism is a subtle and often unconscious form of racism. Carlson and Chamberlain (2004) discuss that this form of racism can rely on both implict and explict behaviors. For example, the notion of *it’s not in my backyard, so I don’t have to deal with it*. While this behavior might not be overt racism, it is still a form of passive or aversive racism. Importantly, aversive racism can occur in healthcare, an example, may be minimizing the importance of the A-HeFT trial. While this trial may be controversial, the significant importance is that a group of researchers conducted a trial specific to a treatment modality targeting self-identified African Americans with HF. Attention to racial and ethnic perceptions with regard to health, healthcare, and health disparity research will be

impartive as the paradigms shift. As cited in Carlson and Chamberlain (2004), education and knowledge is power.

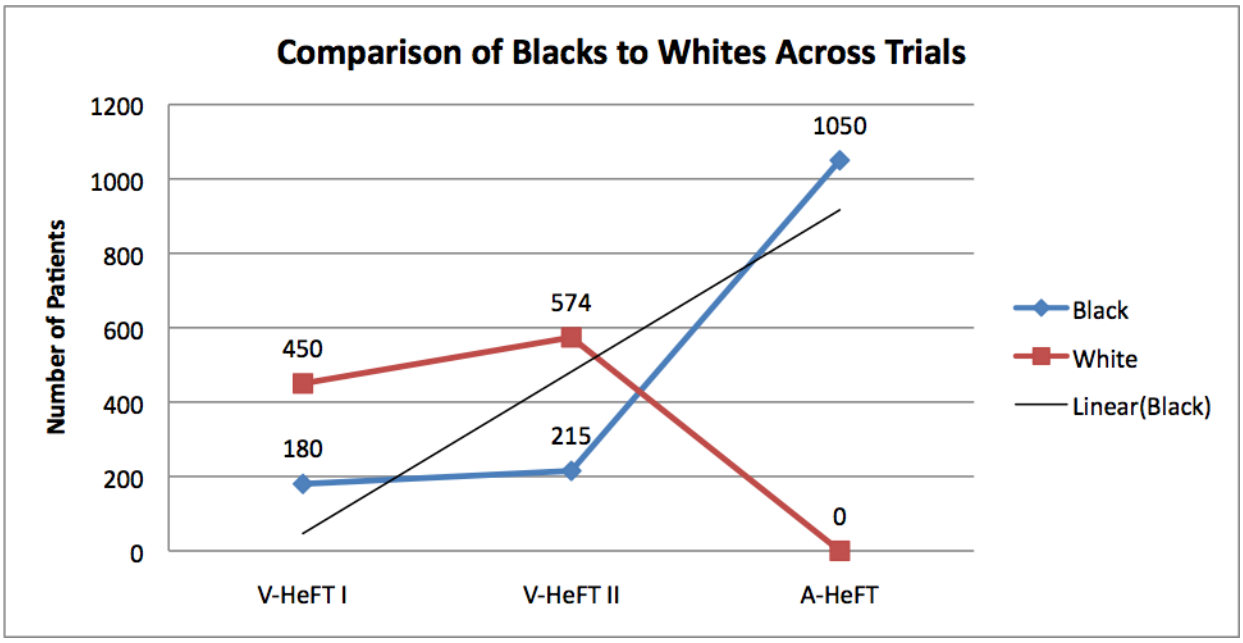
Conclusions

Does race really matter in HF? At this point in time it may be challenging to determine that race correlates to increased mortality. What we do know is that various terms are used to define race, such as African American, Black, Caucasian, and White. The definitions of those races remain unclear. For example, in the V-HeFT I and II and A-HeFT, race was determined on self-identification. Additionally, the language used in the literature is varied and poorly defined, at times interchanged. In the future, perhaps, universal definitions and guidelines for conducting ethnic and racial health research should be considered. Utilizing a combination of social and biological evidence-based research may improve standardization within population based research.

Large population based multicenter trials should be considered with regard to ethnicity, race, and gender. Areas for potential focused research include hypertension, stroke, HF, organ donation, and transplantation. These focus areas have poor representation by minority populations such as females and African Americans. Underrepresentation in clinical trials may signal access to care issues, perhaps this is just the tip of the iceberg. Contradictory findings presented in this paper should be cause for moral discomfort and should trigger desire further investigation.

Health disparities research can also be enhanced by incorporating genomics, pharmacokinetics, and outcome based modalities into trial design. “It is quite likely that the phenotype of “heart failure” in African American patients represents a clustering of genotypes that predispose a more aggressive cardiovascular disease profile” (Yancy, 2003, p.205).

Figure 1. Comparison between Blacks and Whites across the V-HeFT I and II and A-HeFT trials. The enrollment of Blacks increased dramatically as studies evolved.



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Health Policy Analysis

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Abstract

Organ donation and transplantation is a complex and controversial treatment modality. In the United States (U.S.) many more patients are waitlisted for organ transplantation than there are organs available for transplant. In the U.S. and abroad, organs are considered a scarce resource thus leading to potentially unsafe, poorly regulated, and unethical behaviors. Examples include transplant tourism, commercial living donors (CDLs), and organ trafficking. In this health policy analysis, the United Network for Organ Sharing (UNOS) and the Organ Procurement and transplantation Network (OPTN) policy on transplantation of non-resident aliens will be analyzed using an organizational policy analysis framework. A review of literature, alternatives, and projected outcomes will be discussed.

Health Policy Analysis

Organ donation and transplantation is a complex and controversial treatment modality. In the United States, 105,188 candidates are waitlisted as of November 29, 2009 (UNOS, 2009). From January to August of 2009, 19,114 transplants have been performed from 9,754 donors (UNOS, 2009). "The U.S. Congress established the Organ Procurement and Transplantation Network (OPTN) when it enacted the National Organs Transplant Act (NOTA) of 1984. The act called for a unified transplant network to be operated by a private, non-profit under federal contract" (U.S. Department of Health & Human Services, 2009). "UNOS was awarded the initial OPTN contract on September 30, 1986, and has continued to administer the OPTN more than 16 years and four successive contract renewals" (U.S. Department of Health & Human Services, 2009). United Network for Organ Sharing (UNOS) is a collaborative policy development agency and "handles the development, monitoring, enforcement and modification of the policies that govern the allocation, procurement and transportation of human organs" (UNOS, 2009).

The purpose of this paper is to thoughtfully analyze an existing policy set forth by OPTN and UNOS on Transplantation of Non-Resident Aliens and the global impact of transplant tourism and organ trafficking within and external to the United States. The policy was published in June of 2005 and is accessible to the public via the OPTN and UNOS websites. OPTN and UNOS "policies and bylaws must be forwarded for review and approval by the Secretary of the U.S. Department of Health and Human Services (HHS) to become binding under the authority of federal regulation" (U.S. Department of Health & Human Services, 2009). The OPTN/UNOS policy development process consists of six steps: 1) identification of transplant issues; 2) public comment process; 3) transplant community input; 4) committee and OPTN/UNOS Board of Directors review; 5) policy development; and 6) final review and approval see (Figure 1).

This policy analysis will be formatted with the following framework from Collins for clarity and organization: 1) define the context, 2) state the problem, 3) search for evidence, 4) consider policy alternatives, 5) project outcomes, 6) apply evaluative criteria, 7) weight the outcomes, and 8) make the decision (2005, p. 194).

Define the Context

Organ transportation and sharing is a complex and multifactorial process that requires complex procedures and coordination of multiple systems such as transplant centers, OPTN and UNOS regional agencies. The United States is divided into 11 geographic regions to facilitate regional issue resolution and organ allocation see (Figure 2). The geographic regions also assist with timely placement of organs in a fair and equitable manner. Because transplantable organs are considered a scarce resource, the Task Force for Organ Transplantation (1986) has "recommended that no more than 10 percent of all cadaveric kidney transplants in any center be performed in non-immigrant aliens and that extrarenal transplants be offered only when no suitable recipient who is a resident of this country can be found" (U.S. Department of Health & Human Services, 1986, p. 9).

Kidney's were the only specified organ in the task force report and are not specifically addressed in the policy on transplantation of non-resident aliens. However, exportation and importation of organs is specifically addressed in the policy and is noted to be a considerable challenge but technically feasible. The OPTN states that international organ sharing is in the early phases of development (UNOS, 2005, p. 2).

Transplant tourism involves the residents of one country such as the United States traveling to another for the purposes of obtaining a transplant (Bramstedt & Xu, 2007). According to Bamstedt and Xu (2007) the insurance industry is shying away from the term

transplant tourism and is referring to the term medical travel. ‘Transplant tourism’ and ‘medical travel’ for the purposes of obtaining transplantable organs is a cost saving measure. In the U.S., organ transplants can cost in excess of $100,000 and can be obtained over seas for considerably less. In some cases that savings is passed on to the insured in the form of a bonus (Bramstedt & Xu, 2007). Some academics would call this coercion.

Organ trafficking can best be described as the buying and selling of organs for the purpose of transplantation. Commercial living donors (CLDs) are individuals who sell either a kidney or a portion of their liver for financial gain. According to Budiani-Saberi and Delmonico (2008) “the buying and selling of organs in the global markets has become an ethical issue for transplant clinicians everywhere in the world”. The Transplant Society, World Health Organization, Coalition for Organ-Failure Solutions, and UNOS are encouraging transplant community members to propose new alternatives and approaches that address and combat transplant tourism and organ trafficking worldwide.

State the Problem

The current OPTN/UNOS policy on transplantation of non-resident aliens covers the following topics: definitions of resident and non-resident aliens, nondiscrimination and organ allocation, transplant center requirements, fees for service, referrals into the program, community participation, training programs for underserved nations, audit mechanisms, exportation and importation, international organ exchange and ad hoc organ exchange, ethical practices, and consequences for the violation of policy.

The current policy does not specifically address transplant tourism from the U.S. citizen perspective. U.S. citizens are freely able to participate in transplant tourism with potentially underserved and poorly regulated nations. This egocentric view allows U.S. citizens to

participate in global organ trafficking. There are many ethical, moral, financial, and public health concerns around this practice. One example is the transportation of infectious diseases across national borders. Another is the victimization of CLDs in disenfranchised nations.

Key stakeholders include: the public, transplant community providers, government, payors, patients and families, donors and families, and the buyers and sellers associated with organ trafficking and consumerism. The most significant political context is the exploitation of vulnerable populations such as CLDs, their families, and communities. In the following sections, an examination of evidence and proposals for change will be discussed.

Search for Evidence

A recent study assessing the number of U.S. waitlist candidates seeking foreign transplants revealed that there were 173 instances where waiting list removal codes indicated a foreign transplant (Merion et al., 2008, p. 989). The assessment period was from 1987 to 2006 utilizing the Scientific Registry of Transplant Recipients (SRTR). The median time on the waitlist for these candidates was 14 months. “There were a total of 158 kidney transplants (91%), 13 liver transplants and one each for lung and heart transplant” (Merion et al., 2008, p. 989). An additional 200 patients who were not transplanted at the listing center and were not coded as foreign country transplants were found to receive transplants in a foreign country. Countries noted to have at least five transplants from U.S. waitlist patients include: Mexico, Peru, Egypt, Italy, Saudi Arabia, Israel, Iraq, Pakistan, Iran, India, Philippines, China, and Japan.

This study is seminal and represents the most comprehensive assessment of foreign transplants among U.S. waitlisted transplant candidates. California and New York had the highest number of foreign transplant recipients with 105 and 43 respectively. Many patients had greater than high school education and approximately 50% of cases were funded with private

insurance. The SRTR and OPTN have added a new code to assist with capturing transplants occurring outside the United States. This will allow for additional data gathering and transparency.

Global transplant tourism has been fueled by global capitalism and commercialism. Without regulation, patients with wealth and power can dictate the global market for organs and medical care. The ability to pay for *fresh and healthy organs* [emphasis added] fuels this underground demand and market. Scheper-Hughes (2003) is conducting clandestine research on the underground brokerage of human organ donors and transplant recipients. Together Cohen and Scheper-Hughes uses medical student research assistants to get inside the secrete lives of kidney buyers, sellers, and surgeons. The authors "have followed patients from dialysis clinics to meetings with organ brokers in shopping malls, tea shops, and coffee houses, to illicit surgeries in operating rooms of hospitals – some resembling five-star hotels, others reminiscent of clandestine back ally abortion clinics" (Scheper-Hughes, 2003, p. 1645).

Scheper-Hughes has found evidence of transplant tourism brokerage in U.S. cities such as Brooklyn, New York. "Brokers in Brooklyn, New York, posing as a non-profit organization, traffic in Russian immigrants to service foreign patients from Israel who are transplanted in some of the best medical facilities on the east coast of the USA" (Scheper-Hughes, 2003, p. 1646). This evidence implies that violations are occurring with regard to OPTN/UNOS policy on transplanting non-resident aliens. Furthermore, hospitals receiving cash payment or 100 percent reimbursement may be financially coerced into performing the procedure.

In 2007, Shimazono described four modes of international organ trade and organ trafficking. The four modes are as follows:

> Mode 1 entails a recipient traveling from Country B to Country A where the donor and transplant center are located, Mode 2 entails a donor from Country A traveling to Country B where the recipient and transplant center are located, Mode 3 entails a donor and recipient from Country A traveling to Country B where the transplant center is located, and Mode 4 entails a donor from Country A and a recipient from Country B traveling to Country C where the transplant center is located (as cited in Budiani-Saberi & Delmonico, 2008, p. 926).

Consider Policy Alternatives

In this section three policy alternatives will be presented: 1) continuation with current policy, 2) allowing transplant tourism, and 3) restricting transplant tourism. According to Bardach and Collins policy alternatives do not have to be mutually exclusive. In fact one additional component may be helpful in mitigating the problem. For example, adding to or creating an additional policy to augment an existing may be beneficial. However the term alternative often leads the audience to pick one over the other.

Continuation with Current Policy

In the current policy, transplantation of non-resident aliens does not specifically address transplant tourism from the U.S. citizen perspective. OPTN and UNOS do not have a policy on this activity at this point in time. A white paper was released from the UNOS Board of Directors on June 26, 2007 stating that the "report is circulated for informational purposes and to stimulate discussion of a very important subject. The report has been presented to the OPTN/UNOS Board of Directors. It has not been adopted as a policy." The content within the report condemns transplant tourism and will be discussed in the third alternative.

Exportation and importation of organs is addressed minimally with very broad and general statements deferring to the international organ exchange protocol and ad hoc organ exchange protocols. The inclusion of exportation and importation in the current policy discourages the activity but does not prohibit it. Current transplant clinicians and patients are able to work around the policy to export and import organs at this point in time. As evidenced by Shimazono's modes of international organ trade and trafficking. Waitlisted patients with financial liquidity are able to move freely between countries to work around the system. Because of poor reporting mechanisms this activity is very difficult to track. Continuing the current policy will likely lead to a continuation of prohibited activity with poor reporting mechanisms and a policy where those with wealth can access organs that those without are unable to access. A call to actions is warranted for regulating and subsidizing transplant tourism.

Allowing Transplant Tourism

The allowance of transplant tourism is controversial; however, acknowledging that it is occurring underground is the first step to improving conditions and providing regulation and oversight. Regulation and oversight could be performed by an international organ procurement and transplant network. Currently many international societies are joining forces on this topic; however, there is no regulating body at this point in time. The OPTN and UNOS condemn the activity but it is still occurring at various levels throughout the U.S. and potentially more frequently than what is currently understood. Leadership, collaboration, and coordination on policy development with countries participating in this activity could lead to better care and outcomes for both transplant donors and recipients alike.

With the current policy, cash paying candidates and brokers target the poor undermining the altruistic nature of organ donation (Budiani-Saberi & Delmonico, 2008). Education with

regard to legal, ethical, moral, and societal obligation should be strongly considered with this policy alternative. Measuring the impact of education may be challenging and will probably need to be assessed with multiple long-term observational studies. A strong emphasis of social justice should also be included in the development of this policy alternative.

In many countries where foreign transplants occur the commercial living donor (CLD) does not receive appropriate follow-up care. In some instances, donors are only seen and treated during the organ recovery hospitalization period. Often times they are never seen post hospitalization. The average price for a kidney on the black market ranges from $1000 - $30,000 dollars, with urban Turkish, Peruvian, and U.S. sellers commanding the highest prices (Scheper-Hughes, 2003), while the impoverished receive the lowest payment. A famous quote from Radcliffe-Richards J, et al. (1998) "if a living donor can do without an organ, why shouldn't the donor profit and medical science benefit" (as cited in Scheper-Hughes, 2003, p. 1645). Living related organ donation is gaining widespread acceptance within the U.S. healthcare system with high quality outcomes. A similar policy model could be adapted for the commercial living donor.

Restricting Transplant Tourism

The UNOS white paper on transplant tourism strongly condemns the practice of transplant tourism, yet, evidence suggests that the practice still occurs and the scale is unknown at this time. Restricting transplant tourism without regulation will be turning a blind eye to an already established and defined problem. Many clinicians within the transplant society understand that transplant tourism exploits both sellers and recipients. However, they also acknowledge that the practice is poorly regulated, tracked, and managed.

There is also disagreement between patients, clinicians, and the private insurance sector. While the practice may be condemned in the U.S. from a clinical perspective the private

insurance sector is condoning the practice as evidenced by 50 percent of foreign transplants being funded through private insurance (Merion, et al., 2008, p. 992). Reports of bonus payments have also been discovered for traveling outside the U.S. for organ transplantation as a cost saving measure. In addition, when U.S. patients return to the U.S after receiving a foreign transplant, transplant medicine providers experience an ethical dilemma because they must decide whether or not to care for the patient post transplantation. As also reported, the transmission of infectious diseases is also a public health issue, especially with globalization and access to long distance travel.

Restricting transplant tourism will require further transplant and societal conversation, investigation, and reporting to assist with policy and law development. Refining the SRTR and OPTN codes is one intervention aimed at collecting more evidence and reporting to the public. The current policy states that violation of export and import policies will result in reporting to the standards committee and professional suspension in membership to OPTN and UNOS. These ramifications are considered professional and administrative discipline rather than legal. Key stakeholders must educate the public regarding this issue so that a compelling political agenda can be introduced. Unfortunately, this issue is under the political radar agenda but poses significant implications as transplant medicine is progressing rapidly.

Project Outcomes

Continuation with the current policy as is, will likely yield similar results to what is known today about international transplant tourism and organ sharing. The current policy is designed to limit the number of non-resident aliens who are eligible for organ transplantation in the U.S. because organs are considered a scarce resource within the U.S. healthcare system. However, what is not addressed in the policy is the U.S. citizen traveling abroad to access CLDs

who may not be protected in a regulated environment. Continuation with the current policy without action will lead to further problems such as poor reporting, management, and monitoring. Last, it also limits the number of available organs that could be accessed for transplantation within the U.S. and abroad.

Allowing transplant tourism with other regulated countries may be an initial opportunity for trial and error. For example, U.S. citizens may have family members or friends in a foreign country who are prohibited from coming to the U.S. for donation or transplantation due to current policy or because of travel issues (Merion, et al., 2008). Revising the policy to include defined and regulated transplant tourism opportunities with existing international transplant centers may be one way of increasing the number of available organs and access to transplant medicine. Rapid cycle process improvement, quality control methods, and solid reporting structures would need to be establish and in place before fully exploring the potential. An initial opportunity may exist along the boarders of the U.S. with Canada and Mexico. Portions of Canada and Mexico can be incorporated into the geographic regions recognized by OPTN and UNOS. Furthermore, collaboration with other foreign transplant regulatory bodies may benefit the U.S. healthcare system in multiple ways.

Restricting transplant tourism and condemning the idea may increase the demand and market for underground organ trafficking and transplant tourism. It is highly unlikely that policy and law will be able to monitor and control this activity. Currently, there is no means for enforcement or regulation beyond the transplant community. The feasibility and resources needed for managing and enforcing the restriction would be similar to the resources needed to allow transplant tourism, if not more. The evidence presented in this paper supports that restriction may prove to be economically challenging and socially unjust.

Apply Evaluative Criteria

Continuation with current policy requires limited behavioral change and intervention. The policy appears to be well established and recognized by the transplant community. However, as discussed by Bardach (2009), changes in economics, government, organizations, and law may affect the policy over time. Progress, efficiency, effectiveness, and impact are hard to capture because of the current under reporting and tracking within SRTR, OPTN, and UNOS. With time, reporting and tracking may reveal larger numbers of patients receiving foreign country transplants, however, that number is hard to predict at this point in time.

Allowing transplant tourism appears to be a relevant option. However, this alternative would require an overhaul of the current policy to be more defined and regulated. The U.S. and international transplant community would have to come to consensus on this policy alternative. Achieving consensus on this topic may be time consuming and impossible. Allowing transplant tourism to occur on a regulated basis will require extensive action, monitoring and organization. This option could be extremely effective with regards to offering guidance and regulation to poorly regulated nations. Furthermore, the U.S. healthcare system may also benefit from collaborating with other national healthcare systems. Internationally regulated transplant tourism may provide just enough transparency to curb the underground market for international organ trafficking and commercialism.

Restricting transplant tourism is probably an irrelevant policy alternative for organ trafficking and transplant tourism, mostly because this option is going to result in turning a blind eye. The resources that will be needed to enforce this alternative will be very similar to those needed to allow transplant tourism. However in this alternative, the underground market would likely succeed. The progress towards international transplant program training, collaboration,

and coordination will likely suffer as a result of restriction. The efficiency, efficacy, and progress would be hard to track without appropriate resources dedicated to this alternative. The greatest impact to society will be harm.

Weight the Outcomes

Weighing the outcomes is a difficult task. Per Collins "a common error that inexperienced analyst make is to focus on choosing between the alternatives rather than between the projected outcomes" (2005, p. 196). To assist in this process an outcomes matrix can be constructed to provide a visual understanding of how the policy alternatives are evaluated based on the criteria. In Bardach's outcomes matrix, three policy alternatives are listed: 1) continuation of the current policy, 2) allowance of transplant tourism, 3) restriction of transplant tourism. The adapted outcomes matrix rates evaluation criteria with a positive, negative, and neutral impact methodology, see Table 1.

Limited behavior changed will likely result in limited progress being made towards change. In the preceding pages a problem was identified with the current OPTN and UNOS policy on transplantation of non-resident aliens. In this policy U.S. citizens are freely able to participate in transplant tourism regardless of standards or regulation. The policy view is egocentric in nature and does not account for alternative modes of organ trafficking as discussed by multiple sources. Commercial living donors are a vulnerable population that is open to exploitation by waitlisted patients with the financial means to purchase organs on the black market.

Allowance of international transplant tourism and commercial organ donation poses significance ethical, moral, and society concerns that should be thoroughly evaluated and discussed at all levels. These levels include: the public, transplant community, national and

international government, payors, patients and their families, and donors and their families. This analysis does not begin to address those very important issues. However, further investigation and discussion is warranted. In his 1970 classic, *The gift relationship,* Richard Titmuss anticipated many of the dilemmas now raised by the global human organs market. His assessment of the negative social effects of commercialised blood markets in the USA could also be applied to the global markets in human organs and tissues:

> "The commercialism of blood and donor relationships represses the expression of altruism, erodes the sense of community, lowers scientific standards, limits both personal and professional freedoms, sanctions the makings of profits in hospitals and clinical laboratories, legalises hostility between doctor and patient, subjects critical areas of medicine to the laws of the marketplace, places immense social costs on those least able to bear them – the poor, the sick, and the inept – increases the danger of unethical behaviour in various sectors of medical science and practice, and results in situations in which proportionately more and more blood is supplied by the poor, the unskilled and the unemployed, Blacks and other low income groups" (as cited in Scheper-Hughes, 2003, p. 1648).

The statement is an example of the controversy observed since 1970. The global transplant community must be called to action. Continuing to document problems without solutions can no longer be an acceptable practice. According to Henry Hansmann (1989) society is foolish to expect a magic solution to this problem. "Given the disabilities of the current system for obtaining and allocating organs and the improvements that are at least potentially available by permitting appropriate forms of compensation, the present blanket prohibition on any form of payment seems extreme" (Hansmann, 1989, p. 83-84).

Make the Decision

The concept of transplant tourism and commercial living donors is not a new one (Hansmann, 1989). However, the call to action and sense of responsibility should be paramount and priority for the organ procurement and transplant community. The current OPTN and UNOS policy on Transplantation of the Non-Resident Aliens is egocentric in nature and may be producing harm to both residents and non-residents alike. The current policy turns a blind eye on global organ trafficking and transplant tourism. The evidence of organ trafficking and transplant tourism contradicts the altruistic rationale and premise for the current policy.

Patients who voluntarily remove themselves from U.S. transplant lists to seek foreign transplants should receive extensive education and training with regard to the global impact of their decisions. Furthermore, black market and underground organ trafficking should be strongly condemned until standards, fair market value, monitoring, and regulation can be put into place and maintained. The cost in harm to society is far greater than the financial implications of making such a change.

The OPTN and UNOS Board of Directors should strongly consider policy that supports regulated transplant tourism in a fair and equitable manner. Policy that supports regulated transplant tourism may provide enough transparency to curb the underground organ trade. Regulation can be enforced via the transplant community, law, policy, and further research. Vulnerable populations who choose to sell their organs for financial compensation should received high quality and comprehensive care post organ recovery. Last, trial partnerships with Canada and Mexico may be good starting points to assess policy feasibility and sustainability.

Figures

Figure 1. Organ donation and transplantation policy development process, adapted from U.S. Department of Health & Human Services.

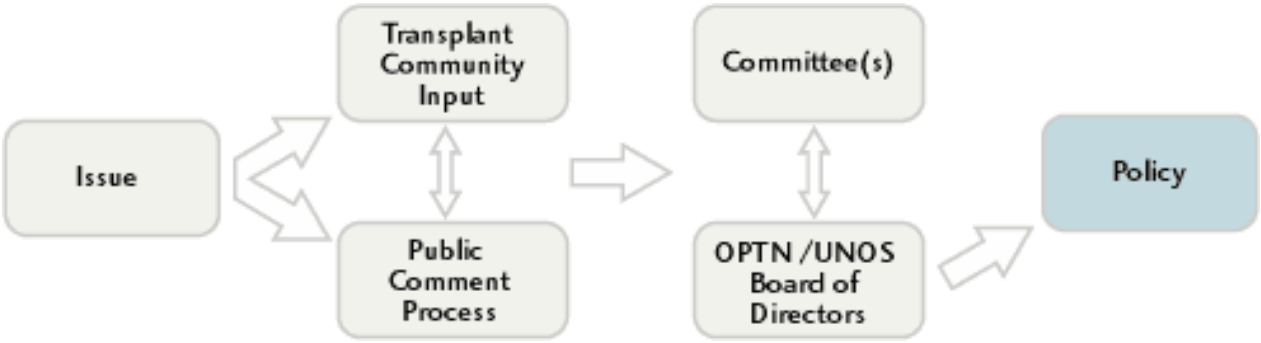
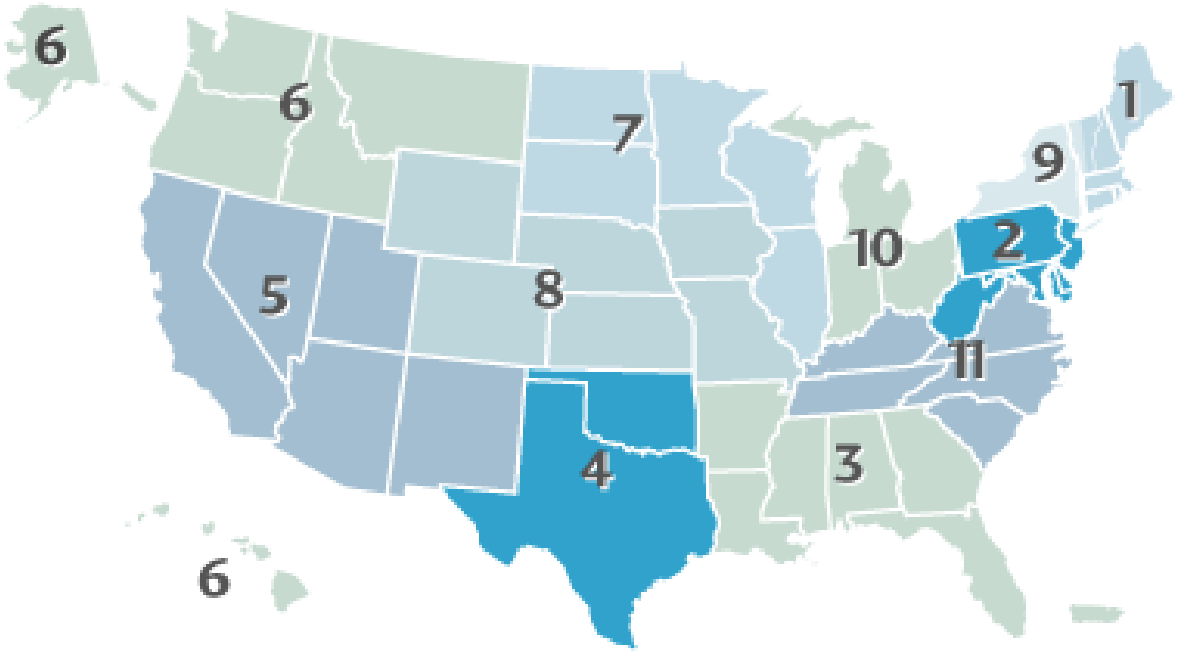


Figure 2. UNOS geographical regions



Tables

Table 1. Bardach's outcomes matrix for policy alternatives

Policy Alternatives	Criteria				
	Relevance	Progress	Efficiency/Finances	Effectiveness	Impact
Continue Current Policy	🟡	🔴	🟢	🔴	🔴
Allow Transplant Tourism	🟢	🟢	🟡	🟢	🟢
Restrict Transplant Tourism	🔴	🔴	🔴	🔴	🔴

Key: positive impact 🟢 negative impact 🔴 neutral impact 🟡

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Running head: ETHICS CASE STUDY

Ethics Case Study

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Case & Dilemma

Patient A is a 28 year old African-American male admitted from Tillamook, Oregon with idiopathic dilated cardiomyopathy, ejection fraction less than 10%, New York Heart Association (NYHA) class IV heart failure, and a history of multiple out of hospital cardiac arrests. Despite multiple cardiac arrests, there was no neurological or cognitive dysfunction. He is obese with multiple medical problems. He was transported to Oregon Health and Science University (OHSU) in severe cardiogenic shock, quickly evaluated for cardiac transplantation, and implanted with a pulsatile left ventricular assist device (LVAD). Due to the severity of his illness, his wife made many medical decisions on his behalf. The couple has been married for several years and has three young children. They are both unemployed and have Medicaid coverage.

After implantation he spent 52 days in the intensive care unit (ICU) with severe right ventricular failure, renal and respiratory failure. After several weeks of being orally intubated, a tracheotomy was performed. Throughout his ICU stay he was dialyzed with continuous veno-venous hemodiafiltration (CVVHDF), a gentle and slow form of dialysis. Once he was able to tolerate conventional dialysis he was transferred to the progressive care unit. He experienced a five-month hospitalization before being discharged back into his community. Tillamook, Oregon is a small coastal community approximately 2 hours away from OHSU.

Upon financial review, the total implant cost was $274,592.26, cost per hospital day $2,117.05 and the total inpatient stay $1,078,164.80. Additionally, weekly clinic appointments, medications, dressing changes and transportation to and from clinic add barriers, burdens, and cost to the clinical case.

Currently, all ventricular assist devices (VAD) approved by the Food and Drug Administration have tunneled drivelines or cannulae exiting the abdominal cavity (Kirklin, et al., 2008). The drivelines or cannulae require a sterile dressing change, special care, and monitoring. Infections within and around the driveline can lead to severe infections systemically and within the pump pocket. Pump pocket infections can be extremely difficult to treat and can lead to sepsis.

Many VADs also have a lifespan. Patient A was implanted with a HeartMate e**X**tended lead **V**ented **E**lectric (XVE) LVAD (Thoratec, 2008). This VAD can be electrically or pneumatically actuated. The average lifespan for this device is 12-15 months (Thoratec, 2008). After that time, a patient on support may start to encounter pump malfunction or device end-of-life symptoms. For example, degradation of the titanium ball bearings, porcine tissue valves, or compromises in the electrical continuity of the motor system (Thoratec, 2008).

Patient A was supported in the community for another eight months post initial discharge from OHSU. He was readmitted several times for dialysis catheter related infections, peripherally inserted central catheter infections, urinary tract infections, and upper respiratory infections. During one of these admissions, the nurse caring for the patient noticed cockroaches in his hospital room. Upon further investigation of his personal belongings and with questioning, evidence of a severe cockroach infestation within the home was evident. Over the course of that hospitalization the treatment team worked tirelessly to remedy the cockroach infestation. This included multiple treatments by a pest control agency. However, shortly after that hospital discharge, the patient called to complain of abdominal distention, bloating, fevers, and chills.

Patient A was readmitted to OHSU for evaluation and management. During this evaluation the patient reported pump stoppage and a grinding within his VAD. These two

findings are classic pump failure symptoms. A right heart catheterization was performed and those findings confirmed that the LVAD was no longer pumping efficiently. The treatment team decided to place him on the pneumatic console so that the pumping chamber would not get locked in the eject position. If this occurs the patient cannot be supported.

At this point in time, should the treatment team list the patient for cardiac and renal transplant or make a referral to palliative care? There is significant concern about risk for infection as related to the home environment. Patient A has had multiple infections while on VAD support. Will his home environment and personal hygiene lead to a poor outcome after transplantation? What is our commitment to him? We did place the VAD as a bridge-to-transplantation.

Review of Topics

Per Jonsen, Siegler, and Winslade (2006) ethical dilemmas can be approached with the following four basic components: 1) medical indication, 2) patient preferences, 3) quality of life, and 4) contextual features. Within these components ethical principals such as beneficence, nonmaleficence, autonomy, and justice exist. The principals are not isolated to any one component. In fact they may be fluid, dynamic, and multifactorial. The purpose of this paper is to analyze a specific case, review the topics, and evaluate a practical and professional approach to handling the dilemma.

Medical Indication

Patient A is a young African-American male with multiple medical problems and advanced heart failure. He presented to OHSU in severe cardiogenic shock and was implanted with a LVAD as a bridge-to-transplantation. His chronic renal failure is secondary to the LVAD

implantation and he has complied with outpatient dialysis and LVAD management for nearly one year.

However, he has experienced chronic recurrent infections within his venous access devices, respiratory tract, and urinary tract. The treatment team has spent a great deal of time, expertise, and resources preparing him for a combined cardiac and renal transplant. A thorough case review has been completed and Medicaid has authorized OHSU to list the patient for a combined transplant. However, the patient has also been recently diagnosed with a LVAD malfunction and catastrophic device failure. Images of the explanted device can be seen in figures 1, 2, and 3.

The only way to keep the LVAD pumping is to maintain the patient on the pneumatic console. This is an immediate short-term solution. The pneumatic console was designed for the previous generation HeartMate IP (implantable pneumatic). However, because the HeartMate XVE can be electrically and pneumatically driven, the pneumatic console can act as an emergency back-up support system. If the patient is not immediately placed on the transplant list with highest priority, he is at extremely high-risk for irreversible end-organ damage and death.

Historically the Transplant Division has performed five combined cardiac and renal transplants. Additionally, many patients on VAD support have experienced a device malfunction. The current standard of practice at OHSU is to upgrade the listing status as medically indicated for device malfunction, failure, or complication.

Patient Preferences

Patient A was fully alert and oriented to his critical condition. At the time of pump stoppage and grinding the patient's wife was at home in Tillamook caring for the children. Prior to being placed on the pneumatic console he was informed of all the potential risks associated

with that intervention. Such as, incomplete blood chamber filling, fixed mode operation, venting the diaphragm every four hours – resulting in a temporary pause in the pumping mechanism, risk for stroke, respiratory distress, anxiety, and thrombus formation. He was able to participate in the decision-making process and elected to be placed on the pneumatic console. He was comforted in the fact that he was involved in decision-making process.

Additionally, the patient's wife was updated via telephone and was informed that she should come to OHSU to be with her husband during this challenging time. Patient A tolerated the venting process for approximately 24 hours. However, he became increasingly anxious and symptomatic with each venting. At one venting he displayed seizure like activity and became incontinent of urine and stool. He became more frightened over time but always remained mentally capable.

Over the next several days, multidisciplinary care conferences occurred multiple times per day. When directly asked what he wanted, he replied, "I want to get my heart and kidneys."

Quality of Life

Patient A would not be able to return home on the pneumatic console. Additionally, due to poor tolerance of the venting process, the ICU nurses felt that he was best suited in the critical care unit and the medical practitioners agreed. The pneumatic console provides 30 minutes of battery power and limited his time for ambulation and mobility. Although, Patient A always seemed to be resilient with regard to his illness, he was beginning to decompensate. He would not be able to return to his normal life, as experienced prior to this device failure. Patient A verbalized the risks and remained committed to staying on the pneumatic console. The multidisciplinary team recommended a palliative care consult, and he politely declined. Patient A

expressed satisfaction with the care plan and stated he would ask for the consult when the time was right for him.

Contextual Features

The patient has a history of chronic infections and a severe cockroach infestation of the home. The patient and his family acknowledged both issues and were appropriately concerned. Prior to admission, the patient had an exterminator provide two treatments to the home to prevent breeding and ultimately kill the insects. Education on maintaining healthy home environment was provided and a home health nurse was scheduled to perform an environment of care survey. However, the transplant team did not have enough time to be clearly convinced that a true lifestyle change had been made.

Additionally, there was concern from the nursing staff that with venting, they were inflicting harm on the patient. Last, various members of the team expressed concern for the fiduciary responsibility to both the institution and society as a whole.

Case Analysis and Recommendations

According to patient management guidelines, when a device failure occurs without systemic or neurological insult, three options exist: 1) replace the pump, 2) list and transplant, and 3) consult palliative care for end-of-life considerations (Thoratec, 2004).

Schulman, et al., (2009) recently conducted a retrospective study to evaluate device-related infections. Additionally they "aimed to determine the effect of device-related infections on post-transplant survival and post-transplant infection" (Schulman, et al., 2009). Device-related infections were defined as the following types of infection: sepsis, pump pocket, drivelines, sternal wound, and bloodstream. Internal blood chamber infections were combined with bloodstream infections.

The only two significant factors affecting survival to transplant were the driveline and sepsis infection groups. Interestingly, the post-transplant survival group demonstrated no statistical significance in survival at 1-year post-transplantation (Schulman, et al., 2009). VAD patients with pre-transplant infections were predisposed to post-transplant infections but not necessarily at increased risk for mortality. However, the length of stay was increased in this group (Schulman, et al., 2009). The researchers concluded that sepsis appears to be the number one cause for increased mortality in LVAD-related infections post-transplant. Lastly, there were several limiting factors to this study such as design, selection bias, and single center experience. The authors call for more clinical research in this area.

This study suggests that patients with LVAD-related infections are at increased risk for post-transplant infections, increased length of stay but not necessarily at increased risk for mortality. Furthermore, the authors suggest expediting the listing status of patients especially if they are not responding to antibiotic therapy. This hypothesis may lead to better outcomes. Conversely, if patients are presenting with sepsis and end-organ damage, practitioners may want to consider de-listing the patient to prevent poor post-transplant outcomes. Initiating the palliative care consult should also be a trigger at this time.

This research was published in March of 2009 and supports our clinical decision to proceed with orthotopic heart transplantation. At the time of transplantation, the patient was stable on antibiotics. He was not showing signs of worsening infection. His symptoms including: abdominal distention, bloating, fevers, and chills was secondary to right heart failure and pump malfunction. An abdominal paracentesis was performed multiple times to decompress his acites. The fluid obtained was not infectious. The following section will explore the patient's preferences, quality of life, and contextual issues.

Ethical Essay

Patient A continuously remained alert and active in his medical decision-making. He was informed of changes in his condition and was asked permission prior to treatment. "Informed consent is the usual way in which patient preferences are expressed. Informed consent is the practical application of respect for the patient's autonomy" (Jonsen, et al., 2006, p. 54). Patient A consented to being placed on the pneumatic console with the understanding that he was at higher risk for neurological insult. Additionally, when a donor heart became available he was consented for the transplant, fully understanding his risks.

The patient's quality of life was severely impacted by this device malfunction. He was not tolerating the venting process and the pneumatic console was not designed for long-term use with the HeartMate XVE. The pneumatic console can be used for emergency backup in the event of electrical or motor malfunction. Due to the patient's complexity, poor tolerance to venting, and shortened battery time, the ICU nursing staff advocated for him to stay in the ICU for closer monitoring and advanced intervention. This is a stellar example of advocacy and moral agency.

In summary, this patient experienced the "worse case scenario" with regards to VAD support and device malfunction. This case was extremely challenging on many levels. The patient was informed and guided through the illness from onset to resolution. The Advanced Heart Failure and Transplant Team were ultimately committed to supporting the patient through this complication despite the financial impact to the payor or institution. OHSU administration is supportive the VAD Program and understands that there may not be a financial gain associated with all VAD implants. However, the treatment team must remain fiscally responsible for program growth and continued service to the people of Oregon and the Pacific Northwest Region.

Figures

Figure 1. Explanted HeartMate XVE at time of orthotopic heart transplant (OHT), courtesy of Thoratec Corporation.

Figure 2. Internal motor chamber with motor degradation and bearing damage, courtesy of Thoratec Corporation.

Figure 3. Close-up image of motor housing with bearing dust, courtesy of Thoratec Corporation.

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Degree: Doctor of Nursing Practice

Title of Study:

Economic, Clinical and Humanistic Outcomes in Patients Implanted with the HeartMate II LVAS: A Single Center Experience

APPRCVED:

Committee Chair: Anne Rosenfeld, PhD, RN, CNS (name and credentials) **Signature:** Anne Rosenfeld

Committee Member: Christopher Lee, PhD, RN (name and credentials) **Signature:**

Committee Member: Antony Kim, MD (name and credentials) **Signature:**

Michael R. Bleich, PhD, RN, MPH, FAAN
Dean, School of Nursing **Signature:** Michael R Bleich, PhD, RN

Date: 6-13-11

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To: **Frederick M. McNeil, MS, RN, ACNP, CCRN**
Acute Care Nurse Practitioner, Instructor
Ventricular Assist Device (VAD) Coordinator

From: Gary Laustsen, PhD, FNP-BC, RN
Associate Professor & Family Nurse Practitioner
Chair, Critical and Acute Specialty Care Integrated Learning Community (ILC)

Re: ILC Presentation

Dear Fred:

On behalf of the members of the Critical and Acute Care ILC, I want to extend our sincere and enthusiastic appreciation for the presentation you gave to our May 4, 2011 ILC meeting. Your presentation gave members a wonderful overview of the evolving technology for heart failure patients as well as addressing the ethical, economic, and quality of life issues.

We greatly appreciated your "nursing focus" both in your presentation and in your clinical/professional work. Health care is challenging for many reasons, but the importance of remembering the human aspects of health care is part of what nurses should continue to promote.

The ILC members wish you success in the conclusion of your Doctor of Nursing Practice program. We also have confidence that your expanded nursing role will be professionally valuable to nursing as well as to the patients and community in which you work.

Thanks again for sharing your time, expertise, and passion with our group!

Sincerely,

Gary Laustsen

Gary Laustsen

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CORPORATION

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Mr. Frederick McNeil
OHSU

Dear Mr. McNeil,

I wanted to personally thank you for your contributions as a faculty member at last weekend's "Destination Life" MCS conference in Orlando. Based on everything I observed, it was a terrific success with lots of learning and enthusiasm. The early feedback we received from attendees, from both our more experienced VAD centers and newer centers, suggests that the program and content were well received, on target and highly valuable.

The curriculum developed and delivered by a diverse faculty, was clearly at the core of this success. I think everyone who attended came away with a feeling that HeartMate II is mainstream therapy and with a clear call to action to consider treating more advanced heart failure patients who could benefit from MCS. I hope that you too found the experience worthwhile, informative, and enjoyable.

Along those lines, I would very much welcome any feedback or input you might have regarding the conference. I would also appreciate any feedback you would like to provide on how Thoratec is doing relative to supporting you and your center. Outside of the conference, are there other things we should be thinking about or doing to help grow the field and/or improve the therapy? I would welcome your thoughts.

We are committed to helping drive education and awareness to improve clinical outcomes, increase heart failure patients' access to advanced therapies and move the field forward. Thanks again for your support and we look forward to continuing to work with you to develop this exciting field of advanced heart failure therapy.

Warm regards,

Gary Burbach
President and CEO
Thoratec Corporation