Deciding about Heart Transplantation or Mechanical Support: An Empirical Study and Ethical Analysis

By

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy
Graduate Department of the Institute of Medical Science
University of Toronto

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Abstract

Purpose: Patients living with advanced heart failure experience dyspnea, fatigue, poor quality of life, depression and cognitive impairment which may threaten their ability to provide informed consent to undergo heart transplant (HTx) or mechanical support (LVAD). Using qualitative and quantitative methods, we asked how patients with advanced heart failure make decisions regarding HTx and LVAD. The variables chosen to reflect the elements of consent included quality of life and symptom severity (voluntariness), depression and cognitive impairment (capacity) and treatment preferences (decision-making).

Methods: 76 patients enrolled in the quantitative arm completed the Minnesota Living with Heart Failure Questionnaire; Visual Analog scales for dyspnea, fatigue and overall health; Beck Depression Inventory; Montreal Cognitive Assessment; Standard Gamble and Time Tradeoff.
Qualitative methods were used to discover concepts, relationships and decision-making processes described by 17 of the 76 patients considering HTx and LVAD.

Results: Patients reported poor quality of life and high symptom severity scores which compelled them to consider surgery as a way to relieve unpleasant symptoms and improve quality of life. Although 30% of patients had evidence of depression and/or cognitive impairment, no patient was deemed incapable of decision-making. Patients were willing to take considerable risk (35%) and trade considerable time (4months) to improve their health. While heart failure-related concepts were important to the decision, entrustment emerged as the meaningful process for decision-making.

Conclusions: Patients who participated in this study were capable of decision-making and understood the risks associated with the surgery. Voluntariness was diminished by disease but not absent, and decisions were free of coercion. These results suggest the entrustment model of decision-making is the dominant process for patients considering high-risk surgical procedures and meets criteria for informed consent. Understanding the process of decision-making will help clinicians support and enable treatment decisions made by patients living with advanced heart failure.
Dedication

I dedicate this dissertation to my patient and friend, Michael Martin (1954-2009) who took me on his journey of decision-making. Illustrating it in terms I could understand - heavy metal and classic rock, good scotch and an appreciation of Monty Python. I did it!
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CHAPTER 1 - INTRODUCTION

Heart failure is reaching epidemic proportions. It affects over 500,000 Canadians, and 50,000 new cases are diagnosed each year.\(^1\) In the past decade, the number of patients admitted to hospital in the United States with a primary diagnosis of heart failure has increased to over 1 million.\(^2\) Ongoing improvements in heart failure management will only increase the number of patients surviving to develop Stage D heart failure. Patients are considered to have Stage D heart failure when, despite optimal medical management, they continue to have symptoms of shortness of breath and fatigue at rest.\(^3\) Patients with Stage D heart failure experience periods of exacerbation and stabilization. With exacerbations, a person experiences an increase in symptom severity. This may require a change in medication, frequent clinic visits, the addition of a new therapy and/or hospital admission. When the symptoms stabilize, it may not be back to their prior level of functioning. At this stage, quality of life is poor and survival is limited. Patients who continue to deteriorate despite optimal medical management may be candidates for advanced surgical therapies such as heart transplantation or implantation of a left ventricular assist device (LVAD). The overall goal of these therapies is to not only improve survival but also to improve quality of life.

Heart transplant or LVAD implant are surgical therapies to replace or assist the failing heart. Patients are referred for heart transplant or LVAD implant when they continue to deteriorate despite optimum medical management. For heart transplantation the patient’s damaged heart is replaced with a functioning heart from a brain dead donor. Following transplantation patients must take life-long immunosuppressive medications and require frequent interventions to
monitor their health. Left ventricular assist devices are mechanical pumps implanted inside the patient’s body to take over the pumping action of the patient’s failing left ventricle. LVADs can be implanted as a bridge-to-transplantation or as destination therapy – an alternative to transplant. Discharge home with an implantable device is possible after an appropriate period of convalescence and patient/family education.

All patients referred for heart transplant or LVAD implant complete a series of diagnostic tests and psychosocial assessments to determine eligibility. Some patients may become extremely ill over a short period of time and this acute presentation may be their first encounter with heart failure. Patients who present acutely may not have had time to consider how they would respond to the need for heart transplant and/or LVAD implant. When heart failure occurs acutely and patients are critically ill, the assessment process can occur over hours or days. Other patients may experience a gradual decline in their health and may be able to anticipate their referral for heart transplant or LVAD implant. Patients who experience a general decline in health may have their assessment occur over weeks. While diagnostic tests and focused psychosocial assessments provide objective information regarding candidacy for transplant or LVAD, factors other than the results of diagnostic tests influence final decisions. One of the challenges for clinicians is to determine patient’s preferences for treatment at end-of-life and their expectations and wishes regarding heart transplant or LVAD implant. In some situations the team knows the patient and expectations of treatment have been discussed prior to referral for heart transplant or LVAD implant. In these situations, clinicians can use patient specific information to clarify expectations in relation to heart transplant or LVAD implant. In other scenarios, patients may present with an acute onset of heart failure, are critically ill and previously unknown to the team.
In these situations, clinicians must use general information based on past experience with this patient group and information from the literature to initiate and advance the discussion regarding heart transplant or LVAD implant.

For many clinicians, patients and family members, discussing how a patient wants to live out the rest of their life is a difficult subject. Compounding the difficult subject matter may be a real or perceived lack of time available for these discussions to occur. Patients may avoid discussions because they perceive there is not enough time or that clinicians are too busy for adequate discussion. They may also perceive that if clinicians do not initiate the discussion it is not pertinent to their situation. While clinicians recognize the importance of these discussions, they may delay initiating them until they sense the patient and family is ready and there is adequate time for an in-depth discussion. In fact, less than 25% of patients report discussing treatment preferences with their physicians.4-6

The impetus for this study came from my experience as an LVAD coordinator in the Toronto General Hospital Heart Transplant/LVAD team. My pre-operative responsibilities included providing patients and their family education about LVAD implant. I would meet with a patient to discuss the teams recommendation about LVAD implant, arrange a teaching session with both patient and family that included a hands-on demonstration with the equipment, discuss the potential for LVAD withdrawal and their wishes for end-of-life care should that become a possibility and participate in a meeting with the patient/family, surgeon and cardiologist to review information to date and sign the consent form. Initially my energy was focused on making sure patients had the necessary information to make an informed decision regarding implantation. I used a variety of methods including booklets, DVDs and discussion. I would spend time making sure patient/family questions and concerns were addressed by the most appropriate member of the team. For the majority of patients the preparation occurred over the
course of 1 week. For patients requiring urgent implant I accelerated the process and accomplished what I felt were similar goals in a shorter period of time. As my experience with this patient population grew, I began to question if the decision to proceed was truly “informed.”

The criteria for informed consent were engrained during my practice of over 20 years of cardiac nursing. Most recently, I had worked as a nurse practitioner in Cardiac Surgery. The process of informed consent in cardiac surgery seemed different than what I experienced as an LVAD coordinator. Patients considering heart surgery were generally well. They had been referred to our program for assessment of either coronary artery blockages or problems with a heart valve. Quality of life was somewhat impaired due to their angina or limited functional ability but cardiac surgery would essentially “fix” the problem and return them, with some limitations, to their former health. While heart surgery is complex, in the hands of an experienced surgeon, the procedure itself is fairly routine and seldom life-threatening. Patients seemed to have lots of time to consider their decision. Additionally, lots of information was available to help patients make their decision – written, electronic and many patients had friends or acquaintances that had had heart surgery and so they knew a little about what to expect. Most patients did not know the surgeon prior to consultation for surgery. However, many trusted the opinion of the cardiologist who made the referral through well-established referral mechanisms. My role in informed consent was either to act as a patient advocate or to support patients while they were making the decision. I conceptualized informed consent as a contract negotiated between the patient/family and surgeon. I believed the decision was well informed, “autonomous” and voluntary. This was the framework for informed consent I was using when preparing patients for LVAD implant.

My experience with the heart failure population challenged my beliefs regarding informed consent. Patients considering LVAD implant were at end-of-life. Without intervention they
faced at least a 50% chance of dying within 6 months. LVAD implant is a high-risk surgical procedure to assist the failing heart. When patients were approached regarding this high-risk surgery, most patients and their families agreed to proceed before the end of the discussion. When I explored their reasons for agreeing, they were motivated by the anticipated relief of symptoms and the promise of improved quality and quantity of life. While I understood they were not being coerced by any external sources, I questioned if their symptoms and limited life expectancy was compelling them to proceed and if their consent was truly voluntary. I was alarmed at the degree of cognitive impairment I was seeing within this patient population. Most patients did not have the energy to read the information I provided, many had noticeable deficits in executive function and short term memory was poor. I felt this impaired their ability to understand the information they needed to make an informed decision. It also raised questions of capacity for decision making. When I met with patients without their families, they talked about the effects that living with heart failure had on their families. They were concerned about “being a burden.” They felt proceeding with LVAD would get them home and once they felt better would reduce the amount of burden they put on family members. Additionally, the decision to proceed seemed to be a group decision based on what is best for the family, not necessarily the patient. This made me question if these decisions were truly “autonomous.” This experience challenged my beliefs regarding informed consent. I identified 2 areas where I needed more information: I needed to understand how patients with heart failure made treatment decisions regarding heart transplant and LVAD implant and I needed more information on the ethical foundations of informed consent.
Informed Consent

Informed consent continues to be a hot topic in bioethics due to the plethora of treatment options available to most patients living with chronic health problems. The theory of informed consent proposed by Faden and Beauchamp will provide the framework for informed consent. This approach is based on a principlist approach to biomedical ethics. Principlism proposes that respect for autonomy, beneficence, non-maleficence and justice are part of common morality and are shared by all moral persons. I chose this framework because most healthcare professionals learn about it during their training and use it to structure and understand ethical problems at the bedside. As such it provides a common language across medicine, nursing and allied health. Autonomy is defined as a capacity for independent decisions and action. Respecting autonomy suggests that healthcare professionals have an obligation to support and enable autonomous decisions.

The historical roots of informed consent can be traced back to the maxim “to help, or at least to do no harm” viewed as the fundamental value of the Hippocratic tradition in medicine and the backbone of the physician-patient relationship. This maxim evolved from the principle of beneficence. In healthcare beneficence includes promoting the welfare of the patient, reducing harm and promoting health. Beneficence was pervasive in the early history of medical care and treatment decisions. The primary obligation of physicians was to provide medical benefits. In terms of truth telling and disclosure, if a physician deemed the information too distressing for the patient or if they thought revealing information may remove hope and therefore hasten death, the physician was under no obligation to disclose. For surgical procedures, a surgeon would inform patients of the need for surgery more from clinical necessity, medical reputation and social decency than a concern for patient autonomy. The decision to proceed rested with
the surgeon who was encouraged to inform and seek agreement before proceeding. While patients had a right of refusal, surgeons were the ones making the decisions.

The mid-1950’s represented a turning point for informed consent. In the 1950’s knowledge of Nazi atrocities, the “rights” orientation in society and the consumer movement led to an increase in societal awareness of the moral right for self-determination – the right for persons to make decisions about what will happen to her/his body. Although the interpretation came from a moral perspective, it was the legal community who spearheaded interest in informed consent. In the legal system, an increased awareness of self-determination led to legal decisions supporting a patient’s right to not only know what the surgeon proposed to do but also the risks and benefits of the procedure and alternative treatment options. While respect for autonomy and self-determination were common societal beliefs in the 1960’s, the requirement of a signed informed consent for surgical procedures did not take root until much later. Results from empiric studies in informed consent done in the early 1970’s, suggest while physicians recognized they had a moral and legal obligation to obtain consent, a procedure-specific consent was not the norm in practice. It wasn’t until the publication of the American Hospital Association Patient’s Bill of Rights that procedure-specific consent became a requisite of medical practice. Publication of a Patient’s Bill of Rights also signified the beginning of the current autonomy model of informed consent for patient care.

Our contemporary understanding of informed consent has 2 distinct applications – one that reflects a moral perspective and another that is based in law. From a moral perspective, informed consent promotes the moral principle of respect for autonomy. Treatment decisions are made by the patient, free of coercion and undue influence. The patient is viewed as independent and rational and decisions are based on factual information excluding emotions or past experience. The role of healthcare providers is to respect the autonomy of patients and to
support and enable them to make decisions. In this interpretation, informed consent is an action and represents the autonomous authorization of medical treatment and/or a surgical procedure.\textsuperscript{7} The other application of informed consent evolved from the legal perspective. In this sense, informed consent is a document that signifies the patient’s permission to proceed with medical treatment and/or a surgical procedure.\textsuperscript{7} This version of informed consent is contractual and the signing of the consent form signifies that the patient has made a voluntary decision. From a clinical perspective, the 2 applications need not be mutually exclusive. The institutional requirement of informed consent is intended to maximize the likelihood that the conditions of informed consent meet the requirements of autonomous decisions.\textsuperscript{9}

Appreciating that informed consent had 2 distinct uses was a key factor in helping me to understand why I was concerned that patients agreeing to proceed with VAD implantation were not “informed.” My understanding of informed consent came from the contractual version. A signed consent form indicated that patients were aware of the risks and benefits of a surgical procedure and any alternatives. Since my experience was limited to patients who consented to a specific surgical procedure for a well-defined problem, the contractual application met my needs. As a VAD coordinator my concern came from an understanding that:

- Many patients with advanced heart failure exhibit signs of cognitive impairment which affects their ability to comprehend and remember information.
- Decisions may not be unduly influenced by clinicians but symptoms of shortness of breath and fatigue may motivate patients to choose treatments that relieve these symptoms. Decisions are fraught with emotion, affect those on whom the patient depends and involve a high degree of uncertainty.
- Independence is but a memory as the progression of heart failure creates social isolation and increased dependence on others.
• Decisions are informed by past experience with the illness and the health care team.
• Decisions will not only affect how a patient lives out their life but may also affect how they die.

My concerns originated from my moral self. In my view, decisions were not independent or rational nor were they based on factual information excluding emotions or past experience. As a nurse I had a role to support and enable patient autonomy and informed consent. For this patient population I needed to understand how poor quality of life, severe symptoms, depression and cognitive impairment affected the decision to proceed with surgery and if the decision fulfilled the requirements of informed consent. Additionally, I felt I needed to determine if there were any additional factors that affected informed consent. Understanding how these factors affect informed consent will improve my ability to support patients considering heart transplant and/or LVAD implant.

Research Purpose
The purpose of this study was to develop a comprehensive model of decision-making for heart transplant and/or LVAD implant and determine if the decision to proceed with surgery fulfilled the requirements of informed consent through the integration and interpretation of findings from a:

1. Quantitative study to describe the factors affecting informed consent for heart transplant and/or LVAD implant.
2. Qualitative data to identify additional factors that may influence informed consent.

Research Questions
1. How do patients with advanced heart failure make decisions regarding heart transplant and/or LVAD implant?
2. For patients considering heart transplant and/or LVAD implant, how do patients rate their:
   a) Quality of life?
   b) Symptom severity?
   c) Overall health?
   d) Cognitive impairment?
   e) Depressive symptoms?
   f) Treatment preferences?

3. Is there a difference between the final decision and patients ratings of:
   a) Quality of life?
   b) Symptom severity?
   c) Overall health?
   d) Cognitive impairment?
   e) Depressive symptoms?
   f) Treatment preferences?

4. Are the results consistent between the quantitative and qualitative data and how do they contribute to understanding informed consent for patients considering heart transplant or LVAD implant?
CHAPTER 2 - REVIEW OF THE LITERATURE

Faden and Beauchamp propose disclosure, comprehension, voluntariness, competence and decision as the elements required for a valid informed consent. These elements are collectively agreed upon within the healthcare community and will provide the framework for the literature review. Disclosure is the responsibility of healthcare professionals. This section will include information on survival, risks and benefits of both heart transplantation and LVAD implantation and our assessment process for heart transplantation and LVAD implantation. Comprehension involves how patients understand information. This section will include information on how patients understand informed consent and the attitudes of patients on prognosis of heart failure. Voluntariness suggests that decisions are free from coercion and the influence of others. While I do not believe healthcare professionals pressure patients to decide one way or another, I do feel living with heart failure and its symptoms compels patients to choose treatments that potentially relieve these symptoms and improve quality of life. This section will include information on the quality of life and symptom severity for patients living with heart failure. Capacity serves as a gatekeeper function in informed consent. Only capable patients can provide valid consent. This section will deal with threats to capacity including depression and cognitive impairment. The final element is decision. This section will review information on treatment preferences of patients with advanced heart failure and discuss the factors influencing decisions.
1. DISCLOSURE

Disclosure is the first element in informed consent. It has been the single most contested element in the courts and legal decisions have defined our current interpretation. Disclosure is different from the other elements since it pertains to healthcare professionals. Healthcare professionals have an obligation to provide patients with the necessary information for decision-making. Necessary information includes: (1) facts or descriptions patients usually consider relevant to decision-making (2), information the professional considers important (3), a recommendation (4), the purpose of seeking consent and (5) the nature and limits of consent as an act of authorization. In terms of surgical procedures, physicians and surgeons typically discuss the diagnosis and natural history of the disease, treatment options, a recommendation with risks and benefits, and alternatives with risks and benefits. Surgeons must now also disclose if they have any conflict of interest – either research or economic, that may affect judgment. Disclosure for patient decision-making for heart transplant and/or LVAD implant includes information on the natural history of heart failure, risks and benefits of surgical intervention and related treatment and alternatives to surgical intervention. Agreeing to proceed with heart transplant or LVAD implant is more than agreeing to a surgical procedure. Patients must also be informed about the expectations of care – for both the patient/family and team, after the operation. The information provided to patients is standardized across our program and based on up-to-date information from the literature and our experience at Toronto General Hospital. We formally meet with a patient and their family to discuss prognosis, risks and benefits of treatment, treatment recommendations and to answer their questions when (1) we first diagnose/confirm heart failure, (2) when a patient deteriorates to Stage D heart failure and (3) during assessment for heart transplant and/or LVAD implant.
The Heart Failure/Heart Transplant team at Toronto General Hospital consists of cardiologists, cardiac surgeons, nurse practitioners, social work and psychiatrists. It is the only center in the Greater Toronto Area with an adult Heart Transplant program and the capability of providing advanced surgical therapies such as heart transplant or mechanical circulatory support. Referrals take place either in the inpatient or outpatient setting. The Heart Function (outpatient) clinic sees approximately 30-60 patients/week. Four attending cardiologists with postdoctoral training in heart failure, heart transplant and LVAD run the clinic. Clinic visits are coordinated so that echocardiograms, cardiopulmonary testing, bloodwork and ECG are completed during the clinic visit. We provide information on prognosis, survival statistics and anticipated quality of life during diagnosis, scheduled clinic visits when prognostic diagnostic tests are completed, when patients progress to Stage D heart failure and at assessment for heart transplant and/or LVAD implant. The information discussed in this section will be based on the typical process for a patient referred to our outpatient heart function clinic with the majority of care taking place in the outpatient setting. The assessment and treatment of patients referred from our inpatient population proceeds along a similar course.

I. Information Regarding Diagnosis/Confirmation of Heart Failure

In 2001, the American College of Cardiology/American Heart Association developed a new rating system for heart failure that emphasizes the progressive nature of heart failure. Stage A includes patients with risk factors for the development of heart failure, Stage B includes patients that are asymptomatic but have structural heart disease, Stage C includes patients with symptomatic heart failure and Stage D includes patients experiencing symptoms at rest despite optimal medical management \(^3\) (See Appendix A). Our patient management is consistent with heart failure guidelines published by the Canadian Cardiovascular Society and the American College of Cardiology/American Heart Association.\(^{11,12}\)
We formally meet with the patient and family to discuss the results of the diagnostic testing and provide information on survival, risks and benefits, treatment options and proposed plan of care when a diagnosis of heart failure is confirmed. Communicating information on prognosis is challenging. We are never sure how patients/family will respond. Typically the attending cardiologist/surgeon, a trainee and/or nurse practitioner attend the meeting. Everyone sits to aid the discussion. The discussion is led by the attending physician. We allow adequate time for discussion in our clinic schedule. First and foremost we inform patients that heart failure is a progressive illness that has an unpredictable course with periods of symptom exacerbation and relative stability. While we know what the literature says regarding life expectancy, applying that information to their particular case is difficult. We inform patients that once they are diagnosed with heart failure, they have a 50% chance of dying within 3-5 years. At this point, the benefit of treating patients with medications and non-pharmacologic therapies exceeds the risks of no treatment. We discuss their risk of sudden death and when appropriate, refer them on for assessment for cardiac resynchronization therapy and/or implantable cardio-defibrillator (ICD). We stress the importance of following instructions regarding their plan of care, informing us when their symptoms change and when their symptoms are stable. Where appropriate, we refer patients who have an ischemic etiology to a cardiac surgeon for assessment of revascularization and/or mitral valve surgery. We also refer patients for cardiac rehabilitation and encourage them to follow-through on those arrangements. Because of the progressive and unpredictable nature of heart failure we also discuss advance care planning. Specifically we talk to patients about identifying a substitute decision-maker, getting their financial affairs in order, developing and then communicating their advance care directives to both their substitute decision-maker and the healthcare team. This discussion can take as long as 1 hour and we encourage patients to ask questions. The amount and type of information discussed at this meeting can be very overwhelming for patients and their families. While we
try and assess comprehension during this visit, we usually follow-up the meeting with either a clinic visit or phone call within 1 month. We offer additional print and/or electronic resources as needed. As long as patients remain Stage C, they are followed and evaluated at least every 6 months. When a patient reaches Stage D heart failure they have a 70% of dying within 1 year.\textsuperscript{13} We formally meet with the patient and their family to review prognosis, risks and benefits of treatment, treatment options and a proposed plan of care.

II. Information Regarding Heart Transplant or LVAD Implant

Patients with Stage D heart failure who continue to deteriorate despite optimal medical therapy are approached to begin assessment for heart transplant and/or LVAD implant. Heart transplant remains the gold standard therapy for patients with Stage D heart failure. With heart transplantation, the patient’s damaged heart is removed and replaced with a functioning heart from a brain dead donor. However, there is a limited supply of donor hearts and mortality while waiting is high. As such, the criteria for heart transplant are strict and standardized across Canada (Appendix B). In Canada approximately 170 heart transplants are performed each year.\textsuperscript{14} At Toronto General Hospital we transplant approximately 25 patients per year. Within the first year post transplant, patients are at a greater risk of dying due to the transplant procedure, high dose immunosuppression, rejection and infection. Three, six and twelve month survival is 95%, 94% and 85%, respectively.\textsuperscript{14} Factors that increase the risk of dying in the immediate post-operative period include older age, longer donor ischemic times, recipient hepatic and renal dysfunction, hemodialysis, prolonged mechanical ventilation, bleeding and infection.\textsuperscript{15} If a patient survives the first year after transplant they have a good chance of living at least 13 years.\textsuperscript{15} After 1-year post transplant, the risk of dying is approximately 3-4% per year.\textsuperscript{15}
Left ventricular assist devices are mechanical pumps surgically implanted to take over the pumping action of the failing left ventricle. LVADs are indicated for patients with Stage D heart failure who are at imminent risk of dying either from an acute event or chronic decompensation of existing heart failure. Patients are categorized under one of 3 device implant strategies based on the patient’s eligibility for transplant; bridge-to-recovery (BTR), bridge-to-transplant (BTT) or destination therapy (DT). Implantation of an LVAD is an effective strategy to prolong survival for patients living with advanced heart failure. The majority of patients in our program receive an LVAD as a bridge-to-transplantation. The goal of LVAD support is to keep patients alive until a donor heart is found and to allow patients to improve their physical condition prior to heart transplantation. Results from LVAD clinical trials suggest LVAD implantation is an effective strategy for improving both quantity and quality of life. Survival for patients supported on a continuous flow pump are 82%, 73% and 72% at 6 months, 1 year and 18 months.\textsuperscript{16,17} It is unclear how LVAD implant impacts transplant outcomes. On one hand, LVAD implant increases risk in the immediate post-operative period.\textsuperscript{15} On the other hand, LVAD support reduces pulmonary artery pressures, improves renal function and nutritional status and for sensitized patients allows time to find a matched donor heart. Regardless, there is no significant difference in mortality between LVAD supported and non-supported patients after 6 months post-transplant.\textsuperscript{18}

During assessment for heart transplant each patient meets with a cardiac surgeon to discuss their particular care, what the surgery involves, risks and benefits and potential complications. If they are a candidate for mechanical support, the surgeon will reiterate that if they continue to deteriorate or if they require admission for intravenous inotropes that we are unable to safely stop, we will approach them regarding LVAD implant (see Appendix B).
We use the same process to assess and inform patients for both heart transplant and LVAD implant. The cardiologist gives a general overview of the process including rationale for the tests, risks, benefits and potential outcomes prior to initiating the assessment process. The heart transplant nurse practitioner coordinates the process and is the contact person for both patient/family and the healthcare team. Each patient is given a transplant manual to supplement the information discussed with various healthcare professionals during the assessment process. The manual is about 100 pages in length and contains information on the assessment process, waiting on the list and specific information on medications and routines following heart transplantation. There is also information on additional resources should the patient or family wish more information. This allows patients to determine the type and amount of information they obtain over the course of the assessment. From my clinical perspective, few patients have the energy required to read, remember and understand the information contained within the manual. Family members usually read it and review important aspects of care with the patient.

The comprehensive content meets institutional requirements for the disclosure element of informed consent. We also encourage patients to attend a general information session and participate in our heart transplant mentorship program. Mentors are patients who have had a heart transplant and have completed a training program specific to patient mentorship. Most patients do attend the session and talk to their mentor. They enjoy meeting other patients who are in similar situations and the staff who may be taking care of them after their procedure.

Once the consultations are done and the result of the diagnostic tests reviewed by the attending cardiologist, the patient’s case is tabled for discussion at heart transplant rounds. Rounds occur weekly and are attended by all members of the multidisciplinary team. The patient’s assessment is reviewed and members are given the opportunity to offer opinions on heart transplant/LVAD candidacy. Typically this discussion leads to 1 of 5 possible decisions: (1) too early for
transplantation, (2) candidate for transplant and LVAD implant, (3) transplant eligible but LVAD ineligible (4) transplant ineligible but eligible for LVAD as an alternative to transplant (5) ineligible for both transplant and LVAD implant. A follow-up visit is scheduled with the patient and family to discuss the decision.

Health care professionals have an obligation to disclose information regarding prognosis, risks and benefits of proposed treatment and the alternative. Our process has established points where relevant information is discussed with patients and their family. These points coincide with a significant change in prognosis and risk of dying. However, the act of providing information is insufficient for valid consent. The next section discusses how patients understand information regarding informed consent and the prognosis of heart failure.
2. UNDERSTANDING

Understanding is the 2nd element of informed consent. Understanding is defined as having pertinent information and relevant beliefs about the nature and consequences of their action. Pertinent information includes the diagnosis, prognosis, nature and purpose of the intervention, alternatives, risks and benefits, and recommendations. You will note that this list is identical to the list required for adequate disclosure. Physicians have a moral obligation to disclose relevant information and also to ensure the information they disclose is sufficiently understood. However, if a healthcare professional provides the same information for the same procedure to 2 patients in a similar situation, the likelihood they will interpret the information in the same way is low. Understanding varies widely between patients based on their level of education, life experience, experience with heart failure and the healthcare team. Understanding is best assessed on an individual basis. This makes it difficult to assess if the population of patients considering heart transplant and/or LVAD implant meet the criteria of “understanding” for informed consent. This section will include: (1) a review on the literature on patient understanding of informed consent in Phase I/II cancer clinical trials, (2) A review of the literature regarding understanding of informed consent for surgical procedures and (3) how heart failure patients perceive prognosis information.

I. Patient Understanding of Informed Consent in Phase 1, 2 Cancer Clinical Trials

The majority of evidence regarding patient understanding of informed consent is found within the cancer population, specifically the experience of patients participating in Phase I/II cancer clinical trials for chemotherapeutic agents. Phase I/II cancer clinical trials are studies designed to determine the metabolic and pharmacologic effects of chemotherapeutic agents in humans. Patients participating in these trials have advanced cancer not amenable to standard therapy.
Trials are designed to determine the toxicities and maximum-tolerated dose of the investigational drug and chance of a therapeutic benefit. Interest in patient understanding of informed consent is motivated by the knowledge that this is a particularly vulnerable group who has almost no chance of therapeutic benefit but need to understand the risks, benefits and alternative treatments prior to participating. Information of risks, benefits and alternative treatments is included in the verbal and written information provided before consent. These studies were chosen for review because of the similarity of patients participating in Phase I/II cancer clinical trials to patients considering heart transplantation and/or LVAD implant. Both populations continue to have disease progression despite optimal medical management and survival time is limited without intervention. Additionally, the majority of patients in the Phase I/II cancer trials were men in their mid-50’s which is similar to the demographics of patients in our program who undergo assessment of transplant and/or LVAD candidacy. How our sample differs is that patients can expect a benefit with treatment.

Studies describing the perceptions of patients participating in Phase I/II cancer clinical trials yield remarkably similar results. Specifically, over 90% of patients participating in these studies stated they had provided informed consent and understood the information.\textsuperscript{20-23} Nearly all patients said that someone had explained the trial and they had been informed about side-effects and risk.\textsuperscript{22,23} Less than half reported being told about alternatives.\textsuperscript{22,23} When asked why they chose to participate in the trial, the overwhelming majority of patients stated it was for possible health benefit.\textsuperscript{22,23} Further, half of the patients in the Daugherty trial stated the purpose of the trial was to determine the response of their tumor to the investigational medications, not for dose determination.\textsuperscript{22} Most patients reported that they trusted their doctor and felt he/she wouldn’t have recommended the trial if there was no chance of benefit.\textsuperscript{21-23} Even though they stated they had been informed of the purpose and risks of the trial, patients demonstrated an irreducible
optimism that their cancer might be cured and confidence in the clinicians who proposed participating in the trials. The consistency of results between the studies suggests motives other than disclosure and understanding might influence patients to participate in Phase I/II cancer clinical trials.

In the discussion section of these papers, the authors allude to the role of hope in mediating expectations regarding effectiveness of experimental treatment.\textsuperscript{21-23} Hope is an attitude of optimism in one’s life, and a belief in a positive outcome. In recruitment to Phase I/II cancer clinical trials, hope may be reinforced by study staff who present information in a positive fashion. In the Cox (2002) study, analysis of recordings identified that staff used words like “study” or “treatment” instead of trial.\textsuperscript{21} Words such as “New” and “American” were common and patients interpreted this as being better/more effective treatments. Presenting trial information in this way was probably a strategy used by study staff to enhance recruitment. However, for patients it may have reinforced hope for a positive outcome from the experimental treatment. In a trial exploring patient (n=45) perceptions of expected benefit to participation in phase I cancer clinical trials, Sulmasy and colleagues identified that patients believed expressing hope and optimism would improve the likelihood that they would experience a therapeutic benefit from their participation.\textsuperscript{24} Patients who participate in Phase I/II cancer clinical trials are at end-of-life and standard treatment was unsuccessful in limiting or curing their cancer. It is possible that even a 5% chance of a response was high enough to overcome the risks associated with treatment. Hope may help to explain why some patients with a poor prognosis may want treatment that others may consider unnecessarily aggressive.\textsuperscript{25} More research is needed to determine how hope influences understanding in informed consent. For now, it’s important to recognize that hope is a factor in how patients make decisions.
II. Patient Understanding of Consent for Surgical Procedures

Robinson (1976) conducted one of the earliest studies of informed consent for 20 patients who had cardiac surgery for atherosclerotic heart disease (n= 9) and acquired valvular heart disease (n=11).26 One to two days before the operation patients met with the surgeon who discussed the diagnosis, proposed procedure, risks and benefits of the procedure and available alternatives. The average length of the interview was 24 minutes. Interviews were recorded and a chart with the information from the interview was developed for each patient. Robinson (1976) stated he felt patients were well informed and comprehended the information prior to surgery. Patients were re-interviewed 4-6 months after the procedure to assess retention of information covered during the initial interview. Overall retention was poor with less than 30% recalling the information included in the initial interview. Study staff then used the chart to review patient-specific information from the initial interview. Even after this prompt, patients could remember only 42% of the information covered in the initial interview. All patients failed to recall major parts of the interview. Most patients (80%) denied ever hearing the information, some made up information and others attributed information to other sources. Four to six months is a long time to remember information. However, in 1976 cardiac surgery was a relatively novel high-risk surgical procedure with a protracted recovery period. Four months probably represented a scheduled post-operative visit to determine the effectiveness of the surgery and ascertain if there were any ongoing concerns. Regardless, patients had forgotten most of the information they discussed with the surgeon prior to the procedure.

Other studies used a qualitative approach to determine patient understanding of procedure-specific informed consent for abdominal aortic aneurysm repair27 or implantable cardioverter defibrillator implanted.28 The perception of having “no choice” and trust in their physicians were common themes across both studies. Specifically, patients in both studies said they
consented to the procedure because they felt they had no choice. Having surgery gave them a chance of staying alive while declining surgery meant probable death. Similar to the studies of patients in Phase I/II cancer clinical trials, surgical patients identified trust in their surgeon as a reason for consenting to the procedure. Patients stated they did not feel they had the information or knowledge to decide if they needed surgery. The surgeon knew best and they trust he/she to make the right decision for them. Trust in the surgeon has also been identified in other studies of informed consent for surgical procedures. Further research is needed to fully understand the role of trust in informed consent.

III. Patient Understanding of Prognosis in Heart Failure

How patients understand prognostic information in heart failure seems to follow a similar course to understanding in informed consent. In studies examining the treatment preferences of community living patients with cancer, heart failure and COPD, who met objective criteria for less than 50% survival at 1 year, Fried et al found that patients did not perceive themselves at end-of-life. The first study included 66 patients with heart failure with 62% reporting at least 2 hospital admissions and 45% with at least 1 intensive care unit admission for worsening heart failure in the past 12 months. When asked to predict their life expectancy, 45% of heart failure patients estimated life expectancy greater than 2 years, 12% chose less than 1 year and 43% were uncertain. These results were consistent with those of the larger group. Expanding on these findings, Fried et al (2006) designed a study to examine changes over time in the understanding of prognosis by community-living seriously ill older patients, who met objective criteria for less than 50% survival at one year. The patient sample included 63 patients with advanced heart failure but results were not stratified by diagnosis. Out of the entire sample, 48% had at least 2 hospital admissions with 34% reporting 1 intensive care unit admission in the past 12 months. At the initial interview, only 27% reported having been told they could die of
their illness and 5% reported they had been given an idea of when. The number of patients reporting discussing life expectancy with their physicians did not significantly increase over time. Only a small proportion of patients estimated life expectancy less than 1 year with 40-55% reporting being uncertain about life expectancy. On further probing, two patterns of responses were identified within the uncertain group. One group became visibly upset and resisted further probing. The other group believed no one, including their doctor, could predict life expectancy so refused to assign a numerical value to the question.

In a study comparing the Seattle Heart Failure model (SHFM) and actuarial survival versus patient predictions of life expectancy, patients living with heart failure over-estimated the number of years they had left to live. Survival predicted by the SHFM, actuarial tables and patient responses were 10 years, 13 years and 20 years respectively. Additionally, over half (51%) felt that heart failure would not shorten their life and 9% felt it would be cured. There was no difference in patient predictions of life expectancy between patients who stated they had discussed prognosis with their physician and those that did not. Younger patients, with a high school education, lower blood pressure and higher heart rate were more likely to predict longer life expectancy than patients who were older.

Disclosure of information is insufficient for informed consent. Patients need to understand the information presented during disclosure. Results from studies examining patient understanding in informed consent for both Phase I/II cancer clinical trials and consent for surgical procedures suggest patients feel they provided informed consent and understood the information. Similarly, patients living with heart failure consistently over-estimate life expectancy regardless of if they have discussed prognosis with their doctor or not. Hope and trust play a role in mediating the understanding of information for informed consent and prognosis but the role they play is poorly understood. Beauchamp & Childress suggest that decisions are never fully informed. They
propose that for informed consent to be valid, patients need to be *adequately* informed.\textsuperscript{7} For patients with Stage D heart failure, understanding how patients make treatment decisions regarding heart transplant and LVAD implantation will help to determine the information patients use to help them understand and the factors that affect decision-making.
3. VOLUNTARINESS

Voluntariness is a fundamental condition of autonomy and is the 3rd element of informed consent. Voluntary actions are actions that are free from external control by others. In fact, the dictionary definitions of autonomy, self-governance and self-determination are all treated as synonymous, specifically as independence from the control of others. In this sense, patients agreeing to heart transplant and/or LVAD implant make a voluntary decision to proceed. While opinions from healthcare providers may influence decisions, the opinion is not given as an ultimatum. The information is offered in the form of a discussion and patients use this information when making their decision. However, if we broaden the definition of voluntary to acting in the absence of controlling influences, then ability of patients to make a voluntary decision is in jeopardy. Patients living with advanced heart failure consistently mention that their quality of life is poor, the sensation of breathlessness is frightening and fatigue is overwhelming. Poor quality of life and unpleasant symptoms may compel patients to accept risks they otherwise would not have considered. This section will review the quality of life for patients living with advanced heart failure and the instruments used to measure quality of life. Finally, a review of the qualitative studies that describe the experience of living with advanced heart failure will be discussed. It is important to note that a thorough review of this literature was not completed until after data collection to avoid biasing my assumptions during analysis of the qualitative data over the course of the study.

I. Heart Failure Quality of Life

Quality of life is a complex concept. It reflects a person’s overall appraisal of their life - how happy, satisfied and content they are and how acceptable their life is to them. It is a subjective evaluation and will differ from person to person based on past experiences, expectations, values and beliefs. While objective measures such as blood pressure or ejection fraction provide
valuable information to clinicians in terms of disease progression and/or prognosis, it is how a
patient perceives the impact of heart failure on her/his life that will determine their quality of
life.

For the purpose of this discussion, quality of life will be defined as “the patient’s perceptions of
the effects of heart failure, and its treatment on his or her daily life” based on the conceptual
model of quality of life in heart failure, described by Rector. In this model, symptoms,
functional limitations and psychological distress are distinct but inter-related concepts that
mediate the pathophysiologic changes associated with heart failure. Symptoms enter into the
equation first since patients must perceive a change in symptoms for quality of life to be
affected. Symptoms impact functional status by limiting a person’s ability to complete physical,
mental and social roles. Unpleasant symptoms of dyspnea and fatigue create negative emotions
such as anxiety, depression and worry that increase psychological distress. The relationships
between symptoms, functional limitations and psychological distress are reciprocal; a change in
one will impact the others. For example, if a patient experiences an increase in shortness of
breath they may limit activity to avoid this sensation. Many patients describe shortness of
breath as frightening, thus anxiety and worry may increase. How a patient perceives the
combined effect of symptoms, functional limitations and psychological distress will determine
how they rate their quality of life. If shortness of breath persists, patients may rate their quality
of life as poorer then they would if they experienced no shortness of breath.

i. Symptoms

Fatigue and dyspnea are the most frequent, distressing and burdensome symptoms of heart
failure. Although fatigue and dyspnea have a pathophysiologic basis for occurring; they are
subjective phenomenon experienced and evaluated differently by each patient. For patients in
Stage D heart failure, fatigue is more than being tired – patients describe it as overwhelming
whole body tiredness. Dyspnea is more than shortness of breath – patients describe it as a sensation of “drowning” or “suffocating” and very frightening. Neither symptom is necessarily associated with activity nor relieved with rest. Both have a significant positive relationship to each other and both are associated with greater physical and emotional distress and lower overall quality of life.37,39,41,42

Describing symptoms in isolation can be problematic since most heart failure patients experience more than 1 symptom at a time. A study by Zambrowski et al (2005) used a cross-sectional design to examine the frequency, severity, distress and burden of symptoms experienced in one week by patients with heart failure and to describe the impact of these symptoms on quality of life.43 The sample (n=53) was mainly NYHA class III/IV (78%), male (66%) with an average age of 55 years. Patients reported experiencing a mean of 15 symptoms over the 1 week period with fatigue and dyspnea being identified as the most frequent, distressing and burdensome symptoms. Quality of life scores were not reported. However, a stepwise regression analysis identified that younger age, higher NYHA classification, higher symptom frequency and greater symptom burden predicted 67% of the variance in MLHFQ scores with symptom frequency and burden providing the greatest impact on quality of life. Other studies have consistently found a significant inverse relationship between symptom severity scores and quality of life. As symptom severity increases, quality of life gets worse.36,44-46

ii. Physical Functioning

As heart failure progresses patients develop functional limitations that prevent them from carrying out their activities of daily living, roles and responsibilities and gradually impinge on their social functioning. Measures of functional limitations are positively correlated with quality of life – as physical function declines, quality of life gets worse.44,47 Studies describing the
psychometric properties of the MLHFQ have consistently found the same 8 items on the questionnaire load onto the physical dimension, which explains 40% of the variance in total MLHFQ scores. \(^{46,48}\) Physical decline leads to disruptions in social roles. First, an increase in symptom severity often leads to changes in medications. Side effects such as lightheadedness from beta blockers or urinary frequency from diuretics may limit the type and amount of social activity a patient is comfortable participating in. Second, the inability to complete physical tasks leads to an increase in dependence on others for support. \(^{49}\) This dependence disseminates into the social world and patients need to rely on others for transportation to and from social events.

iii. Psychological Distress

Patients with advanced heart failure report significant levels of depression, fear, uncertainty, anxiety and a loss of self-esteem. \(^{43,50-52}\) Depression predominates with at least 30% of heart failure patients reporting moderate to severe depression. \(^{53,54}\) Depression is more common in women than men and increases with age. \(^{53,54}\) Depression directly affects physical functioning, symptom severity and overall quality of life. \(^{55,56}\) Patients who are depressed also report more social conflict and less social support. \(^{56}\) Most studies use a composite measure for emotional distress that includes anxiety, depression and hostility. Details regarding individual symptoms are difficult to identify but overall emotional distress and physical disability have been shown to explain as much as 43% of the variance in quality of life. \(^{57}\)

II. Measuring Quality of Life

i. Health Status Questionnaires

Health status questionnaires are the most common method of measuring quality of life in the heart failure population. Health Status questionnaires describe a person’s functioning in 1 or more domain eg, physical, emotional and social. Patients are asked to answer a series of
questions that are designed and tested to represent the concepts or constructs of interest. Answers are converted to numerical scores which can be combined to yield subscale and total scale scores. These scores “quantify” a person’s quality of life. While these scores provide little information on the significance of the impairment to the individual, they are effective in comparing scores within and across patient groupings. Health status instruments can be either generic or disease-specific. Generic instruments such as the Short Form-36 (SF-36) provide information on quality of life that is applicable to a variety of health states. Generic instruments are particularly useful in general survey research where results can be compared across disease groups.

The Minnesota Living with Heart Failure (MLHFQ) questionnaire and the Kansas City Cardiomyopathy Questionnaire (KCCQ) are 2 heart failure specific health status instruments used to describe quality of life for patients living with heart failure. The MLHFQ is a 21-item questionnaire measuring quality of life across physical and emotional domains. The score yields physical and emotional subscale scores which can be combined for a total score. The 21 items are scored from 0-105 with higher scores reflecting poorer quality of life. The MLHFQ has documented reliability and validity and has been used to measure quality of life at various points along the heart failure continuum. The KCCQ is a 23-item questionnaire measuring quality of life across physical limitation, symptoms, quality of life, social limitation and self-efficacy. The 23-items are scored from 1-100 with higher scores representing better quality of life. Scores can be calculated for a functional status score, a clinical summary score and a total score. The KCCQ has documented reliability and validity.

The MLHFQ and KCCQ were originally developed for use in clinical trials to assess the effectiveness of a medication or device on the quality of life of patients with heart failure. When used to measure quality of life before and after an intervention, the MLHFQ should be
administered with at least one other measure of physical functioning. Cardiopulmonary testing which is the most comprehensive measure of physical function requires expensive equipment and specialized training thereby limiting its use. The 6-minute walk test (6MWT) measures the distance a patient can cover on level ground in 6 minutes and is a familiar alternative to cardiopulmonary testing. It is inexpensive and easy to use and is significantly correlated to maximal oxygen uptake making it an adequate substitute for cardiopulmonary testing. In cross-sectional studies, the MLHFQ and KCCQ are used to describe and identify factors that impact quality of life. The majority of cross-sectional studies involving patients with Stage D heart failure use the NYHA classification as a surrogate marker of physical function. On one hand, it is a clinician-rated variable that does not reflect patient perceptions. On the other hand, the NYHA classification is widely used in clinical practice, is quick and easy to use, and provides a vehicle for conveying a large amount of information in 1 simple number. Additionally, studies have shown a significant correlation between the 6MWT and NYHA classification suggesting it can be used as a surrogate for physical functioning.

The MLHFQ has been used extensively to measure quality of life for patients in Stage D heart failure, before and after LVAD implantation, cardiac resynchronization therapy and pulmonary artery guided heart failure therapy. It has also been used to describe quality of life in observational studies and reported in the secondary data analysis of previously reported trials. Due to its widespread use, the MLHFQ was chosen to measure quality of life in the proposed study. Results of these studies suggest higher MLHFQ scores (worse quality of life) are associated with higher symptom severity and lower perceived health scores.

Consistent trends in MLHFQ scores for age, sex and hospitalization have been reported in the literature and may be relevant to results of the proposed study. Younger patients have significantly poorer quality of life than older patients. Rector et al suggested a 10 year
difference in age was equal to 5 points on the MLHFQ. Older patients may have lower physical expectations so a decrease in functional capacity may have less effect on overall quality of life scores. Men rate their overall quality of life significantly higher than women. There are suggestions that women have a greater negative emotional reaction to heart failure which could worsen their overall quality of life scores. While these are important differences to note, they are correlational and not causal. Further research is needed to fully understand how age and sex impacts heart failure quality of life.

Admission to hospital has been shown to lower quality of life. Hospitalized patients with advanced heart failure have mean MLHFQ scores between 70-75 and outpatient scores between 60-65. The difference of 10-15 points in total MLHFQ scores between inpatients and outpatients is clinically significant. Results from the ESCAPE trial which randomized patients with an exacerbation of heart failure to best medical therapy versus best medical therapy guided by the insertion of a pulmonary artery catheter, suggest that most patients experience a significant improvement in MLHFQ scores within 1 month of discharge. Patients who did not experience a significant improvement in MLHFQ scores were more likely to experience hospital readmission or death within 6 months of discharge. Jaarsma et al found similar results but suggested lower MLHFQ scores after discharge were associated with a comparable improvement in symptom severity and distress scores.

Other health status questionnaires have been designed for specific populations. Grady and colleagues have used the same study-specific questionnaires to measure quality of life for patients living with Stage D heart failure, on LVAD support and after heart transplantation. Specific domains included - physical, psychological, emotional, health perceptions, symptoms, stress and coping strategies. The results from this program of research provides the most comprehensive analysis of how quality of life changes as patients progress.
from living with advanced heart failure and subsequent treatments. However, the use of study-specific tools makes comparisons to studies using other instruments, troublesome.

ii. Rating Scales

Rating scales are 100mm horizontal or vertical lines, with anchor points at 0 and 100, that measure a patient’s perception of their symptom severity, overall health or overall quality of life. Patients are asked to place a mark on a line that they feel represents their overall health. The number of millimeters from the 0 anchor point to the line represents the score. Rating scales are quick, simple and inexpensive. While some may think they are crude measures, they have documented reliability and validity and have been shown to correlate with other measures of quality of life.78-80

iii. Living with Heart Failure – Qualitative Studies

Qualitative studies have been used to describe the quality of life for patients living with Stage D heart failure. Qualitative methods differ from quantitative methods by using techniques to elicit, analyze and describe the participant experience. While these studies have small sample sizes, each participant contributes a considerable amount of information. The data is then analyzed to identify concepts and relationships common to the group as a whole. A review of the literature identified 9 qualitative studies describing the experience of patients’ living with heart failure.49,50,52,81-86 The studies were from various philosophical perspectives and used different methodologies to analyze the data. Patients with advanced heart failure (NYHA functional class III & IV) were included in most but not all samples. Inherent in most studies was the concept that for heart failure patients, an acute exacerbation of heart failure increases uncertainty regarding one’s identity, social roles and the future. To mitigate the uncertainty most patients adjust by integrating heart failure into their life. Adjustment occurs over time, allowing the
patient to make sense of their situation and restore order to their life. The mean age for patients in all studies was over 60 which may limit generalization to patients in the proposed study.

The adjustment process begins when a patient experiences an increase in dyspnea, fatigue and/or edema. Patients may delay seeking help because they attribute the increase in symptoms to other things such as being tired or having a cold.\textsuperscript{50,82} Once they seek help they may experience another delay while clinicians diagnose the cause of their symptoms. This delay is more pronounced for younger patients since many healthcare professionals will attribute the symptoms to an episodic illness like pneumonia or a viral illness before considering heart failure. Cumulative delays increase uncertainty as patients struggle with understanding what is going on. Patients with a history of heart failure or heart problems at least have a context in which to place their situation. They are familiar with the diagnostic process and know what it’s like to wait for a diagnosis. If this is a first presentation, a patient has no idea what to think, what to do or what to feel.\textsuperscript{52} For these patients, uncertainty and worry dominate the pre-diagnosis period.\textsuperscript{52} Once a diagnosis is made, patients can at least label their symptoms and begin to make sense of living their lives with a new diagnosis or a confirmed progression of heart failure.

Consistent with results from quantitative studies, qualitative studies describe how the increase in symptoms reduces physical activity and increases emotional distress and may prevent a patient from carrying out usual roles and responsibilities. Uncertainty is heightened as patients struggle to understand the impact of this new diagnosis on their life.\textsuperscript{50} Some patients may look on this period as an opportunity for growth. Others respond with an increase in negative emotions such as fear, anxiety or worry which are common and reasonable responses when uncertainty is high.\textsuperscript{52,81} Emotional distress may be higher if a first encounter with worsening symptoms and a diagnosis of heart failure result in an urgent assessment for heart transplantation or LVAD.\textsuperscript{52}
Older patients seem to accept their diagnosis without reconstructing it, using their age to rationalize their symptoms.49,52,84 Younger patients struggle to adjust because they are at an age where limiting activity or slowing down is often not appropriate.50,52 Over time most patients adopt new behaviors to manage their heart failure and medical regimen while modifying their expectations of themselves and others.52,83 The “new” identity integrates their heart failure and they adjust to life as a heart failure patient.52,83

Both quality of life and uncertainty share a similar path. They fluctuate over time as life events and/or a person’s health changes. Uncertainty, as described in the qualitative literature, begins when an increase in symptoms signifies a change in health and initiates contact with the health care system. Uncertainty is high until a diagnosis is made or a plan of care is developed. The plan of care may include a change in medications, frequent clinic visits, the addition of a new therapy and/or hospital. A period of adjustment whereby patients adopt new behaviors and modify their expectations helps to mediate the uncertainty. When symptoms stabilize uncertainty is low but never gone since the fear of an exacerbation is ever present.81
4. CAPACITY

Capacity is the 4th element of informed consent and identifies persons from whom it is appropriate to obtain consent. Informed consent can only be obtained by persons who are competent or capable of appreciating the consequences of their actions. Alternative means of consent are required for patients who are considered incompetent or incapable. Competence and capacity are often used interchangeably; competence refers to a legal judgment and capacity refers to a clinical assessment. Criteria for assessing capacity include (1) understanding the relevant information, (2) appreciating the situation and its consequences, (3) deliberating about treatment options and (4) communicating a choice. Competence or capacity exists on a continuum from fully competent/capable to fully incompetent/incapable with a threshold at which persons above the line are considered competent and those below the line are considered incompetent. Patients with Stage D heart failure are, in general, considered competent and able to make decisions regarding informed consent. However, the presence of depression and cognitive impairment can threaten their ability to understand the information, reason about treatment options, appreciate the consequence of their choice and make a decision. In the following section I will review the literature on depression and cognitive impairment in heart failure and the impact of depression and cognitive impairment on medical decision making.

I. Heart Failure, Cognitive Impairment and Medical Decision Making

Okonkwo et al (2007) compared 3 groups of patients over the age of 60, referred to a tertiary memory disorder clinic to determine capacity for medical decision making. The three groups included healthy controls (n=56), patients with mild cognitive impairment (n=60) and patients with mild Alzheimer’s disease (n=31). All patients completed a battery of neurocognitive tests. Capacity was assessed with the Capacity to Treatment Instrument (CCTI), a reliable and valid assessment tool which assesses capacity for medical decision making. The CCTI uses 2
vignettes (cancer and cardiovascular disease) and asks patients questions to determine capacity in expressing choice, appreciation, reasoning and understanding. Although all patients with mild cognitive impairment were able to express a choice, they scored significantly below age-, education- and sex-matched controls on appreciation, reasoning and understanding. Specifically, 53% were compromised on understanding, 33% compromised on appreciation and 27% compromised on reasoning.

Fazel et al (2000) compared the preferences for life-sustaining treatment of 100 elderly patients: 50 with a diagnosis of early dementia and 50 healthy controls. Patients were presented with 3 clinically relevant vignettes pertaining to life-sustaining treatments; medical intervention versus no intervention for stroke, rectal bleeding and antibiotics for pneumonia. There was no difference in treatment preferences between the healthy controls and the patients with mild cognitive impairment. The majority of patients opted for medical intervention versus no intervention. However, patients who opted for intervention had significantly lower scores on the Mini-Mental Status Exam (worse cognitive impairment) than those who opted for no intervention. The authors suggest that cognitive impairment may limit the ability to understand the consequences of their decisions, may lead to impulsive decisions and/or over-estimating the risks of treatment or cause a patient to comply with therapies suggested by their medical team.

Heart failure is associated with an increased risk of developing cognitive impairment. The most common mechanism of cognitive impairment is thought to be related to decreased cerebral perfusion secondary to reduced cardiac output. Support for this hypothesis can be found in studies measuring cognitive impairment before and after heart failure intervention, correction of biochemical imbalances, 3 months after cardiac resynchronization therapy and after implantation of a HeartMate 2 LVAD. The prevalence of cognitive impairment in patients living with heart failure has been reported between 30-80%. The wide range is
probably due to studies showing a higher prevalence using cognitive screening tools such as the Mini Mental Status Exam (MMSE) and lower prevalence in studies evaluating cognitive function with standardized neurocognitive testing. Studies using neurocognitive testing suggests cognitive impairment is prevalent in 30% of heart transplant candidates, 35% in patients hospitalized for decompensated heart failure and 30-46% in older heart failure patients living in the community. The most frequently reported cognitive impairments include deficits in memory, attention, psychomotor speed and executive function.

In the largest study to date examining cognitive impairment in heart failure patients, Pressler et al compared cognitive function between patients with heart failure (n= 249), healthy controls (n=63) and patients with diabetes or hypertension (n=102). Cognitive function was measured using formal neurocognitive tests. The mean age of heart failure patients was 63 years and half were NYHA functional class III/IV. Heart failure patients scored worse than healthy controls on almost all measures of cognitive function. Twenty-four percent had deficits in at least 3 domains of cognitive function; memory, psychomotor speed and executive function. At 1 year, 13% of the sample had died. Patients who died had worse scores on global measures of cognitive function (MMSE), memory, recall, psychomotor speed and executive function. A higher 1-year mortality has also been shown in heart failure patients with cognitive deficits measured by formal neurocognitive tests. Sauve and colleagues compared community living patients with chronic heart failure (duration over 6 months) to a matched control group of healthy volunteers. Patients with heart failure performed significantly worse than matched controls on neurocognitive testing and had significant deficits in attention, memory, executive function.

As heart failure progresses, cognitive impairments increase. Putzke et al conducted neurocognitive testing on 62 heart transplant candidates followed within 24 hours by cardiac
catheterization to assess filling pressures. The sample was predominantly male with an average age of 52 years. Seventy-six percent of the sample had deficits in at least 1 area, 20-30% were moderately to severely impaired on 11/19 cognitive tests. Cognitive function was significantly associated with increased hemodynamic pressures. In a similar sample, Dixit and colleagues measured cognitive function in a sample of 20 patients before and after cardiac resynchronization therapy. Cognitive function was assessed using formal neurocognitive tests. The mean age of the sample was 54 and 85% of patients were considered NYHA III/IV Pre-implant deficits were noted in memory, attention and psychomotor speed. Interestingly, all domains improved 3 months after initiation cardiac resynchronization therapy.

II. Heart Failure, Depression and Medical Decision Making

Depression is associated with a number of cognitive changes that could threaten medical decision making. In a study of undergraduate students, those who were depressed showed an inability to make use of available relevant information than students who were not depressed. The “negative thinking” associated with depression could be self-perpetuating and cause future decisions to be evaluated in a negative fashion. Persons who are depressed give higher probabilities for negative events have a tendency to engage in repetitive, self-focused thinking and perceive themselves as having little control to influence outcomes.

The prevalence of depression in patients living with heart failure ranges from 30-50%. Research on depression in heart failure is limited to the relationships with quality of life and mortality and no studies were identified that discussed the impact of depression on medical decision making for patients with heart failure. Heart failure complicated with depression may inhibit the abilities of patients to attend to and synthesize the information they’ve been given for decision making. Complex tasks such as considering each option, the probability of success and potential complications may be beyond the cognitive abilities of heart failure patients with
depression. Given that many patients with Stage D heart failure describe feeling out of control of their lives, patients who are depressed may feel they have little ability to influence the outcomes of the decisions they make. This may threaten voluntariness if they deem others are better able to make decisions that affect their life.

The dearth of information on the impact of depression on medical decision making makes it difficult to make assumptions regarding Stage D heart failure patients who are considering heart transplant and/or LVAD implantation. We do know that information processing is impaired and aside from the persistence of negative thinking and rumination, the deficits are consistent with those discussed in cognitive impairment. Our strategies of ensuring consistent communication, providing written and audiovisual aids to augment understanding and short, frequent meetings to discuss the information should also improve the chance that depressed heart failure patients are providing informed consent. The proposed study presents an excellent opportunity to determine the prevalence of depression and begin to understand how depression influences decision making for patients considering heart transplant and/or LVAD implant.

The purpose of this section was to review the literature on cognitive impairment and depression and how it impacts medical decision making. Some may interpret these results as meaning patients with heart failure who suffer either depression and/or cognitive impairment are incapable of providing informed consent for heart transplant and/or LVAD implant. However, participants in the studies on capacity and cognitive impairment were elderly. Mild cognitive impairment in the elderly may be different from the mild cognitive impairment experienced by younger patients with heart failure. Additionally, interventions that improve cardiac output can improve cognitive impairment. Second, the vignettes were research based, removed from any clinical context in which these patients live. For most of our patients, clinical decisions are made within the context of having considerable experience living with heart failure. The
relationship we establish with our patients and our structured process of reviewing prognosis and treatment options allows us to assess capacity on an ongoing basis. Through this process we can identify threats to capacity and implement strategies to assist in decision making. Strategies we use to communicate the highly technical information include communication within the team to ensure each team member is providing consistent information to the patient and family, written and audiovisual materials to augment discussion, inclusion of the substitute decision maker in discussion and short but frequent visits to discuss content. Decisions that are inconsistent to those previously expressed will be probed for the underlying rationale. We do use a sliding scale approach – as the risk and/or benefit of the intervention increase, we will use more stringent criteria to determine competence. If we believe capacity is at risk we will initiate a formal competency assessment by our psychiatrist. From a research perspective, the proposed study provides an excellent opportunity to determine the prevalence of depression and cognitive impairment and to begin to understand the relationships both share to decision making.
5. DECISION

The Decision is the final element of informed consent. Decision is self-explanatory. It is the act of agreeing to proceed with heart transplantation or LVAD implantation. A review of the literature identified 2 ways of determining treatment preferences for patients living with heart failure. The first approach includes descriptive observational studies. The results from descriptive observational studies suggest patients with Stage D heart failure can make treatment decisions and identify factors that affect decision-making. The second approach uses a utility assessment to determine the amount of risk and amount of time traded by patients to improve health. Each approach will be presented separately and important points pertaining to how patients with advanced heart failure make decisions at end of life will be discussed.

I. Factors Affecting Treatment Preferences in Heart Failure

The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT) was a landmark trial that highlighted the challenges of understanding patient preferences for treatment at end-of-life. SUPPORT used a prospective design to determine how patient treatment preferences, family interactions, disease severity and clinician beliefs influence the way patients make treatment decisions regarding resuscitation. In phase 1 of the study, 9105 critically ill patients with CHF, acute respiratory failure, chronic obstructive pulmonary disease (COPD), cirrhosis and cancer, who had an expected survival of less than 50% at 6 months, were enrolled at 5 academic teaching centers in the United States. Interviews were conducted with the patients, their family and clinicians to determine treatment preferences, attitudes and beliefs about the illness, prognosis and treatment plan. Additional data regarding patient history, course of illness, disease-related factors and communication between patient/family and clinicians was also recorded. Within 3 days of admission to a critical care unit, patients were asked “thinking of your current condition, what would you want your doctors
to do if your heart stops beating? Would you want your doctors to revive you, or would you want your doctors not to revive you?” Patients had to explicitly and unequivocally answer “no resuscitation” to be categorized as such. The answer to this question and information collected from physicians was compared between groups. Although phase 1 data collection for the trial was conducted between 1989 and 1991, the results represent the largest single trial of treatment preferences for patients at end-of-life and continued to be cited in contemporary studies of treatment preferences.

The larger sample of the SUPPORT trial included 936 patients with advanced heart failure defined as admission to a critical care unit for an acute exacerbation of existing heart failure, NYHA function class IV symptoms of heart failure and documentation of a left ventricular ejection fraction $< 20\%$. When asked “thinking of your current condition, what would you want your doctors to do if your heart stops beating? Would you want your doctors to revive you, or would you want your doctors not to revive you?” patients with heart failure responded as follows; 69% chose resuscitation, 23% chose “no resuscitation” and 8% were undecided. Patients who chose “no resuscitation” were older, believed their prognosis was poor, and had activity restrictions prior to admission.

i. Treatment Preferences Change Over Time

Fried et al conducted a prospective study to determine how treatment preferences, measured in terms of willingness to undergo treatment based on its outcomes, changed over time. The sample consisted of 226 community-living patients, over the age of 60, with cancer, COPD and heart failure. Interviews were conducted in the patient’s home every 4 months for 2 years. Patients were asked whether 4 outcomes that could result from treatment were acceptable (would have treatment) or unacceptable (would prefer to die then have treatment). The 4 outcomes included mild physical disability, severe physical disability, cognitive impairment and
moderate to severe pain. The patient sample included 63 patients with advanced heart failure but results were not stratified by diagnosis. Overall, 49% provided a consistent rating of either acceptable or unacceptable at all time points throughout the 2 years. Results for cognitive impairment and pain were relatively stable with 75% rating cognitive impairment and 37% rating pain as unacceptable at all time points. However, for functional impairment, 36% of patients changed their ratings; 27% changed their rating from unacceptable to acceptable and 9% changing from acceptable to unacceptable. Patients were more likely to change their ratings of functional impairment from unacceptable to acceptable, when they experienced a similar decline in their own physical health. Similar results were found in the SUPPORT trial.10 Two months after discharge from the critical care unit, patients who survived were asked the resuscitation question again. Most (81%) gave the same answer as their original response. Of the 19% who changed their preference, most changed their preference from “no resuscitation” to “resuscitation.” No information was provided on the change in their physical or functional status. But, they had survived and were out of critical care. In this small group of patients, treatment preferences had changed. They had re-evaluated their situation as acceptable enough to warrant resuscitation. These findings suggest when a patient experiences a change in their health they reevaluate and adjust their treatment preferences accordingly.

Understanding that treatment preferences may change over time is of importance to clinicians working with patients living with advanced heart failure. As heart failure progresses, patients experience an increase in the frequency of hospital admissions for worsening heart failure symptoms. While changes in their medical management may improve symptoms enough to allow for hospital discharge, it seldom returns patients to their pre-admission level of functioning. The progressive decline in health status with the potential for subsequent changes in treatment preferences makes it difficult to predict if treatment goals are congruent with
patient preferences. Combined with the difficult subject nature and time constraints, clinicians are challenged to ensure that treatment goals match patient preferences during assessment for heart transplant and/or LVAD implant.

**ii. Treatment Outcomes Affect Decisions**

Functional and cognitive impairment as well as prolongation of an inevitable death, being dependent on technology and pain have been shown to be so undesirable patients will reject treatment and choose strategies that promote quality versus quantity of life. Fried et al (2002) assessed the treatment preferences of 226 community-living patients with cancer, COPD and heart failure, who met objective criteria for less than 50% survival at 6 months. Treatment preferences were assessed according to treatment burden (high/low), possible outcomes and the likelihood of these outcomes. Patients were presented with 4 different scenarios; low-burden therapy that restored current health, high burden therapy that restored current health, low burden treatment that resulted in severe functional impairment and low burden therapy that resulted in severe cognitive impairment. For each scenario patients were asked their preference when the outcome was certain and again when the likelihood of an undesirable outcome was consecutively increased from 1 to 100%. When the choice was a low burden treatment (few days or weeks of hospitalization, minor tests and blood tests) with restoration of current health versus no treatment with certain death, 99% of patients chose the treatment. When burden was increased to include at least 1 month in hospital, complex tests +/- surgery resulting in restoration of current health versus no treatment resulting in death, 88% still chose the treatment. Only 26% and 11% wanted treatment when treatment burden was low but resulted in functional or cognitive impairment, respectively. This is an important point. As clinicians we often think of outcomes in terms of probabilities – a mental calculation of the risks of the intervention and the likelihood it will achieve treatment goals. When benefits outweigh
risks, clinicians may consider the treatment acceptable. However, patients conceptualize outcomes in terms of the resulting health state. If a patient perceives that an intervention will return them to an acceptable level of health, they are then willing to assume great risk and large burden to achieve that state. This is of significance in patients considering heart transplant and/or LVAD implant. The burden associated with each intervention is high and is explained to patients during the assessment period. Discussions regarding outcomes are more likely to occur within the context of risk of death and one year mortality rates. However, if patients conceptualize outcomes in terms of health states we may not be providing them with the information they need to make a decision. Perhaps this is just a nuance but further investigation is needed to determine if patients considering heart transplant and/or LVAD implant actually conceptualize outcomes in terms of health states and what information they feel is necessary to make treatment decisions.

iii. Communication of Treatment Preferences

In the SUPPORT trial, the most responsible physician caring for the patient was interviewed between day 3-6 of admission to the critical care unit to obtain data on physician characteristics, and what they thought the patient’s perceptions were regarding resuscitation preferences, prognosis and quality of life. Physicians were asked: “What do you think the patient would want you to do if he/she had a cardiopulmonary arrest?” From the larger sample, 339 patients had matching physician interviews for comparison. Physicians felt the majority of patients (82%) would want to be resuscitated. Factors associated with the physician’s perception of “resuscitation” were younger age, better quality of life and better prognosis. Interestingly, the strongest indicator of patient preference was the physician’s own preference for resuscitation if he/she were in the patient’s condition – if the physician expressed they would not want to be resuscitated if they were in that situation, they assumed the patient would also choose “no
resuscitation.” Overall, most physicians accurately predicted patient resuscitation preferences (66%). Discordance was more likely to occur when patients did not want to be resuscitated, were over 75 years of age or whose resuscitation preferences changed from admission to 2 months after discharge. When patients told their physician about their preferences, physicians were more likely to accurately predict patient preferences. However, less than 25% of patients report discussing preferences for treatment with their physicians.4-6 Patients may avoid discussions because they perceive there is not enough time or they may perceive that if clinicians do not initiate the discussion it is not pertinent to their situation. While clinicians recognize the importance of these discussions, they may delay initiating them until they sense the patient and family is ready and there is adequate time for an in-depth discussion. Treatment preferences are significantly different between persons living with heart failure and healthy controls so are not a valid substitution for discussion.113 Interestingly, cardiologists were more accurate in predicting patient preferences then non-cardiologists suggesting that experience with this patient population is beneficial to understanding the treatment preferences of patients with advanced heart failure.

iv. Caregiver Burden

Caregiver burden is an independent factor influencing treatment preferences. The SUPPORT trial reported that 20% of patients had a family member who had to quit work to care for them and 31% reported loss of all family savings related to the illness.114 The progressive decline at end-of-life leads to an increase in social isolation and dependence on family. As dependence increases, burden on family and friends increases. Patients seem cognizant of this change and worry that any change in their condition or treatment may increase caregiver burden. Results from the literature support this assumption. Patients who perceive treatment will increase caregiver and economic burden are more likely to prefer treatments that improve quality versus
While a public health care system may lessen the economic impact for Canadian families, it does not reduce caregiver burden. The majority of patients with advanced heart failure, cared for in our clinic, have at least 1 family member at home to assist with care. Furthermore, medication costs can be significant in patients without insurance. Anecdotal evidence in our clinic suggests that the reduced income and increased costs associated with treatment are a concern for our patients. However, further investigation is needed to determine if our assumptions regarding caregiver and economic burden actually influence how patients with advanced heart failure make decisions regarding heart transplant and/or LVAD implant.

II. Utilities – Treatment Preferences in Advanced Heart Failure

Patients considering LVAD implantation report they want an LVAD to “save their lives” (53%) or because they “had no alternative” (17%). They are often willing to take tremendous risk to improve both their quantity and quality of life. Utility measures such as the standard gamble and time tradeoff technique are designed to include the significance of quality of life assessments to the individual. Both techniques have been used to describe the treatment preferences of patients living with advanced heart failure and patients considering LVAD implant. The standard gamble measures the degree of risk a patient is willing to take to improve health and the time trade-off measures the willingness of patients to trade time to improve health. Each of these techniques and their application to heart failure end-of-life preferences will be discussed separately. The discussion regarding the TTO will be followed by an account of the Congestive heart failure Offering Individualized Choice Evaluation Study (CHOICES). CHOICES was a study conducted within our program that used a modified TTO to determine the strength of preferences patients had for 3 hypothetical treatments: optimum medical management, oral inotropes and implantation of a HeartMate XVE LVAD.
iii. The Standard Gamble

The standard gamble was developed by von Neumann and Morgenstern to measure the amount of treatment-related mortality a patient was willing to risk to improve health. In a standard gamble, patients are asked to choose between their current health and a “magic pill” that will restore perfect health. If the magic pill is successful, perfect health is restored. If the pill is unsuccessful, it results in immediate death. The chance of achieving perfect health is decreased until the patient is indifferent about their choice. Scores range from 0-1 with higher scores representing an unwillingness to take risks to improve health. Standard gambles have been used to assess the amount of risk a patient is willing to take in a general heart failure population and heart failure patients accepted for LVAD implantation. In the general heart failure population (n=99), mean standard gamble scores were 0.64 and were associated with functional class, lower peak oxygen consumption, higher jugular venous pressure, worse quality of life and symptom severity scores. Translated, these numbers suggest patients with heart failure would accept almost a 40% risk to improve their health. In the pre-LVAD population (n=29), it is important to note that these patients had already made the decision to have an LVAD implanted, or accepted the risk of the intervention, before completing the standard gamble. Pre-LVAD, the mean standard gamble score was 0.55 – almost a 45% risk to improve their health. The amount of risk patients were willing to take decreased significantly following LVAD implantation (20%) and again following heart transplantation (4%). The association with other patient or disease related factors were not reported.

iv. The Time Tradeoff

The time-trade-off technique, developed by Torrance et al is a quantitative measure of a patient’s preference for quality versus quantity of life. The technique asks patient’s to choose how much time in their current health they would be willing to trade for a shorter life in...
excellent health. In general, patients are asked to choose if they would prefer to live one year in their current health or 11 months in excellent health. The amount of time in excellent health is decreased in weeks or months until the patient is indifferent about their choice. Scores are calculated as the fraction of time in excellent health considered equivalent to a year in current health. Scores range from 0-1 with higher scores representing an unwillingness to trade any time to improve health. Time trade-off utilities have been shown to be a reliable measure of patient preferences in the SUPPORT trial and patients with heart failure. In the SUPPORT trial, the mean time trade-off score was 0.83: patients equated living 9.6 months in excellent health to 12 months in their current health state (0.83 x 12 months). Similar findings have been found in the heart failure population. Lewis et al reported a mean TTO score of 0.65 for heart failure patients. Patients would prefer to live 7.8 months in excellent health to 12 months in their current health state (0.65 x 12 months).

Examination of the distribution of time trade-off scores for patients in advanced heart failure identify 2 distinct groups, a larger group unwilling to trade any time to improve health and a smaller group willing to trade almost all time to improve health. A preference to trade time was associated with higher symptom severity scores, lower physical health and poorer quality of life. In the larger SUPPORT trial, patients with lower time trade-off scores were more likely to prefer a do not resuscitate order, perceived a higher burden of care on family and were depressed. Two of these studies measured treatment preferences prospectively. In both studies, small groups of patients changed their preference from symptom relief to longer survival time after they were discharged from the hospital. In the Stevenson et al study (2008), the change in preference was associated with a significant improvement in quality of life
suggesting as quality of life or symptoms improve, patients are less willing to trade time to improve their health.  

v. The Congestive Heart Failure Offering Individualized Choice Evaluation Study (CHOICES)

Treatment options in heart failure have varying effects on survival time, mode of death, treatment burden and changes in quality of life. CHOICES used a study specific tool based on a time tradeoff technique to measure the preferences of heart failure patients for 3 treatment options; optimum medical management (OMM), oral inotropes (INO) and left ventricular assist devices (LVAD). Information on treatment outcome, likelihood of outcome, treatment burden and mode of death was included in the descriptions of each of the treatment options. Treatments were presented in pairs and patients were asked to choose their preferred treatment option. The life expectancy associated with the preferred treatment options was then decreased by 7 day increments until the patient had no preference for one treatment over the other. Utility scores between 0 and 1 were calculated with lower scores representing a willingness to trade more time to stay in the preferred treatment state. Ninety-one patients (48 NYHA II and 43 NYHA IV) were enrolled in the study. There were no differences in treatment preferences between the two functional class groups. In rank order, patients preferred oral inotropes (42%), LVAD (32%) and medical management (26%). Patient preferences correlated poorly with MLHFQ and symptom severity scores. Although not statistically significant, there was a trend towards patients with MLHFQ and symptom severity scores over 60 preferring treatment with something other than medical management. When looking at mean utility scores, patients who chose oral inotropes were willing to trade more time then patients who chose medical management. These results are consistent with those of Stanek et al who “weighted” utilities to determine the contribution of fatigue, dyspnea, depression and survival to treatment decisions. Using this
technique, they also found two distinct clusters of patients. The proportion of heart failure patients preferring a shorter life with fewer symptoms appears to be higher (67%) than in studies using the traditional TTO technique. Patients with poor quality of life and severe symptoms may prefer therapies that offer some degree of symptom relief and may be willing to accept significant risk and burden to achieve a favorable outcome.

Initially we thought patients would find the subject matter presented during CHOICES, especially the information on how they would die, disturbing. This was not the case. Many patients used narratives to describe the experience of living with heart failure and how these experiences influenced their treatment decisions. They had very specific thoughts about how they wanted to live out the rest of their lives and even how they wanted to die. They wanted me, the interviewer, to understand the rationale behind their treatment decisions. For some, oral inotropes were appealing because of the anticipated symptom relief. They stated they were willing to risk sudden death to avoid breathlessness; a sensation many described as frightening. Another patient stated he would never choose oral inotropes. His father had died suddenly and his family had a very difficult time after his death. He preferred an option where death was anticipated. Prior to initiating the study, we were also concerned that participating in CHOICES may increase fatigue for patients with NYHA IV symptoms of heart failure. This was not the case. All patients were eager to participate usually offering that while participation may not help them, what they had to offer may help patients in the future. In the clinic this often involved approaching patients for participation on one visit and scheduling the interview on the next. For patients in the coronary intensive care unit, patients would wait until they had some unscheduled time, recruit the energy and complete the study. For this group of patients, narratives are an important means of conveying information on their preferences for living and dying. Considering that clinicians and patients seem to have differing conceptualizations of life
expectancy and treatment preferences at end-of-life, listening to and analyzing these narratives may help to unscramble the inconsistent results from the literature. As such, a design that incorporates a qualitative study to analyze the narratives of patients considering HT/LVAD is required.

Summary of the Literature Review

The theory of informed consent proposed by Faden and Beauchamp\(^9\) suggests disclosure, understanding, voluntariness, capacity and decision are necessary elements for informed consent. Disclosure is the first element of informed consent. During the assessment process patients are presented with information regarding the natural history of heart failure, treatment options, risks and benefits and alternatives. Information is discussed when patients are diagnosed, when they progress to Stage D heart failure and at assessment for heart transplant and/or LVAD implant. Since this element is the responsibility of clinicians it was not quantified in this study. Understanding is the second element. The literature review suggests that although patients report they have given informed consent, they often do not retain salient facts regarding treatment. Most were prepared to accept significant risks for a small chance of a positive outcome. Hope and trust were factors patients identified that affected their decision. Hope may explain why patients living with heart failure consistently over-estimate their life-expectancy. The literature review identified no validated measure of understanding in heart failure so this element was not measured in the quantitative study. Voluntariness is the third element of informed consent. The literature review suggests internal factors associated with heart failure may compel patients to consider high-risk surgery as a way of relieving unpleasant symptoms and improving quality of life. The variables chosen to reflect the voluntariness element of informed consent include quality of life, overall health and symptom severity. Capacity is the fourth element of informed consent. Patients with heart failure are generally considered
competent and capable of making decisions regarding heart transplant and/or LVAD implant. However, approximately 30% of heart failure patients have depression or cognitive impairment. Both depression and cognitive impairment could affect a person’s ability to attend to or retain information, deliberate or appreciate the consequences of their decision. The variables chosen to reflect the capacity element of informed consent in the quantitative study include depression and cognitive impairment. Decision is the final element of informed consent. Results from the literature review suggest patients living with heart failure are willing to take considerable risk and trade significant time to improve their health. The variables chosen to reflect the decision element of informed consent are treatment preferences, specifically the standard gamble and time tradeoff. Any additional factors that influence informed consent will be identified in the parallel qualitative study. Approaching the question from both a quantitative and qualitative perspective will help identify the greater part of factors that influence the decision to proceed with heart transplant and/or LVAD implant and help determine if the decision fulfills the requirements of informed consent.
Chapter 3 – RESEARCH METHODS

Study Design

The study was a prospective cohort analysis utilizing a mixed methods approach to describe the informed consent process for patients considering heart transplant and/or LVAD implant. Conceptual triangulation was used to combine the findings from parallel quantitative and qualitative studies while maintaining the integrity and findings of each distinct study.122 Conceptual triangulation uses the concepts and constructs emerging from analysis of two distinct methods. The 5-step approach described by Foster describes the process of conceptual triangulation.122

**Step 1: Conducting the parallel studies**

The quantitative and qualitative studies were conducted simultaneously true to the paradigmatic assumptions of each method.

**Step 2: Distinguishing pertinent results within method**

The results from the quantitative and qualitative studies were examined within method to identify pertinent findings for integration into the final model.

**Step 3: Examining confidence in the results**

Results of the quantitative and qualitative studies were examined for threats to rigor according to the methodological assumptions of each method.

**Step 4: Developing criteria for inclusion of results into the final model**

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The results of each study were examined to determine which concepts and constructs should be included in the final model that describes the process patients use to decide about heart transplant or LVAD implant. To be included in the model, variables must demonstrate at least moderate support within each method and at least partial convergence between methods.

**Step 5: Constructing the integrated model**

The final step of conceptual triangulation was development of a model to describe the relationships of the concepts and constructs identified in the parallel studies.

**Patient Sample**

A convenience sample was drawn from all patients followed by the Heart Function service at Toronto General Hospital. They may or may not be known to our service. They may or may not be on maximal medical therapy. Typically they are referred from within the Greater Toronto Area although we have assessed patients from out of province. Our patients are representative of the demographics and diverse cultures of the greater Toronto area. Approximately 118 patients are referred to our program for heart transplant or LVAD assessment every year. Of these, approximately 40-50 patients are accepted for heart transplant and 20 patients for LVAD implant. The average duration of assessment is 40 days with a range from 1-90 days. Patients over 18 years of age, who were currently being assessed for heart transplant and/or LVAD implant and who could speak, write and comprehend English were eligible for enrollment. These were patients who had already been made aware of the potential need for advanced heart failure therapy and had made the decision to proceed with assessment for heart transplant and/or LVAD implant. Patients who were aware of the need for advanced heart failure therapies and
declined the referral for assessment were not included in the sample. All enrolled patients completed the quantitative questionnaires.

The qualitative sample was a highly selected group of patients who had completed the quantitative questionnaires. We selected patients who were representative of the clinic demographics, quantitative study demographics and the range of scores from the quantitative questionnaires. We also chose patients who we felt could articulate their thoughts and experiences. One to two patients were recruited to the qualitative study per month to allow the researcher adequate time to complete the interviews and begin data analysis.

Setting

The Heart Failure/Heart Transplant team at Toronto General Hospital consists of cardiologists, cardiac surgeons, nurse practitioners, social workers and psychiatrists. It is the only adult Heart Transplant program in the greater Toronto area. Patients may be heart failure patients followed by our team or referred in by other cardiologists. Referrals take place either in the inpatient or outpatient setting.

The outpatient Heart Function clinic sees approximately 40-60 patients per week. Four attending cardiologists with training in advanced heart failure, heart transplant and LVAD run the clinic. Clinic visits are coordinated so that echocardiograms, cardiopulmonary testing, bloodwork and ECG are completed during the clinic visit. In the outpatient clinic, data collection was conducted in an examination room. Each room had a desk and examination table. Patients decided whether or not they wanted to sit or lie down during data collection. Qualitative interviews were conducted in a consultation room that was equipped with a table and chairs. Consultation rooms were reserved ahead of time to allow for completion of the interview without interruption.
Inpatient interviews were conducted in either the Coronary Intensive Care Unit (CICU) or the inpatient cardiology ward. The CICU provides care for up to 14 patients requiring care for acute coronary syndromes, decompensated heart failure, cardiogenic shock and congenital heart disease. Care includes advanced technologies such as mechanical ventilation, intra-aortic balloon pump and dialysis. Heart failure patients admitted to the CICU for heart transplant or LVAD assessment may require one or more of the advanced therapies. Patients requiring mechanical ventilation were not included in the sample. Our experience with the Congestive Heart Failure Optimizing Individualized Choice Evaluation study (CHOICES), suggests that patients who are critically ill can participate in research studies involving treatment decisions for advanced heart failure. Interviews in the CICU were conducted at the patient’s bedside. The interview time was arranged in collaboration with the patient, family and CICU staff. Issues that required clinical intervention always took priority over the interview. Interviews on the inpatient cardiology ward were conducted in a meeting room equipped with a table and chairs. The room was reserved ahead of time to allow for completion of the interview without interruption.

All data was collected by me. I am both a clinician and a researcher. However, I was not providing direct patient care to the patients who participated in this study. My clinical role includes outpatient care of patients supported on an LVAD. My experience counseling patients with advanced heart failure has enhanced my interviewing skills and assisted in my ability to establish trust and demonstrate empathy when listening to the stories of patients. I am also able to use my clinical expertise to evaluate the patient’s condition and determine if the patient is well enough to complete the interview. During past research studies, patients have been able to distinguish between my research and clinical roles. Trust established during the research study
often strengthens the clinical relationship and many patients offer suggestions for future research or act as patient advisors when designing new research studies.

**Study Procedures**

The attending physician identified the patients who were being assessed for heart transplant and/or LVAD assessment. Eligible patients were then contacted by a heart failure team member and asked if they would be willing to meet with the researcher. They were informed that the decision to participate in the study was voluntary and their decision to participate or withdraw would not affect their current or future care. I collected data and conducted the interviews. If the patient agreed, I met with the patient to complete the informed consent process.

Interviews were conducted during the assessment process before the final decision had been made regarding transplant/LVAD eligibility. No effort was made to alter the assessment process or to blind patients to their potential outcome. Patients may have had some idea regarding their eligibility based on their pre-assessment discussion with the attending physician. For example, during the pre-assessment discussion, all patients are informed of the absolute and relative contraindications to transplant and/or LVAD implant. They may have been able to adjust the probabilities as they were made aware of the results of their diagnostic testing. I recorded the final decision after the team determined eligibility and if the patient accepted or rejected surgical intervention. One patient who was not a transplant candidate was accepted for LVAD implant. However, he declined surgical intervention. The quantitative and qualitative studies were conducted simultaneously true to the paradigmatic assumptions of each method. Methods for each study will be discussed individually.
Methods of the Quantitative Study

Instruments:

i. **The Minnesota Living with Heart Failure Questionnaire (MLHFQ):**

   The MLHFQ is a 21-item self-administered questionnaire that measures the patient's perception of the effects of heart failure on physical, socioeconomic and psychological aspects of their life within the past month.\(^5\)\(^8\) The scale yields a total score from 0-105 with higher scores representing poorer quality of life. The 21 questions take approximately 10-15 minutes to complete.

ii. **Visual Analog Scales (VAS):**

   Patient perceptions of their overall health, severity of shortness of breath and fatigue were measured using visual analog scales. The 3 scales took a total of 5 minutes to complete. For severity of shortness of breath and fatigue, the anchor points were fixed at 0 (no shortness of breath or fatigue) and 100 (severe shortness of breath or fatigue). For overall health, the anchor points were fixed at 0 (poor health) and 100 (excellent health). The number of millimeters from the 0 anchor point represents the score for each VAS. The scales have been shown to correlate with other forms of quality of life assessment in heart failure patients including the MLHFQ and utility measures.\(^6\)<sub>9</sub>,\(^7\)<sub>8</sub>

iii. **Beck Depression Inventory (BDI):**

   Depression occurs in approximately 30% of heart failure patients. To date, no studies have assessed depression and its relationship to treatment preferences in Stage D heart failure. The BDI is a 21 item self-report tool that measures severity of depressive mood or symptoms. The tool yields a total score from 1 to 63. Scores between 10-18 are indicative
of minor depression, 19-30 moderate depression, and above 30 major depression. The BDI takes about 10 minutes to complete.

iv. Montreal Cognitive Assessment (MoCA):
Cognitive impairment occurs in approximately 30% of patients living with heart failure and has been identified by patients as an undesirable outcome at end-of-life. To date, no studies have measured cognitive impairment and its relationship to treatment preferences in Stage D heart failure. The MoCA is a reliable and valid 30-item clinician administered test that screens for cognitive impairment. The test takes about 10 minutes to administer and yields a total score from 0-30. Scores under 24 are indicative of cognitive impairment. Given our clinical experience with this patient population and the subtle cognitive changes they may experience I chose the MOCA over the Mini Mental Status Exam for its improved ability to detect mild cognitive impairment.

v. Standard Gamble:
The standard gamble measures the amount of risk the patient was willing to take to improve their health. Each patient was presented with a hypothetical scenario requiring them to choose between remaining in their current health or trying a “magic pill” to improve health. When successful, the “magic pill” will return the patient to full health for the remainder of their life. When unsuccessful, it results in immediate death. For example, the patient is asked “would you remain in your current health or take a magic pill that has a 90% chance of restoring excellent health. If the pill doesn’t work it results in immediate death. Would you take the pill?” The probability of restoring excellent health was systematically decreased by 10% until the patient’s preference changed to remain in current health. The percent of risk the patient was willing to take to restore excellent health was recorded.
Scores ranged from 0 (defined as willing to risk everything) to 1 (defined as unwilling to take any risk).

vi. Time Trade-off:

The time tradeoff is a utility that measures the amount of time a patient would trade to improve their health. Since patients who participated in this study had Stage D heart failure, one year was chosen as the maximum amount of time they could live in their current health. Each patient was presented with a hypothetical scenario requiring them to choose between living for 12 months in their current health or taking a magic pill to improve health. If successful, the “magic pill” would give them excellent health for however many months was being discussed. When unsuccessful, it results in immediate death. For example, the patient is asked “would you prefer to live in your current health state for 12 months or take a magic pill that would give you 11 months of excellent health. If the pill doesn’t work it results in immediate death. Would you take the pill?” The number of months in excellent health was systematically decreased in 30 day increments until the patient’s preference changed to live 12 months in their current health. Time trade-off scores were calculated (days traded/365). The calculated scores are between 0 (defined as willing to trade all time) and 1 (unwilling to trade any time).

The instruments were ordered in the following way to minimize confusion for patients as well as reduce administration bias:

1. The MLHFQ, VAS and BDI were shuffled and grouped together.

2. The TTO and SG were grouped together. The order of administration within the grouping was shuffled. The TTO and SG were administered together, either at the beginning or the end of the MLHFQ, VAS’ and BDI grouping.
3. The MoCA was always administered last. Some patients with intravenous lines or balloon pumps could not complete the MoCA due to physical limitations caused by their equipment. Occasionally, if a patient doesn’t do well on the MoCA, they can become disappointed or discouraged and this may affect their ability to attend to and complete the other instruments.

I. Quantitative Data Analysis

Quantitative data were analyzed using descriptive statistics to describe each group’s characteristics, quality of life scores, perceptions of overall health, severity of symptoms, standard gamble, time tradeoff as well as the prevalence of depression and cognitive impairment. Student’s t-test for independent samples was used to determine if there is a difference in the normally distributed data (MLHFQ scores and VAS scores for dyspnea, fatigue and overall health). Chi Square analysis was used to determine the differences in proportion of scores between groups based on demographic characteristics (eg age). Linear regression analysis was used to determine the relationship between variables. One-way ANOVA was used to determine differences in mean MLHFQ scores between 3 groups – listed, too early and not transplant eligible. The SAS system, release 8.2 was used to analyze the data. (SAS Institute Inc., Cary, NC). The level of significance for all tests was pre-set at 0.05. Post-hoc power calculations identified the study was adequately powered for continuous variables.
**Methods of the Qualitative Study**

Deciding to have a heart transplant or an LVAD is an interactive process between the patient, family and clinical team. At every step, the patient and family must interact with the team to understand the information, assess how the decision will impact on their values and beliefs and come to terms with their own mortality. Qualitative data provides a way of seeing, organizing and understanding the decision to have a heart transplant or LVAD from the patient’s perspective, within the context of the high-tech setting of a specialized cardiac center.

This study uses the grounded theory method to discover concepts, relationships and processes described during the decision-making process for heart transplant and/or LVAD implant. Grounded theory is an inductive approach used by researchers to develop theory, grounded in data that is systematically collected and analyzed. Grounded theory was first described by Glazer and Strauss in 1967. In the initial version, Glazer & Strauss believed that the use of grounded theory procedures and techniques would allow the concepts to “emerge” from the data. The researcher’s role was objective and separate from the data. Grounded theory has since evolved into many forms; the classic Glazer and Strauss version (Glaserian grounded theory) to later versions by Strauss and Corbin (1998) (Straussian grounded theory), Charmaz (2000)(constructivist grounded theory) and Clarke (2005) (Situational Analysis). All methods share common characteristics but differ in application of underlying philosophical assumptions. The common methodologic characteristics of grounded theory are:

i.  Reliance on qualitative data through direct observation and interview.

ii.  Theory is grounded in data and not on any predetermined theoretical perspectives.

iii.  Theoretical sampling evolves as the theory is discovered.

iv.  Data analysis centers on coding data into categories for the purpose of comparison.
v. Concurrent data collection and analysis allows for constant comparison of categories so relationships and processes can be identified and refined.

vi. Theoretical saturation, where new data no longer adds to the emerging theory signifies the end of data collection.

For this study, qualitative data was collected and analyzed using Straussian grounded theory procedures described by Strauss and Corbin. This version was chosen because it fits within the post-positivistic paradigm of inquiry, is well suited to answer the research questions and is congruent with the worldview of the quantitative study. Strauss and Corbin also believed the researcher was an integral part of the process. Using their approach, the researcher is encouraged to use creativity to name categories, ask stimulating questions and develop an “innovative, integrated and realistic scheme from masses of unorganized raw data” (pg 13). Strauss and Corbin believe there is not one reality – rather multiple realities. As each person tries to make sense of their lives, events are filtered through experiences, values and beliefs. The challenge for the researcher is to listen to and capture these multiple realities and “construct” concepts and theories that help to explain them. The final product provides a way of understanding the experience of the participants that can be discussed, challenged and refined by others.

I. Qualitative Data Collection

Data were collected through 17 semi-structured face-to-face interviews over 12 months. Every effort was made to schedule the interview within one week of completing the quantitative instruments. Where possible, the qualitative interview occurred immediately following collection of the quantitative data. Informed Consent was obtained prior to the quantitative study. The consent was reviewed prior to the start of the interview and patients were asked if
they wanted to proceed. All interviews were recorded. All participants were informed of the purpose of the study, approximate length of the interview and that they can stop the interview or turn off the recorder at any point in the interview. I conducted the interviews using an interview guide (see Appendix C). This facilitated consistency in the approach to data collection and allowed me to use my clinical knowledge and experience with this patient population to explore and probe relevant concepts.

As concepts developed, theoretical sampling was used to identify patients with a variety of experiences; time living with heart failure, sex, family versus living alone and a variety of ages. I collaborated with the attending physician to identify patients who we felt could articulate their thoughts and experiences. A single interview was deemed appropriate because patients with advanced heart failure experience considerable dyspnea and fatigue which limits their participation as well as the potentially upsetting nature of some concepts that may be discussed.

Outpatient interviews were conducted in a private conference room in the clinic, following an appointment with the heart failure cardiologist. Inpatient interviews were conducted either in the patient’s room if they had private accommodation or in a small interview room on the ward. Only 1 patient was interviewed in the coronary care unit, the door was closed and intrusions kept to a minimum. I allowed patients to choose whether they wanted family members present during the interview. Eight patients included family, 9 did not. I started the interview by asking patients to tell me what it was like living with heart failure. This general question helps me to understand the impact on their lives and helps patients get comfortable with me, the recorder and the room. As much as possible, I let patients control the content they were comfortable sharing. I asked questions about their heart failure symptoms, their quality of life and what it was like to hear they needed a heart transplant or mechanical heart. Sensitive topics such as evaluation of risk and potential for death were explored midway through the interview.
I always introduced the topic as a “sensitive/difficult” topic and allowed patients to refuse to answer. No-one refused. This was followed by questions inquiring about the impact on their family and their relationship with the heart failure team. I ended each interview by asking patients if there was an area important to them that I did not address or if they had anything else they would like to add. As the study progressed, specific questions were changed based on the constant comparative method. For example, when trust in the healthcare team was identified as a concept, I focused questions on the elements of trust, exploring the context in which trust occurs and how trust affects decision-making. Other themes were explored in a similar fashion.

Only two patients required clinical follow-up after the interview. One was a young woman who, when asked, said she had not considered the risk of dying – had not discussed it with her family or completed any advanced care directives. A few weeks later I was told by a nurse practitioner on the inpatient ward that this question had caused her some distress. After discussing it with the nurse practitioner, the patient spent some time creating her advanced care directives and then discussed them with her husband. I was told that these actions resolved her distress. The other patient was a young man who had recently been diagnosed with heart failure and had quickly been referred on for heart transplant assessment. During the interview he started crying and asked to have the interview stopped. With his permission, I referred him on to our psychosocial team for ongoing support.

II. Qualitative Data Management

All interviews were transcribed verbatim by a transcriptionist. Once the transcript was complete it was transferred to a secure data server. I reviewed each transcript for completeness and accuracy by simultaneously listening to the recording while reading the transcript. I made corrections and notations to identify pauses and emotions as needed. The transcriptionist deleted
the recordings and transcripts from his computer system once the transcription had been sent to me.

Transcriptions and audio recordings were imported into NVIVO ® version 8 software (QSR International, Cambridge MA). NVIVO ® allows for electronic coding, word finding and electronic memos. Audio recordings, transcripts and NVIVO® files were password protected on a secure drive through the University Health Network Information system. Initial codes were filed as free nodes. Free nodes are stand-alone codes that have no logical connection to another free node (see Appendix D). They are part of initial coding. As coding progressed they were grouped and categorized into tree nodes. Tree nodes are codes that are grouped together in a hierarchical structure. Each tree node may have 1 or more child node associated with it (see Appendix D). Finally, the tree nodes were grouped into categories and labeled by what they had in common (see Appendix D).

III. Coding Procedures

Analysis began after 2 interviews had been completed. Throughout coding I kept in mind the central question “How do patients with Stage D heart failure make decisions regarding heart transplant and/or LVAD implant?” The coding process described by Strauss and Corbin involves three levels of coding; open coding, axial coding and selective coding. Open coding entails breaking down the data into codes/concepts to begin examining, comparing and categorizing data. To accomplish this, I listened to each interview in its entirety while reading the transcript line-by-line. This process was maintained throughout the analysis. Listening to the interview helped sensitize me to the meaning of the information. If a participant was crying, laughing or paused, it was noted in the transcript and imported into the coded text. As codes were identified I labeled them with the participant’s words and filed them in the NVIVO® program as “free nodes” (Table 1). When a subsequent participant
identified the same code, I would import it into the appropriate file. My thoughts related to the code were filed as memos. Early codes tended to reflect what the patient was feeling or thinking as they described the decision-making process. The open coding process identified 94 free nodes. As open coding proceeded, codes were compared with one another and grouped into categories. I examined each code to determine the meaning, compared codes and reflected on what the participants were saying. The category was then labeled by what they had in common (Table 2). For example, the category “living with heart failure” included the codes activity restrictions, living day-by-day and side effects of medications.

**Table 1 - Examples of Open Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Descriptions and Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Being a burden</td>
<td>Concerns about being a burden to family.</td>
</tr>
<tr>
<td></td>
<td>How does burden affect the decision?</td>
</tr>
<tr>
<td>Burden defined</td>
<td>How participants define burden.</td>
</tr>
<tr>
<td>Family support</td>
<td>Descriptions of how family support the participant – info search, chores, emotional support.</td>
</tr>
<tr>
<td></td>
<td>What are the features of family support?</td>
</tr>
<tr>
<td></td>
<td>Does the participant describe this as a positive aspect? Are there negative aspects?</td>
</tr>
<tr>
<td>Hearing the news</td>
<td>The response to hearing the news they need a transplant/LVAD.</td>
</tr>
<tr>
<td></td>
<td>Includes being overwhelmed, scared, angry etc.</td>
</tr>
</tbody>
</table>
### Table 2 - Examples of Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needs of Others</td>
<td>Impact of family on decision. Includes family participation in decision, burden, family support and family as purpose in life.</td>
</tr>
<tr>
<td>Trust</td>
<td>How trust influences the decision. Includes trust in the medical team, trust in Toronto General (reputation), communication strategies that promote trust.</td>
</tr>
<tr>
<td>Attitude toward risk</td>
<td>How participants conceptualize risk and how that influences decision. Includes risk of dying, rationale for why risk is necessary and risk/reward.</td>
</tr>
<tr>
<td>Quality of Life</td>
<td>Descriptions and factors of quality of life. Includes living with heart failure, this isn’t living and this isn’t normal.</td>
</tr>
</tbody>
</table>

Axial coding involves determining the properties and dimensions of a category as well as identifying relationships among categories. For me, this was the most challenging aspect of the research. I used an iterative process going back and forth between the interviews and transcripts to determine what was similar, what was different and why. Memos were used to record my train of thinking as they developed. For example, under the category living with heart failure, participants described “good days” and “bad days.” How does this relate to their symptoms and/or activity restrictions? Is this an element of quality of life? Axial coding led to the identification of a theme “quality of life”. Quality of life included descriptions of the emotional impact of the heart failure and treatment on the participant. A separate theme was identified “the needs of others” which included the perceived impact of heart failure and its treatment on the participant’s family. Free nodes were collapsed into 11 tree nodes that described broad concepts relevant to the emerging theory. Many of the tree nodes had daughter nodes which described dimensions, variations, conditions of that particular theme.

Selective coding is the process whereby the researcher integrates the broad categories into a conceptual model. I began to think more abstractly about the data. A central category was
identified – making the decision. Quality of life, the needs of others, survival time and attitude toward risk were the categories participants identified that contributed to the decision. Describing quality of life and the needs of others elicited emotion from most participants so these concepts were grouped under the emotional domain. Participants were more pragmatic and reasoned when discussing quantity of life and attitude toward risk. They also talked about the information they used to help them make a decision. These concepts were grouped under the rational domain. I also knew that most decisions involve both an emotional and rational component so for me, this seemed like a natural division. Trust emerged as a separate but related concept. At first, I felt trust was a strategy participants used to help them make a decision. But, after much reflection and discussion with committee members, I realized that trust was a separate process with its own cognitive, affective and behavioral aspects. For example, patients described how the referral process helped them to trust the clinicians at Toronto General Hospital. The concept of transferred trust fit nicely under the rational domain of decision-making. I grouped the other trust-related concepts into their relevant domains. I then changed the labels “emotional” and “rational” to “cognitive” and “affective” which I felt were better descriptions of the categories. Coping was initially identified as a strategy that patients used to help them make a decision but I felt the label of coping was too broad. Patients did use many coping strategies to help them manage the illness and its treatment. However, the strategies specific to decision-making were focused on managing the doubts and fears of the situation so the label was changed to “managing doubts and fears.”

IV. Ensuring Rigor

The purpose of addressing rigor in any study is to clarify the strategies used to minimize error and enhance truthfulness throughout the research process. A number of strategies exist for
ensuring rigor in qualitative studies. As a researcher and clinician working with this patient population, my experience is different from those who either do only research or only work with patients in a clinical setting. This unique experience is integrated into my identity and cannot be disregarded or discarded. I strongly believe it has added creativity by enhancing my ability to ask stimulating questions and make sound assumptions based on the data. Other researchers may not share this perspective and may create a different model based on similar findings. Finally, the purpose of this model is to provide a framework and language to stimulate discussion about how patients make decisions regarding heart transplant and/or LVAD implant. It should be considered a starting point for others to do similar work, challenging assumptions and helping to validate specific aspects of the model. Therefore I feel rigor should be specific to the study and not necessarily reproducible or generalizable to a different patient population. I chose to use the strategies proposed by Beck; credibility, auditability and fittingness. 125

i. Credibility

Credibility is comparable to internal validity and refers to the faithfulness of the description of relationships. 125 Credibility begins with the interview. I began the interview by asking participants to tell me their heart failure story. The interview guide included general questions about their heart failure symptoms, their quality of life and what it was like to hear they needed a heart transplant or mechanical heart (see Appendix C). This approach allowed participants to focus on information that is important to them and they feel comfortable sharing. I would explore and develop concepts as they were identified. During open coding I used the patient’s own words to describe the concept. For example, many patients told me that they weren’t living, they were surviving. The code used to organize these perceptions was labeled “this isn’t living.”
Another aspect of credibility is the researcher’s personal views and insights. My perspective is somewhat unique since both my clinical and research practice involves interaction with patients living with advanced heart failure. I found using the constant comparative method – going back and forth between the data and coding was helpful to reduce incorrect assumptions. I used the interview process to confirm or refute my assumptions. I would then go back and forth between the interviews and codes until I was confident that what I was proposing was from the data and not a preconceived idea. Whenever possible, I used patient words to label codes during open coding. As coding became more abstract and complex, I found the use of memos to describe meanings, dimensions and properties helpful in identifying what I was thinking. The decision to use generic labels in the final model was purposeful. The overriding purpose of this study is to describe to clinicians how patients make decisions regarding heart transplant and/or LVAD implant. I chose to use generic labels and described participant meaning in my explanation of the category.

A final aspect of credibility is the use of the literature review. A literature review was required to develop the research questions and compose the proposal. I did a thorough literature review on quantitative studies describing the treatment preferences for patients with advanced heart failure. During the literature search I did identify qualitative studies that may also be applicable to this study. I made a conscious choice not to read these articles. I felt the less I knew about other researcher’s constructions the more faithful I could be to our participant sample. I felt any additional reading might further bias my interpretations towards my preconceived views and the results of prior studies. After completing the model I completed a thorough literature search in the qualitative literature and used them to discuss my results. In hindsight, I feel this was a wise decision. I am confident that the constructed model is a fair representation of how patients make decisions regarding heart transplant and LVAD.
ii. **Auditability**

Auditability refers to the ability of another researcher to follow the decisions made by the original researcher. There are 2 main aspects that apply to auditability; specifying the criteria used in the researcher’s thinking and describing how the sample was selected. In the previous section, I described the process I used to develop codes and categories. In describing the model, I included information on my thinking as the concepts developed. For example, at one point I thought the decision to proceed was a mutual decision between the participants and their family. I was able to explore this concept in subsequent interviews and determined that while it was easier if family agreed with the decision, patients made the final decision. Another aspect of auditability is describing how the sample was selected. The decision to interview a participant was made by me and the attending staff physician. We initially chose patients with a range of heart failure experiences to promote the identification of several codes. As the study progressed, we used theoretical sampling to ensure we had participants of each sex, marital status, varying age groups and length of time since diagnosis.

iii. **Fittingness**

Fittingness refers to the suitability of the results to others. One strategy to enhance fittingness is member checking. In member checking, the researcher seeks feedback on the model from participants in the study. I consciously did not do member checking with participants. The model is constructed from the interpretations of multiple patient realities during the assessment period. I believe that if I asked participants to provide feedback, they would instinctively give feedback based on their own experience. While certain elements may be applicable, others may not. Additionally, member checking would have occurred after they knew the decision regarding transplant or LVAD implant. Their perspectives may have changed over time and with knowledge of the decision. Finally, contacting patients after the model
was developed would have violated study consent that stipulated a 1-time meeting for data collection.

As a novice researcher I also felt it was important to adopt strategies that supported trustworthiness and rigor throughout the research process. To achieve this I followed the systematic application of Straussian grounded theory – moving between the data and analysis to ensure there was enough evidence to support the emerging concepts and categories. The data was organized with a computer program developed for use in qualitative research allowing for visualization if codes and concepts as they developed. Second, in the results section the descriptions of categories and concepts include verbatim quotes from participants so the reader can judge the trustworthiness of the interpretations. Finally, I reviewed the proposed model with committee members, heart failure clinicians and researchers. I described how the model works and listened to their feedback. All those who reviewed the model felt it represented the process patients use to make decisions regarding heart transplant and LVAD. The model underwent some minor alterations, but theoretically it remained the same. From a theoretical perspective, the model represents substantive theory since it is situated within the context of our program and patient population.

**PROTECTION OF PATIENTS’ RIGHTS**

Approval to conduct this study was obtained from the University Health Network Research Ethics Board and the University of Toronto Research Ethics Board. The attending physician screened all patient referrals for eligible patients. A member of the Heart Failure/Heart Transplant team approached eligible patients to see if they were willing to participate. If the patient was agreeable, the researcher met with the patient to discuss the study, review the
consent and sign the consent form. Each willing patient was informed that the decision to participate was voluntary and their decision to participate or withdraw would not affect their care. Patients were informed that all answers were confidential and that their names would not appear on any records. A copy of the consent form that lists risks and benefits of participation is located in Appendix E.
CHAPTER 4 – RESULTS

RESULTS OF THE QUANTITATIVE STUDY

A total of 110 patients were candidates for participation in the study. Of these, 34 declined participation. Reasons for not participating included patient not interested/too tired/too nervous (47%), a decision not to approach made by attending physician (21%) and patient too sick/intubated (12%). A total of 76 patients were enrolled in the study. Sample characteristics are displayed in Table 3. The sample was representative of our clinic demographics with an average age of 55+/− 11 years (range 22-82) and the majority of patients were men (68%). Etiology of heart failure was idiopathic dilated cardiomyopathy (46%), ischemic cardiomyopathy (36%) and other (18%). The majority of patients in the other category had chemotherapy-induced cardiomyopathy (n=4). Two-thirds of the patients (64%) were known to the team when they were referred for transplant. The majority of patients were outpatients (66%) at the time of the interview. Inpatients were evenly divided between inpatient ward (17%) and the coronary care unit (17%). In terms of medical management, 80% were on either an angiotensin-converting enzyme inhibitor (ACE)/angiotensin receptor blocker (ARB), 80% were on a beta-blocker and 58% were taking an aldosterone receptor blocker. Most patients had an ICD in-situ (70%) and 34% had CRT. Outcomes for the sample included 48% listed for transplant, 24% were considered “too early” and 28% were not transplant eligible. Patients considered “too early” are those the team felt would benefit by changes to their medical management. They would be re-assessed for transplant if their heart failure did not respond to ongoing medical management.
Table 3- Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value (n = 76)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), Mean (range)</td>
<td>55 (22- 82)</td>
</tr>
<tr>
<td>Sex (% Male)</td>
<td>68</td>
</tr>
<tr>
<td>Etiology (% CAD)</td>
<td>36</td>
</tr>
<tr>
<td>Previous Cardiac Surgery (%)</td>
<td>18</td>
</tr>
<tr>
<td>On ASA (%)</td>
<td>96</td>
</tr>
<tr>
<td>Mean ejection fraction (%)</td>
<td>22</td>
</tr>
<tr>
<td>Admit &lt; 6 mos (%)</td>
<td></td>
</tr>
<tr>
<td>Ward</td>
<td>74</td>
</tr>
<tr>
<td>CCU admission</td>
<td>40</td>
</tr>
<tr>
<td>Mean Systolic blood pressure (mmHg)</td>
<td>97</td>
</tr>
<tr>
<td>Mean heart rate (bpm)</td>
<td>74</td>
</tr>
<tr>
<td>Mean JVP (cm)</td>
<td>4</td>
</tr>
<tr>
<td>Serum Sodium (mmol/L)</td>
<td>136</td>
</tr>
<tr>
<td>Serum Creatinine (umol/L)</td>
<td>117</td>
</tr>
<tr>
<td>Serum BNP (pg/ml)</td>
<td>1068</td>
</tr>
<tr>
<td>Medications (%)</td>
<td></td>
</tr>
<tr>
<td>Diuretic</td>
<td>84</td>
</tr>
<tr>
<td>ACE/ARB</td>
<td>82</td>
</tr>
<tr>
<td>Beta Blockers</td>
<td>82</td>
</tr>
<tr>
<td>Aldosterone Antagonist</td>
<td>58</td>
</tr>
<tr>
<td>Known to team prior to referral (%)</td>
<td>64%</td>
</tr>
</tbody>
</table>

CAD = Coronary artery disease; CCU = coronary care unit; JVP = jugular venous pressure; BNP = brain natriuretic peptide; ACE/ARB = angiotensin converting enzyme inhibitor/angiotensin receptor blocker

The sample had an overall poor quality of life with a mean Minnesota Living with Heart Failure Questionnaire (MLHFQ) score of 64. Higher MLHFQ scores (poorer quality of life) were associated with higher dyspnea scores (r = 0.34; p < .05) higher fatigue scores (r = 0.39; p < .05) and lower overall health scores (r = 0.39; p < .01) (Table 4). There was a trend towards patients under the age of 55 having higher MLHFQ scores but it was not
statistically significant (p< .06). Patients with 2 or more admissions to hospital within 6 months of study participation had significantly higher MLHFQ scores than patients who had 1 or no admission to hospital (p< .05). There was a trend towards patients with at least 2 admissions to hospital having worse dyspnea and fatigue scores but this not statistically significant (p < .07 and p< .08 respectively).

Table 4 - Quality of Life Indicators (n=76)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD)</th>
<th>Range of Instrument</th>
<th>Clinical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLHFQ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>63.6 (23.4)</td>
<td>0 – 105</td>
<td>Higher scores = worse quality of life</td>
</tr>
<tr>
<td>Physical</td>
<td>26.6 (10.5)</td>
<td>0 – 40</td>
<td>Total MLHFQ scores &gt; 60 = NYHA IV 58,128</td>
</tr>
<tr>
<td>Emotional</td>
<td>14.8 (7.5)</td>
<td>0 – 25</td>
<td>Total MLHFQ scores 40-60 = NYHA III58,128</td>
</tr>
<tr>
<td>VAS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>53.1 (31.3)</td>
<td>0 – 100</td>
<td>Higher scores = worse symptom severity</td>
</tr>
<tr>
<td>Fatigue</td>
<td>61.7 (29.0)</td>
<td>0 – 100</td>
<td>Dyspnea scores &gt; 50 = NYHA IV 45</td>
</tr>
<tr>
<td>Overall Health</td>
<td>40.3 (29.9)</td>
<td>0 – 100</td>
<td>Fatigue scores &gt; 65 = NYHA IV45</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lower scores = poorer overall health</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Overall health scores &lt; 30 = NYHA IV45</td>
</tr>
<tr>
<td>BDI</td>
<td>12.6 (7.8)</td>
<td>1 – 63</td>
<td>Higher scores = greater depression</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Scores 10-18 = mild depression129</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Scores 19-30 = moderate depression129</td>
</tr>
<tr>
<td>MoCA</td>
<td>25.8 (3.9)</td>
<td>0 – 30</td>
<td>Lower scores = worse cognitive impairment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Scores &lt; 24 = cognitive impairment123</td>
</tr>
<tr>
<td>Standard Gamble</td>
<td>0.66 (0.2)</td>
<td>0 – 1</td>
<td>Higher scores = less willing to take risks or trade time</td>
</tr>
<tr>
<td>Time Tradeoff</td>
<td>0.69 (0.3)</td>
<td>0 – 1</td>
<td>Scores 0.3-0.65 = NYHA III/IV 67</td>
</tr>
</tbody>
</table>

The Beck Depression Inventory (BDI) was used to measure depression. Thirty-eight percent of the sample was at least mildly depressed (BDI scores 14-19) with 13% scoring in the range of moderate depression (BDI scores 14-19) and 5% severely depressed (BDI scores ≥
Depression scores were associated with higher MLHFQ total ($r = 0.44; p < .05$), physical subscale scores ($r = 0.37; p< .01$), emotional subscale scores ($r = 0.54; p < .05$), higher dyspnea scores ($r = 0.38; p < .05$), higher fatigue scores ($r = 0.4; p< .05$) and lower overall health scores ($r=0.4; p< .01$) (Table 4). No relationships were found between depression scores and either the SG or TTO scores. There was a trend towards patients with at least 2 admissions to hospital having worse BDI scores than patients with 1 or no admission to hospital but it was not statistically significant ($p < .06$).

The Montreal Cognitive Assessment tool (MoCA) was used to assess for cognitive impairment. Only 64 patients completed the MoCA. The main reason for non-completion was an inability to write and fatigue. Mean scores for the MoCA were 25.8 +/- 4. Thirty percent of patients had scores indicative of mild cognitive impairment (< 24). Deficits were identified in the attention, short term memory and executive function domains of this instrument. There were no significant relationships between cognitive impairment and quality of life, symptom severity, depression, SG or TTO.

Patients were asked to complete a standard gamble (SG) and time tradeoff (TTO). The mean standard gamble score was 0.66 (range 0.1-0.99) suggesting that patients were willing to take at least a 35% risk to improve their health. The mean time tradeoff score was 0.69 suggesting patients were willing to trade at least 4 months to improve their health. There was a strong correlation between standard gamble and time tradeoff scores ($r=.75, p< .001$). Additionally, patients who were under the age of 55 were significantly more likely to take risks and trade time than patients who were over 55 ($p<.05$). No significant associations were identified with either the standard gamble or the time tradeoff and any of the other variables.
It is important to note that patients were unaware of their transplant and/or LVAD candidacy during data collection. The decision regarding transplant or LVAD candidacy was determined after patients had completed the questionnaires and interviews. The decision for each patient was recorded after it had been made during transplant team rounds. The sample was then compared based on this eligibility; patients listed for transplant (n=37) versus patients not listed for transplant (n=38). Not listed patients included those who were deemed “too early” and those who were not transplant eligible. Patients who were listed had a significantly higher mean score on the physical subscale of the MLHFQ (p < .05). There was a trend towards poorer overall QL, overall health and time tradeoff scores for patients who were listed but this did not reach statistical significance (p .08). The group was then divided into 3 groups; listed (n=37), too early (n=18) and not transplant eligible (n=21) (Table 5). A one-way ANOVA identified that patients who were not transplant eligible had significantly lower MLHFQ total and physical subscale scores (better quality of life) than patients who were listed (p<.05) (Table 5). However, the average age in this group was 61 years which was significantly older than either of the other 2 groups. Therefore, we cannot attribute the significant difference in quality of life to transplant eligibility alone.
Table 5 - Comparison of Quality of Life Scores between Patients who are Listed, Too Early and Non-Transplant Eligible

<table>
<thead>
<tr>
<th></th>
<th>Listed (n=37)</th>
<th>Too Early (n=18)</th>
<th>Not Transplant Eligible (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLHFQ Total Scores Mean (SD)</td>
<td>68.6 (19.9)*</td>
<td>65.4 (24.0)</td>
<td>54.43 (26.9)*</td>
</tr>
<tr>
<td>MLHFQ Physical Scores Mean (SD)</td>
<td>29.44 (9.6)*</td>
<td>26.06 (11.6)</td>
<td>22.33 (10.1)*</td>
</tr>
<tr>
<td>Age Mean (SD)</td>
<td>52.4 (11.2)*</td>
<td>52.37 (8.3)</td>
<td>61.14 (10.9)*</td>
</tr>
<tr>
<td>NYHA</td>
<td>IV</td>
<td>IV</td>
<td>IV</td>
</tr>
<tr>
<td>% EF</td>
<td>23</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td>BNP</td>
<td>1186</td>
<td>1035</td>
<td>1059</td>
</tr>
</tbody>
</table>

*p < 0.05;  NYHA = New York Heart Association classification; EF = Ejection Fraction; BNP = Brain Natural Peptide

RESULTS OF THE QUALITATIVE STUDY

If we consider the results of the quantitative study as a whole, symptoms of heart failure contribute significantly to quality of life but quality of life does not contribute to the patient’s decision to proceed with heart transplant or LVAD implant. This interpretation is supported by the lack of a significant relationship between measures of quality of life and either the standard gamble or the time tradeoff. However, taken individually we can conclude that overall quality of life is poor and many patients are willing to take significant risks and trade considerable time to improve their health. Understanding how patients make decisions regarding heart transplantation and LVAD implantation involves concepts that may not be easily captured by quantitative measures. Talking to patients about how they make the decision may help us better understand factors they identify that influence the decision to have a heart transplant and/or LVAD implant. Seventeen interviews were included as part of
the qualitative study. The characteristics of the qualitative sample are reported in Table 6. They were representative of our clinic population, 70% male with an average age of 56 years. Most patients were followed by the Toronto General heart failure team prior to initiating the assessment (70%) and were interviewed in the heart function clinic after their visit (82%). The interviews were conducted and the data analyzed according to the constant comparative methods proposed by Strauss and Corbin.124

Table 6 - Characteristics of the Qualitative Sample

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Qualitative Sample (n=17)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>56</td>
</tr>
<tr>
<td>Range</td>
<td>41-77</td>
</tr>
<tr>
<td><strong>Sex, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>70</td>
</tr>
<tr>
<td><strong>Etiology (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Dilated</td>
<td>30</td>
</tr>
<tr>
<td>Ischemic</td>
<td>40</td>
</tr>
<tr>
<td>Other</td>
<td>30</td>
</tr>
<tr>
<td><strong>Location of Interview (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Clinic</td>
<td>71</td>
</tr>
<tr>
<td>Inpatient</td>
<td>29</td>
</tr>
<tr>
<td><strong>Known to Team (%)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>70</td>
</tr>
</tbody>
</table>

The concepts emerged over time and through the use of the constant comparative method. There were 2 main categories influencing the decision to proceed with heart transplant and/or LVAD implant; heart failure-related and those pertaining to trust. Entrustment emerged as the meaningful process used by patients to make decisions regarding heart transplantation and/or LVAD implantation. Patients trusted the physicians to make good decisions regarding their candidacy for heart transplantation and trusted the surgeons to get them safely through the operative procedure. Entrustment had 3 main domains; (1) a cognitive domain consisting of facts and information patients use to make a decision (2) an affective domain including perceptions and emotions that influence how and why decisions are made and (3) a
behavioural domain consisting of strategies patients may use to help them manage the doubts and fears elicited by their situation. Concepts associated with heart failure that impact this process have been categorized into these respective domains. These are the patient’s stories, told by them and interpreted by me. Where relevant I have labeled concepts the same as those defined by McKneally et al (2000). I present it here not as a definitive model but as a representation to encourage reflection and discussion about how patients with heart failure make decisions regarding heart transplantation and/or LVAD implantation. Text that is in *italics* identifies a patient’s own words.

I. The Cognitive Domain

The cognitive domain includes the facts and information patients use to help them make a decision. Heart failure-related factors that affect the cognitive domain of decision-making include survival time and attitudes towards risk. Consistent with the results of the quantitative study, patients reported they were prepared to take significant risks and trade considerable time to improve their health. There was little variability in the information discussed by patients. It is important to note that while survival time and attitude toward risk are divided out for the purpose of this discussion, the two concepts interact to influence decisions regarding heart transplant and/or LVAD implant.

i. Survival Time

The concept of survival time includes perceptions of the information regarding prognosis patients received from the team and their own information search. Many patients quoted their perception of survival statistics: “30% show improvement in health, 30% go on to heart transplant or mechanical heart and 30% die.” Many had done their own research, talking to their doctors, searching information on the internet and talking to friends and family. The information search focused on options available for advanced heart failure, specifically heart
transplantation. Family often assisted patients in this process. The information they were discussing was biased towards survival – they all made the assumption they would survive the surgery if they proceeded with the surgical intervention.

The prominent feature in this section was not so much the information I heard, it was how it was presented. The 3 patients with acute onset heart failure did not want to talk about dying; it increased their emotional distress. They all cried when talking about dying and 2 wanted the interview stopped. I interpreted their comments and actions as being afraid to die. The response was very different for patients who had been living with heart failure for at least 1 year. Most of these patients discussed survival time and death in a calm and rational manner. They maintained eye contact. They did not become upset. Some made jokes. From this group of patients the response was they did not fear death.

“I’m totally not afraid of dying. I used to be, but not anymore.”

“No, I don’t believe I am scared of dying. When I think of it, it doesn’t traumatize me at all. Everyone dies.”

“When I was in emergency, I just about died. It’s not hard. There’s not a lot to do (laughs).”

“Dying doesn’t bother me.”

Discussions of dying led to talk regarding advance care planning and resuscitation preferences. Patients talked about “getting their affairs in order.” Getting your affairs in order included preparing a will, identifying a substitute decision-maker, reviewing their financial position and ensuring their family would “not suffer financially” should they die. One patient offered that this had been done, on the advice of the cardiologist, when he was told his prognosis. Another
patient offered that it was a difficult process “I know it’s not a very nice topic but you have to discuss it.” Some patients went on to discuss their resuscitation preferences.

“I don’t want to be resuscitated if I’m to a point where I’m no good, you know what I mean, like there’s no way of coming back or I’m going to be normal or whatever, I don’t want to be living on a machine.”

“I told the doctors in Bracebridge, if I don’t make it through the night, don’t you resuscitate me”

In addition to thinking through and identifying their preferences, these patients also said they had discussed them with either a family member or a clinician. Getting their affairs in order, identifying and communicating their advance care plans were strategies they used to avoid any additional burden on family if they die. It is interesting to note the acute onset patients who became upset had not done any advance care planning or determined their resuscitation preferences. They were in survival mode and wanted everything done to sustain life. Patients with an acute onset who did not become upset had survived cancer. They did not become upset when discussing death and had done some advance care planning during treatment for cancer. When asked how their cancer experience influenced their reaction to needing a heart transplant or LVAD, both patients matter-of-factly stated they had “dealt with their fear of dying” with the cancer diagnosis. They were not afraid. Many patients talked about a belief in a higher power. Patients who were religious talked about God. Others labeled it as fate. Belief in a higher power was manifested in 2 ways. Some felt they had no control over when they would die “Life is in God’s hands....” Almost as though life was pre-programmed and when they had achieved their purpose in life, it would end. For
others, dying was a transition to another life – it was not something to fear. One patient who believed in resurrection described dying:

“We have faith of resurrection. And resurrection would bring me back; so it’s just a matter of a long sleep. Faith is the main thing with that.”

The outcome of the decision was ultimately in a higher power’s hand. The patient’s job is to cope with whatever that outcome is. If death occurs, so be it.

ii. Attitude toward Risk

Patients reported 2 distinct attitudes towards the risk of surgical intervention. First, risk was specific to the surgical procedure. Very few patients went on to talk about the risks of living with a transplanted or mechanical heart. Second, patients dichotomized their situation into certain death with no intervention versus a chance of life with a heart transplant or LVAD. The acceptance of death discussed under survival time, allowed patients to consider taking significant risks for a chance at life. Worst case scenario, they died. With very little left to lose, most said they felt they had “no choice” but to proceed with heart transplant or LVAD implant.

“I have had a really awful 2 weeks here with some close calls. My heart is going downhill, I’m getting VT, which is now being controlled, but when I came in it wasn’t (pause) things are not going to improve. It’s (heart transplant) do you want to live or die?”

“Sure you can die (with the surgery). I got no choice.”

“The rewards (of a heart transplant) outweigh the risk”

For patients who had been living with heart failure for at least 1 year, the topic of risk was also discussed in a calm and rational manner. They acknowledged the risk associated with heart
transplant and or LVAD implantation. Patients commented that surgical intervention offered a chance of life versus certain death and the risk was acceptable. Following these remarks some raised an eyebrow, gave a slight grin – as if challenging me to suggest otherwise. Although not specifically addressed in the interviews, the patients who were calm and rational discussing death and risk were the same patients who talked about having their “affairs in order” and communicating their advance care plans. Perhaps completing these activities beforehand provides a sense of comfort to those considering heart transplant or LVAD implant.

iii. Transferred Trust

The cognitive domain of trust discriminates amongst individuals or institutions that a person deems trustworthy. In their heart failure narrative, patients described the series of referrals from general practitioner to our specialized heart failure program. When the needs of the patient exceeded the abilities of the attending physician, the patient was referred on to a higher-level of care. Patients talked about the trusting relationship they had with their general practitioner. Trust was transferred from the general practitioner to the local cardiologist and finally to our program at Toronto General Hospital. The recommendation of a trusted individual contributed to the ongoing development of trust through the successive levels of care. One patient described:

“....he basically told me there is nothing we can do more for you here, I have to transfer you. But then you know, he reassured me as well saying that “Dr.X is one of the finest in Ontario” so that also gave me a little bit of confidence.”

The transfer of care to Toronto General Hospital also affected trustworthiness. Toronto General Hospital has an excellent reputation in Canada and the media often portray it as a place where patients can get the help they need for complex or exceptional illness. The
transfer to Toronto General Hospital reinforced the perception that the patient was very sick and required the specialized care our program provides.

“Being transferred to Toronto General means you are really sick. I thought – this is really big!”

Patients trusted Toronto General Hospital and transferred that trust onto the practitioners who worked here. One woman who had very little experience with the team stated:

“I’m surrounded with so many brilliant individuals and they have all spent time with me, I feel confident that everything is going to go well.”

The recommendation of a trusted physician and the reputation of Toronto General Hospital promoted trust and may have influenced patients to enter into the relationship with our team in a position of trust.

iv. Behaviors that Supported Trust

Patients described how the attitudes and behaviors of our team enhanced the trusting relationship. All patients appreciated the direct and honest approach in delivering information about prognosis and treatment options. One patient described a situation that fostered trust:

“she said my name every time….. “

And a situation that fostered distrust:

“He (a medical resident) told me - You don’t have to worry about those numbers, that’s my business - and then he ran out again and I thought, am I dreaming or did he just treat me like crap. “
Spending time with the patient and “getting to know them” was also identified as enhancing trust. Patients felt physicians understood their values, beliefs and expectations. It facilitated treatment and made patients more likely to trust future treatment decisions:

“…..she says double up on the Lasix and within a week I have lost 13 pounds and I am sleeping a bit more. We know then that she knows exactly what she is doing.”

The cognitive domain of decision-making consists of facts and information patients use to help them make a decision. In our sample, patients were aware they faced certain death without intervention. Risk was irrelevant as patients perceived they had no choice but to proceed with surgical intervention. Trust was identified as a key component of decision-making and was established long before patients met our team.

II. The Affective Domain

Experience with this patient population has led me to start almost every encounter by asking patients to tell me their “heart failure story”. These narratives are an important means of conveying information on quality of life and identifying relationships that may not be easily captured by quantitative instruments. Consistent with the quantitative study, patients described how worsening symptoms of dyspnea and fatigue contributed to poor quality of life. However, though quality of life had no relationship to treatment preferences in the quantitative study, it was identified as a major factor in decision-making in the qualitative study. Specifically, the emotional distress generated by poor quality of life persuaded patients to proceed with heart transplant and/or LVAD implant. The needs of others were also identified by patients as an important factor in decision-making. Caregiver burden and worry were 2 additional concepts that affected patient perceptions regarding the needs of others.
iii. Quality of Life

In this sample, most patients described their overall quality of life as poor. Dyspnea, fatigue and poor concentration were the symptoms patients consistently identified that contributed to a poor quality of life. Symptoms elicited negative emotions – the sensation of breathlessness was described as “frightening”, fatigue as “troublesome” and poor concentration like “living in a fog”. Symptom severity and the unpredictable nature of heart failure were integral to their overall assessment of their quality of life. The distressing and unpredictable nature of their symptoms meant patients were living with a high degree of uncertainty in their lives. Uncertainty increased emotional distress. The distress seemed to be manifested in different ways depending on the length of time patients had been living with heart failure.

Five of the patients who were interviewed were experiencing their first acute exacerbation of heart failure. Three of these patients described their symptoms as life-threatening and were scared and/or overwhelmed. One patient described feeling like “being hit by a bus” another as “I got scared....I cried.” Patients experiencing their first acute episode did not comment on the unpredictable nature of heart failure. They focused almost exclusively on the symptom severity. Three of the patients cried and 2 asked to stop the interview when they got upset. They were not only experiencing severe symptoms, they also had very little energy left to get their emotions under control. These patients were in survival mode and decisions were instinctive and not rational. They wanted to feel better and would do just about anything to survive. The other 2 patients were cancer survivors and did not respond in this fashion. They were neither scared nor overwhelmed. Their experience with cancer had mediated their emotional response to living with heart failure.

Patients who had been living with heart failure for at least 1-2 years were the majority of those interviewed. They were also experiencing a high level of emotional distress but they
were frustrated, not scared. They mentioned their symptoms but focused on how symptoms disrupted their lives. One patient summed it up by declaring “I am sick and tired... of being sick and tired!” When patients had minimal symptoms they were able to get out and enjoy life with family and friends. When patients experienced unpleasant or high symptoms, they were unable to do even the simplest of tasks. Patients described heart failure as “taking over their life” causing them to give up things they’d enjoyed and making sacrifices.

“Heart Failure is a hideous disease as there is no pattern to it and it drives people insane if they try to formulate a pattern to it. One minute you feel great, the next minute you feel shitty. It’s all over the board. As much as you try to say, ‘well if I do this, if I don’t do that’, it doesn’t seem to follow any pattern. That is just it. I’m just at the point now of saying, just get this thing (points to heart) out of there and let’s go on with a new heart and stabilize.”

Patients were frustrated, some were angry at the disruption the heart failure was causing in their life. It was as if they were mourning the loss of their former lives. These patients used “normal” to describe their life before heart failure and “not normal” to describe their life with heart failure. For example, one patient described having a transplant as “A milestone...my chance for a normal life again.” Another patient described a period of relative stabilization as her “feeling normal again.” It seems having a heart transplant is envisioned as a way of restoring two essential elements of their normal lives – predictability and freedom from symptoms.

Finally, I interviewed three men in their 70’s who had been living with the disease for over 5 years. These patients had been living with heart failure for a long time and were able mitigate the emotional effect of living with heart failure. Being older, they were
also more accepting of life’s inevitable conclusion. These 3 patients were resigned to living with heart failure.

“If things just carry on the way they are now; I can live like this and still enjoy life.”

“I get up in the morning, I eat well. I still go shopping, travelling now and again, maybe when I shouldn’t. But otherwise, no, it (quality of life) doesn’t bother me.”

Perhaps it was their age, but the 3 men described ways to continue enjoying life while living with heart failure. They did experience anger and frustration with the limitations imposed on them by heart failure, but it was short-lived. They talked about how they developed strategies to manage their symptoms. They described living day-to-day, accepting the unpredictable nature of heart failure but not dwelling on it. They described just getting past the bad days and resuming activity when symptoms improved. They accepted the life-limiting nature of heart failure and had decided to live out the remainder of their lives without intervention. They knew they were going to eventually die from heart failure but for them, that was ok. When I asked them why they were considering heart transplant and/or LVAD they responded that they wanted to make sure they had considered all the options. If they were deemed acceptable candidates, they would then make the decision whether or not to proceed.

iv. The Needs of Others

As heart failure progresses, relationships with friends slowly fade. One patient describes this process as:

“When you’re healthy you are part of the herd. When you’re not healthy you are not part of the herd, and they tend to cull you out.

That’s just the way we are; a herd of elephants and a herd of humans,
not that different. The stronger you are, you perform a function, you’re fine, they keep you around. When you’re weak, they may toss you.”

As friends disappear, the responsibility associated with worsening heart failure is assumed by family. Patients described how family provided both direct patient care and assumed roles formerly allocated to the patient. Patients also reported how their family provided emotional support, listening and helping patients work through their feelings as well as compensating for memory deficits caused by fatigue and cognitive impairment. Using a cellular analogy, the importance of family becomes up-regulated in Stage D heart failure. Family becomes their purpose in life.

“to be a family and to do the things that your put on this earth to do; a wife, a mother, to take care of your family”

“I’m looking forward to seeing my kids get married and having grandchildren.”

Another patient with no family did not want to proceed with heart transplant. He described:

“A lot of times I think this (heart transplant) will just prolong this, and it’s not good to anybody. It’s not like I want to die, but life sucks. The only thing I’ve got in life right now is my dog.”

Initially I thought the decision to proceed with heart transplant or LVAD implantation was a mutual decision made by the patient and family. Further inquiry suggested this was not the case. Families assisted in the decision-making process by helping patients examine the pros and cons of the decision, to help them remember information they had forgotten and to discuss potential outcomes of the different options. When patients were asked if they would proceed with transplant or LVAD implant even if their families were not in agreement, they
responded “yes.” They wanted to feel better. They offered that making a decision that was in agreement with the family was easier, but not essential. Family saw their role as supporting the patient in whatever decision they made. However, I did not interview any patient that held a different opinion from family members on whether to proceed with heart transplant or LVAD implant. Patients who disagree with family regarding the decision to proceed with heart transplant and/or LVAD implant might experience and describe a different set of circumstances than the patients interviewed in this study.

**Caregiver Burden**

Patients were worried about the effect heart failure was having on their family members. They consistently commented that caregiver burden was a significant determinant in their decision to proceed with surgical intervention. Burden was defined as “…not being able to care for yourself,” “being dependent on others” and “constantly depending on others to look after you.”

One patient regretted being sick because her teenage daughter “was taking an adult role at 16 because we live alone…….I just don’t want her to feel she has to take on everything”. Some patients seemed to understand that caregiver burden was unavoidable when there was a person living with heart failure. However, they did seem to regret the effect their illness was having on their family;

“She knows that I’m going to die before her. I’m sure sometimes she thinks better sooner than later. It’s still a romantic story…ours, so she would be upset. She must think about it. I’ve become a burden.”

Having a heart transplant and/or LVAD implant was not only a way for patient’s to feel better it was also a way to reduce the burden their illness has on the family. Little mention was made of
the effect of living with a transplanted or mechanical heart on caregiver burden. Patients tended
to focus on the transplant procedure and avoided thinking too far into the future.

Worry

Throughout the interviews there was an undercurrent of worry that permeated discussions
about the needs of others. Patients described feeling that they had little control over the effect
of their illness and its treatment on their family. Worry surfaced as a significant factor for
patients who had experienced an ICD shock. Receiving or witnessing an ICD shock was
consistently described as distressing. While patients and family members acknowledged they
could not predict a shock, the worry about it firing again prevented many of them from
engaging in activities that may provoke it. One patient talked about the worry of her ICD
firing again:

“You know it is there to protect you, but you don’t want it to go off – cause it hurts like hell. I’ve
been on the receiving end of it. So you have to get your mind around that, which is difficult in
itself.”

I asked patients when they thought they would stop worrying. They responded “when I get a
new heart.” Worry is an emotion focused on an anticipated threat and won’t stop until the
threat is eliminated. Getting rid of their old heart was a way to eliminate the threat. A new
heart would improve their health and minimize burden as well as get rid of the implanted
leads that deliver an ICD shock. Worry seemed to reinforce the need to make a decision that
was in the best interest of the family unit and may explain why I initially thought the decision
to proceed with heart transplant and/or LVAD implantation was a mutual decision between
patient and family. In a broader sense, the work of worry takes energy away from efforts to
manage emotions for decision-making. Given the limited energy these patients have, worry may hinder their ability to manage emotions and indirectly affect decision-making.

The affective domain of trust stresses the relational aspect of decision-making and acknowledges the moral agency of the physician. Patients living with Stage D heart failure have limited resources to manage the emotional distress while attending to and remembering the complex information regarding the risks and benefits of the proposed procedure and alternatives. Patients regularly commented on how they felt they did not have the required knowledge or expertise to determine if heart transplantation and/or LVAD implantation was the right thing to do. Instead they described trusting the physician and surgeon to make good decisions on their behalf. Patients identified trusting the expertise of the physician rather than medical information as the deciding factor when they resolved to proceed with heart transplant or LVAD implant.

v. A Belief in Expertise Rather than Medical Information

Patients described the information regarding heart transplantation and/or LVAD implantation as complex. The consistently reported how they felt unqualified to understand the information, apply it to their situation and determine if heart transplantation and/or LVAD implantation was the right thing to do. Patients described how they trusted the physicians to synthesize the complex information and make recommendations based on their specific situation.

“You put yourself in the hands of the people who know....”

“I just trust her judgment totally. So if she thinks I need a transplant... then I need a transplant...I don’t question it.”
The complex nature of the information and the limited resources available to manage emotional distress meant most patients preferred to believe physician assessments over an interpretation of information. Patients trusted the physicians to decide the most appropriate course of action based on expert knowledge and the values, beliefs and treatment goals of the patient.

vi. **Acceptance of an Expert Recommendation as Consent to Treatment**

The degree of trust used for decision-making varied amongst patients. Those who presented with their first episode of heart failure and were referred for transplant assessment based much of their decision on trust. They could not recruit the energy required to mediate the emotional distress. They wanted to live and needed to trust the team to help them do so. One patient who based his decision on an expert recommendation started to get angry when I kept asking about his role in decision making. He stated:

“I think you’re making it like it was an offer or a choice I had. I had no choice on the thing. They came they asked me a few questions about state of mind and about this and about that and then said we’ve decided that we’re going to put you on the list. It wasn’t like I had a choice. There was no decision making there on my part. It’s just how do you feel, how’s this, how’s that. I could only provide information. The decision was nothing to do with me.”

He did not perceive himself to be making an informed decision. He based his decision on the expert recommendation of the physicians.

Others who had a long-term relationship with the team and who were relatively stable focused on “getting on the list.” Meeting the requirements for transplantation and/or LVAD implantation was a milestone. Getting on the list meant the team felt you were an appropriate
candidate for heart transplantation. Patients talked about heart transplantation as a limited resource where only the best candidates are accepted.

“….as long as I’m being put on the list….not everyone gets put on the list, they only have so many hearts and there are so many people. Who is the most likely candidate that will succeed with a new heart and he happens to meet that criteria.”

These patients trusted the rigorous assessment process to determine if they should proceed with heart transplant and/or LVAD implant. Finally, the decision to be placed on the transplant list demonstrates the trust patients place in the physician, the team and the institution.

III. The Behavioral Domain

The behavioural domain includes strategies that patients use to manage the doubts and fears associated with the decision. The label “managing doubts and fears” has been used to describe this process. In earlier versions of the model I originally labelled these strategies as coping. In their interviews patients reported using a plethora of coping strategies to help them manage the emotional distress associated with having heart failure. It is important to note that I did not specifically ask patients about how they were coping or what coping strategies they found helpful. Coping was identified as a concept after I had completed selective coding on a number of the interviews. When I looked back at my list of codes, I noticed a number that were coping-related codes. Descriptions of coping were not explicit. They were embedded in the patient’s description of their heart failure story and their reaction to hearing they needed a transplant. Patients used a range of coping strategies, both positive and negative, in various combinations. However, I felt managing doubts and fears was a more accurate description of the specific strategies patients used during the decision-making process. Patients described comparisons to
other patient groups, comparisons to previous stressful situations and “thinking positive”.

Reframing the illness in this way helped modulate the negative emotions evoked by the illness.

Comparisons were made to two main patients groups; people who had survived a heart transplant and patients with cancer. Many patients described meeting a heart transplant recipient in a mentor role from our program or others within their social circle who had survived a heart transplant. When describing the heart transplant group, patients focused on the positive aspect - golfing, going back to work and travelling to Florida. For example, one patient described his experience:

“……we could overhear this guy, he seemed like he just won the lottery. He had his transplant in May and this was July. It was pretty encouraging. And my friend in Ottawa, in the newsprint business, he was pretty encouraging too. He couldn’t golf, and he had a transplant and now he’s back golfing and feeling pretty good. We’ve met people who have had a positive experience about heart transplant. And that makes you hopeful.”

Comparing themselves to others who had been in a similar situation and survived supported the decision to proceed with heart transplant or LVAD implant.

Patients also compared their situation to others living with cancer. In this respect, they focused on negative aspects of cancer – incurable, a difficult death and painful.

“A number of people, they have cancer, and the life was not good…. they have died very difficult because of cancer.”

Patients seemed to dichotomize cancer and heart failure into incurable and curable respectively. One patient described it as:
“I’m blessed that I have this option. I have to look at it realistically. It’s not like someone came in and said, ‘you have 6 months to live, and by the way, we don’t have any options for you.’ I think that would be tougher. At least this way, there is an option, great.”

This patient was referring to the diagnosis of cancer which he perceived as having no treatment options. On the other hand, there were options in heart failure. Comparing themselves to others who they perceive as being worse off helped make their situation seem less dire.

Comparisons were also made to other stressful situations in their past. Having survived something in the past seemed to induce confidence that they would also survive heart failure. One patient described how life had been tumbling out of control. But, he felt his illness was an opportunity to readjust his lifestyle:

“If I got a heart transplant….then I have to go back to doing what I was doing. Which although I love my job, was extremely stressful, extremely hard work and I don’t think people appreciate how difficult it is. It’s been my biggest fight…trying to control my life, control my workload, and control my stress. So partly it’s (heart failure) a little bit of a blessing, now I don’t have to argue about that, this is just what it is.

His illness gave him a reason to slow down and limit his work. Framed in this way, heart failure is an opportunity. Other patients reflected back on difficult medical situations in their past, cancer diagnoses, emergent cardiac surgery and recovery from drug addiction. One patient offered: “This is not the worst situation I’ve been in….It’s not the worst thing!” Past experience with an acute illness was a powerful tool. Strategies developed with their past illness can now help them fight this situation.
Finally, almost all patients chose to reframe the emotional aspects of their illness in a positive way. Patients used phrases such as “being positive,” “Looking at the bright side” and “being optimistic” to describe their outlook. One man offered:

“And we’ll move forward from there, march straight ahead into a positive experience.”

Reframing the situation as positive seemed to offset the worry some patients and their families were experiencing in response to heart failure. Positive thinking allowed worry to be modified into problems they had control over. One patient’s wife described it as:

“I don’t worry anymore – I have to get positive. As long as something is going on and we’re progressing....as long as he’s being put on the list....”

Worrying about him getting sicker was ineffective. Instead, she chose to focus on his acceptance to the heart transplant recipient list. Similar to positive thinking, hope was also a strong mechanism. Hope included “hope for the better,” “hope for a miracle” and “hope to stay alive long enough to receive a donor heart.” Positive thinking and hoping for a good outcome were effective strategies this group of patients employed to help them manage the negative emotions associated with heart failure and its management. With this perspective they felt heart failure was a manageable experience.

IV. Living with the Decision

In the interviews patients talked as if they “knew” what the outcome of the assessment process would be. In most instances they were right. “Knowing” was influenced by 2 clinician-generated factors. First, the physician would often give their opinion on the patient’s likelihood of being transplant/LVAD eligible prior to initiating the assessment process. Second, during the assessment process patients were informed of the results of their
tests when they were available and told how the results would affect their eligibility. Patients used this information to help them foreshadow their future and they talked about how their life would change once the decision was made. For patients who believed they were transplant eligible, getting on the list was a milestone. Once on the list, patients recognized they would have to make some changes in their life to make sure they were still transplantable when a donor heart was found. These changes were minimized.

“...carry a beeper and be available. Have to stay close to home. Not a problem, that’s my life right now.”

When I asked what the future would look like, very few patients talked about living with a transplanted or mechanical heart. Most patients focused on the procedure itself. Patients talked about being scared about having open heart surgery, post-operative pain and one patient even mentioned being scared of the “rib separator.” Other patients, who had either heart surgery or an ICD implant, talked about the procedure within that context. Having survived a surgery seemed to give them some confidence but they worried about recovery from surgery:

“I’ve had heart surgery before and I wasn’t really afraid of that but I think this is just different because they’re actually taking a body part out. And just wondering what I’m going to feel like after, you know hoping everything’s going to be ok...”

Patients assigned surgical competence based on their interactions with the surgeon. One patient explained her interaction with the surgeon:
“Dr (surgeon) came in to see me and he was quite entertaining and I knew he was really good at what he does, and he just made me feel so much more confident in the procedure. So that really helped.”

Believing in the skill of the surgeon helped patients accept the risk of the procedure and gave them confidence they would have a good outcome. Since they had no actual knowledge of his operative skills, they used their interactions to determine competence.

Patients who thought they had a low probability of being accepted for transplantation were older patients who had been living with heart failure for a number of years. For these patients, going through the transplant assessment process was a way to ensure they had considered all potential treatment options. One patient was not transplant eligible but was being considered for LVAD support. He describes his thoughts:

“When I was told that heart transplant wasn’t an option it made me think more seriously….what is the positive? There is another option (LVAD). Maybe the heart transplant wouldn’t have been what I wanted. So being told I couldn’t have it wasn’t a disappointment.”

Further on in the interview he discussed that although LVAD implantation was an option, he had decided that his current quality of life was acceptable and he wouldn’t proceed with that option. His reasoning being that without a LVAD:

“….I can look after myself, I prefer to do that….short of breath, tired, I can live like that...... I can live like this and still enjoy life.”

Another man who had lived with heart failure for a number of years talked about the possibility of having a heart transplant: He described his thinking as:
“I guess you have to think, um, my heart is still working, so I don’t know how much worse it has to get. Right now, I don’t know whether I would say yes or no. It (heart failure) hasn’t stopped me from doing what I want to do.”

These 3 patients told me that proceeding with the assessment process is a way of ensuring they’ve considered all available treatment options. They did not think they would be transplant eligible. The acceptance of their ineligibility, prior to the final decision, may represent the team’s ability to ascertain and successfully communicate who is and is not eligible for transplant. It may also represent the patient’s preference to forgo the surgery. Regardless, all 3 felt they had made the decision not to proceed, had reframed their quality of life as acceptable and had gotten on with living. Two of the 3 patients were not eligible for either heart transplant or LVAD implant. They accepted the final decision. The third patient was eligible for LVAD implant but declined the surgery. He preferred to live out his life without intervention.

Entrustment was the meaningful process of consent and formed the basis for the risk taking required to proceed with the high-risk surgery. The entrustment model of consent for high risk surgical procedures can be summarized as follows. The cognitive domain consists of facts and information patients use to help them decide if they will proceed with surgery. Patients reported dichotomizing the information on survival time and risk as either certain death without intervention or a chance at life with surgery. Patients who had identified a substitute decision-maker and completed advance care directives said it made it easier for them to accept the risks associated with surgery. If they died, they felt they had done as much as they could to ease the burden of decision-making on those they left behind. Patients also reported how the series of referrals, initiated by a trusted general practitioner and the reputation of Toronto General Hospital as a trustworthy institution, led patients to enter into a relationship with our team in a position of trust. Communication strategies demonstrated by our team enhanced trust. They felt
the clinicians on our team understood their goals, values and expectations. The affective domain includes the perceptions and emotions that affect the decision to proceed with surgery. Patients described wanting to proceed with surgery to improve their poor quality of life, high symptom severity and reduce the worry and burden experienced by their caregivers. Additionally, patients felt the information presented during the assessment process was complex and felt ill-prepared to determine if proceeding with the surgery was the right thing to do. They reported how they trusted the team to synthesize the information and make a recommendation based on their specific situation. Patients agreed to proceed with surgery based on this expert recommendation. Finally, comparison to other people, past situations and positive thinking were behavioral strategies that helped manage the doubts and fears associated with the decision. Reframing their situation in this manner helped patients manage the emotional distress generated by their situation. This model is appropriate for decisions regarding high-risk surgery where choice is binary – accept intervention or die. It integrates the perspective of the patient who is responsible for articulating their treatment goals, values and expectations and emphasizes the moral agency of the physicians who are responsible for narrowing the treatment options down to those that are medically reasonable.
COMPARISON OF RESULTS BETWEEN STUDIES

The results of each study were examined to determine which concepts would be included in the final model of decision-making for heart transplantation and/or LVAD implantation. Results for inclusion demonstrated moderate support within either the quantitative or qualitative method and at least partial convergence between methods.

I. Convergent Results

The mean scores from the quantitative instruments were compared between the quantitative and qualitative samples (Table 7). The qualitative sample had similar ratings on the quantitative instruments to the quantitative sample. The qualitative sample did have lower overall health and higher dyspnea scores than the quantitative sample. The relationship between quality of life, overall health and symptom severity was corroborated in the qualitative study as patients described how higher symptom severity meant poorer quality of life.

The mean scores on the standard gamble and time tradeoff suggested patients were willing to take significant risk and trade considerable time to improve their health. This finding was also supported in the qualitative study. Patients reported how they wanted to proceed with heart transplant and/or LVAD implant to help them live longer and feel better. They described being willing to take significant risks to improve health. Accepting death and “getting their affairs in order” were strategies patients identified that helped them accept the life-limiting nature of heart failure and accept the risks associated with the surgical procedure.
Table 7 - Comparison of Mean Scores on Quantitative Variables between the Quantitative and Qualitative Samples

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Quantitative Sample (n=76)</th>
<th>Qualitative Sample (n=17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLHFQ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>63.6</td>
<td>64.5</td>
</tr>
<tr>
<td>Physical</td>
<td>26.6</td>
<td>28.2</td>
</tr>
<tr>
<td>Emotional</td>
<td>14.8</td>
<td>14.1</td>
</tr>
<tr>
<td>VAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall Health</td>
<td>40.3</td>
<td>33.6</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>53.1</td>
<td>60.6</td>
</tr>
<tr>
<td>Fatigue</td>
<td>61.7</td>
<td>60.9</td>
</tr>
<tr>
<td>BDI</td>
<td>12.6</td>
<td>10.7</td>
</tr>
<tr>
<td>MoCA</td>
<td>25.8</td>
<td>26.9</td>
</tr>
<tr>
<td>Standard Gamble</td>
<td>0.66</td>
<td>0.70</td>
</tr>
<tr>
<td>Time Tradeoff</td>
<td>0.69</td>
<td>0.61</td>
</tr>
</tbody>
</table>

Consistent results were also identified for the concept of living with the decision. Specifically, patients who were deemed not transplant eligible had significantly lower MLHFQ scores (better quality of life) than patients who were considered candidates. This finding was supported in the qualitative study. Patients who were later deemed not transplant eligible described an acceptable quality of life. They were proceeding with assessment to ensure they had considered all treatment options. However, this group of patients was significantly older than patients who were deemed transplant candidates. It is unclear why this group of patients had significantly better quality of life. Patients who know they are not transplant candidates may be resigned to living out their life with heart failure and find ways to make the remaining time as enjoyable as possible. Older patients may be more accepting of death since they have had time to live their life and achieve goals they established when they were younger.
The quantitative scores for the 3 men who described an acceptable quality of life in the qualitative sample were examined. The average age for the 3 patients was 68 years. The mean ratings were as follows: age dyspnea (60), fatigue (64), MLHFQ total (42) and overall health score (41). This suggests that they were experiencing a level of symptom severity similar to the larger qualitative and quantitative samples. However, they rated their quality of life and overall health as better than patients in the quantitative sample. As described in the results section, these 3 patients had found ways to manage the unpredictable nature of heart failure and reported having an acceptable quality of life. It is an interesting finding that would benefit from further exploration in future studies.

II. Divergent Results

The main divergent finding was how quality of life affected the decision to proceed with surgery. No relationship was found between quality of life and treatment preferences in the quantitative study. However, in the qualitative study, patients described feeling compelled to proceed with surgery to improve their poor quality of life and reduce their symptom severity.

Analysis of the mean quality of life and symptom severity scores from both samples suggest ratings were comparable between the 2 groups. The type and amount of emotional distress may not have been easily captured by MLHFQ. Furthermore, quality of life was associated with the affective domain while the standard gamble and time tradeoff were associated with the cognitive domain. This example illustrates the complementarity of a mixed methods design. Sometimes quantitative instruments don’t capture the real issues facing patients. The cognitive and affective domains are separate constructs that require different methods to capture the essence of their contribution to the decision.

The needs of others and the related concepts of caregiver burden and worry were also identified as affecting patient decision-making. The needs of others were identified by all
patients who participated in the qualitative study as affecting the decision to proceed with surgical intervention. Caregiver burden and worry were mentioned by most. For this reason it has been included under the affective domain in the proposed model.

Finally, the interview transcripts were examined to determine how many of the patients in the qualitative sample mentioned trust. Twelve of the 17 patients mentioned trust during the interview. Ten of these patients were eligible for either heart transplant or LVAD implant and agreed to proceed with surgical intervention. One was not transplant eligible and the other declined surgery. Of the 5 patients who did not mention trust, 3 were listed - one was the first patient interviewed in this study, one had been diagnosed less than 1 month and one was an outpatient recently referred to our program. The remaining 2 decided not to proceed with surgery before the assessment was complete. Additional comments made by 30% of patients who would trade no time and take no risks during the standard gamble and time tradeoff in the quantitative study suggested they preferred physicians to determine if proceeding with heart transplantation and/or LVAD implantation was the right thing to do. Results from this study were found to confirm and extend the assumptions of entrustment identified in the McKneally et al (2000) study. It enriches the understanding of the consent process for patients considering high-risk surgical operations. Earlier versions of the model are included in Appendix F.
Figure 1- The Entrustment Model of Consent for Heart Transplant or LVAD Implant
CHAPTER 5 - DISCUSSION

The purpose of this study was to determine how patients make decisions regarding heart transplant and/or LVAD implant. The study design included a quantitative study to determine the factors that affect patient treatment preferences and a qualitative study to explore the process of deciding to have a heart transplant and/or LVAD implant. Results were compared to determine corresponding and contradictory findings between the 2 studies. Findings were configured into a model that illustrates the factors affecting the decision to proceed with heart transplant and/or LVAD implant. The theory of informed consent proposed by Faden and Beauchamp suggests understanding, voluntariness, capacity and the ability to make a decision are necessary elements for informed consent. Do patients with Stage D heart failure meet the requirements of informed consent? The results of this study suggest they do. Voluntariness was diminished by poor quality of life and high symptom severity and understanding was replaced by trust in the expertise of the physician/surgeon to make good decisions on their behalf. Entrustment emerged as the meaningful process for patient/family decision-making for heart transplant and/or LVAD implant. The discussion will include the application of the results of the study to the elements of informed consent followed by a discussion on the entrustment model of consent for high-risk surgical procedures.

THE ELEMENTS OF INFORMED CONSENT

I. Voluntariness

The traditional model of informed consent focuses on external factors such as force, coercion or manipulation that affect voluntariness. However, internal elements associated with heart failure may compel patients to consider heart transplant and/or LVAD implant as a way to
relieve unpleasant symptoms, improve survival time and quality of life. The results of this study support this interpretation. Voluntariness is diminished as patients perceive that if they want to feel better they need to accept the risks of surgery associated with heart transplant and/or LVAD implant.

Quality of life, symptom severity and perceived overall health were the variables associated with voluntariness. Most patients rated their overall quality of life as poor. Poor quality of life was associated with higher symptom severity scores, lower overall health and depression. These findings support the conceptual model of heart failure quality of life described by Rector.\textsuperscript{35} An increase in symptom severity limits physical activity reflected in the mean score of 26 (range 0-40) on the physical subscale on the MLHFQ. Unpleasant symptoms such as dyspnea and fatigue generate negative emotions such as anxiety, depression and worry resulting in increased emotional distress which is reflected in the mean score of 15 (range 0-25) on the emotional subscale of the MLHFQ. Low scores on both MLHFQ subscales result in a cumulative effect and a higher mean total score of 64 (range 0-105). The reciprocal relationship between symptoms, physical and emotional distress is supported by the significant relationship between MLHFQ total, physical and emotional subscale scores and each of the following; symptom severity, depression and overall health scores.

Patients were allocated into treatment groups by the decision (listed, “too early”, not transplant eligible). The transplant ineligible group reported significantly better quality of life than patients who were listed. However, the transplant ineligible group was significantly older than the listed group. Other studies have found that older patients have significantly better quality of life than patients who are younger.\textsuperscript{48,70-72} However, no such finding has been reported for transplant eligibility. Having a decision earlier in the process may give patients time to come to terms with
their situation and reframe their outlook in a more positive fashion. Thereby, allowing them to enjoy their remaining time with family and friends.

The results of this study support earlier reports of a significant relationship between hospital admissions and quality of life. Patients who had experienced at least 2 hospital admissions within 6 months of participation in the study had higher MLHFQ scores (worse quality of life) than patients with 1 or no hospital admissions. Multiple hospital admissions may increase patient concerns about caregiver burden, worry and uncertainty which increase emotional distress and contributes to poorer overall quality of life.

II. Capacity

Depression and cognitive impairment were the variables associated with the capacity element of informed consent. There was no association between depression or cognitive impairment scores and treatment preferences. These results are novel since no other study has examined the relationship between depression or cognitive impairment and treatment preferences in patients with heart failure.

Thirty percent of patients had scores indicative of mild cognitive impairment which is comparable to the rates identified using formal neurocognitive testing in candidates for heart transplantation. Deficits were identified in attention, short term memory and executive function which are also similar to those identified in other heart failure studies. The MoCA is a reliable valid tool that is quick and easy to use with an improved ability to identify mild cognitive changes compared to the Mini Mental Status Exam (MMSE). Adding administration of the MoCA to the transplant assessment protocol might help clinicians to identify mild cognitive impairments that might have been missed without the tool. Information regarding transplant assessment can then be tailored to offset cognitive deficits.
Thirty-eight percent of patients had scores indicative of depression with 13% scoring within the range of moderate depression. These rates are similar to depression rates identified in other heart failure studies. Like cognitive impairment, depression is under-recognized and underreported. The prevalence rate of 30% is concerning – these patients may be at risk of evaluating their situation negatively and failing to appreciate the positive aspects of treatment. Treating depression also offers another avenue to improve overall quality of life.

III. Decision

The Time Tradeoff (TTO) and Standard Gamble (SG) are utility measures that represent the decision element of informed consent. Consistent with findings from other studies, patients in our study reported they were willing to take considerable risks and trade substantial time to improve their health. Studies using the time tradeoff to measure treatment preferences for patients with heart failure have consistently found 2 distinct groups, a larger group preferring therapies that prolong survival time and a smaller group who prefer strategies that improve quality of life. The discrepancy in results from this study and past studies could be explained by sample composition. Results from past studies represent the treatment preferences of patients with Stage C & D heart failure. They were not at end-of-life. When presented with a hypothetical scenario about treatment decisions at end-of-life, patients may predict they would sacrifice quantity of life to improve quality of life. However, treatment preferences change. This sample was a homogenous group of patients with Stage D who were making end-of-life treatment decisions and our results may reflect treatment preferences for heart failure patients at end-of-life.

Patient- and situation-related factors such as perceptions, attitudes and beliefs affect how patients make treatment decisions. Attitudes toward risk and quantity of life were factors associated with the cognitive domain of decision-making that supported the decision to proceed
with surgical intervention. Many patients said they were aware they had a high risk of dying within 6 months. Most stated they did not fear death and many had identified substitute decision-makers, completed wills and advance care directives and had communicated their wishes to either family or the physician. Patients who had completed advance care directives were able to discuss death in a calm and rational fashion. Their approach was to proceed with surgery. They took comfort in knowing they had done everything they could to minimize the burden of decision-making for their family. Singer et al (1998) found that patients on dialysis for end-stage kidney disease (n=48) who had completed advance care directives, identified that completing ACD helped them prepare for death by giving them a sense of control and helped minimize the burden of decision-making for loved ones should they die. Additionally, patients identified that the ACD process gave them a way to think about and talk to their loved ones about dying. Materials that support the process of advance care planning are readily available in print, electronic and video formats. Encouraging patients to engage in the process is a relatively easy way for clinicians to help patients manage the emotional distress they may experience when they progress to Stage D heart failure.

The needs of others emerged as an important concept in the affective domain of decision-making. Worry and caregiver burden were concepts associated with emotional distress that seemed to predispose patients to prefer intervention. Past studies have identified that patients prefer treatments that decrease caregiver burden. The concept of worry has not been previously described in the literature on treatment preferences in heart failure. Patients who participated in this study acknowledged that they could not predict or prevent a shock from their defibrillator yet described how they constantly worried it was going to happen. Patients described worry as self-limiting and they felt it would stop when they received a new heart. Eliminating the threat (damaged heart), would resolve worry and re-establish control over their
lives. A new heart would eliminate future ICD shocks and their improved health would minimize caregiver burden. In this sense, worry supports a decision to proceed with surgical intervention. It is important to note that the surgical procedure was the limit of their deliberation. Patients did not consider how a transplanted or mechanical heart would influence caregiver burden.

IV. Understanding

The traditional model of informed consent proposes that patients take an active role in understanding the risks, benefits and alternatives to treatment prior to making a decision. As McKneally et al suggest, this model may work in the academic realm of ethics or law but does not represent the sick and vulnerable patients considering surgery for a life-threatening condition. The results of this study suggest patients considered the information complex and difficult to understand. Patients described how they trusted the expertise of the physician/surgeon to apply the information to the patient’s situation and determine if heart transplant and/or LVAD implantation was the right decision. This finding is consistent with the results from other surgical studies which found that patients do not fully comprehend the information disclosed during the informed consent process and instead trust in the surgeon to make good decisions on the patient’s behalf. Acknowledging trust as a substitution for understanding during the consent process does not negate the need to disclose information related to the proposed intervention, available alternatives, risks and benefits. Strategies such as consistency of information between team members, including family members in discussions, and using a variety of methods to provide information can improve the chance that patients will understand.

The majority of patients who participated in this study perceived having no choice but to proceed with surgery. Choice implies having more than one option from which to choose. For
example, patients with controlled atrial fibrillation may be asked to choose; (1) initiate anti-coagulation and do not attempt to convert the arrhythmia; (2) undergo chemical cardioversion with prescribed anti-arrhythmic medications that may or may not convert the arrhythmia over time or (3) undergo elective direct cardioversion where the patient is anesthetised and the heart is shocked back into sinus rhythm. Each choice has related risks and benefits and the patient can deliberate and choose which option best suits their needs. The patients in this study perceived that they had no choice. They dichotomized the situation as choosing to reject the intervention and face certain death or assume the risks associated with the procedure for a chance at life. Most patients did not engage in the thoughtful weighing of risks and benefits of surgical intervention suggested by the traditional model of informed consent. Entrustment emerged as the meaningful process of consent for heart transplant and/or LVAD implant. The patients in our study consistently reported how they trusted our physicians to make good decisions regarding their candidacy for heart transplantation and/or LVAD implantation and to get them safely through the surgery. Trusting the expertise of others has been offered as an alternative to the vigilance and rational calculation of risks, benefits and alternatives recommended by traditional models of informed consent.135

THE ENTRUSTMENT MODEL OF CONSENT

FOR HIGH-RISK SURGERY

Entrustment was the meaningful process of decision-making and formed the basis for the risk-taking required to proceed with heart transplant and/or LVAD implant. This process applies to patients considering high-risk interventions for life-threatening illnesses. Trust is an attitude of optimism in the goodwill and competence of another.130 It is a fundamental value in social relationships. As a driver I trust pedestrians not to cross the road against a red light and as a
pedestrian I trust drivers to stop at a red light. Children trust their parents and patients trust their doctors. Trust in the knowledge, skill and expertise of the clinicians becomes an important component of their decision. Additionally, a trustworthy person is someone in whom you can place trust and feel confident that your trust will not be betrayed. The entrustment model of consent for surgical treatment was described by McKneally et al (2000) in a sample of 36 patients considering high-risk esophagectomy for esophageal cancer. The entrustment model describes how patients considering high-risk surgical procedures progress from feeling vulnerable to feeling confident that the surgeon would make good decisions on their behalf with a high level of competence and fidelity to their trust. The entrustment model has 6 elements; cultural belief in surgical cure, enhancement of trust through the referral process, idealization of the specialist surgeon, belief in expertise rather than information, resignation to the risks of treatment and acceptance of an expert recommendation as consent to treatment. These elements are classified here into the cognitive, affective and behavioural domains of trust as identified by Lewis and Weigart.

I. The Cognitive Domain of Trust

The cognitive domain of trust helps discriminate among persons or institutions that are trustworthy. In their narratives patients described how trust was established even before they met our team. Patients trusted the referral process which was initiated by their general practitioner, a person they trusted to help them live longer and feel better. Trust was transferred from the general practitioner to the local cardiologist and finally to our program at Toronto General Hospital. Each successive referral reinforced their perception that they were sick and required the expertise of the physician or program they were being referred onto. Patterns of physician referral have been shown to play a part in supporting trust.
Patients described how the transfer of care to Toronto General Hospital was viewed as a last resort. Toronto General Hospital is perceived by the public as a place where patients can get the help they need for complex or exceptional illness. Patients trusted Toronto General Hospital and transferred that trust onto the practitioners who worked there. Once engaged with our team, patients described how communication strategies enhanced trust. Techniques such as sitting, making eye contact and active listening support trust in the doctor-patient relationship. Communication skills that promote trust are practiced by our attending physicians. All team members are encouraged to model these behaviors when interacting with patients. Having a program which emphasizes communication skills supports the trusting position of the patient considering heart transplant and/or LVAD implantation.

II. The Affective Domain of Trust

The affective domain of trust stresses the relational aspects of decision-making and acknowledges the moral agency of the physician. The relationship between the patient and the surgeon will be used to illustrate this point. High-risk operations like a heart transplant and/or LVAD implant involve the agreement of two people, the patient having the surgery and the surgeon who will perform the operation. Surgeons are independent moral agents who have made a commitment to their profession to serve the needs of patients. A surgeon’s character is cultivated over time and with the proper socialization habits are modified, practiced and ingrained. The pre-operative interview is not only an opportunity to disclose relevant information; it is also a chance to prepare the patient and surgeon for a potentially difficult pre-operative and post-operative course. Surgeons have identified that they would consider proceeding with high-risk surgery if the patient demonstrated a determination to recover or an intense will to live as long as the patient and family understand the risks involved and are willing to take those risks. In these situations, patients trust the surgeon to get them safely
through an operation and the surgeon trusts the patient to do as much as they can to promote recovery.

When patients trust, they delegate the responsibility for decision-making to the doctor. The decision to proceed is based on the expert recommendation of the doctor, not on a rational consideration of the risks and benefits of the procedure. Proceeding with a decision based on the expert recommendation of the physician was the rationale for the 30% of patients who were willing to take no risks or trade any time during the SG and TTO. All offered that they would defer to the expert recommendation of the physician and surgeon. They felt ill-equipped to determine if having a heart transplant and/or LVAD implant was the right thing to do. They trusted the cardiologist to determine if they were candidates. They trusted the surgeon to get them safely through the surgery. If the cardiologist and surgeon agreed they were candidates, they would proceed based on this expert recommendation.

The degree of trust used for decision-making varied amongst patients. Patients who were acutely ill and experiencing high emotional distress stated they did not make the decision to proceed with heart transplant and/or LVAD implant, the physician did. On the other end of the spectrum, patients in the non-transplant eligible group stated they made the decision to forgo intervention, not the physician. Even patients who value self-determination may defer decision-making to an expert when they are ill or uncertain. Insisting patients review and understand the complex information required for “informed” decision-making could undermine patient trust and have consequences for the therapeutic relationship after recovery from surgery.

III. The Behavioural Domain of Trust

The behavioural domain of trust includes strategies patients use to manage the doubts and fears associated with the decision and has been described as “living as if certain possible futures will
Specifically, an expectation of success with the transplant/LVAD surgery seemed to give them the strength to proceed. In the interviews, most patients said they expected to survive the surgery and anticipated a good quality of life with their transplanted or mechanical heart. Patients who perceive an intervention will return them to an acceptable level of health are willing to assume high risks to achieve that state. Results from the SG and TTO suggest that patients in this study were willing to take at least a 35% risk to improve their health. Some patients (25%) were willing to take as much as a 50% risk to improve their health. Believing you will be one of the few who benefits from intervention may provide incentive to keep going; accepting the risks of treatment for the small chance of a positive outcome. Knowing you are going to die and hoping you won’t, is a paradox that may not be easily captured by quantitative instruments.

The expectation of success described by the participants in this study may represent dispositional optimism. Dispositional optimism is a general and stable trait wherein a person expects that good outcomes will occur across life events. In a sample of 31 patients listed for heart transplantation, Leedham et al measured pre-operative optimism to determine its effect on post-operative adjustment, adherence and physical recovery. Optimism was measured using 7-items from the study specific “Quality of Life Scale” and included items regarding patient beliefs about the efficacy of treatment, chances for future health and survival and general feelings about the future. Data was collected at time of heart transplant listing, prior to discharge following heart transplantation and 3-6 months after surgery. At the time of listing, patients reported poor quality of life, moderate levels of distress and high optimism. After surgery, there were significant improvements in quality of life and distress. Optimism remained high and did not change over the duration of the study. At 6 months, there were significant positive relationships between optimism and quality of life, adherence and physical recovery as
well as a significant inverse relationship between optimism and distress. The relationship between preoperative optimism and postoperative quality of life has also been reported in samples of patients recovering from ACB\(^{143}\), women recovering from ACB\(^{144}\) and patients recovering from elective surgery.\(^ {145}\) Scheier et al\(^ {143}\) proposes both a direct and indirect effect of optimism on surgical outcomes and quality of life. Optimists are more likely to use problem-focused coping strategies such as setting goals, seeking information and making plans. In situations where there is a high degree of uncertainty optimists use positive reframing and humor to manage distress. The positive reframing used by patients in this study may in fact represent optimism. Although there is some evidence to support the positive effects of optimism on surgical outcomes, it remains unclear how optimism affects decision-making. Optimism is easily measured using the Revised Life Orientation Test (LOT-R). It would be beneficial to measure optimism in future studies examining treatment preferences for patients living with Stage D heart failure.

There is also evidence from both the quantitative and qualitative studies that patients engaged in a process of reframing their situation. In the quantitative study, patients who were not transplant eligible had lower scores on the MLHFQ (better quality of life) than patients who were candidates. The mean MLHFQ score of 54 for the transplant ineligible group is comparable to patients living with NYHA class III heart failure.\(^ {146}\) In the qualitative arm, patients who were not transplant eligible were resigned to living with heart failure and over time they had found ways to not only manage their symptoms but also to mitigate the emotional distress. All described their quality of life as acceptable. This small group of patients also perceived having a choice. They didn’t feel compelled to proceed with surgery and were using the assessment process as a way of ensuring they considered all treatment options before making a decision.
LIMITATIONS OF THE STUDY

First and foremost, the results of this study must be interpreted within the context of the sample. This was a highly selected group of patients with Stage D heart failure who had made the decision to consider surgical intervention and agreed to proceed with assessment for heart transplant and/or LVAD implant. Additionally, this was a vulnerable group of patients where the majority reported they felt they had no choice but to proceed with intervention to improve quality of life and their symptom severity. This may have unintentionally introduced some bias. First, there may be a social desirability bias if patients perceived how they answered the questions during the interview would affect their candidacy. This may have been amplified by the knowledge that the researcher was also a member of the clinical team. Emphasizing that the results of this study, or my participation in data collection, would not affect their clinical care may have been insufficient to overcome their desire to please the clinicians. Patients may have given responses which they thought clinicians would want to hear and may improve their chances of being accepted on the transplant recipient list. Second, the results of this study may represent a dispositional optimism bias. Optimism was not measured and this sample of patients may represent a particularly optimistic group. Third, patients who had considered and rejected surgical intervention and did not proceed with the assessment were not included in this study. It remains unclear how patients who consider and reject surgical intervention make decisions or if their decisions would satisfy the criteria of informed consent. To address the issues raised by these potential biases, future studies can examine informed consent by means of a prospective study starting when patients reach Stage D heart failure and following them over the course of their illness and decision-making. Measures of dispositional optimism should be included to determine how dispositional optimism affects results. Additionally, patients may answer
differently when the researcher is not associated with the team and patients are confident their responses will not affect their clinical care.

The MLHFQ was originally developed for use in clinical trials to assess the effectiveness of a medication or device on the quality of life for patients living with heart failure. As such, the 21 items on the MLHFQ focus on the physical and emotional characteristics of heart failure that you may expect to change with an intervention. Treatment preferences are not an intervention and the MLHFQ may not be responsive or sensitive enough to capture all the elements of quality of life that go into deciding to proceed with surgical intervention. In cross-sectional studies, its use may be limited to describing quality of life and examining differences between groups.

Sample size determination was based on studies reporting the relationship between quality of life and symptom severity for patients with NYHA II-IV heart failure. In retrospect, the sample size may have been too small to detect a significant relationship between quality of life and symptom severity to treatment preferences for a homogenous group of patients with Stage D heart failure. Our study represents actual treatment preferences at end-of-life and the real-time nature of this decision may have unintentionally introduced a source of measurement error and contributed to the lack of significant findings between the TTO and SG and other study variables. Past studies were conducted on patients with less severe heart failure where the scenario proposed by the TTO and SG was truly hypothetical. However, in this study, some patients had difficulty with the “magic pill” scenario used in the TTO and SG. They knew there was no “magic pill” and had difficulty equating its use to determine treatment preferences for a surgical intervention. Comments that arose during administration of the SG and TTO suggest that many used their current situation to answer the TTO and SG. In addition, the effect of fatigue, alterations in attention and/or memory associated with Stage D heart failure may have
limited their ability to engage in the complex reasoning skills required to complete the SG and TTO. Future studies using the TTO and SG to determine treatment preferences for patients in Stage D heart failure considering surgical intervention will need to incorporate these factors into the design.

In our program we support and encourage the process of advance care planning at time of diagnosis and with significant clinical change. Many of the patients who participated in this study would have received information and encouragement to develop and communicate their advance care directives. This may be why accepting death and advance care planning were identified as an important part of the overall decision-making model. It is unclear if the results obtained here are representative of other patients in different programs.

**FUTURE DIRECTIONS**

1. Implications for Research

The preponderance of cross sectional studies examining the relationships between quality of life, symptom severity and treatment preferences for patients living with heart failure is troublesome. Cross sectional studies are less expensive and easier to conduct than larger prospective trials. They yield important information regarding factors affecting treatment preferences at a specific point in time. Perhaps it is time to consider prospective analysis. Information on quality of life, symptom severity and treatment preferences could be collected at regular intervals from diagnosis of Stage D heart failure until surgical intervention or death. Results could be analyzed to determine if treatment preferences and/or the relationship to quality of life changes over time. Results from a prospective trial would also provide information regarding the relationship between quality of life and transplant eligibility; or if there is a threshold in quality of life and/or symptom severity that causes treatment preferences to change.
The results of this study suggest factors such as perceptions, attitudes and beliefs affect how patients make treatment decisions. These are factors not easily captured by quantitative instruments. Qualitative studies can be designed to explore how these factors affect decision-making. For example, the concept of worry has not been previously described in the literature on treatment preferences in heart failure. Understanding how worry affects the decision will help clinicians design interventions that reduce the anxiety provoked by worry.

Clinicians acknowledge and support trust in their clinical practice. Future studies need to acknowledge trust in patient decision-making for high-risk interventions. This is difficult since trust is a hard concept to measure. A mixed methods approach is an effective way to identify all factors that affect patient decision-making. The entrustment model of decision-making provides a framework for future studies. Studies could be conducted with other patient groups to ascertain if the concepts are applicable to other patient populations. Additionally, studies focusing on individual concepts would help to define and develop the concept as well as identify factors that affect it. For example, a qualitative study could develop the concept of transferred trust identifying factors that support or oppose trust. Both patients and clinicians could be interviewed to improve the reliability of results. Understanding the process of transferred trust would be helpful when a patient enters into a relationship with a specialist in a position of distrust. The process of transferred trust can be used to help clinicians identify how and why distrust occurred. Efforts can then be directed towards re-establishing trust between patient, family and the specialist team.

II. Implications for Practice

Patients who are not transplant or LVAD eligible may benefit from an earlier decision regarding transplant eligibility. However, referring patients for earlier transplant assessment is not feasible and in itself may cause increasing distress if the referral is unnecessary. Experienced
clinicians are fairly accurate in determining transplant eligibility prior to formal assessment and are mindful to balance the need to inform against the preservation of hope. If a clinician suspects a patient is not transplant eligible, the assessment could be initiated earlier to determine actual transplant eligibility. Those patients who are not transplant eligible can then be informed of the decision. The improved quality of life from the earlier decision would give non-transplant eligible patients more time enjoying life with family and friends.

The results of this study also suggest that approximately 30% of patients referred for transplant and/or LVAD implant have evidence of depression or cognitive impairment. Adding administration of the BDI and MoCA to the transplant assessment will help identify patients with depression or cognitive impairment. Diagnosing and treating depression or cognitive impairment earlier in the assessment period can help patients prepare for and manage the complex tasks associated with either heart transplant and or LVAD implant. Information regarding transplant assessment can then be tailored to maximize the cognitive abilities of patients. Ensuring consistency of information between team members, including family members in discussions, and using a variety of methods to provide information will also improve patient understanding.

Patients considering heart transplant and/or LVAD implant experience significant emotional distress that affects decision-making. The levels of emotional distress may not be high enough to warrant referral for formal psychosocial assessment and management. Additionally, many psychosocial teams are functioning on limited resources and may not be able to adequately manage each patient who is referred for transplant assessment. In our program referrals to the psychosocial team are limited to patients with clinical anxiety, depression and other psychiatric problems. This leaves most patients to manage emotional distress within their support network. Mindfulness based stress reduction (MBSR) uses a group format to help patients identify and
manage the stress associated with their illness. At Toronto General Hospital, we have implemented a MBSR program for post-transplant patients in our multi-organ transplant program. The program is well attended by both patients and family and evaluations have been positive. However, MBSR requires a trained facilitator and we are currently unable to provide this program to patients on the heart transplant waiting list. Peer support through our transplant mentor program has also been an effective measure. Mentors are post-heart transplant patients, identified by staff as having qualities amenable to peer support. They are provided with training to help others manage the wait for a donor heart as well as information on when someone needs additional support. If a mentor feels additional emotional support is needed they encourage the patient to seek help from the clinical team. This has been an effective strategy to provide most patients with some additional psychosocial support. Social media and remote monitoring may provide additional avenues to help patients manage the emotional distress associated with advanced heart failure and during the wait for a donor heart. Meeting the emotional needs of patients will continue to be a challenge for most heart transplant programs.

III. Implications for Education

The results of this study suggest patients who prepare advance care directives are more accepting of death and are able to discuss their chance of dying and the risk of surgery in a calm and rational manner. Information on advance care directives is readily available in video, print and electronic formats. Clinicians need to be proactive about providing patients with information on advance care directives. Our process of encouraging patients to complete and communicate advance care directives when they are diagnosed with heart failure seems to be an effective approach. Advance care directives can then be reviewed with any significant change in their condition. Discussing end-of-life treatment preferences with patients can be a difficult situation for some clinicians and programs need to provide opportunities for trainees to develop
these skills. Encouraging trainees to engage in these discussions with patients will help them build the confidence they will need to address these concerns as staff physicians.

CONCLUSIONS

The results of this study indicate patients with Stage D heart failure considering heart transplant and/or LVAD implant had poor quality of life and high symptom severity. Treatment preferences, measured with the TTO and SG, were not related to either quality of life or any of the symptoms: dyspnea, fatigue, depression or cognitive impairment. Patients who were not transplant eligible had significantly better quality of life than patients who were either too early to be listed or not eligible for transplant. Some patients who were not transplant eligible understood they were not transplant candidates at the time of referral; they were participating in the assessment process to ensure they had considered all available treatment options.

Transplant ineligible patients reframed their quality of life as acceptable, allowing them more time to enjoy their remaining life with family and friends. It is unclear whether it is older age or transplant eligibility that initiated the reframing process.

Other studies have found a significant relationship between quality of life, symptom severity and treatment preferences. However, past studies were conducted on patients with less severe heart failure (NYHA II-IV) using hypothetical scenarios to determine what they thought they would prefer if they were to progress to Stage D. This study was conducted when patients were making their decision regarding future high-risk surgical intervention for Stage D heart failure. For this group of patients quality of life and symptom severity were not related to treatment preferences. Decisions were affected by attitudes, perceptions and emotions not easily captured by quantitative instruments. Entrustment emerged as the most meaningful process for decision-making - patients trusted the physicians to make good decisions regarding their candidacy and the surgeons to get them safely through the surgery.
Do patients with Stage D heart failure meet the ethical and legal requirements of informed consent as described by Faden and Beauchamp? Capacity serves a gatekeeper function for informed consent. If a person is capable then it is a prima facie moral obligation to seek consent from that person (pg. 288). However, clinicians need to be aware that approximately 30% of patients living with Stage D heart failure have evidence of depression or cognitive impairment. Diagnosing and treating depression or cognitive impairment early in the assessment phase can help patients prepare for and manage the complex tasks associated with decision-making. Knowing the cognitive abilities of patients can also help clinicians tailor the complex information to maximize abilities and compensate for existing impairments.

The patients who participated in this study accepted the risks associated with surgery. Patients described how surgery would allow them to live longer, improve their quality of life and symptom severity as well as relieving caregiver burden and worry. In this sense, voluntariness was diminished but not absent and therefore meets this criterion for informed consent. The perception that they have no choice is a powerful motivator for patients considering heart transplant and/or LVAD implant. This perception is important for clinicians to understand and acknowledge when supporting and enabling patients making decisions regarding high-risk surgical interventions.

The informed consent model proposed by Faden and Beauchamp suggests patients should take an active role in understanding the risks, benefits and alternatives to treatment to fulfil the understanding element of informed consent. They felt the information presented to them during assessment for heart transplant and/or LVAD implant was complex and difficult to understand and described feeling unqualified to determine if proceeding with heart transplant and/or LVAD implant was the right decision. Although patients had difficulty comprehending information, the results of this study suggest they do understand. They understood they had a life-threatening
illness and without intervention they would die. They also understood the surgical risks including the risk of death during or after surgery. Patients understood that decisions were guided by national criteria that define candidates with the best chance of survival. They knew that if they were deemed transplant or LVAD ineligible, proceeding with surgery was of no benefit. From a broader perspective, patients seemed to understand that physicians and surgeons are duty-bound to offer interventions that are approved, acceptable and likely to benefit the patient. They understood the institutional and legal requirement to document the decision with a signed consent form. The signed form represented informed consent to them-their decision to voluntarily proceed with surgical intervention. Understanding is more than the comprehension of information. Understanding is appreciating the consequences of a decision. In this sense, the understanding demonstrated by patients who participated in this study fulfilled the requirements of informed consent. The entrustment model as described by our patients satisfies the criteria for informed consent. Understanding the experiences and perceptions described by the patients in this study will help clinicians support and enable treatment decisions made by patients living with Stage D heart failure.
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Stages in the Development of Heart Failure Recommended Therapy by Stage. ACEI indicates angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; EF, ejection fraction; FHx CM family history of cardiomyopathy; HF heart failure; LV, left ventricular; LVH, left ventricular hypertrophy; and MI, myocardial infarction.
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Appendix B:
Canadian Cardiac Transplant Group Criteria for Acceptance for Heart Transplantation and Left Ventricular Assist Device Implantation

1. Criteria for Acceptance for Heart Transplantation:

These criteria are designed to identify those patients who are at the greatest risk and will derive the greatest benefit from transplantation.

- Advanced functional class
- Poor 1-year survival – All ambulatory patients should undergo cardiopulmonary testing.
- A patient with a VO2 < 15 ml/kg/min or 55% predicted for age and sex is considered to have severe cardiac dysfunction and warrant further evaluation for transplantation
- Failed maximal medical therapy
- No surgical options - high risk revascularization should be considered
- All patients should exhibit the capacity for rehabilitation after transplantation
- Absence of contraindications

The following represent a list of co-morbidities that represent relative or absolute contraindications to transplantation.

1. Fixed pulmonary hypertension:

The following measurements after aggressive challenge with 1-2 inotropic or vasodilator agent and a SBP of 85mmHg should be considered a relative contraindication:

- Transpulmonary gradient > 15
- Systolic pulmonary artery pressure > 50 mmHg
- Pulmonary vascular resistance > 4 wood units
- Pulmonary vascular resistance index > 6.
2. Primary systemic disease that may limit the long-term survival e.g., hepatic, pulmonary
disease, renal insufficiency (creatinine > 200 µmol/l).

3. Active infection.

4. Technical issues as well as psychosocial issues, drug or alcohol abuse, and documented non-
compliance.

5. Recent malignancy (non basal cell carcinoma type).

6. Morbid obesity (> 140% ideal body weight) or marked cachexia (< 60% ideal body weight).

7. Osteoporosis, vascular disease (cerebral or peripheral) and diabetes mellitus with evidence
of end organ damage.

Criteria for Acceptance for LVAD Implantation:

Patients will be considered for LVAD Implantation when:

1. A low output state persists despite the use of at least 2 intravenous inotropic agents and/or
intra-aortic balloon pump support. Hemodynamic parameters include:
   - Systolic blood pressure <80mmHg
   - Pulmonary capillary wedge pressure (PCWP) > 20mmHg
   - Cardiac index <2.0L/min/m²

1. End-organ failure is imminent
   - Mixed venous saturation <60%
   - Rising serum creatinine in association with oliguria

2. There is a risk of imminent death

All other candidates must be screened and accepted for cardiac transplantation prior to
consideration of device implantation.
Appendix C: Interview Guide

Thank you for agreeing to participate in this interview. There are several reasons behind the study that we are conducting. One of them is to explore the factors patients’ consider when making decisions about heart transplantation or ventricular assist device implantation. Learning more about those factors allows the heart failure team to better understand the patient experience and to address these issues with patients before their operations.

There are no right or wrong answers for these questions. Your privacy, of course, will be maintained at all times and no one outside of the research team will be able to know how you answered these questions. The following questions are standardized for all participants, and are not necessarily specific to your clinical situation or treatment.

Do you have any questions or comments about any of this?

1. Can you tell me a little bit about yourself?

2. Can you tell me about when you were diagnosed with heart failure?
3. In general, do you believe that your illness has changed the way you view yourself? Has it changed the way that others see you? Has it changed in any way, the various roles that you play in your life? Please explain.

4. Who/what has been the most helpful in managing your heart failure?

5. What’s it like for your family?

   Who do you talk to about how your feeling?

6. Can you describe a typical day for you?

   What makes it a good day/bad day?

7. What it’s like to hear someone tell you, you need a transplant/LVAD?

   What did your family think/feel?

   Did you ever consider you may need a transplant/LVAD (die?)

8. How do you normally make decisions?

   Is this the same or different?
What/who helps you make decisions?

What factors do you consider in making the decision? Can you elaborate?

9. How much longer do you think you’ll live if you don’t have a HT or LVAD?

How does this influence your decision?

10. How long have you known the doctors taking care of you?

11. What do you think is the most important thing we can do to help you make this decision?

12. Do you feel that you have all the information you need to make this decision? Do you have any unanswered questions?

13. Is there anything else you think I should know or understand better?

14. Is there anything you would like to ask me?
Appendix D:
Examples of Free Nodes, Tree Nodes and Categories

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Hierarchical Ordering of Categories

- Making the Decision
  - Managing Emotions
    - Considering Others
      - Burden
        - Burden Defined
        - Worry
    - Quality of Life
      - Symptoms
        - Concentration
        - Dyspnea
        - Fatigue
        - This isn't living......
        - This isn't normal
        - Doesn't look sick
Appendix E: Approved Consent for Participation in this Research Study

Consent Form for Participation in a Research Study


PRINCIPAL INVESTIGATOR: Jane MacIver
CO-INVESTIGATORS: Dr. Martin McKneally
Dr. Heather Ross
Dr. Vivek Rao
Dr. Patricia McKeever

Introduction
You are being asked to participate in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation of the proposed study procedures. The following information describes the purpose, procedures, benefits, discomforts, risks and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time. In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the study doctor or study staff to explain any words you don’t understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

Purpose
This study is designed to try and understand how patients make decisions regarding heart transplantation or ventricular assist device (artificial heart) implantation. Talking to patients while they are actually making the decision may help us better understand the process and identify areas of importance not described in previous studies. During this study we will ask you to complete some questionnaires. These questionnaires give us general information on your quality of life, symptoms and treatment preferences. We may also ask you to take part in an interview. The interview provides us with information on how your values, beliefs and experiences of living with heart failure influence your decisions. Your answers and comments will provide insight into how patients with heart failure make treatment decisions.

Procedures
If you agree to participate in this study, you will be asked to complete 6 questionnaires before you meet with the doctor to discuss your treatment options (about 30 minutes). We would also...
like to collect information about your heart failure and your medications from your hospital chart. If you agree to be interviewed, you will have a one-on-one interview with a member of the research team. This interview will take about 1 hour to complete. If you are an outpatient, the interview will be done on a day that you would normally come for your clinic visit. The interview will add about 1 hour to your clinic visit. If you are admitted to the hospital, the interviewer will talk to your nurse to arrange a convenient time for the interview. All interviews will be recorded on audiotape, be transcribed and analyzed by the study researchers. Once the study and analysis are complete, the tapes and transcripts containing your interview will be destroyed. Until then, all study materials will be kept in a safe and secure location.

**Risks**
There are no anticipated medical risks to participating in this study. Some questions are very personal having to do with your ability to perform tasks of everyday living. It is important that you know that you do not have to answer any question you do not wish to answer and that you can stop at any time. It may also be embarrassing for you if the results of your questionnaire became known publicly. For this reason the research team will do everything to maintain the confidentiality of the questionnaires. Individual results will not be published. Only group findings will be made public.

You may find some of the questions upsetting. If you become upset, the interview will be stopped and your concerns addressed. We may ask you to meet with a member of our psychosocial support team if we think it may help.

While participating in this study you may disclose information the interviewer feels the team should know to help them care for you. If this happens, the examiner will identify their concern. With your permission, we will notify the appropriate member of the heart failure team or psychosocial support team.

**Benefits**
It is not expected that you will benefit by joining this study. Some patients do find it helpful to openly and honestly discuss their concerns and worries about living with heart failure and deciding whether or not to have a heart transplant or ventricular assist device, but this is very personal and you may not feel the same way. Your answers and comments may benefit the scientific community at-large, and possibly influence the care of future patients.

**Confidentiality**
All information obtained during the study will be held in strict confidence. You will be identified with a study number only. No names or identifying information will be used in any publication or presentations. No information identifying you will be transferred outside the investigators in this study or this hospital.

Representatives of the University Health Network Research Ethics board may look at the study records and at information that could identify you. This might be done to ensure that the study followed applicable laws and guidelines.

Version date
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Participation
Your participation in this study is voluntary. You may refuse to participate or you may withdraw from the study at any point without any effect on your medical care.

Costs of the Study
The investigators in this study will not be paid for designing or conducting this study. Similarly, you will not be paid for participating in this study.

Questions
If you have any questions about the study, please feel free to call Jane MacIver at 416-340-4622, or Dr. Heather Ross at 416-340-3482 or Dr. Vivek Rao at 416 340-3562.

If you have any questions about your rights as a study participant, please call Dr. Ron Hesseltine, Chair of the University Health Network Research Ethics Board, at (416) 340-4557.

Consent
I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I consent to take part in this study and understand I may withdraw at any time. I understand that I will receive a signed copy of this consent form.

☐ I would like to participate in the interview

☐ I do not want to participate in the interview

<table>
<thead>
<tr>
<th>Subject's Name</th>
<th>Signature</th>
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I confirm that I have explained the nature and purpose of the study and that all questions about the study have been answered.

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<th>Person Obtaining Consent</th>
<th>Signature</th>
<th>Date</th>
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Version date
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Appendix F: Drafts of the Decision Process

First Draft:
Second Draft:

- Symptoms
- Quality of Life
- The Needs of Others
- Worry Burden
- The ICD

Emotion:
- Trusting
- Coping

Reason:
- Symptoms Depression
- Quantity of Life
- Attitude toward Risk

Decision:
- Living with the Decision
- Accept Death Faith
Third Draft:

Symptoms

Quality of Life

The Needs of Others

Worry
Burden

The ICD

Affective

Entrustment

Doubts and Fears

Decision

Living with the Decision

Accept Death

Cognitive

Quantity of Life

Attitude toward Risk

Accept Death

Living with the Decision

Decision

Living with the Decision

Accept Death

Entrustment

Doubts and Fears

Symptoms
Fourth Draft:

- **Cognitive Domain**
  - Transferred Trust
  - Strategies that enhance trust

- **Decision**
  - Managing doubts and fears
  - Living with the Decision
  - Age
    - Transplant eligibility

- **Affective Domain**
  - Expertise over information
  - Acceptance of a recommendation
  - Symptoms
  - Worry Burden
    - Quality of Life
    - Needs of others

- **Heart Failure**
  - Trust
    - Accept Death
    - Attitude Toward Risk
    - Quantity of Life

- **Trust**
  - Transplant eligibility
  - Decision

- **Symptoms**
  - Quality of Life

- **Needs of others**
  - Acceptance of a recommendation