Enhancing Informed, Shared Decision Making in a Chronic Population:

Use of an Advance Directive Decision Aid

for Patients Living with Heart Failure

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Abstract

Background: Heart failure (HF) is a progressive, costly, highly symptomatic, and deadly disease process that affects more than 6 million people in the United States alone. The burden of HF is felt by patients, caregivers, and treatment teams alike. Often times, the symptom burden increases as the disease worsens. In an effort to alleviate symptoms and extend life, heart failure teams may offer novel, high-tech treatments and devices and complicated medication regimens to patients. Patients and their caregivers are then tasked with making complex treatment-related decisions for which they may be inadequately prepared. Furthermore, despite the high mortality rate associated with heart failure, current rates of advance care planning discussions and advance directive completion remain very low. Decisions, therefore, are made that may not be congruent with patient and/or caregiver wishes or based on an accurate understanding of diagnosis, prognosis, and likely outcomes. This in turn, is associated with poor-quality decision making, decisional conflict, and later regret. Recently, the use of a theory-based decision aid has been shown to improve quality decision making, decrease decisional conflict, and later regret, in other chronic populations such as oncology. The use of decision aids has been shown to enhance communication between patients, caregivers, and treatment teams, while also promoting a quality decision-making process.

Purpose: The primary aim of this pilot study was to test the feasibility and acceptability of an intervention, an *Advance Directive Decision Aid*, among hospitalized HF patients and their designated caregivers. The secondary aim was to describe the levels of decisional conflict and regret associated with ACP discussion and consideration of

completing an advance directive in a sample of hospitalized HF patients and their caregivers.

Methods: This mixed-methods pilot study used convenience sampling to recruit 30 dyads (30 patients and 30 caregivers) from the inpatient HF service over a 12-month period. Feasibility was assessed by tracking: a) the number of eligible dyads versus the consented dyads, and reasons for refusal to participate; b) the number of those who enrolled and completed the study with reason for non-completion; and c) the amount of recorded time to deliver each intervention session while the patient and caregiver completed the decision balance sheet for an advance directive. Provider acceptability was measured by completion of a follow-up survey. Patient and caregiver acceptability were assessed by completion of a follow-up survey and a semi-structured interview. Patient and caregiver decisional conflict and regret were measured by completing a decisional conflict scale (DCS) and a decisional regret scale (DRS) following completion of the intervention.

Results: The intervention, an *Advance Directive Decision Aid*, was rated favorably by patients, caregivers, and clinicians. Qualitative findings from the interviews supported and expanded the survey data. Both patients and caregivers reported decreased anxiety and gratitude about ACP discussions. Despite characterizing the intervention as positive and helpful, patients reported that the intervention did not prompt them to complete advance directives. They explained that they did not feel a sense of urgency, nor did they believe that an advance directive would change their caregiver's understanding of treatment desires. Participants enrolled in this study were mostly Caucasian males, 54% were diagnosed with HF <1 year, and 70% were NYHA IV. The mean age of participants was 56.5 years (SD = 12.17) and those in the refusal sample were found to be

significantly younger ($p = 0.011$). While the intervention was found to be favorable, there were several issues such as caregiver presence, willingness to discuss ACP and advance directives, and denial of illness severity that made this intervention less feasible. Patients and caregivers expressed moderate decisional conflict, though there was no statistical difference between the two groups. However, caregivers were found to have significantly more decisional regret compared to patients ($p = 0.008$).

Implications and Conclusion: In the short term, results of this study revealed that the intervention was acceptable and that patients and caregivers appreciated the conversation; however, ACP and completion of advance directives remain difficult to discuss and are often avoided. Information obtained from this pilot study will inform a future randomized controlled trial to determine the intervention effect for patients with HF. This trial will include modifications such as: a) providing well-timed end-points to assess decisional conflict and later regret; b) enrolling in both inpatient and outpatient settings; c) adding a health-related quality of life assessment; and d) increasing engagement of physicians with the ACP discussions by introducing the purpose of the decision aid and advanced practice provider who will help with the process, as well as helping to affirm the decision to complete an advance directive at the end of the ACP session for patients with heart failure.

Keywords: Heart Failure, Advance Care Planning, Decision Aid, Advance Directive

Dedication

This dissertation is dedicated to my family: Jason (husband), Corey and Aubrey (children), Russ and Tracy (parents), and my Grandpa - who have all provided unwavering support, encouragement, grace, and love to get through this adventure.

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Definitions

Advance Care Planning (ACP): Making healthcare decisions specific to the patient should they become unable to speak for themselves. This can be a series of multiple discussions between the patient, loved ones, family, friends, and providers to determine healthcare decisions based on the patient's personal values and preferences (The National Hospice and Palliative Care Organization [NHPCO], 2019).

Advance Directive: A legal document (such as a living will) that allows individuals to articulate which treatments they want if they were permanently unconscious or dying. The document is specific to the individual completing it and is detailed about personal decisions regarding end-of-life care ahead of acute events. The document must be signed by a competent person to provide guidance for medical and health-care decisions (such as termination of life support or organ donation) in the event the person becomes incompetent to make such decisions (MedlinePlus, 2019).

Decision Aid (DA): A tool developed to supplement discussion between patient and treatment teams by making the decision at hand explicitly clear by providing information about options and outcomes and clarifying personal values (The Ottawa Hospital Research Institute, 2019).

Heart Failure (HF): A left ventricular ejection fraction of 40% or less rendering the heart unable to meet the blood flow and oxygen demands of the body (Mayo Clinic, 2019).

Hospice: Care for a patient with a terminal illness, or less than 6 months to live if the illness runs its natural course. While similar to palliative care, hospice care is comprehensive comfort care for the patient, while also providing support for the family. The main difference from palliative care is that all attempts to *cure* the illness are stopped (National Institute of Aging [NIA], 2017).

Palliative Care Services (PCS): Care that focuses on quality of life and helping with symptoms. Palliative care can help patients understand their treatment choices. Palliative care services can be provided in addition to curative treatment (NIA, 2017; The World Health Organization [WHO], 2019).

Chapter 1: Introduction

Description of the Problem

The leading cause of death in the United States is cardiovascular disease with nearly one in four deaths caused by heart failure, coronary heart disease, and heart attacks (Centers for Disease Control and Prevention [CDC], 2017). Heart failure (HF) comprises a significant portion of cardiovascular deaths and is brought about by the inability of the heart to circulate blood throughout the body. HF is a progressive, life-limiting condition affecting more than 6.5 million people in the United States (Benjamin et al., 2018). HF is associated with significant mortality and morbidity. In fact, the 1-year mortality rate associated with HF is currently around 50% (Benjamin et al., 2018). Among Medicare beneficiaries with HF, the over-all 1-year mortality rate is around 29% (Benjamin et al., 2018). HF carries an extremely high symptom burden, including but not limited to fatigue, shortness of breath, activity intolerance, and volume overload. As the disease progresses, the symptoms increase in severity, leading to a decreased quality of life (QoL). All age groups are susceptible to this aggressive disease process, though the majority of the HF population is comprised of individuals 65 years and older (Mozaffarian et al., 2016). The incidence rate of HF is 21 out 1000 people over the age of 65 years (Benjamin et al., 2018).

In 2012, the total cost for HF in the U.S. was estimated at $30.7 billion and by 2030 it is projected to more than double to $69.7 billion (Benjamin et al., 2018). Over the lifetime of a HF diagnosis, it is estimated that a Medicare individual will consume more than $80,000 for hospitalizations and treatment of HF (Kilgore et al., 2017). This poses a substantial financial burden to the healthcare system and the tax payer. Due to the

complexity of treatment and severity of symptoms, hospitalizations for HF are frequent and costly. The mean cost per HF admission among Medicare beneficiaries is roughly $14,631 (Kilgore et al., 2017). Given the cost to treat, decreased QoL, and frequent hospitalizations, technological advances have been developed to more aggressively treat HF. Treatments such as cardiac transplant, surgically implanted left ventricular assist devices (LVADs), and implantable pacemakers continue to improve technologically and have also demonstrated overall improved survival within the HF population.

Complications and Disease Trajectory

While technological advances have been shown to be effective in increasing longevity and controlling troubling HF symptoms, the disease is never fully "cured." Patients, caregivers, and treatment teams work with a complicated set of trade-offs to pursue these aggressive treatments (Allen et al., 2012). Long-term anticoagulation, immunosuppression, surgically placed mechanical pumps inside the body, and frequent appointments or procedures are just a few of the trade-offs made to pursue aggressive treatments. These technological advances pose a substantial amount of risk to the patients, and outcomes are often uncertain (Allen et al., 2012). The inability to predict risk associated with successful treatments has dramatically complicated an already complex decision-making process in a chronically ill population (Allen et al., 2012). Thus, patients end up pursuing aggressive treatments of which they do not fully understand the procedure details, side effects, mortality, and long-term goals. This poor decision making ultimately increases the financial, physical, and emotional burden on patients, caregivers, and treatment teams (Allen et al., 2012).

Advance Care Planning

The complex HF trajectory and high mortality associated with the disease has prompted authoritative bodies, such as the American Heart Association (AHA) and the CDC, to recommend advance care planning (ACP) with completion of an advance directive (Allen et al., 2012). ACP assists the patient, family, and treatment team to have meaningful engagement of all involved parties to accurately articulate the patient's treatment desires and goals of care *prior* to an acute event (Allen et al., 2012). ACP early and often throughout the HF illness trajectory can decrease caregiver burden, patient dissatisfaction, and improve QoL by aiding the patient to articulate treatment desires in a non-threatening environment. Early and frequent end-of-life discussions prepare the patient and family about timing and specific symptoms to expect, as well as preparedness to talk about individual goals of care and wishes which reflect held values (Allen et al., 2012; Waldrop & Meeker, 2012; Whellan et al., 2014).

Contrary to current belief, ACP can serve to prevent futile treatments and/or hospitalizations that are undesired or unrealistic for HF patients. ACP does not change the final outcome, death, but rather allows the patient to vocalize preferences on aggressive treatment options. The current era of HF management is experiencing the consequences associated with avoiding ACP, including exponential financial burden secondary to futile or unwanted care that does not change the outcome of death, and a substantial physical and emotional toll placed on the patient and caregiver(s). Despite recommendations from the AHA, CDC, and positive evidence from other chronic disease states such as oncology, ACP is not a standard of practice within the HF population and

many within the HF population have not completed an advance directive (Allen et al., 2012).

Advance Directive Completion

There are a variety of ways to complete an advance directive: a) treatment teams are prompted through the electronic medical record (EMR), though those vary per institution and EMR; b) patients and caregivers can independently complete an advance directive through various online options; c) attempts to increase completion of advance directives have also included the addition of a social worker to the HF multi-disciplinary team; and d) early engagement of palliative care services (PCS) to assist patients in clarifying goals of care. Specific to the HF population, completing an advance directive online could pose significant problems as the patient and caregiver may agree to a treatment that is not compatible with their disease, they do not qualify for, or simply do not understand. This increases the likelihood that the patient could receive unwanted and futile care throughout their HF journey. Despite these readily available options, it is estimated that only one in three individuals has completed an advance directive (Yadav et al., 2017).

Over the past two decades, there is a negative stigma associated with completion of advance directives due to fear of treatment cessation, and/or the psychological distress associated with the contemplation of impending death, or experiencing poor and undesired outcomes associated with a chronic disease such as HF (Allen et al., 2012). Current practice continues to involve avoiding ACP discussions for a variety of reasons including: a) lack of time; b) difficult subject to broach; c) avoidance of emotional distress to patients and caregivers about current disease state; d) assumption that

palliative care is hospice; and e) sudden decompensations requiring hospitalizations (Allen et al., 2012). Both HF and oncology possess poor survival rates and consume a high proportion of ineffective, expensive, and uncomfortable treatments that do not prevent the inevitability of death in the later stages of the disease (Howlett et al., 2010). Yet, ACP has proven to play an essential role in high-quality care in patients with similar chronic diseases such as oncology (Temel et al., 2010).

In a landmark study published by Temel et al. (2010), end-stage lung cancer patients demonstrated that ACP, such as end-of-life (EOL) discussions and advance directive completion, promoted a peaceful and satisfactory dying process. Temel and colleagues dispelled a long-held myth – that collaboration with palliative care services, and completion of an advance directive and do not resuscitate (DNR) forms *did not* hinder standard treatment. It is estimated that only 7% of the HF population is adequately referred to PCS as compared to 48% in oncology services (Gadoud et al., 2014). ACP avoidance (a) leaves the patients and caregivers unprepared about their state of illness; (b) promotes frequent hospital visits for disease progression, which places the treatment team in a position to provide a curative treatment to a failing organ system; and (c) more importantly, creates poor decision making leading to the potential of later regret (Allen at al., 2012; Gadoud et al., 2014).

Study Purpose

The purpose of this mixed-method pilot study is to determine the feasibility and acceptability of an advance directive decision aid in hospitalized patients with HF.

Summary of the Problem

While evidence-based medication therapies and advanced therapy options, such as cardiac transplant and/or LVADs, are increasingly successful, the survival rates associated with HF remain extremely difficult to predict. ACP including EOL discussions and completion of an advance directive, should not hinder treatment, but rather align both patient and provider treatment plans to reflect that of the patient's desires. Despite widespread agreement in the literature that shared decision making is essential to high-quality patient care, expert recommendations from authoritative bodies, including the AHA and CDC, and evidence that current decision-making support for patients with advanced HF is inadequate and associated with adverse patient and caregiver outcomes (Butler et al., 2014; Bidwell et al., 2017), no theory-based DAs have been empirically tested in the HF population.

Recently, *DecisionKEYS for Balancing Choices: Cancer Care,* a DA based on Janis and Mann's conflict theory of decision making (Janis & Mann, 1977, 1982), has shown to be well-received in cancer patients similarly faced with complex treatment-related decisions (Hollen et al., 2013). Using an expert panel, *DecisionKEYS,* has been modified for use in patients with HF and their designated caregivers. The purpose of this single group, pilot study using a mixed-method approach was two-fold: a) to determine the feasibility and acceptability of a clinic-based, cognitive-behavioral skills intervention (DA) for patients with HF and their designated caregivers, who are considering completing an advance directive; and b) to assess decisional conflict and decisional regret after the intervention in the study sample.

Specific Aims

The specific aims for this study were the following:

1. To determine the feasibility and acceptability of implementing a clinic-based, DA (cognitive-behavioral skills intervention) for patients with HF and their caregivers who are considering completion of an advance directive. The DA will be evaluated on the following mixed-methods criteria:
    1.1. Appropriateness of the design (recruitment plan, estimated intervals of decision time points, and evaluation of minimum number of measures).
    1.2. Quantitative evaluation of the possible number of participants (evaluable cases with complete data).
    1.3. Quantitative evaluation of the intervention by the interventionist (e.g., time to deliver) by the participants and by the clinicians on the Advanced HF team.
    1.4. Qualitative evaluation of the intervention by capturing the experience of the patient and caregiver participants (perception of the burden of participating in the intervention, acceptability of the intervention, the timing of the intervention, the fit between the decisional conflict theory and experience, and the usefulness of the intervention and its various parts).
2. To describe decisional conflict and decisional regret in the study sample of hospitalized HF patients and their designated caregivers.

The results of the study will inform a larger, prospective trial designed to test the effects over time of the DA on patient and caregiver outcomes, including decisional conflict and later regret. Having completed a well-designed and executed pilot study will greatly increase the likelihood of successfully moving forward with a rigorous,

hypothesis-testing intervention trial (Kistin & Silverstein, 2015; Moore et al., 2011). Enhancing decision making and improving communication between patients, their caregivers, and their treatment teams is crucial to improving an inadequate system. Improving communication, through informed**,** shared decision making, can prevent unnecessary treatments and promote a dignified death (when the time is appropriate) once the patient, and chosen caregiver, are able to communicate the patient's values and wishes. Advance care planning is having the difficult discussions early so that they simplify difficult decisions in the future (Allen et al., 2012) and promote quality decision making with decreased decisional conflict and later regret.

Chapter 2: Literature Review

Heart Failure

Heart failure (HF) is a complex and deadly diagnosis that is plaguing nearly 6.5 million people (Mozaffarian et al., 2016) and the incidence of new cases of HF in the U.S. is around 960,000 per year (Benjamin et al., 2017). Annually, nearly one million people are hospitalized due to HF (Jackson et al., 2018). The majority of the HF population is comprised of individuals 65 years and older, though it can affect all ages (Mozaffarian et al., 2016). HF with a reduced ejection fraction (HFrEF) is defined as an ejection fraction (EF) that is less than 40% (The National Heart, Lung, and Blood Institute [NHLBI], 2018). A normal left ventricular EF is around 50-60% and promotes normal blood flow and oxygen delivery throughout the body.

There are a variety of ways in which the heart loses its ability to circulate blood. Ischemic cardiomyopathy (ICM) is when there is a narrowing or blockage of the coronary arteries, which results in a loss of blood flow to the cardiac tissue and subsequent damage, and ultimately decreases the ability to circulate blood and oxygen around the body (Mayo Clinic, 2019). Non-ischemic cardiomyopathy (NICM) is a weakened ventricle caused by genetic, viral, or infiltrative processes that damage the ventricle (Mayo Clinic, 2019). HF with a preserved ejection fraction (HFpEF) pertains to people with an EF >40%, but it shares similar symptoms to those with HFrEF. HFpEF is characterized by the inability of the ventricle to relax, which decreases the amount of blood the heart is able to circulate throughout the body (Borlaug, 2014).

New York Heart Association Classification

HF is very difficult to quantify for both patients and caregivers alike. The New York Heart Association Classification (NYHA) is an assessment of the HF patients' symptoms and activity level (AHA, 1994). The NYHA functional classification ranges from Class I to IV (see **Appendix A**). Class I involves the patient presenting with no limitations in physical activity or shortness of breath. Class IV is when the patient is unable to carry on any physical activity due to shortness of breath and even experiences HF symptoms at rest. The NYHA objective classification is provider based and ranges from Stage A (no evidence of cardiovascular disease) to Class D (objective evidence of severe cardiovascular disease). The functional and objective assessments are used together to aid the provider in quantification of disease severity (see **Appendix A**).

The Burden of Heart Failure

The complex and unknown trajectory of HF poses many burdens for those diagnosed with the disease. This also includes those who provide *care* for loved ones with the disease, and those who provide *treatment* for individuals living with the disease.

The Financial Burden

Due to the complexity of treatment and severity of symptoms, HF is one of the most expensive diseases in the United States. In 2014 alone, the average HF admission was three days and cost nearly $11,552.00 per patient, with a total estimated cost over $11.3 billion (Jackson et al., 2018). As the disease worsens, symptoms progress and require emergency room visits and hospital transfers for escalation of care (Jackson et al., 2018). Given the cost to treat, decreased QoL, and frequent hospitalizations, more aggressive treatments have been developed to treat HF. Treatments such as cardiac

transplant, surgically implanted LVADs, and implantable pacemakers offer overall improved survival, though they are associated with significant cost and risk to the patient.

The Patient Experience

Patients with HF experience a wide variety of symptoms such as shortness of breath, fatigue, anxiety, depression, and activity intolerance (AHA, 2017). These symptoms differ in severity per HF patient and are difficult to manage as the disease progresses. Symptoms are often caused by the disease itself, though the medications used to treat HF can cause similar symptoms. The unpredictable nature of HF can cause a patient to experience a slow decompensation over a period of months or a rapid decline in which the patient is required to seek out emergency care and hospitalization due to severity of symptoms (Schiff et al., 2003).

Shortness of Breath and Anxiety. As HF worsens, patients often experience volume overload as the heart is unable to pump the blood throughout the body. As extra volume accumulates in the body, the patient experiences edema (swelling) in their legs or abdominal bloating, in addition to fluid in the lungs (Simon et al., 2013). This often leads to severe shortness of breath that often limits activities and requires a clinic visit for medication adjustment or a hospital admission for aggressive treatment. Anxiety is strongly correlated with HF disease progression and increases as the disease worsens (Simon et al., 2013).

Isolation. Isolation for the HF patient has been described as the inability to partake in various activities as a result of fear, intricate medication regimen, and peer pressure to ignore dietary restrictions (Jeon et al., 2010). Isolation can also be utilized as

a coping mechanism in order to prevent family, friends, and loved ones from knowing the severity of illness (Jeon et al., 2010).

Depression and Hope. Depression is very common throughout the HF population and increases in severity with worsening of the disease (Rutledge et al., 2006). Treatments offered and results of treatment are correlated to the level of depression in the HF population (Rutledge et al., 2006). HF patients vocalize a sense of hope for a variety of reasons such as: a) hope for success in treatments offered; b) hope that the providers correctly diagnose and treat the disease; and c) hope for continued family support; however, they also sense hopelessness in realizing the best part of their life has probably already been lived (Horne & Payne, 2004).

Knowledge Deficit. HF patients display extensive knowledge deficits related to symptoms and medications throughout the illness trajectory despite repeat education opportunities (Gallacher et al., 2013). Both newly diagnosed and long-term HF patients struggle with understanding the purpose of their medications and diet restrictions, which negatively impacts their symptoms and overall survival (Gallacher et al., 2013). Also, HF symptom awareness decreases as the disease progresses secondary to a decrease in brain perfusion and is further complicated by the normal aging process (Kaasalainen et al., 2013).

The Caregiver Burden

A *caregiver* is defined as an individual who takes on the role of caring for the patient with HF, manages medications and appointments, while also understanding the patient's preferences to assist or confirm decisions and treatment preferences (Wingham et al., 2015). *Caregiver burden* is defined as the emotional, medical, and financial

challenges in providing care for a family member/friend with HF (Hooley et al., 2005). A dedicated caregiver for a HF patient takes on the role of polypharmacy management, appointment transportation, emergency room visits, discussing health status with treatment teams, and constant angst about possible death in their loved one and/or friend (Hooley et al., 2005). The caregiver often spends the most time with the HF patient and is expected to know what the patient would like in case of an emergency, or to aid in decision making with regards to treatment options. However, the communication between the patient and caregiver is not always clear and can leave the caregiver in a difficult position in an emergent situation (Fried et al., 2005).

Treatment Burden

Treatment burden fluctuates throughout the HF patient's course of illness and involves the caregiver and treatment team as well. *Treatment burden* can be defined as the "work load" of health care on the patient and caregiver (Gallacher et al., 2013). The complexity of the work load increases as the disease progresses with addition of medications and treatments that require frequent clinic appointments, hospitalizations, and procedures. Treatment burden has been shown to reduce the capacity to follow management plans, ultimately raising the risk for failure and increasing mortality (Gallacher et al., 2013).

Complexity of Decision Making in Heart Failure

Decision making in the HF population is extremely complicated for a variety of reasons. The disease trajectory is unpredictable, but considered deadly with a five-year mortality at 50% (Jackson et al., 2018). HF patients can experience a slow decline in their health over a period of years, or experience a sudden event requiring hospitalization and

immediate consideration of escalation care with initial diagnosis. This is extremely difficult to predict and places both patients and treatment teams in difficult decision-making circumstances. HF patients often carry a variety of comorbidities that make prognostication of the disease extremely difficult. Co-morbid conditions such as hypertension, diabetes mellitus, chronic kidney disease, atrial fibrillation, and frailty further complicate the ability to predict outcomes associated with treatment options (Jackson et al., 2018).

The complexity of HF and high mortality rate has prompted many technological advances in HF treatment, including medications and procedures such as cardiac transplant, LVADs, and implantable pacemaker/defibrillators. These technological advances have improved overall survival, though thoroughly complicated the decision-making process in an already compromised disease. Treatment teams now juggle the difficult balance of estimating the risks based on HF patients' comorbid conditions and attempting to prognosticate risk factors in a clinic visit for consultation, or upon hospitalization in acute decompensation. Patients and their caregivers may also be inundated with commercials and advertisements that promise improved QoL with HF, though the information is misleading and does not encompass the individual's specific risk factors.

Typical clinic visits for HF can be filled with the basic healthcare evaluations, such as physical assessment, labs, and history – leaving little to no time for goals-of-care or prognosis discussions such as ACP. The lack of ACP in this chronically ill population leads to unnecessary, undesired, and futile care (Allen et al., 2012). In a complex disease process such as HF, the lack of ACP has contributed to the astronomical cost of

treatment, and perhaps more importantly, compromised the patient's QoL without changing the final outcome, death. Avoidance of ACP discussions has resulted in poor-quality decision making in which patients, caregivers, and treatment teams experience decisional conflict and later regret (Allen et al., 2012; Hollen et al., 2013; Temel et al., 2010).

Recommendations to Improve the Patient and Caregiver Experience

Given the complexity of treatment-related decision making, a high mortality rate, and risk for sudden death associated with HF, the AHA and CDC recommend disease-specific ACP with completion of an advance directive (Allen et al., 2012). Early and frequent ACP discussions prepare the patient and family about timing and specific symptoms to expect as the disease progresses, while also preparing them to talk about individual goals of care (Waldrop & Meeker, 2012; Whellan et al., 2014). Borrowing from data in other chronic disease populations such as oncology, there is evidence to support that successful ACP discussions and completion of an advance directive does not stop treatment. ACP has been shown to decrease decisional conflict for the surrogate decision maker, while also decreasing their anxiety, depression, and stress following the loss of their loved one (Chiarchiaro et al., 2015).

Negative Stigma of ACP

The misconceptions and fear of stopping treatment or dying after completing an advance directive often fuel the negative stigma associated with ACP. This negative stigma is experienced by patients, caregivers, and treatment teams. Oftentimes, the negative stigma is fueled by the unpredictable nature of HF and concern (from treatment teams) that premature discussions can cause the patient undue emotional harm and

diminish hope (Gadoud et al., 2014).

What Has Been Tried

Authoritative bodies such as the CDC and AHA have placed emphasis on the importance of ACP discussions and completion of an advance directive, though the way in which this takes place has not been regulated. Hospitals and clinics have attempted to increase documentation and completion of advance directives *without* understanding the full intended purpose of ACP discussions and advance directive completion. Given the complexity of initiating ACP discussions and completing an advance directive, there have been many attempts to remove barriers and streamline the process.

Incorporating ACP and Completion of Advance Directives in Routine Care. Current practice of ACP and advance directive completion throughout the HF population is limited to the provider remembering to initiate ACP discussions and suggest completion of an advance directive. This is intended to be completed while performing a physical assessment and evaluating the state of HF in a short clinic visit or upon an urgent hospitalization secondary to decompensation (Allen et al., 2012). There are even EMR prompts to remind treatment teams to review completion of advance directives, but they do not necessarily prompt the discussion.

Easy Access to Advance Directive Materials. In another attempt to enhance advance directive completion, hospitals and clinics have strategically placed advance directive paperwork, or the *Five Wishes* packets throughout nursing stations and clinic rooms, but completion rates remain poor largely due to the lack of understanding pertaining to an advance directive. *Five Wishes,* an advance directive form created in 1997, assumed a non-threatening approach to promote conversations with loved ones to

identify patient wishes and preserve dignity while dying (Aging with Dignity, 2020). *Five Wishes* is now available for use in all 50 states, though it is not currently mandated to be completed. Electronic advance directive forms are also available through government websites such as Medicare.gov (2019) to complete an advance directive in the privacy of the patient's own home, though the online format does not have the ability to answer questions specific to the patient's disease, prognosis, or possible complications associated with his/her/their specific disease. This method can possibly lead to the patient completing an advance directive without fully understanding what is being declined or accepted.

Palliative Care Referrals. Further attempts to increase completion of advance directives in the HF population included the engagement of palliative care services (PCS). Given the successful relationship between PCS and other treatment teams such as oncology, governing bodies such as the AHA and American College of Cardiology (ACC) recommend the integration of PCS into HF (Lemond & Allen, 2011). However, the unpredictable trajectory of the disease and limited number of palliative care staff compared to HF patients created an unsuccessful implementation of this partnership. Consequently, the aforementioned efforts have *not* led to a substantial increase in ACP discussions or increased advance directive completion rates; however, there is evidence in other chronic diseases, such as oncology, that early engagement with ACP discussions and completion of advance directives does not hinder treatment plans, but rather improves quality of life (Temel et al., 2010).

What Has Worked

As published by Temel and colleagues, (2010), end-of-life discussions or ACP

and advance directive completion, promoted a peaceful and satisfactory dying process for the oncology population. The oncology and HF populations are similar in that they both possess poor survival rates and consume a high proportion of ineffective, expensive, and uncomfortable treatments that do not prevent the inevitability of death in the later stages of the disease (Howlett et al., 2010). As stated earlier, it is estimated that only 7% of the HF population is adequately referred to PCS as compared to 48% in oncology services (Gadoud et al., 2014).

Decision Aids

Decision Aids (DAs), defined by The Ottawa Hospital Research Institute (2019), are tools developed to supplement discussion between patient and treatment teams by making the decision at hand explicitly clear by providing information about options and outcomes while clarifying personal values. According to a Cochrane review of 105 trials comparing the use of a DA to usual care, Stacey and colleagues (2014) reported five positive outcomes for DAs: a) knowledge; b) accurate risk perception; c) congruence between the chosen option and informed values; d) decreased decisional conflict; and e) increased participation in decision making.

While there is extensive literature to demonstrate the effectiveness and benefits of ACP and advance directive completion in oncologic populations, there is little evidence specific to the HF population. The AHA clearly stated a need to identify a quality DA, utilize a DA, and measure quality decision making in the HF population to align with the guidelines by the Institutes of Medicine or IOM (Allen et al., 2012).

There is a critical shortage of DAs that reflect the standard set out by the International Patient Decision Aids Standards Collaboration (IPDAS) (Butler et al.,

2014), and there are no available DAs related to advance directives for a chronic population, except one in a series known as *DecisionKEYS*, developed for the oncologic population by Hollen and colleagues (2013). Utilizing a DA specific to advance directives, can assist the patient and caregivers to ask appropriate questions, effectively articulate treatment desires, and aid the treatment team in guiding care that is congruent with the patient's values and goals.

The DecisionKEYS Intervention

A decision aid, *DecisionKEYS for Balancing Choices: Cancer Care,* developed by Hollen and colleagues (2013) is based on Janis and Mann's conflict theory of decision making (Janis & Mann, 1977, 1982) and has been shown to be feasible and well-received in several oncologic patient populations (Hollen et al., 2013; Jones et al., 2013). The intent is to improve the decision-making process when there are complex and stressful choices, help with a specific decision (e.g., starting, changing or stopping chemotherapy), and provide structured time for support by health care providers for difficult decision making as a means of reducing decisional conflict and later regret (Hollen et al., 2013). Positive results for feasibility and acceptability have been published for several types of cancer (newly diagnosed breast cancer, advanced lung cancer, and advanced prostate cancer).

Overview of Theoretical Underpinning of Proposed Intervention

Janis and Mann's conflict model of decision making predicts decision-making behavior in *consequential* decisions; that is, those decisions that are emotionally charged, motivationally driven, and in which all available options are associated with a downside or trade-offs. The theory maintains that when confronted with consequential decisions

three preconditions influence the degree of stress people experience: a) the risk they associate with the consequences of their choices; b) the hope they have for finding a better solution; and c) the time-frame in which they must make a decision.

The level of stress in turn, influences the decision-making style employed. Stress levels that are either too high or too low are associated with poor-quality or shortcut decision-making styles. Moderate stress levels (i.e., those high enough to motivate engagement, and low enough to avoid immobilization by anxiety), are associated with quality decision making, which is characterized by: a) clarifying goals and values involved in the decision; b) exploring options; c) seeking and appraising information; d) comparing and contrasting alternatives; e) augmenting/clarifying information; f) weighing advice from experts; and g) formulating contingency plans. People who engage in quality decision making tend to experience less decisional regret, more satisfaction with their decision, and are less likely to reverse their original choice.

Description of the Components of the Intervention

As presented in the original *DecisionKEYS* intervention (Hollen et al., 2013, p. 892), there are several critical steps to quality decision making using a DA that are facilitated through the use of a decisional balance sheet and an interactive process. The intervention includes the following components and procedures.

Social Support. Decisions are rarely made independently. It was mandatory to have a designated caregiver to participate and engage in the conversations about preferences and decisions with regard to completing the DA.

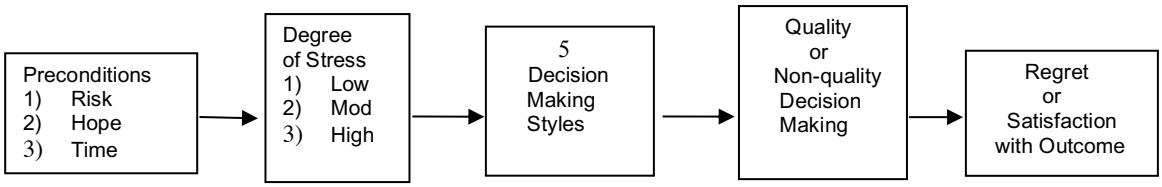
Anticipatory Guidance. The oncologist and oncology nurses were educated about the study and viewed the DA components. All patients and caregivers, as a dyad,

received an example of a decision balance sheet called *"Telling Others,"* as a part of the education process.

Brief Decision-Making Tutorial. A brief tutorial diagram (see **Figure 1**), including the rationale for quality decision-making followed by an "easy-recall method" of the theory components, was presented to every dyad as a part of the intervention: a) purpose of the DA; b) outcomes in quality decision making; c) preconditions; d) uses of decision-making theory; e) decision-making styles; f) steps in quality decision making; and g) criteria for evaluating decision making.

Figure 1.

Brief Tutorial Diagram for Quality Decision Making (Adapted by Hollen et al., [2013] from Janis and Mann's Conflict Theory of Decision Making)



Values Clarification and Preference Discussion. Using a decisional balance sheet, a summary report for values/concerns/conflict designed by Janis & Mann (1977, 1982) to weigh in terms of the benefits and risks for oneself and others, which results in values clarification for the patient and caregiver with regard to completing a decision balance sheet (see **Appendix B)**. The decision balance sheet exercise involves completion of a four-cell table related to the pros and cons for self and others and was used as an interactive process during completion. The patient and caregiver were encouraged to discuss preferences throughout every treatment received.

Structured Time with Providers (Physician or APP) to Discuss Difficult Decisions. Given the difficult nature of treatment options specific to various cancers, additional time was spent between the PI and the dyad to discuss individual questions. Questions and concerns were relayed to the treatment team for further discussion as appropriate.

Knowledge Gap

To date, no studies pertaining to the utilization of DAs to complete advance directives in the HF population have been published. There is a critical shortage of DAs that reflect the standard set out by the IPDAS (Butler et al., 2014) and there are no available DAs related to advance directives for a chronic population, except this one in a series, known as *DecisionKEYS*, developed for oncology by Hollen and colleagues (2013), though it has not yet been tested in the HF population. Therefore, it is not yet known whether the decision aid is feasible and acceptable, and whether it will resemble results observed in the oncology population such as decreased decisional conflict and later regret.

Purpose of the Study

The purpose of this mixed-method pilot study is to determine the feasibility and acceptability of an advance directive decision aid in hospitalized HF patients.

Potential Impact of the Study

The research void in this area is at a critical impasse that must be addressed. The short-term contribution of this pilot study is to inform and develop a larger trial for effect. As called to attention by the IOM, the medical world must now regain focus on patient QoL and dignity, despite a myriad of advanced treatment options available (Bechtel et al., 2013). Systemic avoidance of ACP and potential EOL discussions is detrimental to an

already frail patient population and exhausted caregiver and treatment teams. ACP utilized throughout the continuum of care received, has the potential to decrease anxiety/fear for the patient and caregiver(s) as they develop a trusting relationship over time with the treatment team and feel as though the treatment team truly understands the patient's values and desires.

The potential long-term effect of this study is to add to evidence-based tools that function to empower patients and caregivers to meaningfully engage in quality decision making. Including ACP early and often throughout the HF illness trajectory can decrease caregiver burden, patient dissatisfaction, and improve QoL of the dyad by aiding the patient to articulate treatment desires in a non-threatening environment.

Chapter 3: Research Design and Methods

Innovation of the Advance Directive Decision Aid

The combination of a high mortality rate, complex disease process, and unknown illness trajectory has compromised the vulnerable HF population. The current lack of ACP and decreased completion rates of advanced directives promotes poor-quality decision making, decisional conflict, distress, decisional regret, and care that may be inconsistent with patient and family values and preferences. According to the IPDAS, there are no specific DAs for advance directives in a chronic population (Butler et al., 2014). However, a DA known as *DecisionKEYS for Balancing Choices*, developed for treatment choices specific to the oncology population (newly diagnosed breast cancer, advanced prostate cancer, and advanced lung cancer) by Hollen and colleagues (2013), is available, but lacks testing in other chronic populations such as HF. The primary purpose of this mixed-method pilot study was to determine the feasibility and acceptability of an *Advance Directive Decision Aid* in hospitalized HF patients.

Research Design

For pilot testing this *Advance Directive Balance Sheet*, as part of the series and with a different population than cancer, a single-group, mixed-methods, pilot study was conducted. The two-fold purpose was to: a) examine the feasibility and acceptability to patients, caregivers, and HF providers, of incorporating a DA designed to promote high-quality shared decision making about advance directives into the routine care of patients with HF; and b) describe, in this study sample of HF patients, decisional conflict and decisional regret *after* the intervention.

This particular research design was chosen for its potential to facilitate the identification of actual barriers related to the DA and its delivery as part of routine clinical care, as well as potential barriers related to conducting a future larger intervention effect trial with HF patients (Kistin & Silverstein, 2015; Moore et al., 2011). Completing a well-executed pilot study greatly enhances the likelihood of moving forward with a rigorous, hypothesis-testing intervention trial (Kistin & Silverstein, 2015; Moore et al., 2011).

Study Setting

All study participants were recruited from the inpatient cardiology service at The University of Colorado Hospital (UCH), a 678 bed, academic medical center in the greater Denver area. Each year approximately 50,000 patients are admitted, with 800 of those specifically for HF-related treatment (UCHealth.org, 2019). Individuals treated at this institution range from newly diagnosed to end-stage HF requiring advanced therapies, such as cardiac transplant or surgical implant of a durable LVAD to treat their HF. The sociodemographic characteristics of the greater Denver area include the following: 49.9% female, 50.02% male; declared race: 76% Caucasian, 9.5% African American, Hispanic 5.49%, Asian 3%.; over 25% of the population speaks Spanish as a native language (World population review, 2019).

The cardiology service at UCH is divided into two main groups: a) the general cardiology service, who primarily provides care to the acute heart attack population post-intervention; post-procedure patients such as implantable cardioverter defibrillator (ICD's), valve placements, and/or ablation; and newly diagnosed HF patients not requiring prolonged inotropic support or temporary assist devices; and b) the Advanced

HF team, which provides care for critically ill patients with HF requiring inotropic support, pressors, temporary circulatory assist devices, and those being considered for advanced therapies such as cardiac transplant and/or LVAD. Participants from this study were followed by the Advanced Heart Failure team only. The Advanced HF team at UCH is comprised of eight attending Cardiologists and five Advanced Practice Providers (APPs). The attendings rotate inpatient coverage weekly throughout the year. The APPs cover the inpatient service in addition to the attending physicians, providing direct patient care with collaboration as needed. Recruitment, data collection, and intervention delivery took place in the inpatient setting; however, follow-up measures were completed by telephone or traditional mail.

Access to the setting was facilitated by several factors: a) the principal investigator (PI) or PhD student, is a nurse practitioner (NP) on the Advanced HF team, and as such, has access to the EMR and daily HF email list; b) two members of the Data and Safety Monitoring Board (DSMB), Dr. Larry Allen and Dr. Colleen McIlvennan, are also on the Advanced HF team and have extensive experience conducting research at UCH with the target population.

Intervention Description

The *DecisionKEYS* decision aid was modified for the HF population with the approval of Hollen and colleagues (2013) and expert opinion of the DSMB. The *DecisionKEYS* decision balance sheet for an advance directive (originally made for the cancer population) was modified to be applicable for the HF population (see **Appendix B)**. *DecisionKEYS* has proven to be highly feasible and acceptable to all three groups of patients with solid tumors and their supporters (total of 160) as well as 10 health

professionals, specifically physician and nurse interventionists (Hollen et al., 2013; Jones et al., 2013). Much like the oncologic population, the HF population experiences a high level of stress in which they must make decisions that are often associated with decisional conflict and later regret.

Advance Directive Decision Aid

The *DecisionKEYS* intervention was modified per expert opinion from the DSMB to reflect terminology specific to the HF population, though main content was not significantly modified. The Advance Directive Decision Aid (ADDA) is approximately a 45-minute, single session, guided discussion delivered by a trained interventionist, the PI. The ADDA consists of the following seven components as summarized in **Table 1**. Based on the original *DecisionKEYS* DA, the content elements and the process of delivery were similar as well as the estimated time needed for delivery.

Table 1

Description of Key Components for Advance Directive Decision Aid

Component	Content Elements	Process
Social Support	Includes a designated caregiver present to participate in decision-making with patient.	On-going inclusion of support person throughout process.
Anticipatory Guidance re: disease, treatment, and advance directive ~30 minutes	An informational meeting was held with APPs, cardiologists, and social workers *prior* to initiation of study.	All participants and caregivers received this.
A quality decision making process tutorial ~15 minutes	Tutorial includes: rationale for quality decision making, followed by easy-recall method of theory components: 1) purpose of DA; 2) outcomes in quality decision making; 3) preconditions; 4) uses of decision-making theory; 5) decision making styles; 6) steps in quality decision making; and 7) criteria for evaluating decision making	Handout with graphics used to reinforce material presented.

Component	Content Elements	Process
Values Clarification ~15-20 minutes	The patient/caregiver dyad was given the Advance Directive Decision Aid, a modified version of the original. The balance sheet exercise involves completion of a four-cell table related to the pros and cons for self and others to facilitate values clarification for the dyad.	After practice session with non-consequential decision, dyad completed *Advance Directive Balance Sheet* in interactive process.
Structured time with HF provider (physician or APP) to discuss difficult decisions ~1-5 minutes	DA was reviewed with dyad. 5 wishes document provided to dyad and reviewed advance directives further as needed. Additional time with team members as needed; followed by 5 minutes additional structured time with HF cardiologist.	Balance sheet used for focused review with team; decision finalized with patient/caregiver dyad after lingering questions/concerns addressed. Provided 5 wishes document to dyad.

**Adapted with permission from Hollen et al., 2013*

Nurse Interventionist

The nurse researcher, PhD student, has extensive experience working with patients with HF. She is a practicing nurse practitioner with over 17 years of cardiology experience. Prior to beginning recruitment, she completed the same training, designed by Hollen et al. (2013) as the interventionists on the *DecisionKEYS* study.

Intervention Delivery Setting

The intervention was delivered in a private patient room during a patient's hospital admission. If a patient was identified as not having completed an advance directive, and they were medically stable to participate, the study was completed within the first few days of admission. However, if the patient did not have a completed advance directive, and was not medically stable to participate (i.e., intubated, immediate surgery, or hemodynamically unstable), the patient was approached once medically stable and/or prior to discharge.

Patients were approached about participation in the morning, following rounds, when a plan of care had been identified for the day. If the patient and caregiver were amendable to participation, they designated a time of day that would work best to complete the study. However, participants were not consented on days in which they were scheduled for procedures.

Intervention Fidelity

Intervention fidelity, defined as the degree to which the interventionist adhered to the intervention protocol, was maintained by having one interventionist (the nurse researcher), trained in intervention delivery, and by using an intervention checklist that had been previously developed and used by Hollen et al. (2013) in the other *DecisionKEYS* studies. Checklists were monitored by dissertation mentors and the DSMB.

Sampling Plan

Convenience sampling was used to recruit 30 dyads from the inpatient HF service over a 12-month period, from November 2018 through October 2019. The sample included 60 participants (30 patients and 30 caregivers). Each dyad consisted of a patient and his/her designated caregiver. As defined earlier, the *caregiver* is an individual, who takes on the role of caring for the patient with HF, managing medications and appointments, while also understanding the patient's preferences to assist or confirm decisions and treatment preferences (Wingham et al., 2015).

Given the complexity, gravity, and necessity of a caregiver to make a decision when the patient cannot (i.e., intubated, post-cardiac arrest, etc.), it was mandatory to have a designated caregiver present to participate in the study. Decisions are rarely made

independently and the purpose of this pilot study was to enhance discussions between the caregiver, patient, and treatment team.

Sample Size Justification

Based on an estimated 800 patients with HF admitted during the one-year recruitment period at UCH, the primary endpoints of feasibility and acceptability of this pilot study, and recommendations from researchers with expertise in this area, a sample size of 30 dyads (30 patients and 30 caregivers) was deemed appropriate. The fundamental purpose of conducting a pilot study is to examine the feasibility of the approach that is ultimately intended to shape a larger, future study (Leon et al., 2011).

Inclusion and Exclusion Criteria

Patient inclusion criteria were the following: a) adults ages 18 and older; b) diagnosed with heart failure (NYHA I-IV); c) actively receiving treatment for their HF; d) a caregiver present and willing to participate; e) able to read, write, and speak in the English language; f) without a previously completed advance directive; and g) medically stable (i.e., not intubated).

Caregiver inclusion criteria were: a) adults 18 years and older; b) willing and able to participate; and c) able to read, write, and speak English. Adults with severe developmental delay that prevented their ability to understand the study, specifically the risks and benefits of participating in the study, were excluded. Patients without capacity, those who had previously completed an advance directive, had no caregiver willing and/or able to participate, or were sedated, intubated or critically ill, were also excluded.

Instruments

A battery of instruments was used in this pilot study. All instruments and their psychometric properties have been included for review (see **Appendix A, C-E**). The trained nurse researcher delivered the intervention to every dyad, including ensuring completion of all instruments.

Instruments to Measure Outcomes of Interest

The following outcome measures, based on the theory of Janis and Mann (1977, 1982), were shown to be reliable and valid in previous *DecisionKEYS* intervention studies (Hollen et al., 2013). Two outcome measures were assessed following completion of the *Advance Directive Balance Sheet* by each dyad in this order: a) decisional conflict; and b) decisional regret.

Decisional Conflict, is defined as the state of uncertainty about the course of action to take (O'Connor, 1995). The Decisional Conflict Scale (DCS) was developed by Annette O'Connor (1995) to determine the levels of conflict experienced with decision making (see **Appendix D**). There are three dimensions (subscales) of conflict:
(1) uncertainty about the decision; (2) modifiable factors such as information about the decision, unclear personal values, and feeling unsupported; and (3) quality of choice selected. The DCS was originally developed and tested in people who were considering vaccinations and breast cancer screenings, though its use has spread to the oncology population (O'Connor, 1995).

There have been three new editions of the original scale, with recent adaptions revolving around literacy level and number of questions. The scale is available in three different languages and has a high test-retest reliability. In its original studies, the scale

demonstrated improved scores following decision supporting events with high internal consistency ($\alpha = 0.78$) using Cronbach's alpha (O'Connor, 1995). The outcome of *decisional conflict* was assessed using the mean score from the DCS*,* a 13-item, 5-point Likert scale (*1 = strongly agree to 5 = strongly disagree*), originally developed by O'Connor (1995), and modified and tested by Hollen, et al., (2013). For this particular study, *decisional conflict* revolved around ACP discussions and consideration of completing an advance directive.

Decisional Regret, is defined as remorse or distress over a decision (Brehaut et al., 2003). Given the high stakes associated with medical decisions in particular, there can be a significant amount of regret associated with the outcomes related to the decision, ultimately influencing subsequent decisions. The Decision Regret Scale (DRS) was developed by Brehaut and colleagues (2003) to better evaluate satisfaction with one's decision (see **Appendix E**). For example, higher regret scores were associated with lower satisfaction for the decision made and showed high internal consistency (Cronbach's alpha, *0.81 to 0.92*). The DRS was originally tested in four different populations: 1) 177 menopausal women choosing hormone replacement therapy or not; 2) doctor-patient communication patterns during consultation sessions in which 395 patients with breast cancer decided whether to proceed with adjuvant therapy after the primary surgical intervention; 3) the decision-making preferences and information needs of 200 women deciding between lumpectomy and mastectomy for the treatment; and 4) a sample of 56 men considering different options for prostate cancer treatment (Brehaut et al., 2003).

The outcome of regret was assessed using the mean score from the *DRS,* a 5-item, 5-point Likert scale (1= *strongly agree to 5 = strongly disagree),* originally developed by

Brehaut et al, (2003) and item responses modified into all negative statements by Hollen, et al., (2013). For this particular study, *decisional regret* revolved around the decision to participate in ACP discussions and consideration of completing an advance directive.

Study Schema

The study schema outlines the study measures by time point (see **Table 2**). The maximum total time required for the dyad was approximately 85 minutes. The DCS and DRS were collected at bedside following completion of the *Advance Directive Balance Sheet*. All interviews were collected at bedside following completion of baseline measures.

Table 2

Study Schema of Participants and Measures by Time points

Instruments by Participant	Time	Time 1 (Baseline)	Time 2 (30 days from 1st visit)
Study Nurse			
Review of Demographics	5 minutes	**X**	
NYHA Classification	1 minute	**X**	
Inclusion/Exclusion Form	1 minute	**X**	
Exit Interview Form	10-20 minutes		**X**
Patient/Caregiver			
Consent completion	5-15 minutes	**X**	
Telling Others Balance Sheet	5-10 minutes	**X**	
ADDA Balance Sheet	5-10 minutes	**X**	
Decisional Conflict Scale (*post-intervention)*	5-10 minutes	**X**	
Decisional Regret Scale (*post-intervention)*	5-10 minutes	**X**	
Exit Survey	5-10 minutes		**X**
Exit Interview Form	10-20 minutes		**X**
Provider	1-2 minutes		**X**

Procedures

IRB Approval

Institutional Review Board (IRB) approval was obtained through the UCH IRB (IRB # 18-0293). A copy of the approval letter and protocol can be reviewed (see **Appendix F**). The potential risks associated with participation in this study were minimal but include: a) breach of confidentiality for patient participants and their caregivers; b) fatigue, exacerbated by participating in discussions and interviews; and c) emotional distress, brought on by discussing experiences and thoughts related to having a life-limiting illness, or being the loved one of a patient with a life-limiting illness. Several measures were instituted to minimize the risks described above.

Participant Recruitment and Consent

As an NP on the Advanced HF team, the PI had access to both the electronic medical record (EMR) and a daily HF admission list. Both were reviewed to identify potentially eligible patient participants. Only potentially eligible patients were approached by a member of the care team (attending physician) or the PI, who then assessed interest in hearing about the study. The PI described the study, including the purpose, design and methods of data collection, the principles of informed consent, and answered any questions. Each eligible patient participant was asked to identify a caregiver (defined earlier) involved in his/her care or in making health care decisions, who might be willing to participate in the study with the patient.

Consent forms that were developed in collaboration with the PI's mentors and approved by UCHs' IRB, were provided to the dyad and reviewed with potential participants. Time was allotted for clarification and discussion. Potential participants

were reassured that participation was voluntary and may be withdrawn at any time without fear of reprisal or change in treatment. They were also told that measures, discussed in the Protection of Human Subjects section, would be in place to protect against potential risks. Once both patient and caregiver signed a consent form, collection of baseline measures and intervention delivery took place immediately.

For those who agreed to participate, the signed consent form was retained and stored in a locked cabinet. A copy of the signed consent form, which included the PI and IRB contact information, was given to the participants (see copies of the patient, and caregiver consent forms in **Appendix G & H**). Once consent was obtained, the NYHA classification and demographic data were collected and documented. If a potential participant declined participation, they were thanked for their time. They also were reassured that care would not be adversely affected by declining participation.

Recruitment Strategy Rationale to Providers. The recruitment strategy was developed in consultation with the PI's dissertation advisors, DSMB board members, and field experts, Dr. Larry Allen and Dr. Colleen McIlvennan. The study was introduced by the nurse researcher (PhD candidate), who was also the study PI. The PI presented the study to the Advanced HF team (Cardiologists and APPs), social workers, and bedside nursing staff on the inpatient cardiac units. They received verbal and written information about the original intervention, *DecisionKEYS*, its effectiveness in lung, prostate and breast cancer populations, and modifications that were made for HF patients and their caregivers.

Vulnerable Populations of Interest. This study included vulnerable populations of women and minorities. Both women and men were included, if they were formally

diagnosed with HF. The catchment area in Colorado was approximately 51% male, and 49% female. Ethnic minorities in the catchment area in Colorado were approximately 41%. Racial/Ethnic categories in the catchment area in Colorado are limited but include: Hispanic or Latino, 20%; Black or African American, 4%; American Indian and Alaska Native, <1%; Asian, 2%; Native Hawaiian and Other Pacific Islander, <2%; Other, 8%; White, 81%. No gender or minority was excluded from participating in the study. No children were included in the study. Every effort was made to recruit minority participants for the study, including consulting with co-investigators who have been involved in studies in which minority participants were successfully recruited and retained.

Recruitment Challenges. In response to very low enrollment rates during the first three months of this pilot study, the PI, in consultation with dissertation mentors and the DSMB, modified the recruitment strategy to focus on the inpatient population and include enlisting the cardiology team social worker and unit charge nurse in identifying potential eligible participants.

Provider Recruitment and Consent

Following IRB approval, providers were educated about the study and consented. Providers were recruited to participate in the study based on the PI involvement and primary patient group treated by the Advanced HF team. Given the role of the APP on the Advanced HF team, physicians were notified about patient participation and the PI discussed briefly the advance directive decision following patient enrollment to study.

Delivery of Decision Aid

Once consented, the PI educated the dyad about the study basis using the conflict decision theory diagram, using a brief tutorial diagram as a component of the intervention (see **Figure 1**). A brief overview of advance directives was provided to the dyad. After all questions were answered, the dyad was asked to complete the "*Telling Others,"* balance sheet as practice. The dyad was encouraged to ask further questions after completing *"Telling Others."* The *Advance Directive Balance Sheet* was then completed by the dyad. Dyads were encouraged to ask questions and discuss their concerns with the nurse interventionist (PI) while completing this balance sheet as a part of this interactive intervention.

Following completion of the balance sheet, the dyad was asked about his/her/their decision preference and the attending physician on service was notified of the decision preference. Following completion of the *Advance Directive Balance Sheet,* patients and caregivers were asked if they had any more questions pertaining to completing an advance directive. The dyad was then provided an advance directive to complete if they felt agreeable to do so following the study, though it was not a requirement. If the dyad completed an advance directive, a copy was made and placed in the EMR, then the dyad took home the original advance directive.

Obtained Data for Specific Aim 1

Participant New York Heart Association Classification and Sociodemographic Data

New York Heart Association Classification (NYHA). The NYHA functional capacity and objective assessment is the standard of classifying severity of heart failure. This instrument is used daily within the HF population to determine acuity of illness with

all HF patients. In 1928, the New York Heart Association united to publish a basic system to aid providers with identifying and classifying HF patients (AHA, 1994). While the measure has no psychometric properties associated with it, the NYHA quickly gained momentum and remains the single most popular prognostic indicator for HF patients (see **Appendix A**). Early editions of the NYHA relied solely on functional capacity status to determine classification; however, in the early 1970's, medical tests, such as echocardiograms, were recommended to more accurately identify classification. The NYHA classification system predicts prognosis, despite some considerable limitations, which warrants its use as a measure of correlation instead of a single diagnostic measurement of HF (Raphael et al., 2007).

Sociodemographic Data. Once the patient and caregiver had signed consent to participate, additional clinical and sociodemographic data was collected for the study. Clinical data such as the NYHA classification and insurance type were collected immediately following consent via chart review. Sociodemographic data such as: identified race, marital status, annual income, years of education, years since diagnosis, and distance from hospital were asked in person, to the patient and recorded on a demographic sheet prior to theory education and completion of the "*Telling Others*" balance sheet. This information was important to better define the HF population enrolled in this study and compare it to other studied HF populations.

Feasibility

The first aim sought to determine the feasibility and acceptability of the intervention, the *Advance Directive Balance Sheet* in hospitalized patients with HF. Feasibility was assessed by tracking: a) the number of eligible dyads versus the consented

dyads, and reasons for refusal to participate; b) the number of those who enrolled and completed the study with reason for non-completion; and c) the amount of time to deliver each intervention session was recorded while the patient and caregiver completed the specific balance sheet. Both patients and caregivers were given the same 30-day follow-up survey to further assess feasibility and acceptability of the advance directive decision aid.

Acceptability to Participants

Patient and caregiver acceptability were measured by: a) completing a follow-up survey (see **Appendix I**); and b) participating in a semi-structured exit interview 30 days +/- 7 days following enrollment (see **Appendix J**).

Follow-up Survey. The purpose of the survey was to determine if the intervention was acceptable to both patients and caregivers alike; thus, patients and caregivers were given the same evaluation form. There were 16 Likert-style questions (1 = Strongly disagree to 5 = Strongly agree) pertaining to the intervention. Examples of questions included: "The decision aid was easy to read*"* and "The decision aid was helpful in reviewing the necessary steps needed for good decision making about completing an advance directive."

Semi-Structured Exit Interview. Both dyad members were invited to participate in semi-structured interviews, conducted over the telephone or in-person in their private hospital room. The purpose of the interview was to provide qualitative data on the feasibility and acceptability, specifically ease of completion and the participating dyads' experiences of and perspectives on the intervention. All interviews were conducted by the PI, using the interview guide, developed by Hollen et al. (2013) and used in previous

DecisionKEYS studies. Questions such as: a) What made you decide to participate in the study; b) Who was there with you; and c) If you were to tell other patients and their caregivers about the DA, what questions would you tell them were asked of the participants (see **Appendix J**).

Upon consent of the study, the participants were informed that the exit interview would be recorded. If the patient remained hospitalized at the conclusion of the study, they were approached about participating in the interview, and if amenable, the interview took place at the bedside, in a face-to-face fashion. Prior to beginning the interview, participants were again asked permission to record the interviews.

Interview and Retention Challenges. Despite three phone calls with a detailed voice mail and a scripted hand-written note sent to the dyad, participants were consistently lost to follow-up. There were no completed surveys or exit interviews for the first 20 dyads. After consultation with the DSMB and mentors, the decision was made to complete the interview following completion of the initial study measures. This was done in order to obtain critical qualitative data to determine participant acceptability for the study.

Acceptability to Providers via Follow-up Survey

Providers were notified of a patient's enrollment depending on which attending was on inpatient service at the time of enrollment. Following completion of patient enrollment, providers were asked to evaluate the feasibility and acceptability of the DA through completion of a 12 question, Likert-style survey (see **Appendix K**).

Obtained Data for Specific Aim 2

The focus of aim 2 was to describe decisional conflict and decisional regret related to participating in ACP discussions and consideration of completing an advance directive, by the study sample. Due to the recruitment challenges, the purpose was changed to obtaining data regarding appropriate use of these measures for HF patients and their caregivers vs. actual change over time for this pilot study sample of dyads.

Patient and Caregiver Decisional Conflict

The DCS was used to indicate the level of *conflict or difficulty* experienced by patients and caregivers in participating in ACP discussions and consideration of completing an advance directive. Both patients and caregivers were given the DCS, in person, to complete once they finished the *Advance Directive Balance Sheet*.

Patient and Caregiver Decisional Regret

The DRS was used to indicate the level of *decisional regret* experienced by patients and caregivers related to ACP discussions and consideration of completing an advance directive. Again, both patients and caregivers were given the DRS to complete, in person, following completion of the DCS.

Data Management and Analysis

Data Management

A secure, password-protected study drive was set up and maintained at UCH of which only the PI had access to the data. All quantitative data was stored on an excel spreadsheet, on a password protected computer. The qualitative data was entered on separate Word documents on a password protected computer that only the PI had access.

Interviews were transcribed in person, then typed up verbatim, reviewed for accuracy, and stored as Word documents.

Data Analysis

Data was analyzed using SPSS Statistical Software® version 26. Descriptive statistics were used for categorical data, including frequencies and percentages. The means and standard deviations were calculated for all continuous variables. Continuous data were evaluated for skewness.

Specific Aim 1: Feasibility and Acceptability

Feasibility. *Feasibility* data were summarized using descriptive statistics (the proportion of eligible dyads who enrolled and completed study), and reasons for non-completion. Descriptive statistics were used for categorical data including frequencies and percentages. The means and standard deviations were calculated for all continuous level variables. Continuous data were evaluated for skewness. Independent t-tests were used to examine group differences on a continuous level such as age, education, etc. Chi-square was utilized to examine group differences on categorical level variables (such as gender, caregiver, patient, etc.). A Fisher's exact test was utilized to examine group differences based on factors (such as race, etc.). A One-Way ANOVA was used to compare the means of independent groups, such as gender or caregiver vs. patient (categorical) and DCS/DRS answers (continuous).

Participant Acceptability. Participant acceptability was measured with both quantitative and qualitative measures. Patients and caregivers were given the same follow-up survey to complete to assess feasibility and acceptability of the intervention.

Mean scores on the intervention follow-up survey were calculated for patients and caregivers. A mean score of *80% or higher* was used to indicate acceptability.

Deductive qualitative content analysis techniques were used to analyze the transcribed interview data. This involved first reading the entire interview to get a sense of the whole. This was followed by line-by-line coding beginning with a start list of codes (see **Appendix L**). Codes were developed *a priori* and based on the interview guide (Miles et al., 2018). As analysis proceeded, 35 codes were derived, and then were further reduced into 10 code families or categories (Miles et al., 2018). For example: Fear, anxiety, and anger were collapsed into the category entitled *"Feelings."* To facilitate comparisons within and across dyads, 5 matrices were created; one for each main category. For example, the matrix entitled, "*Feelings About ACP discussion,"* included categories such as initial emotional response of patient/caregiver, later emotional response of patient/caregiver, etc. Once matrices were created, each patient perspective was compared to that of his/her/their caregiver and those of the other patient participants, noting similarities, differences, and trends. Summary statements, each representing an aspect of the participants' experience, were supported by excerpts from the interview data. Primary analyses were conducted by the PI (Emily Benton), with guidance from her dissertation co-chair (Dr. Maureen Metzger) and DSMB member (Dr. Colleen McIlvennan), both with experience in qualitative data analysis.

Provider Acceptability. Providers were given a clinician specific follow-up survey to complete in order to assess for study feasibility and acceptability. Mean scores on the intervention evaluation form for clinicians were calculated. Again, a mean score of *80% or higher* was used to indicate acceptability.

Specific Aim 2: Participant Outcomes for an Informed, Shared Decision Process

Decisional Conflict. As measured by the DCS, mean scores were calculated for each question, with scores ≥ 2 indicating difficulty in making choices about completing an advance directive.

Uncertainty Subscale Score. There were three items on the DCS specific to determine uncertainty about a decision being made (questions 10-12). Questions 10 to 12 were totaled to sum item scores and independent t-tests were used to examine group differences on a continuous level (score) compared to patient vs caregiver.

Informed Subscale Score. Three questions on the DCS (questions 1 to 3) were specific to determining if the patient and caregiver felt as though they had enough information to complete an advance directive or participate in ACP. Questions 1 to 3 were totaled to sum item scores and independent t-tests were used to examine group differences on a continuous level (score) compared to patient vs caregiver.

Values Clarity Subscale Score. DCS questions 4 to 6 were used to determine if the dyad gained clarity in personal values with regard to advance directives and ACP discussions. Questions 4 to 6 were totaled to sum item scores and independent t-tests were used to examine group differences on a continuous level (score) compared to patient vs caregiver.

Support Subscale Score. DCS questions 7 to 9 were aimed at identifying dyad support to participate in ACP and consider completing an advance directive. Questions 7 to 9 were totaled to sum item scores and independent t-tests were used to examine group differences on a continuous level (score) compared to patient vs caregiver.

Effective Decision Subscale Score. DCS questions 13 to 16 were specific to decisions made and satisfaction with the decision to participate in ACP and consider an advance directive. Questions 13 to 16 were totaled to sum item scores and independent t-tests were used to examine group differences on a continuous level (score) compared to patient vs caregiver.

Reliability Test by Cronbach's Alpha. Cronbach's alpha reliability coefficients were obtained for both patients and caregivers, then individually, to estimate internal consistency of the measures for this sample and to verify previously established reliability coefficients. Independent t-tests were used to examine group differences on a continues level of DCS score as compared to patient vs. caregiver.

Decisional Regret. As measured by the DRS, mean scores were calculated for each of the 5 questions, with >2 indicating less satisfaction or increased regret about decision to participate in ACP and consideration to complete an advance directive. In order to complete statistical evaluation of the DRS, question 2 (I regret the choice that was made) and 4 (The choice did me a lot of harm) had to be reverse scored. For example, if a patient/caregiver answered 2, the answer was converted to a 4 for data analysis. This was done to evaluate for Cronbach's alpha reliability coefficients.

Reliability Test by Cronbach's Alpha. Cronbach's alpha reliability coefficients were obtained for both patients and caregivers, then individually, to estimate internal consistency of the measures for this sample and to verify previously established reliability coefficients. Independent t-tests were used to examine group differences on a continues level (i.e., patient to caregiver).

Methodological Rigor

To enhance methodological rigor for this study, a statistician was consulted in the collection, management and analysis of all quantitative data. All data analyses conducted in SPSS were done so in collaboration with a statistician experienced in clinical research. For the qualitative data, methodological rigor was maintained by having all interview data collection and analysis procedures guided by mentors with expertise in qualitative methods, peer debriefing, and parallel analyses.

Human Subject Protection

Protection Against Risk, Emotional Distress, and Confidentiality

This research did not involve greater than minimal risk to participants. The only record linking the subject and the research was the consent document and the only principal risk was potential harm resulting from a breach of confidentiality. Concerns related to discussing completion of an advance directive included discussion of overall prognosis, death, and resuscitation wishes. Monitoring of any unexpected physical or behavioral responses was ongoing.

Emotional reaction to the subject matter elicited questions related to death, treatment options, and emotional loss for both patient and caregiver. The PI was cognizant of any signs of discomfort shown by the patient or caregiver during the study and discussed material in as much detail as desired, based on physical and verbal prompts (including body language and questions). If a participant reported or demonstrated evidence of emotional distress during the intervention, several options, depending upon the participant's wishes, and the level of distress, were available. If a participant became visibly upset during the intervention process, the PI paused and offered emotional

support. The dyad was given the options of delaying, ending or rescheduling the intervention, and being referred for more formal support as appropriate. The dyad was assured that he/she could withdraw from the study at any time, and that all previously collected identifying information would be destroyed. However, no participants withdrew.

Participants in the study were assured that all efforts were taken to maintain confidentiality throughout the consent/assent process, respectively. Patient names and subject identification numbers were kept together in a single location, secured in a locked cabinet, with access available only to the PI. Participants were assigned an identification number for all forms. The PI entered all collected data from the instruments into a password-protected computer accessed only by the PI.

Data Safety and Monitoring

Each participant was given a study identification number that was linked to the completed surveys and a preferred method of contact (i.e., telephone number) for follow-up interviews. The researcher maintained a master list that linked the names of the participants to the assigned de-identified codes with contact information. Every attempt was made to maintain confidentiality of the participants and to secure all data collected. No data was stored on personal computers or external hardware devices.

Monitoring for Adverse Events

A data and safety monitoring board (DSMB) consisting of three members: Two physicians (one from the University of Virginia and another from the University of Colorado) and one nurse faculty dissertation committee member from the UVA School of Nursing. The DSMB received monthly reports on: a) summaries of accrual rates and

patterns; b) information on all adverse events and protocol violations; and c) where applicable, stopping or escalation/de-escalation decision rules.

Based on the nature of this non-invasive behavioral study, definitions related to adverse events and reporting mechanisms were: a) *severe emotional distress/discomfort* related to sensitive questions around difficult decision-making while being treated for HF; and b) any *breach of confidentiality*, in which dyad identity was revealed. Possible adverse events included serious unstable physical or emotional problems related to this behavioral intervention, such as the participant revealing thoughts of suicide or a suicide attempt due to dealing with difficult choices such as stopping treatment. No such events occurred throughout the completion of this pilot study.

Risk/Benefit Ratio

While this study posed mild risk such as emotional distress in discussing end-of-life and possibility of death, there were several potential benefits that may result from the study. These potential benefits included the following: (a) participants may gain knowledge about their decision making, their values, HF and related complications, and dying with dignity; (b) health care providers and society may benefit from the research findings through knowledge transfer; (c) participants may feel more satisfied with their decision and experience decreased decisional regret; (d) the provider/patient/caregiver relationship may be strengthened as a result of informed, shared decision making through an interactive process with a health professional; (e) participants may feel the freedom to articulate their wishes and experience decreased decisional conflict and regret; (f) providers may also experience ease in understanding patient desires for aggressive treatments; and (g) this pilot study may help improve healthcare provider communication

with patients and caregivers with regard to prognosis and QoL while living with HF. The study may also increase provider understanding and confidence of the impact DAs can have in reducing patient and caregiver decisional conflict, improving completion of advance directives, and avoiding/decreasing decisional regret.

Chapter 4: Results

Study Sample Characteristics

Sixty participants, 30 patients diagnosed with HF and their 30 designated caregivers, were recruited from the Advance HF Service at the UCH. All patients in this study were diagnosed with HFrEF and actively admitted to the hospital for treatment of their HF.

Patient Sample

A majority of the patients (70%) were receiving inotropic therapy due to the severity of their HF and were NYHA functional class IV. The mean length of stay for patients was 18.6 days, with the longest being 65 days, and the shortest admission being 2 days. The average distance from UCH was 172 miles. Nearly 40% of the participants lived over 150 miles from the facility.

As shown in **Table 3**, the sample as a whole was fairly young for the enrolled participants (M =56.5, SD = 12.7) and were mostly married males (men, 67%; women, 33%). The enrolled sample was predominantly Caucasian (73%). And, a majority (53.3%) of the patients had been diagnosed with HF for less than 1 year.

Table 3

Descriptive Statistics of the Enrolled Patient Participant Sample

Variable	*N* (%)
Total number of participants	**30**
Age	Range: 22-76 years Median: 60 years Average: 56.5 years
Gender	Male: 20 (66.6%) Female: 10 (33.3%)
Race	Caucasian: 22 (73%) African American: 4 (13%) Hispanic: 3 (10%) Asian: 1 (3%)
Education	Range: 10 >20 years Median: 12 years Average: 13.72 years
Marital Status	Married: 19 (63.3%) Not Married: 11 (36.7%)
Annual Income	>$50,000: 15 (50%) $25,000-49,000: 12 (40%) $10,000-24,999: 3 (10%)
Insurance Type	HMO: 9 (30%) PPO: 6 (20%) Self-pay: 5 (16.7%) Other: 9 (30%) None: 1 (3.3%)
Years Since Diagnosis	<1 year: 16 (53.3%) 1-4 years: 6 (20%) 5-9 years: 3 (10%) >10 years: 5 (16.7%)

Caregiver Sample

The majority of participant caregivers were spouses (63%) or significant others (13%) of the patient participants. The remaining caregivers, who were designated caregivers, were other family members: 4 daughters (13%), 2 sisters (6%), and 2 parents (6%). As expected, the majority of the caregiver sample was female (77%).

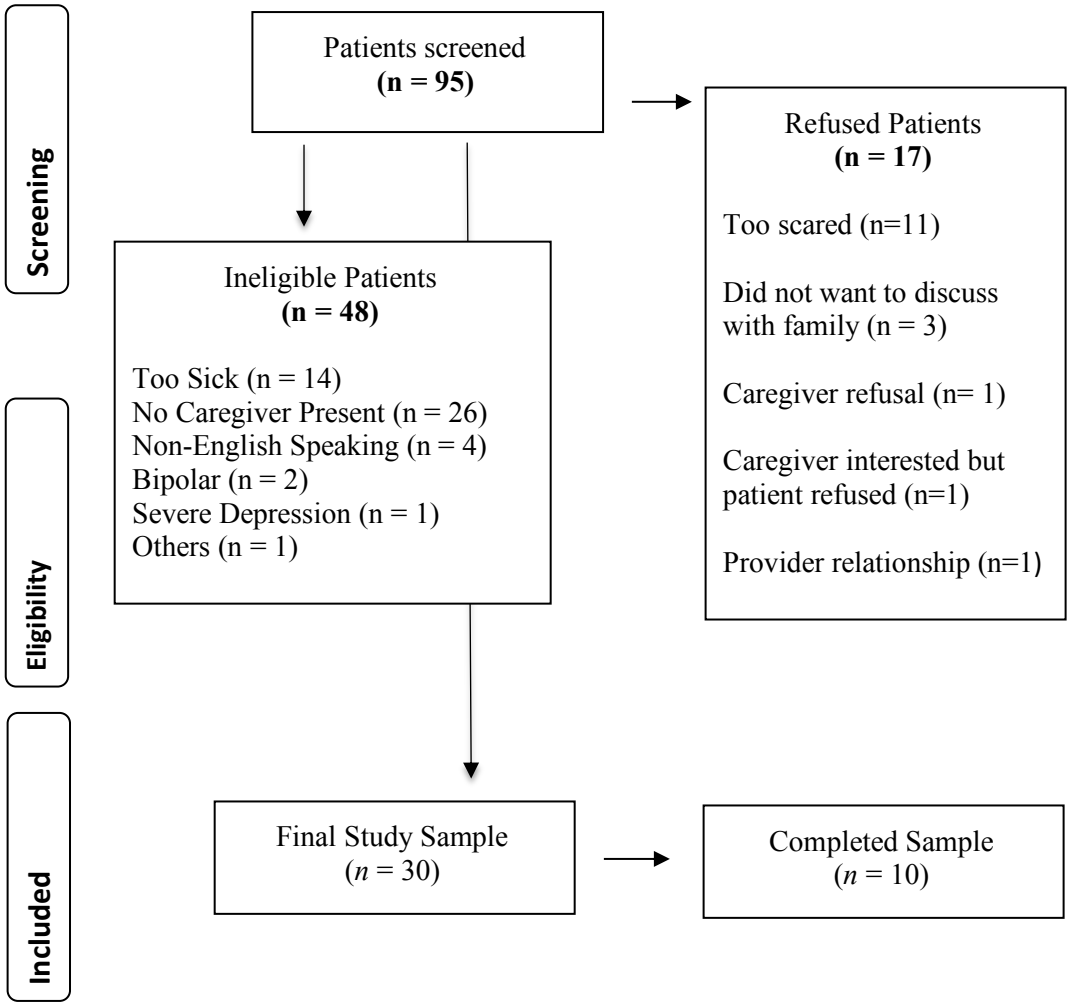
Specific Aim 1: Feasibility and Acceptability

Description of Sample

Enrollment took place from 11/1/2018 and was completed on 10/31/2019. A convenience sample of 95 patients were assessed for participation in the study. Of the 95, 48 patients were eligible to participate, 30 enrolled, and 17 refused. Of the 30 enrolled, all completed the baseline measures. However, only 8 dyads (26.6%) completed an advanced directive and only 10 dyads completed the follow-up survey and interview. And, two participants (6%) were lost to attrition. For the outcomes of interest, 30 dyads completed the post-intervention DCS and DRS. For enrollment flow, see **Figure 2.**

Figure 2

Advance Directive Decision Aid PRISMA Diagram

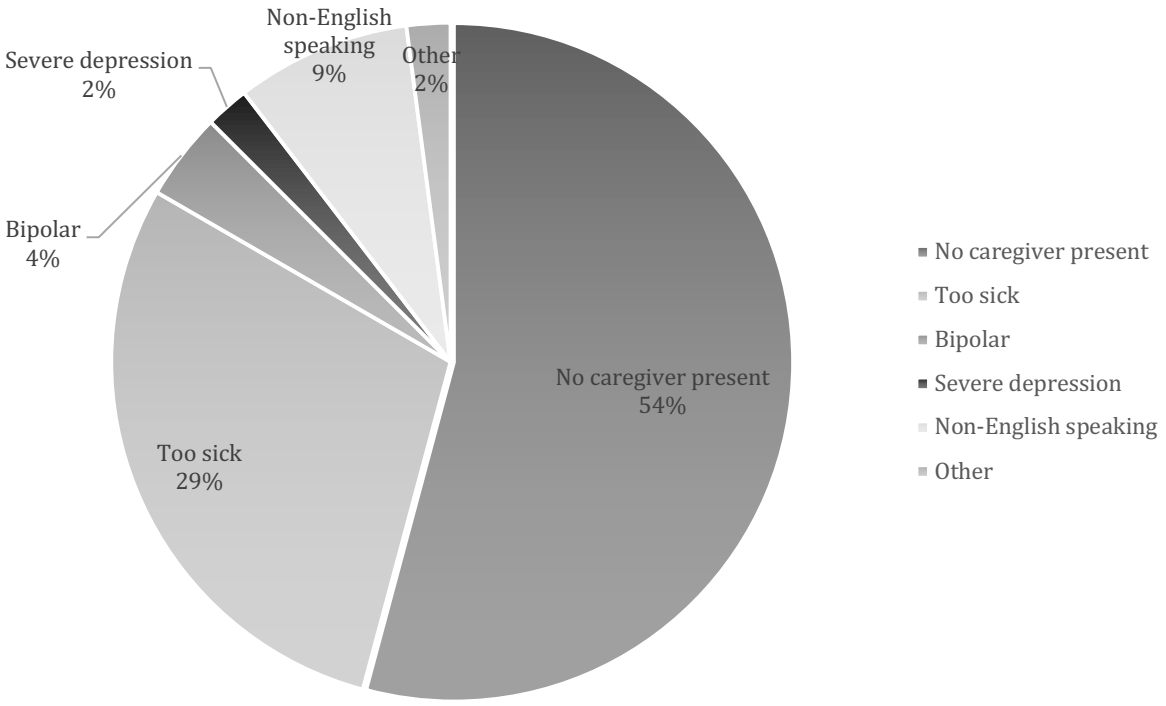


As planned, all 30 dyads were approached, consented, and completed baseline measures in a private hospital room. Most all dyads (93%) were able to complete the testing in a single sitting, although one dyad intervention was interrupted due to testing (radiology), and for the other dyad, the intervention was interrupted due to an unexpected family visitation. The time to deliver the intervention (balance sheet, DCS, and DRS) ranged from 20 minutes to 1 hour and 45 minutes. Time varied widely based on amount of discussion stemming from the balance sheet.

Ineligible Sample. There were 48 patients who were screened but not consented. The ineligible sample was predominantly male (62%) and similar to the enrolled group age (*M* = 56.10, SD = 13.212). There were 13 ineligible participants 49 years or younger, compared to 35 ineligible participants that were 50 years or older. The race/ethnicity for the ineligible sample consisted of: Caucasian (65%); African American (12.5%); Hispanic (16%); and Native American (2%). There were several reasons for ineligibility to participate (see **Figure 3**).

Figure 3

Reason for Ineligibility to Participate



The most common reason for patient participant ineligibility was lack of a caregiver that was willing and able to participate. In fact, despite multiple attempts 54% of the ineligible participants lacked presence of a caregiver. Individuals were approached anywhere from a single time to five times in attempt to allow the potential participant a

chance to identify an eligible caregiver, unless the individual identified no caregiver present upon initial approach (n = 18). If the potential participant identified a possible caregiver, they were asked to identify a time of day that the caregiver would most likely be present, and if the patient thought the caregiver would be interested in participation.

Refusal Sample. There was a total of 17 individuals that refused participation. The majority (53%) were less than 49 years of age and Caucasian (M = 49.47, SD = 17.183). The gender of those less than 49 years of age consisted of 5 males and 4 females. The gender of those who were 50 years and older consisted of 7 males, and 1 female. The race/ethnicity of the refusal group was the following: Caucasian (58.8%); African American (5.9%); Hispanic (17.6%); Asian (5.9%); Native American (5.9%); and Other (5.9%). An independent samples t-test was conducted to compare age amongst the enrolled, ineligible, and refused samples. There was a statistically significant difference in age between the enrolled and refused samples (p = 0.011); and ineligible and refused (p = 0.014). The mean age of each group was: enrolled (M = 56.5); ineligible (M = 56.10); and refused (M = 49.47). A chi-square test of independence was performed to examine the relation between group (enrolled, ineligible, and refused) to gender. There was no significant difference found. A Fisher's exact test was used to assess the difference between group (enrolled and refused) and race. Again, there was *no* statistical difference found.

The most common reason for refusal was patients stating they were "*too scared*" to discuss an advance directive (n = 7). This was separated from individuals who stated specifically that they preferred *not* to discuss an advance directive with their family out of fear of being a burden to the family (n = 3). Only one caregiver refused to participate,

while the patient was interested in participating; similarly, there was one case in which the caregiver was interested in participating and the *patient* was not ready to participate prior to discharge. A single dyad refused to participate stating their preference was to hold the advance directive discussion with their primary care provider, given their years of experience with him.

Lost to Follow-up Sample. *Lost to follow-up,* defined as the inability to contact the patient (via 3 telephone calls on separate days with voicemails or handwritten letter with pre-stamped envelope to return the study survey) accounted for the majority (66.6%) of the sample. After three phone calls with detailed voicemails, it was considered "passive refusal" and the study was concluded for that dyad. Due to the fact that many participants did not respond to multiple contact attempts, and/or did not show up for follow-up care appointments in the HF clinic, their reasons for not completing outcome measures is unknown.

Of the 30 enrolled dyads, only 10 dyads participated in the follow-up survey and exit interview, meaning that only one-third (33%) of the enrolled participants completed the study. The dyads who completed the study were, 8 males and 2 females and Caucasian (60%). An independent samples t-test was conducted to compare age between those that completed the study, and those who did not. The mean age for the completion group (M = 59.1, SD = 8.595) was comparable to the non-completion group (M = 55.2, SD = 14.370). There was *no* statistical difference in age between groups. Of note, all caregivers for those that completed the study were female.

Patient and Caregiver Evaluation

Decision Balance Sheet. Acceptability of the *Advance Directive Balance Sheet* was determined by patients and caregivers answering 4 (agree) or 5 (strongly agree) on 80% or more of the follow-up survey questions. Only 10 dyads completed the follow-up survey. Of those 10 dyads, patients and caregivers reported that it took 1-3 minutes to complete the balance sheet, which was slightly less than recorded times, which ranged from 2-5 minutes. All patients and caregivers within the 10 dyads reported that the balance sheet was easy to read, use, and was helpful.

Decision Aid Intervention Overall. Patients and caregivers responded favorably that the DA was helpful overall with a mean score of 4.4 (out of a score of 5). Patients responded favorably ($M = 4.3$, SD = 0.823) that the DA assisted with communication between the provider about their personal values. There was no statistical difference between patient and caregiver responses for the follow-up survey. Interestingly, patients responded that the DA helped them arrive at a decision ($M = 4.2$, SD = 0.789), although only two of the ten dyads that completed the follow-up survey actually completed an advance directive by the conclusion of the study.

Provider Evaluation

The providers were asked to complete a survey following enrollment of a patient while they were on service. Scores on quantitative and qualitative aspects indicating the majority (80%), whose experience was favorable or highly favorable were considered to indicate acceptability. Out of a total of 13 providers, 9 providers (8 physicians and 1 APP) completed the survey.

Decision Balance Sheet. Overall provider response was positive, with 8 out of 9 providers reporting that: a) the balance sheet instructions were clear; b) the DA was easy to use; and c) the reading level was appropriate for this sample of HF dyads. However, the providers were disappointed with the lack of follow-up and completion of advance directives within the study sample. Almost all of the 9 providers (88.8%) stated they would recommend the DA to other colleagues, and more than half (66%) of the providers thought they could use the DA on a daily basis with their patients.

Informed, Shared Decision Making. Again, 8 out 9 providers stated the DA enhanced discussions between providers, patients, and caregivers, although 4 out of 9 (44.4%) felt neutral on whether the DA increased satisfaction with the patient visit. Within this small sample of HF providers, 50% felt as though the DA lengthened their visit, while the other half did not feel it changed the clinic time substantially. Most providers (6 out of 9) vocalized concern that the DA did not increase the amount of completed advance directives.

Patient and Caregiver Acceptability: Perspectives of Decision Aid and Study Participation

Dyads were asked to participate in a structured exit interview to assess their perspectives on overall participation in the study. The questions were open ended and both patients and caregivers were asked the same questions. The following results are based on analysis of interviews with the 10 dyads (20 participants).

Patients and caregivers reported different reasons for deciding to participate in the study. Some patients were motivated to discuss their end-of-life treatment preferences, as they sensed their illness was worsening, such as “I have undergone a lot of procedures

during this hospitalization. It makes me realize how sick I really am." Others expressed a desire "to pay it forward and help others."

Caregivers were more consistent in their responses, reporting that they were motivated by a desire to clarify their loved one's wishes before a traumatic event, such as "I need to know what is needed before they can't speak." Caregivers expressed a sense of urgency and weight to making such decisions without an advance directive, such as "You just can't guess on this" or "How am I supposed to know if we don't talk?" Caregivers were largely motivated to participate out of a desire to better understand their loved one's desires in a difficult situation. One caregiver stated, "This gives us an open opportunity to talk about this difficult issue *before* something happens."

As part of the intervention, patients and caregivers received information about Janis & Mann's theory of conflict and regret using a brief tutorial diagram, the purpose of a decision balance sheet using an example, and instructions on how to identify and prioritize risks and benefits when discussing advance directives. Participants also were asked to share their perceptions of the balance sheet and one reported, "The theory helped me understand the big picture, but it didn't help make the decision to complete an advance directive any easier." All participants reported that the tutorial and subsequent completion of the balance sheet facilitated a much-needed discussion about advance directives. Patients appreciated the opportunity to acknowledge the severity of their illness and express their fears as well as their concerns. As one patient participant explained, "I realized I might actually be as sick as they are telling me, and may not survive much longer."

As illustrated by the following excerpt, caregivers vocalized their understanding in acknowledging the complexity of decision making, "The study helped discuss desires, but it will still be very difficult to turn things off." The education about the balance sheet assisted the patient and caregivers to have a more grounded and sincere discussion about advance directives. Patients appreciated the ability to articulate their fears through the balance sheet. Patients also reported that the education and process of completing the balance sheet forced them to acknowledge their illness and that they could no longer deny the disease, although as one patient stated, "They keep telling me I am going to die, but I keep living. I think this balance sheet helped me understand my own fears in acknowledging that I have a bad heart."

Patients and caregivers were asked to share their thoughts and feelings upon completion of the intervention, noting whether they had changed over time. Participants consistently reported feeling a sense of relief upon completing the *DecisionKEYS* discussion. As one patient stated, "It was easier than I thought," and "This conversation resembled one in our house a couple of weeks ago. This study echoed my wife's concerns over not knowing what to do with me because I don't like to talk about it."

These statements were in marked contrast to their feelings before participation. Patients described feeling anxious, fearful, and uncertain. "No matter how you bring up this subject (*advance directives*), talking about death is scary." Patients in particular expressed uncertainty and denial about their disease, "How many more times can my body go through this?" and "I believe that if we complete an advance directive, it means that I am acknowledging that I will die." Caregivers, on the other hand, expressed anxiety

about not knowing what to do, “How do I know what she wants, when she won’t talk to me about her desires?”

Interestingly, despite agreeing that the intervention was beneficial and that advance directives are important, many participants deferred completing advance directives upon conclusion of the study. They expressed optimism that they would complete them in the future, but did not feel ready at the time the interview was completed. For example, “This study helped with a very difficult discussion I needed to have, but I am not ready to complete an advance directive right now.” Patients continued to endorse their sense of survival and completing an advance directive might convey to the treatment team that they are ready to quit, “I am now realizing how sick I am, but I don’t want my doctor to think I am done if I fill one of these out” and “They keep telling me I am going to die and then I survive. If I complete one of these, that would make me die.” Caregivers on the other hand stated they would have appreciated an advance directive to be completed, although they felt a greater understanding of the patient’s wishes were achieved even through the mere discussion from the study.

An overwhelming majority (90%) of the dyads who completed interviews were positive about the study. Both patients and caregivers alike verbalized an enhanced understanding in the importance of decision making, such as “It helped me understand the bigger picture.” There was a strong sense of urgency to enhance communication within the dyad, and from the dyad to the treatment team, “How do we (*caregiver and treatment team*) know what you (*the* patient) want if we don’t have these discussions?” Patients stated that they gained a better understanding of their illness and the unpredictable nature of HF, which ultimately made the need for an advance directive

clearer, but not necessary. Patients and caregivers were united in stating that the decision balance sheet was great to encourage and enhance the discussion, however, it *did not* provide the necessary incentive to complete an advance directive.

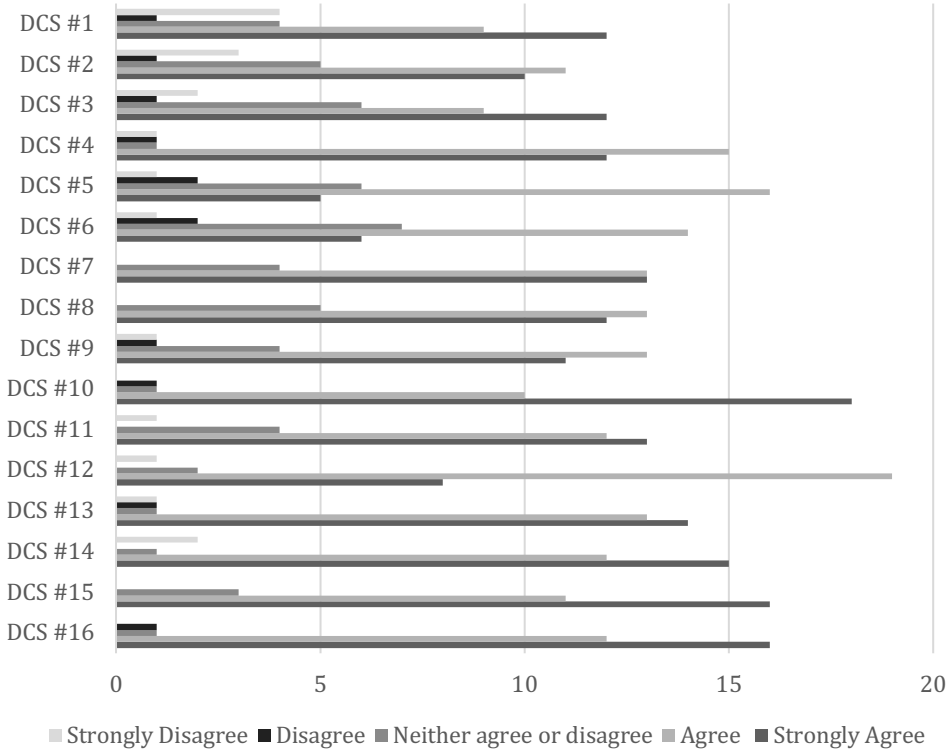
Specific Aim 2: Outcomes Measures Related to Quality Decision Making

Decisional Conflict Scale

Following completion of the *Advance Directive Balance Sheet*, the enrolled dyad was asked to complete the decisional conflict scale (DCS). All 30 dyads completed this measure. The DCS took anywhere from 2 to 5 minutes to complete for both patients and caregivers. Patients and caregivers did express moderate conflict in discussing advance directives and engaging in ACP discussions (see **Table 4).** There was no statistical difference between patients and caregivers throughout all 16 DCS questions.

Table 4

Patient Results of Decisional Conflict Scale



Uncertainty Subscale Scores. Patients and caregivers expressed a moderate amount of uncertainty; however, there was no significant difference between patients (M = 43.16, SD = 14.40) and caregivers (M = 45.71, SD = 17.93). Scores ranged from 0 (feels extremely certain about best choice) to 100 (feels extremely uncertain about best choice).

Informed Subscale Scores. Despite the theory-based intervention, patients and caregivers reported that they did not have enough information to make a decision. Scores ranged from 0 (feels extremely informed) to 100 (feels extremely uninformed). There was no significant difference between patients (M = 53.84, SD = 29.37) and caregivers (M = 54.41, SD = 22.04).

Values Clarity Subscale Scores. Patients and caregivers gained some value clarity in participating in ACP. Scores ranged from 0 (feels extremely clear about personal values for benefits and risks/side effects) to 100 (feels extremely unclear about personal values). There was no significant difference between patients (M = 52.75, SD = 21.81) and caregivers (M = 45.53, SD = 13.9).

Support Subscale Scores. Patients and caregivers felt moderately supported through this process. Scores ranged from 0 (feels extremely supported in making decision) to 100 (feels extremely unsupported in decision making). There was no significant difference between patients (M = 44.98, SD = 16.31) and caregivers (M = 48.03, SD = 15.57).

Effective Decision Subscale Scores. Patients and caregivers were indifferent in feeling as though their decision was effective. Scores ranged from 0 (good decision) to 100 (bad decision). There was no significant difference between patients (M = 41.25, SD = 18.82) and caregivers (M = 43.75, SD = 14.49).

Reliability Test by Cronbach's Alpha. *Preliminary* combined (patient and caregiver) estimates on decisional conflict as measured by the DCS was reliable ($\alpha = 0.936$) for this sample of 30 dyads within the HF population. However, when separated patient reliability was ($\alpha = 0.949$) and caregiver reliability was slightly lower ($\alpha = 0.916$), both results interpreted as high reliability compared to original testing with ($\alpha = 0.78$) by O'Connor (1995).

Decisional Regret Scale

The decisional regret scale (DRS) was completed immediately following the DCS and took anywhere from 1 to 5 minutes to complete for both patients and caregivers. All

dyads completed this measure. The overall total scores for patients and caregivers were not statistically different.

Caregiver Regret Subscale Scores. For the most part, patients and caregivers answered similarly on the DRS (see **Table 5**). However, on question number 2 (I regret the choice that was made) caregivers ranked their regret higher ($M = 3.63$) compared to patients ($M = 4.27$). There was a statistically significant difference in reported regret for the choice that was made between caregivers and patients ($p = 0.008$).

Table 5

Decisional Regret Scale Results Between Patients and Caregivers

Decision Regret Scale Items	**Patients (n = 30)**		**Caregivers (n = 30)**	
	M	**95% CI**	***M***	**95% CI**
I would not make same choice again	*M* 1.57 SD .679	[1.31, 1.82]	*M* 1.67 SD .606	[1.44, 1.89]
I regret the choice that was made	*M 4.27* SD .691	[4.01, 4.52]	*M 3.63* SD 1.066	[3.24, 4.03]
The choice did me a lot of harm	*M* 1.80 SD .761	[1.52, 2.08]	*M* 1.93 SD .868	[1.61, 2.26]
The decision was not a wise one	*M* 4.20 SD .714	[3.93, 4.47]	*M 4.03* SD .999	[3.66, 4.41]
It was not the right decision	*M* 1.73 SD .868	[1.41, 2.06]	*M* 1.80 SD .610	[1.57, 2.03]

Note. As regret is a negative concept, responses were stated as negatives.

Reliability Test by Cronbach's Alpha. *Preliminary* combined (patient and caregiver) estimates of decisional regret as measured by the DRS was reliable ($\alpha = 0.841$) for this sample of 30 dyads within the HF population. However, when the dyad was

separated, patient reliability was ($\alpha = 0.883$) and caregiver reliability was slightly lower ($\alpha = 0.794$). These findings were similar when compared to the original testing with ($\alpha = 0.81$ to 0.92) as per Brehaut and colleagues (2003).

Summary of Results

There were 95 people evaluated, with 30 enrolled, and 17 refusals for this pilot study related to evaluating the feasibility and acceptability of a DA for patients with HF. The main limiting factor for those approached, was lack of a designated caregiver. The refusal sample was statistically different (younger) in age than both the enrolled group and the ineligible group.

There were five important issues related to feasibility and acceptability for this pilot study: a) the recruitment plan resulted in a large portion of ineligible patients due to a lack of a caregiver, and also there was a large number of patients that refused to participate; b) a substantial portion of the enrolled sample *did not* complete the study; c) over 2/3 of the enrolled population did not complete an advance directive, although they were positive about the study; d) there were only 10 dyads with completed data, thus, it is difficult to draw substantive conclusions from such a small portion of the chosen sample; and e) due to the single decision timepoint (upon enrollment) and the substantial lack of follow-up, there is no data to conclude if there was long-term decisional conflict and later regret for participating in ACP and considering completing an advance directive.

In summary, despite the challenges encountered in dyad recruitment and retention, informative results were obtained. Patients and caregivers reported little to no decisional conflict; however, caregivers reported significantly increased decisional regret

compared to patients. Dyads reported that the study enhanced discussions pertaining to completing an advance directive, although it did not necessarily change their beliefs about advance directives or make them feel obligated to complete an advance directive. Providers thought the study was feasible and would be easy to implement on a routine basis; however, they were concerned that it did not increase the advance directive completion rate.

Chapter 5: Discussion

Summary of Study Findings

The purpose of this study was to examine the feasibility and acceptability of a DA, shown to be effective in patients with lung, breast, and prostate cancers, in a sample of patients with HF, and to describe the decisional conflict and decisional regret in this sample of patients with HF and their caregivers. While results indicated that participating patients, caregivers, and clinicians rated the DA invention for an advance directive very favorably, numerous challenges with recruitment and retention suggest that substantive changes will be necessary to enhance feasibility.

Patients and caregivers were found to have a mild to moderate amount of decisional conflict; however, there was an interesting significant difference of increased decisional regret experienced amongst caregivers compared to patients with regard to participating in ACP and considering completion of an advance directive. Overall, the pilot study yielded findings that will inform both the modification of the DA and the study processes to enhance the rigor of future studies design and enhance quality decision making for HF patients, caregivers, and treatment teams.

Study Strengths and Contributions to Science

Some of the findings of this pilot study supported those reported by other researchers examining treatment-related decision making and ACP in patients with HF. However, this study was able to identify additional reasons HF patients are reluctant to participate in ACP and complete an advance directive, in addition to several barriers within the ACP and advance directive process that prevent completion or participation.

Addressing these specific issues in larger studies could help increase completion of advance directives and enhance quality decision making for the HF population.

Appropriate Timing for Advanced Care Planning Discussions

Study results indicated that this sample of HF patients and their designated caregivers were interested in discussing potential outcomes and goals of care; however, appropriate timing of these discussions was not clearly identified. In participating in the exit interview, both patients and caregivers expressed that ACP discussions were beneficial, though neither knew how to initiate with their treatment team, or even each other. The dyads repeatedly stated that the balance sheet was very helpful in identifying personal fears for avoiding ACP conversations and completing an advance directive, but it did not necessarily make it easier to discuss. This pilot study also uncovered some barriers in patient perception of illness and struggle with ACP discussions.

Denial of Illness. Patient participants and those who refused to participate in this study consistently vocalized a denial of illness severity, and an overwhelming sense of fear and anxiety in discussing the possibility of death. It was interesting to note that despite the fact that the patient was hospitalized due to their worsening HF, the patient still did not want to acknowledge the severity of illness. As stated by Ambardekar et al. (2017), there is quite a difference in perceived illness severity between HF patients and their providers. For the most part, patients do not believe they are as sick as their treatment team tells them and this promotes decisional conflict and poor decision-making quality. Dyads within this study stated that consistently hearing about the gravity of illness was depressing at times, but did help them understand that the treatment team was concerned about the patient's trajectory and mortality. While it is good that patients may

live longer than their providers predict, denial does not help the patients with the burden of engaging in challenging discussions and treatment decisions, even when they become absolutely necessary (Ambardekar et al., 2017).

Stop Asking When, Discuss Early and Often. Over half of patient participants in this study were diagnosed with HF for less than one year. For many of these patients, it was difficult to understand why they were sick and why such difficult treatment decisions were being asked in a short time period. Dyads expressed gratitude to hear the facts and repeatedly requested that their prognosis not be "sugar coated." Participants that were diagnosed with HF for more than a year stated that while they may not agree with the treatment team's evaluation of their HF prognosis, they appreciated the honesty and in-depth conversation that occurred while admitted for their HF. Participants in this study revealed that they are, indeed, ready to hear and discuss their illness, but do not know how to initiate the discussion and, therefore, just wait for their treatment team to initiate the difficult conversations.

Early and frequent ACP discussions and completion of advance directives continue to be suggested by multiple studies (Allen et al., 2012; Jinshil et al., 2020; Temel et al., 2010). Per the findings of this study and a literature review, no one individual is taking responsibility to have ACP discussions. As Mullick et al. (2013) reveals, patients verbalize that ACP discussions are irrelevant when they are feeling well, *and/or* they have insufficient information to make educated decisions. Consequently, patients feel time constraints imposed by their treatment team and, thus, patients sense that *providers* avoid the ACP discussion all together, including completion of an advance directive (Allen et al., 2012; Jinshil et al., 2020; Mullick et al., 2013). Indeed, the authors

agree these are difficult topics to discuss within a routine clinic visit; however, the continued avoidance of ACP discussions and waiting for physicians to initiate ACP discussions has created this epidemic problem.

In order to correct this practice of avoidance, the pointing fingers for *who* is responsible (patient vs. provider) and the question of *when* needs to be removed from the equation. A universal standardization and routine ACP discussion and completion of an advance directive would benefit patients, caregivers, and treatment teams alike. As suggested by Allen et al. (2012), a yearly HF check, including ACP with a prognosis discussion, could prove beneficial in this frail and unpredictable patient population. From the provider perspective, it is very difficult to gauge the severity of their patients' HF; however, early and frequent ACP discussions would eliminate the need to *guess* when the time is right and just engage in discussion regardless of severity.

From the patient perspective, ACP discussions are difficult to fully participate in as they force the patient to think about *possible* experiences they may encounter with their disease, and even *predict* future experiences associated with their disease (Mullick et al., 2013). Whether the discussions occur while the patient is seen in the outpatient clinic or inpatient hospital admission, ACP is a difficult topic for all involved parties (patients, caregivers, and treatment teams) as it requires acknowledging the mortality of the disease and where the patient is on the disease trajectory.

Completion of Advance Directives

Study participants, both patients and caregivers, indicated that the intervention prompted much needed discussions about the HF disease process and treatment options, and resulted in decreased anxiety and feeling "relieved" afterwards. Yet, despite these

perceived benefits, many patients did not complete an advance directive. Thus, overall completion rates remained low. Decreased advance directive completion rates among HF patients is not new (Allen et al., 2012). However, when participants in this study were queried about their on-going reluctance to complete advance directives after the intervention, they reported that the completion of an advance directive seemed unnecessary. Once the conversation had taken place, they felt satisfied. Even if advance directive completion did not occur, ACP discussions are still beneficial according to this sample. Patients repeatedly stated that completing an advance directive did not change their desires or decrease their caregiver's knowledge about treatment preferences. In moving forward, it would also be important to help patients see the importance of "formalizing" wishes in the form of completing an advance directive.

While this study found that patients remain reluctant to complete an advance directive, providers hold a responsibility to engage in ACP discussions with their patients. A recent study evaluating perspectives in ACP amongst providers found that only 15% of cardiologists feel the responsibility to have ACP discussions compared to 68% of oncologists (Chandar et al., 2017). According to Chandar and colleagues (2017), cardiologists reported that ACP and completion of advance directives would best be completed in the outpatient setting; however, there is a lack of time to conduct ACP during a single clinic visit, and cardiologists fear that they will offend or take away the hope of a HF patient in holding ACP discussions. It was also mentioned that due to the busy clinic schedules, these difficult conversations are often deferred until the patient is hospitalized, and then it is a different treatment team with the patient (Chandar et al., 2017).

Standardizing the timing of ACP discussions with completion of advance directives would streamline the process, debunk the myths of treatment cessation, and perhaps improve advance directive completion rates throughout the HF population. Early and frequent ACP discussions with completion of an advance directive can make the patient's desires known to both the caregiver and treatment team, ultimately decreasing decisional conflict and later regret for all involved (Jinshil et al., 2020). A provider that understands the main wishes of his/her/their patients can offer treatments that are congruent with the patient's desires instead of offering a myriad of treatments with high risk, low yield, and potential bad outcomes.

Younger Age in Refusal Group

In this study, the patients who declined to participate were younger than those who were enrolled. The refusal sample was comprised of mostly Caucasian males who ranged in age from 22 to 74 years old; however, there were five males and four females in total that were less than 40 years of age. The *Advance Directive Balance Sheet* proved beneficial to those who participated; however, getting participants to engage in this pilot study was challenging, as those who refused repeatedly stated they were *too scared* to engage in the conversation. The question of *how* to get patients and caregivers recruited remains at the forefront of the advance directive discussion, but especially for those younger HF patients.

According to a report by Barasa et al. (2014), the largest share of the increase in HF incidence is from individuals less than 45 years of age in Sweden. Barasa and colleagues (2014) believe that this trend is true throughout the United States as well, and will be published with population updates in the next few years. To date, there is little

data published about young adults with HF. While the cause of HF varies from a congenital birth defect, dilated cardiomyopathy, or substance abuse (such as alcohol or illicit drugs abuse), the treatment for HF remains the same as it does for older adults. According to Wong et al. (2013), HF is significantly worse in the younger, male population (anywhere from 18 years of age to less than 50 years of age) and they are more likely to be non-adherent with medications and diet restrictions, while also experiencing a worse QoL, than those who are 60 years and older. While older HF patients may experience an unpredictable disease trajectory, the younger HF population may experience more complications and hospitalizations secondary to the disease process (Wong et al., 2013).

The treatment, evaluation, and risk assessment for living with HF has been focused on those who are 65 and older, which may not change substantially for the younger population; however, the decision-making process might be more complicated. Issues such as life style and reproductive limitations are just a couple of differences that may impact decision making in the younger HF population. The complexity and growing younger-aged HF population poses a significant problem for cardiology treatment teams. First, the younger a patient is diagnosed with HF, or even requires consideration of advanced therapies such as LVAD or cardiac transplant upon initial diagnosis, by default means that they will have more healthcare encounters for treatments, more exposure to risks and complications associated with advanced therapies, and, therefore, experience more complex decisions to make throughout the course of his/her/their illness. Secondly, the topic of ACP and completion of advance directives are currently difficult subjects between treatment teams and individuals 65 and older. Indeed, how much more difficult

will they be to hold with a patient that is 20 years of age? Thirdly, younger-aged patients are most often reliant on his/her/their parents for both emotional and financial support. With a diagnosis such as HF, there may be conflicting ideas of treatment between parents and the younger patient, which can also increase decisional conflict and later regret, ultimately decreasing quality decision making. Therefore, it is critical to gain a better understanding of the decision-making process to aid this growing, younger-age group of the HF population.

Caregiver regret

While caregiver burden is a widely discussed topic throughout the HF population, the notion of caregiver *regret* is not well developed. In this particular pilot study, caregivers expressed a statistically higher ($p = 0.008$) sense of regret compared to patients with regard to making a decision about advance directives. There are a few reasons the caregivers may have expressed higher regret: a) an advance directive was not completed; b) the topic was difficult to discuss with their loved one; c) the caregiver is unsure what to do for the patient in case of an emergency because no decision was made; or d) the caregiver may regret being in the sole position to make the challenging decisions.

Caregivers acknowledged the gravity of the situation and that he/she may actually have to make a difficult decision for their loved one if or when the time comes. Throughout completion of this study, caregivers often commented on the lack of clarity and avoidance of conversation between themselves and the patient, which ultimately increased caregiver burden and regret due to the difference of opinion on treatment offered vs. simply not knowing the patient's desires. According to Jinshil et al. (2020),

there is moderate disagreement in treatment preferences between patient/caregiver dyads associated with poor understanding about advance directives and end-of-life care. This finding was consistent throughout this pilot study as well. Caregivers vocalized a better understanding of the patient's illness and also attempted to vocalize their concern that if an unfortunate event were to occur with their loved one, they would appreciate knowing what his/her/their preferences would be. Inconsistent messages from both patients and providers place undue stress on the caregiver to understand prognosis and aid in quality decision making that is congruent with the patient's desires (Jinshil et al., 2020).

Caregivers provide an unbelievable amount of support for their loved ones. This may be seen through the day-to-day activities such as cooking, laundry, etc., though it also encompasses clinic appointments, medication management, and being at the bedside when their loved one is hospitalized. As discussed by Magid et al. (2016), caregiver *regret* may be experienced by a lack of a support for themselves and a constant high-level of stress about their loved one, resulting in emotional and logistical exhaustion in providing care to a loved one. Aiding the caregiver to better understand the wishes (treatment and end-of-life care) for their loved ones, may assist the caregiver to participate in quality decision making and, ultimately, help to decrease their overall burden (Jinshil et al., 2020). This pilot study revealed the known importance of a caregiver for quality decision making, but also unearthed the fact that the caregiver may be experiencing more regret than previously understood. Further exploration of this finding is definitely warranted, as caregivers play a vital role in the journey of the HF patient.

Study Limitations

There were several general limitations related to this pilot study. This study was conducted at a single academic center, confined to the inpatient setting, and drew from a limited demographic region. While there were several similarities to previous research within the HF population, as this was a pilot study, results cannot be generalizable to the HF population or be related as the full potential impact of the intervention on outcomes for the HF population as a whole.

Recruitment Process

Upon initiation of the study, recruitment was targeted for both the inpatient and outpatient settings; however, enrollment was extremely slow for the first three months. Factors limiting outpatient enrollment were: a) lack of caregiver to travel with patient to clinic; b) geographic proximity to clinic; and c) inconsistent follow-up in clinic (i.e., no show for scheduled clinic visit). It was imperative to have a patient and caregiver dyad to participate in this study as evidence that difficult decisions, especially those like completing an advance directive, are not made in isolation (Hollen et al., 2013). Therefore, there was a strong rationale to include both patient and caregiver as a dyad.

After consultation with the DSMB and guidance received from field experts, Dr. Larry Allen and Dr. Colleen McIlvennan, this pilot study was shifted solely to the inpatient setting to provide a higher caregiver presence due to inpatient admission, and then an engaged population given the recognition of an acute illness. Despite focusing only on the inpatient HF patients, enrollment remained low. Additional education and recruitment procedures such as involving the unit charge nurse and advanced therapies social worker (SW) were implemented and dramatically improved enrollment rates.

Retention Rates

Follow-up rates for the survey and exit interview were very low for this pilot study. This could be for a variety of reasons. First, the time point for follow-up was too far from the enrollment. Perhaps a better follow-up time period would be within two weeks of enrollment so that the patient and caregiver remember the study and are still interested to complete. The two-week time period has been previously validated in the Kansas City Cardiomyopathy Questionnaire (KCCQ) to be successful in allowing the patient to recall memories and answer questions about their disease process appropriately (Green et al., 2000). Second, the dyad may have been inundated with information following discharge and were too overwhelmed to complete the follow-up survey. Unfortunately, this may not change pending the chosen timepoint for follow-up. Even while dyads were still hospitalized, they felt overwhelmed with information and opted out of completing the survey and exit interview. Third, a lack of desire to complete the study was based on the nature of the difficult discussion of potential mortality. This topic is highly emotional and may have prompted discussions that the dyads were not ready to continue or complete following discharge from the hospital.

Exit Interview

Even though patients and caregivers responded very positively to the interview, they were very afraid to participate in a recorded interview. Upon enrollment, both patients and caregivers vocalized their concern and fear that their relationship with the physicians would be altered as the physician might recognize the dyad's voices in discussing his/her/their fear of completing an advance directive. During the consenting process, a total of 13 patients openly stated that they would not agree to a recorded

interview, despite being reassured that the recording would not be used with providers or affect their care. In the end, all participants refused the recording, though some (n = 10), were willing to engage in a face-to-face interview and have their responses written down.

Low Enrollment Secondary to the Need for a Designated Caregiver

Enrollment was much lower than anticipated for this population. Low enrollment was largely limited by a lack of a designated caregiver. Patients that were screened to participate often vocalized that his/her caregiver was unable to take additional time off from work to be present throughout a hospitalization. However, if the patient was in a critical state (intubated, temporary mechanical heart device, inotrope or pressor requirement, or recent life sustaining efforts such as cardiopulmonary resuscitation [CPR]), then the caregiver did feel the need to stay in the hospital with the patient. Oftentimes, the patients requested that the caregiver be contacted via phone call by the treatment team to give a verbal update during a work break. Patients stated during the study screen that "they couldn't afford to have another income missing in the home." While reviewing the intent of the study and the purpose of the caregiver's participation, very few patients (12 out of 30) stated that they would make a serious decision alone, such as completing an advance directive. After completing the study, more than half of the patients (56%) verbalized understanding of the importance of the caregiver as well as the role of the caregiver throughout their own illness.

Inpatient vs. Outpatient Setting

This study was initially approved to be conducted in both the inpatient and outpatient settings; however, after substantial difficulty in enrolling the outpatient population, the decision by study advisors and field experts was to move to the inpatient

setting only for delivery of the DA intervention. The rationale for this change was the continued lack of caregiver availability not only for enrollment, but also lack of availability for attending follow-up at a scheduled visit. Indeed, discussions for an advance directive in both settings are equally important, although have the potential to take on different meaning based on the setting. For instance, if a patient is admitted to a hospital and was admitted for a life-threatening arrhythmia, the discussion of CPR becomes much more pertinent.

Assessment of Decisional Conflict and Later Regret

A major limitation of this study was the single timepoint of assessing decisional conflict and regret. Although the dyad completed the DCS and DRS following completion of the *Advance Directive Balance Sheet*, they were not evaluated again prior to completing the study. As a part of feasibility, the one timepoint only allowed assessment of length of time to complete and reliability of the measures for this HF sample. Nonetheless, there was significant lack of follow-up with the exit survey and interview with the 30 day +/- 7 days schedule, and it is assumed that there would have been poor follow-up with a repeat DCS and DRS.

Future studies should include obtaining the DCS at the baseline visit and a follow-up timepoint for later regret with the DRS, but both measures following completion of the advance directive, to better gauge the level of decisional conflict and later regret and to evaluate the informed, shared decision intervention for an advance directive. The timing of the follow-up timepoints for both measures also require further evaluation for a future study, as later regret is more valuable than immediate regret. Lastly, given the finding that caregivers experienced more regret than the patients, it would also be crucial

to see if the later decisional regret amongst caregivers also decreased following completion of an advance directive by the patient.

Missing Data

This pilot study collected much valuable information; however, there was a substantial amount of missing data for this pilot study. Given the fact that only 10 dyads completed the study in its entirety, it is very difficult to know whether the remaining sample would have similar thoughts or feelings towards the DA as those who completed the study. For future studies, the follow-up timepoint may need to be moved up to 14 days post-intervention to increase retention and completion rates, as well as the opportunity to again discuss if an advance directive was completed as a result of the study.

Study Implications

Despite the challenges and limitations encountered during the study, there are implications for further research and practice in the short-term and potentially policy and education in the longer term. These implications can potentially embolden current nursing practice and after additional studies, possibly influence policy for HF patients, caregivers, and treatment teams.

Embolden Nursing Practice

Nurse Practitioners (APP's). Nurse practitioners hold an interesting and very influential position in this area. APP's are recognized providers that prescribe treatment to patients and are, therefore, able to entertain and engage in ACP discussions and complete advance directives with patients and their caregivers. Given the current lack of ACP discussions and completion of advance directives by physicians, APP's hold the

possibility to engage in these crucial discussions with patients and their caregivers while also including physicians throughout the process. APPs can initiate the ACP discussion, complete the advance directive, and then engage the physicians as a sign of affirmation of the decision. This approach would provide a united, treatment team front, that the patient and caregiver are able to rely on throughout the HF treatment journey.

Engagement of the physicians, about 5 minutes additional time for an introduction to the advanced practice practitioner to the patient who delivered the DA, but also participation in closure of the ACP session to affirm the decision outcome with the patient and practitioner, proved to not only be beneficial, but also played a vital role in the success of the *DecisionKEYS* research by Hollen et al., (2013). The role of the APP is evolving and the level of responsibility and treatment decisions are also increasing. The increasing number of APPs and division of work flow means that physicians are no longer the primary decision maker with a patient and their caregiver; however, the buy in from the physician can prove critical in the success of this DA to enhance quality decision making for the HF population. Given the division of responsibility of providing care for the HF population, APPs provide a constant face in the treatment of HF by seeing patients on a regular basis, both in the hospital and clinical setting, developing lasting relationships to form a level of trust in order to have these emotional and difficult conversations. The positive influence of APP's managing patient care while engaging in ACP discussions can further encourage physicians to follow suit, as both balance heavy clinic schedules and engage in patient discussions on a daily basis.

Influencing Policy

Although this pilot study cannot yet influence current policy, future studies stemming from this pilot study may help shape policy. First and foremost, the negative stigma associated with ACP discussions and advance directive completion needs to be recognized and confronted. While it would be difficult to mandate completion of an advance directive for all patients, perhaps patients could be incentivized to complete advance directives.

This pilot study, in addition to previously conducted research such as *DecisionKEYS*, revealed that informed, shared decision making is critical in a chronic population such as oncology or HF. Given the high stakes of treatment options, risks, and complications associated with HF, quality decision making needs to be placed at the forefront of practice. The benefits of quality decision making are substantial and will make a dramatic improvement on: a) the patient, caregiver, and treatment team burden; b) potentially decrease cost associated with unwanted and futile care in the HF population; and c) increase patient QoL with pursuing or denying treatments that are better aligned with patient desires.

Future Research

This pilot study, directed at HF dyads and their providers, has uncovered several areas for future research within decision making, advance directives, as well as decisional conflict and decisional regret as important outcomes. Following the completion of this pilot study, the next step in a program of research would be to apply for one NIH grant (Study #1) and a foundation grant (Study #2).

Study #1

The focus of this study would be to enhance enrollment and increase completion of advance directives with the *Advance Directive Balance Sheet* by conducting a larger, multi-site study within the HF population. There would be a few modifications to this future study including: a) consideration of incentivizing completion of an advance directive; b) assessment of decisional conflict *prior to* receiving the balance sheet and *following* completion of an advance directive; c) adding a well-timed endpoint for both decision measures, especially later regret; d) enrollment of participants in both the inpatient (hospital) setting and the outpatient (clinic) setting; e) adding a health-related QoL measure, such as the Kansas City Cardiomyopathy Questionnaire (KCCQ); and f) increasing physician engagement with ACP discussions by introducing the purpose of the DA and the APP who will help with the process, as well as helping to reinforce the completion of an advance directive for patients with HF.

In addition, this future study would include the presence of APPs in initiating ACP discussions and completing advance directives, though also adding the presence of the physician in reinforcing the introduction of ACP and importance of completing an advance directive as shown to be previously successful in the *DecisionKEYS* study (Hollen et al., 2013; Jones et al., 2013). Utilizing the decision balance sheet to aid discussions between the patient, caregiver, and treatment teams may increase and enhance ACP discussions. Obtaining a better understanding of the patient's fears and anxiety related to completing an advance directive can guide future discussions and minimize the negative stigma associated with completing an advance directive. The current practice of avoiding the discussion, or asking the patient to complete an advance

directive without discussing the options in full is hindering completion rates. These current practices may ultimately have an effect on this frail and vulnerable population by: a) increasing decisional conflict; b) increasing later regret; and c) decreasing QoL. Change is needed for the HF population. If oncologists and oncology APPs have time to engage in an informed, shared decision process, then cardiologists and cardiology APPs may change to this process if supported by study data.

Study #2

Another area of future research would be focusing on the aspect of caregiver regret and how to decrease or minimize caregiver regret in a larger, multi-site, qualitative study. It is difficult to interpret the findings in this pilot study as there may be a variety of reasons that the caregiver experienced a higher level of regret compared to the patient; however, this is crucial to identify in moving forward with this growing and complex HF population. By focusing on caregiver regret, one may be able to identify the cause of the regret, such as lack of communication, uncertainty of patient desires, disagreement with treatment choice, etc., which may help guide conversations from providers, both cardiologists and cardiology APPs, to patients and their designated caregivers.

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Appendix A

New York Heart Association Classification
American Heart Association. (9th edition). (1994)

Functional Capacity	Objective Assessment
Class I. Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	**A.** No objective evidence of cardiovascular disease.
Class II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	**B.** Objective evidence of minimal cardiovascular disease.
Class III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.	**C.** Objective evidence of moderately severe cardiovascular disease.
Class IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	**D.** Objective evidence of severe cardiovascular disease.

Appendix B

Balance Sheet for Personal Decision Making: Advance Directives

Instructions:

- It may help to talk about difficult decisions with your health care team. You may want to write down your thoughts about what you value to help you make your decision.
- In the box, please **check (√)** statements <u>important</u> to you for this decision. Be sure to identify these for yourself and for others that you care about. If there are other areas of importance, please write them in.
- Please review again and **star (*)** those statements <u>MOST important</u> to you.
- If any statement is not clear to you, be sure to ask your doctor or nurse.

Person Involved	"Advance directives" can help people specify their wishes regarding their future care in case they cannot speak for themselves. They may want to document now what level of care they want to include or refuse in the future. These decisions would include such areas as life-prolonging treatments and artificial means of life support. *As I consider putting an advance directives document in place now, what are the benefits and risks?*_____	
	Benefits (+)	Risks (–)
Gains/Losses for MYSELF	It will provide me with the opportunity to discuss end-of-life decisions □ I will be able to maintain my ability to plan my care by deciding now □ I will be at peace that my wishes will be respected □ I will not have to worry that my care will burden those I care about □ This planning may be in keeping with my religious or spiritual beliefs □ It will increase my discussion with my doctor □ Other benefits for yourself?	I will need to think about issues that may be difficult and upsetting □ I will need to grapple with what I value at the end of life □ I do not like dealing with uncertainty and this will force me to face the process of my dying □ I may have to go through the hassles of updating the document if what I want now is not what I want later □ I may not receive medical treatment when I need it. □ Other risks for yourself?
Gains/Losses for OTHERS	By being clear now, the document may later prevent conflict for those I care about □ There may be fewer legal issues for my family members to have to sort through □ My family may feel relief that they do not have to make such stressful decisions later □ My family may be relieved to know that they can help me by honoring my wishes □ It will take care of some of the burden for my health care providers □ Other benefits for others you care about?	My family may disagree with my choices and may be uncomfortable in honoring my wishes □ By choosing advance directives, there may be issues brought up that my family members do not wish to discuss or confront □ My family may go through this and then the situation may be entirely different □ The document may be going against what my doctor advises later □ Medical treatment may change over time and may not match my document □ Other risks for others you care about?

Appendix C

Study Instruments ADDA Domains and Items of Interest

Constructs	Health-related Quality of Life			
Variables of Interest	• All patients with ejection fraction of <40% • English reading only 2-week time period for reporting			
Domains	1. Decisional Making Quality • Searches for choices • Accounts values and goals desired • Weighs pros and cons • Seeks information • Processes new information • Reviews choices • Makes detailed plan with backup	2. Decisional Conflict • Informed • Values clarity • Support • Uncertainty • Effective decision	3. Decision Regret	4. Evaluation
Instruments to Measure Each Domain	Baseline scores for both reliability and responsiveness cohorts	Decisional Conflict Scale (DCS)	Decisional Regret Scale (DRS)	Participant evaluation forms
Methods to Capture Each Construct	7-Item questionnaire	16-Item questionnaire	5-Item Questionnaire	Determine feasibility and overall acceptability of DA
Level of Measurement	Likert-type rating scale (assess the degree to which a person adheres to seven quality decision making criteria	Likert scale (1-5 based on degree of difficulty)	Likert scale (1-5 strongly agree, strongly disagree with statement)	Likert scale (0-3 not at all true, very true)

Appendix D

Decisional Conflict Scale (DCS)

Instructions: Now, thinking about the **choice you just made**, please look at the following comments made by some people when making decisions.

Please show **how strongly you agree or disagree** with these statements by **checking (√)** the number from 1 (strongly agree) to 5 (strongly disagree), which best shows how you feel about the choice you just made.

1. This decision is easy for me to make.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

2. I'm sure what to do in this decision.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

3. It's clear what choice is best for me.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

4. I'm aware of the options I have in this decision.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

5. I feel I know the advantages of each option.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

6. I feel I know the disadvantages of each option.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

7. I am clear about <u>how important</u> the advantages are to me in this decision.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

8. I am clear about <u>how important</u> the disadvantages are to me in this decision.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

9. For the main options I am considering, I am clear about which is <u>more</u> important to me (the advantages or disadvantages).

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

10. I am making this choice without any pressure from others.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

11. I have the right amount of support from others in making this choice.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

12. I have enough advice about the options.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

13. I feel I have made an informed choice.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

14. My decision shows what is important to me.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

15. I expect to stick with my decision.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

16. I am satisfied with my decision.

Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1	2	3	4	5

Appendix E

Decision Regret Scale (DRS)

Instructions: Please reflect on the decision you made about *completing an advance directive* after talking with your physician. Please show **how strongly you agree or disagree** with these statements by **checking (√)** the number from 1 (strongly agree) to 5 (strongly disagree), which best shows how you feel about the decision you just made.

1. It was the right decision.

Strongly Agree_____	Agree_____	Neither Agree Nor Disagree_____	Disagree_____	Strongly Disagree_____
1	2	3	4	5

2. I regret the choice that was made.

Strongly Agree_____	Agree_____	Neither Agree Nor Disagree_____	Disagree_____	Strongly Disagree_____
1	2	3	4	5

3. I would go for the same choice if I had to do it all over again.

Strongly Agree_____	Agree_____	Neither Agree Nor Disagree_____	Disagree_____	Strongly Disagree_____
1	2	3	4	5

4. The choice did me a lot of harm.

Strongly Agree_____	Agree_____	Neither Agree Nor Disagree_____	Disagree_____	Strongly Disagree_____
1	2	3	4	5

5. The decision was a wise one.

Strongly Agree_____	Agree_____	Neither Agree Nor Disagree_____	Disagree_____	Strongly Disagree_____
1	2	3	4	5

Appendix F

University of Colorado Hospital IRB Approval Letter

Colorado Multiple
Institutional Review Board, CB F490
University of Colorado Anschutz
Medical Campus 13001 E. 17th Place,
Building 500, Room N3214 Aurora
Colorado 80045

303-724-1055 [Phone]
303-724-0990 [Fax]
comirb@ucdenver.edu [Email]
FWA00005070 [FWA]

University of Colorado Hospital | Denver Health Medical Center | Colorado Prevention Center | Children's Hospital Eastern Colorado Health Care System (Denver VAMC)

Certificate of Approval

26-Jun-2019

Title:	**Enhancing Informed, Shared Decision Making in a Chronic Population: Use of an Advance Directive Decision Aid in the Congestive Heart Failure Population**
Subject:	**COMIRB Protocol 18-0293 Continuing Review**
Investigator:	Colleen McIlvennan
Sponsor(s):	None~
Effective Date:	25-Jun-2019

Submission ID: CRV001-1

SUBMISSION DESCRIPTION:

Study Status: Enrolling

This study was reviewed and approved under the "2018 Requirements" of the Federal Policy for the Protection of Human Subjects.

If continuing review is required for your research, your submission is APPROVED until the expiration date listed above. The investigator will need to submit this research for Continuing Review at least 30 days prior to the expiration date. If a study's approval expires, investigators must stop all research activities immediately (including data analysis) and contact the COMIRB office for guidance

If your study has not been assigned an expiration date continuing review is not required for your research.

Regardless of continuing review, you are required to submit changes to your research for approval prior to implementing those changes. You are required to report unanticipated problems and serious or continuing noncompliance to COMIRB. When your research is complete you must report the study closure to COMIRB.

UCD Panel D

Appendix G

Patient Consent Form

Principal Investigator:
Colleen McIlvennan, DNP, MS, BSN
COMIRB No:18-0293
Version Date: 05/15/2018

Study Title: Enhancing Informed, Shared Decision Making in a Chronic Population: Use of an Advance Directive Decision Aid for Patients Living Heart Failure

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Participation by both the patient and caregiver is required to participate in this study. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about decision making in patients who are currently living with heart failure. The main goal of this study is to help patients, caregivers, and their treatment team to understand goals of care, patient specific desires about their treatment of heart failure, and ultimately to complete an advance directive to document those desires. There is currently a negative perception associated with completing advance directives. This study strives to change that perception and enhance quality decision making.

You are being asked to be in this research study because you have been diagnosed with heart failure and do not have a completed advance directive.

Up to *60* people will participate in the study.

What happens if I join this study?

If you join the study, you will be provided with an interactive decision aid, information that will guide you and your chosen caregiver through a series of questions that may help you in completing an advance directive, that documents your desires for treatment. It is important to understand that completing an advance directive will not change your heart failure treatment, but rather, aid in communicating your treatment desires with your caregiver and treatment team so that your wishes are honored.

It is estimated that this study will last about 4 weeks. If you agree to participate, you will receive the decision aid during the first clinic visit, and then be contacted by phone about 4 weeks following the first visit to complete the study.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include minimal to no physical risk.

Other possible risks include emotional distress related to the discussion of advance directives, which may prompt questions related to the disease, treatment options, the possibility of death, and potential emotional loss for both the patient and caregiver.

If you experience any emotional distress, you are encouraged to discuss your concerns during your clinic visit or any time after. There will be a social worker available, who is familiar with the study. Please contact the study nurse if you need to get in contact with the social worker to discuss any distress.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about completing advance directives by using a decision aid in the heart failure population. This study is not designed to treat any illness or to improve your health. The findings of this research will be published in a relevant nursing journals for the study group as a whole.

Completing an advance directive can be associated with negative feelings such as worry that treatment will stop, or that family, caregivers, or treatment teams may not fully understand your treatment desires.

This study is designed to use a decision aid to help answer questions and document patient treatment wishes in a process that decreases decisional conflict and decisional regret.

There may not be a benefit to participation.

Who is paying for this study? There is no current sponsor at this time.

Will I be paid for being in the study? Will I have to pay for anything?

You will not be paid to be in the study. But, it will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Who do I call if I have questions?

The researcher carrying out this study is Emily Benton, NP-C. You may ask any questions you have now or for any questions you have later, you may call the study nurse: Emily Benton, NP-C at 720-848-0000.

You may have questions about your rights as someone in this study. You also can call the study nurse Colleen McIlvennan, DNP, MS, BSN at 720-848-0000 with questions.

You can also call the Multiple Institutional Review Board (IRB) for any study concerns. You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include: University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise**.**

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your

information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Colleen McIlvennan*, DNP, MS, BSN*
University of Colorado Anschutz
Medical Center Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) thatprotect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- *There is currently no sponsor* who is paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

Consent Forms and Decision Aid Balance Sheets will be kept in a locked, secure department cabinet that only the Principal Investigator and study nurse (PhD student nurse interventionist) will have access to these study materials.

At the conclusion of the study (4 weeks after first visit) a phone call with audio recording will be conducted to assess ease of completing the study, balance sheets, and also to assess if an advance directive was completed (though not required). The recordings will be kept according to protocol and destroyed after 7 years from completion of the study date.

You have the right to request access to your personal health information from the Investigator.

The investigator (or staff acting on behalf of the investigator) will also make *all or some* of the following health information about you available to:

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, race/ethnicity, address, phone number, etc.
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, and procedure results.

What happens to data that is collected in this study?

The audio recordings and all study data will be kept according to university research policy and destroyed after 7 years (shredded) from completion of the study date.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:

Print Name:_____

Consent form explained by:_____ Date:

Print Name: _____

Appendix H

Caregiver Consent Form

Principal Investigator:
Colleen McIlvennan, DNP, MS, BSN
COMIRB No:18-0293
Version Date: 05/15/2018

Study Title: Enhancing Informed, Shared Decision Making in a Chronic Population: Use of an Advance Directive Decision Aid for Patients Living with Heart Failure

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Participation by both the patient and caregiver is required to participate in this study. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about decision making in caregivers who are currently living with or providing care for an individual with heart failure. The main goal of this study is to help patients, caregivers, and their treatment team to understand goals of care, patient specific desires about their treatment of heart failure, and ultimately to complete an advance directive to document those desires. There is currently a negative perception associated with completing advance directives. This study strives to change that perception and enhance quality decision making.

You are being asked to be in this research study because you are currently living with or providing care for an individual with heart failure that has not completed an advance directive.

Up to *60* people will participate in the study.

What happens if I join this study?

If you join the study, you and the patient will be provided with an interactive decision aid, information that will guide you and the patient through a series of questions that may help the patient in completing an advance directive, that documents his/her desires for treatment. It is important to understand that completing an advance directive will not change his/her heart failure treatment, but rather, aid in communicating

his/her treatment desires with you the caregiver and the treatment team so that his/her wishes are honored.

It is estimated that this study will last about 4 weeks. If you agree to participate, you will receive the decision aid during the first clinic visit, and then be contacted by phone about 4 weeks following the first visit to complete the study.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include minimal to no physical risk.

Other possible risks include emotional distress related to the discussion of advance directives, which may prompt questions related to the disease, treatment options, the possibility of death, and potential emotional loss for both the patient and you the caregiver.

If you experience any emotional distress, you are encouraged to discuss your concerns during your clinic visit or any time after. There will be a social worker available, who is familiar with the study. Please contact the study nurse if you need to get in contact with the social worker to discuss any distress.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about completing advance directives by using a decision aid in the heart failure population. This study is not designed to treat any illness or to improve your health. The findings of this research will be published in a relevant nursing journals for the study group as a whole.

Completing an advance directive can be associated with negative feelings such as worry that treatment will stop, or that family, caregivers, or treatment teams may not fully understand your treatment desires.

This study is designed to use a decision aid to help answer questions and document patient treatment wishes in a process that decreases decisional conflict and decisional regret.

There may not be a benefit to participation.

Who is paying for this study?

There is no current sponsor at this time.

Will I be paid for being in the study? Will I have to pay for anything?

You will not be paid to be in the study. But, it will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Who do I call if I have questions?

The researcher carrying out this study is Emily Benton, NP-C. You may ask any questions you have now or for any questions you have later, you may call the study nurse: Emily Benton, NP-C at 720-848-0000.

You may have questions about your rights as someone in this study. You also can call the study nurse Colleen McIlvennan, DNP, MS, BSN at 720-848-0000 with questions.

You can also call the Multiple Institutional Review Board (IRB) for any study concerns. You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.
We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the

University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Colleen McIlvennan, *DNP, MS, BSN*
University of Colorado Anschutz
Medical Center Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) thatprotect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- *There is currently no sponsor* who is paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

Consent Forms and Decision Aid Balance Sheets will be kept in a locked, secure department cabinet that only the Principal Investigator and study nurse (PhD student nurse interventionist) will have access to these study materials.

At the conclusion of the study (4 weeks after first visit) a phone call with audio recording will be conducted to assess ease of completing the study, balance sheets, and also to assess if an advance directive was completed (though not required). The recordings will be kept according to protocol and destroyed after 7 years from completion of the study date. You have

the right to request access to your personal health information from the Investigator.

The investigator (or staff acting on behalf of the investigator) will also make *all or some* of the following health information about you available to:

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, race/ethnicity, address, phone number, etc.

- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, and procedure results

What happens to data that is collected in this study?

The audio recordings and all study data will be kept according to university research policy and destroyed after 7 years (shredded) from completion of the study date.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:

Print Name:_____

Consent form explained by:_____ Date:

Print Name: _____

Appendix I

Patient and Caregiver Evaluation Form

Directions: This questionnaire is to **evaluate the new patient information program for heart failure, called a decision aid.** How **TRUE** do you think each of these statements is about you? Use a ***check mark (√)*** for your answer.

Feasibility

1. The **decision balance sheets** were ***easy to read***.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1	2	3	4	5

2. Once I understood the **decision balance sheet**, it was ***easy to use***.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1	2	3	4	5

3. About ***how long did it take you to learn to use*** the **first decision balance sheet**?

Less than one minute	_____
1-3 minutes	_____
4-5 min minutes	_____
More than 5 minutes	_____

4. The ***time needed*** to fill out the ***balance sheets at each visit*** to provide the doctor with a summary report for my part in the treatment decision making was ***acceptable***.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1	2	3	4	5

Parts of the Decision Aid

5. The **"decision guide" or theory** was ***a helpful review of quality decision making***.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1	2	3	4	5

6. The **decision balance sheet** (**"Completing an Advance Directive"**) was ***helpful***.

Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1	2	3	4	5

Communication Aid

7. The **decision aid** was helpful in ***reviewing the necessary steps needed for good decision making*** about completing an advance directive**.**

Strongly Disagree _____	Disagree _____	Undecided _____	Agree _____	Strongly Agree _____
1	2	3	4	5

8. The **decision aid** ***helped me to sort through the amount of information*** related to my treatment choices ***in terms of what is important to me.***

Strongly Disagree _____	Disagree _____	Undecided _____	Agree _____	Strongly Agree _____
1	2	3	4	5

9. The **decision aid** ***helped me in speaking with the doctor or nurse about my personal values*** related to my treatment choices.

Strongly Disagree _____	Disagree _____	Undecided _____	Agree _____	Strongly Agree _____
1	2	3	4	5

10. The **decision aid** ***helped me be thorough in weighing my treatment choices with my doctor.***

Strongly Disagree _____	Disagree _____	Undecided _____	Agree _____	Strongly Agree _____
1	2	3	4	5

11. The **decision aid** ***helped me in discussing my treatment choices <u>with my caregiver</u> (my family member or friend).***

Strongly Disagree _____	Disagree _____	Undecided _____	Agree _____	Strongly Agree _____
1	2	3	4	5

Overall Value

12. The **decision aid** was ***helpful for arriving at the decision*** for my treatment with the doctor**.**

Strongly Disagree _____	Disagree _____	Undecided _____	Agree _____	Strongly Agree _____
1	2	3	4	5

13. The **decision aid** ***helped me feel that I shared in the decision making*** for my treatment.

Strongly Disagree _____	Disagree _____	Undecided _____	Agree _____	Strongly Agree _____
1	2	3	4	5

14. How did the **decision aid** ***affect my clinic visit?***

    1) It made my visit more difficult. _____
    2) It enhanced my visit. _____
    3) Neither of the above. _____

15. The **decision aid** ***increased my satisfaction with my treatment decision.***

Strongly Disagree _____	Disagree _____	Undecided _____	Agree _____	Strongly Agree _____
1	2	3	4	5

16. I would ***advise other patients to use the decision aid*** to help in making ***informed decisions*** about their treatments with their doctors.

Strongly Disagree _____	Disagree _____	Undecided _____	Agree _____	Strongly Agree _____
1	2	3	4	5

Thank you!

Appendix J

Structured Interview Guide for Patients and Caregivers

Directions: Use these open-ended questions to help the patient and caregiver ***tell their story***. Try to ***keep the interview around an hour*** to not burden the participants. Explain how the caregiver will be asked to add comments throughout the interview with the patient as the primary interviewee, and then separate at the end of the interview.

---

1. Tell me about the ***day you decided to be in the study***. Who was with you? What made you decide to be in the study?

2. Tell me about the ***first time you received training in decision making as a part of the study***. Who was with you? Tell me in detail what you did and what it felt like for you.

3. Tell me about the ***decision to complete an advance directive for the study*** – the decision about discussing your care and end of life desires with your relatives and friends – if that was the first decision you made after the training. Who was with you? What were you thinking? How were you feeling? How did you decide?

4. Tell me about the ***completing an advance directive***. Who was with you? What were you thinking? How were you feeling? How did you decide?

5. If you were to ***tell other patients and their caregivers about the decision aid***, what would you tell them? Would you ***add anything else about participating in the study***? Any comments about the ***questionnaires***? Any comments about the ***theory for decision making***? Any comments about the ***chosen decisions***?

** Please thank the participants and close the study for these participants.*

Appendix K

Provider Evaluation Form

Directions: Please answer these questions in relation to the intervention for all participants. Use a ***check mark (√)*** for your answer.

Feasibility

1. The ***instructions for the decision aid*** were easy to follow.

not at all true	not very true	somewhat true	very true
_____	_____	_____	_____

2. The ***decision aid*** was easy to use.

not at all true	not very true	somewhat true	very true
_____	_____	_____	_____

3. The ***reading level for the materials*** seemed appropriate.

not at all true	not very true	somewhat true	very true
_____	_____	_____	_____

4. The ***study questionnaires seemed reasonable*** within a practice setting.

not at all true	not very true	somewhat true	very true
_____	_____	_____	_____

5. The ***estimated time to complete the additional physician component*** per decision in a practice setting was:

Less than 5 minutes	_____
5 minutes	_____
6-10 minutes	_____
More than 10 minutes	_____

6. ***Adherence to the intervention*** by participants was good.

not at all true	not very true	somewhat true	very true
_____	_____	_____	_____

Value as a Communication Aid

7. I believe that the decision aid can ***enhance physician-patient communication.***

not at all true	not very true	somewhat true	very true
_____	_____	_____	_____

8. The decision aid ***helped increase my satisfaction with the patient visit.***

not at all true	not very true	somewhat true	very true
_____	_____	_____	_____

9. The decision aid ***lengthened my average consultation time*** with the patient.

not at all true	not very true	somewhat true	very true
_____	_____	_____	_____

Overall Value

10. I believe the ***decision aid is effective.***

not at all true	not very true	somewhat true	very true
_____	_____	_____	_____

11. I would ***recommend the decision aid to physician colleagues.***

not at all true	not very true	somewhat true	very true
_____	_____	_____	_____

12. I would ***use the decision aid in my daily clinical practice***.

not at all true	not very true	somewhat true	very true
_____	_____	_____	_____

Additional Comments: Please list ***any needed changes for the study*** on the back of this form.

Appendix L

Final Conceptual Categories and Example Matrix for Qualitative Data

Final Conceptual Categories:

Thoughts and feelings related to discussing advance directives:
- Fear, anxiety, anger, sadness, and pressure

Participants motivation to participate:
- Helping others, paying it forward, and increase communication within family

Preparation on decision making while using balance sheet:
- Understanding the importance of decision making, acknowledging prognosis

Discussing advanced directives:
- Initial thoughts/feelings/reactions, uncertainty, denial

Will you/have you completed an advance directive:
- Not necessary right now, will continue to think about it, too scared

Recommending the study to other people:
- Encourages transparency, helps with difficult discussion, does not encourage completion of advance directive

Example Feelings Matrix

Initial Coding Categories	**Preliminary thoughts**
Fear	▪ "Scared to think about how close I am to dying" ▪ "I came really close to death this time. This is the most scared I have ever been" ▪ "Increased hospitalizations have made me scared that I am sicker than I want to admit" ▪ "No matter how you bring up this conversation, it makes me very scared to know that death is a possibility"
Anxiety	▪ "I have undergone a lot of procedures without success, makes me nervous how close to death I am" ▪ "I believe that if I complete an advance directive, it means that I acknowledge my death is imminent and that makes me very anxious"
Sadness	▪ "It makes me sad to think my family will have to make this decision"
Anger	▪ "What did I do to deserve this illness?" ▪ "Why me? I have done nothing to deserve this" ▪ "I shouldn't have to *talk* with my family for them to know what I am or want – they should know this from all our years together and I am not going to acknowledge this now"
Pressure	▪ "It is hard to make a decision right now" ▪ "How will I know I am doing the right thing based off right now"