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## Device Related Concerns Pertaining to Primary Caregivers of LVAD Patients

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Device Related Concerns Pertaining to Primary Caregivers of LVAD Patients

Submitted in Partial Fulfillment of the Requirements for the Degree of Doctor of Nursing  
Practice at the University of Kentucky

By

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Lexington, Kentucky

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## **Abstract**

PURPOSE: The purpose of this project was to focus on caregiver education with an emphasis on caregiver concerns regarding the LVAD; additionally, evaluating the efficacy of an educational video acknowledging those device-related concerns identified by caregivers. The goal of this project is to improve caregiver knowledge and decrease the rate of device related concerns among the primary caregivers.

METHODS: This project is a single center cross-sectional, pre-post-test implementation design to determine the efficacy of device related concerns education on primary caregivers' knowledge and concerns. A 16-point device related concerns scale was designed to appraise primary caregiver concerns. The scale used a 0-4 Likert scale ranking, 0- not concerned and 4- very concerned. An educational video was developed and implemented to address the concerns in the device related concerns scale. A post device related concerns scale used to evaluate the efficacy of the educational video. Data collection took place between November 2020 and February 2021.

RESULTS: Thirty primary caregivers of VAD patients agreed to participate in this study. Twenty-eight of those participants started with only twenty-one completing the online survey. There was a significant decrease in caregivers concerns following implementation of the educational video.

CONCLUSION: The findings from this cross-sectional pre- post- test study supports the implementation of educational video in caregiver discharge teaching. As a result of this intervention, caregivers reported a lower post concerns scale score, this coincides with a better understanding and comfort with the LVAD

## **Acknowledgements**

I would like to express my sincerest appreciation to my advisor and committee chair, Dr. Melanie Hardin-Pierce. Your continued support has been paramount in my success throughout this program. I greatly appreciate your constant willingness to challenge, advise, mentor, and encourage me through times of stress. I cannot thank you enough. I would also like to extend my gratitude to Dr. Sheila Melander for your willingness to provide insight, advice and support throughout this project. Dr. Devan Costelle, my clinical mentor, your support, and guidance were essential in the progress and completion of this project. Dr. Amanda Wiggins- Thaxton thank you for your assistance regarding the statistical portion of this project. Lastly, a special thank you the University of Kentucky LVAD coordinator's Carissa Smith and Rachel Unger, your willingness to donate your time, and expertise were imperative to this project. This project wouldn't have been possible without you!

## **Dedication**

This paper is firstly dedicated to my parents, Nancy and Greg. As a child you raised me to believe in myself and never give up. You supported my goals and aspirations even when they might have seemed a little out of reach. You've both provided your continuous love and support throughout these last 5 years, keeping me motivated on the days that my faith and determination faltered. I hope that I'm exceeding your expectations. To my friends, thank you for your continuous support, for lending a shoulder to cry on and a listening ear on days when school and work seemed unbearable. You all are truly amazing! Lastly, I would like to thank my managers and coworkers in the CVICU. Thank you for being understanding and supportive through my bad days and celebrating me in my good days.

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## Device Related Concerns pertaining to Primary Caregivers of LVAD Patients

### **Background and Significance**

The number of Americans diagnosed with heart failure (HF) continues to rise annually, as expected so does the demand for heart transplants. Each year the United Network for Organ Sharing (UNOS) transplant list grows, leading providers and patients to consider alternative treatment methods because of the scarcity of organ availability. Advancements in medical technology and the introduction of Left Ventricular Assist Devices (LVAD) made it feasible for individuals with HF to live longer, more meaningful lives while waiting on heart transplantation. LVADs are mechanical circulatory support devices that help pump blood through the body in the setting of heart failure. The projected number of LVAD implants rises annually, with approximately 150,000 to 250,000 individuals eligible for implant each year (Magid et al., 2016).

Although caregivers are provided a tremendous amount of education from LVAD coordinators, cardiac surgeons, and bedside nurses, they still leave the hospital with lingering concern and doubt. It is not enough to educate these individuals pre-operatively and throughout the course of their loved one's hospitalization; it is imperative they are provided continuous education post-discharge. To date, the education provided is insufficient in preventing device related concerns identified by primary caregivers. Additionally, while VAD technology may have progressed over time. The current educational content available to patients and caregivers is based on outdated statistics and information created for a target population with higher health literacy levels than a majority of LVAD caregivers (Iacovetto, 2014). The Center for Health Care Strategies states that nearly 36% of American adults have low literacy levels, reading at a fifth-grade level; currently the majority of health care related

educational materials are written at a tenth-grade level (CHCS, 2013). Teaching and education are often limited by the time and resources provided by LVAD centers. Furthermore, there is little research focused on the device related concerns specific to the caregiver's perspective. For continual improvement in LVAD survival rates and quality of life (QOL) the current educational and knowledge gaps need to be minimized or eliminated; this starts with placing more focus on educational needs and device related concerns identified by caregivers.

### **Context of the Problem**

Heart failure is a chronic disease process categorized as the reduction in the hearts ability to pump blood to meet the needs of the body (Savarese & Lund, 2017). Nearly 5.7 million Americans are affected (CDC, 2019), or 26 million people worldwide (Savarese & Lund, 2017). Current data predicts a 46% increase in diagnoses rates, with an overwhelming 8 million Americans diagnosed with HF by 2030 (Savarese & Lund, 2017). Approximately 915,000 new diagnoses of HF occur annually in the U.S (Savarese & Lund, 2017.) Presently, individuals diagnosed with HF are managed medically, as their disease progresses the treatment alternative include cardiac transplant or Mechanical Circulatory Support (MCS) such as LVADs. In 2000, United Network for Organ Sharing (UNOS, 2015) documented 2,199 heart transplants; sixteen years later in 2016 there were 3,191 documented heart transplants. Due to the advancement in medical therapies, patients have survived longer, becoming increasingly more ill, and causing a spike in donor heart demand. Eisen, Hunt, & Yeon (2016) report that close to 5,000 cardiac transplants occur globally yearly. However, close to 50,000 individuals are waiting on the transplant list. Due to increased demand in the absence of adequate availability of organs, we've seen a rise in mortality of patients on the UNOS transplant list.

## **Scope and Consequences of the Problem**

Over the last decade, there have been significant technological advancements in both the medical and bioengineering fields, allowing medical professionals to provide improved treatment, thus increasing longevity. Due to the excess of patients experiencing physical decline while waiting on the transplant list, physicians worldwide have turned to MCS devices, such as the LVAD, because the availability of these devices are essentially limitless (Bowen, Graetz, Emmert, & Avidan, 2020).

The LVAD is a viable option for individuals diagnosed with end-stage heart failure. Currently there are three indications in which an LVAD would be implanted: bridge-to-transplant (BTT), destination therapy (DT), and Bridge-to-recovery (BTR). The 2017 INTERMACS report Kirklin et al., 2017 revealed that, 22,866 patients received an FDA approved MCS device between June 23, 2006 and December 31, 2016 with implantation rates close to 2,500 per year (pg. 1080); of those patients who received a BTT LVAD implant, 30% went on to receive a cardiac transplant.

In order to determine candidacy for an LVAD, specific workup must be done. The process from initial evaluation to implant is extensive and focuses primarily on the patient. However, road to implantation can be overwhelming and emotionally draining for both the patient and their primary caregivers. Research indicates that 39.8 million individuals provide unpaid care to another adult in the United states annually (Birriel, Alonso, Kitko, & Hupcey, 2019). A pre-requisite for all LVAD programs nationally requires the commitment from a primary caregiver; although the requirements from each institution vary (Magid et al., 2016).

Caregivers must be available for everyday management of the patient with a LVAD device including but not limited to driveline dressing changes, battery changes, medication management, arrangement of follow up appointments/ensuring transportation, and responding to/ troubleshooting device alarms (Magid et al., 2016). The healthcare organization for this project requires round the clock care for a minimum of 3 months, however, depending on post-operative complications and patient quality of life, can continue throughout their lifetime.

Technology has improved tremendously resulting in positive patient experience and improved quality of life, better patient outcomes, and an 80% 1-year survival rate in the U.S. (Birriel, Alonso, Kitko, & Hupcey, 2019). Patient caregiver engagement plays a large role in the positive trend in patient outcomes and survival rate. Patients with caregivers who are engaged in their care, remain informed, and take part in education and care discussions have reduced mortality risk (Bruce et al., 2016). The role of primary caregiver can be burdensome; causing added levels of stress (Kirkpatrick et al., 2015). To date most studies focused on caregivers of LVAD patients are concentrated around caregiver role strain and quality of life post-discharge.

This project is important to the institution/setting for this study because of its growing population of LVAD patients and the continual rise in LVAD implants. Improving caregiver knowledge and decreasing the rate of device related caregiver concerns has the potential to decrease the risk of poor patient outcomes, re-admission rates, and inappropriate calls to LVAD coordinators. As well, improving caregiver knowledge also has the potential to increase survival rates. Improvements in the matters discussed above could ultimately reduce the overall financial burden on the Institution's program. This research will allow for identification of areas

for improvement in device education while providing insight into creating interventions to close these knowledge gaps.

### **Purpose of the Project**

The purpose of this project is to evaluate efficacy of a device related concerns educational video on reducing caregiver concern. The goal to improve caregiver knowledge and decrease the rate of device related concerns among primary caregivers. The project has 4 objectives.

### **Study Objectives**

1) Identify device-related concerns among primary caregivers, 2) enhance caregiver education with video tailored to device related concerns, 3) determine the effects of the educational video on caregiver concerns, 4) determine correlation between caregiver burden and level of device related concern.

### **Theoretical Framework/Process Improvement Model**

The framework for this project followed that of the uncertainty of illness theory (UIT). This model focuses on the individuals' inability to identify the meaning of their loved one's illness. Neville (2003), states that uncertainty can affect an individual's psychosocial ability to adapt as well as the outcome of their health. The UIT model focuses on three categories: antecedents, appraisal, and coping with uncertainty (Mishel & Clayton, 2008). Lack of information or vagueness in regard to a stressful situation can generate a negative health trajectory. This theory focuses on individuals who have been diagnosed with or who provide care for those diagnosed with chronic illnesses. Health care providers can facilitate a reduction in caregiver's uncertainty and improve their confidence in providing care.

Caregivers of individuals with LVADs are often anxious and concerned by their loved one's heart failure diagnosis. After LVAD implantation they are overwhelmed with information necessary to care for an LVAD. Additionally, they must understand the intricacies and management of the device. It is the job of the healthcare provider to provide well thought out, concise information tailored to the caregiver to help alleviate uncertainty. The goal of the pre-post questionnaire design with LVAD Concerns educational video is to identify device-related concerns, provide educational video and then take the post-questionnaire. The hope is that the video will alleviate the caregiver's uncertainty related to the LVAD and help them adapt to their new role and the stressors and uncertainty that come with it.

## **Review of Literature**

### **Search Methods**

A literature review was conducted by a thorough and extensive search of University of Kentucky's online library using the following key terms "LVAD", "left ventricular assist device", "education", "video", "educational video", "LVAD education" and "caregiver". This was a multi-database search including PUBMED, CINAHL, and EBSCO HOST.

Inclusion criteria for this search was limited to full text, peer reviewed academic journals, published in the last 20 years, human subjects, adults  $\geq 18$  years of age. Exclusion criteria includes non-English, non-academic, non-peer-reviewed journal articles, written before 2003. A total of 74 articles were found during the initial literature search. After careful review and elimination based on exclusion criteria, only 5 articles remained. The research team consisted of one member enrolled in the University of Kentucky Doctoral of Nursing Program

(DNP), with seven years of CVICU experience in the Cardiovascular intensive care unit (CVICU), working with LVAD patients and caregivers.

### **Synthesis of Evidence**

The five studies in this sample includes one cross-sectional study, one quality improvement project, one randomized and prospective study-controlled trial, and 2 controlled clinical studies. The individuals included in all five studies underwent an intervention that included an educational video (Costelle, D., Harman, J., & Moser, D. 2019; Du, W., Mood, D., Gadgeel, S., & Simon, M.S., 2008; Gause, A., & Rehman, Z., 2017; Gonzalez-Arriagada, W.A. de Andrade, M.A.C., L.M.A., Bezerra, J.R.S., Santos-Silva, A.R., & Lopes, M.A., 2013; Park, J.S., Kim, M.S., Kim, S.I., Shin, C.H., Lee, H.J.,...& Moon, S., 2016).

All five studies used a pre- post-test design to evaluate the efficacy of the intervention. While research shows correlation between educational videos and improvement in post-test scores, only three studies found implementation of the educational video statistically significant in improving outcomes (Costelle, D., Harman, J., & Moser, D. 2019; Park, J. S., Kim, M. S., Kim, H., Kim, S. I., Shin, C. H., Lee, H. J., ... & Moon, S., 2016; Du, W., Mood, D., Gadgeel, S., & Simon, M.S., 2008). Costelle, Harman, & Moser (2019) found their LVAD concerns educational video produced a statistically significant reduction in concerns among LVAD recipient's post-implantation (p-value of 0.002). Their pre- post- test was a 15-point scale scored using a Likert scale. Results showed statistical significance in seven of the 15 concerns (Costelle, D., Harman, J., & Moser, D. 2019). Park et al., (2016) established that the educational video produced statistically significant results. Their study focused on the impact an educational video on bowel preparation pre-colonoscopy effected the OTTAWA score post colonoscopy. Results showed

those who were enrolled in the educational video group exhibited better bowel preparation, with a P-value of <0.001 and an OTTAWA score of < 6, compared to the non-video group (Park et al., 2016). A study performed by Du, W., Mood, D., Gadgeel, S., & Simon, M.S. (2008) focused on the efficacy of an educational video on an individual's attitudes concerning enrollment in clinical trials. Results from their study revealed a statistically relevant impact on patients' attitude towards participation in a clinical trial ( $p= 0.019$ ); however, there was no statistically significant increase in clinical trial enrollment (2013; Du, W., Mood, D., Gadgeel, S., & Simon, M.S., 2008).

Furthermore, two studies found no statistically significant change with the implementation of an educational video intervention. Gause, A., & Rehman, Z., 2017 performed a quality improvement pilot study that implemented a video based LVAD education program to evaluate the Knowledge of the LVAD population in Certified Registered Nurse Anesthetists (CRNA's) and Student Registered Nurse Anesthetists (SRNA's). Gonzalez et al. (2013) performed a longitudinal control clinic trial aimed at assessing the effects of an educational video on improving knowledge and understanding of radiotherapy treatment complications. Data disclosed no statistical significance in post-test results between the control group and video group (Gonzalez et al., 2013).

## **Discussion of Literature Review**

### **Limitations**

The discriminating power of a study can be significantly decreased by small sample sizes; four of the five studies (Gonzalez-Arriagada, W.A. de Andrade, M.A.C., L.M.A., Bezerra, J.R.S., Santos-Silva, A.R., & Lopes, M.A., 2013; Du, W., Mood, D., Gadgeel, S., & Simon, M.S.,

2008; Gause, A., & Rehman, Z., 2017; Costelle, D., Harman, J., & Moser, D., 2019) were limited by small sample size. The sample in Gonzalez et al., (2013) was limited due to the severity of the disease and deterioration of patients; several patients were either too ill or deceased before completing their post-test. The small sample size in Du, Mood, Gadgeel, & Simon (2008) limited the studies ability to identify statistical power to show difference in clinical trial enrollment rate pre- and post-intervention. Studies performed by Costelle, Thompson, & Moser (2019) and Gause & Rehman (2017) were also limited to a small sample size due to their single-center study design; this also decreased the ability for generalization among other LVAD centers.

### **Identifying Gaps in Practice**

It should also be noted that none of the studies included in the literature review for focused on the LVAD caregiver (Costelle, D., Harman, J., & Moser, D. 2019; Du, W., Mood, D., Gadgeel, S., & Simon, M.S., 2008; Gause, A., & Rehman, Z., 2017; Gonzalez-Arriagada, W.A. de Andrade, M.A.C., L.M.A., Bezerra, J.R.S., Santos-Silva, A.R., & Lopes, M.A., 2013; Park, J.S., Kim, M.S., Kim, S.I., Shin, C.H., Lee, H.J.,...& Moon, S., 2016). Presently there are more than a few studies that incorporated educational videos as their intervention; a majority of those studies focus on the patient population, with very few focused on the caregiver perspective. An LVAD concerns educational video has been used as an intervention in a recent single center cross-sectional study, the population of focus were the LVAD recipients themselves. To date there are no published studies using an LVAD concerns educational video with principal focus being the primary caregivers of LVAD recipients. Additionally, there are very few studies concentrating on device related concerns and even fewer studies that place emphasis on the caregiver role. The

lack of cohesion in research has created a gap in knowledge causing difficulty in identifying methods to bridge that knowledge gap.

### **Project Agency Description**

#### **Site Description**

This is a single center study performed at a tertiary care academic medical center in Lexington, Kentucky. The University of Kentucky is Level 1 Magnet certified, Academic trauma center. UK Gill Heart & Vascular institute is a certified Left Ventricular Assist Device program holding The Joint Commission Gold seal of approval since 2009 (UK Healthcare, n.d.) University of Kentucky is an 865-bed facility in central Kentucky that admits and treats patients throughout Kentucky and its surrounding states.

The Cardiothoracic program at UK hospital performed their first LVAD implant in 1995 (Perry, A., 2014); they currently perform roughly 20-25 LVAD implants annually. The LVAD program employs two cardiothoracic surgeons, four LVAD coordinators, three heart failure physicians and a multitude of nurse practitioners that provide specialized care for these patients.

#### **Congruence of DNP project to organizations, missions, goals, and strategic plan**

University of Kentucky Health Care's (UKHC) mission, vision, and values have developed a healthcare enterprise that's been ranked as the number one Hospital in the state of Kentucky. The mission statement that guides their care reads "providing leading-edge care while advancing professional nursing and practice" (UK healthcare, n.d). Senior leadership at UKHC are focused on providing exceptional care to their patient population by identifying and incorporating cutting edge and evidence-based practice to their healthcare strategy.

UK Healthcare implemented their first five-year strategic plan in 2004; they've continued to use these plans as a road map to development and improvement of the enterprise, creating a firm foundation to build for the future (Capilouto, E., n.d.). Growth in complex care is identified as a key pillar in the 2015-2020 strategic plan, providing advanced sub-specialty care to every Kentuckian, every time, ensuring that every aspect of care needed can be obtained in the state of Kentucky. The Gill heart institute identified their strategic aspiration was to become a leader in the management of organ failure through focused patient outcomes (Capilouto, E., n.d.).

### **Description of Stakeholders**

The stakeholders include UK Director of HF, Heart failure Operations Director, LVAD coordinators, and caregivers of LVAD patients. The success of this project was dependent on the willingness and support from many different parties. Before beginning, Director of Heart Failure and the LVAD team pledged their help and resources for this project. Active participation by LVAD coordinator (Carissa Smith) was instrumental in the creation and development of the device related concerns survey and educational video. LVAD coordinator, Rachel Unger, was key in identifying primary caregivers that fit criteria for participation in this study. The MCS/LVAD secretary assisted with initial contact and obtaining interest in study participation. Buy in from the primary population was critical; without their willingness and cooperation this study would not have been possible. Additionally, it is this group who will be most affected by data obtained from this study.

## **Site-Specific Facilitators and Barriers**

Barriers to this study include unwillingness of the primary caregiver to participate in this study. All LVAD patients have an identified primary caregiver when they begin their initial evaluation prior to implant. Overtime, some caregivers become less involved in the care of their loved one. This would reduce their desire to take part in this study. Another barrier to implementation involved the caregiver completing the survey once receiving it. Once agreeing to participate, the caregiver must take the time to go online and complete it. Potential difficulty navigating the online survey and ability to use technology could hinder survey completion.

Alternatively, an important facilitator to this study involved the Principal Investigator (PI) being a current CVICU nurse at UK healthcare. This allowed her the opportunity to build a rapport with the LVAD coordinators as well as the patient population and their families.

## **Project Sample and Recruitment**

The target population for this study includes the primary caregivers (Mom, Dad, wife, husband, child, etc.) of LVAD patients who receive follow-up care through the UK LVAD program. Inclusion criteria for this project included: 1) primary caregiver of LVAD patient, 2) only primary caregivers of LVAD patients receiving follow up care by UK LVAD program, 3) able to speak and write English, 4) able to fill out a questionnaire. Exclusion criteria: 1) not the primary caregiver of LVAD patient, 2) caregiver less than 18 years of age, 3) primary caregivers of LVAD patients receiving follow up care outside of UK LVAD program 4) unable to speak or write English, 5) unable to complete questionnaire.

All primary caregivers of individuals receiving follow-up care at UK were reviewed for suitability for this study. Provided with the inclusion/exclusion criteria the LVAD coordinator

compiled a list of potential candidates, that list was passed along to the Mechanical Circulatory Support (MCS) secretary who called those individuals for potential participation. The first 30 participants to provide consent were included in the study. Thirty-three caregivers were contacted for participation; thirty primary caregivers (n=30) consented to participate in the study.

### **Project Design and Methods**

The aim of this study was to identify specific device related concerns that afflict the primary caregivers of patients implanted with LVAD devices and observe the effect an educational video has on alleviating the caregiver's concerns. This project is a single-center study that took place at the University of Kentucky; it follows a cross-sectional, pre- post-test design.

#### **Description of Intervention**

##### **LVAD Concerns Scale**

The LVAD concerns scale is 16-point scale developed to identify device related concerns. This scale was adopted for use based on the LVAD concerns scale used in a cross-sectional study focused on device related concerns in individuals who underwent recent LVAD implantation at University of Kentucky Chandler Medical Center (Costelle, 2019). That scale was altered and tailored to focus on device related concerns pertaining to the primary caregivers of LVAD patients. The survey used a Likert scale rating of 0-4: 0- not concerned at all, 1- a little concerned, 2- somewhat concerned, 3- quite a bit concerned, 4- very concerned. The concerns listed were extrapolated from the most commonly asked questions experienced by the LVAD

caregivers at the University of Kentucky. Before using this scale, it underwent a face validity test involving review and approval by the LVAD coordinators.

### **LVAD Concerns Educational Video**

The device related concerns educational video was developed and guided by the device related concerns scale. The script for the video was created by an LVAD coordinator at the University of Kentucky. The completed video was reviewed by LVAD coordinator and CVICU nurse at the University of Kentucky to ensure all concerns were included with information that is clear and concise. In addition, the information provided was delivered at a health literacy level approved by the University of Kentucky.

## **Procedures**

### **IRB Determination**

Approval for the study was obtained from the University of Kentucky Office of Research and Integrity (IRB) on October 6<sup>th</sup>, 2020. A waiver of documentation of informed consent was approved for this study. The application underwent intense scrutiny by the IRB board and ORI privacy specialist; it was determined that Health Insurance Portability and Accountability Act (HIPAA) applied. The UKHC IRB representative notified the PI of the request for Form K, HIPAA Waiver of Authorization. The electronic pre-and post-device related screening survey were sent to participants via email through UK REDCaps system, a secure web-based application for building and maintaining databases.

### **Data Collection**

The primary investigator (PI) provided a list of the inclusion and exclusion criteria to the UK healthcare LVAD coordinator. The LVAD coordinator then compiled a list of all potential

participants then referred it to the MCS/LVAD secretary. These individuals were then contacted by the MCS/LVAD secretary to identify potential interest in study participation. If aggregable to further discussion, the secretary forwarded their contact information to the PI. Individuals were contacted by the PI and provided an in-depth explanation about the study including the purpose and what participation entailed. Time was provided for each individual to ask any questions or identify any concerns. Potential participants were notified that they could, at any time, remove themselves from the study. Once the individual agreed to participate, the PI engaged in a discussion identifying the next steps. The participants provided their email address to the PI who then sent them a survey link that was developed using REDcaps. The survey link provided a seamless transition from one aspect of the study to the next. The transition through the link was as followed: cover letter, sociodemographic survey, device related concerns scale (pre), educational video, device related concerns scale (post). All data was collected using REDcaps provided de-identified data to the PI. This data was saved on the PI's personal password protected laptop and encrypted flash drive.

The study measures used are exhibited in (table 1). The dependent variable for this study is the primary caregivers with device related concerns. These are concerns identified, in the past, by primary caregiver to LVAD coordinators or bedside nurses. Furthermore, the independent variable and subsequently the intervention of this study is the device related concerns video. The instruments used to complete this study included: Sociodemographic survey (Appendix A); Device Related Concerns Scale (Appendix B).

## **Data Analysis**

Research procedures included collection and analysis of descriptive statistics comprised of means and standard deviations or frequency distributions, as appropriate. These tests were used to summarize the sociodemographic and clinical characteristics of the sample of caregivers. Spearman's correlation coefficient was used to examine the association between burden of disease and level of concern with LVAD operations. Comparisons of pre- and post-educational intervention level of concern with LVAD operations were conducted using a paired t-test. All data analysis was conducted using SPSS, version 25, with an alpha level of .05 throughout.

## **Results**

### **Sample Characteristics**

A total of 33 primary caregivers were contacted by the PI for potential participation, 30 caregivers agreed to participate, 28 started the survey with only 21 completing it. Of the twenty eight caregivers completed the sociodemographic study, the average age was 55.1 years (SD= 15.4; see table 2). The majority of the participants were female (82%) and partnered (75%). Most of the participants were white/Caucasian (86%), with the rest being black/African American (14%). Almost one-third identified as having some college/associates degrees (61%). Overall, 92.9% (n=26) identified they were the primary caregiver to only one individual, 13% (n=1) caring for two individuals and 13% (n=1) caring for three or more individuals. Over half the participants (57.1%) indicated they were currently employed. When identifying the presence of additional conditions, other than HF and LVAD, their loved one was diagnosed with, nearly one-third (32.1%) identified one extra condition; furthermore, one-third (32.1%)

identified an additional four conditions. Overall, data showed that loved ones suffered from: congestive Heart failure (89%), chronic pulmonary disease (37.5%), Myocardial infarction (28.6%), Diabetes Mellitus (28.6%), stroke (21.4%), kidney disease (21.4%), peripheral vascular disease (14.3%), connective tissue disease (10.7%), peptic ulcer disease (10.7%), dementia (7.1%), and cancer 7.1%).

### **Outcome**

Implementation of the educational video resulted in a significant reduction in concern with a p-value 0.025 (table 3). A further dive into the data revealed that five of the 16 device related concerns showed significant reduction in concerns. Measured on a scale of 1-5, with higher scores representing more concern, there was a significant decrease in fear of the LVAD stopping abruptly (M= 2.6 pre vs. M= 2.0 post,  $p = .029$ ). Additionally, there was a significant decrease in concern for the LVAD alarming (M= 2.0 pre vs. 1.6 post,  $p = .012$ ). The intervention also had an effect in reducing concerns regarding both drive line infection (M= 2.38 pre vs M= 2.00 post,  $p = .042$ ) and concern for the future (M= 2.67 pre vs. M= 2.05 post,  $p = .009$ ). Lastly, there was a significant reduction in concerns regarding secondary risk factors (M= 2.57 pre vs. M= 2.14 post,  $p = .025$ ). There was no significant reduction in the remaining device related concerns: batteries dying ( $p = .08$ ), loved one's condition worsening ( $p = .095$ ), traveling with an LVAD ( $p = .171$ ), intercourse ( $p = .171$ ), driveline trauma ( $p = .055$ ), anxiety ( $p = .309$ ), loss of independence ( $p = .358$ ), calling the coordinator ( $p = .056$ ), calling EMS ( $p = .666$ ), re-hospitalization ( $p = .590$ ), and lastly, concern that something will happen when the caregiver is gone ( $p = .162$ ). See (table 4).

Additionally, the spearman's coefficient test was used to identify the relationship between caregiver burden and level of concern. There was a significant association between level of sickness (caregiver burden) and level of concern  $\rho = 0.42$  ( $p = .016$ ). Refer to table 5. For breakdown of correlations.

### **Discussion**

Previous studies have focused on device related concerns from the perspective of the LVAD patient. The purpose of this cross-sectional pre- post- test study was to identify caregiver specific device related concerns and determine the efficacy of a tailored educational video. Overall, data showed a statistically significant reduction in caregiver concerns following implementation of the educational video. Each participant filled out a device related concerns scale before watching the educational video. This scale was comprised of 16 concerns; of those 16 concerns participants experienced a significant reduction in five.

A majority of the participants acknowledged concerns regarding the future of their loved one now that they have an LVAD, the other regarding secondary risk factors of LVAD implantation. Caregivers of individuals diagnosed with chronic diseases, such as HF, are often faced with the uncertainty of their loved one's future. Implantation of the LVAD provides them with hope for longer life expectancy allowing them the ability to move on with their lives. However, living with an LVAD can generate its own concerns, particularly those involving the future and occurrence of secondary risk factors such as gastrointestinal bleeding and stroke. This development implies that throughout pre and post LVAD education, more emphasis could be applied in detailing what to expect in the future while highlighting the potential for

secondary risk factors. From the data it can be determined that the change in level of concerns demonstrates the caregivers responded well to the intervention.

Despite extensive education and training throughout the implant process caregivers are unaware of fears that may overwhelm them. It's vital to understand that the LVAD is necessary in keeping the loved one alive; and fear of pump failure is not just specific to the LVAD patient. The caregivers of these individuals live with the constant fear of pump failure or malfunction. Of Note in this study participants expressed concern pertaining to the actual LVAD, including the device stopping without warning and the device alarming and not knowing what to do. Assessment of the post concerns scale revealed the implementation of the educational video was valuable in reducing these concerns.

The next steps for this study would include expanding enrollment by including other LVAD centers across the nation. A larger multi-center study would provide better insight on generalizability of this device related concerns scale and the educational video. Additionally, it is recommended to include in-person meetings when discussing and disseminating the survey to participants. This alteration could help mitigate any technological issues while also providing extra support to participants experiencing difficulty. In future studies, it may be beneficial to limit enrollment to caregivers of LVAD patients implanted within the last 6 months to a year as this population likely may be more affected by device related concerns. Additionally, future research could focus on identifying the of this educational video when comparing level of concern among caregivers of loved ones implanted with an LVAD less than a year ago versus long-term caregivers caring for individuals implanted greater than a year ago. It is likely that all caregivers suffer from concerns, however the concerns experienced by long term caregivers are

to differ from those individuals caring for individuals implanted less than a year ago. Addressing the unique concerns for each group of caregivers could provide better insight into development of more precise education.

The study identified two driveline associated concerns among caregivers: drive line infection and driveline trauma. The driveline is an important aspect of the LVAD, providing power necessary for the device to function. The driveline is prone to trauma and infection; this can lead to hospitalization, antibiotic therapy, and possible operation. The pre concerns scale recognized presence of concern for both driveline trauma and infection. Post concerns scale data recognizes the educational video was successful in reduction of concerns regarding driveline infection but not driveline trauma. This highlights the needs for re-education and further instruction regarding drive line management from the caregiver perspective.

Despite increased access to LVAD educational resources and materials, device related concerns still linger. Tailored education is important for individuals caring for LVAD patients requiring more assistance. Study data illustrates a positive correlation between caregiver burden, how sick caregivers perceive their loved ones are, and the level of concern among the caregivers. Individuals living with higher levels of caregiver burden identified having higher levels of device related concern. The evidence suggests that providing tailored education focused on device related concerns for caregivers should be optimized prior to hospital discharge.

### **Implications**

Several implications can be drawn from the evidence derived from this study. The first being there is a need for further research into the efficacy of educational videos on reducing

device related concerns, particularly those that afflict the primary caregiver. Future research could identify efficacy of the video among new LVAD caregivers (<1 year) compared to long-term caregivers (>1 year). Additionally, research could provide more detailed insight, while identifying educational interventions to help improve current gaps. Another aim could focus on evaluating the number of phone calls to the emergency number experienced by LVAD coordinators.

Furthermore, the pre- post- data collected in this study deduced that a tailored educational video was successful in the reduction in concerns among caregivers. Additionally, these findings support the need for additional education both pre and post hospital discharge. Development and implementation of standardized caregiver-based education sessions at 6 months and 1-year post- implantation.

### **Limitations**

There are several limitations to this study. The first and most notable limitation was small sample size. Having a larger sample size would have provided more data therefore providing more conclusive results. Additionally, this was a single center study with a relatively small LVAD population. The concerns identified in this study were those only recognized by the LVAD coordinators from UKHC. The coordinators work with patients and caregivers from KY and the surrounding regions; while these concerns may be significant to this patient population it may not match those from other regions. Additionally, due to the Covid-19 pandemic all elective procedures were cancelled causing a reduction in the number of LVAD implants in 2020. Furthermore, the global pandemic limited visitation at UKHC; therefore, instead of

performing this study in person the participants were sent a survey link over email. Therefore, potentially limiting the number of survey results received.

### **Conclusion**

The study showed the educational video had a significant impact. Data revealed that there was a significant reduction in device related concerns when comparing pre-score to post-scores. Caregivers reported a lower post concern score which coincides with a better understanding and comfort with the device. These scores along with the reduction in the device related concerns indicated the need for an educational video to be included in the caregiver discharge teaching at the University of Kentucky. It also identifies the need for further research focused on gaps in caregiver education and device related concerns.

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## Appendices

### Appendix A: SOCIODEMOGRAPHIC CHARACTERISTICS

1. Sex: 0. \_\_\_\_\_ Female      1. \_\_\_\_\_ Male      2. \_\_\_\_\_ Other
2. Age: \_\_\_\_\_ Years Old
3. Marital Status:
  1. \_\_\_\_\_ Single
  2. \_\_\_\_\_ Married
  3. \_\_\_\_\_ Divorced/Separated
  4. \_\_\_\_\_ Widowed
  5. \_\_\_\_\_ Co-Habitate
4. Ethnicity: select all that apply
  1. \_\_\_\_\_ Black or African American (Not Hispanic or Latino)
  2. \_\_\_\_\_ White or Caucasian (Not Hispanic or Latino)
  3. \_\_\_\_\_ Hispanic or Latino
  4. \_\_\_\_\_ American Indian or Alaskan Native
  5. \_\_\_\_\_ Native Hawaiian or other Pacific Islander
  6. \_\_\_\_\_ Other (Please specify \_\_\_\_\_)
5. What is the Highest Level of Education you have Completed?
  1. \_\_\_\_\_ Less than high school graduate
  2. \_\_\_\_\_ High school graduate
  3. \_\_\_\_\_ Some post high school
  4. \_\_\_\_\_ Some college
  5. \_\_\_\_\_ Associate Degree
  6. \_\_\_\_\_ Bachelor's Degree
  7. \_\_\_\_\_ Master's Degree
  8. \_\_\_\_\_ Professional Degree
  9. \_\_\_\_\_ Doctoral Degree
6. How many individuals are you the Primary Caregiver for?
  1. \_\_\_\_\_ 1
  2. \_\_\_\_\_ 2
  3. \_\_\_\_\_ 3
  4. \_\_\_\_\_ 4
  5. \_\_\_\_\_ 5

6. \_\_\_\_\_ 6 or more

7. Are you currently employed?

0. \_\_\_\_\_ No

1. \_\_\_\_\_ Yes

8. How sick/complicated do you think your loved one (with an LVAD) is?

1. \_\_\_\_\_ Only problem they have is LVAD with HF

2. \_\_\_\_\_ One Conditions in addition to HF and LVAD

3. \_\_\_\_\_ Two Conditions in addition to HF and LVAD

4. \_\_\_\_\_ Three Conditions in addition to HF and LVAD

5. \_\_\_\_\_ Four conditions in addition to HF and LVAD

6. \_\_\_\_\_ Five or more conditions in addition to HF and LVAD

9. What other conditions does your loved one have? Select all that apply

Does the participant have?

- |   |                             |                              |
|---|-----------------------------|------------------------------|
| 1. Myocardial Infarction (Heart attack)                                 | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 2. Congestive Heart Failure   | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 3. Peripheral Vascular Disease  | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 4. Cerebrovascular Disease (Stroke)                                     | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 5. Dementia   | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 6. Chronic Pulmonary Disease (COPD, Asthma)                             | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 7. Connective Tissue Disease (Lupus, rheumatoid arthritis, scleroderma) | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 8. Stomach or Peptic Ulcer Disease                                      | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 9. Hemiplegia (paralysis)   | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 10. Diabetes  | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 11. Moderate to severe Kidney disease/failure                           | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 12. Cirrhosis or liver disease  | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 13. Cancer  | <input type="checkbox"/> No | <input type="checkbox"/> Yes |

**Appendix B: LVAD Concern Scale**

<b>LVAD Concerns Scale</b>					
<b>I am worried about:</b>	<b>0 Not concerned at all</b>	<b>1 A little concerned</b>	<b>2 Somewhat concerned</b>	<b>3 Quite a bit concerned</b>	<b>4 Very concerned</b>
<b>LVAD battery/s dying</b>					
<b>LVAD stops working suddenly and without warning</b>					
<b>LVAD alarming and not knowing what to do</b>					
<b>Their heart condition getting worse and the LVAD not being enough to support their heart</b>					
<b>Being able to travel (driving, flying, etc.) with the LVAD</b>					
<b>Having intercourse and their LVAD alarming or stop working</b>					
<b>Trauma to driveline site</b>					
<b>Infection of Driveline site</b>					
<b>My anxiety or nerves affecting my relationship/making them worry too much</b>					
<b>The future now that they have an LVAD</b>					
<b>Patient losing their independence with their health because I do too much for them</b>					
<b>Concerns related to Secondary risk factors (stroke, GI bleed) related to LVAD placement</b>					
<b>When to call the LVAD coordinator</b>					
<b>Concerns regarding calling 911</b>					
<b>Concerns regarding re-hospitalization</b>					
<b>Something happening to them while I'm gone</b>					

## Tables

**Table 1: Study Variables**

variable	Strategy for measurement (chart audit or survey—specify which surveys you will be using)	Level of measurement	Timing of measurement	Test Statistic
Outcome Variable 1 Device related concerns pre-LVAD educational video	Device Related Concerns Scale	Individual item scores and overall score.	Pre-intervention	Paired t- test
Outcome Variable 2 Device related concerns post-LVAD educational video	Device Related Concerns Scale	Individual item scores and overall score.	Post-intervention	Paired t- test
<b>DEMOGRAPHIC VARIABLES – For Primary Caregivers of LVAD Patients ALL MEASURED AT STUDY COMPLETION</b>				
Age	Age of participants in years	Continuous	At study completion	Mean and standard deviation
Race/ethnicity	Ethnicity (African American/Black, Caucasian/White, Hispanic/Latino, American Indian/Alaskan native, Native Hawaiian or other Pacific Islander, Other)	Nominal	At study completion	Frequency and percentage
Marital Status	Married, divorced/separated, single, widowed, co-habitation	Nominal	At study completion	Frequency and Percentage
Sex	Sex (male, female, other)	Nominal	At study completion	Frequency and Percentage
Level of Education	Less than High school graduate, High school graduate, Some post high school, Some college, Associate degree, Bachelor’s degree, Master’s degree, Professional degree, Doctoral degree	Nominal	At study completion	
Number of Individuals Primary Caregiver for	1, 2, 3, 4, 5, 6 or more	Nominal	At study completion	
Employment Status	Yes or No	Nominal	At study completion	
Sick/complicated illness of loved one	LVAD and HF, one condition in addition to LVAD and HF, 2 conditions in addition to LVAD and HF, 3 conditions in addition to LVAD and HF, 4 conditions in addition to HF, 5 or more conditions in addition to LVAD and HF	Nominal	At study completion	
Additional Conditions	Select all that apply	Nominal	At study completion	Frequency and Percentage

**Table 2: Sociodemographic Data (N = 28)**

Characteristic	Mean (SD) n (%)
Age	55.1 (15.4)
Gender	
Male	5 (17.9%)
Female	23 (82.1%)
Partnered status	
Partnered	21 (75.0%)
Not partnered	7 (25.0%)
Race	
White/Caucasian	24 (86%)
Black/African American	4 (14%)
Education	
High school or less	5 (18%)
College/Associates degree	17 (61%)
Bachelors/master's degree	6 (21%)
Caregiver to # of individual	
1 individual	26 (92.9%)
2 individuals	1 (3.6%)
3 or more individuals	1 (3.6%)
Employment	
Yes	16 (57.1%)
No	12 (42.9%)
How many conditions in addition to HF and LVAD	
One Condition in addition	9 (32.1%)
Two Conditions in addition	3 (10.7%)
Three Conditions in addition	7 (25%)
Four or more Conditions in addition	9 (32.1%)
Other Conditions	
MI	8 (28.6%)
CHF	25 (89.3%)
PVD	4 (14.3%)
Stroke	6 (21.4%)
Dementia	2 (7.1%)
CPD	10 (35.7%)
CTD	3 (10.7%)
PUD	3 (10.7%)
Paralysis	0 (0%)
DM	8 (28.6%)
KD	6 (21.4%)
Liver disease	0 (0%)
Cancer	2 (7.1%)

**Table 3: Comparison of Concerns Pre and Post video implementation**  
**Paired Samples Test (Table 3)**

Paired Differences

95% Confidence Interval of the

Difference

	Mean	Std. Deviation	St. Error Mean	Lower	Upper	T	Df	Sig. (2-tailed)
Pair 1 concernPREfix- concernPOST	5.19048	9.80622	2.13989	.72674	9.65421	2.426	20	.025

**Table 4: Comparison of Concerns Pre and Post Video Implementation by question**

On a scale of 1 -5, how concerned are you about .....	Pre-intervention <i>Mean (SD)</i>	Post-intervention <i>Mean (SD)</i>	<i>p</i>
LVAD battery dying	2.0 (1.3)	1.6 (1.0)	.08
LVAD stops working	2.6 (1.3)	2 (0.98)	.029
LVAD alarming	2 (1.4)	1.6 (0.93)	.012
Condition worsening	3.05 (1.5)	2.62 (1.16)	.095
Travel	2.0 (1.3)	1.76 (0.995)	.171
Intercourse	1.52 (0.981)	1.48 (0.928)	.715
Trauma	2.33 (1.197)	2.05 (1.024)	.055
Infection	2.38 (1.244)	2.00 (1.049)	.042
Future	2.67 (1.238)	2.05 (1.071)	.009
Anxiety	2.05 (1.499)	1.91 (1.167)	.309
Independence	2.14 (1.236)	1.95 (0.973)	.358
Secondary Risk factors	2.57 (1.207)	2.14 (0.964)	.025
Call coordinator	1.62 (1.161)	1.38 (0.973)	.056
EMS	1.33 (0.577)	1.43 (1.076)	.666
Re-hospitalization	2.29 (1.271)	2.14 (1.315)	.590
Gone	3.19 (1.436)	2.81 (1.47)	.162

**Table 5: Correlation of caregiver burden to concern**

			how_sick	concernPOST
Spearman's rho	How_sick	Correlation coefficients	1.000	.519
		Sig. (2-tailed)	.	.016
		N	28	21
	concernPOST	Correlation Coefficient	.519*	1.000
		Sig. (2-tailed)	.016	.
		N	21	21
	concernPREfix	Correlation Coefficient	.247	.664**
		Sig. (2-tailed)	.206	.001
		N	28	21

\*. Correlation is significant at the 0.05 level (2-tailed).

\*\*. Correlation is significant at the level (2-tailed).