PROTOCOL TITLE: *Use of simulation to improve ventricular assist device self-management: A Quantitative Study*

PRINCIPAL INVESTIGATOR:
Jeffrey H. Barsuk
Department of Hospital Medicine and Medical Education
312-926-3680
jbarsuk@nm.org

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2

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OBJECTIVES:

AIM 1. Compare performance of VAD self-management skill of sterile dressing changes and VAD-related controller functions, between SBML-trained and the usual VAD training group immediately following training, and at one and three months after VAD implantation.

Hypothesis 1a: VAD patients and their caregivers will demonstrate better VAD self-management skills when trained with the SBML intervention compared to the usual VAD training group.

Hypothesis 1b: VAD patients and their caregivers will demonstrate better VAD self-management skill retention at one and three months compared to the usual VAD training group.

AIM 2. This exploratory aim will examine VAD-patient driveline infections, and all-cause and infection-related re-hospitalizations through one and three months after VAD implant, between the SBML intervention group as compared to the usual VAD training group.

Hypothesis: Patients who complete the SBML VAD curriculum with their caregivers will have lower infections and re-hospitalizations compared to the usual VAD training group.

BACKGROUND:

Over 5.1 million Americans suffer from heart failure (HF), with over $32 billion expended annually.[1] Although survival from HF has improved, a diagnosis of HF is similar to some forms of cancer, with 50% of patients dying within 5 years of diagnosis.[1] Ventricular assist devices (VADs) have improved survival in patients with advanced HF.[2] Over 17,000 patients with advanced HF have received VADs in the last decade, and implantation rates are expected to increase with newer generation devices.[3] VADs may be used as "destination" (e.g., permanent) therapy or as a "bridge to transplant." Patients on Destination Therapy will remain on the VAD for the rest of their lives. Bridge to Transplant patients will remain on the VAD until time of heart transplant. VAD devices are surgically implanted into the apex of the left ventricle of the heart and are connected to the aorta, providing circulatory support to the patient. A driveline passes from the device through the skin, connecting to a system controller that in turn is connected to external power. A frequent and often deadly complication after VAD implantation is driveline infection. Infection can cause pump failure from thrombosis, which requires surgical pump exchange if the patient survives the event.[4]

Immediately prior, and around the time of VAD implantation, patients and their caregivers are educated about VAD self-management. However, patients are often critically ill during this hospitalization, and caregivers (often family) are under emotional duress; thus skill retention with this traditional education may be lacking. After discharge, patients and caregivers are required to engage in significant daily VAD self-management including: driveline exit site dressing changes; performing controller self-tests; changing power sources; troubleshooting emergent VAD-related malfunction; and recognizing VAD-specific signs and symptoms requiring immediate contact with the VAD team. With insufficient VAD-related knowledge and improper VAD self-management, these patients can die from **preventable** complications including driveline infections.[5]

Unfortunately, no rigorous standardized training exists for patients and caregivers to ensure mastery of VAD self-management. Traditionally, VAD training occurs via the "see one, do one, teach one" method, where a VAD patient and caregiver watches a video or live demonstration of VAD-related techniques (e.g., dressing changes), and are then expected to perform the task, first under supervision, and, within days, independently. This process leads to uneven skill acquisition and may cause unnecessary harm to the patient. Simulation-based mastery learning (SBML) can be used to prevent such uneven skill acquisition and potential patient harm.[6-14] Mastery learning is an intense form of competency-based education in which learners are required to meet or exceed a predetermined level of skill.[15-17] In mastery learning, training *time* varies, but *outcomes* (skill achievement) are uniform. Current technology allows for SBML, in which learners must demonstrate mastery in a simulated setting before performing the skill in actual clinical practice. Our research demonstrates that SBML is a more effective strategy than traditional education in improving various clinical skills and patient care for procedures such as Advanced Cardiac Life Support,[14,18,19] paracentesis,[8,11] lumbar puncture,[6] and central venous catheter insertion[7,10,12,13] and maintenance.[9] Proper techniques for central line maintenance are similar to driveline care. Therefore, we propose to create and test an SBML intervention for VAD self-management skills and compare the intervention to traditional (usual) VAD training.

LITERATURE CITED

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INCLUSION AND EXCLUSION CRITERIA:

Patient inclusion criteria include being a previous or current VAD implantation patient, age >18, English-speaking, receiving implantation and VAD care at NMH, and meet hospital criteria for VAD implantation. We expect to recruit 75 patients. Caregiver inclusion criteria include being a caregiver identified by a previous or current VAD implantation patient, age >18, and English-speaking. We expect to recruit 75 caregivers.

Vulnerable populations of patients will not be included in this study (including fetuses, neonates, children, pregnant women, prisoners, mentally retarded or incompetent individuals, institutionalized individuals, or individuals unable to give consent due to their medical condition). Fetuses and neonates are not the focus of our study. Pregnant women will not be included

since pregnancy is a contraindication to VAD implantation It is possible that VAD caregivers may be pregnant at the time of the study. . Patients with mental retardation, mental incompetence, or patients who are unable to give consent due to their medical condition will not be included as they will not be able to complete measures. Lastly, institutionalized individuals will not be included as access will be a problem, and these individuals are rarely referred for VAD implantation

STUDY TIMELINES:
Each individual enrolled will participate in the study for approximately 3 months. We anticipate enrollment of study subjects will take approximately 15 months. We hope to complete all analyses 2 two years.

STUDY ENDPOINTS:
The primary study endpoints are we have enough patients enrolled to compare VAD-care SBML training and usual training groups.

PROCEDURES INVOLVED:
Approximately 60 advanced HF patients undergo VAD implantation at NMH yearly. During our 15-month study period, up to 75 participating patients and 75 caregivers will be eligible to receive either the SBML VAD self-management curriculum or usual VAD training. Eligible patients will be about to undergo VAD implantation at NMH, age >18, and English-speaking. Eligible caregivers will be identified by a VAD implantation patient, age >18, and English-speaking. Advanced HF patients who are scheduled for VAD implantation will receive information about the study at their pre-implantation clinic visits or during hospitalization. Consenting patients will be asked to provide the name and contact information of their primary caregiver; we will contact the caregivers to explain the study and assess their interest. Patients and caregivers must both agree to participate in the study to be enrolled. All Patient and caregiver VAD self-management training begins before implantation and continues up to the hospitalization for VAD placement.

Study randomization will be conducted via random number generator. After randomization, demographic data including age, sex, race/ethnicity, and socioeconomic (SES) factors such as zip code, highest level of education, and employment status will be collected from patients and caregivers.

Two VAD nurses will perform usual training only, which is the current standard of care. First, patients and caregivers watch a video produced by the VAD manufacturer. Subsequently, the VAD nurse trains the patient and caregiver per usual routine with a non-implanted VAD. These meetings occur 1 to 3 times depending upon patient and caregiver availability and are not standardized. During the VAD implantation hospitalization, the caregiver completes a written examination to assess knowledge. The VAD nurse observes patient and caregiver completion of skills and deems competence based only on observation. Historically, patient and caregivers are variably able to participate in training sessions. If the patient is too ill to participate in training before VAD implantation, only the caregiver completes training and the patient is trained during the hospital stay for implantation at which point they are significantly clinically improved.

Three VAD nurses will administer SBML training. The SBML training group will first 1) watch the VAD video, then 2) participate in pre-intervention assessments using the simulator for a) driveline exit site sterile dressing changes; b) performing controller self-tests; c) changing power sources; d) troubleshooting emergent VAD-related malfunction; and e) recognizing specific signs and symptoms requiring immediate contact with the VAD team. The patient and caregiver

then will participate in deliberate practice on the simulator with feedback from the instructor. We anticipate 2 training sessions of 1-2 hours each to become proficient in these skills. After training, the patient and caregiver complete a post-intervention assessment on the simulator using the checklists. At the end of training, the patient and caregiver will complete the written examination to assess knowledge and will be required to meet or exceed the MPS on the checklists and written examination. If they fail to meet the MPS, they will receive additional training until they meet the MPS. If the patient is ever too ill, only the caregiver will participate in the training and the patient will be trained during the hospital stay for implantation.
Both training groups. After training, we will ask participants to rate their educational experience and their confidence in performing each of the 5 VAD self-management tasks [via a questionnaire adapted from our previous work. All participants will demonstrate the five skill domains on the actual VAD patient during the implantation hospitalization (Time 0), and at one and three months after training to assess skill retention. Assessments will be performed during office visits, as patients are seen at least monthly after VAD implantation, or re-hospitalizations. If caregivers cannot attend, assessments will be performed via internet video. We anticipate the majority of enrolled patients will have internet access; alternatively, we will arrange sessions at their local library.

A trained VAD nurse (who is not assigned to teach the curriculum) will perform all patient and caregiver assessments using the checklist. In the absence of this nurse, the PI or a Co-I will perform assessments; we expect this to be rare. The trained VAD nurse, the PI and COCo-I will be blind to the intervention received by the patient and caregiver. A random sample of 25% of all assessments will be double scored by both the VAD nurse and PI or Co-I to assess inter-rater reliability.

After VAD implant, patients are managed by the VAD team with frequent office visits. Complications and re-hospitalizations are documented in outpatient and/or inpatient medical records. Patients admitted to a local hospital are typically transferred to NMH for care. If patient is admitted to another hospital, they are customarily transferred to NMH to manage the VAD. We believe we will be able to capture all data about driveline infections and re-hospitalizations prospectively.

NMH's infection prevention department also tracks *all* VAD related driveline infections using definitions in the INTERMACS database.[37] We will assess patient factors at time of infection and during re-hospitalization to evaluate differences between the SBML and usual VAD training groups such as age, sex, body mass index, and the Charlson comorbidity codes. The Charlson score is based on 19 chronic disease comorbidities derived from the International Classification of Disease Revision 9 (ICD-9) codes and predicts one-year mortality for hospitalized patients. We can obtain all admission ICD-9 codes from our Enterprise Data Warehouse[93] which also convert ICD-10 codes to their corresponding ICD-9. We will obtain additional data using the INTERMACS database (includes all NMH patients), which provides type of VAD, VAD indication (DT vs. BTT), and infection and re-hospitalization rates.

DATA AND SPECIMEN MANAGEMENT:
Primary outcome measures are comparisons of VAD-care checklist assessments on the patient and written examination scores between SBML and usual training groups. Secondary outcome measures include self-management skill decay in the five domains from 0 to 3 months and comparisons of post-training questionnaires between groups.

We will estimate checklist score inter-rater reliability using the Kappa (κ) coefficient[84,87] Our prior work shows the difference between traditional training and SBML interventions is approximately 33%; traditionally trained simulated skill checklist performance averages 61.47% (SD=24.48) items correct while SBML training performance averages 94.88% (SD=6.63).[9,48,51,53,88] We anticipate the usual training group in our study will perform similarly to the traditionally trained healthcare providers in our prior studies. Sample sizes of 65 in each group (total =130) achieve 82% power to detect at least 10% difference between the usual group and the SBML training group assuming a mean checklist score of 85% in usual group (SD=25) and 95% in the SBML training group (SD=10) with a significance level of 0.05 using a two-sided t-test. As the distribution of % items correct is likely to be non-parametric, adding 15% requires 75 in each group.[89] Therefore, our study will be overpowered to detect a 33% difference. We will compare checklist scores on actual patient assessments between usual care and SBML-trained groups using the independent *t*-test or Wilcoxon rank sum test (if data are non-parametric). We will compare age, sex, race/ethnicity, level of education, employment status, zip code, type of VAD, and VAD indication (DT vs. BTT) between groups using either Chi Square test or independent *t*-tests. If there is a difference between the randomized groups in any of these variables at the level of $p \leq 0.1$, we will use multiple linear regression or multiple quantile regression (for non-parametric data) to assess these variables independently on scores between the two groups. We will measure skills decay between groups using an analysis of variance (ANOVA) or a non-parametric analysis of variance at 0, 1 and 3-month assessments. Questionnaire results will be compared between groups using Chi-Square, independent t-test, or Wilcoxon rank sum where appropriate.

We will compare driveline infections and re-hospitalization rates at one and three months after VAD implantation between the SBML and the usual training groups using the Chi Square test, recognizing that we may be underpowered for this exploratory aim due to the short study time frame. We will compare age, sex, race/ethnicity, level of education, employment status, zip code, type of VAD, VAD indication (DT vs. BTT), and Charlson scores between groups using either the Chi Square test or independent t-tests. If there is a difference between the randomized groups in any of these variables at the level of $p \leq 0.1$, we will perform multiple logistic regression to control for these independent variables between groups. If some patients have more than infection, we will use random effects modeling to account for clustering by patient.

The study PIs, co-investigators, as needed, VAD nurse, and Research Coordinator (RC) will have access to individually identifiable data. Otherwise, a unique identification code will be assigned to each enrolled patient, and all of the data entered into the system for that patient will be identified by this code rather than by name.

Socio-demographic and medical records data will be collected by INTERMACS and exported to a secure web server at Northwestern University. Socio-demographic data collected from VAD caregivers and checklist of VAD self-maintenance tasks-performance data will be collected on paper but will be de-identified using a unique identifier for each patient or caregiver. This data will be stored on a Northwestern Server that is password protected and encrypted. All data will be collected specifically for research purposes.

WITHDRAWAL OF PARTICIPANTS:
Participants are free to withdraw from the study at anytime without consequences.

RISKS TO PARTICIPANTS:

There are two potential risks of participating in this study for patients:
1. Potential for breach of patient confidentiality. This is a very serious potential risk to patients, but safety measures, as described above, have been put into place and are monitored by the Northwestern University IRB.

2. The simulation training may be superior or inferior to usual care, which means patients assigned to either simulation or usual care groups may receive worse VAD related self-management care training. We will review data from our study every 3 months and if there are significant differences in complications between groups, we will either stop the study or provide a cross-over arm.

POTENTIAL BENEFITS TO PARTICIPANTS:
There may be no potential benefit to the individuals participating in this study if the intervention proves equipoise with the usual care. However, the information gained from these results will inform healthcare providers how to better train patients and their caregivers in self-management techniques. Furthermore, if the intervention is successful, the benefit to patients and their caregivers could be improved knowledge of VAD self-management techniques and reduction in VAD-related complications.

SETTING:
Patients will be recruited either at the medical center (while the patient is hospitalized) or during a clinic visit. Training and assessments will take place in the patient room or in NMH conference rooms.

RESOURCES AVAILABLE:
Jeffrey Barsuk, MD, MS, Principal Investigator
Dr. Barsuk is a Clinical Associate Professor in the Department of Medicine and Medical Education at Northwestern University Feinberg School of Medicine. He also serves as the Director of Simulation and Patient Safety and Associate Program Director for the Internal Medicine Residency Program. He has extensive experience with the use of simulation for healthcare education. He has lectured at national and international conferences on curricula development and procedure skills training, and has assisted several institutions in setting up simulation-based training programs similar to those described in this grant application. Additionally, Dr. Barsuk has close to 50 peer-reviewed publications using simulation-based mastery learning for training physicians and has won international awards for his research which has been previously funded by Agency for Healthcare Research and Quality. As PI of this study, Dr. Barsuk will be responsible for study design and IRB approval, administrative oversight and training of research personnel, curriculum development, simulation training, data acquisition storage and analysis, and manuscript preparation.

Kathleen Grady, PhD, Co-Investigator
Dr. Grady is a Clinical Professor in the Department of Medicine and Surgery. She is a cardiovascular nurse specializing in patients with advanced heart failure. The National Institute of Nursing Research, National Heart Lung and Blood Institute, National Institute on Aging, and the American Heart Association have previously funded Dr. Grady. She currently chairs the Quality of Life Committee for the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), funded by an NHLBI contract (#HHSN268200548198C) which will be used to track patient outcomes in this study. Dr. Grady's effort on this grant will be focused in study design (both qualitative and quantitative methods), patient enrollment, data collection, analysis and manuscript writing. Dr. Grady has previously worked with Dr. Barsuk on several hospital-related heart failure quality initiatives to reduce length of stay and readmissions.

Kenzie Cameron, PhD, MPH, Co-Investigator
Dr. Cameron is a Research Associate Professor in the Division of General Internal Medicine and Geriatrics at Northwestern University Feinberg School of Medicine. She has extensive expertise in communication message design, persuasion, behavior change interventions, and the integrated use of quantitative and qualitative methodologies. Her behavioral intervention research related to preventive health issues (i.e., influenza vaccination, pneumococcal vaccination, colorectal cancer screening) has been funded by multiple federal agencies (CDC, NCI, NIA, AHRQ). Dr. Cameron has collaborated with Drs. Barsuk and Wayne on projects related to simulation-based mastery learning in the context of central venous catheter infections. In her role as Co-Investigator for this project, Dr. Cameron will be responsible for working with the entire research team in the production of scientific reports and manuscripts.

Jane Wilcox, MD, MSc, Co-Investigator
Dr. Wilcox is an Assistant Professor in the Division of Cardiology. She is an advanced heart failure physician with extensive experience in caring for patients with end stage heart failure and ventricular assist devices. She has also worked with Dr. Barsuk on other simulation-based projects. She will serve as a medical advisor to the design of this study, interpretation, and data analysis. Dr. Wilcox will assist with patient recruitment and enrollment, study design, data collection and manuscript writing.

Diane Wayne, MD, Co-Investigator
Dr. Wayne is the Dr. John Sherman Appleman Professor, Vice Dean Education, and Chair of the Department of Medical Education at Northwestern University Feinberg School of Medicine. Dr. Wayne has extensive experience using simulation-based mastery learning for medical education and linking this training to improved patient outcomes. Her expertise and leadership in medical education will make her a valuable resource to Dr. Barsuk and she will be available for guidance as needed throughout the project in her role. Dr. Wayne will be responsible for helping to design and implement the curriculum proposed in this application. She will also assist in the preparation of scientific reports and manuscripts.

William McGaghie, PhD, Co-Investigator
Dr. McGaghie is Professor of Medical Education at Northwestern University Feinberg School of Medicine. Dr. McGaghie is an authority on medical education and is experienced with creating research methodologies for educational practices as well as developing medical simulations. Dr. McGaghie has an international reputation and is the inventor of simulation-based mastery learning. Dr. McGaghie will assist with study design, curricula development with a mastery learning model, data interpretation, and manuscript writing.

Julia Lee, PhD, Co-Investigator
Dr. Lee is an Assistant Professor in the Department of Preventive Medicine and faculty member of Northwestern University's Biostatistics Collaboration Center. She will be responsible for development of final data analysis plan, implementation of all elements of the data analysis plan, participating in evaluation and interpretation of results of the study, and preparation of all resulting manuscripts. Over the past 7 years, she has collaborated with Dr. Barsuk and published with other investigators in the Division of Hospital Medicine and gained a broader understanding of improving patient and hospital level outcomes.

Clyde W. Yancy, MD, MSc
Dr. Yancy is Magerstadt Professor of Medicine, Chief of Cardiology at Northwestern University Feinberg School of Medicine, and Associate Director of the Bluhm Cardiovascular Institute at

Northwestern Memorial Hospital. His research interests are in heart failure, heart transplantation, quality of care and health care disparities and he has a significant record of prior government funding. He recently served on the Advisory Committee to the Director for the NIH and remains as an active consultant to the National Institutes of Health; he is also a member of the NIH Scientific Management and Review Board. He is the immediate past chair of the FDA Cardiovascular Devices Panel; is an ad hoc consultant for AHRQ; holds a position on the Methodology Committee for the Patient Centered Outcomes Research Institute and previously served on the Committee for Health, Science and Policy for the Institute of Medicine. He sits on several clinical trial oversight committees within the NHLBI including SPRINT and the Cardiothoracic Clinical Trials Research Network. Dr. Yancy's extensive experience in research and peer review will be valuable for the success of this project.

Elaine Cohen, MEd
Ms. Cohen has extensive experience working with Dr. Barsuk as his research coordinator for studies using simulation-based mastery learning. She has also extensive experience and training in study design, statistical analysis, and assessment. She has significant understanding of qualitative assessment and will be integral in coding interview data. Ms. Cohen will also be responsible for data collection, security, and organization. She will assist with study design and implementation deadlines.

Our institution will contribute to the probability of the success of this project in multiple important ways. First, we implant a large number of ventricular assist devices (VADs) compared to other hospitals. Second, our ability to recruit patients for studies through our recruitment and enrollment efforts at Northwestern Memorial Hospital (NMH) and our outpatient clinics will also ensure success. We also have expert clinicians, research experts in qualitative study design, experts in simulation-based education, a statistician, and research staff who will be valued resources for this proposed grant application. Finally, we have more than adequate computer services with servers to which we can upload interview transcripts, clinical data, demographic, self-reported?, performance-based and clinical data from the Electronic Data Warehouse and Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) for analyses.

RECRUITMENT METHODS:
The research settings for recruitment and enrollment of patients is Northwestern Memorial Hospital, Northwestern University, Chicago, IL. Patients will be recruited either at the medical center (while the patient is hospitalized) or during a clinic visit. The co-investigators, who provide care to patients with ventricular assist devices (VADs) will share information about the study with patients. If the patient's caregiver is not present at this time, we will contact them via phone or via mailed brochure to explain the study and then consent in person when they arrive for their VAD training.

The PI, CO-I or VAD nurse, will further explain the study to patients and caregivers, encourage them to ask questions, and obtain written informed consent. Patients and caregivers will be informed that if they decline to participate in the study, it will not prejudice current patient care, and they may discontinue participation at any time during the study with no adverse impact to their treatment or care. Verbal and written information provided to potential participants during informed consent will include the following: the purpose of the study, the nature of the questions asked during interviews, the method and frequency of skills assessment completion, the length of time required, the voluntary nature of participation in the study, the ability to not respond or participate in any parts if requested, the freedom to withdraw from the study at any time without consequences, the potential risks and benefits of study participation,

and the confidentiality of information gathered. A brochure with an overview of the study will also be provided. Patients will also be shown their study results, if desired. Patients who are enrolled in INTERMACS will also be informed that INTERMACS will securely transmit data to Northwestern, as well, which is already done for other studies. We will also incorporate language into their consent form that includes a statement about INTERMACS protected health information being transmitted securely to Northwestern. Patients who agree to participate in the study will sign an informed consent form. A copy of the signed consent form will be given to the patient, a second copy of the consent form will be placed in the patient's medical record, and the original copy will be kept and filed by the RC

NUMBER OF LOCAL PARTICIPANTS:
We expect to recruit 75 patients and 75 caregivers. One caregiver will be identified by each patient subject.

CONFIDENTIALITY:
Procedures are in place to ensure the confidentiality of identifying information in INTERMACS, the Enterprise Data Warehouse, and Northwestern University protected research servers. These procedures are described in detail below.

We will incorporate a section into the informed consent that authorizes the study investigators to share personal health and other information from this study with persons and/or entities identified on the form, according to the rules and regulations of the Health Insurance Portability and Accountability Act (HIPAA). These procedures will thus inform patients of authorized personnel with whom data will be shared in a secured fashion and contribute to the confidentiality of a subject's identifying information and its protection from unauthorized access.

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INTERMACS currently follows Federal Information Security Management Act of 2002 (FISMA) guidelines using the National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53 Rev 4 for the protection of federal data. This security guideline helps ensure that all data entered and processed within INTERMACS is protected using specific security controls for integration of information security and privacy into organizational processes including enterprise architecture. INTERMACS also uses HIPAA overlays in addition to FISMA requirements for the protection of sensitive information. In addition to federal requirements, all sensitive data is sent to its recipients via secure encrypted e-mail. The INTERMACS Data Coordinating Committee facility has limited access via the use of electronic locking mechanisms and tracking. Only authorized INTERMACS personnel (CO-I) will have access to INTERMACS data.

All data will be stored on the research assistants' or PI's computer that is encrypted and password protected. Each patient and caregiver will be assigned a unique ID used to identify them. All paper records, including checklists, surveys, consent forms, and manual chart review forms will be locked in the Research Assistant's office in a locked file cabinet. Only IRB approved investigators on this IRB protocol form will have access to collected data. All data will be destroyed one year after study publication.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS:
Individual's participation will be voluntary. Only the PI, and co-investigators will have access to the data. The information gathered will not effect the patient or their care in any way other than for educational research purposes to improved communication skills training. Each patient and caregiver will be assigned a unique ID used to identify them.

CONSENT PROCESS:

Patients

Patients who participate in our proposed research will provide informed consent. Patients will be recruited either at the medical center (while the patient is hospitalized), during a clinic visit, or via an opt-out letter and follow-up telephone call. The co-investigators who provide care to patients with ventricular assist devices (VADs) will share information about the study with patients.

The PI, CO-I or VC, will further explain the study to patients, encourage them to ask questions, and obtain written informed. Patients, will be informed that there will be no penalty for not participating in this study. Verbal and written information provided to potential participants during informed consent will include the following: the purpose of the study, the method and frequency of skills assessment completion, the length of time required, the voluntary nature of participation in the study, the ability to not respond or participate in any parts if requested, the freedom to withdraw from the study at any time without consequences, the potential risks and benefits of study participation, and the confidentiality of information gathered. Patients who are enrolled in INTERMACS will also be informed that INTERMACS will securely transmit data to Northwestern, as well, which is already done for other studies. We will also incorporate language into the consent form that includes a statement about INTERMACS protected health information being transmitted securely to Northwestern. Patients who agree to participate in the study will sign an informed consent form. A copy of the signed consent form will be given to the patient, a second copy of the consent form will be placed in the patient's medical record, and the original copy will be kept and filed by the research coordinator.

Caregivers

Caregivers who participate in our proposed research will provide informed consent. They will be recruited either at the medical center (while the patient is hospitalized), during a clinic visit, or via an opt-out letter and follow-up telephone call. The co-investigators who provide care to patients with ventricular assist devices (VADs) will share information about the study with caregivers. If a patient wants to enroll in the study and their caregiver is not present at the time, we will contact them via phone to explain the study and then consent in person when they arrive for their VAD training.

The PI, CO-I or VC, will further explain the study to caregivers, encourage them to ask questions, and obtain written informed consent. Caregivers, will be informed that there will be no penalty for not participating in this study. Verbal and written information provided to potential participants during informed consent will include the following: the purpose of the study, the method and frequency of skills assessment completion, the length of time required, the voluntary nature of participation in the study, the ability to not respond or participate in any parts if requested, the freedom to withdraw from the study at any time without consequences, the potential risks and benefits of study participation, and the confidentiality of information gathered. Caregivers who agree to participate in the study will sign an informed consent form. A copy of the signed consent form will be given to the caregiver, a second copy of the consent form will be placed in the patient's medical record, and the original copy will be kept and filed by the research coordinator.