

ABOUT THE DECISION AID
Deciding Together

Program Information

- Overview
- Educational Content
- Target Audience
- Method of Participation
- Application of IPDAS Standards
- Disclaimer
- Acknowledgement of Support
- Production Release Date and Updating Policy
- BCM Development Team – Disclosure
- Reference and Evidence Sources

Overview

Patients and caregivers make more informed decisions about their healthcare when they understand the full range of options available for addressing end-stage heart failure helps. The decision aid *Deciding Together* is designed to help patients and caregivers consider what is important to them in deciding with their doctors about whether to pursue Left Ventricular Assist Device (LVAD) therapy versus other approaches to treating heart failure.

Educational Content

The sections of the decision aid offer important considerations for decision-making. They are intended to educate patients and caregivers as well as to generate questions and concerns to discuss with a healthcare team. These sections include:

- Overview of Heart Failure
- Overview of LVAD
- How to Decide
- LVAD Surgery
- Living with an LVAD
- About Palliative Care and Hospice
- Patient and Caregiver Stories

The decisional aid also includes the following stand-alone pull-out sections:

- LVAD by the Numbers
- Caregivers' Guide
- LVAD And Your Values
- Questions To Ask Your Doctor And Questions To Ask An LVAD Patient
- Resources For LVAD Patients And Caregivers
- Your LVAD Knowledge

Trial-Tested for Efficacy

After an extensive, user-centered design process, we conducted a multi-site randomized trial of the DA compared to standard education (SE) among inpatients considering LVAD treatment for advanced heart failure. The main outcome was LVAD Knowledge at 1-week and 1-month following administration of the DA versus SE, using a validated scale. Secondary measures included pre-specified quality decision-making measures recommended by International Patient Decision Aid Standards. Of 105 eligible patients, 98 consented and were randomly assigned to the DA or SE arm. Patients receiving the DA exhibited significantly greater LVAD knowledge than the SE group at 1-week follow-up ($p=0.01$) but not at 1-month ($p=0.47$). No differences were found between DA and SE patients in rates of acceptance versus decline of LVAD treatment (85% vs. 78%, $p=0.74$). Recipients in the DA arm reported greater satisfaction with life post-implant compared to non-recipients (28 vs. 23 out of 30, $p=0.008$), though both arms reported high satisfaction. Patients rated the DA high in acceptability and usability.

Our trial results show that DA enhances LVAD knowledge, particularly in the short-term (1-week) during the peak period of decision-making. The aid does not encourage decision direction and reflects patient-, caregiver- and physician-preferences for content and format.

Target Audience

This decision aid is intended to address the needs and concerns of patients and their caregivers who are deciding with their doctors about whether or not to pursue LVAD therapy for end-stage heart failure.

Method of Participation

Information in this decision aid comes in an interactive paper-based toolkit that provides important information as well as space to document patient and caregiver notes and reflections as they read through the aid. Patients and caregivers are encouraged to bring the aid to their medical appointments to discuss any concerns with their doctors. Supplementary information is also available on the website: lvaddecisionaid.com.

Application of IPDAS Standards for Development of the Patient Decision Aid

The development of this decision aid was guided by the International Patient Decision Aid Standards (IPDAS) checklist. The checklist is based on the consensus of a wide range of decision aid developers, researchers, practitioners, patients and policymakers regarding the importance of each criterion. This list of 30 criteria represent quality

standards that the IPDAS voting panel rated as most highly important, with complete agreement among all voters.

Items in the specific checklist presented here are used by the Ottawa Hospital Research Institute and was adopted by the John M. Eisenberg Center for Clinical Decisions and Communications Science at Baylor College of Medicine (EC-BCM) as quality standards for patient decision aids. The checklist is listed below, organized by the following categories: content items (Table 1), development process items (Table 2), and effectiveness items (Table 3). In each table it is indicated whether the decision aid Deciding Together meets each criteria. Please note that in some cases, the standards are not applicable.

Table 1. Abbreviated IPDAS Checklist: Content Items

IPDAS CHECKLIST CRITERIA	YES	NO	N/A	COMMENTS
CONTENT				
Does the patient decision aid provide information about the options in sufficient detail for decision-making?				
01 The decision aid describes the condition (health or other) related to the decision.	✓			
02 The decision aid describes the decision that needs to be considered (the index decision).	✓			
03 The decision aid lists the options (health care or other).	✓			
04 The decision aid describes what happens in the natural course of the condition (health or other) if no action is taken.	✓			
05 The decision aid has information about the procedures involved (e.g., what is done before, during, and after the health care option).	✓			
06 The decision aid has information about the positive features of the options (e.g., benefits, advantages).	✓			
07 The decision aid has information about negative features of the options (e.g., harms, side effects, disadvantages).	✓			
08 The information about outcomes of options (positive and negative) includes the chances they may happen.	✓			
09 The decision aid has information about that the test is designed to measure.				This is a treatment aid.
10 The decision aid describes possible next steps based on the test results.				This is a treatment aid.
11 The decision aid has information about the chances of disease being found with and without screening.				This is a treatment aid.
12 The decision aid has information about detection and treatment of disease that would never have caused problems if screening had not been done.				This is a treatment aid.
13 The decision aid presents probabilities using event rates in a defined group of people for a specified time.	✓			
14 The decision aid compares probabilities (e.g., chance of a disease, benefit, harm, or side effect) of options using the same denominator.		✓		Date on outcome probabilities directly comparing options are lacking.
15 The decision aid compares probabilities of options over the same period of time.		✓		Date on outcome probabilities directly comparing options are lacking.
16 The decision aid uses the same scales in diagrams comparing	✓			

options.				
17 The decision aid asks people to think about which positive and negative features of the available options matter most to them.	✓			
18 The decision aid makes it possible to compare the positive and negative features of the available options.	✓			
19 The decision aid shows the negative and positive features of the options with equal detail.	✓			

Table 2. Abbreviated IPDAS Checklist: Developmental Process Items

IPDAS CHECKLIST CRITERIA	YES	NO	N/A	COMMENTS
DEVELOPMENT PROCESS				
20 Users (people who previously faced the decision) were asked what they need to prepare them to discuss a specific decision.	✓			
21 The decision aid was reviewed by people who previously faced the decision who were not involved in its development and field-testing.	✓			
22 People who were facing the decision field-tested the decision aid.				The PDA is currently undergoing efficacy testing in a multi-site clinical trial.
23 Field testing showed that the decision aid was acceptable to users (the general public and practitioners).	✓			
24 Field testing showed that people who were undecided felt that the information was presented in a balanced way.	✓			
25 The decision aid provides references to scientific evidence used.	✓			References included in this document.
26 The decision aid reports the date when it was last updated.	✓			
27 The decision aid reports whether authors of the decision aid or their affiliations stand to gain or lose by choices people make after using the decision aid.	✓			
28 The decision aid is understood by those with limited reading skills.	✓			Flesch-Kincaid Grade Level score: 7 th Grade

Table 3. Abbreviated IPDAS Checklist: Effectiveness Items

IPDAS CHECKLIST CRITERIA	YES	NO	N/A	COMMENTS
EFFECTIVENESS				
29 There is evidence that the decision aid (or one based on the same template) helps people know about the available options and their features.			✓	The aid's effectiveness has not yet been evaluated.
21 There is evidence that the decision aid (or one based on the same template) improves the match between the features that matter most to the informed person and the option that is chosen.			✓	The aid's effectiveness has not yet been evaluated.

Our decision aid also meets several other criteria such as review by clinicians and professionals not involved in its production

The development of our decision aid is described in detail in the following paper:

Kostick, Kristin, Estevan D. Delgado, Lidija A. Wilhelms, Courtenay R. Bruce, Jerry D. Estep, Matthias Loebe, Charles Minard, and Jennifer S. Blumenthal-Barby.

"Development and Pilot-Testing of a Patient Decision Aid for Left Ventricular Assist Device Placement." *The VAD Journal* 2, no. 1 (2016): 1.

Disclaimer

The content provided in this patient decision aid is intended for educational purposes only and is not intended to replace the advice and expertise of a doctor. Any questions or concerns about decisions for treatment should be addressed to a professional clinical team.

The creators of this decision aid make every effort to provide accurate, up-to-date information for users. The creators are not responsible for how the information is used; that is, no warranty or liability is offered. In cases where the decision aid provides references to other resources for decision-making, referrals do not constitute an endorsement. Users who access other referred links are subject to each site's terms and conditions.

All medical decisions should be made in consultation with a doctor.

Acknowledgement of Support

This patient decision aid is supported through a Patient Centered Outcomes Research Institute (PCORI) Program Award (1306-01769). All information conveyed in the decision aid does not necessarily represent the views of the Patient-Centered Outcomes Research Institute, its Board of Governors or Methodology Committee.

Production Release Date and Updating Policy

The release of the updated decision aid is scheduled for April 2016. The aid is currently undergoing efficacy testing in a multi-site clinical trial. Please stay tuned to the website for updates on trial progress. The decision aid will be updated according to the policy developed with the Patient Centered Outcomes Research Institute (PCORI), ideally every 2 years or if a significant change in evidence occurs.

Decision Aid Development Team – Disclosure

The content and design of the patient decision aid Deciding Together were developed together by a team of experts in the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, TX in collaboration with clinical experts and hospital staff in the The Houston Methodist DeBakey Heart & Vascular Center at the

Houston Methodist Hospital, and experts in medical decision-making at the University of Texas MD Anderson Cancer Center (Houston, TX).

All affiliates of these institutions are required to maintain balance, independence, objectivity and scientific rigor in all sponsored educational activities and programs. They are expected to disclose any significant relationships that may pose a conflict with the principles of balance and independence.

Disclosure:

Drs. Estep and Loebe receive consultant and research support from Thoratec Corporation. The corporation had no role in the funding or development of this decision aid.

No other members of the development team have affiliation to disclose.

Leads (PI and Co-Is)

Jennifer Blumenthal-Barby, PhD, MA
Baylor College of Medicine, Associate Professor

Courtenay Bruce, JD, MA
Baylor College of Medicine, Assistant Professor

Robert Volk, PhD
MD Anderson Cancer Center, Professor

Dr. Jerry Estep, MD
The Houston Methodist, DeBakey Heart & Vascular Center

Charles Minard, PhD
Baylor College of Medicine, Assistant Professor

Sheryl McCurdy, PhD
University of Texas School of Public Health, Associate Professor

Project Management, Research & Writing/Editing Team

Kristin M. Kostick, PhD
Baylor College of Medicine, Research Associate and Analyst

Estevan Delgado, BA
Baylor College of Medicine, Senior Project Coordinator

Lidija Wilhelms, BA
Baylor College of Medicine, Project Coordinator

Holland Kaplan
Baylor College of Medicine, MS2

Mackenzie Nettlow
Rice University, Undergraduate Research Intern

Decision Aid Design Team

DesignGood, Ltd.
<http://designgood.com/about-design-good/>

Web Development and Design Team

Estevan Delgado, BA
Baylor College of Medicine, Senior Project Coordinator

DesignGood, Ltd.
<http://designgood.com/about-design-good/>

Skyscape Studios
<http://www.skyscapestudios.com>

Medical Content Experts

Dr. Brian Bruckner, MD
The Houston Methodist, DeBakey Heart & Vascular Center

Dr. Matthias Loebe, MD, PhD
The University of Miami, Miami Transplant Institute

Patient Partner Representatives

Brenda M.

Mary Y.

Kenneth M.

References and Evidence Sources

Overview of Heart Failure

Fields AV, Kirkpatrick JN. Ethics of the heart: ethical and policy challenges in the treatment of advanced heart failure. *Perspect Biol Med*. 2012;55(1):71–80.

Hunt SA, Baker DW, Chin MH, Cinquegrani MP, Feldman AM, Francis GS, et al. ACC/AHA guidelines for the evaluation and management of chronic heart failure in the adult: executive summary. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to revise the 1995 Guidelines for the Evaluation and Management of Heart Failure). *J Am Coll Cardiol*. 2001 Dec;38(7):2101–13.

Kirkpatrick JN, Kim AY. Ethical issues in heart failure: overview of an emerging need. *Perspect Biol Med*. 2006;49(1):1–9.

O’Connell JB. The economic burden of heart failure. *Clin Cardiol*. 2000 Mar;23(3 Suppl):III6–10.

Roger VL, Go AS, Lloyd-Jones DM, Benjamin EJ, Berry JD, Borden WB, et al. Heart Disease and Stroke Statistics—2012 Update A Report From the American Heart Association. *Circulation*. 2012 Jan 3;125(1):e2–e220.

Starling RC. *The Cleveland Clinic Guide to Heart Failure*. New York, NY: Kaplan Publishing; 2009.

<http://www.heartware.com/patients-caregivers>

<http://www.mylvad.com/content/advanced-congestive-heart-failure>

<http://heartmateii.com/understanding-heart-failure.aspx>

Overview of LVAD

Fang JC. Rise of the machines--left ventricular assist devices as permanent therapy for advanced heart failure. *N Engl J Med*. 2009 Dec 3;361(23):2282–5.

Kirklin JK, Naftel DC, Kormos RL, Stevenson LW, Pagani FD, Miller MA, et al. Third INTERMACS Annual Report: the evolution of destination therapy in the United States. *J Heart Lung Transplant*. 2011 Feb;30(2):115–23.

Kirklin JK, Naftel DC, Kormos RL, Stevenson LW, Pagani FD, Miller MA, et al. The Fourth INTERMACS Annual Report: 4,000 implants and counting. *J Heart Lung Transplant*. 2012 Feb;31(2):117–26.

Long JW, Healy AH, Rasmusson BY, Cowley CG, Nelson KE, Kfoury AG, et al. Improving outcomes with long-term “destination” therapy using left ventricular assist devices. *J Thorac Cardiovasc Surg*. 2008 Jun;135(6):1353–1360; discussion 1360–1361.

Slaughter MS, Rogers JG, Milano CA, Russell SD, Conte JV, Feldman D, et al. Advanced heart failure treated with continuous-flow left ventricular assist device. *N Engl J Med*. 2009 Dec 3;361(23):2241–51.

Rose EA, Gelijns AC, Moskowitz AJ, Heitjan DF, Stevenson LW, Dembitsky W, et al. Long-term use of a left ventricular assist device for end-stage heart failure. *N Engl J Med*. 2001 Nov 15;345(20):1435–43.

<http://www.heartware.com/patients-caregivers/what-vad>

<http://www.mylvad.com/content/what-lvad-how-does-it-work>

<http://heartmateii.com/understanding-lvads.aspx>

<http://heartmateii.com/heartmate-ii-system.aspx>

How to Decide

Stacey, D., Kryworuchko, J., Belkora, J., Davison, B. J., Durand, M. A., Eden, K. B., ... & Street, R. L. (2013). Coaching and guidance with patient decision aids: A review of theoretical and empirical evidence. *BMC medical informatics and decision making*, 13(Suppl 2), S11.

LVAD Surgery

Healy, A. H., Stehlik, J., Edwards, L. B., McKellar, S. H., Drakos, S. G., & Selzman, C. H. (2014). Preoperative Risk Factors for Early Mortality in Patients Bridged to Transplant with a Continuous Flow Left Ventricular Assist Device. *The Journal of Heart and Lung Transplantation*, 33(4), S56.

Piccione, W. (2000). Left ventricular assist device implantation: short and long-term surgical complications. *The Journal of heart and lung transplantation*, 19(8), S89-S94.

Living with an LVAD

MacIver, J., & Ross, H. J. (2012). Quality of life and left ventricular assist device support. *Circulation*, 126(7), 866-874.

Marcuccilli, L. (2012). Patients' and caregivers' inside perspectives: living with a left-ventricular assist device as destination therapy. Dissertation. Wayne State University. Available: http://digitalcommons.wayne.edu/oa_dissertations/516/

Modica, M., Ferratini, M., Torri, A., Oliva, F., Martinelli, L., De Maria, R., & Frigerio, M. (2014). Quality of Life and Emotional Distress Early After Left Ventricular Assist Device Implant: A Mixed-Method Study. *Artificial organs*.

Wissman, S., Naftel, D. C., Myers, S. L., Kirklin, J. K., Moskowitz, A., Gelijns, A., ... & Grady, K. L. (2012). 26 Predictors of Health-Related Quality of Life at 6 Months after Left Ventricular Assist Device Implantation: Findings from INTERMACS. *The Journal of Heart and Lung Transplantation*, 31(4), S18.

About Palliative Care and Hospice

Hui, D., De La Cruz, M., Mori, M., Parsons, H. A., Kwon, J. H., Torres-Vigil, I., ... & Bruera, E. (2013). Concepts and definitions for “supportive care,” “best supportive care,” “palliative care,” and “hospice care” in the published literature, dictionaries, and textbooks. *Supportive Care in Cancer*, 21(3), 659-685.

LeMond, L., & Allen, L. A. (2011). Palliative care and hospice in advanced heart failure. *Progress in cardiovascular diseases*, 54(2), 168-178.

<https://www.nia.nih.gov/health/publication/end-life-helping-comfort-and-care/introduction>

<https://www.nia.nih.gov/health/publication/advance-care-planning>

Patient and Caregiver Stories

Bekker, H. L., Winterbottom, A. E., Butow, P., Dillard, A. J., Feldman-Stewart, D., Fowler, F. J., ... & Volk, R. J. (2013). Do personal stories make patient decision aids more effective? A critical review of theory and evidence. *BMC medical informatics and decision making*, 13(Suppl 2), S9.

Shaffer, V. A., & Zikmund-Fisher, B. J. (2012). All Stories Are Not Alike A Purpose-, Content-, and Valence-Based Taxonomy of Patient Narratives in Decision Aids. *Medical Decision Making*, 0272989X12463266.

LVAD by the Numbers

The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) produces an overall quarterly statistical report that is available to the public. This overall report is intended to give a current status of the InterMACS Registry. We consulted the Q3 and Q4 reports from 2014, as well as the 5th and 6th INTERMACS reports, all of which can be accessed through the following link:

<https://www.uab.edu/medicine/intermacs/stat-summaries/intermacs-stat-summaries/intermacs-qtr-reports>

Jorde, U. P., Kushwaha, S. S., Tatoes, A. J., Naka, Y., Bhat, G., Long, J. W., ... & Park, S. J. (2014). Results of the destination therapy post-food and drug administration approval study with a continuous flow left ventricular assist device: a prospective study using the INTERMACS Registry (Interagency Registry for Mechanically Assisted Circulatory Support). *Journal of the American College of Cardiology*, *63*(17), 1751-1757.

McIlvennan, C. K., Magid, K. H., Ambardekar, A. V., Thompson, J. S., Matlock, D. D., & Allen, L. A. (2014). Clinical Outcomes Following Continuous-Flow Left Ventricular Assist Device: A Systematic Review. *Circulation: Heart Failure*, CIRCHEARTFAILURE-114.

Caregivers' Guide

Blumenthal-Barby, J. S., Kostick, K. M., Delgado, E. D., Volk, R. J., Kaplan, H. M., Wilhelms, L. A., ... & Bruce, C. R. (2015). Assessment of Patients' and Caregivers' Informational and Decisional Needs for Left Ventricular Assist Device Placement: Implications for Informed Consent and Shared Decision Making. *The Journal of Heart and Lung Transplantation*.

Kitko, L., Hupcey, J., Gilchrist, J., & Boehmer, J. (2012). The Experience of Caring for a Spouse with End-Stage Heart Failure Following Implantation of a Left Ventricular Assist Device as Destination Therapy. *Circulation*, *126*(21 Supplement), A14686.

Marcuccilli, L., Casida, J. J., Bakas, T., & Pagani, F. D. (2014). Family caregivers' inside perspectives: caring for an adult with a left ventricular assist device as a destination therapy. *Progress in Transplantation*, *24*(4), 332-340.

McIlvennan, C. K., Jones, J., Allen, L. A., Lindenfeld, J., Nowels, C., Swetz, K. M., & Matlock, D. D. (2014). Caregiver Experiences with Decision Making in Destination Therapy Left Ventricular Assist Devices: A Qualitative Study. *Circulation: Cardiovascular Quality and Outcomes*, *7*(Suppl 1), A318-A318.

LVAD And Your Values

Barry, M. J., & Edgman-Levitan, S. (2012). Shared decision making—the pinnacle of patient-centered care. *New England Journal of Medicine*, *366*(9), 780-781.

Fagerlin, A., Pignone, M., Abhyankar, P., Col, N., Feldman-Stewart, D., Gavaruzzi, T., ... & Witteman, H. O. (2013). Clarifying values: an updated review. *BMC medical informatics and decision making*, *13*(Suppl 2), S8.

Questions To Ask Your Doctor And Questions To Ask An LVAD Patient

Blumenthal-Barby JS, Kostick KM, Delgado ED, Volk RJ, Kaplan HM, Wilhelms L, McCurdy S, Estep JL, Loebe M, Bruce CR. Assessment of Patients' and Caregivers' Informational and Decisional Needs for Left Ventricular Assist Device Placement: Implications for Informed Consent, *Journal of Heart and Lung Transplantation* (forthcoming).

Your LVAD Knowledge

Kostick K, Minard C, Wilhelms L, Volk R, Nettlow M, Bruce C, Estep J, Blumenthal-Barby JS. Development and Validation of a Patient-Centered Knowledge Scale for LVAD Placement (in progress).