

Supporting Evidence for the Development of a Decision Aid for Left Ventricular Assist Device (LVAD): A Device for Patients with Advanced Heart Failure

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Introduction

Patients with advanced heart failure may be eligible for a left ventricular assist device (LVAD), which is a partial artificial heart. An LVAD could either be used as bridge-to-transplant while patients are awaiting a heart transplantation, or as destination therapy for permanent treatment for patients who are ineligible for transplant. While LVADs are likely to increase survival, they also come with serious risks – including stroke, infection, bleeding, and rehospitalization – and lifestyle changes. Additionally, caregivers are required by many programs for patient eligibility, which further complicates the decision making process by including family and friends.

Therefore, we developed patient decision aids (PtDAs):

- Paper: 8-page pamphlet
- Video: 26-minute video

Both paper and video are available for free online at patientdecisionaid.org/LVAD. These online PtDAs describe the decision of whether to receive an LVAD or not, benefits and risks of both, lifestyle changes, palliative and hospice care, caregiver responsibilities, and include value exercises. These tools are designed to be supplemental information for patients to use in discussions with their clinicians.

Development and Research Team

Larry A. Allen, MD, MHS

Associate Professor of Medicine, Director of Advanced Heart Failure, University of Colorado School of Medicine, Department of Medicine, Division of Cardiology

Daniel D Matlock, MD MPH

Associate Professor of Medicine, University of Colorado School of Medicine, Department of Medicine, Division of Geriatrics

Director of the Colorado Program for Patient Centered Decisions, Adult and Child Consortium for Health Outcomes Research and Delivery Science (ACCORDS)

Core Lead, D2V

Colleen McIlvennan, DNP, ANP

Assistant Professor, University of Colorado School of Medicine, Department of Medicine, Division of Cardiology

Jocelyn S. Thompson, MA

Senior Professional Research Assistant, University of Colorado School of Medicine, ACCORDS

Development Process

The development of the PtDA followed the principles as outlined in the Ottawa Decision Support Framework and the International Patient Decision Aid Standards (IPDAS).^{1,2}

Ottawa Decision Support Framework (ODSF)

The Ottawa Decision Support Framework (ODSF) is an evidence-based, practical, mid-range theory for guiding patients making health or social decisions. It uses a three-step process: assess client and practitioner determinants of decisions to identify decision support needs; provide decision support tailored to client needs; and evaluate the decision-making process and outcomes.¹

I. Needs Assessment

Patient, Caregiver, and Provider Needs Assessments

As part of the needs assessment, we performed a qualitative study of interviews with (1) patients who went through the LVAD decision-making process, (2) caregivers of patients who went through the LVAD decision-making process, and (3) LVAD coordinators who work with patients and families during the decision-making process. These needs assessments were published:³⁻⁵

McIlvinnan CK, Allen LA, Nowels C, Brieke A, Cleveland JC, Matlock DD. Decision making for destination therapy left ventricular assist devices: "there was no choice" versus "I thought about it an awful lot". Circ Cardiovasc Qual Outcomes. 2014;7(3):374-380. [PMID: 24823949]

McIlvinnan CK, Jones J, Allen LA, Lindenfeld J, Swetz KM, Nowels C, Matlock DD. Decision-making for destination therapy left ventricular assist devices: implications for caregivers. Circ Cardiovasc Qual Outcomes. 2015;8(2):172-178. [PMID: 25759442]

McIlvinnan CK, Matlock DD, Narayan MP, Nowels C, Thompson JS, Cannon A, Bradley WJ, Allen LA. Perspectives from mechanical circulatory support coordinators on the pre-implantation decision process for destination therapy left ventricular assist devices. Heart & Lung. 2015;44:219-24. [PMID: 25724116]

These provided crucial background on patient, caregiver, and provider experiences, needs, and desires during the decision-making process for LVAD, which helped shape the PtDAs. Elements of these were integrated and went beyond IPDAS requirements, including addressing emotions and fear of death, framing around life, inclusion of palliative and hospice care information, and inclusion of the caregiver experience.

Environmental Scan

In addition to the needs assessments, we also conducted an environment scan of existing decision support materials for LVAD. This study found that no materials that met the criteria of a decision aid existed for LVAD, and many educational materials mentioned benefits but did not mention risks, and were scored as being biased. Full results published:⁶

Iacovetto MC, Matlock DD, McIlvinnan CK, Thompson JS, Bradley W, LaRue SJ, Allen LA. Educational resources for patients considering a left ventricular assist device: a cross-sectional review of internet, print, and multimedia materials. Circ Cardiovasc Qual Outcomes. 2014;7:905-911. [PMID: 25316772]

Review of Evidence

We conducted a systematic review of all LVAD studies to date, so that we may have the most accurate survival and risk data to present in the PtDA. Full systematic review data published:⁷
McIlvannan CK, Magid KH, Ambardekar AV, Thompson JS, Matlock DD, Allen LA. Clinical outcomes after continuous-flow left ventricular assist device: a systematic review. Circ Heart Fail. 2014;7:1003-1013. [PMID: 25294625]

To keep up-to-date with new studies, we continually monitor the LVAD clinical trial literature and re-assess statistics every year. When the MOMENTUM 3, ENDURANCE and LATERAL trial data were published, we updated survival with an LVAD to 87%, changed “disabling stroke” to “stroke”, and removed device re-implant due to clot.⁸⁻¹⁰ Additionally, pump imagery and details (such as length of battery life, weight of equipment) were updated to reflect the new centrifugal pumps.

II. Decision Aid Development

Decision Aid Development

Based on IPDAS, our needs assessments, environmental scan, and systematic review, we developed an initial draft of the paper tool which underwent a process of iterative testing to assure accuracy, readability and lack of bias. Once a solid draft of the paper version was completed, a script for a video was iteratively developed, a beta-version of the video produced, and then a final version with patient and caregiver testimonials. Feedback on every draft version of the paper and video decision aids was obtained through interviews conducted with (1) patients who received an LVAD, declined an LVAD, were not yet eligible for an LVAD but had heart failure, and were currently being evaluated for LVAD, (2) caregivers of all patient categories, and (3) providers, including advanced heart failure cardiologists, cardiothoracic surgeons, advanced heart failure nurse practitioners, LVAD coordinators, social workers, and palliative care specialists. A total of 24 patients, 20 caregivers and 24 providers, as well as several provider groups, were interviewed, and 19 versions of the paper and 4 versions of the video were developed for the final product. Full details of the development process were published:¹¹

Thompson JS, Matlock DD, McIlvannan CK, Jenkins AR, Allen LA. Development of a decision aid for patients with advanced heart failure considering a destination therapy left ventricular assist device. JACC Heart Fail. 2015;3(12):965-976. [PMID: 26671675]

A log of feedback provided by patients, caregivers and clinicians was maintained to track the iterative process. All changes were agreed to by the study team.

Pilot Study

Once final versions were produced, a pilot study was completed with 10 patients being evaluated for LVAD and 10 of their caregivers, where they received the PtDAs as part of their education process for the LVAD evaluation. Results from the pilot study were published:¹²

McIlvannan CK, Thompson JS, Matlock DD, Cleveland JC Jr, Dunlay SM, LaRue SJ, Lewis EF, Patel CB, Walsh MN, Allen LA. A multicenter trial of a shared decision support intervention for patients and their caregivers offered destination therapy for advanced heart failure: DECIDE-LVAD: Rationale, design, and pilot data. J Cardiovasc Nurs. 2016;31(6):E8-E20. [PMID: 27203272]

DECIDE-LVAD Trial

The Patient-Centered Outcomes Research Institute funded a 3-year trial titled A Multicenter Trial of a Shared Decision Support Intervention for Patient and Their Caregivers Offered Destination Therapy for End-Stage Heart Failure: DECIDE-LVAD Trial. The DECIDE-LVAD trial

aimed to assess the effectiveness and implementation of the PtDAs using a hybrid design. We conducted a stepped wedge, multi-center trial that was randomized at the hospital-level for a phased role out of the intervention to each hospital sequentially. In this design, all the groups received the intervention, but the time when they received it was randomly ordered allowing simultaneous assessment of effectiveness and implementation at 6 sites. The primary outcome was patient and caregiver knowledge and values-choice concordance. Patient knowledge significantly improved with the PtDA intervention, and while caregiver knowledge also improved, it was at a non-significant rate. Both patient and caregiver concordance between their value score and reported treatment preference was significantly higher with the intervention. Full results were published:^{13,14}

Allen LA, McIlvannan CK, Thompson JS, Dunlay SM, LaRue SJ, Lewis EF, Patel CB, Blue L, Fairclough DL, Leister EC, Glasgow RE, Cleveland JC, Phillips C, Baldrige V, Walsh MN, Matlock DD. Effectiveness of an intervention supporting shared decision making for destination therapy left ventricular assist device: The DECIDE-LVAD randomized clinical trial. JAMA Intern Med. 2018;178(4):520-529. [PMID: 29482225]

McIlvannan CK, Matlock DD, Thompson JS, Dunlay SM, Blue L, LaRue SJ, Lewis EF, Patel CB, Fairclough DL, Leister EC, Swetz KM, Baldrige V, Walsh MN, Allen LA. Caregivers of patients considering a destination therapy left ventricular assist device and a shared decision-making intervention: The DECIDE-LVAD trial. JACC Heart Fail. 2018;6(11):904-913. [PMID: 30316931]

In addition to effectiveness, implementation was successful at all 6 participating sites, where the PtDA intervention was delivered to 95% of eligible patients and caregivers, and nearly always provided by clinical (non-research) personnel. Qualitative interviews were also conducted with clinicians at each of the 6 sites to better understand adoption, implementation and maintenance of the PtDAs.

Overall, the DECIDE-LVAD trial showed that the PtDA materials were effective and could be used in real-world clinical settings.

Revisions

Once the DECIDE-LVAD Trial was completed, several updates were made based on qualitative interview results with site LVAD teams, feedback from end-users, and lessons learned. The primary changes included:

1. Making the PtDA non-indication specific, where it would no longer be for destination therapy (DT) only but for both DT and bridge-to-transplant (BTT). This was due to the following reasons:
 - a. DT and BTT indications are often fluid. In the most recent INTERMACS 8th Annual Report, only 34% of patients implanted as BTT had undergone transplant by 1 year, whereas 12% had died; conversely, more than 10% of DT patients eventually go on to transplant.¹⁵
 - b. During the conduct of the DECIDE-LVAD Trial, all 6 programs used the DT-specific PtDA for their BTT patients as well.
 - c. A study of passive dissemination of the PtDA showed that most programs who had started using the PtDA employed them for both DT and BTT patients, and the primary reason some programs that were initially interested in the PtDA decided to not use it was because it did not include BTT indication.¹⁶

- d. When revising the PtDA from DT-specific to address both DT and BTT populations, we found surprisingly few sections needing updates. This was due to the following:
 - i. Available devices have generally gained approval for both indications. Thus, the device, the surgery, and the post-operative care are essentially identical.
 - ii. Outcomes experienced by DT and BTT patients are relatively similar. In our systematic review of clinical trials, we found survival, health status, hospitalization, and adverse events to be comparable.⁷
 - iii. Lifestyle considerations, caregiver needs, and end-of-life care are still applicable to BTT patients.
 - e. The newest clinical trial—MOMENTUM 3—enrolled patients regardless of indication and again found similar outcomes among the two types of patients.⁸
 - f. One version of the PtDA for all patients (DT and BTT) provides important simplicity to aid in dissemination and implementation.
 - g. Many of the above factors also indicate clinician buy-in for the DT and BTT PtDA, as many programs already used the existing PtDA with BTT patients and have expressed acceptability of the updated version. Additionally, in discussions with various clinicians about the changes, we have received strong support for this change.
2. Updating statistics to reflect new MOMENTUM 3, ENDURANCE and LATERAL trial data.⁸⁻¹⁰
 3. Updating pump imagery and details, such as length of battery life and weight of equipment, to reflect new centrifugal pumps, since those were approved for use and becoming standard.
 4. Updating the literacy level, changing from an 8th grade to 6th grade reading level, in order to satisfy some LVAD programs in areas with low-literate populations.

The Development Team will annually review the literature for changes in statistics or in advances in technology to incorporate into the PtDAs.

III. Sources of Statistics Put Forth in Decision Aid

SURVIVAL WITH AN LVAD

STUDY	YEAR	SUBJECTS (N=)	DURATION	POPULATION	DESIGN	RESULTS		
						INTERVENTION	CONTROL	P-VALUE
Systematic Review ⁷	2014	21 publications, including 16,397 patients	Studies published from January 2007 to December 2013	Patients with advanced heart failure on medical management or continuous flow LVAD as destination therapy or bridge-to-transplant	Systematic review summarizing data across relevant studies	LVAD – 80%	Medical Management – 17%	N/A
MOMENTUM 3 ⁸	2019	1028 patients	2 years	Patients with advanced-stage heart failure who received either a centrifugal-flow pump or axial-flow pump	Non-blinded, randomized trial comparing centrifugal-flow pump with an axial-flow pump	6 months – 90%; 1 year – 86.6%; 2 years – 79%	6 months – 88.7%; 1 year – 84.1%; 2 years – 76.7%	N/A
ENDURANCE ⁹	2017	446 patients	2 years	Patients with advanced-stage heart failure who received either a centrifugal-flow pump or axial-flow pump as destination therapy	Randomized trial of a 2:1 ratio comparing centrifugal-flow pump with an axial-flow pump	60.2%	67.6%	0.17
LATERAL ¹⁰	2019	144 patients	6 months	Patients with advanced heart failure who received the HVAD centrifugal-flow pump through thoracotomy implant	Prospective, single arm trial evaluating the thoracotomy implant technique of the HVAD system	6 months – 92%; 1 year – 89%; 2 years – 87%	N/A	N/A
INTERMACS Annual Report ¹⁷	2019	18,539 patients	1 year	Patients who underwent isolated continuous flow LVAD implant between 2012-2017	Data reported to INTERMACS registry on continuous flow, including both centrifugal and axial, pumps	Centrifugal – 85%	Axial – 84%	0.02

SURVIVAL WITHOUT AN LVAD

STUDY	YEAR	SUBJECTS (N=)	DURATION	POPULATION	DESIGN	RESULTS		
						INTERVENTION	CONTROL	P-VALUE
Systematic Review ⁷	2014	21 publications, including 16,397 patients	Studies published from January 2007 to December 2013	Patients with advanced heart failure on medical management or continuous flow LVAD as destination therapy or bridge-to-transplant	Systematic review summarizing data across relevant studies	LVAD – 80%	Medical Management – 17%	N/A
REMATCH ¹⁸	2001	129 patients	2 years	Patients with chronic end-stage heart failure and contraindications to transplantation who received a pulsatile-flow LVAD or optimal medical therapy	Randomized trial comparing pulsatile-flow LVAD to optimal medical therapy	1 year – 52%; 2 years – 25%	1 year – 25%; 2 years – 8%	0.002; 0.09

REHOSPITALIZATION RATE WITH LVAD

STUDY	YEAR	SUBJECTS (N=)	DURATION	POPULATION	DESIGN	RESULTS		
						INTERVENTION	CONTROL	P-VALUE
Systematic Review ⁷	2014	12 publications, including 2,651 patients	Studies published from January 2007 to December 2013	Patients with advanced heart failure on medical management or continuous flow LVAD as destination therapy or bridge-to-transplant	Systematic review summarizing data across relevant studies	LVAD – 55%	N/A	N/A
MOMENTUM 3 ⁸	2019	1028 patients	2 years	Patients with advanced-stage heart failure who received either a centrifugal-flow pump or axial-flow pump	Non-blinded, randomized trial comparing centrifugal-flow pump with an axial-flow pump	2.26 events per patient-year	2.47 events per patient-year	N/A
ENDURANCE ⁹	2017	446 patients	2 years	Patients with advanced-stage heart failure who received either a centrifugal-flow pump or axial-flow pump as destination therapy	Randomized trial of a 2:1 ratio comparing centrifugal-flow pump with an axial-flow pump	84.1%	79.2%	0.23
INTERMACS Annual Report ¹⁷	2019	18,539 patients	1 year	Patients who underwent isolated continuous flow LVAD implant between 2012-2017	Data reported to INTERMACS registry on continuous flow, including both centrifugal and axial, pumps	Centrifugal – 79%	Axial – 77%	0.001

STROKE RATE WITH LVAD

STUDY	YEAR	SUBJECTS (N=)	DURATION	POPULATION	DESIGN	RESULTS		
						INTERVENTION	CONTROL	P-VALUE
Systematic Review ⁷	2014	20 publications, including 9,150 patients	Studies published from January 2007 to December 2013	Patients with advanced heart failure on medical management or continuous flow LVAD as destination therapy or bridge-to-transplant	Systematic review summarizing data across relevant studies	LVAD – 10%	N/A	N/A
MOMENTUM 3 ⁸	2019	1028 patients	2 years	Patients with advanced-stage heart failure who received either a centrifugal-flow pump or axial-flow pump	Non-blinded, randomized trial comparing centrifugal-flow pump with an axial-flow pump	9.9%	19.4%	<0.001
ENDURANCE ⁹	2017	446 patients	2 years	Patients with advanced-stage heart failure who received either a centrifugal-flow pump or axial-flow pump as destination therapy	Randomized trial of a 2:1 ratio comparing centrifugal-flow pump with an axial-flow pump	29.7%	12.1%	<0.001
LATERAL ¹⁰	2019	144 patients	1 year	Patients with advanced heart failure who received the HVAD centrifugal-flow pump through thoracotomy implant	Prospective, single arm trial evaluating the thoracotomy implant technique of the HVAD system	11.2%	N/A	N/A
INTERMACS Annual Report ¹⁷	2019	18,539 patients	1 year	Patients who underwent isolated continuous flow LVAD implant between 2012-2017	Data reported to INTERMACS registry on continuous flow, including both centrifugal and axial, pumps	Centrifugal – 20%	Axial – 13%	<0.0001

DEVICE-RELATED INFECTION RATE WITH LVAD

STUDY	YEAR	SUBJECTS (N=)	DURATION	POPULATION	DESIGN	RESULTS		
						INTERVENTION	CONTROL	P-VALUE
Systematic Review ⁷	2014	20 publications, including 10,948 patients	Studies published from January 2007 to December 2013	Patients with advanced heart failure on medical management or continuous flow LVAD as destination therapy or	Systematic review summarizing data across relevant studies	LVAD – 10%	N/A	N/A

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				bridge-to-transplant				
MOMENTUM 3 ⁸	2019	1028 patients	2 years	Patients with advanced-stage heart failure who received either a centrifugal-flow pump or axial-flow pump	Non-blinded, randomized trial comparing centrifugal-flow pump with an axial-flow pump	“Major infection” – 58.3%; “Driveline infection” – 23.3%	“Major infection” – 56.4%; “Driveline infection” – 19.4%	0.96; 0.60
ENDURANCE ⁹	2017	446 patients	2 years	Patients with advanced-stage heart failure who received either a centrifugal-flow pump or axial-flow pump as destination therapy	Randomized trial of a 2:1 ratio comparing centrifugal-flow pump with an axial-flow pump	“Driveline exit-site infection” – 19.6%	“Driveline exit-site infection” – 15.4%	0.30
LATERAL ¹⁰	2019	144 patients	1 year	Patients with advanced heart failure who received the HVAD centrifugal-flow pump through thoracotomy implant	Prospective, single arm trial evaluating the thoracotomy implant technique of the HVAD system	“Driveline infection” and “line sepsis” – 8.3%	N/A	N/A
INTERMACS Annual Report ¹⁷	2019	18,539 patients	1 year	Patients who underwent isolated continuous flow LVAD implant between 2012-2017	Data reported to INTERMACS registry on continuous flow, including both centrifugal and axial, pumps	Centrifugal, “Pump-related infection” – 28%	Axial, “Pump-related infection” – 25%	0.01

SERIOUS BLEED (REQUIRING MEDICAL ATTENTION) RATE WITH LVAD

STUDY	YEAR	SUBJECTS (N=)	DURATION	POPULATION	DESIGN	RESULTS		
						INTERVENTION	CONTROL	P-VALUE
Systematic Review ⁷	2014	24 publications, including 9,489 patients	Studies published from January 2007 to December 2013	Patients with advanced heart failure on medical management or continuous flow LVAD as destination therapy or bridge-to-transplant	Systematic review summarizing data across relevant studies	LVAD – 20%	N/A	N/A
MOMENTUM 3 ⁸	2019	1028 patients	2 years	Patients with advanced-stage	Non-blinded, randomized	“Any bleeding” – 43.7%;	“Any bleeding” – 55.0%;	<0.001; <0.001;

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				heart failure who received either a centrifugal-flow pump or axial-flow pump	trial comparing centrifugal-flow pump with an axial-flow pump	"Bleeding requiring surgery" – 9.7%; "Gastrointestinal bleeding" – 24.5%	"Bleeding requiring surgery" – 17.6%; "Gastrointestinal bleeding" – 30.9%	<0.0001
ENDURANCE ⁹	2017	446 patients	2 years	Patients with advanced-stage heart failure who received either a centrifugal-flow pump or axial-flow pump as destination therapy	Randomized trial of a 2:1 ratio comparing centrifugal-flow pump with an axial-flow pump	"Requiring reoperation" – 15.2%; "Requiring transfusion" – 15.2% "Gastrointestinal" – 35.1%	"Requiring reoperation" – 18.1%; "Requiring transfusion" – 22.1% "Gastrointestinal" – 34.2%	0.52; 0.09; 0.92
LATERAL ¹⁰	2019	144 patients	1 year	Patients with advanced heart failure who received the HVAD centrifugal-flow pump through thoracotomy implant	Prospective, single arm trial evaluating the thoracotomy implant technique of the HVAD system	"Requiring reoperation" – 5.6%; "Requiring transfusion" – 22.9% "Gastrointestinal" – 14.9%	N/A	N/A
INTERMACS Annual Report ¹⁷	2019	18,539 patients	1 year	Patients who underwent isolated continuous flow LVAD implant between 2012-2017	Data reported to INTERMACS registry on continuous flow, including both centrifugal and axial, pumps	Centrifugal, "Gastrointestinal bleeding" – 20%	Axial, "Gastrointestinal bleeding" – 25%	<0.0001

ONGOING HEART FAILURE RATE WITH LVAD

STUDY	YEAR	SUBJECTS (N=)	DURATION	POPULATION	DESIGN	RESULTS		
						INTERVENTION	CONTROL	P-VALUE
Systematic Review ⁷	2014	18 publications, including 9,390 patients	Studies published from January 2007 to December 2013	Patients with advanced heart failure on medical management or continuous flow LVAD as destination therapy or bridge-to-transplant	Systematic review summarizing data across relevant studies	LVAD – 18%	N/A	N/A
MOMENTUM 3 ⁸	2019	1028 patients	2 years	Patients with advanced-stage heart failure who received either a centrifugal-flow pump or axial-flow pump	Non-blinded, randomized trial comparing centrifugal-flow pump with an axial-flow pump	34.2%	28.3%	0.18

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ENDURANCE ⁹	2017	446 patients	2 years	Patients with advanced-stage heart failure who received either a centrifugal-flow pump or axial-flow pump as destination therapy	Randomized trial of a 2:1 ratio comparing centrifugal-flow pump with an axial-flow pump	38.5%	26.8%	0.02
LATERAL ¹⁰	2019	144 patients	1 year	Patients with advanced heart failure who received the HVAD centrifugal-flow pump through thoracotomy implant	Prospective, single arm trial evaluating the thoracotomy implant technique of the HVAD system	"Requiring RVAD" – 0.7%	N/A	N/A

IV. Patient, Caregiver and Provider Feedback Logs

Date	Version #	Changes
6/5/2013	0	Created outline of what we want on each page.
7/2/2013	1	Created first draft of decision aid
7/10/2013	1	<p>Pg. 1: Make this page more emotional. Address emotion and choice. Normalize death, explain that they are in a tough spot because of not being eligible for transplant, dying of HF. Put bottom grey box language at top of page. Take out patient quotes on this page. Change picture to one of a sad person pondering. Put HF explanation in separate box. More white space. Dan had language suggestions for this page-- you are in a tough spot.</p> <p>Pg. 3: Remove LVAD life path figure. Present this as options. Option 1=LVAD. Option 2=Medical therapy and hospice. Present info about each option, in parallel, and format as a figure with two sides. Bullet points. Put patient quotes here. At bottom, put info about hospice and pall care.</p> <p>Pg. 4: Remove LVAD life paths figure. Use parallel options formatting for this page, too, with two options. Split up survival figure to be placed under each option. Change heading language to "each option". Two sections: benefits of each option; risks of each option.</p> <p>Pg. 5: Change heading to say "If I get an LVAD, how will my life change". Move top portion language to previous page, under benefits. Make graphics smaller. Add cost component (per Sterling's dad's recommendation).</p> <p>Pg. 6: Put at top "This is a major decision for caregivers, too" in large font, blocked off. Change "I" language in subheadings to "an LVAD patient". Combine sections "How will my loved one's life change" and "How will my caregiver's life change". Put that combined section into bullet points.</p> <p>Pg. 8: Add language "there is no right or wrong answer--it's based on what is important to you". At end, wrap up with less language and address emotions again.</p>
7/17/2013	2	<p>Pg. 3: Separate the two options more--maybe put a line in between. For option 1, include information about permanent reliance on the device, major surgical intervention. For option 2, change to "No LVAD" as descriptive option instead of "Medical therapy and hospice". Make hospice and pall care information look more separate--it looks too similar to the option portion of the page. Take out of the boxes, make it look separate from top portion. Maybe move to next page. Shorten pall care info.</p> <p>Pg. 4: Remove risks and benefits language. Instead, make one large box for each option, with the heading "What might my life look like with each option?" The top of the box includes survival information, with the survival graphic, and the heading "How long will I live?" The second section talks about burdens of each options. On option 1, list risks of LVADs as burdens. With this, make sure to list all stats as "x in 10 patients", keep this stat measure the same throughout. It also may be good to use "approximately" language. Keep at 2 yrs timeframe for stats. For Option 2, list how there are less burdens with this options, such as hospice and symptoms treatment. Maybe put pall care and hospice info here.</p> <p>Pg. 6: Try and get across that death is an option and it's not a failure. Keep information on LVAD caregiver details on top, then below, on bottom of page, put option 1 and 2 formatting with quotes from caregivers.</p> <p>Pg. 7: For "On a scale" exercise, switch the options on either side to keep consistent throughout DA (Left side is option 1: LVAD; right side is option 2: No LVAD). Put box with questions for doctor and family on next page.</p> <p>Pg. 8: For patient quotes, swap sides (Left side is option 1: LVAD; right side is option 2: No LVAD). Put these patient quotes on previous page under the "on a scale" exercise. Add a page on how to tackle fear and emotions--we need to give tools for addressing emotion and fear. Right now, we address</p>

		<p>this but don't provide much more guidance. We need a call to action on managing emotions to make a decision.</p>
<p>7/19/2013</p>	<p>2</p>	<p>Pg. 1: Larry changed wording quite a bit to include more detail. Also wanted to explore the "stages of grief" model and play with that language on this page. Recommended adding a stages of grief figure to this page.</p> <p>Pg. 4: Change language after survival figure to be more technical. Below option boxes, add a comment about acknowledging fear, sadness or grief here. Larry suggested language of "everybody dies eventually". Larry also added last bullet to Option 2's burden section.</p> <p>Pg. 6: Add info about relationships changing between LVAD patients and caregivers. Put piece about diminished sexual activity and sexual counseling in bottom section (per prior discussion and emails with Nowels and McIlvannan).</p> <p>Pg. 8: Needs something more. Add an extra page with notes of ideas to bounce off of people. A page on how to tackle fear and emotion. A list of questions for patients to consider. Stages of grief (googled stages of grief figures for ideas). Jocelyn added "questions to consider" section to pg. 8.</p>

8/6/2013	3	<p>Pg. 1: Dan changed much of the language back or altered from Larry's changes in previous edit. Made wording easier, simpler, shorter, lower health literacy. Also, since much of the same wording is in the first paragraph, Dan took out the "Why an LVAD?" box. Also, significantly shortened the content in "What is HF?" box. Remove "Stages of grief" figure. Likes the new picture. Change "an LVAD" to "a LVAD" throughout.</p> <p>Pg. 2: Changed language and shortened content. Reworded many parts and removed sentences and phrases. Add a subheading above the body figure--something like "some LVAD terms".</p> <p>Pg. 3: On option 2, swith the last two bullets. Make the boxes around patient quotes bigger, so the quotation mark isn't right next to the outline. Shortened pall care section and changed wording on pall care and hospice. Switch second acceptor quote with one on page 7, switch both decliner quotes with ones on page 7.</p> <p>Pg. 4: For survival figure, make the men more distinct--either darken the blue ones, hollow out the grey ones, or make the grey ones lighter. Take out "current" in option 2 bottom part.</p> <p>Pg. 5: (Sterling) Shortened a lot of the language on this page to provide more spacing between figures. Add another figure for "sleeping and other activities" to make more consistent (rather than just having text at the bottom).</p> <p>Pg. 6: Put "why do LVAD pts need caregivers" section first--swap with "what does the caregiver need to do" section. The "why" needs to be read first and should be main focus. Take out of the box. Put the bulleted list in a longer box to the right. Shortened and simplified a lot of the language on this page. Also shortened the caregiver quotes. Took out the third bullet in the bottom section. Took out the line about sexual counseling.</p> <p>Pg. 7: Slightly changed wording in options for "on a scale" to make shorter and more succinct. Switched patient quotes on this page with ones on page 3. Make "reflection" answer box bigger and square. Add "with or without a LVAD" to the last question in "reflection" to make it sound clearer.</p> <p>Pg. 8: Changed wording in top section to make shorter and more succinct. Took out some language in "asking questions" box.</p>
8/8/2013	4	<p>Pg. 5: Made significant wording edits. Suggests we possibly put "emotions" seccion on previous page with risks.</p>
8/8/2013	4	<p>Pg. 1: Slightly changed wording in main text. Added details to "what is HF" box.</p> <p>Pg. 2: Slightly changed language.</p> <p>Pg. 5: Changed language.</p> <p>Pg. 6: Slightly changed language on "how will a caregivers life change" section. Suggests adding a bullet about something positive.</p> <p>Pg. 7: Slightly changed language in "on a scale".</p> <p>Pg. 8: Added language to top portion about how difficult discussions now can make the future easier. Thinks "questions to consider" seems redundant. Would like a motivational piece there instead. In the "asking questions" box, added a seperate section for writing questions for current LVAD patients. Wants to add something about normalizing or framing emotion. Trying to brainstorm innovative ideas.</p> <p>Add something about deactivation of the device--"If you proceed with DT LVAD and it doesn't turn out well, you have the option of turning it off. Nearly all patients die within 20 minutes of turning the device off."</p>
8/11/2013	4	<p>Pg. 1: Heading--change "for" to "about". Minor language change in first paragraph.</p> <p>Pg. 2: Language changes in "batteries" section. Added "heart" in front of "transplant" in last sentence of first paragraph.</p> <p>Pg. 3: Added language to option 1 about LVAD needing to be turned off at some point.</p> <p>Pg. 5: Minor language changes. Suggests verification of battery life length. Rearranged order of</p>

		<p>items--put "emotions" last, "driveline care" third.</p> <p>Pg. 6: Added third bullet in "how will a caregivers life change" section--positive piece.</p>
8/14/2013	5	<p>Pg. 1 & 2: Make a new first page that asks open endedly for people's impressions and concerns. Larry wrote opening paragraph and questions. Later, Larry and Jocelyn formatted the first page together, sectioning out the title of the DA and putting a small LVAD picture. Also, included a "two paths" picture on the front for symbolic aesthetics. The old first page moved to the second page of the DA, with a line at the top stating "Now that you've written down your first impressions, let's talk through the details of this decision", which replaced the heading that was on the top of this page. All other content on this page remained the same.</p> <p>Pg. 8: Changed the language on the top of the page to reflect back on the new first page and its questions. Took out the "questions to consider" portion, as it is now redundant.</p>
8/30/2013	6	<p>Pg. 2: Bottom of page, replace "factors" with "information" for better health literacy.</p> <p>Pg. 3: Change "mechanical device", as it may be too advanced for some patients. Put "destination therapy" in quotes, and put "DT LVAD" in parenthesis after, as the acronym is referenced later.</p> <p>Pg. 4: Thinks "the LVAD requires lifestyle changes" is too vague and should be explained more by saying it will be detailed later in the booklet. Also, minor grammatical errors.</p> <p>Pg. 5: Stat about infection--needs to be clarified. Uncertain about the 3 out of 10 stat. Doesn't like the third bullet in option 2, "leave behind burdens". But suggests we test with patients.</p> <p>Pg. 8: Doesn't like "natural" in the right side scale response on "on a scale". May be criticizing those who choose an LVAD, as they may think that's natural.</p>
8/30/2013	6	<p>Pg. 1: Make simpler. Shorten first paragraph and make less repetitive. Change wording. Remove some of the questions, and put in a "think about" format with bullet point statements. Don't ask patients to write down thoughts, just to think about them. Make text much shorter with less spacing in between, and make "two paths" image larger, about half the page.</p> <p>Pg. 2: Change heading to say "thought about" instead of "written down". Remove some of the repetitive wording. Take out third paragraph, which is repetitive after first page language. Switch the bottom two paragraphs--makes more sense and sounds better.</p> <p>Pg. 3: Make arrows and subheadings blue instead of red (red is bad for color blind people). Add a caption on the LVAD picture at bottom (per Cliff's recommendations). Take out the words "must" in the bottom paragraph, change language slightly to be less authoritative (per Cliff's request).</p> <p>Pg. 4: Take out first patient quote on each option. They don't really fit here. Leave just one quote each.</p> <p>Pg. 5: Need to add an aspect about functional status and quality of life improving with an LVAD (Cliff's recommendation). Add a section under survival stating "How will I feel?", which then lists stat about NYHA functional status improvement. Also, change the subtitles for the next sections to say "complications" for option 1, and "what do I get without an LVAD" in option 2. Move summary paragraph that was under survival to the end of each option figure, with the title "how do I balance these outcomes?". Change wording of this paragrph slightly. Remove "Everybody dies eventually" section at bottom. Brainstorming other ideas--famous quotes. Put Steve Jobs quote about life and death there as reflection piece.</p> <p>Pg. 6: Add "sex" section here. Move sex info from caregiver page to this page. Add a line at the bottom of page about how patients get used to these lifestyle changes and they aren't as scary as they seem (per Cliff's and Forrestine's recommendations, saying this page is scary and overwhelming). Remove the word "Immediately" from "power source" section, as to not confuse</p>

		<p>people (per Barney's recommendation). Add a line about medications being less with a VAD to the "medicine" section (per Cliff). Put a happy/sad face (drama masks) for "emotions", rather than just a sad face, because some people may be happy with device. Put a better driveline picture, with a caption and arrow pointing to driveline (per Cliff).</p> <p>Pg. 7: Remove sex piece from end of last paragraph, as not all caregivers will be spouses or partners. Put on previous page. Change wording of end of first paragraph under "how will caregivers life change". Explain how caregiving can be minimal for some patients (per Cliff and Forrestine).</p> <p>Pg. 8 & 9: Combine these last two pages into one. Put the main exercises on one page to see which ones should stay. Add a line at top about taking time to consider all that patients have learned about LVADs. Remove a lot of the language that was on the top of Pg. 9, as it is a bit repetitive.</p>
<p>9/4/2013</p>	<p>7</p>	<p>Pg. 1: This page still seems too long and repetitive. Shorten the first paragraph. Change language from "being offered an LVAD" to "considered for an LVAD". Also, put a phrase in there about how this booklet will explain what an LVAD is, for those who don't yet know much about it, to tell them we will explain it more. Remove "goal" sentence. Remove "How do you feel" as first question. Just keep this first question line simple.</p> <p>Pg. 5: In the survival figure, combine the top sentence and bottom sentence into one, put at top. This will shorten the content and make it less repetitive. Change the stat listed under option 1's "how will I feel" to make less confusing. Don't use a number, just say "most" or "nearly all". Remove right heart failure stat from "complications" section, as this can become confusing for readers and isn't as important of a side effect to list here. Double check rehospitalization stat, as it doesn't sound right to Colleen--change stat to reflect data. Remove the "how do I balance these outcomes" sections under both option figures. Instead, put an overarching comment at bottom of page. Remove Steve Job's quote, as it is not quite right for this audience and could be received poorly (Colleen also thinks it favors not getting a VAD). Instead, use this space to tell patients they have time to think about this decision, and that this may be an overwhelming time for them--patient should take their time.</p> <p>Pg. 6: Shorten all items in order to make more space between items, so the page looks less cluttered. Removed some of the language of each to make all items three lines. Removed the "sleeping and other activities" item, as it is not crucial. Remove the line at the bottom of the page. Instead, add a line in "emotions" section, saying some people feel grateful and happy for the LVAD and get used to lifestyle changes, and then talk about negative emotions--emotions can be negative or positive, so include the positive aspect here. Change driveline picture so it has more context of where driveline is placed on the body.</p> <p>Pg. 8: Make the line at the top "take some time to consider..." much bigger and more pronounced.</p>

		<p>Put something on this page about patients taking their time to make a decision, and letting them know they have time to consider all they've learned. Remove first two questions and answer boxes in "reflection" to make it smaller--just include the bottom two. Make more room and white space. Change "a LVAD" to "an LVAD" throughout DA, as this is grammatically correct.</p>
<p>9/6/2013</p>	<p>8</p>	<p>Pg. 2: Remove bottom sentence, as it is repetitive with what's on the first page. Pg. 5: In bottom section, change the word "tough" to "difficult" in first paragraph. Remove bottom paragraph about "having time", as it is repetitive with the last page. Pg. 6: Remove white arrow pointing to driveline site. Not necessary. Pg. 8: Indent the "on a scale" and "reflection" sections to break up the page--make them slightly separated.</p>
<p>9/18/2013</p>	<p>9</p>	<p>Pg. 1: Changed the subtitle from "A device to increase heart function for patients with advanced heart failure" to "A device for patients with advanced heart failure". This was changed per the recommendations from CCOR members, who stated that using "increase" was too positive and implied the pump always helped. Pg. 2: Removed picture of thinking old man, as CCOR members were adamantly against this for several reasons: 1. People won't identify with this man, as patients are all different ages, races and genders, so it limits the relatability to old, white men. 2. It is poor form to have a picture of a white male. 3. It looks depressing and evokes too much emotion. 4. A picture of a real person in general should not be used. This picture was replaced with a picture of the famous Rodin statue "The Thinker", per Larry's suggestion, as it conveys the intense thinking and decision making needed/occurring during this process/at this time. Pg. 4: Removed patient quotes from the option boxes to make them separate from the direct option choices, per CCOR recommendations. Associating the quotes with the choices was not recommended, and they actually reinforce the emotions as the driving decision making factor. Also, put a title of "Patient Perspectives" to further separate and explain the quotes purpose. Added more quotes that are less emotional, provide more variety. On acceptor quote, changed "get better" to "feel better", as "get better" implies the LVAD is a cure and the only choice for improving health. For the decliner quote, removed the last sentence, "I have absolutely no fear of death", in order to make the quote less emotional, and to work in conjunction with other decliner quotes. Pg. 7: Removed the caregiver quotes from the associated option 1 & 2 and put a title, "Caregiver Perspectives" above quotes. For the same reasons as Pg. 4 patient quotes.</p>

<p>9/20/2013</p>	<p>10</p>	<p>Pg. 1: Did not change ‘considered’ to ‘offered’ or ‘eligible’, as recommended by CCOR. "Considered" makes the DA broader for HF population that is still being assessed for eligibility. Changed language of “think about” bullets to match and circle back to exercises on pg. 8. Added page numbers through whole booklet.</p> <p>Pg.2: Changed “offered” to “considered for” in last sentence of first paragraph--keep consistent with first page. Changed Thinking Man picture to be less real and muscular, and more of an illustration—makes more conceptual. Removed “other” from end of last sentence in first paragraph under “this is a major decision”, per CCOR recommendation to make it less judgmental. Added “and possibly” instead of “or” in front of “go to hospice”, per CCOR recommendation.</p> <p>Pg. 3: In “Driveline”, changed “outside of your body” to “outside THE body” to make more uniformed.</p> <p>Pg. 4: Removed Option “1” and “2”, per CCOR, to avoid ranking problems. Instead, just use "Option: LVAD" and "Option: No LVAD". Added sentence about pall care for both LVAD and non LVAD patients at end of pall care section so patients know they can have access to resources in both options and also to remind patients they may need both resources, even if they are getting a VAD. Took out “It was a hard decision” from beginning of first acceptor quote to make it sound better, easier to read. Changed “get better” to “feel better” in second acceptor quote to soften quote, per CCOR recommendation. Changed first decliner quote, last sentence, to remove “other people” language. This makes it simpler, more understandable, and less judgmental. Puts it on pt, not on other people. Changed color of quote box to be lighter, to improve the look and readability on B&W printing.</p> <p>Pg. 5: Removed Option “1” and “2”, same as pg. 4. In Option: LVAD's "How will I feel?" section, changed “have substantial” to “feel big” to improve health literacy level. May need to change this further.</p> <p>Pg. 6: Emotions: Added language to include caregiver in this. Changed from “The LVAD may cause emotional effects” to “...for patients and caregivers”. Then changed “some patients” to “some people” at beginning of next sentence. Third sentence, took out “patients” and just had “while others”. Took this emotion information off of caregiver page, so included caregivers in emotions on this page. Sex: Added “and their partners” to first sentence to also be inclusive.</p> <p>Pg. 7: Changed color of quote box to be lighter, to improve the look and readability on B&W printing. Took out “Because” on second sentence of first acceptor quote, per Larry--to make clearer/easier to read. Changed the language on first decliner quote to be more clear—instead of “it”, I wrote “the LVAD”. And in second sentence, changed “he” to “my husband”. In second decliner quote, changed “declined” to “not get the LVAD”—to make clearer/easier to read. Took out bullet point list in bottom section to make room for other language and to make this page less negative. Put emotional information for caregivers on previous page with patient lifestyle changes (Emotions). Changed first part of "How will a caregiver's life change?" section-- took out first sentence, added line about caring for HF pts, and slight change to LVAD care, per Reales comments. Erased quitting job or keeping job for health insurance lines (seems unnecessary and awkward now in this section). Moved first bullet from old list to end of this paragraph. Added sentence about caregiving for decliners, per Neil and Reales (not direct recommendations, but based on feedback—too make it less negative towards VADS-- show caregiving isn’t just for VADs, but also an experience when dealing with advanced HF pts, and also to make it more equal, and keep the parallel theme throughtout). Added sentence about support for caregivers, per Reales and Neil recommendations.</p> <p>Pg. 8: Took out supporting sentences at top, as it is repetitive with heading. Took out second scale to make page less cluttered—first scale is better than second one, per Larry’s decision. Changed the heading of that scale to more directly match the first page and loop back, and to also sound cleaner</p>
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and simpler. Made Reflection answer box bigger to provide more space for writing, per Larry's suggestion. Changed language of question box to match the front page more. More white space.

<p>9/24/2013</p>	<p>11</p>	<p>Change to make DA less negative, focusing more on "living" and less on death, per pall care docs recommendations at HFSA. Also focus on lowering health literacy level by changing some language and wording.</p> <p>Pg. 2: In last paragraph, second sentence, change "decline an LVAD" to "decide not to get an LVAD", for literacy reasons.</p> <p>Pg. 4: Change title of the page to something that mentions life. Changed to: "How do you want to live the rest of your life?" Put a subtitle going into detail about focusing on how they want to live. In patient quotes, instead of saying "patients who received/declined an LVAD, change to "Patients with/without an LVAD" for literacy reasons. Add a sentence above pall care and hospice sections saying how these can be used by people in both groups. Say "with each option", so patients know they get pall care and hospice with LVADs too. Also, say patients have the chance to "live life to its fullest", per Dan's recommendation. Take out last sentence in pall care section, as this is now repetitive with the new sentence above. In hospice section, change "provided" to "given", and "psychological" to "mental", for literacy reasons.</p> <p>Pg. 5: In Option: LVAD, "How will I feel?", change "have substantial improvements..." to "feel big improvements...", for literacy reasons. Add sentence explaining further what "improvements in heart failure symptoms" means--include info on SOB, fatigue and energy. In Option: No LVAD, add another sentence to the "How will I feel?" section saying symptoms will not improve, giving examples of what symptoms. In "...what might occur?" section, last bullet, change "chronic" to "long-term", for literacy reasons. In the survival figures, change "declined" to "did not get", for literacy reasons. For figures on both options, make the "dead" grey men look more pronounced, so when printed in B&W, they look better. At bottom of page, add more language about living and people getting to choose how they want to live.</p> <p>Pg. 7: Make wording changes for literacy reasons. In box, change "dressing" to "bandage", examining" to "checking", "maintenance" to "care", "medication" to "medicine", "vital signs" to "blood pressure and pulse", "providing transportation" to "driving". In first paragraph, change "unable to complete some functions" to "have a hard time doing some tasks". In "How will my caregivers life change?" section, first paragraph, sentence three, change "minimal" to "short", "burdensome" to "feelin like a burden". In caregiver quotes, change "received/declined" to "with/without", like on page 4.</p>
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<p>9/25/2013</p>	<p>12</p>	<p>Make the whole DA more positive--focus on living and not on death. Change language throughout to be about living. Per pall care docs recommendations at HFSA.</p> <p>Pg. 1: Page title--change "booklet" to "decision aid", per pall care doc suggestion--this is a decision aid, not just informational. Title now reads "A decision aid for Left...". Take out last three sentences in first paragraph (risks and benefits, emotions as important as med facts). Replaced with language about how the choice is about how patients want to live. Focus more on "living"</p> <p>Pg. 2: Second paragraph ("Mant patients..."), add emotions to the first sentence. Not just "scary" but also "confusing" and "pressured", per pall care doc recommendations. In third paragraph ("You are facing..."), change "better" to "more at peace" in second sentence. In last paragraph, take out second part of second sentence (about current treatment and hospice)--mentioned later in DA and not as fitting here. On last sentence changed "what is important to you" to "how you hope to live the rest of your life", to focus more on living and how they want to live.</p> <p>Pg. 3: "Pump" section, changed the language to make it clearer that the pump is inside the body, and also change the word "surgically" to make lower literacy level. Changed to: "The pump is put inside the chest and attached to the heart during surgery." Remove the word "circulate", as it is high literacy. Just say the pump helps the heart work better--explanation of blood flow is in top paragraph already. "Batteries" section, change the word "batteries" to "Battery packs" in the description, so people don't think it's just AA batteries or small regular batteries, but large packs of batteries. In bottom paragraph, take out some language. Remove "maintain and live with" in explanation of education sessions. Take out "and completed all education" in following sentence. Take out "lifestyle" in last sentence. Make this section shorter and clearer. In top paragraph, changed "surgically" to "through surgery" for literacy reasons (Jocelyn's edit).</p> <p>Pg. 4: Change wording at top of page slightly--focus again on living. Change "Option: LVAD" to "Option: Living with an LVAD" and "Option: No LVAD" to "Option: Living without an LVAD"--again, more emphasis on "living". Re-do bullet points in both options. Add length of living bullets at top of both options. In Option: Living with an LVAD, remove bullet about managing device and being hooked up to power, and reword lifestyle change bullet. Take out the "nearly all patients die within 20 min of device shut off" line at end of last bullet, as it is confusing and doesn't really fit here. Just say "at a later time" (Jocelyn's edit). In Option: Living without an LVAD, take out bullet about medications and them eventually not working--we already told them their medications already do not work anymore on page 2. Instead, add a bullet about how patients may stop taking their HF meds. Add a bullet about how patients get to leave the hospital earlier without and LVAD. Take out pall care and hospice bullets on this, in order to have them referred to in both options. Add a separate section below saying pall care and hospice are available for both options, and add a line to "see below for descriptions" so they can be directed to read the pall care and hospice descriptions at the bottom of the page. For line above pall care description, take out the part about "living life to its fullest". Under hospice description, in second sentence, change "for patient who are dying" to "for patients when they are dying", per pall care doc recommendation.</p> <p>Pg. 5: Change the option language, as changed on page 4. Change "will" language in subtitles and put "might" instead--"How long MIGHT I live?", "How MIGHT I feel?"--makes it less certain and emphasizes more of the unpredictability of living and dying. In Option: Living with an LVAD, under "How might I feel?", change "most" to "many", per Dan's recommendation. Change the second sentence to be less certain and positive--"may feel less winded and may be able to do more." In bleeding complication, add a line about how some bleeding can be quite severe, so people know it's not just nose bleeds and minimal things. Look into stroke statistics--is it per year? Then maybe change stat to 2 in 10. In Option: Living without an LVAD, under "How might I feel?", change the second sentence, as patients' symptoms are managed through pall care. Not so severe of a sentence. Changed the language to show symptoms don't go away, but they can be managed</p>
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(Jocelyn's edit). Changed all of the bullets under "What might occur if I don't get an LVD?". Change this to say patients will die sooner, but will not have all the LVAD complications. Change the language at the bottom of the page. Remove second sentences of both paragraphs and make shorter into one paragraph. Slightly change the language of second sentence.

Pg. 6: In "Carrying Equipment", change "Batteries" to "battery packs", same as on page 3. In "Driveline care", italicize "carefully" in order to emphasize. In "Emotions", in third sentence, change "worry daily about..." to "worry OFTEN about...". All per pall care doc recommendations.

Pg. 7: In title, change "The LVAD" to "An LVAD", per pall care doc recs. Take out some words in top paragraph to make shorter and easier to read.

Pg. 8: In title, add a line about living the rest of your life: "and think about how you want to live the rest of your life"--bring it back to living and focusing on life for the decision making. In "On a scale", change "How do you hope to live..." to "How do you WANT to live..." in order to keep it more consistent with the lines on the first page. For the right sided response, change the "die" language to "live" language to make more positive and focus on living. Changed to "Live with whatever time I have left...". In "Reflection" box, change the first line to talk about hopes, in order to more directly go back to and connect with the first page points. Change from "How might your life change?" to "What are you hoping for...". Take out text above question box, as that doesn't add anything to this page. It is not repetitive and ethereal compared to the changes we've made. To provide more room to write, and to use the extra space better, add an extra line for people to write on each of the question sections in the question box.

<p>9/30/2013</p>	<p>13b</p>	<p>Pg. 1: Remove last two sentences, and put a new one with an emphasis on values and goals. This is to focus on these aspects and to make the "living" language less repetitive. Change the question in the middle of the page to "what are your current feelings", from "what are your first impressions". This more accurately presents what we are trying to get people to do, and people may not yet have "impressions" about LVAD. It also brings in the "feeling" component that we took out from the last sentence.</p> <p>Pg. 3: Change the second sentence in the "pump" section to sound better and more accurately describe what the pump does. In the last paragraph, take out that last sentence, as "lifestyle changes" is mentioned later in the DA. Add "surgery can be dangerous" in order to balance out the last sentence of the paragraph, which states "once you recover". "once you recover" insinuates that everyone recovers, so we added that surgery is dangerous to let people know that there are risks there. Also, added "some stay longer" to the sentence about hospital stays, for the same reason just mentioned. We want people to know that there is a chance they can be hospitalized for months.</p> <p>Pg. 4 & 5: Changed the formatting of these pages. Moved the options boxes with survival and complication stats to page 4. Combined the main introductory information from the option boxes on page 4, and put in a paragraph form at the beginning of the other option boxes, above survival stats. Combined these option boxes to make the DA less repetitive. The option boxes that were on page 4 had a lot of the same information other pages throughout the DA, so we removed the repetitive parts, put an introduction paragraph, and added a few bullets to the bottom section of the page 5 options boxes. Moved palliative care and hospice information, patient quotes, and the bottom line about "everybody eventually dies" onto page 5. Other changes: Change "Option: Living with an LVAD/Living without an LVAD" back to "Option: LVAD/No LVAD". On survival figure, add the word "about" in front of the stat, in order to cover our bases in case someone combats us with other stats. On "How might I feel", changed the second sentence on both options to be more accurate. On No LVAD side, add "see description on next page" for pall care mention. On "What complication might occur?", add language about 2 year timeframe and also using "about", again, to cover our bases. On "What might occur if I don't get an LVAD?", put a bullet point about how patients can continue on current medical treatment or just take meds that help with pain and symptoms. On the next page, bottom statements ("everybody eventually dies"), change the second sentence to say patients have some control over how they'll live, instead of saying they get to choose how they want to live. This change is because it is not totally true that patients get to choose how they want to live, because everyone would choose to go back to being healthy--that statement then is not quite right or appropriate.</p> <p>Pg. 8: On top line, change "all that you've learned" to "what you have learned". In reflection box, answer box titles, bold "with" and "without".</p>
<p>9/30/2013</p>	<p>14</p>	<p>Pg. 4: On "How might I feel?" change the second sentence to remove quality of life statement, as Dan thinks the data is messy on this and it would be better not mentioned. Also, changed "patients" to "survivors" in order to remind people that this statement only applied to those who are still alive. On "complications" section, change the bleeding stat to be 3 in 10 and to only reflect bleeding that required surgery. Also, changed language on pump replacement to say that it's for pumps no longer working "correctly". Looking into statistics to make sure they are correct and represented well, per Dale Hency discussing the DA stats with Dr. Brieke.</p>
<p>10/1/2013</p>	<p>14b</p>	<p>Pg. 4: Change language on complication statistics to appease clinicians who are disputing them. Change bleeding numbers further. Rearrange order of complication stats.</p>

<p>10/9/2013</p>	<p>14c</p>	<p>Pg. 4: Add reference citations to statistics. Add sentences at the top of the page to explain that statistics are general numbers and should not be taken as exact predictions. Also to illustrate uncertainty for the patient further.</p> <p>Pg. 8: Add reference list at bottom of page. Add contact information at bottom of page. Add "Draft" watermark across all pages.</p>
<p>10/16/2013</p>	<p>15</p>	<p>Pg. 2: In top section, make the word "decision" a larger font, all caps and italicized. This is to emphasize what this page is about and to let the reader know the content of this page--a theme now done on every page, per Larry's request.</p> <p>Pg. 3: In title, make the word "LVAD" a larger font and italicizes, to emphasize what the subject of this page is. Shorten the top paragraph slightly to make more readable and succinct. Edit all four sections of "Parts of an LVAD" to make all consistent, more literate, and more succinct. Start all sections with "A [blank]" wit description of what it is. Shortened "What is the process..." pargraph to make more succinct, less repetitive.</p> <p>Pg. 4: Made "each option" larger font, all caps and italicized in the title, again to display what the page is about. Shortened the top portion to just say that these numbers are a summary, to diffuse critics of the numbers, and to put a piece about uncertainty, that these numbers can't predict what will happen to each person. Removed the first sentence that was there. Changed the title of each option box to "Life WITH an LVAD" and "Life withOUT an LVAD". This is more explanatory, and the "option:" language no longer makes sense because the option boxes are only on this page now. Made sure to emphasize the "with" and "withOUT" in the titles by making font bigger, all caps and italicized. Removed the top paragraphs in each box, as they were long, unnecessary and repetitive. Put the language about living unde the "How long might I live?" section, above the survival figure. Removed the top text from the survival figure and put as its own text in the box in order to make it bigger font. Italicized font to make it seperate from the top line (Jocelyn). In "How might I feel?" section, changed the word "people" to "patients" to keep the language consistent throughout the page (Jocelyn). Changed the first clause to "of those patients who get through surgery", and take out the "2years" timeframe. This helps illustrate that not everyone lives through surgery, and these improvements in symptoms is true throughout the time with the VAD, not just at 2 years. On the other side, remove the "2 years" clause also, and just say "nearly all patients without an LVAD continue..." For "What complications might occur?" section, make bullet points a size 12 font to make it smaller and take up less room. Leave the first sentence a size 14 and unbulleted. Change the beginning of sentence to say "For patients", in order to qualify who these complications are happening to (Jocelyn), as we removed "patients" in the statistics sentences below. Take out "patients" from first and last bullet. Change bleed language to "requirgin a visit to the hospital" to lower literacy and understanding. Change some other minor wording in this sentence. In the other box, add a sentence to the beginning of the "What might occur if I don't get an LVAD?" section, which states up front that patients will likely not be alive at 2 years. Leave this sentence unbulleted and size 14. The bullets reduce to size 12. Remove part about patients continuing current medical treatment from bullet 3. Some other minor language changes here.</p> <p>Pg. 5: Remove the "For both options" box, which doesn't make sense anymore now that the option boxes on the page before are no longer titled with "Option:". Also, it was repetitive with the info below and didn't add anything by being in a box and bulleted. Instead, just make a title that explains that these resources are available for people with or without an LVAD. Make this like a title for the page, with "end of life care" being larger font, all caps and italicized to emphasize core of this page (Jocelyn). Below hospice information, add a line about how patient with VADs also have the option to turn off the device in the future. This line was originally on pg. 4 in the top paragraph, which was removed. We felt it was important to include this line somewhere in the DA, and it goes with end of life care infomation, so we added it to pg. 5. For "Patient Perspectives" box, changed the</p>

		<p>background to be lighter color and the font to black so that it's readability when printed in black and white.</p> <p>Pg. 6: In title, made "life change" a bigger font, all caps and italicized to show theme of page. Changed the driveline picture to the one of Barney, since we now have permission to use the picture. Moved the driveline site caption to the side so it can all fit.</p> <p>Pg. 7: Make "caregivers" bigger font, all caps and italicized at the top. Move th "How does a caregivers life change" section to the top, addressing the emotional aspects first. Add something about "on one hand, caregivers are happy to have their loved ones around, on the other hand, it's a lot of work", per Dan's experience with CG qualitative findings. Change some of the wording in this section slightly. Remove the information in the "Why do I need a caregiver" and "What does a caregiver need to do" sections, as it's not really important or adding anything. It's assumed information. Move the bulleted list box below the emotional piece. Remove the grey background to keep consistent with the new format. Blue box outline, no fill color (Jocelyn). Some of the important facts from the first two sections we removed, put in a bulleted list. Place under the title of "caregiver facts", which is information that may be helpful for a CG and patient to know, such as some hospitals requiring CGs, the training, the committment, and support for CGs (Jocelyn). For "Caregiver Perspectives" box, change background color to be lighter and font to black for readability when printed in B&W.</p> <p>Pg. 8: In top sentence, make "cosider" bigger font, all caps and italicized (Jocelyn).</p>
<p>10/23/2013</p>	<p>16</p>	<p>Page 4: "What compications might occur?" section, change the top part to include stat on hospitalizations, with all complications bulleted below it. This is to show that the complications below are part of the hospital readmission rate. It's more succinct and illustrative.</p> <p>Page 5: Change title of page to say "...there are services available to HELP WITH SYMPTOMS and suffering of advanced illness." Important to take out "end of life care" as pall care doesn't like this language used, and it's not as helpful for people. Highlight "help with symptoms", as that is what pall care and hospice hope to do, and that's what this page is about.</p>
<p>11/19/2013</p>	<p>17</p>	<p>Page 5: Under "Patient Perspectives", change attribution to say "Patients who get an LVAD" and "Patients who chose NOT to get an LVAD" to clarify that the decliners were offered an LVAD and chose against it, not that they simply weren't offered an LVAD.</p>

12/16/2013	18	<p>Danny worked on the graphics of DA, with the same content.</p> <p>Page 1: Removed fork in the road picture. Made LVAD pump graphic our own and bigger, not at top of DA.</p> <p>Page 2: Rearranged content; removed thinking man picture; added a heart graphic to "What is heart failure" section.</p> <p>Page 3: Redesigned the graphic to be our own and to not be Thoratec branded.</p> <p>Page 5: Rearranged content, put "Patient Perspectives" in vertical box to the side. Put attributions on top of quotes.</p> <p>Page 6: Made graphics our own.</p> <p>Page 7: Removed hand "caregiver" picture. Rearranged content, put "Caregiver Perspectives" vertical and to the right side. Put attributions on top of quotes. Removed "The LVAD caregiver helps with" and "Things to consider" out of the boxes and stacked them on top of each other.</p> <p>Page 8: Took "What are your biggest questions" out of the box.</p>
12/19/2013	19	<p>Email to Danny about making the DA as a whole more graphic, warm and friendly (less sterile, too white, too much text without contrast of pictures). Add life back into it, add pictures, etc.</p> <p>"Our pilot work suggests that patients making this decision are scared to death (literally). One of the innovative things we trying to do with the LVAD DA is to infuse some emotion and values into the decision aid to help people making this decision. While the human pictures weren't necessarily great before - they did have the advantage of being human. Right now, the DA is beautiful but it feels like a 1950s hospital with sterile white tile, sterile white walls, no plants, and not pictures on the walls (that is by no means a criticism). On the flip side, it isn't cheesy and feels very clinically appropriate which is awesome.</p> <p>Using your artistic mind, do you have any ideas on how to make it less sterile and more human without being cheesy - I think this may be a very tough sweet spot to find but I'd be curious to know if you have any ideas."</p>
12/20/2013	19	<p>Page 1: Put the fork in the road picture back on page. Use different fork in the road picture.</p> <p>Page 2: Change wording of first sentence under "This is a major decision" to say "If your doctors feel you eligible, you are facing a major decision. Such a decision may make some people feel uncomfortable." This is to get at the eligibility issue, and to let readers know that they may not for sure be eligible for LVAD even though they're receiving this information.</p> <p>Page 3: For the "What is the process of getting an LVAD" section, put the text in bullet points. This was recommended by a clinician to make the information easier to read and for literacy purposes.</p> <p>Page 4: For survival graphic, make the colors of the men more distinct, as they look too similar when printed in black and white. For the infection bullet point in complications, change "serious infection" to "life threatening infection" in order to make the stat more accurate and diffuse clinican critics, per our systematic review.</p> <p>Page 5: For the sentence "patients with an LVAD will have the option of turning the pump off", change to be clearer and to state the point more directly, as this can be a confusing statement. A clinician reviewer recommended this change to say something like "Even with an LVAD, some patients will continue to feel worse or get sicker due to other health problems...." Also, put more of a space between this sentence and the "What is hospice" description, as they are seperate topics. Seperate the last section, "Whether we like it or not" more from the text above. This is completly seperate idea and should be stand alone, should stand out, and be obviously seperate.</p> <p>Page 8: Change the bottom credit section to include info about contacting us for advice or suggestions.</p>

Supporting Evidence For The Development of Left Ventricular Assist Device (LVAD) Decision Aids

12/30/2013	19	<p>Page 1: Added new fork in the road picture and put "Exploring options" text on it.</p> <p>Page 2: Added a road sign to make it more graphic.</p> <p>Page 3: Added a hospital sign to make it more graphic.</p> <p>Page 4: Changed color of dead men to white to have more contrast when printing.</p> <p>Page 5: Put a line between "What is hospice" and deactivation information to make more separate. Made font bigger, colored and italicized for the "Whether we like it or not" section, in order to make it stand out and be its own idea, separate from rest of page. Add picture of hands holding, showing care, difficult decision, and to add more life into DA.</p> <p>Page 7: Added a red cross image to make more graphic.</p> <p>All pages: Made the bolded, all caps words in titles (to highlight the content on page) underlined instead.</p>
1/9/2014	20	<p>Page 7: Change the first caregiver quote in "Patient Perspectives" to one of Vicie from the filming we did. Lynne Warner Stevenson said the caregiver for decliner quotes were too negative and biasing towards getting an LVAD, and so we added a more positive quote about declining the LVAD, rather than a quote illustrating the negatives of the LVAD.</p> <p>Page 8: Add a creative commons license to bottom of page.</p> <p>All pages: Put page numbers.</p>
1/17/2014	20	<p>Page 4: Change the survival statistic for accepting an LVAD to 7 out of 10 (instead of 6 out of 10). This is more accurate with what we found in the systematic review. Shade the men graphic accordingly.</p> <p>Page 8: Add this line to the disclosure at bottom of page, to be more compliant with what the NIH asks "The content is solely the responsibility of the authors and does not necessarily represent the official views of funding agencies and medical centers."</p>
1/17/2014	Video Script	<ul style="list-style-type: none"> • Insert more values pieces throughout - Keeps it more consistent/heavy throughout • Make the two options more distinct and clearer; We hop around between LVAD and NO LVAD too much; After survival, put all LVAD stuff first, then NO LVAD (pall care/hospice) - This runs the risk of biasing people toward LVAD up front, since NO LVAD appears later. Perhaps just move the lifestyle changes above "What happens without LVAD" and pall care/hospice, then have a separate section on just "Caregivers" <p>o Or present "Life without an LVAD" first, right after survival, then life with an LVAD, then "Services" of pall care/hospice, then caregivers</p> <p>o Do we want to have an outline/roadmap at beginning of video? Literally right after intro slide, with Amy voiceover listing what's in video, or after Dan's introduction, with Dan discussing what will be in video</p>

<p>2/5/2014</p>	<p>Video Beta Version</p>	<p style="text-align: center;">CCOR Feedback:</p> <ul style="list-style-type: none"> • Give a road map or outline at beginning of video so it's clearer and they know what's coming up <ul style="list-style-type: none"> o As is, it feels like it's going to end several times and then keeps going <ul style="list-style-type: none"> • Keep concepts separate o Getting confused about what the real tradeoffs are <ul style="list-style-type: none"> • Why would I not get an LVAD - list o Frame declining formally • Make it clear that it's a 2 year window for all stats—bring it out and say it after every stat <ul style="list-style-type: none"> • Explain more about how the pump is internal and not sitting on top of chest <ul style="list-style-type: none"> o Show pump over Cliff • Mention caregiver earlier on so you know it's coming—right now it comes out of nowhere <ul style="list-style-type: none"> • Add to complication slide the number of people who die through surgery <ul style="list-style-type: none"> o Have to live through surgery to get to those survival benefits • More information on surgery—it's just kind of brushed off now • A summary section somewhere to say why people would/would not get an LVAD <ul style="list-style-type: none"> • The first segment feels really heavy, whereas the rest feels light. <ul style="list-style-type: none"> o Hopes and wishes don't get addressed until the very end <ul style="list-style-type: none"> § Move up early or repeat language throughout o Reminders of values needs to be put more throughout video
<p>2/12/2014</p>	<p>Video Beta Version</p>	<p style="text-align: center;">Patient, caregiver feedback:</p> <ul style="list-style-type: none"> • Wants information on life expectancy with the LVAD <ul style="list-style-type: none"> o How long do they expect you to live with an LVAD? o It says 2 years, but what happens after that? Survival language for ICD video <ul style="list-style-type: none"> o Use intermacs data for 5 years at 48% o "Some patients can live many years longer." Add after survival stat. <ul style="list-style-type: none"> • He would like to see the pump in real time in order to understand the true size <ul style="list-style-type: none"> o In the graphic, it looks "monstrous" o Would like to see someone hold a real pump to know the true size and what's going in you <ul style="list-style-type: none"> o "seeing it [the pump] would be huge" o Should we show HMII in film and in paper <ul style="list-style-type: none"> o "here's the current FDA approved device"—picture of just HMII o Show image of HMII before the "Parts of an LVAD" section for size comparison—in video <ul style="list-style-type: none"> o Show in someone's hand in paper

<p>2/26/2014</p>	<p>Video Beta Version</p>	<p style="text-align: center;">Patient, caregiver feedback:</p> <ul style="list-style-type: none"> • Able to understand the aspects of the pump better on the pamphlet than in video (“Parts of an LVAD”). <ul style="list-style-type: none"> • Confusion with the 2-year survival statistics: • Need more details of surgery. Need to know about the testing, the pain, the process of surgery—many people don’t know what’s involved in “open heart surgery”. • The video needs to have the pros and cons of both options listed. Cliff is happy with his device, but what are his cons about it? <ul style="list-style-type: none"> • She asked what it means to not be eligible for a transplant—it wasn’t clear when watching the video why people were not eligible for transplant. Perhaps add more details about eligibility? <ul style="list-style-type: none"> • When presenting the information, make it more sentimental or sensitive. Show patients/caregivers personal feelings about the whole process, how much stress they were under, and how they worked through it. • Better explanation of plugging into the module for power. Right now it sounds like people just plug into a wall outlet. More explanation on how you’ll be tethered at night. <ul style="list-style-type: none"> • Show different ways to carry batteries. • May be helpful to hear a few testimonies about how serious a commitment this is for a caregiver, because “it’s a very serious commitment... It’s a 24 hour thing, total commitment.”
<p>8/5/2014</p>	<p>Video Final Version</p>	<ul style="list-style-type: none"> • Title introduction page—make like v.1 with the screen capture images—with Clyde, Ruth and Dale, Cliff or Forrestine, and Don? • Cut Cliff’s first clip—after “...and hope for the best.”—this is a process clip, and then end part is more outcome. We discussed removing this between v.1 and v.2 • Add a title halfway through “Weighing Options” section—“What Might Happen with or without an LVAD?”—sections within: “How may I feel with an LVAD?”, “What problems might happen with an LVAD?”, “Life without an LVAD” <ul style="list-style-type: none"> • Shorten hospice clip—less Ginger, cut back to Jean sooner. • “The Rest of your Life” title—do we like? Seems a little odd to me.

<p>8/15/2014</p>	<p>Video Final Version</p>	<ul style="list-style-type: none"> • Vicie’s clips are redundant • Don’s 2nd, 3rd, 4th clips—look at to shorten. Cut Pall Care clip? • Cut Vicie’s last clip—doesn’t add anything to end and interrupts the flow of Clyde’s talk. • Take out second half of intro slide (Amy talking)—repetitive with Clyde’s mention of taking notes • During complications piece, cut Joe’s line at “2 hospitalizations per year” to remove “related to the LVAD”—as we can’t know for certain if hospitalizations are related to the LVAD, and this may be a concerning stat for some people. • Watch Vicie and Don’s clips and look at script to remove redundancies • Cliff’s first clip—second half move and add onto his second clip—this is more of an outcome, and the rest of the clip is ‘process’—this will also help to remove some of the concern with the beginning being too ‘pro-VAD’ <ul style="list-style-type: none"> • Remove the “Rest of your Life” title slide • Restructure the format to be a little easier to follow and to bring the lifestyle changes demo closer to the top (a lot of people’s favorite parts) <ul style="list-style-type: none"> o Also would make more sense to put Don’s death acknowledgement piece near the end—it’s awkward to have this heavy piece and then all of a sudden just change subjects. <ul style="list-style-type: none"> • Remove Don’s Pall care clip • Remove title page “how might this affect the caregiver”, as not necessary and can shorten the video slightly
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