

Patient-Centered Outcomes in Heart Failure

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Clinical Effectiveness and Decision Science

March 22, 2017



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Disclosures

- Employee of PCORI
- No other conflicts to disclose



Overview

- Introduction – Towards Patient-Centered Outcomes – *William Lawrence*
- The DECIDE-LVAD Study – *Larry Allen*



Our Mission and Strategic Goals

PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from **research guided by patients, caregivers, and the broader healthcare community.**

Our Strategic Goals:



Increase quantity, quality, and timeliness of useful, trustworthy research information available to support health decisions



Speed the implementation and use of patient-centered outcomes research evidence



Influence research funded by others to be more patient-centered



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

We Fund Patient-Centered Outcomes Research

PCOR is a relatively new form of Comparative Effectiveness Research (CER) that....

- Considers patients' needs and preferences, and the outcomes most important to them
- Investigates what works, for whom, under what circumstances
- Helps patients and other healthcare stakeholders make better-informed decisions about health and healthcare options



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

We Fund Research That...

What we mean by...

“Patient-centeredness”

- The project aims to answer questions or examine outcomes that matter to patients within the context of patient preferences
- Research questions and outcomes should reflect what is important to patients and caregivers



“Patient and stakeholder engagement”

- Patients are partners in research, not just “subjects”
- Active and meaningful engagement between scientists, patients, and other stakeholders
- Community, patient, and caregiver involvement already in existence or a well-thought-out plan

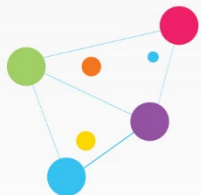


Decision Support in End-Stage Heart Failure: The DECIDE-LVAD Study



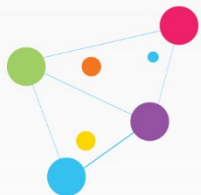
Larry A. Allen, MD, MHS

Medical Director, Advanced Heart Failure, University of Colorado



Disclosures

Relationship	Company(ies)
Speakers Bureau	
Advisory Committee	NQF
Consultancy	Novartis, Janssen, ZS Pharma
Review Panel	PCORI, AHA
Board Membership	PCPI, Boettcher Foundation
Honorarium	
Ownership Interests	



Outcomes should help patients choose treatments right for them



Classes of Treatment Decisions

1. **Benefit >> Risk**: ***Behavioral counseling*** is used when scientific evidence for benefit strongly outweighs harm (e.g. smoking cessation, beta-blocker for HFrEF), and decision support designed to describe, justify, recommend, and **engage** is most appropriate.

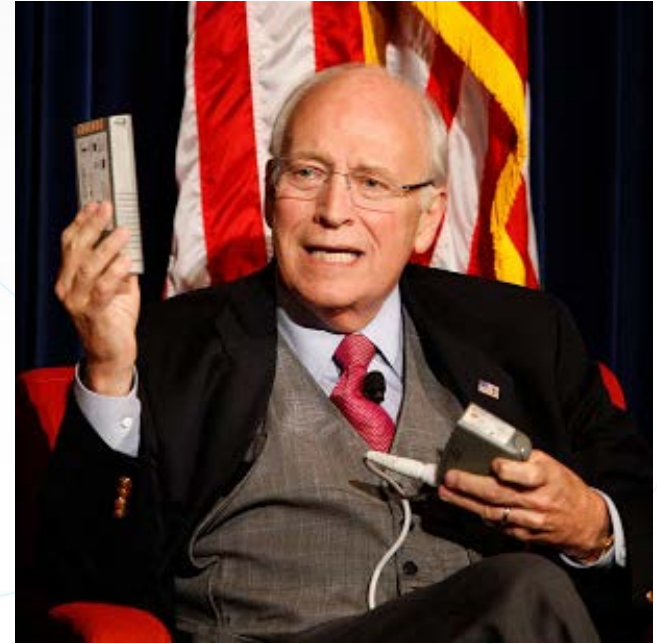
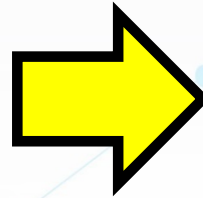
Relevant outcomes

2. **Benefits ~ Risks**: ***Shared decision making*** is most easily applied to ***preference-sensitive*** decisions, where both clinicians and patients agree that equipoise exists, and decision support helps patients think through, forecast, and **deliberate** their options.

Artificial Heart Technology – A Case Study



Barney Clark
1982



Dick Cheney
2010





The NEW ENGLAND JOURNAL of MEDICINE

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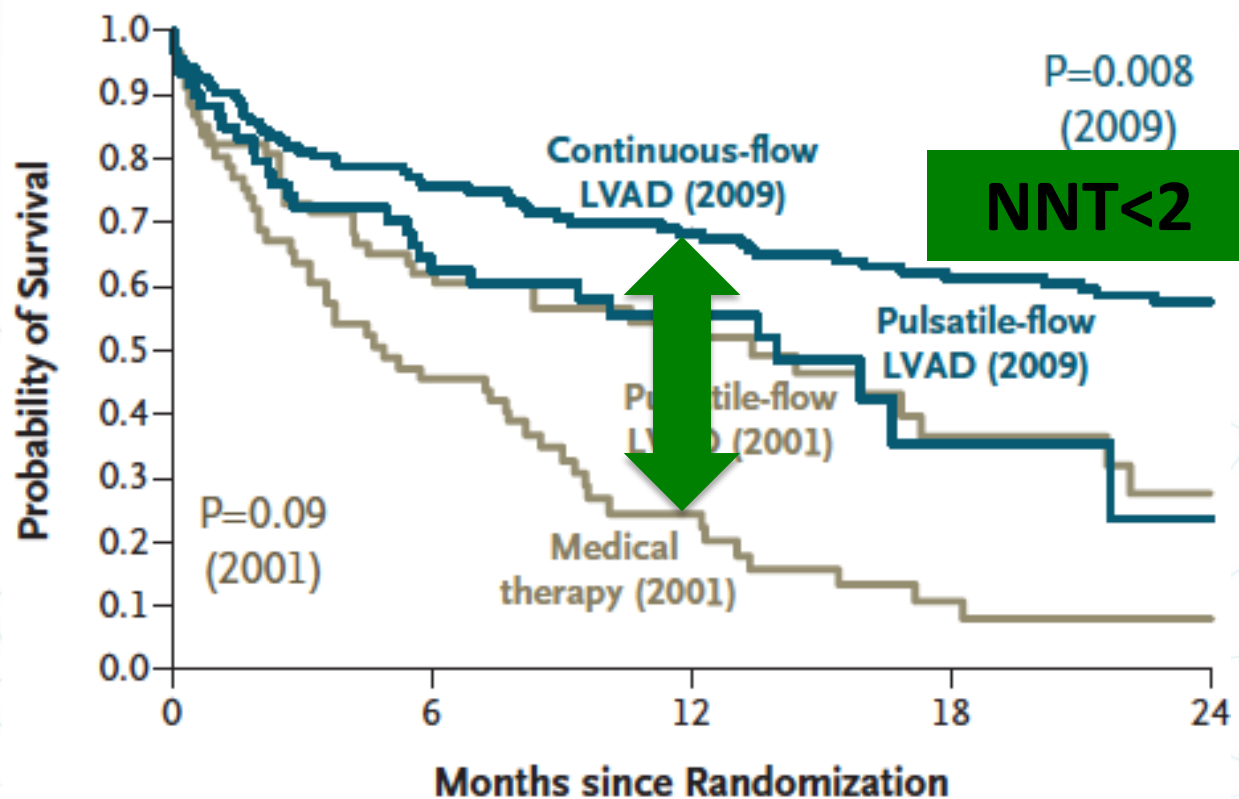
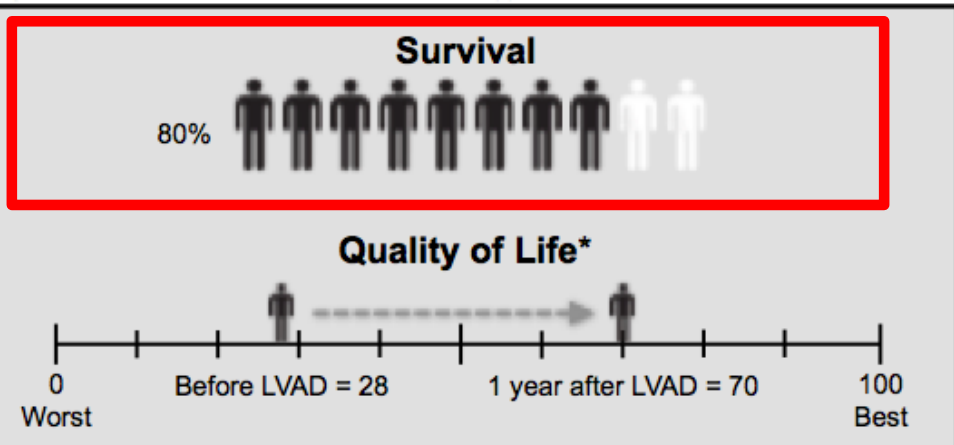
ENDURANCE



Mechanical Circulatory Support (MCS) and *Complex Trade-Offs*



Benefits 1 year

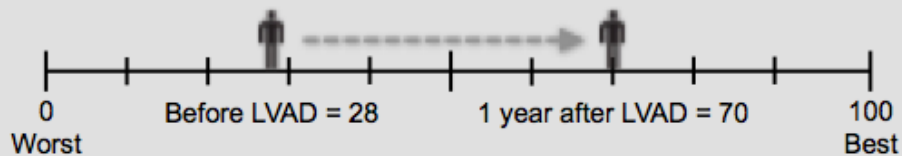


Benefits 1 year

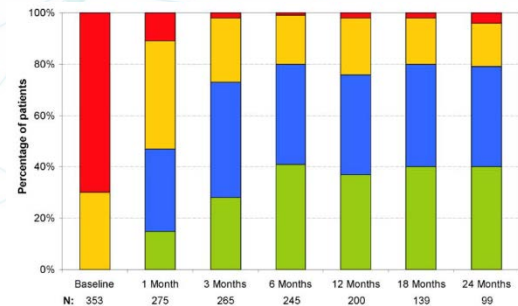
Survival



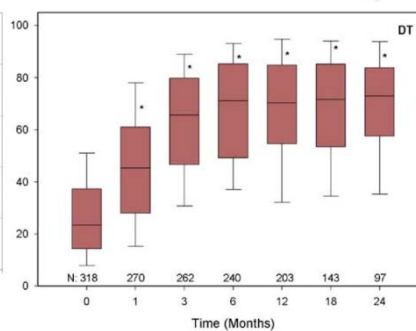
Quality of Life*



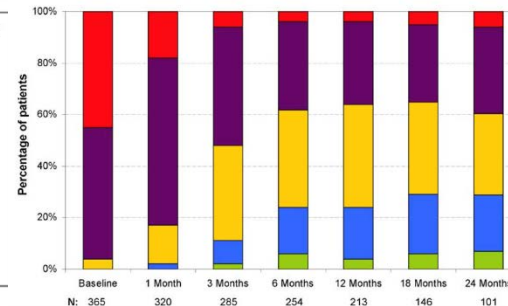
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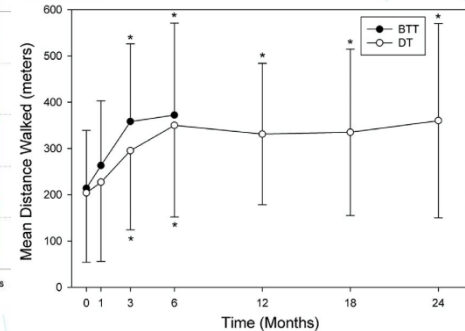
NYHA



KCCQ



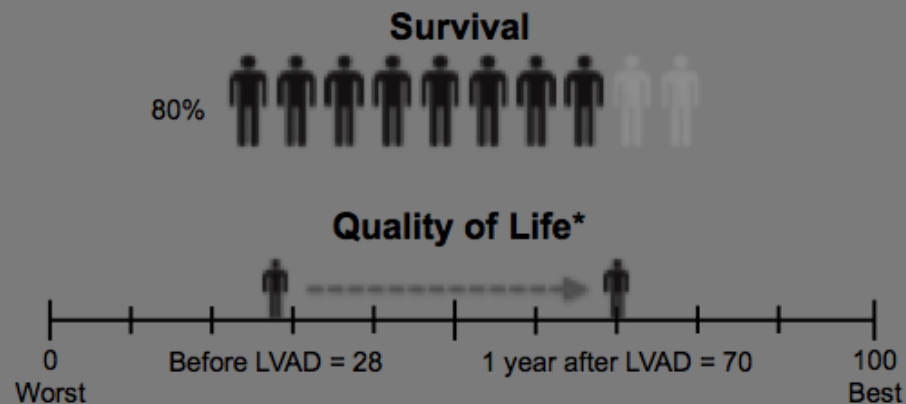
Exercise



6MWT

Benefits

1 year



Risks

1 year

Rehospitalized for Any Cause



Major Bleeding†

0-1 month after LVAD (typically surgical)



1-12 months after LVAD



Stroke‡



Serious Device-Related Infection§



Device Malfunction Due to Clotting||



Ongoing Heart Failure¶



Bereaved Caregiver Perspectives on the End-of-Life Experience of Patients With a Left Ventricular Assist Device

Colleen K. McIlvennan, DNP, ANP; Jacqueline Jones, PhD, RN; Larry A. Allen, MD, MHS; Keith M. Swetz, MD, MA; Carolyn Nowels, MSPH; Daniel D. Matlock, MD, MPH

IMPORTANCE For patients and their loved ones, decisions regarding the end of life in the setting of chronic progressive illness are among the most complex in health care. Complicating these decisions are increasingly available, invasive, and potentially life-prolonging technologies such as the left ventricular assist device (LVAD).

OBJECTIVE To understand the experience of bereaved caregivers and patients at the end of life who have an LVAD.

DESIGN, SETTING, AND PARTICIPANTS Semistructured, in-depth interviews were conducted between September 10 and November 21, 2014, with 8 bereaved caregivers of patients with an LVAD who were recruited from a single institution. Data were analyzed from December 13, 2014, to February 18, 2015, using a mixed inductive and deductive approach.

MAIN OUTCOMES AND MEASURES Themes from semistructured interviews.

RESULTS The 8 caregivers (6 females) described 3 main themes that coalesced around feelings of confusion in the final weeks with their loved ones: (1) the process of death with an LVAD, (2) the legal and ethically permissible care of patients with an LVAD approaching death, and (3) fragmented integration of palliative and hospice care.

CONCLUSIONS AND RELEVANCE Despite increasing use of LVADs in patients with advanced heart failure, bereaved caregivers of patients with an LVAD describe a high level of confusion at the end of life. There remains a need for the health care community to develop clear guidance on the management of patients with an LVAD at the end of life. Future work will focus on the educational process and the ideal timing and reiteration of such information to patients and families.

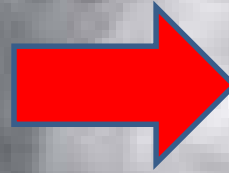
JAMA Intern Med. doi:10.1001/jamainternmed.2015.8528
Published online March 21, 2016.

← Invited Commentary

+ Supplemental content at
jamainternalmedicine.com

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Corresponding Author: Colleen K. McIlvennan, DNP, ANP, Section of Advanced Heart Failure and Transplantation, Division of Cardiology, University of Colorado School of Medicine, 12631 E 17th Ave, Mail Code B130, Aurora, CO 80045 (colleen.mcilvennan@ucdenver.edu).



High-stakes

Complexity

Caregivers

Emotion

Uncertainty

Cognitive Biases

Decision Making for Destination Therapy Left Ventricular Assist Devices

“There Was No Choice” Versus **“I Thought About It an Awful Lot”**

Colleen K. McIlvennan, DNP, ANP; Larry A. Allen, MD, MHS; Carolyn Nowels, MSPH; Andreas Brieke, MD; Joseph C. Cleveland, MD; Daniel D. Matlock, MD, MPH



AUTOMATIC
Self-preservation

REFLECTIVE
Utilitarian

“Informed” consent is broken

APPENDIX 1 –Universal Consent Form

J Heart Lung Transplant 2013;32:157–187

XXX HOSPITALS & HEALTH CENTERS

Request and Consent to Evaluation and Expectations for Mechanical Circulatory Support Device (MCSD) Implantation Bridge to Transplantation-Destination Therapy (BTT or DT)

Your heart failure is defined as a condition in which your heart is unable to pump enough blood to support the basic needs of your body. This can make you feel tired, have abnormal rhythms, and shortness of breathe, in addition to causing your other organs to fail (e.g. liver or kidneys). You are being offered this treatment option because you have a marked increase risk of irreversible end-organ damage or death over the (time period). For this reason, you are being considered for placement of a Mechanical Circulatory Support Device (MCSD) at (XXX Hospital & Health System). The heart pump is designed to take over the pumping action of your heart but before you undergo this procedure, it is important that you and your family understand the options, benefits, risks, and expectations associated with having a MCSD. It is required that you and your proposed caregiver(s) understand and agree with the treatment plan and are willing to participate in the guidelines outlined in the following pages.

At this time, you are being considered for a MCSD or more commonly called a Ventricular Assist Device (VAD) for Bridge to Transplantation. Bridge to transplant (BTT) is when a VAD is used to help extend the life of someone waiting for a heart transplant. This is subject to change pending the results from your evaluation and your Physician's decision. This consent pertains only to VAD therapy; you will receive information regarding heart transplantation allocation, procedures, and risks from the transplant program at a different time. Although you are being considered for MCSD implantation for Bridge to Transplantation, it is possible that you will not be a transplant candidate after you receive the MCSD if your medical condition worsens.

Marketing versus Education

Art was implanted with HeartMate II in 2006

Hear Art's story and see how he's doing now.



"I received HeartMate II and feel so much better. I can breathe. I can walk. I can do almost anything now."

– Art

Actual HeartMate II recipient



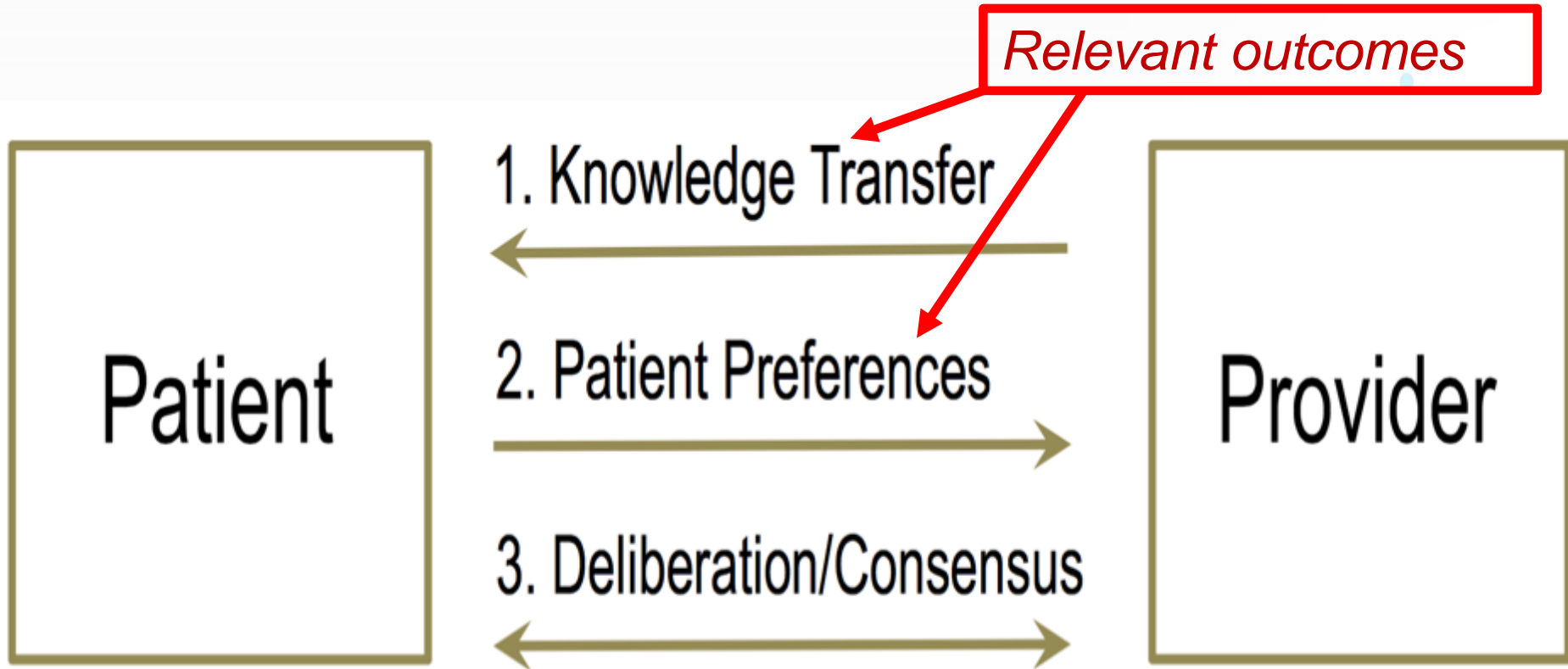
Marketing versus Education

Content Summary

77 VAD Patient Education Materials (%)

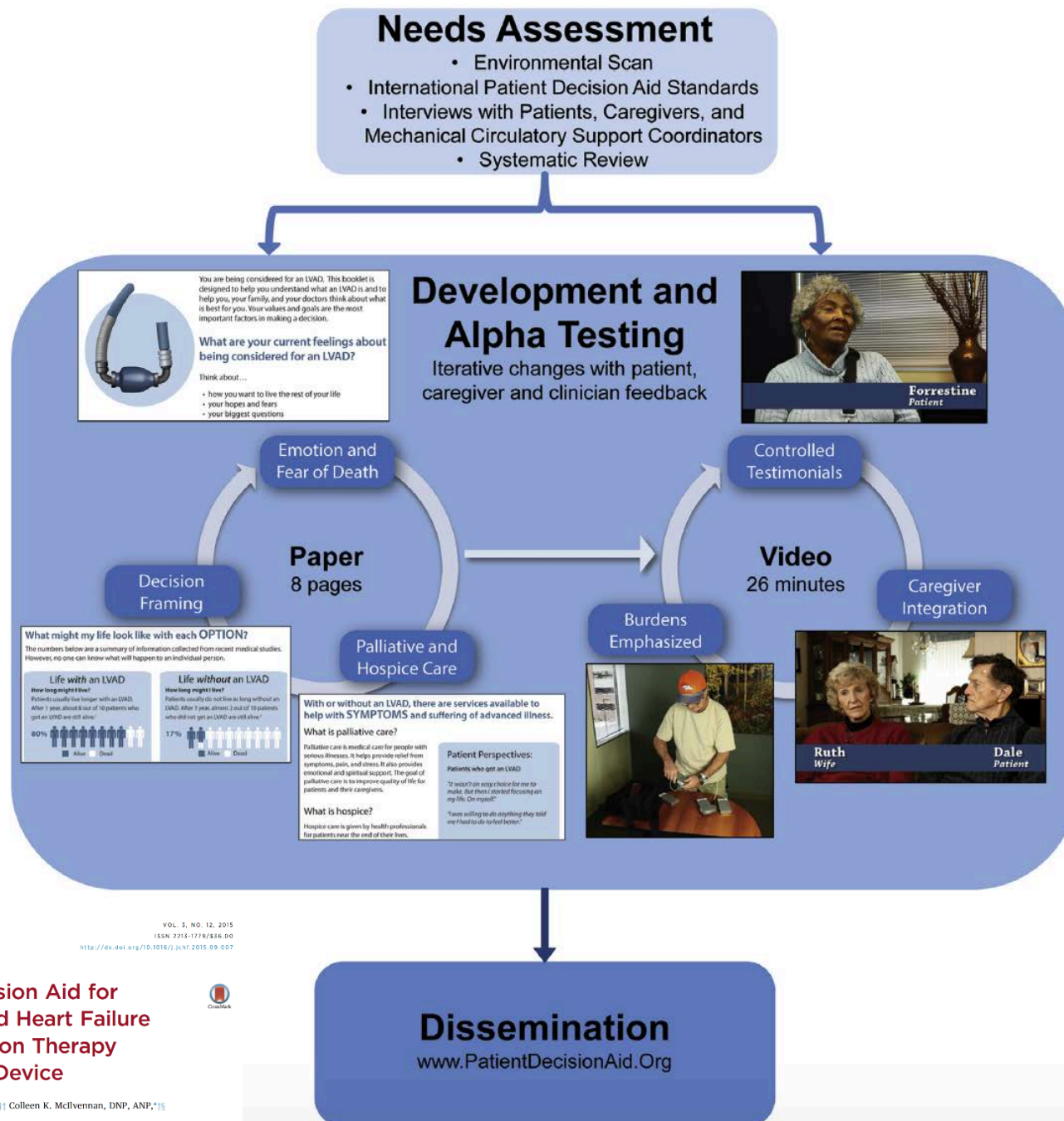
- 41(53) Contained risks
- 75(97) Contained benefits
- 28(36) Contained lifestyle considerations
- 8(10) Contained caregiver information
- 25(32) Contained details on surgical procedure
- 1(1) Mentioned hospice or palliative care

Patient Decision Aids



"A meeting between two experts"

FIGURE 1 Project Overview



Patient Testimonials (N=1)

HeartMatePro.com

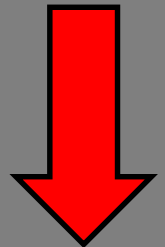
www.patientdecisionaid.org



Implementation: DECIDE-LVAD study

- **6-site:** CU, Brigham, St Vincent's, Mayo, Barnes, Duke
- Prospectively enroll **patient-caregiver dyads**

Site	Pre 4 months	Phase 1 4 months	Phase 2 4 months	Phase 3 4 months	Phase 4 4 months	Post 4 months
Coordinating Site						
2 Random Sites						
2 Random Sites						
1 Random Site						



Control Period



Roll-Out



Intervention Period

Control: current education and consent process

Intervention: new shared decision support

- Decision aids (replace industry decision materials)
- Communication training

****Standard of care for the program*

Reach: Percent of patients getting [

Effectiveness: (*patient, caregiver*)

- Knowledge
- Value-treatment concordance
(*aggressiveness of care*)

Adoption: Which providers using?

Implementation: How do they use i

Maintenance: Do they continue after the study stops?



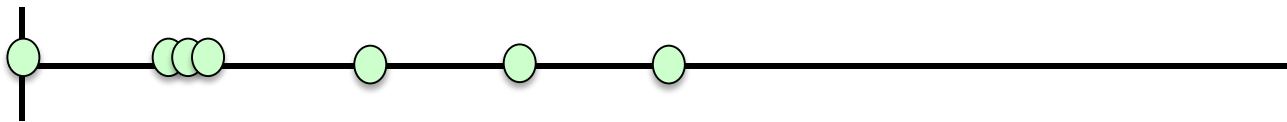
Study Outcomes

Measure	PATIENT				CAREGIVER			
	BL 1	BL 2	1m FU	6m FU	BL 1	BL 2	1m FU	6m FU
DT-LVAD Decision Quality Knowledge	X	X	X	X	X	X	X	X
DT-LVAD Decision Quality Values	X		X	X	X		X	X
Decision Conflict	X	X	X	X	X	X	X	X
Decision Regret								
Preferred Control	PRE (n=10)				POST (n=9)			
Control Preferences Scale – Preferred	Preferred Role				Active=5 Shared=3 Passive=1			
Actual Control: Control Preferences Scale – Actual								
Illness Acceptance: PEACE Illness Acceptance Scale								
Stress: Perceived Stress Scale								
Anxiety/Depression: Hospital Anxiety and Depression	Active=4 Shared=2 Passive=4				Active=5 Shared=3 Passive=1			
Quality of Life: EQ5D-3L and VAS								
Caregiver Preparedness: The Preparedness for Care								
Demographics								
Satisfaction with Caregiver Involvement: CANHELP								
Questionnaire – Role of the Family								
Caregiver Involvement in Decision Process								
with Care Questionnaire								
Acceptability of Educational Materials: Acceptability Questionnaire								
Bereaved Caregiver Satisfaction with End-of-Life Care:								
CANHELP Bereavement Questionnaire [for bereaved caregivers only]								
Bereaved Caregiver – DT LVAD Specific Questions [for bereaved caregivers only]								

*BL1=Baseline 1 Survey; BL2=Baseline 2 Survey; 1m FU=1-Month Follow-Up Survey; 6m FU=6-Month Follow-Up Survey

Values

1. If you were able to choose how your loved one lives the rest of his/her life, between the values at each end of the line below, where do you think you would want him/her to be? Please mark an "X" on the line where you think you would want to be.



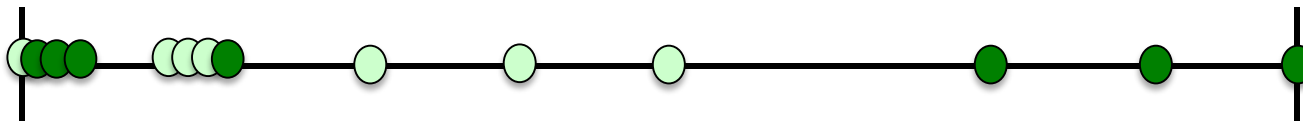
Do everything my loved one can to live longer, even if that means having major surgery and being dependent on a machine.

CAREGIVERS

Have my loved one live with whatever time he/she has left, without going through major surgery or being dependent on a machine.

Values

1. If you were able to choose how your loved one lives the rest of his/her life, between the values at each end of the line below, where do you think you would want him/her to be? Please mark an "X" on the line where you think you would want to be.



Do everything my loved one can to live longer, even if that means having major surgery and being dependent on a machine.

CAREGIVERS

Have my loved one live with whatever time he/she has left, without going through major surgery or being dependent on a machine.

Results so far ...

DECIDE-LVAD trial

- Recruitment completed 2/1/17, 6-month f/u 8/1/17
- **OVERenrolled**: Seems to fill an important need

Site #	Site Name	Target n, Patients	Actual n, Patients – Entire Study	Actual n, Patients – MRR* Only	Target n, Caregivers	Actual n, Caregivers	Target n, Combined PTs & CGs	Actual n, Combined Patients & Caregivers
1	University of Colorado	-	41	3	-	27	-	71
2	Brigham and Women's Hospital	-	22	1	-	14	-	37
3	Duke Medical	-	59	-	-	58	-	117
4	Mayo Clinic	-	35	4	-	33	-	72
5	St. Vincent Heart Center	-	55	1	-	27	-	83
6	Washington University	-	36	6	-	23	-	65
	TOTAL	168	248	15	168	182	336	445

Organic Dissemination and Natural Implementation

- 39 inquiries from 31 programs
- 10 non-study sites using

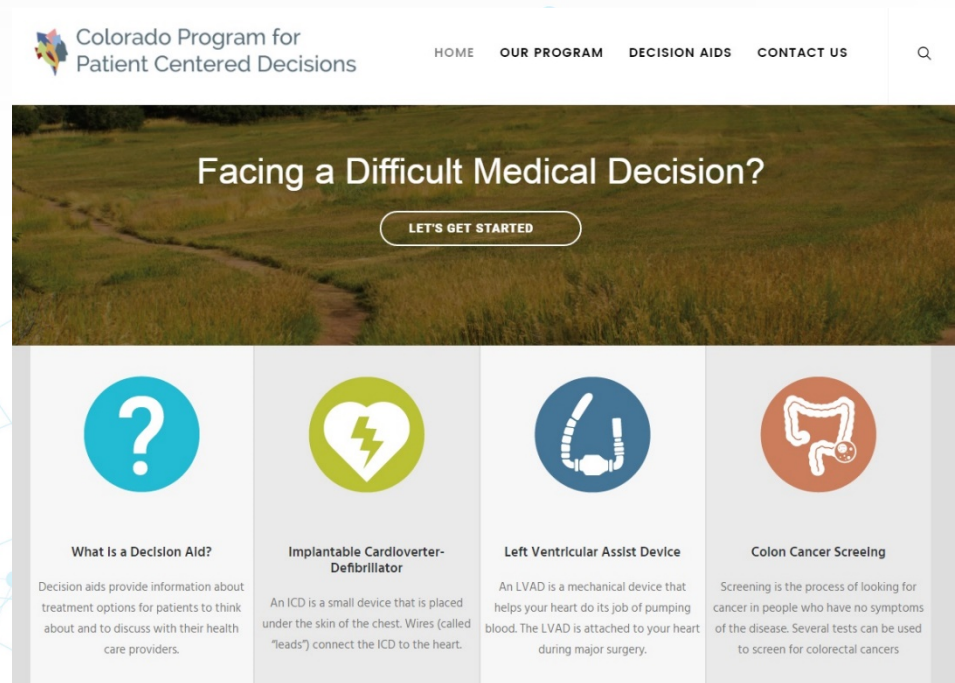


Learn More

patientdecisionaid.org

www.pcori.org

info@pcori.org



The screenshot shows the homepage of the Colorado Program for Patient Centered Decisions. The header includes the program name, navigation links (HOME, OUR PROGRAM, DECISION AIDS, CONTACT US), and a search icon. The main banner features a landscape image with the text "Facing a Difficult Medical Decision?" and a "LET'S GET STARTED" button. Below the banner are four featured topics, each with an icon and a brief description:

What Is a Decision Aid?	Implantable Cardioverter-Defibrillator	Left Ventricular Assist Device	Colon Cancer Screening
Decision aids provide information about treatment options for patients to think about and to discuss with their health care providers.	An ICD is a small device that is placed under the skin of the chest. Wires (called "leads") connect the ICD to the heart.	An LVAD is a mechanical device that helps your heart do its job of pumping blood. The LVAD is attached to your heart during major surgery.	Screening is the process of looking for cancer in people who have no symptoms of the disease. Several tests can be used to screen for colorectal cancers.

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Summary

- If we want to help patients make informed decisions about new heart failure technologies, then we need their input from the start!
 - Understand what the important questions are
 - Understand what the important outcomes are
 - Help provide the data in a form patients can understand and incorporate into their decision-making

