The Science of Patient Centered Decisions: An ACCORDS Seminar Series

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The Science of Patient Centered Decisions: An ACCORDS Seminar Series

Shared Decision Making & ICDs/LVADs



Dan Matlock, MD, MPH & Larry Allen, MD, MHS

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Request a Planning or Support Consultation with the Education Program Thank you!

Shared Decision Making and Implantable Defibrillators

Dan Matlock, MD, MPH Associate Professor of Medicine University of Colorado School of Medicine Implementation Scientist - GRECC



Colorado Program for Patient Centered Decisions

Implantable Defibrillators



Example: Implantable Defibrillators



Potential Harms of ICDs

• Procedural risks (Infection, Bleeding, etc.)

Additionally:

- Increased HF admissions (Goldenberg I, Circulation. 2006)
- Anxiety/Depression/PTSD (Sears SF, Heart. 2002)
- Inappropriate shocks (Sears SF, Am. J of Card. 2006)
- Device malfunction (Washizuka T, Int. Heart J. 2005)
- Potential suffering at the end-of-life (Goldstein NE, Annals Int. Med. 2004)
- Quality of Life (Noyes K, Medical Care. 2007)

Type of Death



Lunney, JAMA. 2003

Tools: Decision Aids

International Patient Decision Aid Standards (IPDAS)

- 1. Provide information about options
- 2. Present probabilities (unbiased and understandable)
- 3. Provide methods for clarifying values
 - Structured guidance for deliberation and communication

What is a good decision?

• Cochrane Review of 115 trials of Decision aids

- Improved knowledge
- Improved patient/doctor communication
- Improved patient involvement
- Improved Satisfaction
- Improved value/treatment concordance
- Lowered decision conflict
- Lowered decision regret
- Lowered the proportion undecided

Shared Decision Making

Design and Testing of Tools for Shared Decision Making

Daniel D. Matlock, MD, MPH; Erica S. Spatz, MD, MHS



Matlock, Spatz Circulation CVQO, 2014





Colorado Program for Patient Centered Decisions

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> IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	A decision aid for patients considering ICD therapy for primary prevention.	WATCH VIDEO
> BENEFITS AND RISKS > VALUES		DOWNLOAD BOOKLET
> NEXT STEPS		
> LIFE WITH AN ICD		DESCARGAR FOLLETO ESPAÑOL

Decision Aid: Paper Tools

Path 1

You may choose to get an ICD. You may be feeling like you usually do, then a dangerous heart rhythm could happen. The ICD may help you live longer by treating a dangerous heart rhythm. You will continue to live with heart failure that may get worse over time.



"I'm not ready to die. I have so much I'm trying to stay alive for. Even if it means getting shocked, I'm willing to do anything that can help me live longer."

Path 2

You may choose to NOT get an ICD. You may be feeling like you usually do and then a dangerous heart rhythm could happen. You may die quickly from the dangerous heart rhythm.



"I've lived a good life. The idea of dying quickly sounds like a painless way to go. I've always said I hope to die in my sleep. Going through surgery and getting shocked is not the kind of thing I want."

With an ICD Without an ICD 29 die, 71 live 36 die, 64 live $\odot \odot \odot \odot \odot \odot$ \otimes \otimes \otimes \otimes \otimes \otimes $\mathbf{\Theta}\mathbf{\Theta}$ $\mathbf{\Theta}\mathbf{\Theta}$ $\odot \otimes \otimes \otimes \otimes \otimes$ \times \times \times \times \times $\otimes \otimes \otimes \otimes \otimes$ $\otimes \otimes \otimes \otimes \otimes$ \otimes \otimes \otimes \otimes \otimes \otimes \times \times \times \times \times $\otimes \otimes \otimes \otimes \otimes$ \mathbf{x} \times \mathbf{X}

Number of people who live because of the ICD

Number of people who die

 \odot

Number of people not affected

www.patientdecisionaid.org

Benefit: Results from a 5-year study

With an ICD 29 die, 71 live

 \times \times \times \times \times \times \times XXXX $\mathbf{x} \mathbf{x} \mathbf{x} \mathbf{x} \mathbf{x}$ $\infty \times \times \times \times \times$ $(\mathbf{X} \times \mathbf{X} \times \mathbf{X})$ $\infty \propto \infty$ 1:5 $(\bigcirc)(\bigcirc)$ (\odot) (H) [+ +] (...) (...) (...) (++)

Without an ICD 36 die, 64 live



Death

Death

Last years of life

"I'm not ready to die. I have so much I'm trying to stay alive for. Even if it means getting shocked, I'm willing to do anything that can help me live longer."

Last years of life

"I've lived a good life. The idea of dying quickly sounds like a painless way to go. I've always said I hope to die in my sleep. Going through surgery and getting shocked is not the kind of thing I want."

Decision Aid Tools: Video

www.patientdecisionaid.org

Pilot Trial



- DAs were feasible within three practice settings
- Utilizing clinic staff facilitated patient identification
- Patients:
 - Felt the DAs were helpful and balanced
 - Would recommend them to other patients
 - Non significant trends in improvements in decision quality (pilot trial)
 - Patients preferred the paper and video (not website)
- Clinicians wanted decision aids related to reimplantation and biventricular pacing

Implementation is hard!

- Who will deliver the Decision aid?
 - Provider?
 - Staff member
 - empowered to provide DA on behalf of provider

• <u>How will the DA be delivered?</u>

- Electronically
 - With EHR? Patient portal? Email?
- In person or mailed
 - Print, DVD?

Implementation is hard!

Medical decisions require different depths of deliberation
Daily, reversible vs. single, irreversible decisions

• When will the DA be delivered?

Timing important for shared decision making

- Before visit may set up SDM
- In visit can directly support SDM interactions



Elwyn et al. BMC Medical Informatics and Decision Making 2013, 13(Suppl 2):S14 http://www.biomedcentral.com/1472-6947/13/S2/S14



Medical Informatics & Decision Making

REVIEW

Open Access

"Many miles to go ...": a systematic review of the implementation of patient decision support interventions into routine clinical practice

- Clinicians lacked confidence in the content of the DAs
- Many concerns about DAs disrupting established workflows
- Lack of incentives a major barrier

DECIDE - ICD

NITE National Heart, Lung, and Blood Institute

Center for Translation Research and Implementation Science

Stepped-Wedge Design

Site	Control Period 5 months	Phase 1 Intervention Roll-Out 5 months	Phase 2 Intervention Roll-Out 5 months	Phase 3 Intervention Roll-Out 5 months	Phase 4 Intervention Roll-Out 5 months	Phase 5 Intervention Roll-Out 5 months	Phase 6 Intervention Roll-Out 5 months	Intervention Continued 5 months
St. Luke's/MAHI								
Denver VA								
Providence								
Baptist								
UC Health/ Denver Health								
Beth Israel								

Stepped-Wedge Design

- Why not something else?
 - Classic <u>patient-level</u> randomization difficult due to diffusion; intervention is largely program-based
 - <u>Cluster</u> randomization (3 sites DA, 3 sites none)
- Advantages:
 - Still random
 - Phased implementation over time allows study
- Disadvantages:
 - Other changes in ICD care over the intervention period
 - Medicare mandate a major secular trend!



Reach



received intervention

eligible for intervention

Deceptively simple -> denominator challenges

Effectiveness



Primary: 1. <u>Knowledge</u> (IPDAS standard) 2. <u>Value-treatment concordance</u> (decision quality) Secondary: Decision conflict Decision regret Control preferences

Adoption/Implementation



Interviews with:
Clinical and Operational Staff involved with the Defibrillation patient education and decision making process
Cardiologists
Nurses
Administrators

Maintenance at the clinic level



What we will measure:
Clinics that maintain, adapt, and discontinue use of PtDAs
How we will measure:
Key informant interviews about why

2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: Executive Summary

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society

Developed in Collaboration With the Heart Failure Society of America

14. Shared Decision-Making

Recommendations for Shared Decision-Making					
References that support the recommendations are summarized in Online Data Supplement 60.					
COR	LOE	Recommendations			
I	B-NR	 In patients with VA or at increased risk for SCD, clinicians should adopt a shared decision-making approach in which treatment decisions are based not only on the best available evidence, but also on the patients' health goals, preferences, and values (1-5). 			
I	B-NR	2. Patients considering implantation of a new ICD or replacement of an existing ICD for a low battery should be informed of their individual risk of SCD and nonsudden death from HF or noncardiac conditions and the effectiveness, safety, and potential complications of the ICD in light of their health goals, preferences and values (1-5).			

Decision Memo for Implantable Cardioverter Defibrillators (CAG-00157R4)

For these patients identified in B4, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1)) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5)) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

"For these patients identified in B4, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1)) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5)) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit."



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Medicare



Requirements for Shared Decision Making
Lung Cancer Screening
Left Atrial Appendage Closure Devices
Implantable Defibrillators

Thank You

- Bryan Wallace
- Paul Varosy
- Jocelyn Thompson
- Channing Tate
- Colleen McIlvennan
- Fred Masoudi
- Carmen Lewis
- Jean Kutner
- Chris Knoepke
- Russ Glasgow
- Pilar Ingle
- Gracie Finnigan-Fox
- Monica Edwards
- Larry Allen





daniel.matlock@ucdenver.edu www.patientdecisionaid.org

Shared Decision Making For LVAD in End-Stage Heart Failure

Larry A. Allen, MD, MHS ACCORDS Conference February 2019





Colorado Program for Patient Centered Decisions



J Heart Lung Transplant, June 2018

IMACS, International Society for Heart and Lung Transplantation Mechanically Assisted Circulatory Support.



High Reward





Risks/Burdens



Risks/Burdens 1 in 10 have a disabling stroke 10%

2 in 10 have a serious bleed that requires medical attention







Driveline care, power source management



Aggressive V. Nonaggressive \$1000 bet **N D r** set station news arts & life music programs shop 🛔 🔍 🔍 Shots HEALTH NEWS FROM NPR OPINION TREATMENTS 14 Perspective: A Heart Device Can Save 7 Lives, But Doctors Need To Explain The Downsides \sim September 30, 2018 · 11:07 AM ET DR. MATTHEW MOVSESIAN FROM 909 wbur





Informing Patients about LVAD has been Deferred to <u>Marketing</u>

In 2014, identified 77 LVAD educational materials...

- 97% discussed **benefits**
- 53% mentioned any **risks**
- 36% mentioned **lifestyle** considerations
- 1% mentioned **palliative care** or hospice as an option
- 0% met majority International Patient Decision Aid Standards



lacovetto, Matlock, Thompson, McIlvennan, Bradley, Larue, Allen. CircCQO. 2014;905.



Whether patient decision aids help real people should be U



← Return to Awards Map

A Multicenter Trial of a Shared Decision Support Intervention for Patients and their Caregivers Offered Destination Therapy for End-Stage Heart Failure

Principal Investigator:

Larry A. Allen, MD, MS

Organization

Funding Announcement

University of Colorado Denver

Communication and Dissemination Research

A decision aid for Left Ventricular Assist Device (LVAD) A device for patients with advanced heart failure



You are being considered for an LVAD. This booklet is designed to help you understand what an LVAD is and to help you, your family, and your doctors think about what is best for you. Your values and goals are the most important factors in making a decision.

What are your current feelings about being considered for an LVAD?

Think about...

- how you want to live the rest of your life
- your hopes and fears
- your biggest questions

To view a video about this decision or for an online version of this booklet, visit <u>patientdecisionaid.org</u>.

DECIDE-LVAD Trial

Test the <u>effectiveness</u> of a shared decision support intervention for patients considering DT LVAD consisting of:

- 1. Site-based training
- 2. Implementation of patient decision aids

A decision aid for Left Ventricular Assist Device (LVAD) for Destination Therapy A device for patients with advanced heart failure





You are being considered for an LVAD. This booklet is designed to help you understand what an LVAD is and to help you, your family, and your doctors think about what is best for you. Your values and goals are the most important factors in making a decision.

What are your current feelings about being considered for an LVAD?

Think about...

how you want to live the rest of your life

your hopes and fears
 your biggest questions

Design: 6-Site, Stepped Wedge Trial

• Enrollment: June 2015 – Jan 2017. Phased rollout of intervention.

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



Patients, Caregivers and Data Collection



Patients, Caregivers and Data Collection



Intrusive Research?



Patient Participants

248 patients enrolled (from n=385 eligible; power/planned n=168)

• Enrolled patients more likely to be white non-Hispanic than non-enrolled (75% vs. 64%)

	Control (n=135)	Intervention (n=113)
Age	63.5 (9.7)	63.2 (10.2)
Ma	02 20/	86.7%
Wh	And Production on march order	82.7%
Sor	in the ICU near death.	69.2%
On		32.0%
Ma	72.5%	65.4%
Dia	11.9%	12.4%
Enrolled in ICU	21.5%	26.5%
INTERMACS 4-7 (p<0.01)	18.3%	44.6%

Intervention Delivery

- Training
 - All sites participated: 31-72 staff per site
- Patient decision aid exposure
 - 88% received pamphlet decision aid
 - 92% received video decision aid
- "Educational materials" felt to be biased in favor of LVAD
 - 54% of control patients
 - 43% of intervention patients (p=0.13)

Primary Outcome: DECISION QUALITY

"The extent to which medical decision making reflects the considered preferences of a well-informed patient."

Values-Choice Concordance



Knowledge

Knowledge

- Control: 59.5%→64.9%
- Intervention: $59.1\% \rightarrow 70.0\%$
- Adjusted difference of difference: 5.5%



Values-Choice Concordance



Values-Choice Concordance



Discordant

Values-Choice Concordance

- Control: 0.17 correlation coefficient
- Intervention: 0.48 correlation coefficient
- Adjusted difference of difference: 0.28



Secondary Outcomes: 6-month implant

Adjusted for Site and Time Period



LVAD No LVAD

Maybe?



LVAD No LVAD

Caregivers

182 caregivers enrolled (from n=217 eligible; power/planned n=168)

• No significant differences between enrolled/non-enrolled and control/intervention

	Control (n=111)	Intervention (n=71)
Age, mean years (SD)	60.2 (11.2)	11.5)
Female	82.9%	92.5%
White, non-Hispanic	81.8%	86.4%
Some college or more	66.4%	63.6%
Employed	41.7%	43.9%
Married	86.4%	82.1%
Relationship to patient, spouse	73.9%	79.1%
Caregiver lives with patient	82.9%	83.8%

Knowledge

Non-significant

- Control: 64.2%→73.3%
- Intervention: $62.6\% \rightarrow 76.4\%$
- Adjusted difference of difference: 4.8%



Percent difference, mean (baseline 1 to baseline 2)

Values-Choice Concordance

Significant

- Control: 0.12 correlation coefficient
- Intervention: 0.49 correlation coefficient
- Adjusted difference of difference: 0.36



Percent difference, mean (baseline 1 to baseline 2)

Do You Have the Stomach for Results?

- Decision Conflict scores decreased significantly less after viewing decision aids compared to control period materials
 - Baseline 1: control 19.0, intervention 21.4
 - Baseline 2: control 2.6, intervention 9.3 (p=0.009)
 - Higher score=higher decision conflict

Are we just raising people's anxiety?

Bereaved Caregivers...



20% of subjects dead by6-month data collection

Bereaved Caregivers...

Original Investigation

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.

UTS The 8 caregivers (6 females) described 3 main themes that coalesced around of confusion in the final weeks with their loved ones: (1) the process of death with an 5, (2) the legal and ethically permissible care of patients with an LVAD approaching death, d (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

Author Affiliations: Section of Advanced Heart Failure and Transplantation, Division of Cardiology, University of Colorado School of Medicine, Aurora (McIlvennan, Allen); Colorado Cardiovascular Outcomes Research Consortium, University of Colorado School of Medicine, Aurora (McIlvennan, Allen, Matlock): University of Colorado School of Nursing, Aurora (Jones); Division of General Internal Medicine, University of Colorado School of Medicine, Aurora (Nowels, Matlock); Birmingham/Atlanta Geriatric Research, Education, and Clinical Center, Department of Veterans Affairs, Birmingham VA Medical Center, Birmingham, Alabama (Swetz); Center for Palliative and Supportive Care, University of Alabama at Birmingham (Swetz). 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).



Considerations

Strengths

- Real-world look through a hybrid effectiveness-implementation design
- Rare upstream capture of patients *considering* for DT LVAD (not just LVAD recipients)

Concerns

- Stepped-wedge is a quasi-experimental design
- Missing data due to death and withdrawal of patients not implanted

Next Steps

- Updated decision aids
- PCORI Dissemination and Implementation
 - Disseminate decision aids to all **173 LVAD** programs across the U.S.
 - Targeted implementation strategies based on level of adopters at program



Thank You! Larry.Allen@ucdenver.edu

- Collaborators:
 - Dan Matlock
 - Colleen McIlvennan
 - Jocelyn Thompson
 - And many more! (It takes a village)
- Patients and Caregivers
- Clinicians and clinical programs

Decision aids available for free at: http://patientdecisionaid.org/LVAD/





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