

What is ACCORDS?

Adult and Child Center for Outcomes Research and Delivery Science

ACCORDS is a 'one-stop shop' for pragmatic research:

- A multi-disciplinary, collaborative research environment to catalyze innovative and impactful research
- Strong methodological cores and programs, led by national experts
- Consultations & team-building for grant proposals
- Mentorship, training & support for junior faculty
- Extensive educational offerings, both locally and nationally



ACCORDS Upcoming Events

November 9 & 16, 2023 9:00-3:00pm MT Zoom	<u>Overview of Dissemination and Implementation (D&I) Science Workshop</u> <i>Lead facilitators: Tina Studts, PhD and Borsika Rabin, PharmD, PhD</i>
November 20, 2023 AHSB 2200/2201, Zoom	<u>Statistical Methods for Pragmatic Research</u> <i>Randomization-based Inference for Cluster Randomized Trials</i> <i>Presented by: Dustin J. Rabideau, PhD (Massachusetts General Hospital)</i>
December 6, 2023 AHSB Conf. Center, Zoom	<u>Ethics, Challenges, & Messy Decisions in Shared Decision Making</u> <i>Incorporation of Patient Reported Outcome Measures in Shared Decision-Making in Breast Surgical Oncology</i> <i>Presented by: Sarah Tevis, MD (CU); Clara Lee, MD (UNC)</i>
December 18, 2023 AHSB 2200/2201, Zoom	<u>Statistical Methods for Pragmatic Research</u> <i>Presented by: Maren Olsen, PhD (Duke)</i>
January 10, 2024 AHSB 2200/2201, Zoom	<u>Ethics, Challenges, & Messy Decisions in Shared Decision Making</u> <i>Presented by: Ellen Lipstein, PhD (Cincinnati Children's Hospital)</i>
January 22, 2024 AHSB 2200/2201, Zoom	<u>Statistical Methods for Pragmatic Research</u> <i>Presented by: Jun Ying, PhD</i>

*all times 12-1pm MT unless otherwise noted



Ethics, Challenges, and Messy Decisions in Shared Decision-Making

2023-2024 Seminar Series

Ethics in Shared Decision-Making: Principles and Applied Examples



Dan Matlock, MD, MPH



Laura Scherer, PhD



Matthew Wynia, MD, MPH



Ethics in Shared Decision-Making: Principles and Applied Examples

Ethics, Challenges, and Messy Decisions in Shared Decision-Making - 2023-24 Seminar Series

Dan D. Matlock, MD, MPH

Professor of Medicine, Division of Geriatrics

Colorado Program for Patient Centered Decisions

Adult and Child Consortium for Outcomes Research and Delivery Science



**Colorado Program for
Patient Centered Decisions**



Colorado Program for
Patient Centered Decisions

“Difficult Patients”



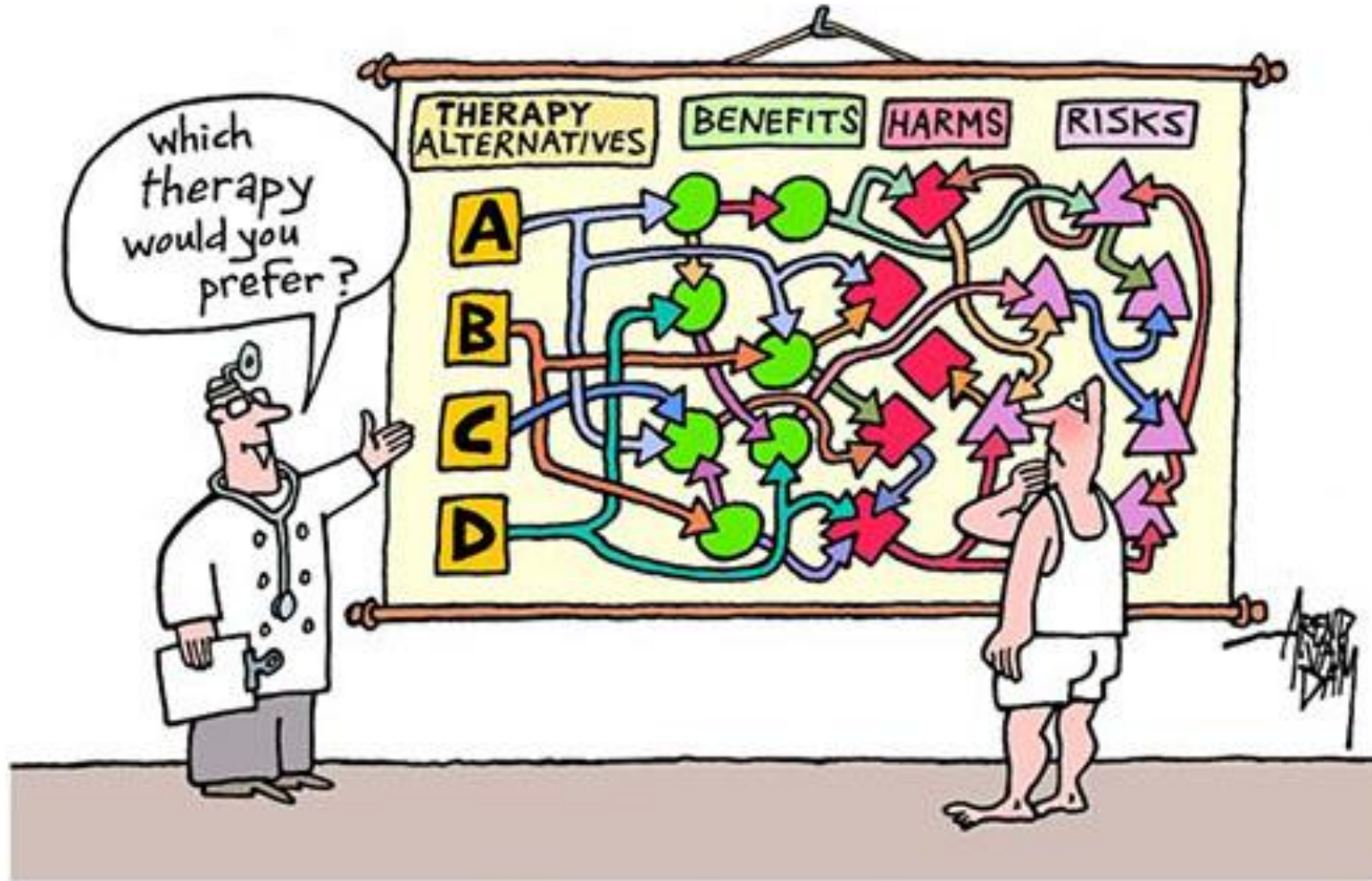
Background

- Disempowerment among patients:

"...is the guy going to be pissed at me for not doing what he wanted? ...Is it going to come out in some other way that's going to lower the quality of my treatment?...Will he do what I want but...resent it and therefore not quite be as good...or in some way...detrimental to my quality of care."

- Frosch et al. Health Aff May 2012





informed consent

Shared Decision Making

NATIONAL QUALITY PARTNERS™ ACTION BRIEF

Shared Decision Making: A Standard of Care for All Patients



NATIONAL
QUALITY FORUM

WHAT IS SHARED DECISION MAKING?

Shared decision making (SDM) is a process of communication in which clinicians and patients work together to make optimal healthcare decisions that align with what matters most to patients. SDM requires three components:

- clear, accurate, and unbiased medical evidence about reasonable alternatives—including no intervention—and the risks and benefits of each;
- clinician expertise in communicating and tailoring that evidence for individual patients; and
- patient values, goals, informed preferences, and concerns, which may include treatment burdens.



Shared Decision Making
"A meeting between experts"

Tuckett , 1985



Paternalism

Consumerism
(abandonment)

Examples from the field

English Version

IDEDECIDELVAD

Better conversations, better decisions

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



Exploring Options



You are being considered for an LVAD. This booklet should help you understand what an LVAD is and help you and your family 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?


- How do you want to live the rest of your life?
- What are your hopes and fears?
- What are your biggest questions?

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

Scan QR code to view video about this decision



Decision Aids Our Program For Clinicians



Left Ventricular Assist Device (LVAD)

IDEDECIDE[®] ICD

Better conversations, better decisions

A decision aid for
Implantable Cardioverter-Defibrillators (ICD)
For patients with heart failure considering an ICD who are at risk for sudden cardiac death (primary prevention).



See the back page for real-life sizes of the device.

You are being offered an ICD.

This booklet will

- Explain how an ICD works and why your doctor is recommending it.
- Help you make your decision based on your values and wishes.

Imagine two 60-year-old men with
end stage heart failure

Cliff



Don



Parts of an LVAD

Driveline

A cord that connects the pump to the outside. This passes through the skin and holds important electrical wires.

Batteries

A power source for the pump. The pump must always be plugged into either batteries or an electrical wall outlet.

Controller

A computer that operates the pump. The controller displays messages and sounds alarms about the device.

Pump

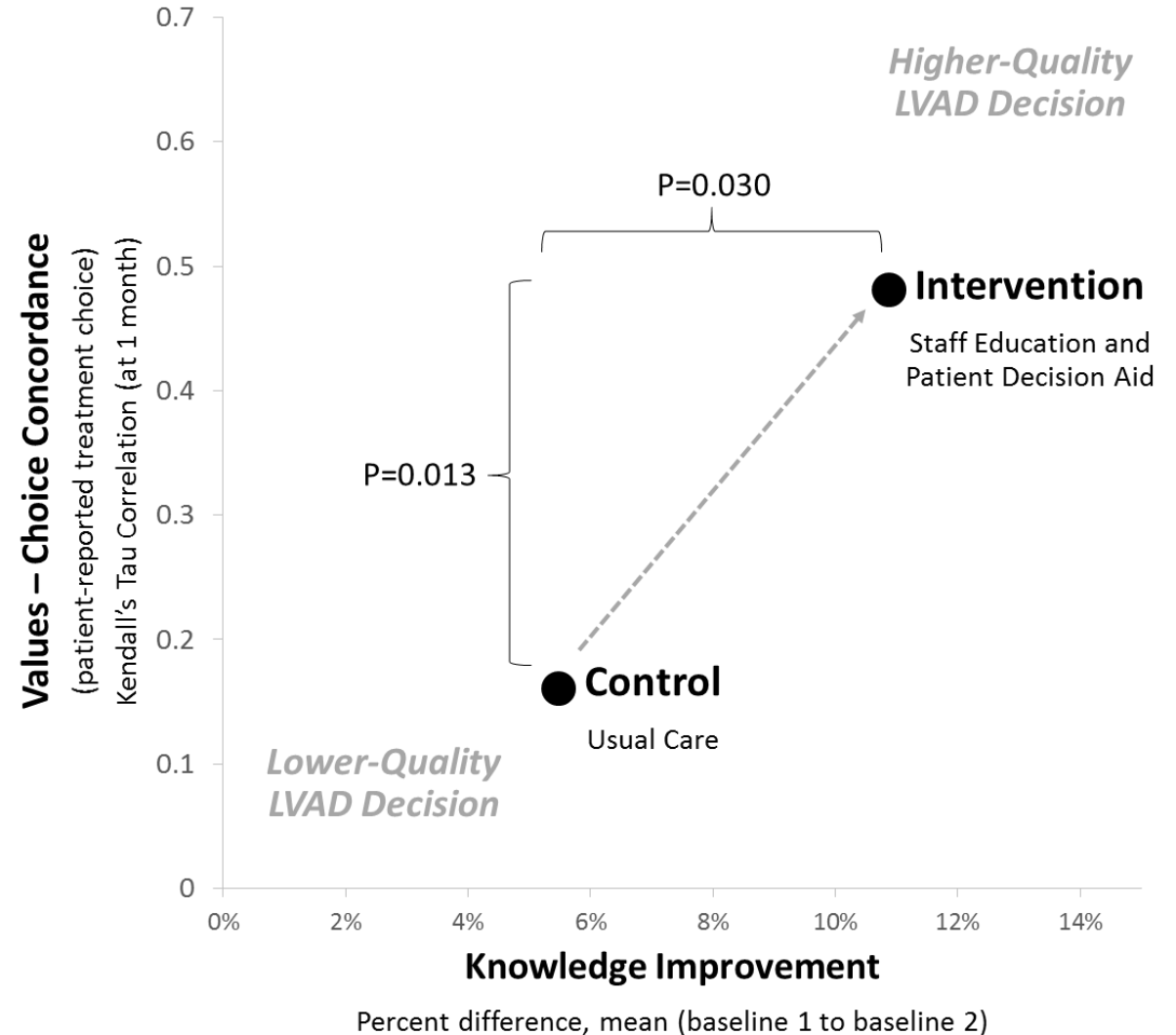
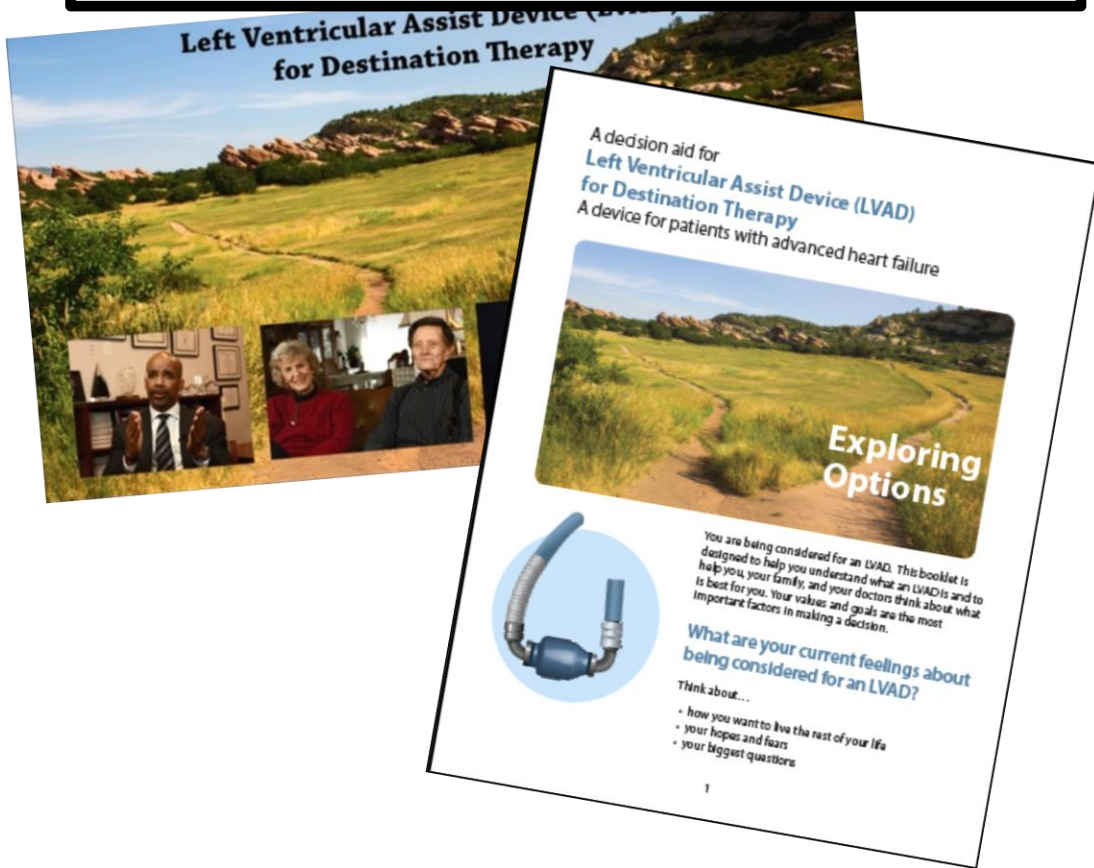
A motor placed inside the chest. It pushes blood from the heart to the body.



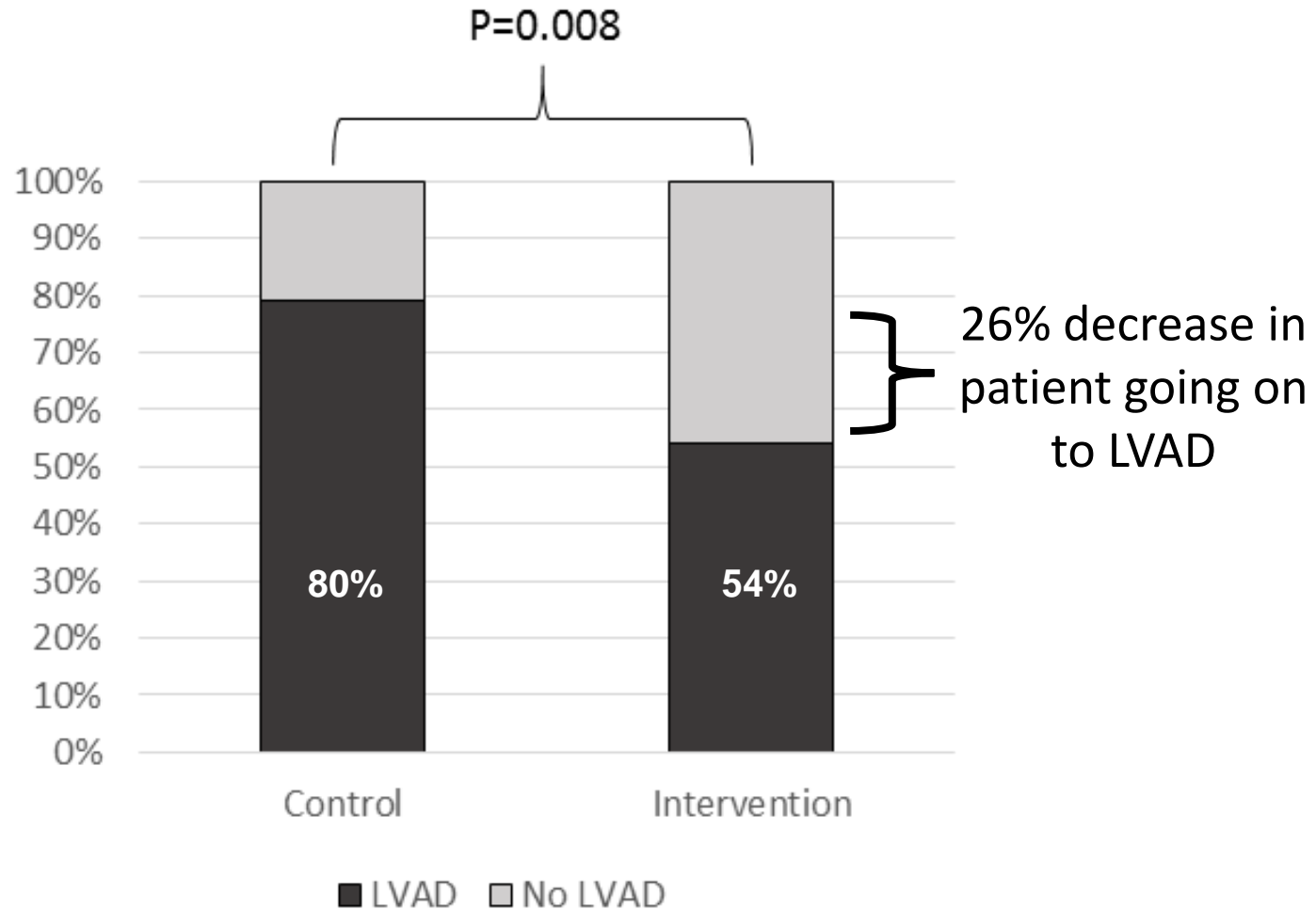
DECIDE-LVAD Trial – Effective Decision Aid

JAMA Internal Medicine | Original Investigation

Effectiveness of an Intervention Supporting Shared Decision Making for Destination Therapy Left Ventricular Assist Device
The DECIDE-LVAD Randomized Clinical Trial



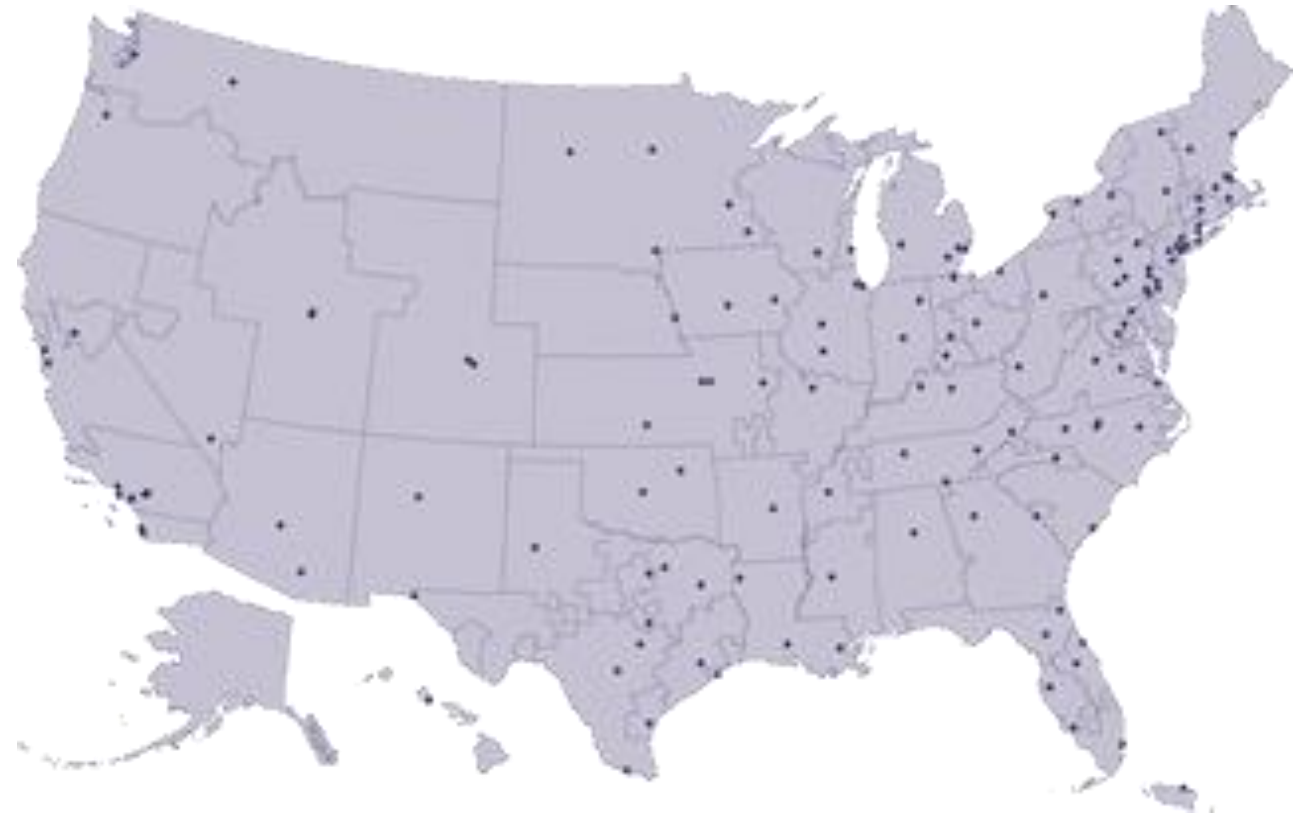
Secondary Outcomes: 6-month implant



I DECIDE: LVAD – Decision Aid Dissemination

Go BIG!

Implement the decision aid at **all**
175 CMS-certified LVAD programs
in the United States



I DECIDE LVAD

Better conversations, better decisions

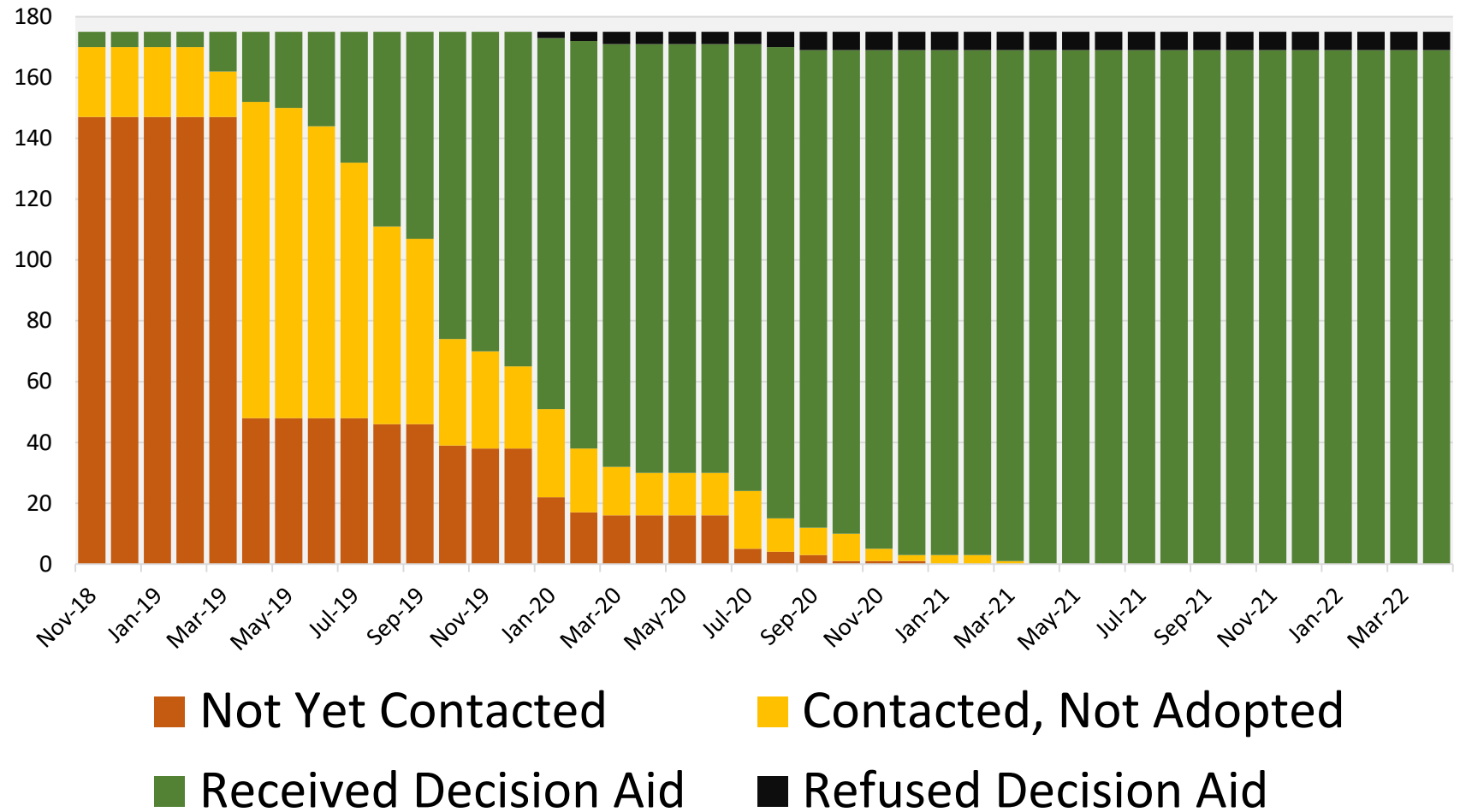
patientdecisionaid.org

Network Building + Adoption

Adoption

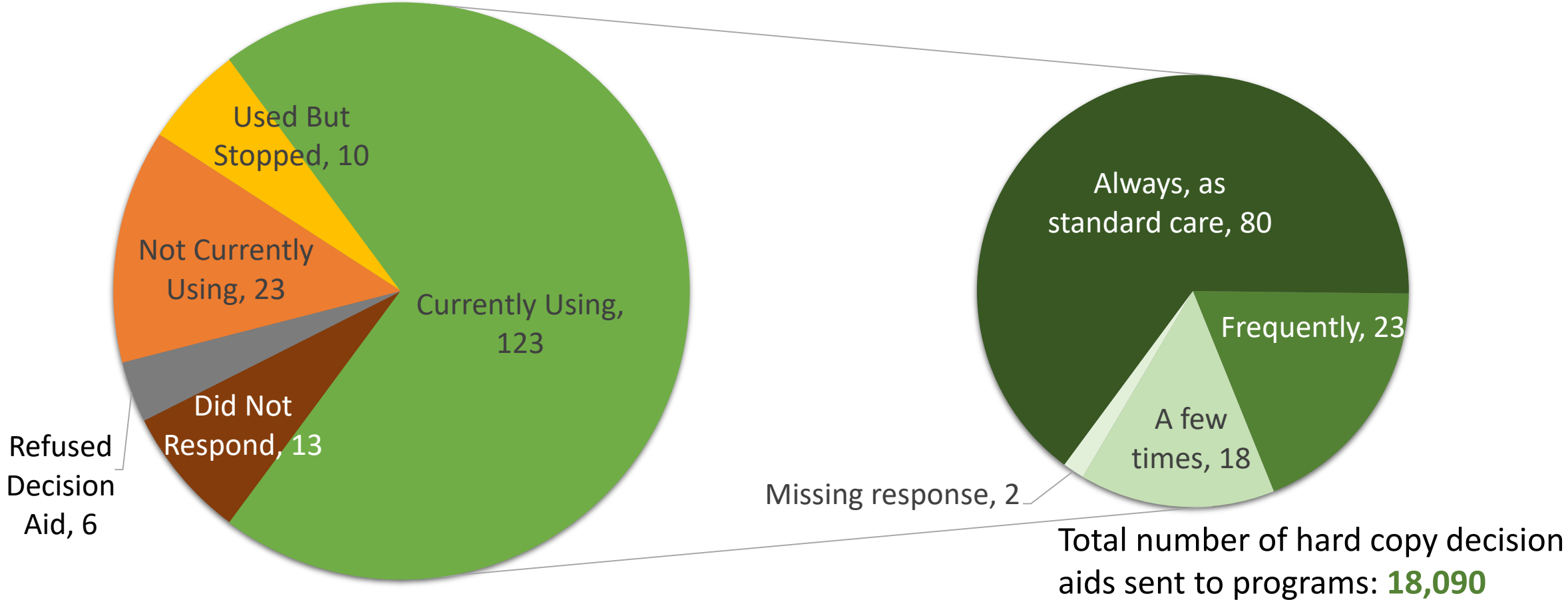
- Contacted every program
- **169 adopted decision aid** (were interested in and received 50 free hard copies of decision aid)

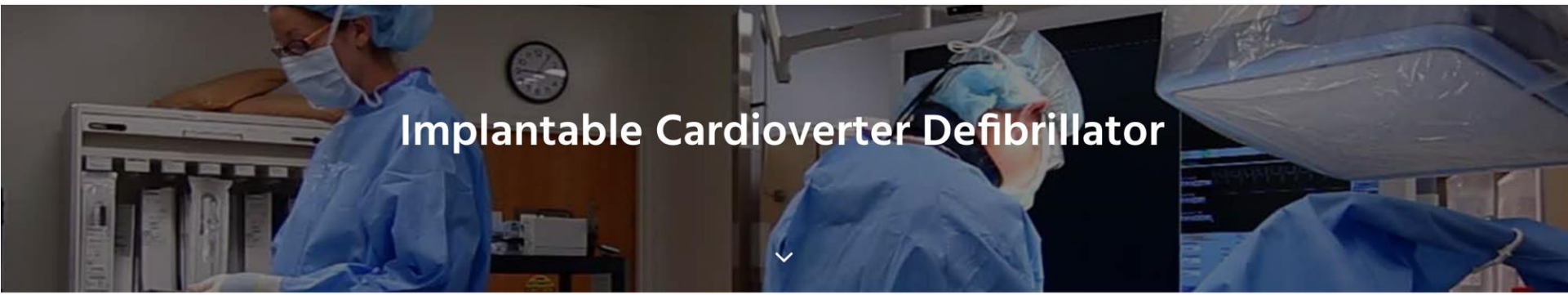
Adoption Over Time



Implementation

Reported use of decision aid by primary clinician contact at each program every 4-6 months over project period.





- > IMPLANTABLE
CARDIOVERTER
DEFIBRILLATOR
- > BENEFITS AND RISKS
- > VALUES
- > NEXT STEPS
- > LIFE WITH AN ICD

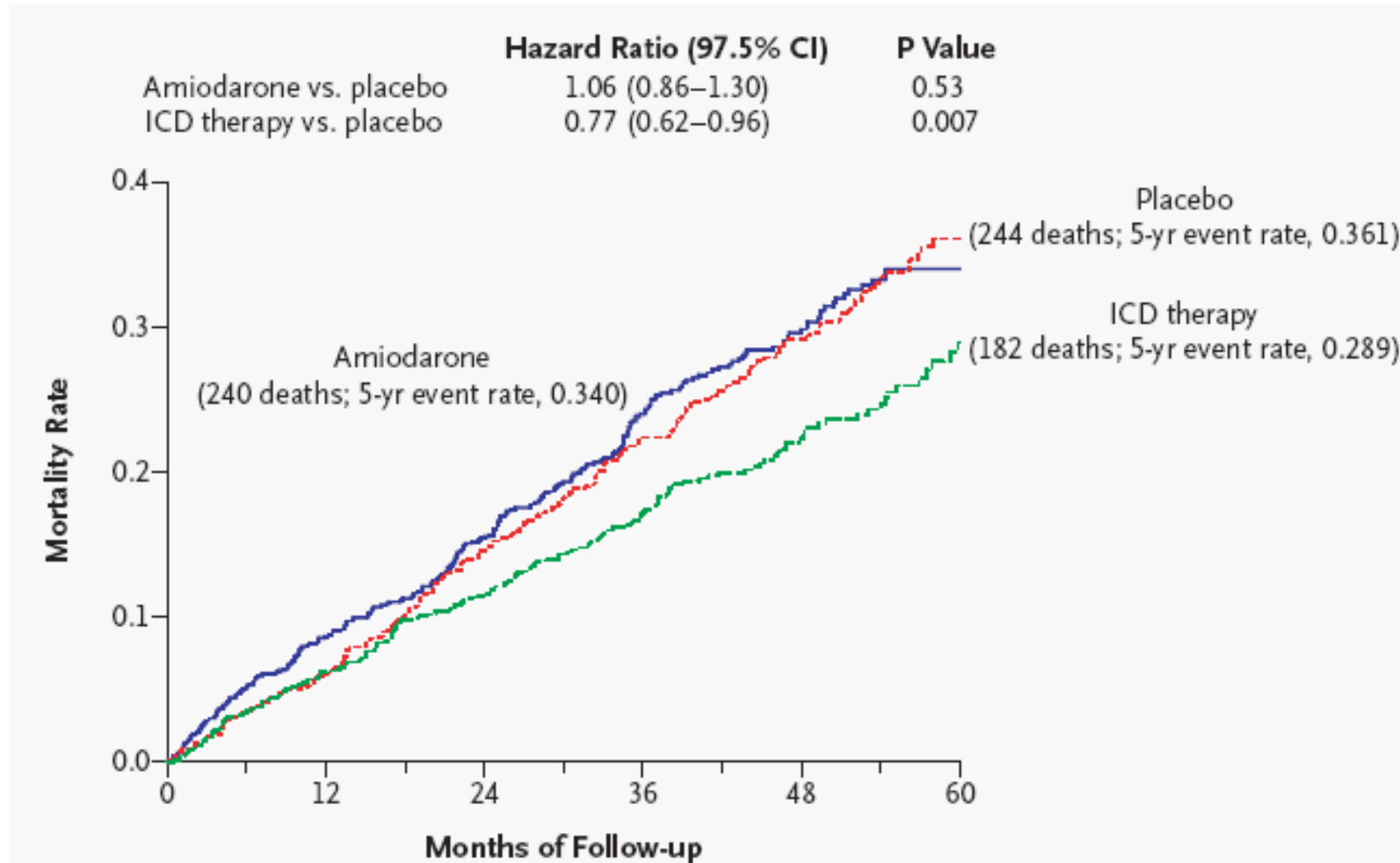
**A decision aid for patients considering ICD
therapy for primary prevention.**

WATCH VIDEO

DOWNLOAD BOOKLET

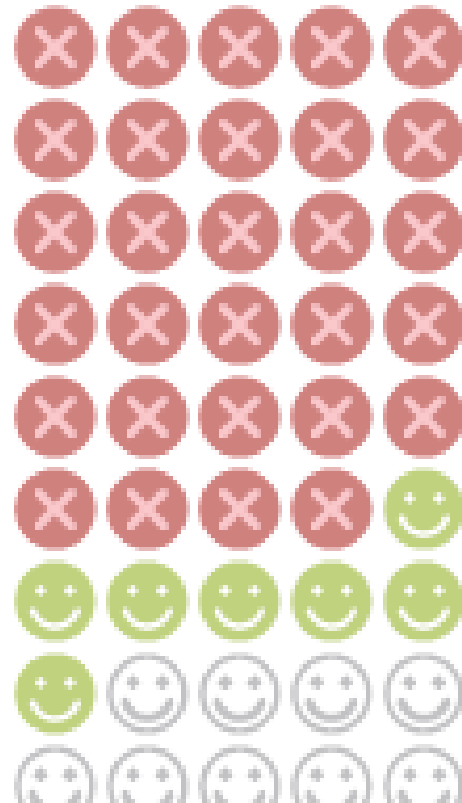
DESCARGAR FOLLETO ESPAÑOL

Defibrillator Benefits: SCD-HeFT

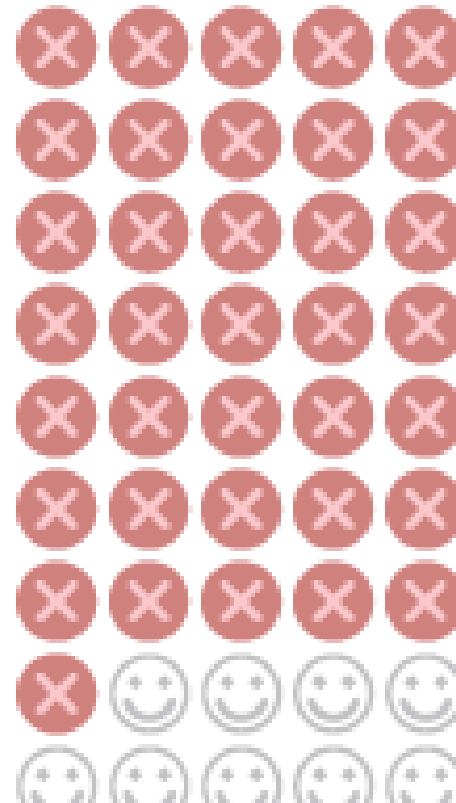


Benefit: Results from a 5-year study

With an ICD
29 die, 71 live



Without an ICD
36 die, 64 live



Medicare Mandate



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.”



DECIDE-LVAD and DECIDE-ICD Trials

Understand the effectiveness and implementation of a shared decision support intervention for patients considering LVAD or ICD.

NIH RePORT > RePORTER

[Search Results](#) > [Project Details](#)

[Back to Search Results](#)

Description >

Details

pcori Patient-Centered Outcomes Research Institute

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ABOUT US FUNDING OPPORTUNITIES RESEARCH & RESULTS GET INVOLVED MEETINGS & EVENTS

Research & Results

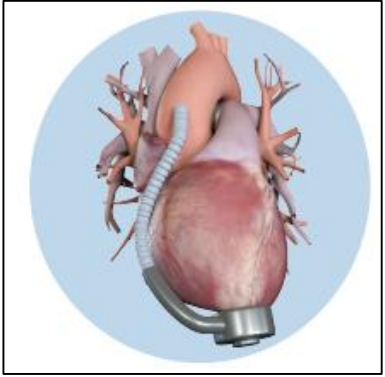
OUR PROGRAMS

RESEARCH WE SUPPORT

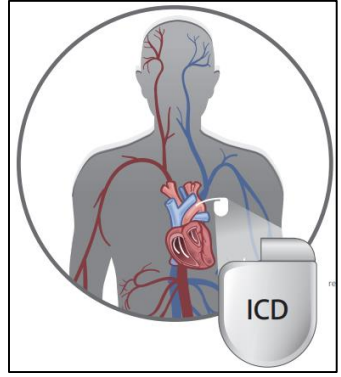
A Multicenter Trial of a Shared Decision Support Intervention for Patients and their Caregivers Offered Destination Therapy for End-Stage Heart Failure

[A Multicenter Trial of a Shared DECision Support Intervention for Patients offered implantable Cardioverter-DEFibrillators: DECIDE - ICD Trial](#)

Project Number	Contact PI/Project Leader	Awardee Organization
1R01HL136403-01	MATLOCK, DANIEL D	UNIVERSITY OF COLORADO DENVER

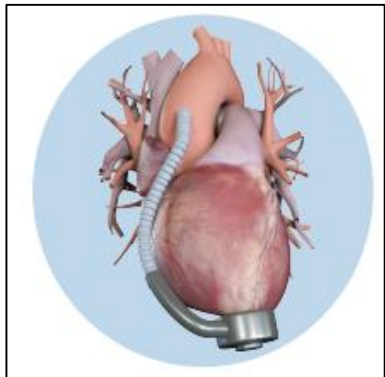


LVAD vs. ICD

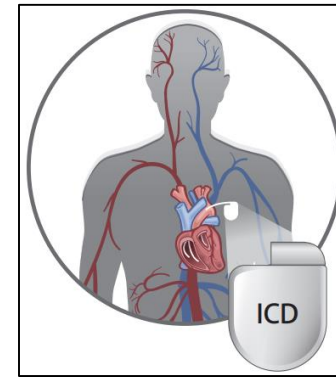


- **Who** will deliver the decision aid?
 - **LVAD coordinator:** built in role for education and consent process
- **When** will the decision aid be delivered?
 - Before and during **designated education session** with LVAD coordinator

- **Who** will deliver the decision aid?
 - **Electrophysiologist:** clinician with standard clinic time
- **When** will the decision aid be delivered?
 - After visit with EP as **take-home resource**



LVAD vs. ICD



Advantages for LVAD:

- Clinicians saw **need for SDM**
- Obvious timing for when SDM should take place – **initiated with an evaluation**, education with LVAD coordinators



Challenges for ICD:

- SDM not seen as universal need among clinicians (despite a mandate from CMS)
- Discussion not always triggered by specific/large event

Challenges for LVAD:

- Very sick population and urgent implants



Advantages for ICD:

- Typically outpatient visits with mostly well population

Ethics questions

- *Should all decisions be shared decisions?*
- *Is the goal of shared decision making to change decisions?*
- *Should Medicare or other payers get involved in mandating shared decision making?*





ACCORDS

ADULT AND CHILD CONSORTIUM FOR HEALTH OUTCOMES
RESEARCH AND DELIVERY SCIENCE

UNIVERSITY OF COLORADO | CHILDREN'S HOSPITAL COLORADO



Colorado Program for
Patient Centered Decisions

Thank You



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



Colorado Program for
Patient Centered Decisions

When (under what circumstances) should clinicians engage in shared decision making?

Laura D. Scherer, PhD

Associate Professor, Division of Cardiology & VA Denver COIN

Colorado Program for Patient Centered Decisions

Adult and Child Consortium for Outcomes Research and Delivery Science



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Overview

- 3 on-the-ground examples that raise the question:

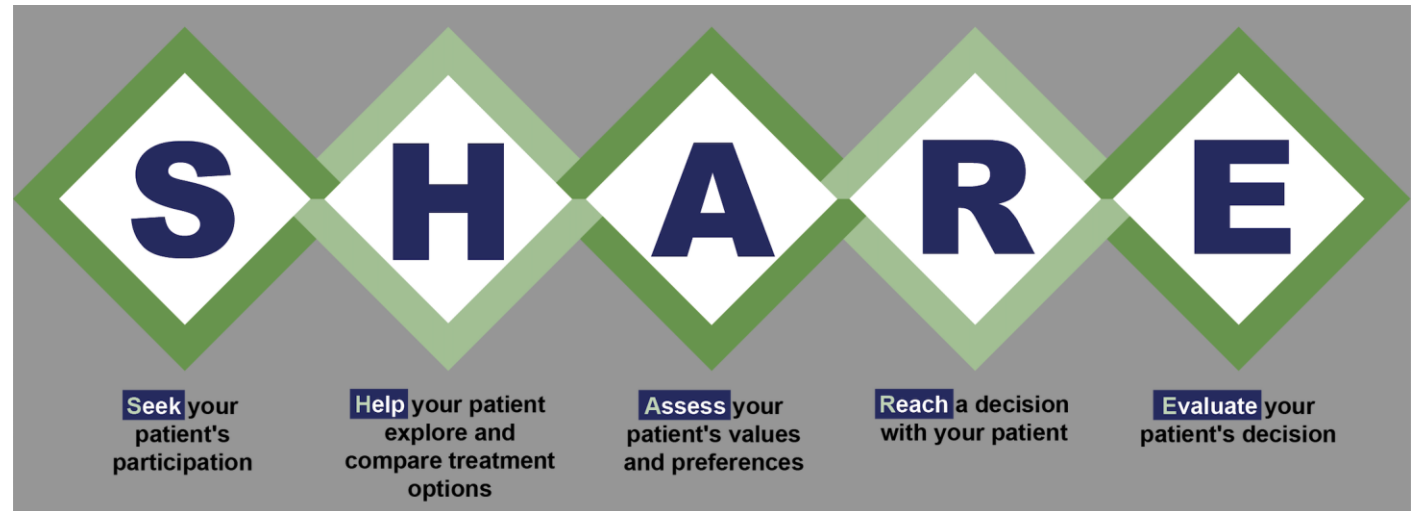
Should we be doing shared decision making here?

1. *The SHARE Approach evaluation: Clinicians' reactions to "clinical equipoise"*
2. *The SHARE Approach evaluation: COVID-19 vaccination*
3. *Breast cancer screening for women age 40-49: USPSTF guideline vs. values*



The SHARE Approach

- A SDM clinician training curriculum, developed by AHRQ in 2014
- Teaches clinicians 5 essential elements of SDM
- Teaches a general approach to SDM:
 - When there are multiple options, we don't know what's best ("clinical equipoise")
 - When reasonable people might weigh benefits and harms differently
 - When complex problem solving is needed



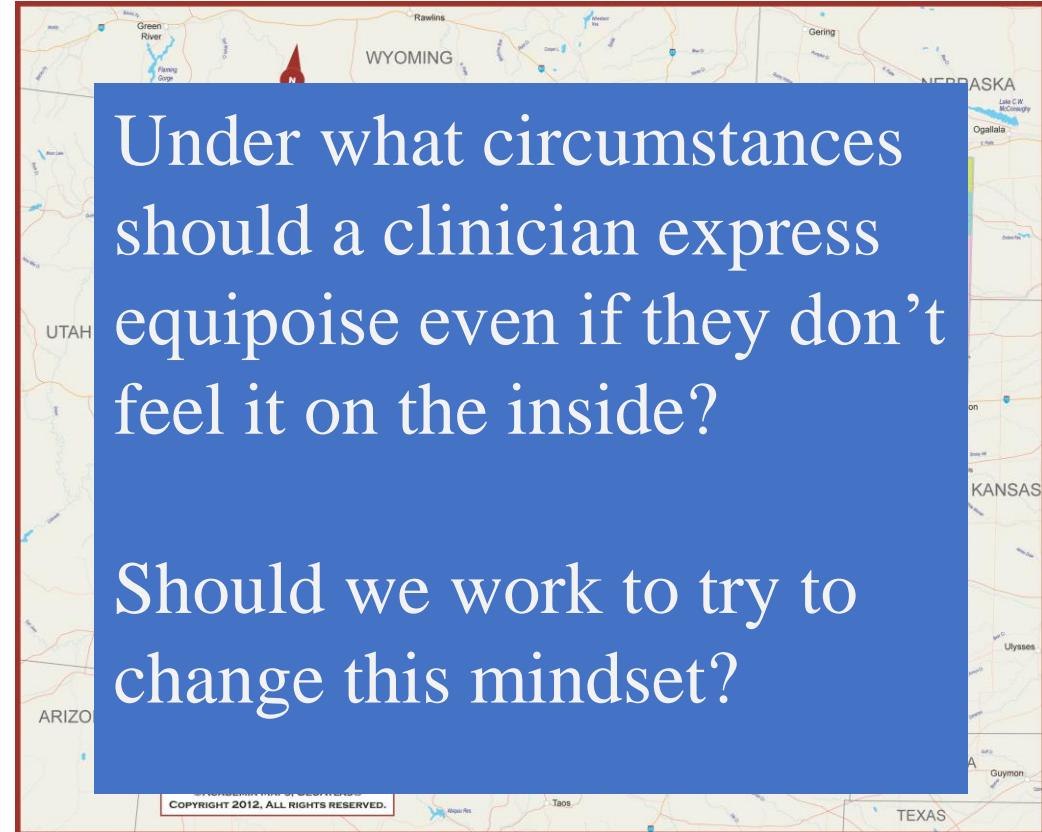
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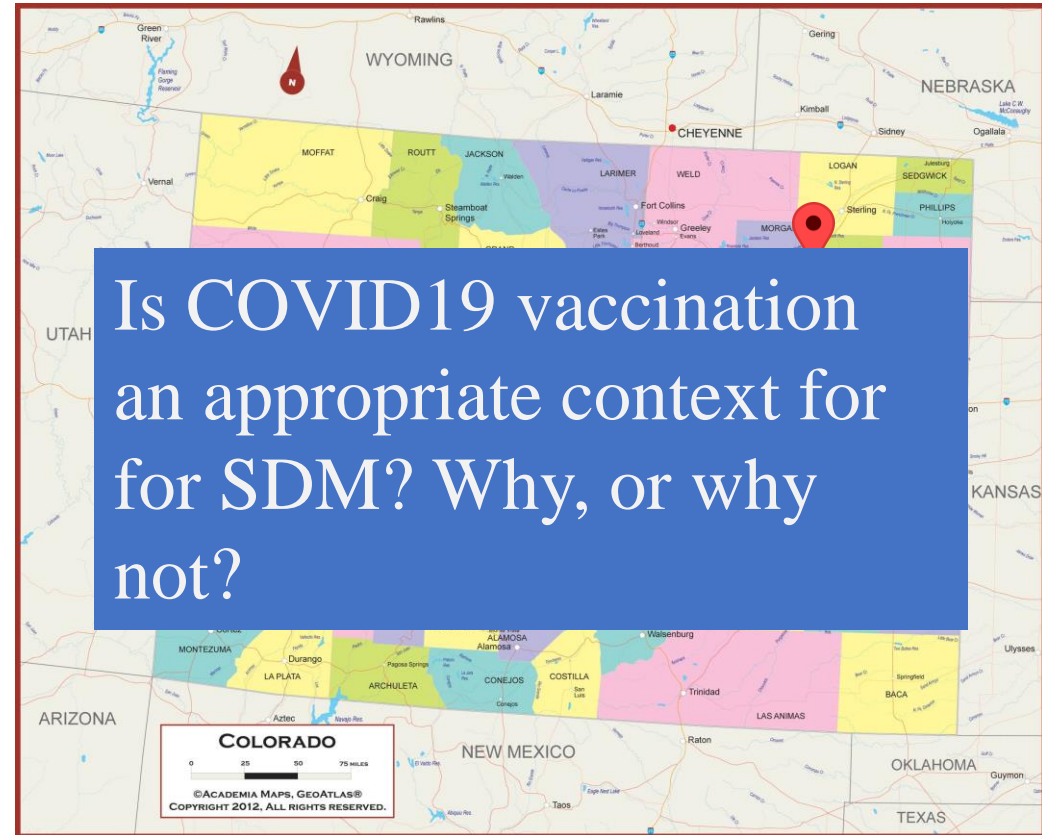
Insights from Implementing SHARE

- Implemented in 12 primary care and cardiology practices
- Insight #1: Clinicians were unfamiliar with the notion of clinical equipoise
- Insight #2: *“I never have equipoise. If that’s when I’m supposed to do SDM, I’ll never do it.”*



Insights from Implementing SHARE

- We implemented SHARE during the COVID19 pandemic
- Common request from many practices: [A COVID19 decision aid](#)
- Decision aids communicate benefits and harms; result in an informed decision
- The idea: Data will convince people to get vaccinated
- SDM \neq persuasion



Topic pivot: Mammograms for women 40-49

- From 2009-2023: Women age 40-49 should make a decision with their doctor about when to start having mammograms
- 2023: All women should start biennial screening at 40
- 2022: USPSTF in JAMA writes that SDM is a “core value” and should happen at all levels of their recommendations



What is the ethical imperative to inform women about both benefit and harms of mammograms, given that...

- It takes time & money
- It might dissuade screening at age 40