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

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

*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
“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

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*”

Paternalism

Consumerism (abandonment)

Tuckett, 1985
Examples from the field

**I DECIDE LVAD**
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. The hospital will explain to you what an LVAD is and how it will 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.

**I DECIDE ICD**
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).

You are being offered an ICD.

- Reasons why
- How to talk to your doctor and why your doctor is recommending it.
- Help you make your decision based on your values and needs.
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

Effectiveness of an Intervention Supporting Shared Decision Making for Destination Therapy Left Ventricular Assist Device

The DECIDE-LVAD Randomized Clinical Trial

Values – Choice Concordance (patient-reported treatment choice) vs. Decision Aid

Exploring Options

Higher-Quality LVAD Decision

P=0.030

Intervention

Staff Education and Patient Decision Aid

Lower-Quality LVAD Decision

P=0.013

Control

Usual Care

Knowledge Improvement

Percent difference, mean (baseline 1 to baseline 2)
Secondary Outcomes: 6-month implant

P = 0.008

26% decrease in patient going on to LVAD

Control: 80%
Intervention: 54%

LVAD  No LVAD
I DECIDE: LVAD – Decision Aid Dissemination

Go BIG!

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

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)
Implementation

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

- Currently Using, 123
- Not Currently Using, 23
- Used But Stopped, 10
- Refused Decision Aid, 6
- Did Not Respond, 13
- Missing response, 2

Total number of hard copy decision aids sent to programs: 18,090

- Always, as standard care, 80
- Frequently, 23
- A few times, 18
A decision aid for patients considering ICD therapy for primary prevention.
Defibrillator Benefits: SCD-HeFT

<table>
<thead>
<tr>
<th>Treatment Comparison</th>
<th>Hazard Ratio (97.5% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiodarone vs. placebo</td>
<td>1.06 (0.86–1.30)</td>
<td>0.53</td>
</tr>
<tr>
<td>ICD therapy vs. placebo</td>
<td>0.77 (0.62–0.96)</td>
<td>0.007</td>
</tr>
</tbody>
</table>

- Placebo: 244 deaths; 5-yr event rate, 0.361
- Amiodarone: 240 deaths; 5-yr event rate, 0.340
- ICD therapy: 182 deaths; 5-yr event rate, 0.289
Benefit: Results from a 5-year study

With an ICD
29 die, 71 live

Without an ICD
36 die, 64 live
“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.
**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 LVAD:
• Very sick population and urgent implants

Challenges for ICD:
• SDM not seen as universal need among clinicians (despite a mandate from CMS)
• Discussion not always triggered by specific/large event

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?*
Thank You

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

Under what circumstances should a clinician express equipoise even if they don’t feel it on the inside?

Should we work to try to change this mindset?
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 ≠ persuasion

Is COVID19 vaccination an appropriate context for SDM? Why, or why not?
• 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