Improving Medical Decision Quality: Implementing Shared Decision Making

Dan Matlock, MD, MPH
Assistant Professor of Medicine
University of Colorado School of Medicine

Conflicts of Interest/Acknowledgments

- No conflicts to disclose

- Acknowledgments:
  - NIH (NIA, NHLBI)
  - The Patient Centered Outcomes Research Institute (PCORI)
  - The John A. Hartford Foundation/American Federation for Aging Research
There is a 30% chance of rain tomorrow

30% chance of rain

750 people on the street were asked what does this mean

- It will rain tomorrow in 30% of the region
- It will rain tomorrow for 30% of the time
- It will rain on 30% of the days like tomorrow

Gigerenzer, Psychologic Science and the Public Interest, 2008
30% chance of rain

750 people on the street were asked what does this mean

- It will rain tomorrow in 30% of the region
- **It will rain tomorrow for 30% of the time**
- It will rain on 30% of the days like tomorrow

Gigerenzer, Psychologic Science and the Public Interest, 2008

People on the street

“3 out of 10 meteorologists believe it will rain.”
“Thirty percent means that if you look up to the sky and see 100 clouds, then 30 of them are black.”
“It’s not about time, it indicates the amount of rain that will fall”
“If we had 100 lives, it would rain in 30 of these tomorrow”

Gigerenzer, Psychologic Science and the Public Interest, 2008
Overview

- The Problem: Poor decision quality
- The Consequence: Erosion of trust
- The Solution: Better Shared Decision Making
Quality Care is:

- Patient-centered
- Safe
- Effective
- Equitable
- Timely
- Efficient

"Patient-centered: providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions."

- Crossing the Quality Chasm, 2001 – 6 Aims of Quality Improvement
Decision Quality: Definitions

‘the extent to which a decision reflects the considered preferences of a well-informed patient, and is implemented’

* Sepucha, Health Affairs, 2004
Decision Quality: Knowledge

• 1995, the UK Committee on Safety of Medicines issues a warning:

  “oral contraception pills increase the risk of potentially life-threatening blood clots by 100%”

Pill Scare in England

![Graph showing abortion rates from 1990 to 2000](image)
Pill Scare in England

- Actual increase: $1/7000 \rightarrow 2/7000$

- Relative Risk of 100%; Absolute Risk 0.014%

- 1996
  - 13,000 additional abortions
  - 13,000 additional births
  (Risk of blood clots with pregnancy and abortions 10 fold higher than with OCPs)

Relative vs. Absolute Risk Reduction

<table>
<thead>
<tr>
<th></th>
<th>Relative Risk Reduction</th>
<th>Absolute Risk Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>100/100 \rightarrow 50/100</td>
<td>50%</td>
</tr>
<tr>
<td>B</td>
<td>2/100 \rightarrow 1/100</td>
<td>50%</td>
</tr>
</tbody>
</table>
Relative vs. Absolute Risk Reduction

What’s wrong?

• Denominator Neglect: Humans think that relative risks are absolute risks

• Framing:
  • Benefits – relative risks
  • Harms – absolute risks

Example: Implantable Defibrillators

<table>
<thead>
<tr>
<th>Treatment</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>

Bardy, NEJM 2005
Example: Implantable Defibrillators

**RRR = 0.36-0.29/0.36 = 0.20 (20%)**
**ARR = 0.361-0.289 = 0.072 (7.2%)**

Bardy, NEJM 2005
Survey of 295 people with ICDs

![Graph showing number of lives saved out of 100 over 5 years](image)

Matlock, AHA QCOR Abstract, 2012

Potential Harms of ICDs

- Procedural risks (Infection, Bleeding, etc.)

  Additionally:
  - Increased Heart Failure admissions (Goldenberg I, Circulation. 2006)
  - Anxiety/Depression/PTSD/QOL (Sears SF, Heart. 2002, Noyes K, Medical Care. 2007)
  - Inappropriate shocks (Sears SF, Am. J of Card. 2006)
  - Potential suffering at the end-of-life (Goldstein NE, Annals Int. Med. 2004)
Type of Death

Lunney, JAMA. 2003

Type of Death

Lunney, JAMA. 2003
Type of Death

Lunney, JAMA, 2003

Physicians and ICDs (n=11)

- “...I have the EP doctors actually explain it to them in much more detail.”
  - General Cardiologist

- “...and most of them have already made up their mind by the time they come to see me.”
  - Electrophysiologist

Matlock, PACE, 2011
Physician Survey \( (n=1210, \text{ response rate 12\%}) \)

“To what extent does each of the following factors affect your recommendations regarding ICDs for primary prevention of sudden cardiac death?” (Likert scale responses were scored from 0-4)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality benefit data</td>
<td>3.8</td>
</tr>
<tr>
<td>Guideline recommendations</td>
<td>3.6</td>
</tr>
<tr>
<td>Patients comorbidities</td>
<td>3.6</td>
</tr>
<tr>
<td>Patients functional status</td>
<td>3.3</td>
</tr>
<tr>
<td>Patients ability- follow-up with return visits</td>
<td>3.2</td>
</tr>
<tr>
<td>Patients heart failure symptoms</td>
<td>3.1</td>
</tr>
<tr>
<td><strong>Patients preference for the device</strong></td>
<td>2.9</td>
</tr>
<tr>
<td>Patients adherence- prev medical therapies</td>
<td>2.9</td>
</tr>
<tr>
<td>Financial costs to patient</td>
<td>2.5</td>
</tr>
<tr>
<td>Longer term side effects</td>
<td>2.4</td>
</tr>
<tr>
<td>Financial costs to society</td>
<td>2.2</td>
</tr>
<tr>
<td><strong>Patients knowledge about ICDs</strong></td>
<td>2.2</td>
</tr>
<tr>
<td>Short term side effects</td>
<td>1.9</td>
</tr>
<tr>
<td>Reimbursements from your patients insurance</td>
<td>1.6</td>
</tr>
</tbody>
</table>

Caverly, Matlock, Archives of Internal Medicine, 2012

Beneficence (Paternalism)

- “I think my biggest concern is if I convey the risks to them too strongly, that they will choose or make an unwise decision and not proceed with therapy.”

Matlock, PACE, 2011
Survey of 295 people with ICDs

- 59% said “the ICD should never be turned off”
- 36% were not asked if they wanted an ICD
- 17% did not want the ICD
- 16% were involved in the decision less than they wanted to be

Matlock, AHA QCOR Abstract, 2012

Decision Quality: Values

Top Three Goals and Concerns for Breast Cancer Decisions

<table>
<thead>
<tr>
<th>Condition: Goal</th>
<th>Patient</th>
<th>Provider</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keep your breast?</td>
<td>71%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Live as long as possible?</td>
<td>96%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Look natural without clothes</td>
<td>80%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avoid using prosthesis</td>
<td>0%</td>
<td></td>
<td></td>
</tr>
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KR Sepucha et al/Pt Education and Counseling 73(2008)504-10
**Decision Quality: Values**

Top Three Goals and Concerns for Breast Cancer Decisions

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<th>Provider</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keep your breast?</td>
<td>7%</td>
<td>71%</td>
<td>P&lt;0.01</td>
</tr>
<tr>
<td>Live as long as possible?</td>
<td>59%</td>
<td>96%</td>
<td>P=0.01</td>
</tr>
<tr>
<td>Look natural without clothes</td>
<td>33%</td>
<td>80%</td>
<td>P=0.05</td>
</tr>
<tr>
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<td>33%</td>
<td>0%</td>
<td>P&lt;0.01</td>
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**Where DO People Die?**
- Hospital – 50%
- Nursing Home – 30%
- Home – 20%

**Where do People WANT to die?**
- Home – >90%
- Hospital – Rare
- Nursing Home - Never
Knowledge Values Concordance

The Problem: Poor decision quality
The Consequence: Erosion of trust
The Solution: Better Shared Decision Making

Overview
For you personally, what is the number one barrier to engaging patients in a shared-decision making process?

- Not enough time for detailed discussions: 45%
- Patients have difficulty understanding: 38%
- No trusted source of information for patients: 6%
- Prefer patients rely on my recommendations: 4%

“Difficult Patients”
Background

• Disempowerment among patients:

"...is the guy going to be pissed at me for not doing what he wanted? ...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
The Problem: Poor decision quality
The Consequence: Erosion of trust
The Solution: Better Shared Decision Making
Shared Decision Making

“A meeting between two experts”  
Tuckett, 1985

Paternalism  
Consumerism  
(abandonment)
ICDs & LVADs

Implementation of decision aids in heart failure
Test case: LVAD

Daniel D. Matlock, MD, MPH
Associate Professor of Medicine
University of Colorado School of Medicine
Co-Director – Shared Decision Making Core at ACCORDS
(About and Child Center for Outcomes Research and Delivery Science)
Part of an LVAD

- **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 pumps blood from the heart to the body.
- **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.
The Artificial Heart is For Real

Barney Clark
1982

Dick Cheney
2010

It was the best of times...

McIlvennan, Magid, Ambardekar, Thompson, Matlock, Allen. Circ Heart Fail. 2014
It was the worst of times…

McIlvennan, Magid, Ambardeker, Thompson, Matlock, Allen. Circ Heart Fail. 2014

Heart Failure is increasing

Donor hearts are not

Overview

- Background on the LVAD
- Discussion of our implementation trial
  - Decision aid design for context and culture
  - Trial design (effectiveness/implementation hybrid)
Decision aid design for context/culture

- Address emotion
  - “…it’s get the LVAD or push up daisies…”

- Patient narratives
  - Candidates were already being introduced to patients

- 26 minute video
  - “I wish it was longer”

DECIDE – LVAD trial

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, PhD

Organization
University of Colorado Denver

Funding Agency
Communication and Dissemination Research

Year Awarded
2014

Total Project Budget
$2,352,984

Project Period
3 Years
DECIDE-LVAD Trial

**Objective:** Understand the effectiveness and implementation of a shared decision support intervention for advanced heart failure patients considering DT LVAD.

**Key Considerations:**
1. Desire to evaluate implementation in multiple real-world settings
2. Specific small population (DT LVAD 25-50 per site/year)
3. Max 5-6 sites due to budget constraints ($2M)
4. Randomization needed to assess effectiveness
5. Intervention involves both patients and clinicians/program
Study Design Options for DECIDE-LVAD Trial

- **Classic patient-level randomization**
  - Intervention is patient AND program-based; not at individual-level
  - Diffusion among participants at each site is probable

- **Cluster randomization**
  - Concerns about statistical power with only 6 total sites
  - 3 sites intervention, 3 sites control
  - Homogeneity of intervention participants and control participants

- **Stepped wedge cluster randomization . . .**

---

**Figure 5. Stepped wedge randomization scheme.**

<table>
<thead>
<tr>
<th>Site</th>
<th>Pre 4 months</th>
<th>Phase 1 4 months</th>
<th>Phase 2 4 months</th>
<th>Phase 3 4 months</th>
<th>Phase 4 4 months</th>
<th>Post 4 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coordinating Site</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Random Sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Random Sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Random Site</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

- **Control Period**
- **Roll-Out**
- **Intervention Period**

---
Stepped Wedge Design Ideal When...

- **Diffusion** of intervention to control participants is likely
- **Implementation** is a focus
  - Iterative adjustment possible at each phase
  - All clusters go through implementation (not half)
- **Staggered** rollout provides **logistical**, practical, or financial advantages
- **All sites** wish to receive the intervention

Evaluation Framework

- **Reach:**
  - % eligible patients and caregivers
- **Effectiveness**
  - Increased knowledge
  - Value-treatment concordance
- **Adoption**
  - Taken up by key personnel
- **Implementation**
  - Consistently used
- **Maintenance**
  - Continued use after trial completion
Evaluation Procedures

- **Reach & Effectiveness:**
  - Patients and caregivers
  - Surveys:
    - Baseline
    - 1 month
    - 6 months

- **Adoption, Implementation & Maintenance**
  - Qualitative interviews:
    - Baseline
    - Post-intervention implementation
    - Post-study completion
  - Checklist of education materials/procedures for each patient

Adoption, Implementation, Maintenance

- 5/1/2015 Begin data collection
- 7/1/2017 End data collection
- Interview #1
- Interview #2
- Interview #3
Implementation Intervention

- **Pre-implementation:**
  - Planning, identifying key people

- **Implementation visit**
  - 1 hour: Grand rounds presentation (large audience)
  - 1 hour: Communication Training (heart failure team)
  - 1 hour: Discuss new process
    - Already a delivery process “plug and play”

- **Post-implementation**
  - Ongoing site support
  - Follow-up visit

Communication Training

Four key communication concepts
1. How to introduce the LVAD
2. How to frame the options:
3. How to respond to emotions:
4. How to provide recommendations

“Bad”

“Good”
Disadvantages / Challenges

- **Confounding Factors:**
  - Validity could be challenged by temporal trends
    - LVAD technology changing
    - Shared decision making becoming more accepted
  - Diffusion:
    - Sites may start using intervention principles during the control phase
  - Practical:
    - All sites start and end at the same time
    - Must have committed sites
      - Contracts and IRB executed promptly
      - Agreement to implement intervention at designated time

Diffusion in Colorado
Thank You

- Core Team:
  - Diane Fairclough
  - Erin Leister
  - Jocelyn Thompson
  - Dan Matlock
  - Larry Allen
  - Colleen McIlvennan
  - Laura Portalupi
  - Amy Jenkins
  - Carmen Lewis
  - Russ Glasgow
  - Jean Kutner
- Mayo, Duke, BWH, Wash U, St. Vincent’s
- Univ. of Colorado Hospital
  Advanced HF Program,
  Cardiology, DOM
- Patients and caregivers

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