SHARED DECISION MAKING RESEARCH METHODS: STAKEHOLDERS, DEVELOPMENT, TESTING, AND IMPLEMENTATION

Dan Matlock, MD, MPH - University of Colorado
Kathleen Fairfield, MD, MPH, DrPH - Maine Medical Center
Michael Pignone, MD, MPH - University of North Carolina
Carmen Lewis, MD, MPH - University of Colorado
DISCLOSURES

- Financial Disclosure: All presenters have received funding from The Informed Medical Decisions Foundation

- Unlabeled or unapproved uses: None
OVERVIEW

Workshop Outline

- Introduction
- Background (10 min) – Kathleen Fairfield
- Decision Aid Development (10 min) – Dan Matlock
- Efficacy Trials (10 min) – Michael Pignone
- Implementation (15 min) – Carmen Lewis
- Group Example (35 min) – Lung Cancer Screening
  - 15 minutes of group work
  - 15 minutes of discussion/questions
- Required Session Evaluation (10 min)
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Definition of Shared Decision Making (SDM)

Interactive process between patient (and family) and clinician(s):

- Engages the patient in decision-making
- Provides patient with accurate information about options and outcomes
- Tailors treatment to patient preferences and values

Preference Sensitive Care

Treatments that involve significant tradeoffs affecting the patient’s quality and/or length of life.

Decisions about these interventions – whether to have them or not, which ones to have – ought to reflect patients’ personal values and preferences, and ought to be made only after patients have enough information to make an informed choice.

The Dartmouth Atlas Project www.dartmouthatlas.org
Unwarranted Variation:
The Overuse, Underuse, and Misuse of Care

- There is unwarranted variation in the practice of medicine and the use of medical resources in the United States
- Underuse of effective care
- Misuse of preference-sensitive care
- Overuse of supply-sensitive care

The Dartmouth Atlas Project www.dartmouthatlas.org
Elements for Improving Decision Making

- Training for providers and the care team
  - How to have SDM conversations and use decision aids
- Health policies that encourage or require shared decision making
- Decision aids
What is a Decision Aid?

- tools designed to help people participate in decision making
  - Information on health care options, including risks and benefits, and limits of scientific knowledge
  - Help patients clarify and communicate the personal value they associate with different features of the options
  - Guide patients in their deliberation
The International Patient Decision Aid Standards (IPDAS) Collaboration

Purpose:

- enhance quality and effectiveness of DA by establishing a shared evidence-informed framework with a set of criteria for improving their content, development, implementation, and evaluation
IPDAS's 10 Quality Dimensions

- Providing Information
- Presenting Probabilities
- Clarifying Values
- Providing Guidance
- Systematic development
- Based on Scientific Evidence
- Disclosing Conflicts of Interest
- Plain language (literacy)
- Evaluation
- Establishing Effectiveness
A to Z Inventory of Decision Aids

Search all decision aids:

OR

Browse an alphabetical listing of decision aids by health topic.

The A to Z Inventory of Decision Aids is designed to help you find a decision aid to meet your needs. It contains up-to-date and available decision aids meet a minimal set of criteria.

More information about decision aid developers.

You may search for a decision aid using keywords or browse an alphabetical listing.

Note: Addition of other decision aids to the A to Z inventory is an ongoing process.
Search Results - A to Z Inventory of Decision Aids

Your search: **psa** found the following decision aids (see list below).

Click on a **title** to view a brief description that will help you decide if the decision aid will meet your needs, or try another keyword search to look for other decision aids.

### Search again:

**psa**

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**Prostate Cancer**

- **Hormone Therapy: When the PSA rises after prostate cancer treatment** [Informed Medical Decisions Foundation](#)
- **Is a PSA test right for you?** [Informed Medical Decisions Foundation](#)
- **Prosdex: A PSA decision aid** [Decision Laboratory, Cardiff University](#)
- **Prostate Cancer Screening with PSA Testing** [American Society of Clinical Oncology (ASCO)](#)
- **Prostate Cancer Screening: Should I Have a PSA Test?** [Healthwise](#)
- **Prostate cancer screening: Should you get a PSA test?** [Mayo Clinic](#)
- **Prostate specific antigen (PSA) test** [Option Grid Collaborative](#)
- **PSA (prostate specific antigen) testing for prostate cancer: An information sheet for men considering a PSA test** [University of Oxford](#)
- **Should I Have a PSA Test?** [University of Sydney](#)
- **Should You Get a PSA Test? A Patient-Doctor Decision.** [Virginia Commonwealth University](#)
Overview

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DECISION AID DEVELOPMENT

Dan Matlock, MD, MPH
Assistant Professor of Medicine, University of Colorado
2014 SGIM Shared Decision Making Workshop
DISCLOSURE

- Financial Disclosure: None
- Unlabeled or unapproved uses: None
Step 1 – Understand the decision:
- Evidence review
- Needs assessment

Step 2 – Develop the initial draft of the decision aid:
- Type of Tool
  - Format? When would the tool be used?
  - Use the IPDAS criteria as a guide for what to include in a decision aid.

Step 3 – Iteratively modify the tools with end-users:
- Accuracy, Understandability, and Balance
- Stakeholder engagement
STEP 1: EVIDENCE REVIEW

- Background Evidence Document
- Systematic Review or Meta-analysis
STEP 1: DECISION NEEDS

Ottawa Decision Support Framework

**Decision Needs**

(Knowledge/expectations, values, conflict, support)

**Decision Support**

(Decision Aids, Decision Coaching)

**Decision Quality**

(Informed, Values-based Decisions)
STEP 1: DECISION NEEDS

- Define the Target Group
- Determine who influences the target group
- Key informants, focus groups, surveys
  - How did you feel making this decision?
  - What was difficult about this decision?
  - Who else was involved?
- Understand the context to inform future implementation
DECISION NEEDS: EXAMPLE

- Destination Therapy Left Ventricular Assist Devices
  - Frightened Patients
  - Passive and overly burdened Caregivers
  - Disempowered LVAD coordinators
Step 1 – Understand the decision:

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Step 2 – Develop the initial draft of the decision aid:

- Type of Tool
  - Format? When would the tool be used?
  - Use the IPDAS criteria as a guide for what to include in a decision aid.

Step 3 – Iteratively modify the tools with end-users:

- Accuracy, Understandability, and Balance
- Stakeholder engagement
TYPES OF DECISION AIDS

- Simple paper decision aids (Ottawa, Mayo, Option Grids)
- Videos (IMDF)
- Interactive web sites
- Telenovelas
WHAT BELongs IN A DECISION AID?

International Patient Decision Aid Standards (IPDAS)

http://ipdas.ohri.ca
INTERNATIONAL PATIENT DECISION AID STANDARDS (IPDAS)

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

<table>
<thead>
<tr>
<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>
</tr>
<tr>
<td>ICD therapy vs. placebo</td>
<td>0.77 (0.62–0.96)</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)

Bardy, NEJM 2005
With an ICD
29 die, 71 live

Without an ICD
36 die, 64 live

- 😊 Number of people who live because of the ICD
- ❌ Number of people who die
- 😞 Number of people not affected
INTERNATIONAL PATIENT DECISION AID STANDARDS (IPDAS)

1. Provide information about options
2. Present probabilities (unbiased and understandable)
3. Provide methods for clarifying values
4. Structured guidance for deliberation and communication
What else do you need to help you make your decision?

Many people have questions or concerns. It may be helpful for you to talk with your family and friends. You may want to share the information in this decision aid with them. You should also share with your doctor your questions and concerns before making a final decision. It's important that you have all of the information you need to make a decision that is right for you.

You have the right to make your own choices!

You know what is important to you better than anyone else. Any decision about your treatment should be based on your goals and values!

What questions do you have?
Step 1 – Understand the decision:
- Evidence review
- Needs assessment

Step 2 – Develop the initial draft of the decision aid:
- Type of Tool
  - Format? When would the tool be used?
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Step 3 – Iteratively modify the tools with end-users:
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Evidence synthesis

Needs Assessment
Observations
clinical encounters

Initial prototype

Field testing

Designers
Study team
Patient advisory groups
Clinicians
Stakeholders

Modified prototype

Final Decision Aid

Evaluation (trial)
STAKEHOLDER ENGAGEMENT

“Stakeholders—Includes clinicians (e.g., physicians, nurses, pharmacists, counselors, and other providers of care and support services); patient-advocacy groups; community groups; researchers; health-related associations; policy makers; and organizational providers, purchasers, payers, and industries for whom the results of the research will be relevant.”

- PCORI
Decision Aids – Not a replacement for a discussion with a clinician

“A meeting between two experts”

Paternalism

Consumerism (abandonment)

Tuckett, 1985
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Evaluating the efficacy of decision aids

Michael Pignone, MD, MPH
Professor of Medicine
UNC Department of Medicine
Decision aids are tools that help patients . . .

- Understand they have a decision
- Recognize possible options
- Know pros and cons of each option
- Recognize uncertainty
- Clarify values
- Come to a decision
- Interact with health care system
How can we tell if decision aids are efficacious?
Study design options

• Single group trial (“before-after”)
  – Less costly- may be good for pilot studies
  – Unable to account for secular trend or effects of repeat questions

• Patient-level randomized controlled trial
  – Good for reducing bias / confounding
  – Need to consider what to use as “control”
  – More expensive
  – Harder to account for contamination / co-interventions

• Cluster randomized trial
  – Expensive
  – Better accounts for co-interventions
  – Moderate strength for controlling bias/ confounding

• Stepped wedge design
Populations

• Feasibility / generalizability trade-offs
• Ideally, would like to test in actual patients facing the decision (for the first time)
• In some cases, may need to recruit:
  – Those who faced the decision previously
  – Volunteers who are not facing the decision
• Complex decision issues: surrogacy, family involvement
Intervention

- Decision aid alone
- Decision aid + coaching
- Decision aid + environmental preparation
Comparators

- Usual care
- Attention control
- Alternative decision-making topic
- Enhanced decision support vs. basic decision support
Outcome Measures

- Decision process measures
- Decision quality measures
- Distal outcomes
Decision process measures

• Recognize decision
• Feel informed
• Be clear about what matters
• Discuss preferences with provider
• Be involved in decision making
Decision quality measures

• Knowledge (objective)
  – Can be hard to determine key facts
  – Retention

• Concordance between values and chosen option
  – Not always easy to “map”
  – Can be measured in aggregate; harder at individual level
Distal outcomes

- Treatment choice
- Regret
- Quality of life
- Costs
- All “meaningful” but can be “diluted” by many factors, including heterogeneity of values; requires very large sample sizes
Other Measures

• Potentially important co-variates:

• Individual
  – Prior experience
  – Prior knowledge
  – SES

• Provider / system
  – Economic incentives
  – Local norms
Cochrane Collaboration systematic review

• 115 trials with 34,444 participants
• Decision aids:
  – Increase knowledge, accurate risk perception
  – Reduce decisional conflict
  – Increase value-concordant decisions
  – Effect on test use depends on baseline rate
• Most studies conducted in settings where decision aid use can be ensured
Conclusions

• Decision aids generally efficacious, particularly for proximal outcomes
• Not clear if there is a “class effect” especially for more distal outcomes
• Researchers must balance issues of feasibility with desire to maximize internal and external validity
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DISCUSSION OF IMPLEMENTATION

- Approaches to DA delivery
- Encouraging patient use
- Engaging providers
APPROACH NEEDS TO MATCH DECISION

- Medical decisions require different depths of deliberation
- Primary care decisions
- Specialty care decisions
PRIMARY CARE IMPLEMENTATION

- Variety of decisions
- Competing priorities
- Identifying decision window often difficult
- Engagement may be challenging
SPECIALTY CARE DECISIONS

- Focus on one decision
- Time to deliberate
- One time decision
- Long term consequences
- Engagement likely easier
STEPS TO IMPLEMENTATION

- Identify appropriate patients
- Determine delivery processes
- Outcomes
IDENTIFYING APPROPRIATE PATIENTS

- Process depends on the decision and decision making window
  - Cancer
  - Hip replacement
- Physician identify patients
- Patient requests
- Clinical data using billing and patient reported information and preference
DETERMINE DELIVERY PROCESS

- Who will deliver DA?
- How will it be delivered?
- When will it be delivered?
WHO WILL DELIVER DA?

- Provider if engaged in process
- Staff member empowered to ID patients and provide DA on behalf of provider
- Disease management staff for particular diseases
- Staff for outreach
HOW WILL DA BE DELIVERED?

- Depends on the media
- Electronically
  - With EHR
  - Patient portal
  - email
- In person or mailed
  - Print, DVD,
WHEN WILL DA BE DELIVERED?

- Timing important for shared decision making
- Before visit may set up SDM if provider aware
- In visit can result in SDM interactions
- After visit may have to return for SDM interaction
- Goal informed decision timing not as critical
IMPLEMENTATION OUTCOMES

- Delivery to those eligible
- Use of DA by patients
- Effect on interaction
  - Quality of interaction
  - Shared decision making
- Use of health care services and cost
- Sustainability of delivery
ENCOURAGING PATIENT USE

- Match deliberation with length of the DA
- Make it as easy to use
- Multiple methods may be needed for convenience
- Incentives?
PROVIDER ENGAGEMENT

- Aware of content of DA
- Training in using tools and shared decision making
- Champions to change culture
SUMMARY

- Approach to implementation depends on topic and site
- Consider work flows
- Engage stakeholders
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GROUP EXAMPLE

- Lung Cancer Screening
  - Three groups:
    - Development
    - Efficacy
    - Implementation

- Handout
THANK YOU!

- Evaluation