The Role of Patient Decision Aids in Patient-Centered Outcomes Research

Robert J. Volk, PhD
General Internal Medicine

UTMB R24 Webinar June 13 2014
bvolk@mdanderson.org
Decisional Dilemmas

Cancer Treatment
Localized (low risk) prostate cancer
Intermediate risk prostate cancer and short-term ADT

Cancer Screening
Prostate cancer
Colorectal cancer
Lung cancer

Overview

1. Define IDM / SDM and Patient Decision Support Technologies

2. Are decision aids effective?

3. Certification of patient decision aids
The case for IDM and the need for decision support tools
Patient Engagement Takes Center Stage

- February 2013 theme issue

Patient Engagement Topics

- End-of-life care
- Health costs
- PCOR
- Barriers to SDM
- Data needs of patients
- E-health
- Decision aids

http://www.healthaffairs.org/
The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.
Patient Centered Outcomes Research Institute (PCORI)

- Established by Patient Protection and Affordable Care Act of 2010.
- …to help patients, clinicians, purchasers, and policy makers make better informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.”

www.pcori.org
Affordable Care Act and SDM

• Funds an independent entity to develop consensus-based standards for certifying patient decision aids.
• Funds development and evaluation of patient decision aids.
• Authorizes CMS to test shared-decision making models.
• Implementation may be mandated throughout Medicare.
Defining IDM / SDM and Patient Decision Support Technologies
Shared Decision Making

A process by which a healthcare choice is made between the patient and one or more health professionals. The crux of patient-centered care.

Facilitated by:
- Patient decision aids
- Decision coaching

Shared Decision Making (SDM)

- SDM is defined as “an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences.”

A Model of SDM in Clinical Practice

Deliberation

- Initial Preferences
- Choice Talk
- Option Talk
- Decision Support: Brief as well as Extensive
- Informed Preferences
- Decision Talk
- Decision

Elwyn, JGIM 2013
How do we enhance SDM?

- **Patient tools** – ie, decision aids
- **Clinician training**
- **Decision “coaches”**
- **Change reimbursement**
- **Practice redesign**

SDM is a process; patient decision aids can help facilitate the process. BUT, they are not sufficient to ensure a SDM process occurs (and are not necessary for SDM to occur).
What are Patient Decision Support Technologies?

“Decision support interventions help people think about choices they face: they describe where and why choice exists; they provide information about options, including, where reasonable, the option of taking no action. These interventions help people to deliberate, independently or in collaboration with others, about options, by considering relevant attributes; they support people to forecast how they might feel about short, intermediate and long-term outcomes which have relevant consequences, in ways which help the process of constructing preferences and eventual decision making, appropriate to their individual situation.”

Patient Decision Support Technologies

• They are not designed to:
  – advise people to choose one option over another
  – replace physician consultation

• Bottom line:
  – Patient decision aids prepare patients to make informed, values-based decisions with their health care providers

O’Connor et al Cochrane Library 2009.
When do you need decision aids?

• For preference-sensitive decisions:
  – Decisions where there is uncertainty about the optimal course of action
  – There are clear trade-offs between harms and benefits
  – The patient’s preferences are central to determine which option should be pursued
Decision aids have the potential to...

• Save time during the clinical encounter

• Improve quality of “informed consent”

• Decrease practice variation (and perhaps health care costs) – maybe?
Case Examples

1. Paper-based tools
2. Video tools
3. Web-based tools (multi-media)
4. Entertainment-based tools (multi-media)
5. Encounter-based tools
Ottawa A-Z Decision Aid Inventory

http://decisionaid.ohri.ca/AZinvent.php

- Hundreds of decision aids for all types of healthcare decisions
- International Patient Decision Aid Standards (IPDAS) collaboration, assessment of quality criteria
Paper-Based about End-of-Life Decisions (Ottawa Patient Decision Aids)

Understanding the OPTIONS

Planning care for critically ill patients in the Intensive Care Unit

- [http://decisionaid.ohri.ca/docs/das/Critically_Ill_Decision_Support.pdf](http://decisionaid.ohri.ca/docs/das/Critically_Ill_Decision_Support.pdf)
New “Paper-based” Materials from ACS

16-page Patient Decision Aid

Testing for Prostate Cancer

"Should I be tested? Is it the right choice for me?"

Does the American Cancer Society say that all men should be tested for prostate cancer?

No, we do not. The research that has been done is not clear. Some research shows that finding prostate cancer early will stop some men from dying from the disease. Other research does not show this. And treating prostate cancer can have some serious side effects.

The American Cancer Society says that men should make an informed decision. This means that you should hear about prostate cancer and testing. You should think through the risks and possible benefits. Then, after talking with your doctor, you should decide if testing is the right choice for you.

What are my chances of having prostate cancer?

Based on the way prostate cancer testing is done today, about 17 out of 100 men (17%) who are now age 50 will be diagnosed with prostate cancer during their lifetime.

17 out of 100 men (17%) age 50 will be diagnosed with prostate cancer during their lifetime.

17 out of 100 men (17%) age 50 will be diagnosed with prostate cancer in their lifetime, and 3 out of 109 men (3%) will die of prostate cancer.

What is important to you?

There are many reasons men decide to be tested or not be tested for prostate cancer. Some reasons are listed below. Place a check by the reasons that are important to you.

Some reasons to be tested

- Check what's important to you
- I will have peace of mind when I know the test results.
- I will know if I have prostate cancer or not.
- I will have a better chance of getting cancer treatment if a cancer is found early.

Other reasons important to you? Let them know.

What do you think about testing for prostate cancer today? Look online or call 1-800-ACS-2345.

If you are concerned about prostate cancer or if it is time for you to think about testing, talk. Decide if testing is the right choice for you.
Use of video for patient decision support
Design Requirements

- For use with screen-eligible patients at CPC
- Linear
- Video-based with narration
- Delivered on exam room computers or education rooms
- 5 minutes max
- English only
- 8th grade reading level
- Risk communication modules

Currently being evaluated in PCORI contract CER-1306-03385
Selected Screenshots from Lung Ca Video

- CT scan of lungs.
- Bar graph showing estimated number of deaths per year in the US due to cancer types: Lung, Prostate, Breast, Colon.
- Smiley and sad face emojis indicating different cancer diagnosis conditions:
  - 😞 Diagnosed with Lung cancer.
  - 😞 Sad face with text: Suspicious result, but no lung cancer.
  - 😄 Happy face with text: Result not suspicious for lung cancer.

- Person undergoing CT scan.
Patient Narratives: Experience Narratives

**Video documentary**

- Decision making about End-of-Life decisions
- 50 patients with malignant glioma recruited from outpatient oncology clinics.
- 90% white; 78% some college/grads
- 76% had advanced directives

## Decisions about End-of-Life Care

<table>
<thead>
<tr>
<th>Levels of Care</th>
<th>Verbal Group - audio descriptions of...</th>
<th>Video Group - verbal content PLUS images of...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life-prolonging care (prolong life at any cost)</td>
<td>CPR, intubation, ICU</td>
<td>Patients in ICU, ventilation, simulated code &amp; CPR, IV meds</td>
</tr>
<tr>
<td>Basic medical care (maintain physical/mental function)</td>
<td>Hospitalization, IV fluids, antibiotics (no life-prolonging measures)</td>
<td>Patients receiving IV antibiotics, medical ward, nasal cannula</td>
</tr>
<tr>
<td>Comfort care (maximize comfort, alleviate suffering)</td>
<td>Medications to relieve symptoms (no hospitalization or life-prolonging measures)</td>
<td>Patient on home hospice care, nasal cannula, medical assistant</td>
</tr>
</tbody>
</table>

Results: Goals of Care Preferences

Multi-media, web-based patient tools
Web-based Decision Aids

Taking Control: Non-surgical Treatment Options for Urinary Incontinence in Women

- released by AHRQ September 17, 2013.

http://www.effectivehealthcare.ahrq.gov/index.cfm/tools-and-resources/patient-decision-aids/
 Features of Taking Control

• Visually-engaging, flat design
• Simple navigation
• Multimedia (video, graphics text)
• Normative messaging (quotes)
• Values-prompting questions
• Deliberative messages
• Tailored print-out
Web-based Decision Aids

Knowing Your Options: A Decision Aid for Men with Clinically Localized Prostate Cancer

- released by AHRQ
  September 8, 2011.

http://www.effectivehealthcare.ahrq.gov/ehc/decisionaids/prostate-cancer/?EC=BV
Features of the Aid

- Reinforcing messaging
- Simple navigation
- User-entered data
- Animation
- Visually-engaging design
- Values-prompting questions
- Deliberative messages
- Tailored print-out
Entertainment-based approaches to patient decision support
Entertainment-based Patient Decision Aid for CRC Screening

This project was supported by Award Number R21CA132669 from the National Cancer Institute.
Entertainment-based Decision Aids

Telenovelas to promote engagement

Animations to communicate key learner content
Screenshots of Test Attributes

**Discomfort**
- **FOBT**
- **Flexible Sigmoidoscopy**
- **Colonoscopy**

**Frequency**
- **FOBT**
- **Flexible Sigmoidoscopy**
- **Colonoscopy**

**Complications**
- **FOBT**: None
- **Flexible Sigmoidoscopy**: Possible tears or bleeding
- **Colonoscopy**: Possible tears or bleeding

**Accuracy**
- **FOBT**: GOOD
- **Flexible Sigmoidoscopy**: BETTER
- **Colonoscopy**: BEST
Encounter-Based Decision Aids

(transactional or communication aids)
Mayo Shared Decision Making
National Resource Center

- For use during clinical encounters
- Attribute comparisons (vs option comparisons)
- Some tools only address risk
- [http://shareddecisions.mayoclinic.org/decision-aids-for-diabetes/](http://shareddecisions.mayoclinic.org/decision-aids-for-diabetes/)
**SDM Made Easier**

**Option Grids**
- Encounter-based tools
- Promote discussion
- FAQs by options layout
- Summary of evidence

*Elwyn et al., Pat Ed Counsel 2013.*

---

**What matters most...**

**Osteoarthritis of the Hip**

This grid is designed to help you and your clinician decide how to best manage your hip pain and activity level. The first steps are to become as fit as possible, work to approach your ideal weight, and consider trying physical therapy. Surgery is normally recommended only after non-operative treatments have been tried.

<table>
<thead>
<tr>
<th>Frequently asked questions</th>
<th>Non-operative treatment</th>
<th>Hip replacement surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will this reduce the pain I have in my hip?</td>
<td>It depends on who you are and which of the many possible treatments you try. You should talk to your clinician about which treatments might work best for you. Tablets like acetaminophen (Tylenol), ibuprofen (NSAID), and tramadol as well as steroid injections may also be recommended.</td>
<td>Three months after having surgery, around 84 in every 100 people say they are very satisfied with how the surgery improved their level of pain. One year after surgery, around 87 in every 100 people say they are very satisfied with how the surgery improved their level of pain.</td>
</tr>
<tr>
<td>Will this treatment improve my ability to be active?</td>
<td>It may. As you get pain relief, you should be able to be more active and this in turn can also help to reduce pain. It may help to take pain relievers before being physically active.</td>
<td>Yes, the vast majority of patients experience improvement in their activity level. However, not everyone is satisfied with the improvement in their ability to perform some strenuous activities.</td>
</tr>
<tr>
<td>Are there any risks to this treatment?</td>
<td>All medications have some side effects. For example, codeine may lead to constipation and prolonged use of tablets like ibuprofen (NSAIDs) increases your risk of developing stomach bleeding, high blood pressure, and heart or kidney problems. Around 2 in 100 people who receive a steroid injection will experience joint pain and swelling for a day or so after the injection.</td>
<td>Among those over 65 years of age, roughly 3 in every 100 people experience a serious medical complication after surgery such as infection, bleeding, blood clots in the legs or lungs, heart attack, or death. Rare but possible surgical complications include dislocation, fracture, and leg length inequality. The risks of surgery increase with age and if you have other conditions, such as heart or lung disease, are a smoker or are overweight.</td>
</tr>
<tr>
<td>How long will it take me to feel better after the treatment?</td>
<td>Some people experience pain relief within a few days of starting to take pain relievers but others require a few weeks or longer before they notice a difference in their pain.</td>
<td>Pain relief is gradual and rehabilitation can be challenging. You will stay in the hospital for around two to four days. Most people walk unaided after 1 or 2 months. Full recovery usually takes around 1 year.</td>
</tr>
<tr>
<td>Will I need to have more treatment or surgery?</td>
<td>If things don’t get better with one non-operative treatment, talk to your clinician about other non-operative treatments that might work better for you.</td>
<td>The chance of needing your hip replaced for a second time depends on your age and activity level. Around 10 in 100 people will need a second operation to revise their hip replacement within the first 10 years after surgery.</td>
</tr>
<tr>
<td>What are the long term outcomes for people with arthritis who have this treatment?</td>
<td>Many people cope well by using medication, being as active as possible, and losing weight. Some people are not able to achieve pain relief with non-operative methods alone.</td>
<td>Surgery is usually considered after other options have been tried. Around 95 in 100 people are satisfied with the overall results of their surgery one year after having a hip replacement.</td>
</tr>
</tbody>
</table>

---

*Elwyn et al., Pat Ed Counsel 2013.*

http://www.optiongrid.org
Decision Boxes – University of Laval

The fecal occult blood test (FOBT) to screen for colorectal cancer

- Probabilities of benefits and harms
- Patient’s values and preferences

This document prepares the clinician to discuss scientific data with the patient so they can make an informed decision together.

Presenting the fecal occult blood test to patients

What is this test for?
The fecal occult blood test estimates the risk of having colorectal cancer. If the test is positive, the physician usually offers a diagnostic test, such as colonoscopy, to verify that the individual has colorectal cancer.

How is the test performed?
Stool samples are tested for the presence of occult blood every one to two years.

Who might consider being tested?
- Individuals between 50 - 75 years of age, including individuals with first-degree relatives who have had colorectal adenomas or cancer.
- Individuals younger than 50 with first-degree relatives who developed cancer at a younger age, or with multiple affected first-degree relatives.
- This test does not apply to individuals at greater than average risk for colorectal cancer who should follow guidelines specific to their personal and family histories. Risk factors that put an individual at greater than average risk for colorectal cancer are: inflammatory bowel disease and certain inherited syndromes (Lynch syndrome/hereditary nonpolyposis colorectal cancer (HNPCC), Familial polyposis syndrome).

Why do patient preferences matter when making this decision?
- There are pros and cons to this screening test:
  - PROS: Screening can reduce mortality from colorectal cancer.
  - CONS: The majority (85-90%) of individuals who test positive with the FOBT do not have colorectal cancer. To verify if they have colorectal cancer, they will undergo additional colonoscopy, that can have serious but uncommon side effects.
  - Both doing and not doing the test are acceptable options, so we propose that:
    - The decision takes into account the patient’s values and preferences.
    - The clinician shares this decision with the patient.

Questions to identify the patient’s decision making needs:
- Do you have any questions about the benefits and harms of each option?
- Which benefits and harms matter most to you?
- Do you feel sure about the best choice for you?
- Who will support and advise you in making a choice?

Benefits of screening
- Increased survival
  For each 1000 individuals screened every one or two years during 13 years, 1 death (0.1%) from colorectal cancer is prevented.

- Reassurance
  For each 1000 individuals screened, 974 (97.4%) are identified as being at low risk of having colorectal cancer. These individuals are reassured.

Harms of screening
- False reassurance
  Of the 974 individuals identified as low risk, 3 actually have colorectal cancer. These individuals were falsely reassured.

- False alarm
  For each 1000 individuals screened every one or two years during 13 years, 26 are identified as being at high risk of having colorectal cancer. 23 (90%) of them undergo further diagnostic testing (colonoscopy and/or double contrast barium enema) and 26 will be found to have colorectal cancer.

Diagnostic tests can cause complications:
- Less than 1% experience bleeding or a perforation of the bowel.

Fecal occult blood test performance

1000 persons screened with biannual FOBT over 11 years

- 26 positive FOBT (2.6%)
- 974 negative FOBT (97.4%)
- 23 colonoscopies and other investigations (2.3%)
- 3 received no follow-up testing (0.3%)
- False Reassurance: 3 cancers missed (0.3%)
- False Alarms: 26 cancers detected (2.6%)

How much confidence can we have in these results?
Survival [1]: High. Data are based on a systematic review of 4 randomized controlled trials that showed consistent results across trials.

Reassurance and False Alarms [2-4]: Moderate. Data are based on results from the best available study that used a more accurate test (non-inflated samples) and followed up all participants who originally met the inclusion criteria. Results are consistent across trials but are imprecise (large confidence intervals) likely because of the different methods to analyze samples (rehydration or non-rehydration of hemoccult slides).

Study descriptions and references

Study Design: Randomized controlled trial comparing individuals invited to FOBT screening every two years with individuals invited to be screened. Participants, 121,832 individuals (49% men and 51% women) between the ages of 45-75. Length of follow-up 11 years. Follow-up to positive FOBT confirms colorectal polyps or colorectal cancer.

© Université Laval, 2011 all rights reserved
See page 2 for the current state of knowledge
Are Patient Decision Aids Effective in Promoting Informed Decisions?
Cochrane Review: PtDAs Updates

Stacey, Eisenberg Conference 2013; O’Connor, 1999; 2003; 2009; Stacey, 2011; 2013
# Topics of Decision Aids (N=117)

## Medical (n=27+8)
- 10 HRT
- 3 atrial fib anti-coagulation
- 2 + 1 cardiovascular (Sheridan)
- 2+1 diabetes (Mann D)
- 1 hypertension
- 1 +1 osteoporosis (Montori)
- 1 +1 chemotherapy (Leighl)
- 1 multiple sclerosis
- 1 schizophrenia
- 1 depression
- 1 natural health products
- 1 ovarian risk management
- 1 +1 breast ca prevention (Fagerlin)
- 1 +1 osteoarthritis knee (de Achaval)
- +1 acute respiratory infection (Légaré)
- +1 contraceptives (Langston)

## Screening (n=32+14)
- 12 +4 PSA (Allen, Evans, Myers, Rubel)
- 7 BRCA1/2 genetic
- 6+5 colon cancer (Lewis, Miller, Schroy, Smith, Steckelberg)
- 5+1 prenatal (Björklund)
- 1 colon ca genetic
- 1+1 mammography (Mathieu 2010)
- +2 diabetes (Mann E, Marteau)
- +1 cervix ca (McCaffery)

## Surgical (n=19+6)
- 4+1 mastectomy (Jibaja-Weiss)+1 reconstruction
- 3+1 prostatectomy (Berry)
- 3+1 hysterectomy (Solberg)
- 2 prophylactic BRCA1/2
- 2 dental
- 2 coronary revascularization
- 1 orchiectomy for prostate ca
- 1 circumcision
- 1 back
- +1 bariatric (Arterburn)
- +1 vasectomy (Labrecque)
- +1 long term feeding tube placement (Hanson)

## Obstetrics (n=4+2)
- 2 VBAC
- 1 termination
- 1 breech
- +1 labour analgesia (Raynes-Greenow)
- +1 embryo transplant (van Peperstraten)

## Vaccine (n=2+1)
- 1 infant
- 1 Hep B
- +1 influenza (Chambers)

## Other (n=2)
- 1 autologous blood donation
- 1 CF referral for transplant

Stacey, Cochrane Reviews, 2013
From 2013 Cochrane review compared to standard care, decision aids...

<table>
<thead>
<tr>
<th>Improve Decision Quality</th>
<th>Decisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>↑ 14% knowledge</td>
<td>↓ 20% elective surgery</td>
</tr>
<tr>
<td>↑ 79% accurate risk perceptions</td>
<td>↓ 14% PSA testing</td>
</tr>
<tr>
<td>↑ 50% better match between values and choices</td>
<td>↑ 18% colorectal cancer screening</td>
</tr>
<tr>
<td>↓ 6% decisional conflict</td>
<td>↓ 27% HRT</td>
</tr>
<tr>
<td>↑ 41% help undecided to decide</td>
<td>No/minimal effect on anxiety, depression, regret, consult</td>
</tr>
<tr>
<td>↓ 33% passive participation in decision making</td>
<td>length, or health-related quality of life</td>
</tr>
<tr>
<td>↑ patient-practitioner communication</td>
<td></td>
</tr>
</tbody>
</table>

Does use of patient decision aids lead to reduced healthcare costs?

- Only found 7 studies with costs data.
- Too early to tell.
- Decrease utilization of elective procedures.
- Need to consider the baseline utilization rate in the community.
Standards and Certification of Patient Decision Aids
Affordable Care Act and SDM

- Funds an independent entity to develop consensus-based standards for certifying patient decision aids.
- Funds development and evaluation of patient decision aids.
- Authorizes CMS to test shared-decision making models.
- Implementation may be mandated throughout Medicare.
Standards for Patient Decision Aids

International collaborative of SDM researchers.

- 102 researchers, 10 countries.
- 12 “state-of-the-science” reviews, plus 1 systematic review on implementation.

Inventory of aids, measures, resources or developers
http://ipdas.ohri.ca/index.html
IPDAS Quality Dimensions

1. Systematic development process
2. Disclosing conflicts of interest
3. Information about options, harms, benefits
4. Up-to-date evidence
5. Balancing the presentation of information and options
6. Presenting probabilities
7. Clarifying values and preferences
8. Use of patient stories
9. Health literacy
10. Coaching and guidance
11. Measuring effectiveness
12. Delivering aids on the internet

http://ipdas.ohri.ca/index.html

The “basic science” of SDM.
Current thinking about standards for certification

Goal – using a Delphi process, identify a minimum set of standard from the IPDAS checklist that can be used to "certify" patient decision aids.
## Minimum Standards for Certification

<table>
<thead>
<tr>
<th>Qualifying Criteria (6)</th>
<th>Certifying Criteria (6 or 10)</th>
<th>Quality Criteria (28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Necessary for the tool to be considered a decision aid.</td>
<td>Essential to avoiding risk of harmful bias.</td>
<td>Desirable enhancements, not essential to reduce risk of harm.</td>
</tr>
<tr>
<td>Ex: “The aid explicitly states that a decision needs to be made.”</td>
<td>Ex: “The aid shows the negative and positive features with equal detail.”</td>
<td>Ex: “The aid provides information about the outcome probabilities associated with the options.”</td>
</tr>
<tr>
<td>“The aid describes the negative features of each option.”</td>
<td>“The aid provides information about the funding sources for development.”</td>
<td>“The aid reports readability levels.”</td>
</tr>
</tbody>
</table>

“…if the component was not present or of low quality, there would be a risk of harmful bias and negative impact on patients’ decision making.”

Joseph-Williams, MDM 2013.
1. Who will serve as the certifying body?
   – Unclear at this time.

2. What evidence sources will be deemed credible?
   – Not feasible for certifiers to evaluate quality of evidence.
   – Use existing guidelines, CER reviews?

3. How will conflicts of interest be addressed?
   – Developers may have an interest in “the decision.”
Concluding Comments

• Patient-centeredness is a hallmark of high quality care

• Patient decision aids are one strategy for achieving patient-centered care

• The evidence for patient decision support is extensive and growing (largely efficacy vs effectiveness)

• Certification of patient decision aids is coming (many unknowns)
My perspective on clinical problems “ripe for patient decision support”

“Close calls” where …

...there is over- or under-screening, treatment, and surveillance.
...decisions are often time-limited/acute.
...standardizing information about options available to patients is desirable.
...there is strong interest/commitment from clinical leaders that patient decision support is important.
Thank you and questions