Overview of Shared Decision Making

For the online webcast: Please submit your questions to the panel via the chat box. The online hosts will be collecting the questions during the session to be brought to the panel moderator during the panel discussion.
OVERVIEW OF SHARED DECISION MAKING

THE PINNACLE OF PATIENT-CENTERED CARE

CDRH Patient Preference Initiative Workshop
Michael J Barry, President
September 19, 2013
FOUNDATION MISSION

• The mission of the Foundation is to inform and amplify the patient’s voice in health care decisions
We believe patients should be:

- Supported and encouraged to participate in their health care decisions
- Fully informed with accurate, unbiased and understandable information
- Respected by having their goals and concerns honored
IS INFORMED CONSENT “REAL?”

• In a survey of consecutive patients scheduled for an elective coronary revascularization procedure at Yale New Haven Hospital in 1997-1998:
  • 75% believed PCI would help prevent an MI.
  • 71% believed PCI would help them live longer.
IS INFORMED CONSENT “REAL?”

• While even through the latest meta-analysis in 2009 (61 trials and 25,388 patients):
  • “Sequential innovations in catheter-based treatment for non-acute coronary artery disease showed no evidence of an effect on death or myocardial infarction when compared to medical therapy.”

In a survey of consecutive patients consented for an elective coronary angiogram and possible percutaneous coronary intervention at Baystate Medical Center in 2007-2008:

- 88% believed PCI would help prevent an MI.
- 76% believed PCI would help them live longer.
### ARE PATIENTS INFORMED AND INVOLVED?

<table>
<thead>
<tr>
<th>Question</th>
<th>Percent Who Answered Correctly</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many people</td>
<td></td>
</tr>
<tr>
<td>... get pain relief from joint replacement surgery</td>
<td>28</td>
</tr>
<tr>
<td>... experience a surgical complication (e.g. wound infection)</td>
<td>46</td>
</tr>
<tr>
<td>... will have replacement last at least 20 years</td>
<td>15</td>
</tr>
<tr>
<td>How long most people require to return to normal activity</td>
<td>39</td>
</tr>
</tbody>
</table>

The Decisions Study. Medical Decision Making 2010; 30 supplement 1
## ARE PATIENTS INFORMED AND INVOLVED?

<table>
<thead>
<tr>
<th>Patient Recollection of Decision Making Process</th>
<th>PCa Surgery % (n=685)</th>
<th>CA Stent % (=472)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talked most with specialist (rather than PCP)</td>
<td>83</td>
<td>86</td>
</tr>
<tr>
<td>Doctor discussed reasons for surgery</td>
<td>95</td>
<td>77</td>
</tr>
<tr>
<td>Doctor discussed reasons might not want surgery</td>
<td>63</td>
<td>19</td>
</tr>
<tr>
<td>Doctor discussed any alternative as serious option</td>
<td>64</td>
<td>10</td>
</tr>
<tr>
<td>Doctor asked about your preference for Rx</td>
<td>76</td>
<td>16</td>
</tr>
</tbody>
</table>

Fowler et al, JGIM 2/28/12
### TOP THREE GOALS AND CONCERNS FOR BREAST CANCER DECISIONS

<table>
<thead>
<tr>
<th>Condition: Goal</th>
<th>Pat</th>
<th>Prov</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keep your breast?</td>
<td></td>
<td>71%</td>
<td></td>
</tr>
<tr>
<td>Live as long as possible?</td>
<td></td>
<td>96%</td>
<td></td>
</tr>
<tr>
<td>Look natural without clothes</td>
<td></td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>Avoid using prosthesis</td>
<td></td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

KR Sepucha et al/Pt Education and Counseling 73(2008)504-10
### TOP THREE GOALS AND CONCERNS FOR BREAST CANCER DECISIONS

<table>
<thead>
<tr>
<th>Condition: Goal</th>
<th>Pat</th>
<th>Prov</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>
<td>Avoid using prosthesis</td>
<td>33%</td>
<td>0%</td>
<td>P&lt;0.01</td>
</tr>
</tbody>
</table>

KR Sepucha et al/Pt Education and Counseling 73(2008)504-10
THE SILENT MISDIAGNOSIS

“Many doctors aspire to excellence in diagnosing disease. Far fewer, unfortunately, aspire to the same standards of excellence in diagnosing what patients want.”

FORCES SUSTAINING UNWANTED PRACTICE VARIATION

Patients: Making Decisions in the Face of Avoidable Ignorance

Clinicians: Less than optimal “Diagnosis” of Patients’ Preferences

Poor Decision Quality Unwanted Practice Variation
WHAT IS GOOD MEDICAL CARE?

• It is not just about doing things right
• It is also about doing the right thing
• Proven effective care: For some medical problems, there is one best way to proceed
• Preference-sensitive care: For many and perhaps most medical problems, there is more than one reasonable option
SHARED DECISION MAKING MODEL

• Key characteristics:
  • At least two participants (clinician & patient) are involved
  • Both parties share information
  • Both parties take steps to build a consensus about the preferred treatment
  • An agreement is reached on the treatment to implement

PATIENT DECISION AIDS CAN HELP!

• Tools designed to help people participate in decision-making
• Provide information on the options
• Help patients clarify and communicate the values they associate with different features of the options
PATIENT DECISION AIDS: TOOLS TO FACILITATE SDM

- Describe a specific condition
- Present information organized around specific decisions
- Strive to keep information accessible (charts, graphs) and balanced
- Encourage patients to interpret information in context of their own goals and concerns
- Engage viewers with real patient stories
- Advise patients to make decisions with their physician

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In 86 trials in 6 countries of 34 different decisions, use has led to:

- Greater knowledge
- More accurate risk perceptions
- Lower decision conflict
- Greater participation in decision-making
- Fewer people remaining undecided

### 1.7.2 Intention to treat analysis

<table>
<thead>
<tr>
<th>Study</th>
<th>Cases</th>
<th>Controls</th>
<th>Events</th>
<th>Event Rate</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kennedy 2002</td>
<td>82</td>
<td>300</td>
<td>101</td>
<td>298</td>
<td>0.81 [0.63, 1.03]</td>
</tr>
<tr>
<td>Bernstein 1998</td>
<td>25</td>
<td>65</td>
<td>28</td>
<td>53</td>
<td>0.73 [0.49, 1.09]</td>
</tr>
<tr>
<td>Morgan 2000</td>
<td>45</td>
<td>120</td>
<td>63</td>
<td>120</td>
<td>0.71 [0.54, 0.95]</td>
</tr>
<tr>
<td>Murray 2001a</td>
<td>6</td>
<td>57</td>
<td>1</td>
<td>55</td>
<td>5.79 [0.72, 46.54]</td>
</tr>
<tr>
<td>Vuorma 2003</td>
<td>98</td>
<td>184</td>
<td>88</td>
<td>179</td>
<td>1.08 [0.89, 1.32]</td>
</tr>
<tr>
<td>Whelan 2004</td>
<td>6</td>
<td>94</td>
<td>26</td>
<td>107</td>
<td>0.26 [0.11, 0.61]</td>
</tr>
<tr>
<td>Auvinen 2004</td>
<td>60</td>
<td>104</td>
<td>91</td>
<td>106</td>
<td>0.67 [0.56, 0.81]</td>
</tr>
<tr>
<td>Barry 1997</td>
<td>8</td>
<td>104</td>
<td>16</td>
<td>123</td>
<td>0.59 [0.26, 1.33]</td>
</tr>
<tr>
<td>Schwartz 2009</td>
<td>18</td>
<td>100</td>
<td>15</td>
<td>114</td>
<td>1.37 [0.73, 2.57]</td>
</tr>
<tr>
<td>Tiller 2006</td>
<td>18</td>
<td>68</td>
<td>17</td>
<td>63</td>
<td>0.98 [0.56, 1.73]</td>
</tr>
<tr>
<td>Vodermaier 2009</td>
<td>2</td>
<td>39</td>
<td>5</td>
<td>41</td>
<td>0.42 [0.09, 2.04]</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>1235</strong></td>
<td><strong>1259</strong></td>
<td><strong>100.0%</strong></td>
<td><strong>0.79 [0.64, 0.97]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 368 / 451  
Heterogeneity: $\tau^2 = 0.06$, $\text{Chi}^2 = 27.70$, df = 10 ($P = 0.002$); $I^2 = 64\%$  
Test for overall effect: $Z = 2.20$ ($P = 0.03$)
A CHORUS OF VOICES CALLING FOR SDM
SDM: IMPLEMENTATION NEEDS

- Patients interested in being informed and activated
- Practical protocols for routine use of decision support tools
- Health care systems with incentives for good “decision quality” rather than simply “more is better”
- Clinicians and hospitals receptive to patient participation
Did the patient know a decision was being made?
Did the patient know the pros and cons of the treatment options?
Did the provider elicit the patient’s preferences?

Did the decision reflect the patient’s goals and concerns?

Did the patient know what he or she needed to know?

Objective: to demonstrate that the use of patient decision aids and the process of shared decision making can effectively and efficiently become part of day-to-day care.
Key Objectives For Successful Implementation of SDM with DAs

- Engage Providers and Staff
- Define Target Population
- Identify & Engage Patients
- Distribute DAs
- Encourage Viewing
- Have SDM Conversation
- Measure Impact
- Provide feedback
TESTING OUR FIRST 30-MINUTE BPH PROGRAM

How would you rate the amount of information?
KNOWLEDGE SCORES BY DA EXPOSURE LEVEL: EDUCATION LEVEL

Includes all valid demonstration site surveys in Illume database distributed in a primary care setting as of 8/1/12 (unweighted)
*All significance tests are independent sample t-tests; * = Difference in means is statistically significant (p ≤ 0.05)
1DA Exposure Level definition: Low = none of either OR some of both OR (some of one AND none of the other); Medium = Most of both OR (most or all of one AND (none or some of the other)); High = All of both OR (all of one AND most of the other)
IMPORTANCE RATINGS BY DEMOGRAPHIC GROUP

<table>
<thead>
<tr>
<th>Demographic Group</th>
<th>Extremely</th>
<th>Very</th>
<th>Somewhat</th>
<th>Not at all</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>30</td>
<td>55</td>
<td>14</td>
<td>3,794</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50</td>
<td>32</td>
<td>51</td>
<td>16</td>
<td>625</td>
<td></td>
</tr>
<tr>
<td>50 - 64</td>
<td>30</td>
<td>56</td>
<td>13</td>
<td>1,966</td>
<td></td>
</tr>
<tr>
<td>65+</td>
<td>30</td>
<td>54</td>
<td>15</td>
<td>1,203</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4y college+</td>
<td>29</td>
<td>55</td>
<td>16</td>
<td>1,658</td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>32</td>
<td>56</td>
<td>11</td>
<td>979</td>
<td></td>
</tr>
<tr>
<td>HS or less</td>
<td>31</td>
<td>54</td>
<td>14</td>
<td>1,141</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>29</td>
<td>56</td>
<td>15</td>
<td>2,208</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>32</td>
<td>54</td>
<td>13</td>
<td>1,574</td>
<td></td>
</tr>
</tbody>
</table>

Includes all valid demonstration site surveys in Illume database distributed in a primary care setting as of 8/1/12 (unweighted)

**Statistically significant (p ≤ 0.05) (Chi square test)**
# DECISION ROLE PREFERENCES BY DEMOGRAPHIC GROUP

<table>
<thead>
<tr>
<th></th>
<th>You</th>
<th>Both equally</th>
<th>Your HCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>28</td>
<td>68</td>
<td>4</td>
</tr>
<tr>
<td>n</td>
<td>4,027</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50</td>
<td>21</td>
<td>74</td>
<td>5</td>
</tr>
<tr>
<td>50 - 64</td>
<td>30</td>
<td>65</td>
<td>5</td>
</tr>
<tr>
<td>65+</td>
<td>27</td>
<td>70</td>
<td>3</td>
</tr>
<tr>
<td>p &lt; .001*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4y college+</td>
<td>31</td>
<td>65</td>
<td>4</td>
</tr>
<tr>
<td>Some college</td>
<td>25</td>
<td>71</td>
<td>4</td>
</tr>
<tr>
<td>HS or less</td>
<td>24</td>
<td>71</td>
<td>5</td>
</tr>
<tr>
<td>p &lt; .001*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>31</td>
<td>65</td>
<td>5</td>
</tr>
<tr>
<td>Female</td>
<td>23</td>
<td>73</td>
<td>4</td>
</tr>
<tr>
<td>p &lt; .001*</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Includes all valid demonstration site surveys in Illume database distributed in a primary care setting as of 8/1/12 (unweighted)

*Statistically significant (p ≤ 0.05) (Chi square test)
UNDECIDED PEOPLE TEND TO MOVE TOWARD NON-SURGICAL OPTIONS

Question: “At this time, what are you leaning toward doing?”*

<table>
<thead>
<tr>
<th></th>
<th>HIP (n = 114)</th>
<th>KOA (n = 303)</th>
<th>SST (n = 46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>before DA</td>
<td>35</td>
<td>46</td>
<td>50</td>
</tr>
<tr>
<td>after DA</td>
<td>43</td>
<td>35</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>22</td>
<td>19</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>23</td>
<td>17</td>
<td>9</td>
</tr>
</tbody>
</table>

*Includes only respondents who answered the question both before and after.

Includes all valid demonstration site surveys in Illume database distributed in a primary care setting as of 5/16/12 (unweighted)
HIP AND KNEE DECISION AIDS AT GROUP HEALTH

• Introduced pDAs for hip/knee arthroscopy candidates in 2009
• Reached 28% of eligible knee (N=3510) and 41% of hip patients (N=820)
• Over 6 months:
  • 38% fewer knee replacements
  • 26% fewer hip replacements
  • 12-21% lower costs

Arterburn D, et al. Health Affairs 2012; 31(9)
THE HVHC CMMI PROJECT

- CMMI Innovation Grant
- “HVHC: Engaging Patients to Meet the Triple aim”
- 16 member systems (~50 million served) will deploy “patient and family activators”
- Coaching and pDAs for DM, heart failure, back surgery, hip/knee arthroplasty
THANK YOU!

MBARRY@IMDFOUNDATION.ORG
WWW.INFORMEDMEDICALDECISIONS.ORG
Day Two Wrap Up
Strategies Going Forward
Michelle McMurry-Heath, M.D., Ph.D.

1. Audience Participation
2. Panelist Summaries
3. Steps Going Forward
Is your clicker working?

A. Yes
B. No
Please identify your affiliation:

A. Patient/ Patient advocacy group
B. Professional Society
C. Research/ Academia
D. Provider/Clinician
E. Industry
F. Federal Agency

18% 21% 6% 24%
Where in the medical device total product lifecycle (TPLC) could you see patient preference information best utilized?

A. Discovery & ideation
B. Invention & prototyping
C. Pre-clinical
D. Clinical trials
E. Regulatory decision
F. Product launch
G. Post-market monitoring
Who is best situated to collect patient preference information?

A. Academia
B. Industry
C. Clinicians
D. Patient Groups
E. Regulators
Where and how should patient preference information be communicated?

A. Decision-making conversation
B. Device labeling
C. Health communication
D. FDA Website
E. Other

- A: 35%
- B: 31%
- C: 29%
- D: 2%
- E: 2%
Day Two Wrap Up
Strategies Going Forward
Michelle McMurry-Heath, M.D., Ph.D.

1. Audience Participation
2. Panel Summaries
3. Steps Going Forward
Moderator: *Michelle McMurry-Heath, M.D., Ph.D.*

*Associate Director for Science*
CDRH/Office of the Center Director

Panel:

*Bray Patrick-Lake, M.F.S.*
Clinical Trials Transformation Initiative (CTTI)

*Diana Salditt*
Medtronic, Inc.
AdvaMed

*F. Reed Johnson, Ph.D.*
Research Triangle Institute (RTI-Health Solutions)

*Gregg Rosenberg, Ph.D.*
WiserTogether, Inc.

*William Murray*
Medical Device Innovation Consortium (MDIC)
What Matters?

- Patients
- Context
- Methods
- B-R Ratio
- The TPLC
- Partnerships
- Risk Communications

PATIENT PREFERENCE AND MEDICAL DEVICES
Total Patient Lifecycle

- Patient Preference
- Shared Decision Making
- Patient Reported Outcomes
Thank you for attending.

Please submit any additional questions and comments to the public docket.

Please remember to return your badges and clickers.