Dr. McNaughton-Collins receives salary support as Medical Director of the not-for-profit Informed Medical Decisions Foundation.

Foundation staff and medical editors do not take financial support from the drug and device industries, professional societies, or health plans.
GAMEPLAN

• Clinical Case

• Guidelines

• Evidence

• Shared decision making
A 50 year old man presents for a primary care visit soon after his birthday

No other risk factors for prostate cancer

Maybe he asks about prostate cancer screening...

And maybe he doesn’t!
CLINICAL CASE

• How should the visit unfold?
• Should the option of screening be raised by the clinician if the patient doesn’t?
• Is PSA screening a choice?
A NEJM PERSPECTIVE PIECE

Perspective: One Man at a Time – Resolving the PSA Controversy
Mary F. McNaughton-Collins, MD, MPH
Michael J. Barry, MD
PCA SCREENING GUIDELINES (2013)

• ACS: Offer prostate cancer screening at 50, at 45 with risk factors (40 for very high risk) if >10 yr Life Expectancy
• USPSTF: New recommendation against routine PSA screening of men for all ages
• ACP: Inform men between 50-69 about the limited potential benefit and substantial harm
• AUA: Shared decision making for men aged 55-69
WHAT’S THE LATEST EVIDENCE?

• US PLCO Trial (Update 13 yr)
  • For men 55-74 (N=76,685, annual PSA/DRE)
    • No difference in overall mortality
    • Diagnosis of PCa increased from 9.9% to 11.1% with screening
    • Risk of getting PCa increased 12% (95% CI 7%, 17%)
    • Risk of PCa death similar at 0.4% in both groups
    • RR PCa death 9% higher with screening (95% CI, 13%, +36%)
  • Problem with the PLCO trial
    • “Contamination” of the control group with “usual care” PSA tests may have obscured a small benefit

Andriole, et al. JNCI 2012;104:125
WHAT’S THE LATEST EVIDENCE?

• ERSPC Trial (Update 11 yr F/U NEJM 2012;366:981)
  • For men 55-69 (N=162,388, PSA~q 4 yrs, no DRE)
    • Diagnosis of PCa increased from 6.0% to 9.6% with screening
    • Risk of getting PSA increased 63% (95% CI 57%, 67%)
    • Risk of prostate cancer death decreased from 0.5% to 0.4%
    • Risk of PCa death decreased 21% (95% CI 32%, 9%)
  • Problem with the ERSPC trial
    • Men in the screening group were treated in different places than men in the control group when they were diagnosed with prostate cancer

Schroder et al. *NEJM* 2012;366:981)
EFFECTIVENESS OF THERAPY

• U.S. PIVOT RCT of RP vs. Observation, localized cancer (N=731)
• ~50% of PCa Stage T1c
• Reduced overall mortality from 49.9% in the OBS group to 47.0% in the RP group at 10 years (P=NS, NNT=34)
• Reduced PCa specific mortality from 8.4% in the OBS group to 5.8% in RP group at 10 years (P=NS, NNT=38)

Wilt et al. NEJM 2012;367:203
EFFECTIVENESS OF THERAPY

- Incontinence @ 2 years 17.1% with RP vs 6.3% with OBS (P<0.001, NNH=9)
- Erectile dysfunction @ 2 years 81.1% with RP vs 44.1% with OBS (P<0.001, NNH=3)
- Patient characteristics (age, race, comorbidity) did not modify the effect of treatment
- But tumor characteristics did!
  - PSA≤10 (N=479) overall mortality increased from 43.6% with OBS to 46.2% with RP (P=NS, NNH=38)
  - PSA>10 (N=251) overall mortality decreased from 61.6% with OBS to 48.4% with RP (P=0.02, NNT=8)

Wilt et al. NEJM 2012;367:203
### Morbidity of XRT or RP at 5 Years

<table>
<thead>
<tr>
<th>Complication</th>
<th>XRT</th>
<th>RP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incontinence (requiring pads)</td>
<td>4%</td>
<td>29%</td>
</tr>
<tr>
<td>Erections insufficient for intercourse</td>
<td>64%</td>
<td>79%</td>
</tr>
<tr>
<td>Bothered by bowels</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>Additional treatment (w/in 2-4 years)</td>
<td>24%</td>
<td>25%</td>
</tr>
</tbody>
</table>
2008 MEDICARE RP OUTCOMES STUDY

800 RP pts from Medicare

3 found ineligible

685 / 797 surveys returned (86%)

38 not sure/no answer

220 surgery was not lap, assumed open

427 confirmed surgery was lap

406 confirmed robot assisted

9 not robot assist

12 not sure about robot assist
SIDE EFFECTS BOTHER BY SURGICAL TYPE

- Continence, moderate or big problem:
  - 27% open group vs. 34% robotic group (P=0.087)

- Sexual function, moderate or big problem:
  - 89% open group vs. 88% robotic group (P=0.57)

Barry et al. JCO. 2012;364:1708.
WHAT WE (PROBABLY) KNOW FOR SURE:

• Prostate cancer screening doesn’t “save lives” in terms of reducing overall mortality...but it may reduce the risk of dying of prostate cancer

• Most of the prostate cancer deaths in the trial populations have yet to be counted (70% deaths >age 75)

• Unlikely screening would decrease lifetime risk by more than 3% to 2% (not a 1% shot at immortality...)
WHAT WE (PROBABLY) KNOW FOR SURE:

• Overdiagnosis and overtreatment are major problems at the population level
• But it’s very hard to tell who has been overdiagnosed or overtreated at the individual level
• Need strategies to reduce overdiagnosis and/or uncouple overdiagnosis from overtreatment
  • Higher biopsy threshold?
  • Active surveillance/watchful waiting?
BACK TO THE CASE!
OPTIONS:

• Clinician could just check the PSA box on the lab slip, no discussion
• Don’t ask, don’t tell...
• If asked, discourage testing based on USPSTF draft “D” recommendation
• “Come back when you’re 55!”
• Shared decision making: “Have you heard about the PSA test for prostate cancer screening?”
STOPPING AGE CONSIDERATIONS

• Stop with <10 year life expectancy
Age and self-rated health:
“In the last month, how would you rate your health?”
  • ~70 poor health
  • ~74 fair health
  • ~76 good health
  • ~80 very good/excellent health

STOPPING AGE CONSIDERATIONS

- Population-based case-control study from Malmo, Sweden

  - 1167 men provided a blood sample at age 60, followed to age 85
  - For the 50% of men with PSA <1.0 ng/mL at age 60, risk of prostate cancer death 0.2%

STOPPING AGE CONSIDERATIONS

- Age 60  Sweden case control study
- Age 69  Evidence from randomized controlled trial
- Age 74  Age –based life expectancy
- Ages 70-80  Self rating of health-based life expectancy
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
• PSA screening is a prototypical preference-sensitive decision
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

SHARED DECISION MAKING - DEFINITION

“the process of interacting with patients who wish to be involved in arriving at an informed, values-based choice among two or more medically reasonable alternatives”¹

INFORMED
There is a choice
The options
The benefits and harms of the options

VALUES-BASED
What’s important to the patient

The Clinician  Information  The Patient

¹A.M. O'Connor et al, “Modifying Unwarranted Variations In Health Care: Shared Decision Making Using Patient Decision Aids” Health Affairs, 7 October, 2004
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
COCHRANE REVIEW OF DECISION AIDS

• 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
  • Fewer people choosing surgery and PSA screening

• Ottawa Health Research Institute Inventory of patient decision aids:
  • Access information for over 500 decision aids
  • Includes IPDAS ratings

http://decisionaid.ohri.ca/index.html
THE 6 STEPS OF SHARED DECISION MAKING

• Invite patient to participate
• Present options
• Provide information on benefits and harms
• Assist patient in evaluating options based on their goals and concerns
• Facilitate deliberation and decision making
• Assist with implementation
WHAT INFORMATION SHOULD BE COVERED?

• According to the ACS guideline (parentheses mine):
  • PCa is an important health problem (3 in 100 lifetime risk, 5 in 100 for men with risk factors)
  • Screening with PSA±DRE can detect PCa at an earlier stage
  • Screening may be associated with a lower risk of dying of prostate cancer (evidence is conflicting, at best from 5 to 4 chances in 1000 over about 10 years, longer term unknown)
  • Unclear which men detected by screening will benefit
  • Treatment can lead to urinary, bowel, sexual, and other health problems

Wolf et al. CA Cancer J Clin 2010;60:70
WHAT INFORMATION SHOULD BE COVERED?

• According to the ACS guideline:
  • False positives and negatives possible
  • Abnormal screening results require biopsies which can lead to complications and may miss significant cancer
  • Not all men with PCa detected by screening need treatment, but do need close monitoring

• I’d add:
  • Men who choose regular PSA testing will increase their risk of getting prostate cancer (from around 6 in 100 without screening to 10 in 100 with screening over about 10 years)

Wolf et al. CA Cancer J Clin 2010;60:70
WHAT VALUES SHOULD BE COVERED?

• What matters to you?
  • Doing everything possible to avoid dying of prostate cancer, even if we’re not sure PSA can do that?
  • Only doing things of proven benefit?
  • Avoiding a prostate biopsy?
  • Keeping your sexual and urinary function?

• Are you ready to decide?

• How about, “What would you do if you were me, doc?”
BARRIERS TO SDM FOR PSA SCREENING

• Who has the time and who has the tools?
• Do patients really want to participate in their medical decisions?
• Won’t informing and involving patients just increase demand for more testing and treatment?
• What about malpractice risk?
### DECISION ROLE PREFERENCES BY DEMOGRAPHIC GROUP

<table>
<thead>
<tr>
<th></th>
<th>You</th>
<th>Both equally</th>
<th>Your HCP</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>28</td>
<td>68</td>
<td>4</td>
<td>4,027</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50</td>
<td>21</td>
<td>74</td>
<td>5</td>
<td>628</td>
</tr>
<tr>
<td>50 - 64</td>
<td>30</td>
<td>65</td>
<td>5</td>
<td>2,013</td>
</tr>
<tr>
<td>65+</td>
<td>27</td>
<td>70</td>
<td>3</td>
<td>1,385</td>
</tr>
<tr>
<td>Education</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>4y college+</td>
<td>31</td>
<td>65</td>
<td>4</td>
<td>1,721</td>
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<tr>
<td>Some college</td>
<td>25</td>
<td>71</td>
<td>4</td>
<td>1,013</td>
</tr>
<tr>
<td>HS or less</td>
<td>24</td>
<td>71</td>
<td>5</td>
<td>1,154</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
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<tr>
<td>Male</td>
<td>31</td>
<td>65</td>
<td>5</td>
<td>2,265</td>
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<tr>
<td>Female</td>
<td>23</td>
<td>73</td>
<td>4</td>
<td>1,678</td>
</tr>
</tbody>
</table>

*Statistically significant (p ≤ 0.05) (Chi square test)

Includes all valid demonstration site surveys in Illume database distributed in a primary care setting as of 8/1/12 (unweighted)
PATIENT LEANINGS BEFORE AND AFTER DA: SCREENING

Colon Cancer Screening  
\[ n = 556 \]

<table>
<thead>
<tr>
<th></th>
<th>Before</th>
<th>After</th>
<th>( p &lt; .001^* )</th>
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</thead>
<tbody>
<tr>
<td>Not sure</td>
<td>23</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Being screened</td>
<td>61</td>
<td>71</td>
<td></td>
</tr>
</tbody>
</table>

PSA Testing  
\[ n = 1,138 \]

<table>
<thead>
<tr>
<th></th>
<th>Before</th>
<th>After</th>
<th>( p &lt; .001^* )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not sure</td>
<td>32</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Being screened</td>
<td>42</td>
<td>46</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)

*Significant difference (\( p \leq .05 \)) (McNemar test)
WHAT ABOUT MALPRACTICE RISK?

• Percentage of mock jurors who felt the standard of care had been met when a PSA test was not done and the patient later presents with metastatic prostate cancer:
  • 17% when there is no note in the chart
  • 72% when a note in the chart reads, “Risks and benefits of PSA test discussed, patient declines."
  • 94% when a note in the chart reads, “Patient viewed PSA decision aid, questions answered, declines test.”

TEACHING POINTS

• PSA screening is a “preference-sensitive” decision...reasonable, informed men can make different choices

• Six steps of shared decision making

• Decision aids can help make SDM practical
THANK YOU!