

# Prostate Cancer Screening

John W. Ragsdale III, MD\*, Brian Halstater, MD,  
Viviana Martinez-Bianchi, MD

## KEYWORDS

- Screening • Prostate cancer • Prostate-specific antigen • PSA
- Digital rectal examination • DRE

## KEY POINTS

- The US Preventive Services Task Force recommends against prostate-specific antigen (PSA)-based screening for prostate cancer (Pca) in men of all ages, because evidence suggests that the potential harms of screening outweigh potential benefits.
- The case for Pca screening requires a paradigm shift, one that emphasizes the risks of screening over the risks of undetected cancer.
- For patients who express an interest in Pca screening, primary care providers must use a shared decision-making process, helping patients weigh individual risk factors (eg, age, life expectancy, family history, black race) against probable harms and possible benefits.
- Although there are race-based differences for Pca incidence and mortality, there is insufficient evidence to selectively recommend PSA-based screening based on a patient's race.
- New models of care informed by the Patient Protection and Affordable Care Act, such as accountable care organizations, patient-centered medical homes, and team-based primary care, are poised to assist clinicians in providing recommended preventive care.
- Electronic health records offer a potential means to provide higher quality care at lower cost.

## INTRODUCTION

After skin cancer, prostate cancer (Pca) is the most common cancer in men in the United States.<sup>1</sup> The National Institutes of Health projected that there would be roughly 240,000 new diagnoses and 30,000 deaths from Pca in 2013.<sup>2</sup> Despite a relatively high prevalence of approximately 15%, the lifetime risk of dying from Pca is fairly low (less than 3%), suggesting that conservative management is appropriate for most patients.<sup>3</sup> Conservative management is further warranted given evidence the potential risks of prostate-specific antigen (PSA)-based screening outweigh potential benefits.<sup>4</sup> Primary care providers must understand changes in Pca screening guidelines to effectively communicate and promote informed decision making.

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Conflict of Interest: None.

Department of Community and Family Medicine, Duke Family Medicine Center, Duke University, 2100 Erwin Drive, Durham, NC 27710, USA

\* Corresponding author.

E-mail address: [john.ragsdale@duke.edu](mailto:john.ragsdale@duke.edu)

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## EPIDEMIOLOGY

More than 2.5 million men in the United States are living with Pca.<sup>1</sup> Pca incidence rates decreased, on average, about 2% per year between 2001 and 2010; Pca mortality decreased even more quickly, on average about 3% per year, over the same 10-year period.<sup>5</sup> As shown in **Table 1**, there remains considerable variation in both Pca incidence and mortality when examined by race. The incidence of Pca is substantially higher for blacks when compared with whites, at 192.9 and 115.6 cases per 100,000 men, respectively. Mortality is also substantially higher for blacks when compared with whites, at 48.2 and 20.1 deaths per 100,000 men, respectively.<sup>6</sup>

The literature suggests that several factors likely contribute to these race-based differences, including biological explanations, differences in screening behavior and access to health care, the pattern of care, and the quality of treatment.<sup>7</sup> Even in health care sites such as the US Veterans Administration (in which race-based differences in access, screening, and treatment of Pca are minimized), black men with Pca are more likely than their white counterparts to present with higher-risk disease characteristics, such as greater PSA levels, higher clinical Gleason scores, and more advanced disease at a younger age.<sup>8</sup> Compared with white men, black men also have higher odds of complications with prostate surgery, including an increased need for blood transfusions, longer lengths of stay, and greater inpatient mortality.<sup>9</sup> Research investigating race-based disparities in the pattern of Pca care show that blacks are less likely to receive surgical and radiation treatment, and are more likely to have not chosen a definitive therapy or to have chosen no treatment at all.

A review of epidemiologic studies published over the 39-year period between 1970 and 2008<sup>10</sup> showed no race-based differences in associations between Pca and tobacco use, alcohol intake, and family history of Pca; a modest positive association between height and Pca risk for whites only; and no clear pattern of association with weight, body mass index, physical activity, dietary factors, sexual behavior, sexually transmitted infections, occupational history, and other health conditions (eg, diabetes and high blood pressure). Another review,<sup>11</sup> focusing largely on social determinants of health, suggested that multiple factors likely contribute to black-white differences in Pca, including poorer access to health care and other resources, lower socioeconomic status, cultural and behavioral factors, and ineffective partnerships between patients and clinicians. However, the relative contribution of these factors to mortality is not clear, because biological measures such as Gleason score and PSA (not race) are the most salient predictors of mortality.<sup>12</sup>

Race/Ethnicity	Incidence per 100,000 Men	Mortalities per 100,000 Men
All races	126.1	21.8
American Indian/Alaska native	66.8	15.2
Asian/Pacific Islander	63.7	9.5
Black	192.9	48.2
Hispanic	104.8	18.2
White	115.6	20.8

<sup>a</sup> Age-adjusted to the 2000 US standard population.

Data from Centers for Disease Control and Prevention. US cancer statistics: 2010 cancer types grouped by race and ethnicity. Available at: <http://apps.nccd.cdc.gov/uscs/cancersbyraceandethnicity.aspx>. Accessed January 4, 2014.

Although evidence suggests that the most common alterations in gene expression associated with Pca do not vary significantly by race/ethnicity, several metastasis-related genes have been found to be more highly expressed in tumors from black patients when compared with white patients. Researchers hypothesize that the causes for these differences are multifactorial (environmental, or genetic), noting that the gene signature in tumors of black patients could be associated with viral involvement.<sup>13</sup> Although a recent meta-analysis indicated that BRCA1 mutations do not increase Pca risk,<sup>14</sup> some BRCA2 mutations may.<sup>15</sup> Evidence suggests that BRCA1 and BRCA2 mutations have comparable prevalence among white, black, Asian, and Hispanic populations. Although between-group differences in the spectrum of mutations have been observed, the significance of differences remains unknown.<sup>16</sup> The potential benefits of screening for Pca in men carrying BRCA-related mutations is not known.<sup>17</sup>

Family history of Pca is an established risk factor for men of any race. Men with a family history of a first-degree relative with Pca are at increased risk for the disease compared with those without an affected first-degree relative (**Table 2**).<sup>18</sup> As with those carrying BRCA-related mutations, current evidence cannot satisfactorily determine whether the benefits of Pca screening outweigh the risks among those with a family history of the disease; likewise, there is insufficient evidence to selectively recommend PSA-based screening based on a patient's race.<sup>4</sup>

## THE EFFICACY OF THE DIGITAL RECTAL EXAMINATION AND PSA-BASED SCREENING

Two screening modalities have commonly been used to detect Pca: digital rectal examination (DRE) and PSA assay.<sup>19</sup>

### DRE

Despite its use as a screening tool for many years, a careful evaluation of DRE remains wanting.<sup>20</sup> Research published in the late 1980s showed that of 4160 DREs performed on 2131 men older than 45 years, 144 prostate biopsies were performed and 36 malignant tumors were identified. Researchers concluded that DRE may not add significant benefit over conventional medical care.<sup>21</sup> Although inexpensive, easy to perform, and relatively noninvasive, the effectiveness of DRE is contingent on the experience and skill of the examiner. Since the advent of widely available PSA assays in the late 1980s, DRE by itself is seldom considered as a screening tool.<sup>20</sup>

<b>Risk Group</b>	<b>Relative Risk for Pca</b>
Brother(s) with Pca; diagnosed at any age	3.14
Father with Pca; diagnosed at any age	2.35
1 affected FDR; diagnosed at any age	2.48
≥2 affected FDRs; diagnosed at any age	4.39
Second-degree relative(s); diagnosed at any age	2.52
Affected FDR(s); diagnosed <65 y	2.87
Affected FDR(s); diagnosed ≥65 y	1.92

*Abbreviation:* FDR, first-degree relative.

*Adapted from* National Cancer Institute at the National Institutes of Health. Genetics of prostate cancer (PDQ). Available at: <http://www.cancer.gov/cancertopics/pdq/genetics/prostate/HealthProfessional/#Reference1.21>. Accessed January 4, 2014.

### **PSA-Based Screening**

As noted by the National Cancer Institute, “There is no PSA value below which a man can be assured that he has no risk of prostate cancer.” Although several methods intended to improve the performance of PSA-based screening have been studied (including Pca gene 3 [PCA3], complexed PSA and percent-free PSA, ultrasensitive PSA assay, PSA density, PSA density of the transition zone, age-adjusted PSA, PSA velocity, altering PSA cutoff level, and frequency of screening), evidence shows that none is demonstrably better than total serum PSA.<sup>20</sup>

Over the past several years, the approach to Pca screening has shifted, because new findings indicate that the potential benefits from PSA testing are small.<sup>22–25</sup> For example, the Prostate Cancer Intervention vs Observation Trial concluded that among men with clinically localized Pca that had been diagnosed after PSA testing, radical prostatectomy did not reduce all-cause or prostate cancer mortality, compared with observation, through at least 12 years of follow-up.<sup>26</sup> Similarly, the European Randomized Study of Screening for Prostate Cancer concluded that to prevent a single death from Pca at 11 years of follow-up, more than 1050 men would need to be screened and 37 cancers would need to be detected.<sup>27</sup> In addition, the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial concluded that after 13 years of follow-up, there was no mortality benefit for organized annual PSA screening versus opportunistic PSA screening.<sup>28</sup>

### **POSSIBLE BENEFITS AND EXPECTED HARMS OF PSA-BASED SCREENING AND SUBSEQUENT TREATMENT**

#### **Screening**

As described by the US Preventive Services Task Force (USPSTF)<sup>25</sup> and others,<sup>22,24</sup> PSA-based screening for Pca sets in motion a clinical path leading to overdiagnosis and overtreatment of most patients who screen positive. **Box 1** summarizes the expected harms, as well as the possible benefits. The USPSTF asserts the following:

*There is convincing evidence that PSA-based screening leads to substantial overdiagnosis of prostate tumors. The amount of overdiagnosis of prostate cancer is of important concern because a man with cancer that would remain asymptomatic for the remainder of his life cannot benefit from screening or treatment. There is a high propensity for physicians and patients to elect to treat most cases of screen-detected cancer, given our current inability to distinguish tumors that will remain indolent from those destined to be lethal. Thus, many men are being subjected to the harms of treatment of prostate cancer that will never become symptomatic. Even for men whose screen-detected cancer would otherwise have been later identified without screening, most experience the same outcome and are, therefore, subjected to the harms of treatment for a much longer period of time. There is convincing evidence that PSA-based screening for prostate cancer results in considerable overtreatment and its associated harms.<sup>29</sup>*

Potential harms from the most common forms of Pca treatment include erectile dysfunction, urinary and fecal incontinence, and systemic injury. These harms must be weighed against the likelihood of a lifesaving intervention of only 1 in (approximately) 1000.

A recent study examining the perspectives of primary care providers on discontinuing Pca screening found that most clinicians considered both the patients' age and life expectancy when making decisions about Pca screening, although nearly two-thirds of clinicians noted difficulty in gauging life expectancy. The most commonly cited barriers to not performing Pca screening were patients' expectations and time constraints.

**Box 1****Expected harms and possible benefits from PSA-based screening for Pca***Expected harms*

- False-positive results. About 100 to 120 of every 1000 men screened receive a false-positive test. Most positive tests result in biopsy and can cause worry and anxiety. Up to one-third of men undergoing biopsy experience fever, infection, bleeding, urinary problems, and pain that they consider a moderate or major problem. One percent are hospitalized for complications.
- Overdiagnosis. In most cases, Pca does not grow or cause symptoms. If it does grow, it usually grows so slowly that it is not likely to cause health problems during a man's lifetime. Currently, it is not possible to reliably distinguish indolent from aggressive cancers. Many cancers diagnosed would have remained asymptomatic for life and do not require treatment.
- Overtreatment. Because of the uncertainty about which cancers need to be treated, 90% of men with Pca found by PSA choose to receive treatment. Many of these men cannot benefit from treatment, because their cancer does not grow or cause health problems. Harms of treatment include:
  1. Erectile dysfunction from surgery, radiation therapy, or hormone therapy (29 men affected per 1000 men screened)
  2. Urinary incontinence from radiation therapy or surgery (18 men affected per 1000 men screened)
  3. A small risk of death and serious complications from surgery:
    - 2 serious cardiovascular events per 1000 men screened
    - 1 case of pulmonary embolus or deep venous thrombosis per 1000 men screened
    - 1 perioperative death every 3000 men screened

*Possible benefits*

In an unscreened population, about 5 of every 1000 men die from Pca after 10 years. Results of several large trials have shown that, at best, PSA screening may help 1 man in 1000 avoid death from Pca after at least 10 years. Most likely, the number helped is even smaller. This observation means that with PSA screening, 4 or 5 of every 1000 men die from Pca after 10 years.

*Adapted from* US Preventive Services Task Force. Talking with your patients about screening for prostate cancer. 2012. Available at: <http://www.uspreventiveservicestaskforce.org/prostatecancerscreening/prostatecancerscript.pdf>. Accessed January 5, 2014.

Concerns about malpractice were noted as a barrier by more than half of respondents, and more than a quarter indicated a concern that their patients would think they were trying to cut costs. Researchers concluded that barriers may be mitigated, in part, through the practice of shared decision making within patient-centered medical homes (PCMHs).<sup>30</sup> Both shared decision making and PCMH are described in more detail later.

**PCA SCREENING RECOMMENDATIONS**

Screening recommendations for Pca from the USPSTF, American College of Physicians (ACP), the American Urological Association (AUA), and the American Cancer Society (ACS) are outlined in **Table 3**.

**SHARED DECISION MAKING**

Given the recent shift against Pca screening, primary care providers play an important role in helping patients make informed decisions about Pca screening; however, many

**Table 3**  
**Screening for Pca**

Organization	Recommendations, Guidance Statements, and Clinical Considerations	Evidence Grade
USPSTF <sup>a</sup>	<p>Recommends against PSA-based screening for Pca in the general US population, regardless of age; this recommendation does not apply to the use of the PSA test for surveillance after diagnosis or treatment of Pca</p> <p>In cases in which men request screening, the USPSTF suggests the following:</p> <ul style="list-style-type: none"> <li>The decision to initiate or continue PSA screening should reflect an explicit understanding of the possible benefits and harms and respect patients' preferences</li> <li>Physicians should not offer or order PSA screening unless they are prepared to engage in shared decision making, which enables an informed choice by patients</li> <li>Patients requesting PSA screening should be provided with the opportunity to make informed choices to be screened, which reflect their values about specific benefits and harms</li> </ul> <p>UPSTF Recommendation Summary Sheet: Talking with Patients About Screening for Prostate Cancer<sup>31</sup>: <a href="http://www.uspreventive servicetaskforce.org/prostatecancerscreening/prostatecancerscript.pdf">http://www.uspreventive servicetaskforce.org/prostatecancerscreening/prostatecancerscript.pdf</a></p>	D <sup>b</sup>
ACP <sup>c</sup>	<p>Men aged 50–69 y:</p> <ul style="list-style-type: none"> <li>Clinicians inform patient about the limited potential benefits and substantial harms of screening for Pca</li> <li>Base the decision to screen for Pca using the PSA test on the following criteria: (1) the risk for Pca, (2) a discussion of the benefits and harms of screening, (3) the patient's general health and life expectancy, and (4) patient preferences</li> <li>Clinicians should not screen for Pca using the PSA test in patients who do not express a clear preference for screening</li> </ul> <p>Men aged &lt;50 y, &gt;69 y, or with a life expectancy &lt;10–15 y:</p> <ul style="list-style-type: none"> <li>Clinicians should not screen for Pca using the PSA test in men at average risk</li> </ul> <p>Some men still prefer to be screened, because they may put more value on the possible small benefit and less value on the harms.</p> <p>In these cases, use shared decision making and document the conversation as it relates to the following points:</p> <ul style="list-style-type: none"> <li>Pca screening with the PSA test is controversial</li> <li>The chances of harm from screening with the PSA test outweigh the chances of benefit</li> <li>Most Pca is slow growing and does not cause death</li> <li>Most men who choose not to have PSA testing are not diagnosed with Pca and die of something else</li> <li>Patients who choose PSA testing are more likely than those who decline testing to be diagnosed with Pca</li> </ul>	

The PSA test often does not distinguish between serious cancer and nonserious cancer; men with markedly increased PSA levels (>10 µg/L) may have a reduced chance of dying from Pca by having surgical treatment

There are many potential harms of screening

The PSA test is not just a blood test; it is a test that can open the door to more testing and treatment that may cause harm  
Recommendations about screening may change over time; men are welcome to change their minds at any time by asking for screening that they have previously declined or discontinue screening that they have previously requested

ACP Guidance Statement: Screening for Prostate Cancer: <http://annals.org/article.aspx?articleID=1676183&atab=7>

AUA<sup>d</sup>

Men aged <40 y:

Recommends against PSA screening

C<sup>e</sup>

Men aged 40–54 y at average risk

Does not recommend routine screening

C<sup>e</sup>

Men aged 55–69 y

Recommends shared decision making and proceeding with PSA screening based on a man's values and preferences

B<sup>f</sup>

Men aged >70 y, or with a life expectancy <10–15 y

Does not recommend routine PSA screening

C<sup>e</sup>

To reduce the harms of screening, a routine screening interval of ≥2 y may be preferred over annual screening in those men who have participated in shared decision making and decided on screening

C<sup>e</sup>

Shared decision making between clinicians and men is a strategy for making health care decisions when there is more than 1 medically reasonable option. Shared decision making includes the following characteristics:

Involvement of both the clinician and patient in the decision-making process

Bilateral sharing of information

Joint participation in the decision-making process

Reaching agreement on the management strategy to implement

Decision aids may help facilitate shared decision making (eg, [http://www.asco.org/sites/www.asco.org/files/psa\\_pco\\_decision\\_aid\\_71612.pdf](http://www.asco.org/sites/www.asco.org/files/psa_pco_decision_aid_71612.pdf)<sup>f32</sup>)

AUA Guideline on Early Detection of Prostate Cancer: <http://www.aunet.org/education/guidelines/prostate-cancer-detection.cfm>

(continued on next page)

**Table 3**  
(continued)

Organization	Recommendations, Guidance Statements, and Clinical Considerations	Evidence Grade
ACS <sup>9</sup>	<p>Pca screening should not occur without an informed decision-making process</p> <p>Men aged <math>\geq 50</math> y at average risk</p> <p>    Recommends that asymptomatic men who have a <math>\geq 10</math>-year life expectancy make an informed decision with their health care provider about screening after receiving information about the uncertainties, risks, and potential benefits</p> <p>Men at higher risk (including black men and those with first-degree relative diagnosed with Pca before age 65 y) aged 40–49 y</p> <p>    Recommends men make an informed decision with their health care provider about screening after receiving information about the uncertainties, risks, and potential benefits</p> <p>Men with &lt;10-year life expectancy</p> <p>    Recommends not offering Pca screening</p> <p>Men should either receive this information directly from their health care providers or be referred to reliable and culturally appropriate sources</p> <p>Patient decision aids are helpful in preparing men to make a decision whether to be tested</p> <p>For men who choose to be screened for Pca after considering the possible benefits and risks:</p> <p>    Screening is recommended with PSA with or without DRE</p> <p>    Screening should be conducted yearly for men whose PSA level is <math>\geq 2.5</math> ng/mL</p> <p>    For men whose PSA is &lt;2.5 ng/mL, screening intervals can be extended to every 2 y</p> <p>    A PSA level of <math>\geq 4.0</math> ng/mL historically has been used to recommend referral for further evaluation or biopsy, which remains a reasonable approach for men at average risk for Pca</p> <p>    For PSA levels between 2.5 ng/mL and 4.0 ng/mL, health care providers should consider an individualized risk assessment that incorporates other risk factors for Pca, particularly for high-grade cancer, which may be used to recommend a biopsy</p> <p>ACS Guideline for the Early Detection of Prostate Cancer: <a href="http://mr.crossref.org/iPage?doi=10.3322%2Fcaac.20066">http://mr.crossref.org/iPage?doi=10.3322%2Fcaac.20066</a></p>	
Additional guidelines/resources	<p>National Comprehensive Cancer Network, Prostate Cancer Early Detection (version 2.2012)<sup>33</sup>: <a href="http://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf">http://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf</a> (registration is required to access the guidelines)</p> <p>European Association of Urology<sup>34</sup>: <a href="http://www.uroweb.org/gls/pdf/09_Prostate_Cancer_LR.pdf">http://www.uroweb.org/gls/pdf/09_Prostate_Cancer_LR.pdf</a></p> <p>UK National Health Service<sup>35</sup>: <a href="http://www.nhs.uk/Conditions/Cancer-of-the-prostate/Pages/Prevention.aspx">http://www.nhs.uk/Conditions/Cancer-of-the-prostate/Pages/Prevention.aspx</a></p>	

<sup>a</sup> Adapted from the USPSTF.<sup>4</sup>

<sup>b</sup> Evidence grade D: the USPSTF concludes that there is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.

<sup>c</sup> Adapted from the ACP.<sup>36</sup>

<sup>d</sup> Adapted from the AUA.<sup>22</sup>

<sup>e</sup> Evidence grade C: the AUA concludes that strength of evidence in support of the intervention is low.

<sup>f</sup> Evidence grade B: the AUA concludes that strength of evidence in support of the intervention is moderate.

<sup>9</sup> Adapted from the ACS.<sup>37</sup>

US men describe not having engaged in shared decision making with their clinician when making decisions about Pca screening.<sup>38</sup> The decision to undergo Pca screening must involve an explicit discussion between patient and clinician of the possible benefits weighed against expected harms.

Shared decision making is a technique to help guide a clinical decision by taking into account patient preferences, health literacy, clinical science, available resources, expected benefits, and potential harms. Because it relates to Pca screening, the primary care provider must communicate to patients that the best available evidence does not support routine Pca screening, and that any future testing or intervention is likely to result in more harm than good. Unlike most cancer screening guidelines, which recommend screening unless the patient opts out, Pca screening should not be performed unless the patient opts in. Clinicians must not strive to talk men out of screening if they make an informed decision to be screened; rather, clinicians must clearly communicate the subsequent risks associated with screening, assess patients' understanding of these risks, and document the shared decision-making process in the patients' electronic health record (EHR). For patients who decline screening, future discussions about screening should occur if a patient's risk profile changes, when/if a patient raises the topic themselves, or at an agreed interval reflecting the patient's informed preference (in such cases, this interval should be documented in the patient's EHR). Clinicians must strive to not talk men into screening if they make an informed decision not to be screened.

As highlighted in **Table 3**, the USPSTF, ACP, AUA, and ACS all endorse shared decision making as an essential component of Pca screening. One strategy to assist in shared decision making is through the Elwyn model. There are 3 major steps to the Elwyn model: choice talk, option talk, and decision talk. The purpose of choice talk is to convey to the patient that more than 1 reasonable treatment option exists; option talk includes a more detailed discussion about the various treatment options; and decision talk solicits patients' preferences and values in light of choices and options.<sup>39</sup> **Box 2** outlines several key aspects of choice talk, option talk, and decision talk, and provides examples that are specific to Pca.

## DECISION AIDS: ANOTHER TOOL FOR SHARED DECISION MAKING

Decision aids (tools that provide patients with unbiased, evidence-based information about available treatment options) can improve patients' ability to make educated, value-based decisions about care when more than 1 medically reasonable test or treatment option exists. Decision aids can help to improve patients' health literacy, clarify preferences, improve decision making, align values with treatment options, stimulate shared decision making, and promote follow-through. By helping patients identify health care preferences, decision aids can also reduce health care costs by preventing unwanted or unnecessary care.<sup>40–42</sup>

There are many decision aids available to help men make health care choices relating to Pca screening (see Lin and colleagues<sup>40</sup> for a review on the topic). In addition to the tool developed by the American Society for Clinical Oncology and referenced by the AUA in its guidelines on early detection of Pca (see **Table 3**), Thompson and colleagues developed a prostate risk calculator (available at <http://deb.uthscsa.edu/URORiskCalc/Pages/calcs.jsp>),<sup>43</sup> which generates risk percentages based on an individual patient's Pca risk. Because of its simplicity, the tool could be used within the context of the clinical encounter as a resource to help patients and clinicians make informed Pca screening decisions.<sup>44</sup>

**Box 2****The Elwyn model for shared decision making in Pca screening: choice talk, option talk, and decision talk***Choice talk*

- Assessing knowledge: "Now that you are 50 years old it is time to discuss prostate cancer screening"
- Offering a choice: "There are some new guidelines regarding prostate cancer screening, and I'd like to discuss them with you"
- Justifying the choice: "There are potential risks and benefits to screening, and I am here to help you sort through them"
- Checking reaction: "This is a lot to take in, shall we continue?"
- Postponing closure (if necessary): "I can see you still have concerns, and we don't need to make a decision today. My goal is to help you make a decision that is best for you. Would you like me to describe the screening options in more detail? Please interrupt me if you have questions or concerns"

*Option talk*

- Checking knowledge: "What have you heard about prostate cancer screening?"
- Listing options: provide options in writing
- Describing options (including harms and benefits): engage patient in dialogue and explore their preferences and values
- Providing decision support: consider the use of decision aids (eg, [http://www.asco.org/sites/www.asco.org/files/psa\\_pco\\_decision\\_aid\\_71612.pdf](http://www.asco.org/sites/www.asco.org/files/psa_pco_decision_aid_71612.pdf)<sup>32</sup>)
- Providing summary (and assessing for understanding): review the list of options and ask the patient to describe back to you in their own words

*Decision talk*

- Focusing on patient preferences and values: solicit the patient's point of view
- Eliciting patient preference: help facilitate the conversation by offering guidance; do not rush a decision
- Decision making: ask the patient if they have reached a decision; if not, ask what you can do to help
- Offering review: confirm decisions and make sure that you understand the patient's concerns, preferences, and values

*Adapted from* Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27(10):1361–7.

**FUTURE OF SCREENING**

The potential benefits of Pca screening do not outweigh the probable harms. What is needed are universal screening tool(s) that have both high specificity and high sensitivity (thus, maximizing true positives and true negatives), or an acceptably precise algorithm that correctly identifies those men at risk for developing aggressive forms of Pca. Further studies involving genetic markers, as well as studies of the interaction between genetics and the environment, may provide improved understanding of who to screen, and among those screening positive, who has indolent versus aggressive disease.<sup>13,45</sup>

As current PSA-based screening guidelines are put into practice, continued surveillance will be necessary to assess how changes in screening practice affect Pca

outcomes (including outcomes related to undertreatment and overtreatment) among populations with varying demographic backgrounds.

## **HEALTH CARE DELIVERY SYSTEMS AND PCA SCREENING**

### ***Patient Protection and the Affordable Care Act***

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The Patient Protection and Affordable Care Act (ACA) puts considerable emphasis on USPSTF recommendations, requiring most insurers to provide recommended preventive services at no additional cost to patients. Because the USPSTF does not recommend Pca screening, the Secretary of the Department of Health and Human Services is authorized to deny reimbursement from Medicare for PSA testing.<sup>46</sup> Currently, Medicare covers 1 DRE and 1 PSA-based test per year for male enrollees aged 50 years and older.<sup>47</sup> Given the USPSTF position that patients requesting Pca screening should be provided with the opportunity to make an informed value-based choice, it seems unlikely that reimbursement for PSA testing will be stopped anytime soon; however, limiting payment would result in less screening and a subsequent reduction in overdiagnosis and overtreatment. Observed savings could then be allocated to other screening programs or treatments with proven efficacy. Policies that limit reimbursement may be worth debating, because they have the potential not only to improve patient outcomes (ie, reducing overdiagnosis and overtreatment) but to decrease health care costs.

### ***EHR***

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EHRs have the potential to improve the delivery of preventive<sup>48</sup> and ambulatory<sup>49</sup> health care, including care related to Pca screening. For example, EHRs can be tailored to offer reminders or prompts about the need to discuss current recommendations (ie, not to screen), help facilitate shared decision making among those who wish to pursue screening, and help identify patients at higher risk for Pca based on factors such as age, life expectancy, race, and family history. Reflecting the patient's informed preference, EHRs could also be used to indicate timing for future discussions about screening, as well as document key components of shared decision making. For patients who choose to be screened, EHRs can be used to automatically flag patients who screen positive and require follow-up.<sup>50</sup>

### ***PCMH***

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The Agency for Healthcare Research and Quality defines a PCMH “not simply as a place but as a model of the organization of primary care that delivers the core functions of primary health care[.]” that is, care that is patient-centered, comprehensive, coordinated, enables patient access, and provides a dedicated systems-based approach to quality and safety.<sup>51</sup> Emerging evidence suggests that the PCMH model delivers higher quality care at the same or lower cost than standard care and with increased patient satisfaction<sup>52</sup>; moreover, evidence suggests that patients who receive care in an established PCMH are more likely to undergo cancer screening and to follow the recommendations of their clinician.<sup>53</sup>

Capitalizing on the strengths of each team member, a team-based approach to Pca screening could help to promote several important principles related to the PCMH. In a team-based approach, front office staff could provide men older than 50 years with information about Pca screening when checking in for their appointment (eg, a brochure that outlines the limited possible benefits against the many expected harms). After taking the patient to the examination room, the medical assistant or nurse could ask the patient if they have any questions and provide information (patient education)

as needed. The medical assistant or nurse could then document the conversation in the patient's EHR, including the need for follow-up conversation with the clinician, when applicable. For patients who express an interest in screening, the medical assistant or nurse could provide a decision aid (see [Table 3](#)), documenting its use in the EHR. Clinicians, then, could use the decision aid as a tool to facilitate shared decision making and record the outcome in the patient's EHR. For those choosing to be screened, follow-up tests/care could be coordinated within the medical home and its affiliated clinics, with staff arranging subsequent appointments with the team's preferred provider(s) or the provider of the patient's choosing. Alerts within the EHR could notify the team of test results; if test results remain outstanding, a care manager (or office staff or medical assistant) could follow up with laboratories or other clinics/departments to gather and enter findings into the EHR. At each stage of the screening/testing process, the clinician (or nurse or medical assistant) should confirm that the patient understands the risks of each test/procedure and provide an opportunity for the patient to discontinue the screening/testing process.

Although the specific processes for a team-based approach to Pca screening vary by setting, the key to ensuring an effective team process is careful planning, thoughtful reflection on how things are going, and reworking the care process as needed until it operates smoothly. Team members should continuously strive to ensure that patients are making informed decisions and receiving the right care, at the right time, and in the right care setting(s), and that the process of care is supported and recorded through the use of appropriate technology, which maximizes both quality and efficiency.

### **Accountable Care Organization**

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As defined by the Centers for Medicare and Medicaid Services, accountable care organizations (ACOs) are groups of hospitals, doctors, and other clinicians who work together to give high-quality and coordinated care to a population of patients, with the goal of avoiding unnecessary care or duplication of services. When ACOs successfully deliver high-quality care in a cost-effective manner, those providing the care share in the savings (for more about ACOs, see <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html?redirect=/aco/>).<sup>54</sup> Although Pca screening is not an explicit quality performance measure that ACOs must meet for shared savings, the process for screening (ie, shared decision making) is.<sup>55</sup>

Among the most significant barriers described by clinicians to implementing shared decision making are time constraints.<sup>56</sup> ACOs may help to reduce this barrier: as described by Berwick,<sup>57</sup> coordinated care through an ACO "is meant to allow providers to break away from the tyranny of the 15-minute visit, instill a renewed sense of collegiality, and return to the type of medicine that patients and families want. For patients, coordinated care means more 'quality time' with their physician and care team...and more collaboration in leading a healthy life." Although the verdict is still out on whether ACOs gives primary care providers more time to engage in shared decision making, emerging evidence suggests that patients are more likely to receive education (a key component of shared decision making) if their provider received primarily capitated payment.<sup>58</sup>

### **SUMMARY**

Universal screening for Pca is no longer recommended, because the potential harms associated with screening (overdiagnosis, overtreatment, and subsequent complications) outweigh the potential benefits. For those patients continuing to express an

interest in Pca screening, primary care providers must engage the patient in shared decision making, helping them weigh individual risk factors (eg, age, life expectancy, family history, black race) against harms and benefits. New models of care informed by the ACA, such as ACOs, PCMHs, and team-based primary care, are poised to assist clinicians in providing recommended preventive care. In the case of Pca, screening is not recommended, and effective communication through shared decision making can help patients make informed decisions reflecting their preferences and values.

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