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## A simple schema for informed decision-making about prostate cancer screening

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Screening for prostate cancer with prostate-specific antigen (PSA) remains a problematic aspect of primary care. With the exception of the US Preventive Services Task Force (USPSTF), which made an influential(1) but highly-criticized(2) recommendation against any early detection efforts based on PSA, most guidelines recommend that an informed decision be made by the individual patient following a discussion with a doctor. For example, the American College of Physicians (ACP) states that “doctors and patients should discuss the potential benefits and harms of screening” before PSA testing. This recommendation is made even though the ACP is generally skeptical of the benefits of PSA (“for most ... men, the harms will outweigh the benefits”)(3). Likewise, the American Urologic Association (AUA), while more favorably predisposed to screening, makes a similar statement in “strongly recommend[ing] shared decision-making.”(4)

Yet implementing shared decision-making in primary care is not straightforward, as it must take into account the wide range of information and data that could be discussed, the complex trade-off between immediate harms and long-term benefits, and the limited time primary care clinicians have for in-depth discussions about PSA in the context of a multitude of other issues in a typical visit. Recent years have seen a considerable literature develop on PSA decision-making, including specific advice to primary care providers as to what they should say to individual patients. Our multidisciplinary group, a statistician specializing in localized prostate cancer, a bioethicist who has conducted empirical research about decision-making as to PSA screening, an academic urologic oncologist and epidemiologist, and an academic primary care physician, has followed this literature closely. We think recommendations either specify too little information to allow patients to make a decision or so much as to overwhelm patients’ ability to decide rationally. Recommendations requiring extensive information also have low clinical feasibility — one suggests that doctors inform patients on 16 separate points and ask 12 questions concerning

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Conflict of Interest: Andrew Vickers is named on a patent application for a statistical method to detect prostate cancer.

preferences(5) - include data that might be hard for patients to understand or assign a value to, such as the risk of deep vein thrombosis(6), or cite estimates that are conflicting and questionable, such as PSA leading to either 30(7) or, alternatively, 110(6), extra diagnoses of prostate cancer per 1000 men screened.

Given the inadequacies of current recommendations, and attendant poor compliance, we pose an alternative approach for informed decisions about PSA testing in primary care. This is based on three main principles. First, what is said to the patient must be based on best evidence and, as far as is possible in such a controversial field, must be beyond dispute. This would avoid the situation of many decision tools, such as the infographic provided by the National Cancer Institute(6), in which many of the key numbers cited, such as the risk of overdiagnosis, are subject to considerable controversy. Second, the patient should be presented with a clear framework for a decision. This contrasts explicitly with complex decision aids that provide patients with a large number of estimates and then asks them to integrate these somehow into a discrete choice. Third, the schema should be appropriate for primary care. It should not assume detailed knowledge by the provider, nor require more than a few minutes.

As a starting point, we assume that primary care providers correctly identify eligible patients: men in their mid-forties through mid-seventies with minimal comorbidity. We also assume that providers adopt the “ask-tell-ask” approach that has been previously advocated(8). Starting with the initial “ask”, the clinician finds out critical information regarding what the patient already knows about PSA or what their level of concern or interest may be. This allows the clinicians to tailor their “tell” portion of the conversation more succinctly and directly to the patient’s particular needs and level of current understanding. The “tell” portion of the conversation then follows the simple schema outlined below. The Web appendix provides evidence supporting each point.

### **Key facts about prostate cancer and screening**

1. Prostate cancer is very common: most men will develop prostate cancer if they live long enough.
2. Although only a small proportion of men with prostate cancer die from the disease, the best evidence is that screening reduces the risk of death from prostate cancer.
3. Screening detects many low-risk or "indolent" cancers.
4. In the US, most low-risk cancers do nonetheless end up getting treated, and the treatment itself can lead to problems such as incontinence, erectile dysfunction, and bowel problems.

### **Key take home message**

5. The goal of screening is to find aggressive prostate cancers early and cure them before they spread beyond the prostate.

6. Most cancers found by screening do not need to be treated, and can be safely managed by a program of careful monitoring known as “active surveillance.”

### Discrete decision

7. If you choose to be screened, there is a chance that you will be diagnosed with a low-risk cancer, and you may face pressure from your doctors or family to treat it.
8. If you are concerned that you would be uncomfortable knowing that you have cancer and not treating it, then screening may not be for you.
9. If you are confident that you would only accept treatment for an aggressive cancer, and would not be unduly worried about living with a diagnosis of low-risk disease, then you are probably a good candidate for screening.

This brief decision tool meets our three criteria of being evidence-based, facilitating a discrete decision, and being appropriate for primary care—requiring a relatively limited amount of time and invoking only general knowledge about PSA screening. Following the “ask-tell-ask” approach(8), this sharing of information would be followed by a final “ask”, in which the clinician checks with the patient to see if what he or she has just explained makes sense, and asks for a preference from the patient regarding the decision. With this revised, streamlined approach, clinicians can meet the recommended guidelines of having an informed, evidence-based discussion that provides a clear framework for decision making about PSA screening.

### Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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## Evidence base and rationale

***Most men will develop prostate cancer if they live long enough.***

Autopsy studies show that cancer is often found in the prostates of men who die of other causes, > 60% in men over 80.<sup>(1)</sup>

***Only a small proportion of men with prostate cancer die from the disease.***

The yearly incidence of prostate cancer is about 8 times the yearly mortality rate.<sup>(2)</sup>

***Screening reduces risk of death from prostate cancer.***

There are two major randomized screening trials. The US-based PLCO trial<sup>(3)</sup> was described by the authors as a trial of “systematic vs. opportunistic” screening because about half of those in the control group continued to receive PSA tests despite their randomization to a no screening group. The European ERSPC trial had lower rates of contamination, and truly tested the value of screening in men who would not otherwise be screened. In ERSPC, screening led to a 21% relative reduction in the risk of prostate cancer mortality at 11 years.<sup>(4)</sup> US population trends show that prostate cancer mortality has fallen by over 40% since the introduction of PSA testing<sup>(2)</sup>, an effect difficult to attribute to a cause other than screening<sup>(5)</sup>.

***Screening detects many low risk or "indolent" cancers that do not need treatment.***

In both the ERSPC trial<sup>(4)</sup> and population-based US data<sup>(6)</sup> about 60% of cancers were graded as Gleason 6, indicating low risk disease.

***Most low risk cancers do nonetheless end up getting treated.***

About 90% of US patients with low risk prostate cancer are subject to curative treatment.<sup>(7)</sup>

***Prostate cancer treatment is associated with a risk of serious problems such as incontinence, erectile dysfunction and bowel problems.***

Surgery for prostate cancer can lead to urinary incontinence and erectile dysfunction; radiotherapy is associated with lower rates of erectile dysfunction, but can cause bowel problems.<sup>(8)</sup>

***Most cancers found by screening don't need to be treated and can be safely managed by careful monitoring***

Most cancers detected by screening are low risk. Longitudinal cohort studies show that patients with low risk prostate cancer managed by active surveillance have extremely low rates of cancer-specific mortality.<sup>(9)</sup>

***If you choose to be screened, there is a good chance that you will be diagnosed with a low risk cancer.***

The incidence of prostate cancer in men undergoing screening is approximately 10% at 10 years<sup>(4)</sup>. At least half of these cancers are low risk.<sup>(4)</sup>

***If you have a low risk cancer, your doctors or your family may pressure you to treat it.***

Most urologists and radiation oncologists, especially those outside academic medical centers, routinely treat almost all low risk cancers<sup>(7)</sup>. Family pressure is commonly reported by clinicians who do promote active surveillance.

***If you are concerned that you would be uncomfortable knowing that you have cancer and not treating it, then screening may not be for you.******If you are confident that you would only accept treatment for an aggressive cancer, and would not be unduly worried about a diagnosis of low risk disease, then you are probably a good candidate for screening.***

Most decision-analyses of PSA screening report that the net benefit is borderline<sup>(10)</sup>. Patients who are at high risk of overtreatment are therefore less likely to experience net benefit than those predisposed to choose active surveillance for low risk cancer.

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