

Prostate Cancer Screening in an Era of New Guidelines:

Feasibility and Acceptability of a Prostate Cancer Screening

Decision Aid in Primary Care Settings

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Abstract

Introduction

Prostate cancer is the most common cancer in men in North America and the second leading cause of cancer-related death. Recent changes in understanding of potential benefits and harms from prostate cancer screening have resulted in changes to clinical guidelines, with significant importance placed on involvement of patients in shared decision making about whether to be screened for this cancer. This goal of this study was to evaluate acceptability and usability of a patient decision aid in the primary care setting.

Methods

A convenience sample of screening-eligible men in two primary care clinics were recruited to utilize the decision aid in partnership with their primary care provider. We assessed decisional conflict and satisfaction with the decision aid among patients. To assess acceptability, general feedback questions were asked of the patients and providers after use of the decision aid.

Results

Of 58 patients recruited, 40 enrolled in the study (69% accrual rate) and all 40 participated to completion. All patient participants reported low decisional conflict about their screening choice. Ninety percent of participants were either very satisfied or extremely satisfied with the decision aid while 80% of providers were at least moderately satisfied. Seventy five percent of providers thought the provider guide was moderately to extremely helpful, while 71% thought

the decision aid was moderately to extremely helpful in their conversation with their patient. Sixty five percent of providers thought the patient decision aid reduced decisional conflict for their patient. Eighty two percent of providers thought using the decision aid did not disrupt clinic workflow. Eighty five percent of the providers would recommend the decision aid materials to their patients considering prostate cancer screening. In addition, 85% thought the information in the decision aid was very relevant for their patient.

Conclusions

The decision aid in this study was acceptable and beneficial to patients, its use was feasible in primary care clinic settings, and overall satisfaction with the decision aid among patients and providers was high. Further study of the use of this decision aid in comparison to standard care around prostate cancer screening decisions is a vital next step.

**Prostate Cancer Screening in an Era of New Guidelines:
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Decision Aid in Primary Care Settings**

Introduction

In men in North America, prostate cancer is the most common cancer and the second leading cause of cancer-related death.¹ Screening is intended to identify men with a potentially lethal disease early that may be cured with definitive local therapy. The challenge is to minimize treatment of men with less aggressive disease who may be harmed by therapy. Widespread adoption of prostate-specific antigen (PSA) testing as a screening tool began in the late 1980s. Three large randomized controlled trials (RCT) evaluated the efficacy of PSA-based screening: the CAP randomized clinical trial², the U.S. based Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial³ and the European Randomized Study of Screening for Prostate Cancer (ERSPC).⁴ While the initial reports from the CAP trial revealed no prostate cancer-specific survival benefit for a single PSA screening at follow up at 10 years, and the PLCO trial revealed no significant prostate cancer-specific mortality at 10 years of follow-up, the ERSPC did report a 20% reduction in prostate cancer-specific mortality at a median follow-up of 9 years.^{3, 4} Recently, the ERSPC Swedish cohort revealed a 45% reduction in the risk of death from prostate cancer with screening and surgery versus observation at 23 years of median follow up with 8.4 as the number needed to treat (NNT) to prevent one death.⁵

Recommendations for PSA screening have varied widely. The National Comprehensive Cancer Network (NCCN) and the American Cancer Society (ACS) both recommend a risk-stratified

approach to screening, while the United States Preventive Services Task Force (USPSTF) recommends that PSA screening be a shared decision process with men aged 55-69 years.⁶⁻⁸ Since its introduction, many challenges complicated and limited PSA screening utility. Historically, almost all men diagnosed with prostate cancer were treated, leading to unnecessary morbidity in many. Now, risk stratification tools identify low-risk prostate cancer patients for whom active surveillance is recommended.⁹⁻¹¹ Furthermore, the uncertainty surrounding the appropriate timing of PSA screening led to a randomized population-based screening trial of formal versus opportunistic screening. In this trial, formal screening was associated with reduced prostate cancer-related mortality and lesser overdiagnosis.¹² More detailed protocols may be able to reduce the complications and maintain the benefits of PSA-based screening for prostate cancer.

A shared decision making (SDM) process has the potential to address the uncertainties and complexities of PSA screening. This voluntary process encourages a physician-patient discussion to consider the best available evidence on the benefits and harms of a particular option that incorporates the individual patient values and preferences relevant to those options.¹³ SDM is often used in conjunction with patient decision aids to help facilitate the patient-provider dialogue and the shared decision making process.^{14, 15} The International Patient Decision Aid Standards (IPDAS) Collaboration defines decision aids as “tools designed to help people participate in decision making about health care options.”¹⁶ They provide information about management options, assist patients in communicating their personal values associated with each approach and help make preference-sensitive decisions when there is more than one valid choice.^{13, 14, 17} The aim is to supplement the providers' expert opinion on a nuanced medical

decision with evidence-based information and help address decisional conflict allowing the patients to be informed, engaged, and true participants in their healthcare. In this way, SDM and patient decision aids are complementary tools to help foster dialogue and help patients reach informed decisions about their care. After evaluating hundreds of RCTs of decision aids, the Cochrane Collaboration found patients who used such tools were informed and subsequently adhered better to treatment regimens.^{13-15, 18, 19} Furthermore, the use of high-quality decision aids improves patients' knowledge about options and their outcomes, increases accurate risk perception, results in a better match between values and choices, reduces decisional conflict, and decreases the number of people who remain undecided about healthcare decisions.^{14, 18}

Having implemented an active PSA Screening Clinical Pathway, Duke researchers collaborated with the American College of Preventive Medicine (ACPM) in a project funded through a cooperative agreement with the Centers for Disease Control and Prevention (CDC) to develop and evaluate a standardized, time-efficient decision aid to facilitate SDM for prostate cancer screening.²⁰ To address conflicting guidelines and concerns about PSA screening, Duke and the ACPM assembled experts in prostate cancer and decision aids to develop a paper-based tool that could help facilitate the physician-patient discussion and enhance SDM for men considering prostate cancer screening.²¹

The primary goal of this study was to assess the acceptability and usability of the decision aid for use by patients and their providers in the primary care setting.

Methods

Institutional Review

This study was reviewed and exempted by the Duke University School of Medicine Institutional Review Board.

Design

This is a prospective, non-randomized pilot study to assess feasibility and acceptability of implementing a prostate cancer screening decision aid to facilitate SDM in primary care settings. An iterative process was used to incorporate clinician and patient feedback, including an assessment of readability. The decision aid was then presented to the Duke Cancer Institute's Community Advisory Council, and additional revisions to the decision aid were made based upon their suggestions.

Components of the Decision Aid

The decision aid is a four-page document that includes a guide for patients to use in completing the tool, a patient-completed questionnaire that includes prostate cancer risk assessment, patient attitudes about prostate cancer screening, a means for recording questions the patient might have for his provider and a means for recording their current preference for screening. The intervention is structured around activities utilizing decision aid tools completed by the provider and patient before the visit, during the visit, and after the visit. (Figure 1) The patient completes the patient portion of the guide and brings the paper document to the visit with the provider if completed outside the visit, or returns it to the provider if the document is completed within a patient visit. In addition to this patient-centric document, there is a 1-page guide for providers describing the workflow for using the decision aid. These documents may be downloaded and freely used, with access available publicly at this website:

<https://www.acpm.org/page/prostatecancerscreening>. The materials are also available as supplemental materials included with this manuscript.

Participants

Patients were identified by research staff through the electronic medical record system. Forty men were enrolled from two different Duke primary care sites (one rural and one urban). Participant eligibility included men 45 – 75 years of age, no PSA test in the past 12 months, no history of elevated PSA levels, no history of prostate cancer, and English-speaking. Eligibility also included men who either had no history of PSA-based screening or had a history of intermittent PSA-based screening (i.e. had gone at least four years without a PSA test throughout age-eligible years for this study). History of continuous PSA-based screening was accounted for during the screening of participants in order to limit participant decision bias. Stratification factors included age at study enrollment and race/ethnicity. Among the 58 eligible patients approached, 40 people participated to completion (69% accrual rate). Principal reasons for non-participation were: “did not have enough time,” “not interested,” and “had a lot going on.” Overall study completion rate for the 40 enrolled participants was 100%.

A total of 11 primary care providers were involved in the project. These providers were asked to complete a survey offering their feedback about the decision aid following each patient encounter in which the decision aid was used.

Procedures

The decision aid was given to participants for them to review and complete (based on provided instructions) prior to seeing their primary physician during their appointment. Participants used the decision aid at their appointment to discuss with their primary care provider and make an informed and shared decision about PSA screening. Participants then completed a short survey (Decisional Conflict Scale - DCS)²², and feedback questions during their appointment with a member of the study team. Feedback surveys were also sent to providers within one week following their patient's primary care appointment. Physician feedback was obtained through an emailed link via REDCap (Research Electronic Data Capture) software. The provider feedback survey allowed providers to assess participant decisional conflict and rate the decision aid. Several providers had multiple patients who participated in this study. In total, 11 different providers were involved in discussing the decision aid with their patient and completed the provider feedback survey for each patient who participated.

Measures

As a qualitative review of the decision aid, readability and usability were assessed through feedback obtained from the Duke Cancer Institute's Community Advisory Council before the decision aid was piloted. The research team used the feedback received to edit language and illustrations in the decision aid prior to participant enrollment.

We evaluated the feasibility, acceptability and decisional outcomes of the decision aid to help facilitate a shared decision making process between patients and their primary physicians with regards to prostate cancer screening. We assessed the following measures: accrual rate; rate of completion for all instruments (including reaching a conclusion on screening); utility of outcome

measure for future study. In addition, decisional conflict, acceptability, and qualitative information were assessed.

We measured decisional conflict with the 16-item (statements) DCS.²² Items were scored on a 5-point Likert scale from 0 (strongly agree) to 4 (strongly disagree). Individual patient subscores were obtained by adding the scores (0-4) for the 16 items, dividing the sum by 16, and then multiplying it by 25. Total scores of decisional conflict thus range from 0 (no decisional conflict) to 100 (extremely high decisional conflict). Individual participant uncertainty and informed subscores were also scaled from 0 (feels extremely certain about best choice or feels extremely informed) to 100 (feels extremely uncertain about best choice or feels extremely uninformed) and averaged.²³

To assess acceptability, general feedback questions were asked of the patients and providers after the decision aid session. Likert scale questions for patients and providers included satisfaction with the decision aid and whether they would recommend the tool to others.

Data Analysis

Counts and frequency distributions were used to determine both patient and provider acceptability of the decision aid. Total scores and sub scores for items on the DCS were calculated.²³ Summary descriptive statistics of decisional conflict include mean decisional conflict total scores and sub scores, standard deviations, 95% mean confidence intervals, and frequency of high decisional conflict.

Results

Table 1 presents participant demographic information. The mean age of participants was 55.7 years (SD 8.27); 19 of the 40 participants identified their race as “black” (47.5%). All patients were insured, with 27 (67.5%) having private health insurance, 6 (15%) having public insurance, and 7 (17.5%) having a mix of private and public coverage.

Decisional Conflict

Mean decisional conflict scores are displayed in Table 2. Participants were asked to complete the DCS considering their decision regarding prostate cancer screening. All participants [n = 40 (100%)] completed the DCS. Overall, 100% of participants expressed relatively low total decisional conflict (score ≤ 37.5). Individuals whose scores are greater than 37.5 are uncomfortable with the decision and tend to delay it or are associated with feeling unsure about implementation.²³ The total mean DCS score for participants was 12.03 (SD = 12.03), with only 5% expressing high decisional conflict on the uncertainty subscale (mean = 13.96, SD = 14.91), and 2.5% on the informed subscale (mean = 11.25, SD = 12.88).

Participant and provider satisfaction

Participant and provider satisfaction with the decision aid is presented in Figure 1. 90% of participants were either very satisfied or extremely satisfied with the decision aid, while 80% of providers were at least moderately satisfied with the materials for 80% of the encounters for which providers offered feedback (n=40 encounters).

181

182 General participant feedback

183 Participant response rate for the feedback survey was 100%. The information presented in the
184 decision aid was new to 59% of participants. All participants felt the decision aid was easy to
185 read and understand and would recommend the decision aid to a family member or friend. Over
186 three-quarters (77.5%) of participants remembered the main points from the decision aid when
187 asked at the end of their appointment. Finally, 92.5% of participants responded that the decision
188 aid did not make them feel anxious or fearful.

189

190 General provider feedback

191 The 11 primary care providers in the study completed a feedback survey after each patient
192 encounter (100% response rate). Provider feedback regarding the helpfulness of the provider
193 guide and the patient decision aid is presented in Figure 2. 75% of providers thought the provider
194 guide was moderately to extremely helpful, while 71% thought the decision aid was moderately
195 to extremely helpful in their conversation with their patient. 65% of providers thought the patient
196 decision aid reduced decisional conflict for their patient. 82.5% of providers thought using the
197 decision aid did not disrupt clinic workflow. 85% of the providers would recommend the
198 decision aid materials to their patients considering prostate cancer screening. In addition, 85%
199 thought the information in the decision aid was very relevant for their patient. A single provider
200 reported being “slightly satisfied” for most of the encounters that provider completed. This
201 provider felt that the tools were too long, and that patients relied mostly on that provider’s
202 opinion to make their decisions.

203

204 Discussion

205 Our results indicate a high degree of satisfaction with the decision aids for both patients and
206 providers who used them and a low rate of decisional conflict for patients over the decisions they
207 reached about prostate cancer screening. The study offers information about the use of these
208 tools in the setting in which men most frequently make decisions about screening for prostate
209 cancer, namely their primary care provider's office setting.

210

211 This study found that use of a patient decision aid delivered as part of a multi-component
212 intervention in primary care settings is feasible, acceptable to patients and health care providers,
213 and associated with low decisional conflict among patients. Patients were highly favorable about
214 use of the decision aid, indicating it was helpful in their conversations with their health care
215 providers. Similarly, the majority of providers would recommend the aid to their patients and
216 found its use was feasible within a busy clinical setting. A novel feature of this intervention is
217 that it combines a decision aid completed by the patient prior to the clinical encounter along with
218 summary information that can be viewed by the provider and patient during the encounter.

219 Through this structured process, the patient becomes better prepared to have a conversation with
220 a health care provider and participate more actively in the decision-making process if he desires.

221

222 IPDAS criteria for this decision aid

The decision aid developed for this study was designed to meet certification standards from the National Quality Forum (NQF).²⁴ Based largely on standards for development, content, and evaluation of patient decision aids from the International Patient Decision Aid Standards (IPDAS) Collaboration,²⁵ the NQF identified 7 criteria need to be met before considering a decision aid for certification. The last criterion addresses the patient decision aid helping to clarify patient values. Step 5 of the prostate cancer screening decision aid evaluated in this study asked patients' to consider how they feel about potential benefits and harms of screening using a series of values-prompting questions. Additional attention was paid to reading level, use of engaging visuals, and references to primary evidence sources. Outcome probabilities are included as key talking points in the provider summary.

Strengths and Limitations

The development team for this decision aid could benefit from feedback from a larger number of users representing a larger segment of the population, both among patients and providers in the primary care setting. It could also benefit from head-to-head comparison with other accepted decision aids if they are created in light of updated guidelines. A key limitation of this study lies in its use of a convenience sample from a limited geographic area, so its evaluation among a broader audience of potential users is needed. Finally, the tools may be used more easily and taken up more readily if they are available in both paper and electronic format.

Public health implications

There is an increasing focus on health communication and health information technology at the national level, including a focus on shared decision making between patients and providers.²⁶⁻²⁸ Despite the increasing use of electronic technology for health information,²⁶ there is still a need for non-electronic materials for the public to make sound health decisions that are right for them and their families including those who live in underserved communities.²⁹

Overall significance of this study

The overall importance of this study rests in its relevance to and incorporation of newly-updated recommendations for prostate cancer screening, its grounding in real-life patient and provider experience of the use of the tool, and its implementation in two different primary care settings with a diverse patient population. This study offers a decision aid that will help further understanding of patient values about benefits and harms of screening and treatment for prostate cancer and how those values influence their decisions. Further study will be needed in a clinical trial setting to compare patient and provider satisfaction, decisional conflict and overall usability of these tools compared to other similar tools in clinical settings where these decisions most frequently occur. Such clinical trials have been found to be both useful and desirable in developing infrastructure that supports “informed patient choice as a standard of practice.”³⁰ This type of study would be a critical next step in exploration of the overall value of the tools described in this paper.

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- Andrew Wolf, MD – University of Virginia School of Medicine

References

1. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2015. *CA: a cancer journal for clinicians*. 2015;65: 5-29.
2. Martin RM, Donovan JL, Turner EL, et al. Effect of a low-intensity PSA-based screening intervention on prostate cancer mortality: the CAP randomized clinical trial. *Jama*. 2018;319: 883-895.
3. Andriole GL, Crawford ED, Grubb III RL, et al. Mortality results from a randomized prostate-cancer screening trial. *New England Journal of Medicine*. 2009;360: 1310-1319.
4. Schröder FH, Hugosson J, Roobol MJ, et al. Screening and prostate-cancer mortality in a randomized European study. *New England Journal of Medicine*. 2009;360: 1320-1328.
5. Bill-Axelson A, Holmberg L, Garmo H, et al. Radical prostatectomy or watchful waiting in prostate cancer—29-year follow-up. *New England Journal of Medicine*. 2018;379: 2319-2329.
6. Carroll PH, Mohler JL. NCCN Guidelines Updates: Prostate Cancer and Prostate Cancer Early Detection. *Journal of the National Comprehensive Cancer Network*. 2018;16: 620-623.
7. Grossman DC, Curry SJ, Owens DK, et al. Screening for prostate cancer: US Preventive Services Task Force recommendation statement. *Jama*. 2018;319: 1901-1913.
8. Smith RA, Andrews KS, Brooks D, et al. Cancer screening in the United States, 2018: A review of current American Cancer Society guidelines and current issues in cancer screening. *CA: a cancer journal for clinicians*. 2018;68: 297-316.
9. Hamdy FC, Donovan JL, Lane JA, et al. 10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer. *N Engl J Med*. 2016;375: 1415-1424.
10. Wilt TJ, Jones KM, Barry MJ, et al. Follow-up of Prostatectomy versus Observation for Early Prostate Cancer. *N Engl J Med*. 2017;377: 132-142.

11. Bill-Axelson A, Holmberg L, Garmo H, et al. Radical prostatectomy or watchful waiting in early prostate cancer. *N Engl J Med*. 2014;370: 932-942.
12. Arnsrud Godtman R, Holmberg E, Lilja H, Stranne J, Hugosson J. Opportunistic testing versus organized prostate-specific antigen screening: outcome after 18 years in the Goteborg randomized population-based prostate cancer screening trial. *Eur Urol*. 2015;68: 354-360.
13. Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. *Bmj*. 2010;341: c5146.
14. Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews*. 2017.
15. Elwyn G, Frosch D, Rollnick S. Dual equipoise shared decision making: definitions for decision and behaviour support interventions. *Implementation Science*. 2009;4: 75.
16. International Patient Decision Aid Standards (IPDAS) Collaboration. What are patient decision aids? Available from URL: <http://ipdas.ohri.ca/what.html> [accessed March 6, 2018].
17. Taylor KL, Williams RM, Davis K, et al. Decision making in prostate cancer screening using decision aids vs usual care: A randomized clinical trial. *JAMA Internal Medicine*. 2013;173: 1704-1712.
18. O'Connor AM, Wennberg JE, Legare F, et al. Toward The 'Tipping Point': Decision Aids And Informed Patient Choice. *Health Affairs*. 2007;26: 716-725.
19. Arnsrud GR, Holmberg E, Lilja H, Stranne J, Hugosson J. Opportunistic testing versus organized prostate-specific antigen screening: outcome after 18 years in the Goteborg randomized population-based prostate cancer screening trial. *European urology*. 2015;68: 354-360.

20. Dorfman CS, Williams RM, Kassan EC, et al. The development of a web-and a print-based decision aid for prostate cancer screening. *BMC medical informatics and decision making*. 2010;10: 12.
21. American College of Preventive Medicine. Prostate Cancer Screening Decision Aids. Available from URL: <http://www.acpm.org/page/prostatecancer> [accessed March 5, 2018].
22. O'Connor AM. Validation of a decisional conflict scale. *Medical decision making*. 1995;15: 25-30.
23. O'connor A. User Manual—Decisional Conflict Scale. 1993 [updated 2010]. Ottawa: Ottawa Hospital Research Institute. 2014.
24. National Quality Forum. National Standards for the Certification of Patient Decision Aids: Final Report. Washington, DC: National Quality Forum; December 15, 2016. Available from URL: https://www.qualityforum.org/Publications/2016/12/National_Standards_for_the_Certification_of_Patient_Decision_Aids.aspx [accessed February 8, 2019].
25. Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *Bmj*. 2006;333: 417.
26. Patel V, Barker W, Siminerio E. Trends in consumer access and use of electronic health information. *ONC Data Brief*. 2015;30.
27. Healthy People. Development of Healthy People 2030: Public Comment for Healthy People 2030. Available from URL: <https://www.healthypeople.gov/2020/About-Healthy-People/Development-Healthy-People-2030/Public-Comment> [accessed December 22, 2018].

28. Healthy People. Proposed Objectives for Inclusion in Health People 2030. Available from URL:<https://www.healthypeople.gov/sites/default/files/ObjectivesPublicComment508.updated%2012.20.2018.pdf> [accessed December 22, 2018].
29. US Department of Health and Human Services. Understanding the impact of health IT in underserved communities and those with health disparities. Briefing Paper. NORC at the University of Chicago. 2010.
30. O'Connor AM, Wennberg JE, Legare F, et al. Toward the 'tipping point': decision aids and informed patient choice. *Health Affairs*. 2007;26: 716-725.

FIGURE TITLES

1. Figure 1. Overall participant and provider satisfaction with decision aid materials
2. Figure 2. Helpfulness of provider guide and decision aid in conversation with patient

TABLES

Table 1. Participant Demographics

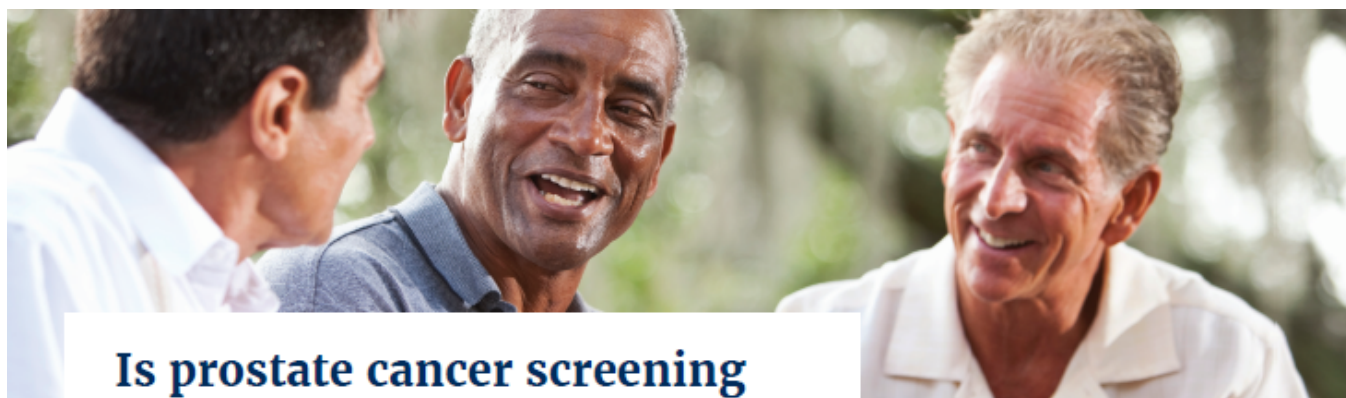
Characteristics	Patients (n=40)
Mean age in years (SD)	55.7 (8.27)
Age, n (%)	
45-54	21 (52.5%)
55-69	16 (40%)
70+	3 (7.5%)
Race, n (%)	
White	19 (47.5%)
Black	19 (47.5%)
Other	2 (5%)
Health Insurance Coverage, n (%)	
Private Insurance	27 (67.5%)
<u>Public Insurance</u>	
• Medicaid	2 (5%)
• Medicare	4 (10%)
Mix, Private and Public	7 (17.5%)

Table 2. Participant Decisional Conflict

Type	Mean (SD)	95% Confidence Interval	Frequency of high decisional conflict*
Total Score (n=40)	12.03 (12.031)	± 3.848	0%
Uncertainty Sub score (n=40)	13.96 (14.906)	± 4.767	5%
Informed Sub score (n=40)	11.25 (12.875)	± 4.118	2.5%

*Score > 37.5 is considered high decisional conflict

Figure 3: Decision Aid Documents



Is prostate cancer screening right for you?

DECISION GUIDE

- ▶ **Start completing this guide now!**
- ▶ **Review each step on pages 1, 2, and 3.**
- ▶ **Bring this guide to your visit.**

STEP 1: WHAT IS INVOLVED IN PROSTATE CANCER SCREENING?

- **A discussion** – Discussion of screening for prostate cancer is recommended for men ages 55 to 69 years, and sometimes at younger or older ages based on individual circumstances.
- **The PSA blood test** – The blood test is known as a ‘PSA test’ because it measures the level of prostate-specific antigen (PSA) in the blood. PSA is a protein made by the prostate gland and also by most prostate cancers.
- **Digital rectal exam** – Sometimes screening may also include a rectal examination by a physician using a finger.

STEP 2: WHAT ARE THE POTENTIAL BENEFITS OF SCREENING?

- **Finding out early** – Finding cancer early may help reduce symptoms, make treatment easier, or prevent death from prostate cancer.
- **A chance to watch it closely** – Most prostate cancers found by screening are considered lower risk and can be managed without surgery, radiation, or chemotherapy. These cases may require regular monitoring with blood tests, x-rays, follow-up appointments and potentially prostate biopsies.
- **Understanding your chances** – Knowing your PSA level, your race/ethnicity, and your family history can help a provider determine your risk for prostate cancer.
- **Maybe getting good results** – A very low PSA level can be reassuring.

STEP 3: WHAT ARE THE POTENTIAL HARMS (RISKS) OF SCREENING?

- **Treatment that may not be needed** – Testing may lead to a diagnosis of a prostate cancer that is not likely to harm you or kill you. Sometimes men have surgery or radiation that is unnecessary.
- **Anxiety** – Waiting for results and receiving results can be stressful for you and your family.
- **Uncertainty** – A high PSA level may not be caused by prostate cancer and a low PSA level can be reassuring even though prostate cancer may still be possible. Only additional testing can diagnose cancer.
- **The possibility of more testing** – Screening results can lead to more testing and lost work days. Testing can cost money and may have some risks, including hospitalization.
- **Complications of treatment** – Treating prostate cancer found through screening may lead to erectile dysfunction or urine leakage. In this way, the treatment of some prostate cancers may cause more health problems for you than the cancer would have if left alone.



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STEP 4: WHAT IS YOUR RISK FOR PROSTATE CANCER?

THINGS THAT CAN INCREASE YOUR CHANCES OF DEVELOPING PROSTATE CANCER

Check and answer EACH that applies to you.

PATIENT
NAME

DATE OF
BIRTH

- ☐ Being 55 years or older
(write in your current age):
- ☐ Being African American
- ☐ Having a family history of prostate cancer
 - ☐ Father (biological) and his age when cancer was found:
 - ☐ Brother or brothers and age(s) when cancer was found:
 - ☐ Other family member and age when cancer was found:

SCREENING HISTORY

Check ONE and provide details about your test results.

- ☐ I have never been screened before
- ☐ Not sure if I've ever been screened before
- ☐ I was screened before with the PSA test
 - ☐ Normal PSA level
 - ☐ PSA level out of range
 - ☐ I don't remember what my result was

COMMON SYMPTOMS

Men with prostate cancer often have no symptoms.
Do you have any of the following symptoms?

- ☐ Having to urinate (pee) more often, or with pain
- ☐ A weaker stream of urine
- ☐ The feeling that you need to urinate right away
- ☐ Having to wake up more often to urinate
- ☐ Difficult, reduced or painful ejaculation
- ☐ Pain or stiffness in your lower back, hips or pelvis

STEP 5: HOW DO YOU FEEL ABOUT SCREENING?

POTENTIAL BENEFITS

How important to you are each of the potential benefits?

- Finding prostate cancer early when it could be easier to treat
- Understanding your risk for prostate cancer
- Receiving test results showing a normal PSA level

NOT IMPORTANT	A LITTLE IMPORTANT	SOMEWHAT IMPORTANT	VERY IMPORTANT	EXTREMELY IMPORTANT
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

POTENTIAL HARMS

How concerned are you about each of the potential harms?

- Receiving treatment for a cancer that may never have caused any symptoms or harm
- Having follow-up testing recommended if your PSA results show there MAY be a problem
- Being told you have prostate cancer that may not need treatment, but will need regular testing

NOT CONCERNED	A LITTLE CONCERNED	SOMEWHAT CONCERNED	VERY CONCERNED	EXTREMELY CONCERNED
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

STEP 6: DO YOU HAVE ANY QUESTIONS FOR YOUR PROVIDER?

- Have you considered your family's and significant other's opinions about screening?
- What are the next steps if PSA test results show there MAY be a problem?
- If you find prostate cancer, what are the different ways you can treat it?
And, what side effects could there be?

Write down any other questions you want to ask during your visit.

► **STOP HERE!**

► **Bring this guide to your visit.**

FINAL PAGE TO DISCUSS WITH YOUR PROVIDER AT VISIT

COMPLETE THIS PAGE WITH YOUR PROVIDER

DISCUSS SCREENING WITH YOUR PROVIDER

- Review all of your answers in this guide.
- Ask any questions you have about screening.

MAKE A DECISION ABOUT SCREENING

☐ **I WANT SCREENING**

- Get an order for a PSA blood test.
- Ask where to get tested.
- Schedule a follow-up visit to discuss the results. Date:

☐ **I DON'T WANT SCREENING AT THIS TIME**

- You can always reconsider this decision.

☐ **I NEED MORE TIME**

- You may want to discuss screening with your family and significant other.
- Schedule a follow-up visit to discuss again. Date:

Sign your name below to confirm that you discussed screening with your provider and you made your decision together.

PATIENT
SIGNATURE

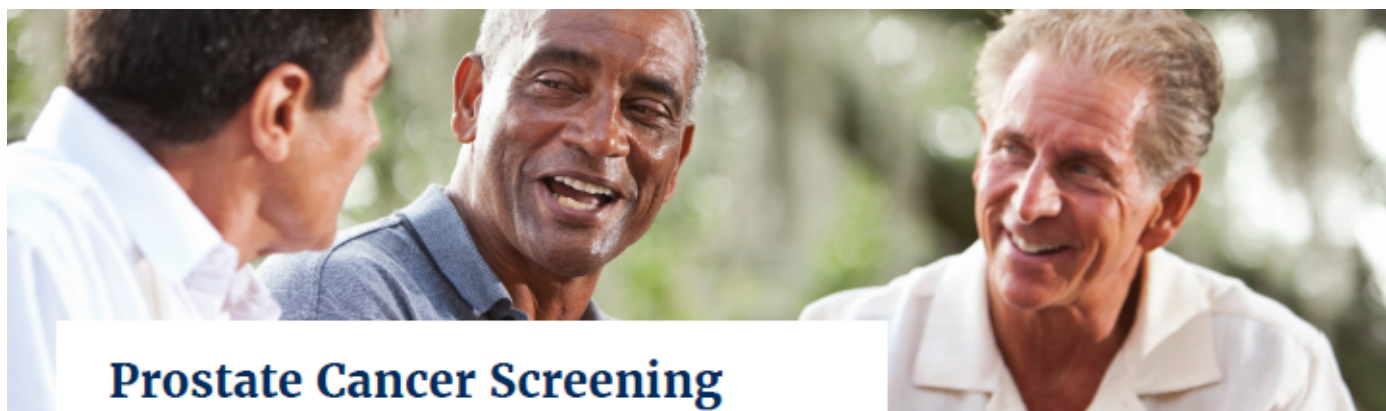
DATE

PROVIDER
SIGNATURE

DATE

THINGS TO REMEMBER

- Tell a clinician if a family member is diagnosed with prostate cancer or you experience any symptoms.
- You can always change your mind about screening.



Prostate Cancer Screening Using the PSA Test

A Summary Guide for Primary Care Physicians

PROVIDER GUIDE

HOW TO USE THIS GUIDE

This *Provider Guide* and the accompanying *Decision Guide* were developed to help clinicians have a meaningful shared decision making conversation with their patients about the choice to screen for prostate cancer with the prostate-specific antigen (PSA) test.

The *Provider Guide* includes updated evidence about the potential benefits and harms of screening with the PSA test and helps prepare primary care physicians for discussions with patients. The *Decision Guide* is intended to introduce patients to the PSA test, the potential benefits and harms of the test, and their responsibility to determine if screening is right for them.

Patients should review and complete pages 1-3 of the *Decision Guide* on their own. During their visit, the patient and provider should review the entire document and complete the last page together. A workflow for incorporating the *Decision Guide* into consultations is available on page 5.

BACKGROUND

ROLE OF PRIMARY CARE CLINICIANS

Primary care clinicians provide routine care for adult men on a regular basis, and are often responsible for helping patients determine which screening tests are done to help them reduce their risk of developing disease or to detect existing disease early. Screening for prostate cancer using the PSA test has been controversial for many years and guidelines are evolving based on emerging evidence. This *Provider Guide* and the *Decision Guide* for patients are intended to support primary care clinicians who are a significant component in the front-line decision making process for patients about whether or not to be screened for prostate cancer with the PSA test.

EPIDEMIOLOGY

Based on 2015 data, about 164,700 American men will be diagnosed with prostate cancer each year and more than 29,400 will die from the disease.¹ Worldwide, roughly 1 million men receive a new diagnosis of prostate cancer annually and more than 300,000 die from the disease.² The risk of developing prostate cancer at some point during a man's lifetime is approximately 11.6 percent (about 1 in 9).³

1. Siegel, R. L., et al. CA: A Cancer Journal for Clinicians. 2018.
2. Heijnsdijk, E. A.M., et al. Int. J. Cancer. 2017.
3. National Cancer Institute. 2017.



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SYMPTOMS

Symptoms potentially related to prostate disease include: frequent or painful urination; weak urinary stream; urgency to urinate; increased urination during sleeping hours; difficult, reduced or painful ejaculation; and pain or stiffness in lower back, hips or pelvis. These symptoms may or may not be related to prostate cancer, but should be discussed with a health care provider.

RISK FACTORS

A patient's age, African American heritage, and family history of prostate cancer may increase their risk for developing prostate cancer. The presence of certain lifestyle factors may also impact risk and outcomes from prostate cancer, including: diabetes, heart disease, obesity, a fatty diet, lack of exercise, and smoking regularly.

OVERVIEW OF THE EVIDENCE

USPSTF GUIDELINES

Guidelines on prostate cancer screening from the U.S. Preventive Services Task Force (USPSTF)—including draft updates released in 2017—apply to adult men who have not been previously diagnosed with prostate cancer and have no signs or symptoms of the disease.^{4,5}

The guidelines recommend that for men:

- Ages 55 to 69 years, the potential benefits and harms of screening for prostate cancer are closely balanced and the decision about whether to be screened should be an individual one.
- Age 70 years and older, the potential harms of screening are greater than the potential benefits, and these men should not be screened for prostate cancer.

The guidelines offer no recommendation on frequency of screening.

Guidelines on prostate cancer screening are also available from the American Cancer Society (ACS), published in 2010.⁶

REVIEW OF RECENT EVIDENCE

Most recent evidence from U.S. and European studies support some benefit and recognize known harms from screening men ages 55 and 69 years, and men in younger age groups who are at higher risk. An evidence review conducted by the U.S. Preventive Services Task Force (USPSTF) in developing new guideline recommendations focused largely on two major trials, the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO)⁷ and the European Randomized Study of Screening for Prostate Cancer (ERSPC) Trial.⁸ The conclusion of the USPSTF evidence review was: "PSA screening for prostate cancer may reduce risk of prostate cancer mortality but is associated with harms including false-positive results, biopsy complications, and overdiagnosis in 20 percent to 50 percent of screen-detected prostate cancers."⁹ The result of their review is a draft set of guidelines that focus on shared decision making for men ages 55 to 69 years, as summarized above. USPSTF did not make a clear recommendation on screening for men younger than the age of 55 who may be at higher risk.⁴

4. U.S. Preventive Services Task Force. 2017.
5. U.S. Preventive Services Task Force. 2012.
6. Smith, R. A., et al. CA: A Cancer Journal for Clinicians. 2017.

7. Andriole G. L., et al. New England Journal of Medicine. 2009.
8. Schroder F. H., et al. New England Journal of Medicine. 2009.
9. Agency for Healthcare Research and Quality. 2017.

SHARED DECISION MAKING

Shared decision making is a collaborative, patient-centered process in which patients and providers make decisions together, within the context of the best evidence and recommendations, and based on the patient's personal values and preferences.

The decision to screen for prostate cancer with the PSA test is one that is best made by a man after reviewing the best available information about the risks and benefits of screening and discussing these options and his decision with a health care provider.

TIPS TO PROMOTE A SHARED DECISION

- Step 1: Seek your patient's participation in the decision making process.
- Step 2: Help your patient explore and compare the potential benefits and harms of prostate cancer screening, and assess your patient's level of understanding.
- Step 3: Assess your patient's values and preferences about prostate cancer screening.
- Step 4: Reach a decision about prostate cancer screening with your patient.

KEY TALKING POINTS FOR PATIENTS

PROSTATE CANCER

- Prostate cancer is the second most common cancer in men in the United States, after skin cancer.
- About 1 in 9 American men will be diagnosed with prostate cancer during his lifetime.
- Many prostate cancers, though not all, grow very slowly and therefore do not need to be treated.

A list of risk factors for prostate cancer, as well as the potential benefits and harms of screening, are included in the Decision Guide.

RISK FACTORS

- Risk increases with age. The older you are, the more likely you are to be diagnosed with prostate cancer.
- Unless symptoms or risk factors are present, screening is not generally recommended for men younger than 50.
- Men with a close relative who had prostate cancer, and African American men, are at the highest risk for being diagnosed.
- Men with a family history of prostate cancer are 2 times more likely to be diagnosed. Risk increases if multiple family members have been diagnosed or received diagnoses early in life.
- African American men are 1.5 times more likely to develop prostate cancer and 2.5 times more likely to die from the disease than Caucasian men.
- Patients with diabetes, heart disease, and other chronic conditions are more likely to be diagnosed with prostate cancer.
- A fatty diet, sedentary lifestyle, obesity, and smoking are also potential risk factors.

SCREENING WITH THE PSA TEST

- Screening can include a blood test and sometimes includes a digital rectal exam.
- The PSA test can provide a more accurate assessment of prostate cancer risk than not testing.
- A PSA level above 4.0 ng/mL is generally considered high.
- PSA level can be high when the prostate is enlarged/infamed, there is a urinary tract infection, or a patient has prostate cancer.
- There is considerable uncertainty about whether PSA screening is beneficial.
- For these reasons, screening is not recommended for everyone.

TALKING POINTS TO SUPPORT THE PATIENT'S DECISION

- Screening is a decision that is best made by a man after reviewing the risks and benefit. Some men may wish to include family members and other important people in making this decision.
- There is no right or wrong answer when deciding about screening.
- I can answer all your questions about screening as you work toward a decision.
- You can always take more time to decide or reconsider your decision at a future date.

A patient's decision about screening should be recorded in the Decision Guide.

REFERENCES

1. Siegel R. L., Miller K. D., Jemal A. Cancer statistics, 2018. *CA: A Cancer Journal for Clinicians*. 68(1). January 4, 2018. doi: 10.3322/caac.21442
2. Heijnsdijk, E. A.M., Bangma, C. H., Borràs, J. M., de Carvalho, T. M., Castells, X., Eklund, M., Espinàs, J. A., Graefen, M., Grönberg, H., Lansdorp-Vogelaar, I., Leeuwen, P. J. v., Nelen, V., Recker, F., Roobol, M. J., Vandenbulcke, P., de Koning, H. J. (2017), Summary statement on screening for prostate cancer in Europe. *Int. J. Cancer*. doi:10.1002/ijc.31102.
3. National Cancer Institute Surveillance, Epidemiology, and End Results Program. Cancer Stat Facts: Prostate Cancer. Available at <https://seer.cancer.gov/statfacts/html/prost.html>. Accessed 12/20/2017.
4. US Preventive Services Task Force Draft Guidelines, Prostate Cancer Screening, 2017. Available at <https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prostate-cancer-screening1>. Accessed 12/20/2017.
5. US Preventive Services Task Force Existing Guidelines, Prostate Cancer Screening. 2012. Available at <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/prostate-cancer-screening>. Accessed 12/20/2017.
6. Smith, R. A., Andrews, K. S., Brooks, D., Fedewa, S. A., Manassaram-Baptiste, D., Saslow, D., Brawley, O. W., Wender, R. C. (2017), Cancer screening in the United States, 2017: A review of current American Cancer Society guidelines and current issues in cancer screening. *CA: A Cancer Journal for Clinicians*, 67: 100–121. doi:10.3322/caac.21392
7. Andriole G. L., Crawford E. D., Grubb R. L., et al. Mortality Results from a Randomized Prostate-Cancer Screening Trial. *New England Journal of Medicine*. 360:1310-1319. 2009. doi: 10.1056/NEJMoa0810696
8. Schroder F. H., Hugosson J., Roobol M. J., et al. Screening and Prostate-Cancer Mortality in a Randomized European Study. *New England Journal of Medicine*. 360:1320-1328. 2009. doi: 10.1056/NEJMoa0810084
9. Agency for Healthcare Research and Quality. Evidence Synthesis Number 154. Prostate-Specific Antigen-Based Screening for Prostate Cancer: A Systematic Evidence Review for the US Preventive Services Task Force. Rockville, MD. April, 2017. Available at <https://www.uspreventiveservicestaskforce.org/Home/GetFileByID/3031>. Accessed 12/20/2017.

PSA SCREENING DISCUSSION DOCUMENTS AND WORKFLOW

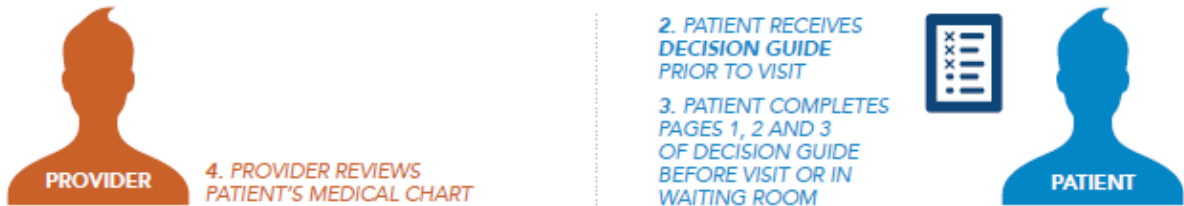
PROVIDER'S RESPONSIBILITIES

JOINT ACTIVITIES

PATIENT'S RESPONSIBILITIES

BEFORE VISIT

1. SCREENING IS CONSIDERED



DURING VISIT



6. PATIENT AND PROVIDER REVIEW DECISION GUIDE PAGES 1, 2 AND 3

7. PATIENT AND PROVIDER COMPLETE DECISION GUIDE PAGE 4 TOGETHER

**8. PATIENT AND PROVIDER REACH A DECISION:
DON'T WANT SCREENING · NEED MORE TIME · WANT SCREENING**

9. PROVIDER AND PATIENT BEGIN TO IMPLEMENT THE PATIENT'S DECISION (REQUIREMENTS LISTED ON DECISION GUIDE PAGE 4)

AFTER VISIT

