

# Effect of a Prostate Cancer Screening Decision Aid for African-American Men in Primary Care Settings

Jennifer D. Allen<sup>1</sup>, Christopher P. Filson<sup>2</sup>, and Donna L. Berry<sup>3</sup>



## ABSTRACT

**Background:** African-American men have an elevated risk of developing and dying from prostate cancer. Shared decision-making (SDM) about prostate cancer screening is recommended but does not always occur.

**Methods:** We pilot-tested an online decision aid (DA) in primary care settings using a pre/postevaluation design among African-American men ages 45 to 70 years. Men completed surveys before and after using the DA, which had interactive segments (e.g., values clarification) and provided individualized assessment of prostate cancer risk. Primary outcomes included prostate cancer knowledge, confidence in ability to make informed decisions, decisional conflict, and satisfaction with the decision. Immediately after the clinical visit, patients reported the degree to which they were engaged by their provider in SDM.

**Results:** Among this sample of men ( $n = 49$ ), use of the DA was associated with increased knowledge about prostate cancer [mean = 55.3% vs. 71.2%; 95% confidence interval (CI), 9.8–22.1;  $P < 0.001$ ], reduced decisional conflict (mean = 33.4 vs. 23.6; 95% CI, –18.1 to –1.6;  $P = 0.002$ ) on a scale from 0 to 100, and a decreased preference to be screened (88% vs. 69%; 95% CI, 0.09–0.64;  $P = 0.01$ ). Most (89%) reported that the DA prepared them well/very well for SDM with their provider. Following the clinical visit with providers, scores on perceived involvement in SDM were 68.1 (SD 29.1) on a 0 to 100 scale.

**Conclusions:** The DA improved men's knowledge, reduced decisional conflict, and promoted the perception of being prepared for SDM.

**Impact:** Findings suggest that use of an online DA to improve SDM outcomes warrants further testing in a future trial.

## Introduction

The currently available screening modality for prostate cancer, the PSA test, remains controversial. The U.S. Preventive Services Task Force recommends against routine screening for prostate cancer screening due to high false positive test results, overdiagnosis of indolent cancers, and overtreatment (1). The American Cancer Society recommends that men at high risk for the disease, including African American men, be offered information necessary to make an informed screening decision at age 45 years (2). Although there are subtle differences in guidelines from other medical organizations, including the age at which screening discussions should start (e.g., 45 or 50 years), there is unanimous agreement that men should be offered the test only *after* being fully informed about the potential risks and benefits of screening and discussing decisions with their health care provider in a process termed “shared decision-making” (SDM; refs. 3–5). Despite this universal recommendation, data from the 2015 Behavioral Risk Factor Survey show that only a quarter (23%) of men who had undergone PSA testing within the past year had discussed the advantages and disadvantages of screening with their providers (6). There are many barriers to fully engaging patients in

SDM, including the short duration of medical appointments and the need to prioritize a range of health concerns (7).

In this context, decision aids (DA) can provide men with easy-to-understand and unbiased information to help them understand the potential benefits, risk, and limitations of prostate cancer screening (8). Meta-analyses and systematic reviews show that DAs can effectively increase patients' knowledge about prostate cancer screening, promote confidence in the ability to engage in decision-making with one's provider, and decrease decisional conflict (9–11). An advantage of DAs is that they can be administered prior to medical visits and could increase meaningful patient engagement in decision-making.

With notable exceptions (12–15), the majority of prostate cancer screening DA studies have been conducted among White men (10). African-American men are 60% more likely to be diagnosed and nearly 2.5 times more likely to die from the disease compared with White men (16). This elevated risk highlights the complexity of this decision for African-American men and amplifies the importance of patient engagement in screening decisions. Data from national surveys show that African-American men are less likely to have had a PSA test within the prior year compared with White men (27% vs. 35%; ref. 17).

To address this need, we previously developed an online prostate cancer DA specifically for African-American men (Prostate Cancer Screening Preparation or PCSPrep) to provide men with the knowledge and skills to participate in a shared decision about prostate cancer screening with their providers (18). We pilot-tested PCSPrep among men recruited from community settings (e.g., barbershops, churches) and found that PCSPrep significantly improved men's knowledge about prostate cancer and reduced conflict about decision-making. However, we did not assess whether participants eventually went on to engage in prostate cancer screening discussions with their providers. The current study extends our prior work by evaluating the impact of PCSPrep on African-American patients in primary care settings immediately prior to and following a routine visit, and by assessing patient report of SDM. Findings of this study inform future efforts to ensure that African-American men are prepared to make informed

<sup>1</sup>Department of Community Health, Tufts University, Medford, Massachusetts.

<sup>2</sup>Department of Urology, Emory University School of Medicine, Atlanta, Georgia; Winship Cancer Institute, Emory Healthcare, Atlanta, Georgia; Department of Surgical Services, Atlanta VA Medical Center, Atlanta, Georgia. <sup>3</sup>Department of Behavioral Nursing and Health Informatics, University of Washington, School of Nursing, Seattle, Washington.

**Corresponding Author:** Jennifer D. Allen, Tufts University, 574 Boston Avenue, Suite 208, Medford, MA 02155. Phone: 6176270366; E-mail: Jennifer.allen@tufts.edu

Cancer Epidemiol Biomarkers Prev 2020;29:2157–64

doi: 10.1158/1055-9965.EPI-20-0454

©2020 American Association for Cancer Research.

decisions about prostate cancer screening in partnership with their providers.

## Materials and Methods

### Sample and setting

Five primary care sites affiliated with an academic medical center in Atlanta, GA, were approached to participate. We visited each site to provide information about the study and answer questions. Sites/providers were informed that the purpose of the study was to determine the impact of an online DA on patients' ability to engage in decision-making about prostate cancer screening. All of the sites and providers agreed to participate. However, one site subsequently declined, due to major restructuring. In total, 29 providers across the 4 sites had patients recruited to the study.

Eligible patients within these sites were African-American men between the ages of 45 and 70 years with a life expectancy of >10 years (as judged by their physicians), with no prior history of prostate cancer, and no serious psychiatric conditions or cognitive impairment. After primary care providers agreed that their patients could be contacted, research assistants examined electronic medical records and scheduling systems on a weekly basis to identify potentially eligible men scheduled for a nonacute primary care appointment during the recruitment period (September 2015–May 2016). Men were mailed information about the study and asked to return a self-addressed opt-out card if they did not wish to be contacted. Those who did not opt-out were screened for eligibility by phone by research assistants and verbally consented to participate. Participants were asked to arrive at the clinic 90 minutes prior to their appointment to provide written informed consent, use the DA, and complete data collection activities on an iPad. Participants were offered a \$100 gift card for their participation. Study procedures were approved by the Institutional Review Boards at Tufts University, Emory University School of Medicine, and the Atlanta VA Medical Center.

### Intervention

The development of PCSPrep is described elsewhere (18). Briefly, we conducted 4 focus groups ( $n = 33$ ) to assess African-American men's reactions to DAs developed in prior studies and to gather information to modify the content and format. The pilot test employed a pre/posttest evaluation design with a convenience sample of  $n = 41$  men recruited from community settings. The DA was based on the Ottawa Decision Support Framework and followed criteria set forth by the International Patient Decision Aid Standards, an international body that offers guidance to enhance the quality and effectiveness of DAs (19). Briefly, the content was designed for African-American men and emphasized that decisions about prostate cancer screening should be based on their individual preferences and values, after considering the potential benefits and harms, and exchange of information with their care provider. Messages were based on content covered in our prior DAs (20, 21), as well as a DA developed by the Centers for Disease Control and Prevention entitled "Is prostate cancer screening right for you? A decision guide for African Americans" (22). The DA provided information about prostate cancer incidence and mortality among African-American men, known risk factors for the disease, characteristics of available screening modalities (including false positives), and potential advantages and disadvantages of screening. Using an "edutainment" approach, information was delivered via a video featuring two African-American actors following the format of a popular television show. The video covered information deemed necessary for decision-making and could not be bypassed. Afterward, users had

options to navigate between additional online modules, including a module to clarify individual preferences about screening. There was also an option to navigate to a personalized disease risk calculator (Your Disease Risk Index; ref. 23) that assessed known prostate cancer risk factors (e.g., age, family history) and provided an assessment of individual risk relative to the population average (i.e., below average, average, above average).

### Data collection

After arriving at the clinic, research assistants obtained written-informed consent and provided participants with an iPad to use the DA and to complete self-administered pre/post surveys in a room that afforded privacy. Men completed the online surveys independently and then proceeded to their medical appointments. Immediately following their clinical visit, patients completed a questionnaire that assessed their perceived involvement in SDM with their provider.

### Measures

We first asked questions about participants' familiarity with PSA testing ("Have you ever heard of the prostate specific antigen test?" (yes/no). Based on this response, men were asked if they had ever had a PSA test (yes/no, do not know), the year of their most recent test ( $\leq 1$  year, within the past 1–2 years, etc.), and whether they would choose to undergo screening at this time, based on questions from the Behavioral Risk Factor Surveillance Survey (24). Demographic characteristics (e.g., age, race/ethnicity, household income) were also assessed with items from the Behavioral Risk Factor Surveillance survey (24).

### Primary outcomes

*Prostate cancer knowledge* was assessed with a 14-item prostate cancer knowledge scale that has been validated among African-American men (25). For example, we asked men: "Which of the following are risk factors for the development of prostate cancer?" Response categories included: black race, having a father or brother who had prostate cancer, and smoking (false) and men were asked to check all that apply. The number of correct responses was then calculated as a 0%–100% score. *Decision self-efficacy* was assessed with items from the validated Decision Self Efficacy Scale (26). Sample items include "I feel confident that I can figure out the choice that works best for me" with response options ranging from "not at all confident" to "very confident." The 10-item low literacy version of the *Decisional Conflict Scale* was used to assess the degree of uncertainty in decision-making, support or pressure from others in choosing an option, and the extent to which an individual feels informed to make a decision consistent with his values (e.g., "Are you clear about which benefits matter most to you?" (yes/no/I do not know; ref. 26). *Decision satisfaction* was measured only at posttest using the validated Satisfaction with Decision Scale, which includes six items such as "I am satisfied that I am adequately informed about the issues important to my decision" and "I am satisfied with my decision" with response options on a 1–5 point Likert scale (27).

### Secondary outcomes

*Values related to screening* were assessed with 8 items that assessed perceived importance of the potential advantages (e.g., "I will have peace of mind if I have prostate cancer screening") and limitations of screening (e.g., "I prefer not to be screened for prostate cancer if there is a chance that the results could be wrong"). These items have been used in prior studies among African-American men and have good internal consistency reliability (15). Responses are on a 4-point Likert scale ranging from "strongly disagree" to "strongly agree." Negative items

were reverse-coded and transformed (0–100) such that higher scores indicate greater importance placed on the potential advantages of screening. *Perceived risk of prostate cancer* was assessed with two items on perceived risk in the next 5 years (“How likely do you think it is that you will develop prostate cancer in the next 5 years?” (very likely = 100, likely = 75, somewhat likely = 50, very unlikely = 0) and perceived risk relative to men of the same age (“Compared to the average man your age, would you say that you are... (more = 100, same = 50, less = 0) likely to develop prostate cancer?”).

*Preparedness for Decision-Making*, asked only at posttest, was measured with the validated 8-item scale that asked participants the degree to which they felt that the DA assisted them in making an informed decision (28). For example, men were asked the extent to which PCSPrep helped them to recognize that a decision needed to be made about screening and whether they felt prepared to talk with their provider about their values related to screening. Response options were on a 5-point scale from “a great deal” to “not at all.” *Perceptions about Shared Decision-Making* was assessed immediately following the clinical visit using the validated 9-item Shared Decision-Making Questionnaire (29). Questions assessed the extent to which patients felt they were involved in the decision-making process with questions such as “My doctor and I selected an option together.” Response options are on a 6-point Likert type scale ranging from “completely agree” to “completely disagree.”

### Analysis

Prostate cancer awareness, prior screening, and demographic information were evaluated with descriptive statistics (frequencies, percentages, and mean). Primary and secondary outcomes were transformed to continuous scores ranging from 0 to 100 for ease of interpretation. Interrater reliability was assessed with Cronbach’s alphas. Thereafter, we performed paired *t* tests to assess changes between pre- and post values for continuous variables and  $\chi^2$  tests for categorical variables. Changes between decisional status before and after use of the DA were assessed using the McNemar’s test of symmetry. Statistical significance was set at  $\alpha = 0.05$ .

## Results

### Study sample

We identified a total of 332 potentially eligible African-American men with a scheduled nonacute primary care appointment based on electronic medical record. After screening these men, we excluded 44 as they were deemed ineligible. Of 288 eligible men, we were unable to reach 72 and 38 opted out. Of the 178 men who verbally consented to participate by phone, 127 kept their medical appointment and 81 (64%) completed the pretest and used the DA. Of those, 49 (60%) completed data collection at the 3 time points (pre- and post-DA, after clinical visit). Reasons for noncompletion of surveys were that patients arrived <90 minutes before their clinic visit and/or that their provider was ready to see the patient before the participant could complete the posttest (see Fig. 1). There were no significant differences in sociodemographic characteristics or screening history between men that completed all surveys versus those that completed only the pretest.

Nearly all men (99%) reported their race to be African American. The mean age of participants was 55.5 years (SD 9.3). Slightly more than half (59%) had at least a high school/GED degree. About two thirds (65%) were married or living as married. Sixty percent reported household incomes of <\$50,000. In terms of familiarity with prostate

screening, 63% of men had heard of the PSA test before using the DA, and of those, 42% had undergone screening with the PSA previously (see Table 1).

### Changes from pretest to posttest on primary outcomes

Nearly all reported that they would choose to undergo screening for prostate cancer before using the DA and they were significantly less likely to choose to undergo screening after using the tool (88% vs. 69%,  $P = 0.01$ ; see Table 2). The percentage of correct responses on knowledge scale was low at pretest and increased significantly between assessments [55.3% vs. 71.2%; mean difference 15.9; 95% confidence interval (CI), 9.8–22.1;  $P < 0.001$ ]. Mean scores on decision self-efficacy were high at pretest and did not change significantly (90.4 vs. 88.7; mean difference  $-1.1$ ; 95% CI,  $-4.5$  to  $-1.1$ ;  $P = 0.23$ ). Mean levels of decisional conflict decreased significantly after using the DA (33.4 vs. 23.6; mean difference =  $-9.8$ ; 95% CI,  $-18.1$  to  $-1.6$ ;  $P = 0.002$ ). In addition, most men reported that they were satisfied with their decisions about screening after using the DA, with means scores of 82.2 (SD 15.2) on a scale of 0 to 100. All scales had acceptable internal reliability (see Table 3).

### Secondary outcomes at posttest

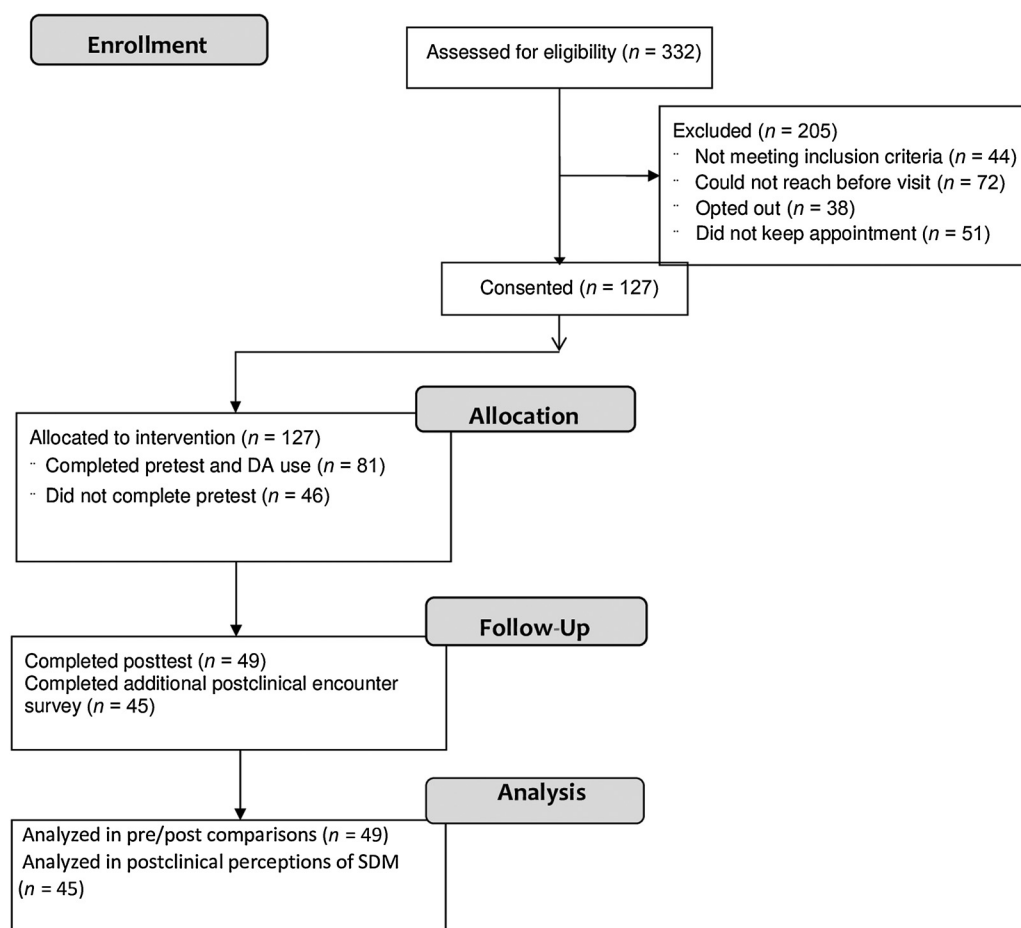
Most men highly valued screening at pretest, and there was a marginally significant decrease between pre- and posttests (85.9 vs. 81.7; mean difference  $-4.2$ ; 95% CI,  $-8.6$  to  $-0.1$ ;  $P = 0.057$ ). There was no change in men’s perceived risk of developing prostate cancer in the next 5 years, although perceived risk compared with others of the same age increased (31.1 vs. 43.3; mean difference 12.2; 95% CI, 1.5–22.9;  $P = 0.026$ ). Most felt that the DA had prepared them “very well/well” for SDM with their providers (mean = 89.5, SD=15.7). Following the clinical visit with their provider, mean score on perceived involvement in SDM was 68.5 (SD = 27.5). All scales had high internal reliability (see Table 3).

## Discussion

Our findings suggest that PCSPrep can help to prepare men to engage in SDM when administered in primary care clinics. After using the tool, men had significantly greater knowledge about prostate cancer screening, experienced reduced decisional conflict, and had a decreased preference to undergo screening. Most men reported that PCSPrep prepared them to engage in SDM and expressed relatively high levels of satisfaction with their decisions.

The observed increase in knowledge after use of PCSPrep is generally consistent with recent reviews of prostate cancer DAs (9–11) and with other DA studies conducted among African-American men (12, 28, 30, 31). Taken together, DAs consistently demonstrate significant improvements in prostate cancer knowledge (12, 14, 30–32). Our finding of an average 15 percentage point increase in prostate cancer knowledge is in line with these previous reports.

Only three prior studies among African-American men assessed changes in decision self-efficacy following DA use, and all found significant improvements (13, 14, 20) as measured by the Decision Self-Efficacy scale (13, 14, 20). We did not observe this in the present study, perhaps due to the fact that scores on Decision Self-Efficacy were very high even before using the DA, so there was little room for improvement. Despite a lack of improvement in self-efficacy, men experienced reduced decisional conflict after using the DA, which is similar to findings from prior DA studies among African-American men (13, 20, 32, 33). Overall, our results suggest that PCSPrep could



**Figure 1.**  
CONSORT flow diagram.

play a role in reducing uncertainty for African-American men considering prostate cancer screening, even after they are informed about their elevated risk for the disease and the potential limitations and risks of screening.

The fact that men reported being satisfied with their decisions further supports potential use of the PCSPrep in promoting decisions that are informed and consistent with values (34). This finding is consistent with systematic reviews which found improved decisional satisfaction among general audiences who use DAs (9). However, we acknowledge that patient satisfaction does not necessarily mean higher quality decisions, and there is a lack of consensus about what constitutes a “high quality” decision (e.g., best process vs. best outcome).

Most studies find a decreased preference for screening after DA use among general audiences (10). It is important to point out that the majority of prostate cancer screening DA studies have been conducted among White men, and systematic reviews have shown that desire to undergo screening is either reduced (9, 10) or unchanged (11). Studies conducted among African-American men, however, have yielded inconsistent findings, with some finding an increased desire or intention to be screened (30, 31) and others finding no significant impact on screening preferences (32, 33). We found that the men in our sample were very agreeable to prostate cancer screening before *and* after using our DA, though the proportion of those who planned to be screened

dropped following its use. We did not anticipate this finding, although our goal was not to promote or deter men from screening. We believe that a reduced preference for screening may have been related to an increased awareness about the rate of false positive test results, which is not often presented in DAs (35). Moreover, men were guided through an explicit values clarification exercise, which is also missing from many DAs (35). An increased appreciation of test limitations coupled with values clarification may have diminished men’s desire to pursue screening.

Given the elevated risk among African-American men and the fact that the PSA is the only currently available screening method, it will be critical to understand the appropriateness of patients abstaining from screening. Long-term follow-up of men declining PSA screening would further explain cancer-specific outcomes related to that decision, particularly given recent concerns that the population-level incidence of metastatic prostate cancer has been increasing after the USPSTF recommended against routine PSA screening in 2008 (for men over 75 years of age) and again in 2011 (for all men; refs. 36–38). On the other hand, understanding the basis for plans to *not* screen will be just as important, so as to optimize screening for the correct patients at the correct time.

Our finding related to patient’s perceived engagement in SDM was somewhat disappointing, as we hoped to have seen even greater involvement of patients in decision-making. However, a recent meta-analysis of randomized controlled DA trials across a variety of

**Table 1.** Characteristics of study sample (N = 49).

Characteristic	Total	
	N	(%)
Age (years)	55.5	(SD 9.3)
Race/ethnicity		
Non-Hispanic Black	48	(99)
Other/missing	1	(<1)
Education		
<High school	3	(7)
High school or GED	23	(59)
Four-year college	8	(19)
More than college	8	(19)
Household income		
<\$25,000	18	(39)
\$25,000–\$34,999	3	(7)
\$35,000–\$49,999	6	(14)
\$50,000–\$64,999	4	(9)
\$65,000–\$74,999	3	(7)
≥\$75,000	12	(26)
Marital status		
Married/living as married	31	(65)
Other	17	(35)
Ever heard of PSA test (yes)	30	(63)
Ever had a PSA test (yes)	18	(43)
Time since last PSA		
≤1 year	8	(42)
>1 and <2 years	2	(11)
>2 and <3 years	0	
>3 years	8	(42)
Do not know/missing	1	(5)

Note: Totals may not sum to 100% due to rounding.

medical decisions found that patients' perceived engagement with SDM ranged widely among those who received DA interventions (mean = 5%–90%; median 49%; ref. 11). National surveys have similarly demonstrated wide variability in patient reports of involvement in cancer screening decisions (10%–45%; refs. 6, 31, 39–41). Among national surveys that have compared perceived SDM between African-American and White men, findings have been inconsistent. In the 2011–2012 Health Information National Trends Survey, African-American men were less likely to report being engaged in SDM (40). In contrast, data from the 2015 Behavioral Risk Factor Surveillance Survey found that African-American men were more likely to have been informed about screening compared with White men (6). However, direct cross-comparison of these national surveys is complicated due to differences in aspects of SDM measured (e.g., having discussed screening vs. being informed of the pros and cons), differences in age groups of men included in the samples, and prior screening histories (e.g., never vs. ever vs. recent). Direct comparison of perceived SDM in DA studies is also challenging due to differences

in the timing of data collection vis-à-vis DA use (i.e., immediately following visit vs. months later) which may influence assessments. Our findings compare favorably with regard to perceived SDM in an aforementioned study; in that study, only 50% of men that received a written DA prior to a primary care visit reported that they had a full discussion of screening. Of those reporting a discussion, 82% reported that they themselves had initiated it. Interestingly, a greater proportion of African-American men reported having screening discussions compared with non-African-American men (60% vs. 29%;  $P = 0.04$ ; ref. 42). This suggests that African-American men may want more engagement in SDM about screening and are willing to initiate such discussions.

A relatively small number of studies have examined actual as opposed to perceived engagement of patients in SDM after DA use (30, 43–45), either measured by patient reports or medical record reviews. Only one study found a statistically significant increase in screening discussions (30). Notably, this was a randomized controlled trial of a telephone counseling intervention conducted among 490 African-American men recruited from a large health care workers' union. Patients who received the telephone counseling intervention were more likely to report *and* have medical record validation of a screening discussion with a provider compared with the control group, although the percentage of men who had discussions was still quite low (8.3% control vs. 15.8% intervention; ref. 30). However, we should note that patient self-report of SDM may be a better indicator of satisfaction with screening discussions and may not align directly with elements of SDM as defined by professional organizations. Although objective measures of SDM, such as the OPTION scale (46), can be utilized to assess the number of SDM elements that occur during clinical consultations, they cannot provide important contextual information, such as the multistaged nature of the SDM process (47).

Before discussing study implications, our findings must be put in context of the limitations of the study design and accrual. We did not randomly assign patients to receive the DA, so cannot infer causality. Furthermore, we had a relatively small sample which limits statistical power to detect changes. We also noted substantial attrition of screen-eligible patients between pretest and posttest, due to lack of time for completion of surveys and appointment no-shows. Although participants who completed all assessments did not differ significantly from those who did not on sociodemographic characteristics or screening behaviors, the possibility of selection bias must be acknowledged. We also note that screening prevalence in this sample is higher than in national probability samples (42% vs. 27%). This may be due to the fact that recruitment took place in primary care settings where men had access to screening. Another limitation is that we did not assess screening decisions following the clinical visit, nor did we examine actual screening participation from medical records. Because provider recommendation is one of the most potent predictors of actual screening (48), it is possible that men changed their decisions following

**Table 2.** Screening preferences at pre- and posttest (N = 49).<sup>a</sup>

What would you choose?	Posttest			Total
	Pretest	Have the PSA test	Not have the PSA test	
Have the PSA test	33	4	6	43 (88%)
Not have the PSA test	0	1	0	1 (2%)
Undecided	1	0	4	5 (10%)
Total	34 (69%)	5 (10%)	10 (20%)	

<sup>a</sup>McNemar's test of symmetry  $P = 0.056$ . Kappa test of agreement = 0.39 (95% CI, 0.012–0.66). Totals may not sum to 100% due to rounding.

**Table 3.** Changes in primary and secondary outcomes from pretest to posttest ( $N = 49$ ).

	Pretest Mean (SD)	Posttest Mean (SD)	Delta Mean (SD)	95% CI	P value <sup>a</sup>
<b>Primary outcomes</b>					
<b>Knowledge</b> (0%-100%) Cronbach's $\alpha = 0.70$	55.3 (23.4)	71.2 (19.1)	15.9 (19.4)	9.8-22.1	<0.001***
<b>Decision self-efficacy</b> (0-100) Cronbach's $\alpha = 0.92$	90.4 (13.2)	88.7 (18.1)	-1.7 (9.2)	-4.5 to -1.1	0.234
<b>Decisional conflict</b> (0-100) Cronbach's $\alpha = 0.93$	33.4 (31.0)	23.6 (31.6)	-9.8 (28.6)	-18.1 to -1.6	0.006**
<b>Satisfaction with decision (posttest only)</b> (0-100) Cronbach's $\alpha = 0.91$	82.2 (15.2)				
<b>Secondary outcomes</b>					
<b>Values about screening</b> (0-100) Cronbach's $\alpha = 0.72$	85.9 (17.9)	81.7 (22.1)	-4.2 (14.0)	-8.6 to -0.1	0.057
<b>Perceived risk</b> (0-100)					
Risk 5 years	32.9 (20.5)	31.6 (18.3)	-1.3 (5.7)	-4.1 to 1.4	0.336
Risk man of same age	31.1 (35.8)	43.3 (40.7)	12.2 (35.6)	1.5-22.9	0.026*
<b>Preparedness for SDM</b> Cronbach's $\alpha = 0.95$					
% "very well/well"	89.5 (15.7)				

Note: \*,  $P < 0.05$ ; \*\*,  $P < 0.01$ ; \*\*\*,  $P < 0.001$ .

<sup>a</sup>Paired  $t$  test.

the clinical visit. A recent commentary on SDM interventions also pointed out that many decisions are not discrete events and may evolve over time. Therefore, assessments at a single visit may not truly reflect ongoing efforts to engage patients in SDM (49). Moreover, we acknowledge that primary care providers may have changed their behaviors given that they were aware of the DA study. If providers were more attentive to engaging patients in SDM because of the study, this may have resulted in higher levels of SDM reported by patients than would have been observed otherwise.

Despite limitations, our study has implications for both practice and future research. In terms of practice, DAs can be introduced prior to routine medical appointments to improve knowledge required for informed decisions and reduce decisional conflict. Men reported that it was helpful in preparing them for SDM and had high levels of satisfaction with their decisions after using the DA. However, patient reports of engagement in SDM were suboptimal. There is growing recognition that provider-directed interventions may be needed to compliment DAs directed at patients. Provider interventions, such as educational materials and reminder systems, could potentially improve communication skills and intention to engage patients in preference-sensitive decisions, although current evidence is of insufficient quality to make broad recommendations about strategies (50).

Additional research will be needed to better understand the feasibility of implementing the DA in primary care from the perspectives of providers and clinic staff. For example, we would hypothesize that DA interventions prior to clinical visits may decrease time required by providers to educate men about the complexity of screening. However, this largely remains an unanswered empirical question, although one recent study suggests that staff in primary care clinics find DA

administration prior to routine visits to be feasible (42). The Centers for Medicare and Medicaid Services has recently started requiring and reimbursing for SDM visits for some preference-sensitive conditions (51), and this would substantially reduce time needed for screening discussions during primary care visits. Furthermore, engagement in SDM is very likely to be dependent on patient characteristics (e.g., prior screening, preferences for control in decision-making, risk aversion/acceptance), and future studies could examine the potential for DAs to be tailored on individual decision-making styles. Future research is needed to examine the efficacy of PCSPrep in a future randomized controlled trial, account for potential clustering effects within provider practices, assess the impact of further DA tailoring on individual characteristics, and the feasibility of implementing the DA on a larger scale in primary care practices.

#### Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

#### Authors' Contributions

**J.D. Allen:** Conceptualization, data curation, methodology, writing—original draft, writing—review and editing. **C.P. Filson:** Conceptualization, data curation, writing—review and editing. **D.L. Berry:** Conceptualization, writing—review and editing.

#### Acknowledgments

Financial support for this study was provided in part by a grant from the National Institutes of Minority Health and Disparities (5R21CA178296, J.D. Allen, PI). The funding agreement ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report. The authors thank Amanda Reich, Elizabeth Harden, Mersiha Torlak, Grace Seung, Anna Bausum, and Martin Sanda.

All authors made substantial contributions to the interpretation of data and have drafted the work or substantively revised it. All study procedures were approved by the Institutional Review Boards at Tufts University, Emory University School of Medicine, and the Atlanta VA Medical Center. The dataset generated and analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

The costs of publication of this article were defrayed in part by the payment of page charges. This article must therefore be hereby marked *advertisement* in accordance with 18 U.S.C. Section 1734 solely to indicate this fact.

Received March 25, 2020; revised July 22, 2020; accepted August 21, 2020; published first August 27, 2020.

## References

1. U.S. Preventive Services Task Force. Screening for prostate cancer: US Preventive Services Task Force Recommendation Statement. *JAMA* 2018;319:1901–13.
2. Smith RA, Manassaram-Baptiste D, Brooks D, Doroshenko M, Fedewa S, Saslow D, et al. Cancer screening in the United States, 2015: a review of current American Cancer Society guidelines and current issues in cancer screening. *CA Cancer J Clin* 2015;65:30–54.
3. Carter HB. American Urological Association (AUA) guideline on prostate cancer detection: process and rationale. *BJU Int* 2013;112:543–47.
4. Moyer VA; U.S. Preventive Services Task Force. Screening for prostate cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med* 2012;157:120.
5. Qaseem A, Barry MJ, Denberg TD, Owens DK, Shekelle P, for the Clinical Guidelines Committee of the American College of Physicians. Screening for prostate cancer: a guidance statement from the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med* 2013;158:761.
6. Cooper DL, Rollins L, Slocumb T, Rivers BM. Are men making informed decisions according to the prostate-specific antigen test guidelines? Analysis of the 2015 Behavioral Risk Factor Surveillance System. *Am J Mens Health* 2019;13:1557988319834843.
7. Tan ASL, Mazor KM, McDonald D, Lee SJ, McNeal D, Matlock DD, et al. Designing shared decision-making interventions for dissemination and sustainability: can implementation science help translate shared decision making into routine practice? *MDM Policy Pract* 2018;3:2381468318808503.
8. Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27:1361–7.
9. Ilic D, Jammal W, Chiarelli P, Gardiner RA, Hughes S, Stefanovic D, et al. Assessing the effectiveness of decision aids for decision making in prostate cancer testing: a systematic review. *Psychooncology* 2015;24:1303–15.
10. Ivlev I, Jerabkova S, Mishra M, Cook LA, Eden KB. Prostate cancer screening patient decision aids: a systematic review and meta-analysis. *Am J Prev Med* 2018;55:896–907.
11. Riikonen JM, Guyatt GH, Kilpeläinen TP, Craigie S, Agarwal A, Agoritsas T, et al. Decision aids for prostate cancer screening choice: a systematic review and meta-analysis. *JAMA Intern Med* 2019;179:1072–82.
12. Ellison GL, Weinrich SP, Lou M, Xu H, Powell JJ, Baquet CR. A randomized trial comparing web-based decision aids on prostate cancer knowledge for African-American men. *J Natl Med Assoc* 2008;100:1139–45.
13. Sultan DH, Rivers BM, Osongo BO, Wilson DS, Schenck A, Carvajal R, et al. Affecting African American men's prostate cancer screening decision-making through a mobile tablet-mediated intervention. *J Health Care Poor Underserved* 2014;25:1262–77.
14. Owens OL, Felder T, Tavakoli AS, Revels AA, Friedman DB, Hughes-Halbert C, et al. Evaluation of a computer-based decision aid for promoting informed prostate cancer screening decisions among African American men: iDecide. *Am J Health Promot* 2019;33:267–78.
15. Taylor KL, Davis JL, Turner RO, Johnson L, Schwartz MD, Kerner JF, et al. Educating African American men about the prostate cancer screening dilemma: a randomized intervention. *Cancer Epidemiol Biomarkers Prev* 2006;15:2179–88.
16. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2020. *CA Cancer J Clin* 2020;70:7–30.
17. Fedewa SA, Gansler T, Smith R, Sauer AG, Wender R, Brawley OW, et al. Recent patterns in shared decision making for prostate-specific antigen testing in the United States. *Ann Fam Med* 2018;16:139–44.
18. Allen JD, Reich A, Cuevas AG, Ladin K. Preparing African American men to make informed prostate cancer screening decisions: development and pilot testing of an interactive online decision aid. *JMIR Mhealth Uhealth* 2020;8:e15502.
19. Légaré F, O'Connor AC, Graham I, Saucier D, Côté L, Cauchon M, et al. Supporting patients facing difficult health care decisions: use of the Ottawa Decision Support Framework. *Can Fam Physician* 2006;52:476–7.
20. Allen JD, Mohllajee AP, Shelton RC, Drake BF, Mars DR. A computer-tailored intervention to promote informed decision making for prostate cancer screening among African American men. *Am J Mens Health* 2009;3:340–51.
21. Allen JD, Othus MKD, Hart A, Tom L, Li Y, Berry D, et al. A randomized trial of a computer-tailored decision aid to improve prostate cancer screening decisions: results from the Take the Wheel Trial. *Cancer Epidemiol Biomarkers Prev* 2010;19:2172–86.
22. Centers for Disease Control and Prevention. Prostate cancer screening: a decision guide for African Americans. Atlanta (GA): CDC; 2003 Oct [cited 2020 Jun 20]. CDC Publication No.: 99-7692. Available from: [https://www.ustoo.org/PDFs/CDC\\_PCa\\_Screen\\_Guide\\_AA.pdf](https://www.ustoo.org/PDFs/CDC_PCa_Screen_Guide_AA.pdf).
23. Colditz GA, Atwood KA, Emmons K, Monson RR, Willett WC, Trichopoulos D, et al. Harvard report on cancer prevention volume 4: Harvard Cancer Risk Index. *Cancer Causes Control* 2000;11:477–88.
24. Centers for Disease Control and Prevention. Behavioral Risk Factor Surveillance System Survey Questionnaire. Behavioral Risk Factor Surveillance System Survey Questionnaire. Atlanta (GA): CDC; 2015 [cited 2020 Jun 20]. p. 1–34. Available from: [https://www.cdc.gov/brfss/questionnaires/pdf-ques/2016\\_BRFSS\\_Questionnaire\\_FINAL.pdf](https://www.cdc.gov/brfss/questionnaires/pdf-ques/2016_BRFSS_Questionnaire_FINAL.pdf).
25. Radosevich DM, Partin MR, Nugent S, Nelson D, Flood AB, Holtzman J, et al. Measuring patient knowledge of the risks and benefits of prostate cancer screening. *Patient Educ Couns* 2004;54:143–52.
26. Bunn H, O'Connor A. Validation of client decision-making instruments in the context of psychiatry. *Can J Nurs Res* 1996;28:13–27.
27. Holmes-Rovner M, Kroll J, Schmitt N, Rovner DR, Breer ML, Rothert ML, et al. Patient satisfaction with health care decisions: the satisfaction with decision scale. *Med Decis Making* 1996;16:58–64.
28. Bennett C, Graham ID, Kristjansson E, Kearing SA, Clay KF, O'Connor AM. Validation of a preparation for decision making scale. *Patient Educ Couns* 2010;78:130–3.
29. Kriston L, Scholl I, Hölzel L, Simon D, Loh A, Härter M. The 9-item Shared Decision Making questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. *Patient Educ Couns* 2010;80:94–9.
30. Lepore SJ, Wolf RL, Basch CE, Godfrey M, McGinty E, Shmukler C, et al. Informed decision making about prostate cancer testing in predominantly immigrant black men: a randomized controlled trial. *Ann Behav Med* 2012;44:320–30.
31. Frencher SK, Sharma AK, Teklehaimanot S, Wadzani D, Ike IE, Hart A, et al. PEP talk: prostate education program, “Cutting through the uncertainty of prostate cancer for black men using decision support instruments in barbershops.” *J Cancer Educ* 2016;31:506–13.
32. Taylor KL, Williams RM, Davis K, Luta G, Penek S, Barry S, et al. Decision making in prostate cancer screening using decision aids vs usual care: a randomized clinical trial. *JAMA Intern Med* 2013;173:1704–12.
33. Williams RM, Davis KM, Luta G, Edmond SN, Dorfman CS, Schwartz MD, et al. Fostering informed decisions: a randomized controlled trial assessing the impact of a decision aid among men registered to undergo mass screening for prostate cancer. *Patient Educ Couns* 2013;91:329–36.
34. Sepucha KR, Borkhoff CM, Lally J, Levin CA, Matlock DD, Ng CJ, et al. Establishing the effectiveness of patient decision aids: key constructs and measurement instruments. *BMC Med Inform Decis Mak* 2013;13(Suppl 2):S12.
35. Riikonen J, Guyatt G, Kilpeläinen T, Craigie S, Agarwal A, Agoritsas T, et al. Decision aids for prostate cancer screening choice: a systematic review and meta-analysis. *Eur Urol Suppl* 2018;17:e381–2.
36. Bandini M, Mazzone E, Preisser F, Nazzani S, Zaffuto E, Marchioni M, et al. Increase in the annual rate of newly diagnosed metastatic prostate cancer: a contemporary analysis of the Surveillance, Epidemiology and End Results database. *Eur Urol Oncol* 2018;1:314–20.
37. Kelly SP, Anderson WF, Rosenberg PS, Cook MB. Past, current, and future incidence rates and burden of metastatic prostate cancer in the United States. *Eur Urol Focus* 2018;4:121–7.

38. Dalela D, Sun M, Diaz M, Karabon P, Seisen T, Trinh QD, et al. Contemporary trends in the incidence of metastatic prostate cancer among US men: results from nationwide analyses. *Eur Urol Focus* 2019;5:77–80.
39. Han PKJ, Kobrin S, Breen N, Joseph DA, Li J, Frosch DL, et al. National evidence on the use of shared decision making in prostate-specific antigen screening. *Ann Fam Med* 2013;11:306–14.
40. Leyva B, Persoskie A, Ottenbacher A, Hamilton JG, Allen JD, Kobrin SC, et al. Do men receive information required for shared decision making about PSA testing? Results from a national survey. *J Cancer Educ* 2016;31:693–701.
41. Woods-Burnham L, Stiel L, Wilson C, Montgomery S, Durán AM, Ruckle HR, et al. Physician consultations, prostate cancer knowledge, and PSA screening of African American men in the era of shared decision-making. *Am J Mens Health* 2018;12:751–9.
42. Warlick CA, Berge JM, Ho YY, Yeazel M. Impact of a prostate specific antigen screening decision aid on clinic function. *Urol Pract* 2017;4:448–53.
43. Krist AH, Woolf SH, Johnson RE, Kerns JW. Patient education on prostate cancer screening and involvement in decision making. *Ann Fam Med* 2007;5:112–9.
44. Landrey AR, Matlock DD, Andrews L, Bronsert M, Denberg T. Shared decision making in prostate-specific antigen testing: the effect of a mailed patient flyer prior to an annual exam. *J Prim Care Community Health* 2013;4:67–74.
45. Partin MR, Nelson D, Radosevich D, Nugent S, Flood AB, Dillon N, et al. Randomized trial examining the effect of two prostate cancer screening educational interventions on patient knowledge, preferences, and behaviors. *J Gen Intern Med* 2004;19:835–42.
46. Barr PJ, O'Malley AJ, Tsulukidze M, Gionfriddo MR, Montori V, Elwyn G. The psychometric properties of Observer OPTION, an observer measure of shared decision making. *Patient Educ Couns* 2015;98:970–6.
47. Williams D, Edwards A, Wood F, Lloyd A, Brain K, Thomas N, et al. Ability of observer and self-report measures to capture shared decision-making in clinical practice in the UK: a mixed-methods study. *BMJ Open* 2019;9:e029485.
48. Liao JM, Ommerborn MJ, Clark CR. Association between features of patient-provider discussions and routine prostate-specific antigen testing. *PLoS One* 2017;12:e0177687.
49. Blumenthal-Barby J, Opel DJ, Dickert NW, Kramer DB, Tucker Edmonds B, Ladin K, et al. Potential unintended consequences of recent shared decision making policy initiatives. *Health Aff* 2019;38:1876–81.
50. Légaré F, Ratté S, Stacey D, Kryworuchko J, Gravel K, Graham ID, et al. Interventions for improving the adoption of shared decision making by health-care professionals. *Cochrane Database Syst Rev* 2010:CD006732.
51. Centers for Medicare and Medicaid Services. CMS quality strategy 2016. Baltimore: CMS; 2016 [cited 2020 Jun 20]. Available from: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf>.