A decision aid versus shared decision making for prostate cancer screening: results of a randomized, controlled trial

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Introduction: *Shared decision making (SDM) is widely encouraged by both the American Urological Association and Choosing Wisely for prostate cancer screening. Implementation of SDM is challenging secondary to time constraints and competing patient priorities. One strategy to mitigate the difficulties in implementing SDM is to utilize a decision aid (DA). Here we evaluate whether a DA improves a patient's prostate cancer knowledge and affects prostate-specific antigen (PSA) screening rates.*

Materials and methods: *Patients were randomized to usual care (UC), DA, or DA + SDM. Perception of quality of care was measured using the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. Outcomes were stratified by long term provider relationship (LTPR, > 3 years) versus short term provider relationship (STPR, < 3 years). Knowledge of prostate cancer screening and the decision regarding screening were assessed. Groups were compared using ANOVA and logistic regression models.*

Results: *A total of 329 patients were randomized. Patients in the DA + SDM arm were significantly more likely to report discussing the implication of screening (33% DA + SDM, 22% UC, 16% DA, p = 0.0292) and answered significantly more knowledge questions correctly compared to the UC arm (5.03 versus 4.46, p = 0.046). However, those in the DA arm were significantly less likely to report that they always felt encouraged to discuss all health concerns (72% DA, 78% DA + SDM, 87% UC, p = 0.0285). Interestingly, STPR patients in the DA arm were significantly more likely to undergo PSA-based prostate cancer screening (41%) than the UC arm (8%, p = 0.019). This effect was not observed in the LTPR group.*

Conclusions: *Providing patients a DA without a personal interaction resulted in a greater chance of undergoing PSA-based screening without improving knowledge about screening or understanding of the consequences of this decision. This effect was exacerbated by a shorter term provider relationship. With complex issues such as the decision to pursue PSA-based prostate cancer screening, tools cannot substitute for direct interaction with a trusted provider.*

Key Words: prostate cancer, prostate-specific antigen based-screening, shared decision making, decision aid, primary care

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Introduction

Prostate-specific antigen (PSA) based screening for prostate cancer became prevalent beginning in the late 1980's and is credited with the substantial reduction in prostate cancer-specific mortality seen in the following decades.[1] However, subsequent attempts to enumerate the impact of PSA-based screening on preventing

deaths due to prostate cancer and growing concerns regarding the harmful side effects of overtreatment have called the value of PSA-based screening into question.[2-7] This is reflected in the most recent U.S. Preventive Services Task Force (USPSTF) guidelines, which recommend against PSA-based prostate cancer screening.[8]

In contrast, the American Cancer Society (ACS) recommends that decisions about prostate cancer screening be made in a setting of shared decision making (SDM).[9] In this setting, decisions are made by patients in conjunction with the provider, considering current scientific evidence as well as the values and preferences of the individual patient. Consistent with this concept, the American Urological Association (AUA) recommends that in men aged 55-69 years, SDM is the preferred model to determine whether patients should undergo PSA-based screening for prostate cancer. Thus, both the ACS and AUA suggest that patient values and preferences should inform such a decision since it carries both benefits and risks.

In addition to SDM, a decision aid (DA) may be used to facilitate the transfer of information. Patient decision aids are tools that help patients to understand the components involved in decision making. Specifically, DA's aim to underscore the exact decision that needs to be made, provide information about options, outcomes, risks and benefits, and clarify personal values. Initially, they were designed to complement rather than replace counseling by a provider. Unfortunately, as time constraints further impact primary care practices, they are increasingly employed as independent sources of information despite seldom superiority to physician judgment.[10]

There is limited data examining the relative effectiveness of SDM and DA, and none to our knowledge that investigate the impact of length of patient-provider relationship in this context. In this randomized study, we sought to determine whether providing a DA with or without SDM during a primary care visit influenced knowledge of prostate cancer screening and rates of PSA-based prostate cancer screening, stratifying outcomes by short term provider relationship (STPR) and long term provider relationship (LTPR).

Materials and methods

This study was approved by the Benaroya Research Institute at Virginia Mason's Institutional Review Board (IRB 13001). Eligible patients included men aged 50 to 75 years who were being evaluated by one of two primary care providers at Virginia Mason Medical Center (VMMC). Non-English speaking patients, patients with a history of prostate cancer, patients screened for prostate cancer in the last 11 months, and patients being seen for a genitourinary complaint were excluded. After obtaining informed consent, patients were randomized in a 1:1:1 ratio to one of three interventions: usual care (UC), a decision aid alone (DA), and shared decision making including discussion of the decision aid (DA + SDM).

For this study, SDM was scripted and UC was defined as reflecting the provider's best practice. Two weeks following the primary care visit, patients were mailed a copy of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey,[11-13] as well as 7 true-or-false "knowledge questions" about prostate cancer and PSA-based prostate cancer screening, Table 1. These questions were developed by the research team based on content in the VMMC prostate cancer screening decision aid. Each question was scored as 1 point and evaluated as adjusted means using least square.

The CAHPS protocol estimated that 45 completed CAHPS surveys from each intervention arm and provider (270 overall) were necessary to determine whether overall provider satisfaction differed by

TABLE 1. **Prostate knowledge questionnaire**

Question	Answer
1. Most men diagnosed as having prostate cancer die of something else.	TRUE
2. The PSA (prostate-specific antigen) test will pick up all prostate cancers.	FALSE
3. If you have an abnormal PSA test result, your doctor may recommend that you have a prostate biopsy.	TRUE
4. Having your PSA tested makes you more likely to be diagnosed with prostate cancer.	TRUE
5. It is always clear which prostate cancers need to be treated.	FALSE
6. Problems with urination are common side effects of prostate cancer treatments.	TRUE
7. Having your PSA tested may reduce your chance of dying from prostate cancer.	TRUE

intervention. Because we anticipated a 40% response rate (based upon the survey return rate of a comparable study), we planned to enroll 113 patients per provider per study group (678 total). The intention however, was to end enrollment once the required number of questionnaires were returned. The randomized subject's decision to undergo PSA-based screening was recorded. A statistical analysis plan was finalized prior to unblinding, including stratifying patients by length of patient provider relationship greater than or less than 3 years.

Baseline and demographic characteristics for survey responders were compared to those who did not return surveys in order to assess selection bias. Based on the CAHPS administration guidelines, we defined the valid survey response set to be patients who returned questionnaires within 120 days of the primary care visit. Demographics and patient characteristics were summarized with descriptive statistics and compared using the chi-square test or ANOVA as indicated. Logistic regression and analysis of covariance (ANCOVA) models, including fixed effects of intervention and provider, were used to summarize binary and continuous outcomes, respectively. Odds ratios or least-square means and 95% confidence intervals were used to summarize model results.

Time to PSA was analyzed using Cox proportional hazards regression including fixed effects of intervention and provider, and Kaplan-Meier survival curves were produced. For time-dependent analyses, time zero was defined as the intervention visit, and patients were censored at the first of total follow up or 1 year post intervention visit.

Statistical tests and 95% confidence intervals were 2-sided. $P < 0.05$ was considered statistically significant, and no adjustments were made for multiple testing. Pairwise differences were explored when overall tests of intervention effects were significant.

Results

There were a total of 329 patients randomized into one of the three arms, and all randomized patients received the intervention to which they were assigned, Figure 1. A total of 11% (37/329) of randomized patients did not return their surveys, and 4% (13/329) returned surveys after the 120 day window pre-specified for a valid response.

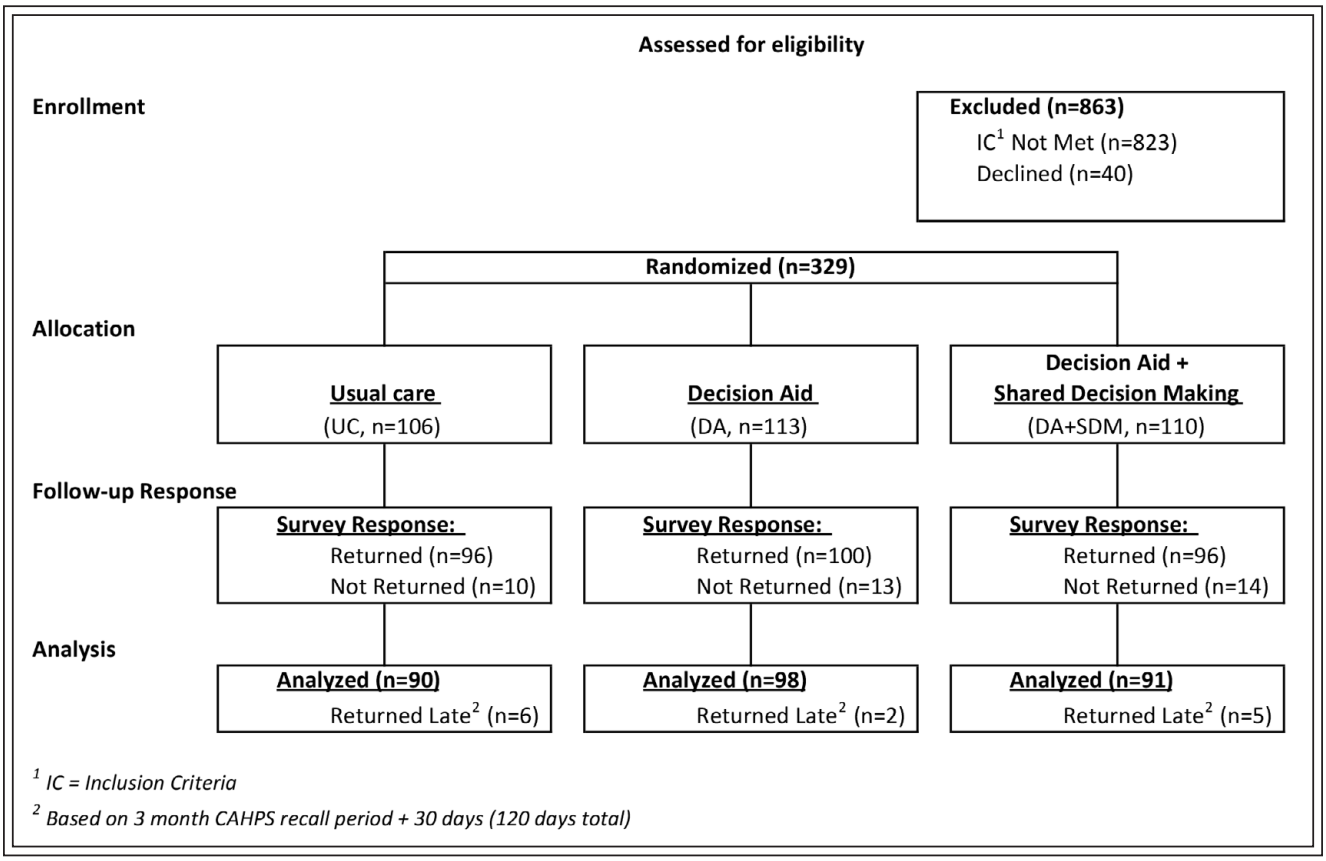

Figure 1. Consort diagram.

TABLE 2. **Comparison of demographic and PSA measures by survey response**

	Survey response (all randomized)		
	Valid (n = 279)	**Late or none (n = 50)**	**None p value**
Age (years)	62.0	60.0	0.315
Median [25th, 75th%]	[56.0, 67.0]	[55.0, 65.0]	
Race			0.411
American Indian or Alaska Native	1 (0.4%)	0 (0.0%)	
Asian	13 (4.7%)	1 (2.0%)	
Black or African American	10 (3.6%)	1 (2.0%)	
Caucasian	232 (83.2%)	40 (80.0%)	
Unknown	23 (8.2%)	8 (16.0%)	
Provider			0.345
Provider 1	136 (48.7%)	28 (56.0%)	
Provider 2	143 (51.3%)	22 (44.0%)	
Randomization assignment			0.707
UC	90 (32.3%)	16 (32.0%)	
DA	98 (35.1%)	15 (30.0%)	
DA + SDM	91 (32.6%)	19 (38.0%)	
PSA within 1 day of intervention	50 (17.9%)	13 (26.0%)	0.181

PSA = prostate-specific antigen; UC = usual care; DA = decision aid; SDM = shared decision making

Nine percent (29) of men had not reached the year post consent date to verify if PSA was drawn. The questionnaire "return rate" was 89%. Demographic characteristics, provider, and randomization assignment were similar for those with a valid survey response and those with late or no response, Table 2.

Overall, the majority of patients were Caucasian, college-educated, and perceived themselves to be relatively healthy, with 61% reporting very good or excellent overall health and 72% reporting very good or excellent mental health, Table 3. Patients were distributed equally between the two providers, 65% had been seeing their primary care physician for at least 3 years, and 56% saw their provider more than once in the 12 month recall period of the CAHPS questionnaire. These characteristics were similar among the three groups.

Patients in the DA + SDM arm were significantly more likely to report discussing the possibility of a diagnostic procedure or surgery (33%) compared to those in the UC

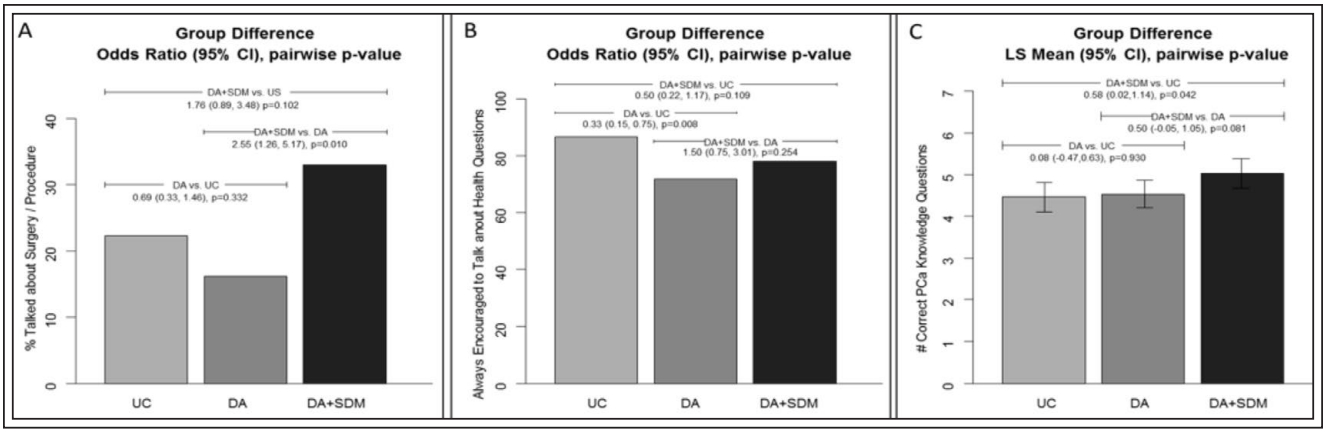

Figure 2. Comparing prostate cancer survey data by treatment arm.

TABLE 3. **Demographic and health assessment characteristics**

	Valid survey response[1]			
	UC (n = 90)	**DA (n = 99)**	**DA + SDM (n = 91)**	**p value**
Age (years)	62.5	62.0	61.0	0.264
Median [25th, 75th%]	[57.0, 68.0]	[56.0, 68.0]	[55.0, 66.0]	
Race				0.822
American Indian or Alaska Native	1 (1.1%)	0 (0.0%)	0 (0.0%)	
Asian	3 (3.3%)	4 (4.0%)	6 (6.6%)	
Black or African American	4 (4.4%)	2 (2.0%)	4 (4.4%)	
Caucasian	75 (83.3%)	83 (83.8%)	75 (82.4%)	
Unknown	7 (7.8%)	10 (10.1%)	6 (6.6%)	
Education				0.72
Some HS, HS Graduate or GED	4 (4.4%)	5 (5.2%)	5 (5.5%)	
Some college or 2 year degree	21 (23.3%)	15 (15.5%)	14 (15.4%)	
4 year college graduate	28 (31.1%)	27 (27.8%)	26 (28.6%)	
More than 4-year college degree	37 (41.1%)	50 (51.5%)	46 (50.5%)	
Self-reported rating of overall health			0.803	
Fair or poor	7 (7.8%)	10 (10.2%)	5 (5.5%)	
Good	28 (31.1%)	27 (27.6%)	32 (35.2%)	
Very good	39 (43.3%)	41 (41.8%)	34 (37.4%)	
Excellent	16 (17.8%)	20 (20.4%)	20 (22.0%)	
Self-reported rating of mental health				0.811
Fair or poor	6 (6.7%)	4 (4.1%)	5 (5.5%)	
Good	20 (22.5%)	24 (24.5%)	19 (20.9%)	
Very good	38 (42.7%)	34 (34.7%)	34 (37.4%)	
Excellent	25 (28.1%)	36 (36.7%)	33 (36.3%)	
Provider				0.935
Provider 1	45 (50.0%)	47 (47.5%)	45 (49.5%)	
Provider 2	45 (50.0%)	52 (52.5%)	46 (50.5%)	
Duration with provider				0.206
≥ 3 years	64 (71.9%)	62 (64.6%)	54 (59.3%)	
< 3 years	25 (28.1%)	34 (35.4%)	37 (40.7%)	
Number of provider visits				0.167
Once	35 (40.7%)	46 (48.4%)	37 (41.6%)	
Twice	31 (36.0%)	32 (33.7%)	23 (25.8%)	
≥ 3 times	20 (23.3%)	17 (17.9%)	29 (32.6%)	

[1]subjects who returned surveys within 120 days of intervention (denominator includes all patients with non-missing data)
PSA = prostate-specific antigen; UC = usual care; DA = decision aid; SDM = shared decision making

arm (22%) and the DA arm (16%) (p = 0.0292, Table 4), with an odds ratio of 2.55 (95% CI: 1.26-5.17, p = 0.010, DA + SDM versus DA, Figure 2a). In addition, patients in the DA group were significantly less likely to report that they always felt encouraged to discuss all health concerns (72% DA, 78% DA + SDM, 87% UC, p = 0.0285, Table 4), with an odds ratio of 0.33 (95% CI: 0.15-0.75, p = 0.008, DA versus UC, Figure 2b).

Knowledge about PSA-based screening also differed among the three groups. The adjusted mean number of correct responses out of 7 total was 4.5 for UC, 4.5 for DA, and 5.0 for DA + SDM (p = 0.046 across all groups, Table 4), with patients in the DA + SDM group answering significantly more questions correctly compared to those in the UC group (p = 0.042, Figure 2c).

TABLE 4. **Demographic and health assessment characteristics**

	Valid survey response[1]		
	UC (n = 90)	**DA (n = 99)**	**DA + SDM (n = 91)**
Communication with provider			
100	59 (65.6%)	58 (58.6%)	53 (58.2%)
< 100	29 (32.2%)	39 (39.4%)	36 (39.6%)
Provider rating			
9-10	80 (88.9%)	79 (79.8%)	76 (83.5%)
< 9	8 (8.9%)	18 (18.2%)	13 (14.3%)
Talked about having surgery or procedure			
Yes	20 (22.2%)	16 (16.2%)	30 (33.0%)
No	68 (75.6%)	80 (80.8%)	59 (64.8%)
Encouraged to talk about all health questions			
Always	78 (86.7%)	71 (71.7%)	71 (78.0%)
Not always	10 (11.1%)	26 (26.3%)	18 (19.8%)
Number of prostate cancer knowledge questions correct			
LS mean (SE)	4.5 (0.18)	4.5 (0.17)	5.0 (0.18)
PSA within 1 day of intervention			
Yes	14 (15.6%)	21 (21.2%)	15 (16.5%)
No	76 (84.4%)	78 (78.8%)	76 (83.5%)

PSA = prostate-specific antigen; UC = usual care; DA = decision aid; SDM = shared decision making

The PSA-based prostate cancer screening rate within 1 day of the intervention was low and did not differ significantly among the three groups (16% UC, 21% DA, 17% DA + SDM, p = 0.833, Table 4). By 1 year post intervention, the PSA-based prostate cancer screening rate was highest in the DA group, although this did not achieve statistical significance (32% UC, 39% DA, 29% DA + SDM, p = 0.586). However, for patients who had been seeing their provider for less than 3 years, those in the DA group (41%) were significantly more likely to undergo PSA-based prostate cancer screening than those in the UC arm (8%), with a hazard ratio of 5.65 (95% CI: 1.33-23.95, p = 0.019), and more likely than those in the DA + SDM group (30%), although this did not reach statistical significance (HR: 3.79, 95% CI: 0.89-16.15, p = 0.072).

Discussion

A shared decision making-based approach is particularly appropriate for prostate cancer screening, in which the benefit-risk profile does not lead to a consistent recommendation for all patients. This model recognizes and synthesizes two important sources of expertise, recognizing that a healthcare professional may have better knowledge of the test and its properties, and the patient has a better understanding of the decision most appropriate for his individual situation. Both forms of expertise are key to making good decisions – ones that are informed, supported by best available evidence, and compatible with the patient's personal preferences, values, and circumstances.[14-17]

While there is little agreement regarding the required specifics for SDM in prostate cancer screening,[18] in general, SDM has three components. First, a patient must have a defined choice. The provider must be clear that a decision is required. Second, a patient must be apprised of his options. The provider must ensure that the patient understands the best available evidence regarding the risks and benefits of each option. Third, a decision must ensue based upon the patient's values, preferences, and provider guidance.[19,20] The key limitations of SDM are increased provider time requirements, lack of provider reimbursement, provider bias, and inconsistent presentation. A key advantage of SDM, however, is the ability to personalize the discussion for individual patients. Indeed, a long-standing patient-provider relationship may allow providers to tailor the discussion and to anticipate questions and concerns of an individual patient.

A DA is a tool provided to patients to supplement shared decision making. From a practical standpoint though, DAs are increasingly used to replace provider interaction.[21] DAs may include decision boards, interactive videos, audio workbooks, or printed materials. The key elements of a decision aid as described by the Cochrane Collaboration include: information tailored to the patient's health, values classification, learning from examples of other patients, guidance towards shared decision making, and a succinct medium of delivery.[22] While the benefits of a DA include consistent presentation of information, reduced required provider expertise, and reduced provider time, DAs are limited due to the absence of individualization and variable patient comprehension.

In this study, we show that the perception of quality of care may have been impacted as a result of the method of communication regarding PSA based prostate cancer screening communication. Specifically, there were differences between the groups in the understanding that PSA screening ultimately could result in procedural based interventions (e.g., biopsy). Patients randomized to DA + SDM were more likely to report that they had discussed the possibility of a procedure or intervention during their visit compared to DA. This absence of comprehensive understanding that PSA-based screening may lead to a procedure or intervention suggests that a DA cannot effectively replace patient-provider dialogue. In addition, patients randomized to DA alone felt less encouraged to discuss all of their health concerns compared to patients randomized to UC. This also suggests that lack of collaborative review when using the DA may lead to confusion.

Patients randomized to DA + SDM had the highest scores on the PSA-based prostate cancer screening knowledge quiz. These scores were significantly higher in comparison to those assigned to UC. This suggests that the conversation about the DA in the context of SDM facilitates learning. The DA alone did not enhance knowledge in comparison to UC. Recognizing the highly educated status of the patients in this study, the effect of a DA may be different in a less educated population.

PSA-based screening rates at 1 day and 1 year after the intervention were not different between groups. However, when stratified by patient-provider relationship length, there was a 30% increase in PSA-based screening with DA compared to UC in the STPR group, which was significant. If the duration of a patient-provider relationship is a surrogate metric for trust, this suggests that such connection has a substantial impact on the effect of the DA. This could reflect a greater weight placed on the DA by patients in settings where the patient-provider relationship is not as robust.

Our study had several strengths, including the randomized nature of the study, the extremely high return rate of patient questionnaires (89%), and the inclusion of patients from multiple providers. It is also worth noting that patients who received UC or DA alone were not prevented from going through the SDM process regarding PSA-based prostate cancer screening with their provider if they expressed interest. This potential crossover may explain the difference in PSA screening between the STPR and LTPR DA groups.

Finally, our study had limitations. The applicability of the conclusions as it relates to the DA may be different in populations with varying levels of education. Second, our prostate cancer knowledge questionnaire is not validated and requires further study to authenticate it's use in future studies. Third, the study assessed usual care in two distinct primary care practices. Each provider brings his/her own inherent bias and data interpretation as it relates to prostate cancer screening. Finally, there was no set script for the usual care group and counseling in this arm was probably variable.

Conclusion

Providing patients with a DA only resulted in comparative reduction in knowledge about PSA screening or understanding of the consequences of this decision. Furthermore, patients with a STPR were more likely to be screened based on a decision aid alone. While a useful tool in the context of SDM, these findings suggest that a decision aid alone is an inadequate substitute for a direct conversation between patients and providers. Contrary to contemporary incentives in medicine, a tool cannot substitute for a direct provider-patient interaction. With tremendous pressure on primary care practices to cover a wide breath of preventative care issues, reimbursement for shared decision making must become a national healthcare priority. □

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