



Patient Preferences and Treatment Decisions for Prostate Cancer: Results From A Statewide Urological Quality Improvement Collaborative

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OBJECTIVES	To examine the relationship between influential factors and treatment decisions among men with newly diagnosed prostate cancer (PCa).
METHODS	We identified men in the Michigan Urological Surgery Improvement Collaborative registry diagnosed with localized PCa between 2018-2020 who completed Personal Patient Profile-Prostate. We analyzed the proportion of active surveillance (AS) between men who stated future bladder, bowel, and sexual problems (termed influential factors) had “a lot of influence” on their treatment decisions versus other responses. We also assessed the relationship between influential factors, confirmatory testing results and choice of AS.
RESULTS	A total of 509 men completed Personal Patient Profile-Prostate. Treatment decisions aligned with influential factors for 88% of men with favorable risk and 49% with unfavorable risk PCa. A higher proportion of men who identified bladder, bowel and sexual concerns as having “a lot of influence” on their treatment decision chose AS, compared with men with other influential factors, although not statistically significant (44% vs 35%, $P = .11$). Similar results were also found when men were stratified based on PCa risk groups (favorable risk: 78% vs 67%; unfavorable risk: 17% vs 9%, respectively). Despite a small sample size, a higher proportion of men with non-reassuring confirmatory testing selected AS if influential factors had “a lot of influence” compared to “no influence” on their treatment decisions.
CONCLUSION	Men’s concerns for future bladder, bowel, and sexual function problems, as elicited by a decision aid, may help explain treatment selection that differs from traditional clinical recommendation. UROLOGY 155: 55–61, 2021. © 2021 Elsevier Inc.

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Of the nearly 200,000 men in the United States diagnosed annually with prostate cancer (PCa), most will have favorable-risk, localized disease that is appropriate for active surveillance (AS).^{1,2} Despite increasing uptake of AS and watchful waiting, evidence points to wide variations in the treatment of favorable PCa.^{3,4,5} Treatment decisions require consideration of trade-offs between risk of disease progression and side effects of therapy, and a shared decision-making process intends to help patients and providers select options based on the patients’ values, preferences and treatment goals. Decision aids are tools that support shared decision-making, by increasing patients’ knowledge about the benefits and limitations of treatment strategies. Decision aids elicit specific patient preferences, thereby reducing decisional

conflict to help patients choose the most appropriate treatment option.^{6,7}

Studies have shown that decision aids are associated with values clarification, improved preparation for decision making and less regret.^{7,8} However, in PCa, it is unclear whether patients who complete decision aids are more likely to make treatment decisions that align with their stated preferences. A previous randomized clinical trial using Personal Patient Profile-Prostate (P3P), a web-based decision aid, has shown that completing P3P did not improve agreement between patient's concerns about potential side effects and the choice of a specific type of active treatment.⁹ However, the association of P3P with treatment decisions in men with newly diagnosed, localized PCa in diverse clinical settings outside of a clinical trial remains unknown. Understanding the relationship between patient preferences and their treatment decisions may enable clinicians to better understand patients' decision-making process. Additionally, evaluating patient preferences regarding future impairment in bladder, bowel, or sexual function may help clarify motivating factors for non-traditional treatment selection (ie patients with clinically significant cancer who decline potentially curative treatment).

In this retrospective study, we examined treatment decisions among newly diagnosed PCa patients who completed P3P in diverse community and academic settings. We stratified patients based on whether future functional status (bladder, bowel, or sexual problems, termed influential factors) influenced their treatment and described the proportion of patient choosing AS versus active treatment (prostatectomy, radiation therapy, or other). We hypothesize that men's treatment decisions will align with men's influential factors. We also examine the relationship between influential factors, confirmatory testing results and treatment decisions.

MATERIAL AND METHODS

Study Population

Established in 2011 with support from Blue Cross and Blue Shield of Michigan, the Michigan Urological Surgery Improvement Collaborative (MUSIC), is a physician-led urologic quality improvement collaborative. MUSIC includes 46 community, private, and academic urology practices throughout Michigan, of which 10 practices contributed to this analysis. MUSIC's data collection processes include previously described annual data quality audits and validation.^{10,11} To participate in MUSIC-led quality improvement efforts, each urology practice obtains regulatory exemption approval from their local institutional review boards.

The study population included newly diagnosed, biopsy-confirmed, localized PCa patients who completed P3P survey module at a participating urology practice within MUSIC between April 2018 and January 2020. Patients were classified into favorable and unfavorable risk groups. MUSIC defines favorable-risk as patients with Grade Group 1 and low-volume Grade Group 2 disease ($\leq 50\%$ of an individual core positive for cancer and ≤ 3 cores positive).¹¹

Decision Aid Instrument: Personal Patient Profile-Prostate (P3P)

In 2018, MUSIC partnered with TrueNTH, a Movember project, and began implementing P3P, a one-time online patient survey and decision aid, into routine clinical workflow in self-selected practices across Michigan. P3P was initially evaluated in a multi-center randomized trial, which found it to be efficacious in addressing decision uncertainty and decisional conflict associated with values clarity and decisional conflict overall.¹² Within MUSIC, P3P is offered to patients with newly diagnosed PCa via an online platform. Patients complete P3P after receiving prostate cancer diagnosis but before consultation with a urologist to discuss treatment options. The MUSIC P3P platform collects clinical and patient demographic information submitted by participating urology practices. P3P includes three main components: a patient survey module, a patient information and communication coaching module tailored to patients' race and age, and a summary report for clinicians.¹² The patient survey includes Expanded Prostate Cancer Index Composite (EPIC)-26 and P3P specific preference elicitation multiple choice questions. The EPIC-26 questions capture bowel, urinary, sexual, and hormonal functions in four weeks prior to questionnaire completion. P3P also asks men about personal factors known to impact decision making including current decisional stage, influential personal outcomes and people in the patients' lives who might impact decisions, and the extent to which patients want to participate in the decision-making process. In this study, we focus on responses to questions asking how much future bladder, bowel, and sexual problems influence patients' treatment decisions. The P3P tool can be accessed and is freely available to patients via the following link www.P3P4me.org.

Outcomes Measures

We evaluated the association between men's concern for future bladder, bowel, and sexual problems (referred to as influential factors) with treatment decisions based on patients' responses to three P3P questions. Men were asked "How much influence might future [bladder, bowel, or sexual] problems have on your care decision?"⁹ Answer choices included "no influence," "a little influence," "some influence" and "a lot of influence." There were 4 potential choices to each question regarding future bladder, bowel, and sexual function and based on prior research from Bosco et al, we dichotomized the responses into "a lot of influence" versus the other remaining three options.⁹ Therefore, there were eight possible permutations of dichotomized responses to the above three questions. For consistency we numbered these as scenarios 1-8, as reflected in [Table 1](#), and will herein refer to them as such. Treatment decisions aligned with influential factors from P3P as follows: if a treatment would potentially impact a future function that patients deemed as "a lot of influence", then we considered the treatment not to be aligned with their reported preferences. The definition of treatment alignment is based on prior research and is summarized in [Table 1](#).⁹ Patients who responded future bladder, bowel, and sexual function all had "a lot of influence" on their treatment were grouped in scenario 1 while patients who responded none of these functions had a lot of influence were grouped in scenario 2.

The primary outcome of the study was to compare the proportion of patients who underwent either AS or definitive treatment at 6 months post-diagnosis, based on self-reported influential factors (scenario 1 vs all other scenarios). We analyzed this outcome within the entire cohort and stratified by

Table 1. Possible scenarios of influential factors and aligned treatment choice

Scenario	Patient Selected "A lot of Influence" on . . .			Aligned Treatment Choice
	Sexual	Bowel	Bladder	
1	Y	Y	Y	Active Surveillance (AS)
2	N	N	N	Any treatment
3	Y	N	N	Radiotherapy, AS
4	N	Y	N	Radical Prostatectomy (RP), AS
5	N	N	Y	Any treatment except EBRT, Brachy, RP
6	Y	Y	N	AS
7	Y	N	Y	AS
8	N	Y	Y	AS

PCa risk groups. Treatment type is prospectively collected within the MUSIC registry. We grouped the small number of patients who did not undergo treatment within 6 months of diagnosis with those on active surveillance.

We tested for differences in rates of AS vs definitive treatment among men in scenario 1 and 2 with either reassuring and non-reassuring confirmatory testing. MUSIC defines a confirmatory test as a repeat biopsy, prostate magnetic resonance imaging, or molecular classifiers obtained within 6 months of initial diagnosis in patients with favorable-risk PCa.^{13,14} Reassuring confirmatory test results were defined as: prostate biopsy remaining GG1 or low volume GG2 as on the initial biopsy; MRI, maximum Prostate Imaging Reporting and Data System (PI-RADS) version 2, score of 1-3; Prolaris <3% probability of PCa mortality, Oncotype Dx >80% freedom from adverse pathology; Decipher <0.45.^{11,15} Patients with metastatic disease, those who were lost to follow up or switched to another practice, and therefore no follow up information on their treatment decision was recorded, were also excluded.

Statistical Methods

Clinical and demographic characteristics of patients were summarized for the entire cohort. Median and interquartile ranges were reported for continuous measures, and frequency and proportion were reported for categorical variables. The frequency and proportion of patients undergoing each type of treatment were reported by patient preference categories. Chi-squared test was used to compare the treatment distribution across groups. All analyses were performed in SAS 9.4, and statistical significance was set at 0.05.

RESULTS

Between April 2018 and January 2020, 509 of the 3860 patients with newly diagnosed PCa among 10 MUSIC practices that offered P3P to their patients, completed P3P. There were no differences in terms of practice setting (academic vs community), number of urologists within each practice and number of patients registered to MUSIC per practice between P3P participating and non-participating practices. However, most of the practices that participated in P3P were located in metropolitan areas. Among the 509 men, 230 (45%) had favorable-risk disease and 279 (55%) had unfavorable risk disease. Median age at diagnosis was 64 (IQR 59-68) and 65 (IQR 60-71) years for favorable and unfavorable risk patients, respectively. Demographic, histopathology, clinical staging, and comorbidity information for patients in both risk groups are provided in Table 2.

Overall, we found that 67% (340/509) patients made treatment decisions that aligned with their stated influential

factors. The proportion of patients with differing responses to the influential factors and their treatment decisions are summarized in Table 3a and 3b. The distribution of responses to each of the influential factor questions (bowel, bladder, and sexual function) is presented in the Supplemental Figure. The most common profile was scenario 2: men who stated that future bladder, bowel, and sexual problems had no to some influence (n = 207, 41%). The second largest group was scenario 1: men who stated that future bladder, bowel, and sexual problems all had a lot of influence on their treatment decision (n = 105, 21%). The influential factor profiles did not differ significantly between favorable and unfavorable risk patients. Among 230 men with favorable-risk PCa, 160 (70%) elected AS and 70 (30%) underwent definitive treatment. Among men with favorable risk, 88% made treatment decisions that were aligned with their stated influential factors. Since MUSIC is based exclusively on urologists' practice, most men (n = 53, 76%) who chose definitive treatment underwent a radical prostatectomy (Table 3a). Among the 279 men with unfavorable risk PCa, 29 (10%) elected AS and 250 (90%) underwent definitive treatment. Among men with unfavorable risk, 49% made decisions that aligned with their stated influential factors (Table 3b).

When comparing treatment decisions between patients who selected that future bladder, bowel, and sexual problems had a lot of influence (scenario 1) on their treatment decision compared to other scenarios we found a higher proportion of men choose active surveillance vs definitive treatment, however this did not reach statistical significance (44% vs 35%, $P = .11$). When analyzing risk groups separately, we again saw a higher but not statistically significant proportion of men in scenario 1 on active surveillance compared with men in other scenarios (Favorable risk: 78% vs 67%, $P = .15$; Unfavorable risk: 17% vs 9% $P = .063$). (Supplemental Table 1).

In this study, 101 (44%) men with favorable-risk disease underwent confirmatory testing, of these 59 (58%) were in scenarios 1 or 2. Since we hypothesized that influential factors would drive behavior among men who indicated very strong preferences, we focused our analysis on the effect of confirmatory testing among men in scenario 1 and 2. In men with non-reassuring confirmatory tests (n = 20) the proportion of those who still selected AS was greater among men in scenario 1 compared to scenario 2 (86% vs 69%, $P = .61$), but this did not reach statistical significance (Fig. 1). Similarly, in men with reassuring confirmatory testing, none of the men in scenario 1 selected definitive treatment compared with 24% (6/25) of men, who reported none of the factors influenced treatment decision, selected definitive treatment ($P = .071$) (Fig. 1).

Table 2. Patient characteristics of personal patient profile-prostate (P3P) cohort stratified by risk group

Characteristics	Risk Group		P
	Favorable	Unfavorable	
No. of study participants	230	279	
Sociodemographic Characteristics			
Age, median (IQR)	64 (59-68)	65 (60-71)	0.024
Race			
White	203 (89.0%)	237 (86.2%)	0.422
Black	23 (10.1%)	32 (11.6%)	
Other	2 (0.9%)	6 (2.2%)	
Marital status			
Married/partnered	198 (86.5%)	216 (77.7%)	0.011
Other	31 (13.5%)	62 (22.3%)	
Insurance type			
Private	148 (64.6%)	153 (55.0%)	0.029
Public	81 (35.4%)	125 (45.0%)	
Tumor characteristics			
Gleason score at biopsy			
GG 1 (3+3)	175 (76.1%)	-	-
GG 2 (3+4)	55 (23.9%)	127 (45.7%)	
GG 3 (4+3)		78 (28.1%)	
GG 4-5 (8-10)		73 (26.3%)	
Clinical staging			
T1	205 (89.5%)	199 (71.6%)	<0.001
T2 or Higher	24 (10.5%)	79 (28.4%)	
PSA, median (IQR), ng/ml	5.3 (4.3-6.9)	6.3 (4.9-9.5)	<0.001
BMI (kg/m ²), median (IQR)	28.7 (25.8-32.4)	29.3 (26.4-33.0)	0.168
Urinary incontinence domain	100.0 (84.4-100.0)	100.0 (85.5-100.0)	0.764
Sexual function domain	66.7 (38.8-91.7)	62.5 (36.2-87.5)	0.511
Charlson comorbidity index			
0	177 (77.0%)	213 (76.3%)	0.910
1	31 (13.5%)	41 (14.7%)	
≥2	22 (9.6%)	25 (9.0%)	

GG, grade group; MUSIC defines favorable-risk as patients with Grade Group 1 (Low Risk) and low-volume (3 or less positive cores with no cores containing >50% cancer) Grade Group 2 disease (Intermediate Risk); all other patients are classified as unfavorable risk.

COMMENT

In this study, we found that 88% of men with newly diagnosed favorable risk and 49% of men with unfavorable risk PCa made treatment decisions that were aligned with their concerns about future bladder, bowel, or sexual

problems (Tables 3a and 3b). Overall, treatment decisions are heavily influenced by risk stratification. This echoes prior studies reporting that guideline concordant care and cancer eradication are some of the strongest influencers of treatment decisions.^{17,18} While the subgroup of men who

Table 3a. Favorable risk prostate cancer patients undergoing active surveillance versus active treatment stratified by influence of bladder, bowel, and sexual functions

Scenarios	"A lot of Influence"			Treatment Decisions at 6 mo Post Diagnosis				
	Sexual	Bowel	Bladder	AS160 (69.6%)	ADT1 (0.4%)	RP53 (23.0%)	RT15 (6.5%)	RT + ADT1 (0.4%)
Scenario 1	Y	Y	Y	36 (78.3%)	0	6 (13.0%)	4 (8.7%)	0
Scenario 2	N	N	N	64 (65.3%)	1 (1.0%)	30 (30.6%)	3 (3.1%)	0
Scenario 3	Y	N	N	19 (67.9%)	0	5 (17.9%)	4 (14.3%)	0
Scenario 4	N	Y	N	4 (40.0%)	0	4 (40.0%)	2 (20.0%)	0
Scenario 5	N	N	Y	2 (100%)	0	0	0	0
Scenario 6	Y	Y	N	3 (100%)	0	0	0	0
Scenario 7	Y	N	Y	0	0	0	0	0
Scenario 8	N	Y	Y	32 (74.4%)	0	8 (18.6%)	2 (4.7%)	1 (2.3%)

Shaded cells represent 88% (202/230) alignment between treatment options and "a lot of influence" of sexual, bowel and bladder functions. We considered active treatment to be any treatment option except active surveillance. We combined information from patients without treatment in the MUSIC Registry at 6-month post diagnosis with patients on AS (n = 12).

AS, active surveillance; ADT, androgen deprivation therapy; RP, radical prostatectomy; RT, radiation therapy.

Table 3b. Unfavorable risk prostate cancer patients undergoing active surveillance versus active treatment stratified by influence of bladder, bowel, and sexual functions

Scenarios	Treatment Decisions at 6 mo Post Diagnosis								
	"A lot of influence"			AS29 (10.4%)	ADT21 (7.5%)	RP179 (64.2%)	RT34 (12.2%)	RT + ADT11 (3.9%)	Other5 (1.8%)
	Sexual	Bowel	Bladder						
Scenario 1	Y	Y	Y	10 (16.9%)	1 (1.7%)	36 (61.0%)	7 (11.9%)	3 (5.1%)	2 (3.4%)
Scenario 2	N	N	N	10 (9.2%)	9 (8.3%)	75 (68.8%)	12 (11.0%)	2 (1.8%)	1 (0.9%)
Scenario 3	Y	N	N	5 (25.0%)	4 (20.0%)	10 (50.0%)	1 (5.0%)	0	0
Scenario 4	N	Y	N	1 (7.7%)	2 (15.4%)	9 (69.2%)	1 (7.7%)	0	0
Scenario 5	N	N	Y	0	0	6 (85.7%)	0	1 (14.3%)	0
Scenario 6	Y	Y	N	2 (33.3%)	0	3 (50.0%)	0	1 (16.7%)	1 (16.7%)
Scenario 7	Y	N	Y	0	0	4 (66.7%)	1 (16.7%)	1 (16.7%)	0
Scenario 8	N	Y	Y	1 (1.7%)	5 (8.5%)	36 (61.0%)	12 (20.3%)	4 (6.8%)	1 (1.7%)

Shaded cells represent 49% (138/279) alignment between treatment options with "a lot of influence" of either sexual, bowel or bladder functions. We considered active treatment to be any treatment option except active surveillance. We combined information from patients without treatment in the MUSIC Registry at 6-month post diagnosis with patients on AS (n = 7). AS, active surveillance; ADT, androgen deprivation therapy; RP, radical prostatectomy; RT, radiation therapy

reported strong influence of future bladder, bowel, and sexual problems on their treatment decision made distinct treatment decisions, the differences in treatment decisions did not reach statistical significance.

The overall rate of treatment decisions that align with influential factors (67%) from this pragmatic multi-institutional sample are much higher than prior data from a randomized controlled trial, using the same instrument and showing that 47% of men chose a treatment that aligned with their influential factors.⁹ Our findings may reflect more contemporary rates as the previous RCT study was conducted between 2007 and 2009. One potential reason for the increase in aligned treatment decisions may be a general increase in the adoption of AS over the past decade. Since AS is an ideal treatment option for men whose future bladder, bowel, or sexual problems have "a lot of influence", an increase in AS rates contributes to an increase in overall treatment alignment for these patients. Shared decision making and decision aids are traditionally recommended for use when patients face preference sensitive decisions. The finding that fewer men with unfavorable risk disease make treatment decisions that align with their influential factors may represent an opportunity to increase use of decision aids. Tools such as P3P can help support men as they weigh tradeoffs between cancer treatment and personal preferences.

MUSIC recommends newly diagnosed favorable risk PCa patients undergo at least one confirmatory test within 6 months of diagnosis.¹¹ Overall, AS rates were higher among those with reassuring tests vs non reassuring (86% vs 77%). However, a large proportion of men with favorable risk PCa who had non-reassuring confirmatory tests but who stated functional outcomes had a lot of influence still elected for active surveillance, in opposition to the confirmatory test results. Similarly, and paradoxical to expectation, a larger proportion of men with reassuring testing but who stated functional outcomes did not have a lot of influence elected for definitive treatment, implying greater concern for cancer control than functional outcomes. Our results suggesting interactions between confirmatory testing and patient preferences may help to explain this phenomenon. In the least, our findings suggest that preferences are an important focus when evaluating treatment decisions and the results of confirmatory testing.

The results of this research should be interpreted within the context of the study limitations. Overall rates of patient completion in P3P were low. Recently published interviews with urologists and staff-members in MUSIC practices showed that P3P is compatible with regular clinic flow, most urologists and staff had an overall positive impression of P3P, and patient receptivity was high.¹⁶ However, we continue to investigate factors that influence P3P completion. While there are demographic and clinicopathologic differences between those who complete P3P and those who did not, we find that patient characteristics contribute very little to completion of P3P, but that the patients' urologists have a profound impact on whether the patient enrolls in P3P (unpublished work). The low rate of P3P

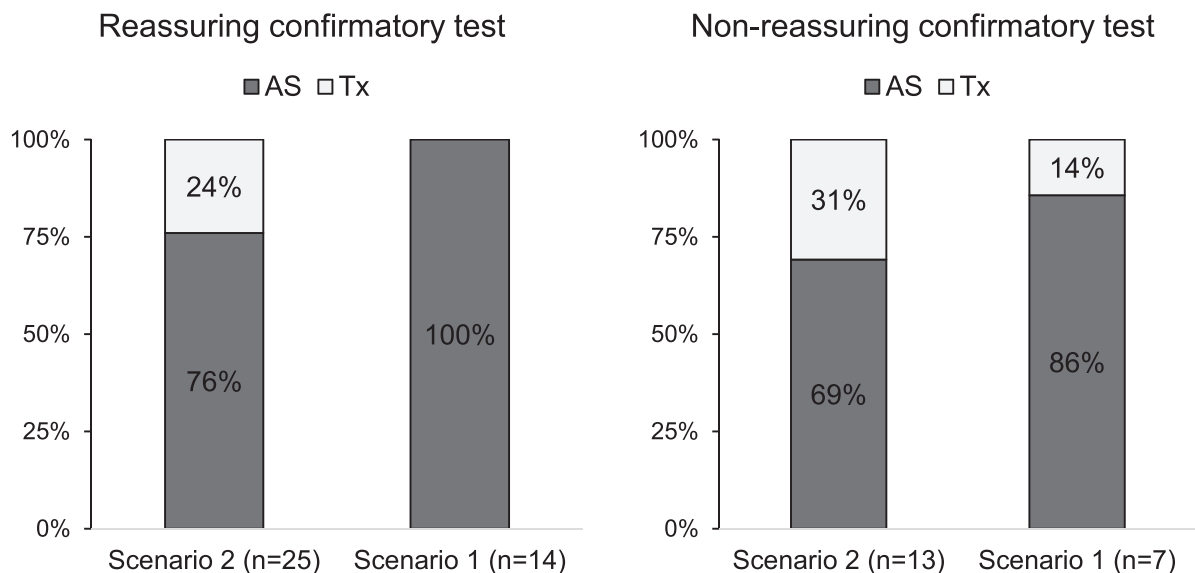


Figure 1. Proportion of favorable-risk patients choosing active surveillance versus treatment stratified by confirmatory testing results and influential factors.

completion also limits our ability to detect differences in treatments based on influential scenarios, and therefore lack of statistical significance should be interpreted as such. However, these results provide practical data to support the use of a decision aid prior to making a decision about prostate cancer treatment. We acknowledge that clinicians influence treatment decisions and that these data, which are based on urology practice patterns & counseling, are skewed towards surgical treatment of prostate cancer. Our results reflect a subset of patients and provider patterns and may not be generalizable to the entire MUSIC collaborative. Despite this, the rates of prostatectomy in our cohort are lower than rates of prostatectomy in a multi-disciplinary randomized control trial of P3P.⁹ Further, national guidelines recommend that “clinicians encourage patients to meet with other prostate cancer care specialists (ie radiation oncology).”¹⁷ Finally, medical decision making is complex and there may be factors such as baseline sexual, bowel or urinary function or relationship status that may contribute to treatment decisions.^{18,19,20,21} However, on exploratory analyses we evaluated whether relationship status is associated with choice of active surveillance and did not find a significant association (favorable risk: 71% vs 58%, $P = .14$; unfavorable risk 12% vs 6%, $P = .24$). Despite these limitations, we found evidence to suggest that the degree of influence of bladder, bowel, and sexual function may impact their treatment decisions up to 6 months after diagnosis.

This study provides real-world experience that reinforces the importance of patient preference elicitation as part of decision making for prostate cancer care. We have previously shown that preference elicitation and use of decision aids are among the least frequently utilized aspects of shared decision making.²² Our study suggests the central role of patient preference in treatment decision-making. Quality interventions that

improve patient preference elicitation should be part of routine clinical encounters.

CONCLUSION

Treatment decisions for prostate cancer care are primarily influenced by the cancer risk group. However, within risk groups, decisions between AS versus definitive treatment may vary by patients’ perception of the influence of future bladder, bowel, and sexual problems on their treatment decision. These findings support efforts to increase patient preference elicitation during clinical encounters for PCa care.

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.urology.2021.04.020>.

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