A prospective evaluation of patient perspectives and financial considerations during prostate cancer treatment decision-making

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ABSTRACT

INTRODUCTION: In universal healthcare systems, patients may still encounter financial obstacles from cancer treatments, potentially influencing treatment decision-making. We investigated the relationship between socioeconomic status and treatment decision-making as it pertains to patient values, preferences, and perceived barriers to care for localized prostate cancer.

METHODS: We conducted a prospective study of patients undergoing a prostate biopsy for the initial detection of prostate cancer. Sociodemographic variables were collected, with validated instruments used to determine health literacy levels. Patients were divided into two groups using self-reported income; those with a positive identification of prostate cancer underwent additional surveys to ascertain their knowledge of their diagnosis, treatment-related preferences, and socioeconomic barriers to care. Descriptive statistics were used.

RESULTS: Of 160 patients, approximately one-third were classified as having low health literacy. Within the low-income group, education levels were lower (34.6% had less than high school education vs. 10.2% in the high-income group) and unemployment rates higher (75.0% unemployed vs. 38.9% in the high-income group). Low-income patients with prostate cancer placed greater importance on indirect out-of-pocket expenses related to treatment (78.3% vs. 33.3%, p=0.001), higher emphasis on treatment-related travel time (50% vs. 15.1%, p=0.004), and more often had difficulty paying for healthcare services in the past (30.9% vs. 9.1%, p=0.02).

CONCLUSIONS: Patients with lower household incomes have unique treatment values and decision-making preferences. They may experience additional challenges and barriers to obtaining cancer care, at least partly related to indirect costs. These findings should be considered when framing prostate cancer treatment discussions and designing patient-facing health information.

INTRODUCTION

Prostate cancer is the most common non-cutaneous cancer affecting men in Canada.[1] Due to the ability to detect prostate cancer with prostate-specific antigen (PSA) screening, the disease is usually localized when diagnosed, and long-term survival rates are high.[2] The management options offered to patients with localized cancer typically include radical prostatectomy (RP), radiation therapy (RT), and active surveillance (AS).[2] Although studies to date have not demonstrated significant survival rate differences between treatment options,[3] there are stark differences between these treatment approaches with respect to their side effect profiles.[3-5] These side effects, including urinary incontinence and erectile dysfunction, can significantly impact health-related quality of life.[4] The lack of consensus for an optimal treatment strategy, combined with variable treatment risk profiles and individualized patient preferences, inherently leads to treatment decisions that are "preference-sensitive."[2,6,7] Although previous studies have evaluated preferences for patients with prostate cancer, there appears to be a paucity of data examining the financial considerations of patients as it pertains to prostate cancer treatment decision-making.[8] This is especially pertinent in universal healthcare systems, such as in Canada, where studies have shown that up to 33% of prostate cancer patients incur significant financial burden from unplanned additional expenses associated with treatment.[9-12]

KEY MESSAGES

- Prostate cancer treatments can impose significant financial burdens for patients due to out-of-pocket expenses.
- Out-of-pocket expenses and travel time are important considerations for many patients choosing prostate cancer treatments, especially those with lower incomes.
- Even in a universal healthcare system, providers should consider potential financial obstacles associated when framing treatment discussions with patients.

In the present study, we sought to prospectively evaluate a cohort of patients presenting for prostate cancer investigations (prostate biopsy), stratified by household income, to investigate patient engagement preferences and financial considerations as it pertains to treatment decision-making.

METHODS

Study design and population

We conducted a prospective, survey-based study of patients undergoing a prostate biopsy for the detection of prostate cancer. Men who presented to the Manitoba Prostate Centre for a biopsy were approached to participate on the day of their biopsy. The Manitoba Prostate Centre is a centralized location in the province of Manitoba whereby the vast majority of prostate biopsies are performed.

Inclusion criteria for the study were: ≥18 years of age, ability to communicate in English, and a PSA level <50 ng/ml (to exclude patients who were more likely to have metastatic disease). Individuals were excluded if they had a pre-existing diagnosis of prostate cancer (including AS patients) or if they were unable to consent due to cognitive impairment. Patients found to have metastatic disease were excluded from the final analysis.

Consented individuals were asked to complete a baseline survey (Part A) to ascertain their socioeconomic demographic information and assess their health literacy. Patients in whom the biopsy was positive for prostate cancer were then asked to participate in a second survey (Part B) that asked prostate cancer-specific questions and treatment decision-making questions. Individuals were contacted via telephone by the research coordinator approximately two weeks after their pathology disclosure appointment with their clinician to ensure the biopsy results were disclosed and the patient had received counselling by their provider regarding treatment options (Figure 1). This study was approved by the University of Manitoba Health Research Ethics Board (ethics file number: HS23972 (H2020:258)), and by the CancerCare Manitoba Research Resource Impact Committee (RRIC #2020-17).

Questionnaires

In Part A of the study, self-reported demographic information, including age, ethnicity, height, weight, marital status, education level, household income bracket, comorbidities, and self-reported dwelling location (urban/rural) were collected (Appendix 1; available at *cuaj.ca*). An electronic chart review provided information on pre-biopsy PSA levels and biopsy results. The Rapid Estimate of Adult Literacy-Short Form (REALM-SF) was used to evaluate reading level.[13] The REALM-SF is a validated, seven-question literacy assessment tool used to estimate reading levels, and has a possible range of 0–7, with the highest score of 7 corresponding to at least a ninth-grade reading level. Patients with less than a ninth-grade reading level likely face difficulties comprehending most patient education materials.[13]

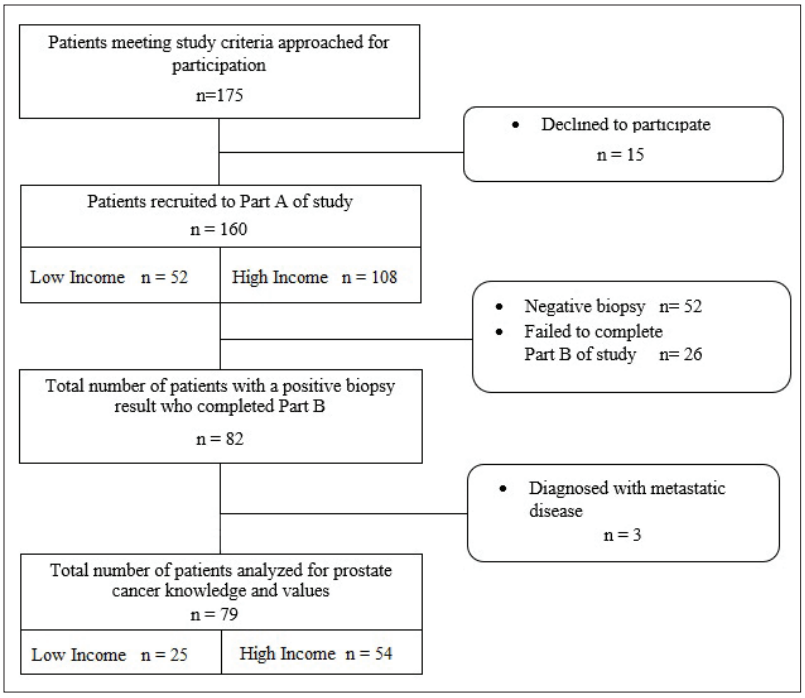

Figure 1. Flow diagram providing an overview of our participant selection process.

A second survey (Part B) was performed in those patients in whom prostate cancer was confirmed on biopsy. In Part B, a series of questions were asked to determine participants' knowledge of their diagnosis and to solicit their understanding of treatment options (Appendix 2; available at *cuaj.ca*). The survey was administered after their pathology report was disclosed to them by their urologist. To elicit their values, we asked a series of closed-ended questions regarding individual factors as it pertained to their treatment decision-making, using an elicitation procedure called prioritization.[14] Participants were then asked questions related to shared decision-making preferences and socioeconomic barriers to care.

Predictor variable

The median total income in Manitoba, Canada for the year 2019 was $72 600. Previous literature has suggested that low-income households are those with less than two-thirds the median total household income,[15] and thus we estimated that a household income less than $50 000 would constitute as having a low income. Participants were grouped according to self-reported household income: <$50 000/year or ≥$50 000/year. Comparing responses between those with incomes >$100 000 to those with incomes between $50 000–100 000, there were no differences. Thus, $50 000/year was used to distinguish between groups.

Statistical analyses

Descriptive statistics were expressed as mean ± standard deviation (SD) for normal continuous variables; median and interquartile ranges (IQR) for non-normal continuous variables; and percentages for categorical variables. The Chi-squared test or Fisher's exact test, as appropriate, were used to compare the two groups. Missing data were handled by multiple imputations using the proc MI procedure in SAS.[16] All analyses were performed using SAS 9.4 (SAS Institute, Cary, NC, U.S.).

> "In our universal healthcare system, patients do not pay directly for medical services but many may experience financial stress from their therapy *indirectly*."

RESULTS

Study population

Between July 1, 2020, and June 30, 2021, 175 individuals were screened to meet study criteria, of whom 160 consented to participate in the study (Figure 1). Of these individuals, 52 (32.5%) had a yearly household income <$50 000 and 108 (67.1%) had a household income ≥$50 000. Table 1 highlights the baseline demographic, clinical characteristics, and health literacy scores of the study groups.

Compared with patients in the high-income group, those with lower income were older (mean age 71.7 years vs. 65.8 years) and presented with a higher PSA (mean PSA level 10.1 ng/ml in the low-income group compared with 8.7 in the higher-income group). In the lower-income group, a smaller proportion of individuals had a post-secondary education (36.5% vs. 67.1% in the high-income group) and patients were more comorbid (44.2% had three or more comorbidities, compared with 18.5% in the higher-income group). Most respondents were Caucasian in both groups (>80%). The higher-income group were more commonly married (83.3% married compared to 55.8% in the low-income group). In both groups, approximately one-third of patients had reduced health literacy and would struggle reading health information.

Prostate cancer knowledge and decision-making

In the lower-income group, 76.0% of individuals correctly recalled their diagnosis, compared to 92.5% in the higher-income group (p=0.07), and 20% of lower-income individuals correctly recalled their Gleason score compared to 40.7% in the higher-income group (p=0.07) (Table 2).

Among patients who selected active treatment (RP or RT), 28.6% in the low-income group selected RP compared with 38.3% in the high-income group (Table 3). A sub-analysis exploring treatment selection among those less than 70 years old was conducted; among the 55 patients included in this sub-analysis, there were no significant differences in treatment selection.

Values, preferences, and patient engagement

Table 4 displays the values that were considered important when the study participants were deciding on a prostate cancer treatment. Lower-income individuals placed greater importance on out-of-pocket expenses associated with treatment (78.3% of the lower-income

group compared with 33.3% in the higher-income group ranked this category as very important, p=0.001). Time required to travel for treatments was deemed a very important consideration more often in the lower-income group (50.0% in the lower-income group compared with 15.1% in the higher-income group, p=0.004). Additionally, lower-income patients were more likely to consider being a burden to their spouse, family, and/or friends to be a very important consideration (75% in the lower-income group compared to 69.8% in the higher-income group, p=0.05). Table 4 also displays the reported level of shared decision-making preferred for individuals with a positive biopsy result; 79.2% of lower-income individuals preferred at least some degree of patient-physician shared decision-making compared to 92.3% in the higher-income group (p=0.1).

Socioeconomic barriers

Table 5 displays results on potential socioeconomic barriers to care. In the past 12 months, 90.7% of individuals in the higher-income group reported to never have difficulties paying for health services, equipment, or medications compared to 66.7% in the lower-income group (p=0.02).

DISCUSSION

In this study, patients presenting for prostate biopsies were stratified based on their self-reported annual household income and evaluated on their health literacy, decision-making considerations, and treatment-related values and preferences. We found that more than a third of our study population had limited health literacy levels and identified that, in addition to considering the different risk profiles of treatment options, patients also considered financial implications associated with each treatment. Lower-income patients were more likely to consider out-of-pocket expenses and time requirements related to travel as factors related to their treatment selection. These findings highlight the hidden barriers that patients may face when accessing prostate cancer care.

IIn the Canadian universal healthcare system, patients do not pay directly for medical services yet many people may experience financial stress from their therapy indirectly.[17,18] A study from Newfoundland and Labrador, Canada, with 170 prostate cancer patients, found that 15.9% of patients had significant additional treatment-related costs consuming greater than 7.5% of their quarterly income.[10] Another study, including 216 prostate cancer patients, found that 33% experienced financial burden, with a higher burden experienced by patients with lower household incomes.[9]

Table 1. Demographic and clinical characteristics for individuals presenting for a prostate cancer biopsy stratified by yearly household income level (n=160)

Characteristic	Low income <$50 000/year in household income	Higher income ≥$50 000/year in household income
n (%)	52 (32.5)	108 (67.1)
Mean age ± SD, years	**71.7±9.0**	**65.8±7.6**
Education, n (%)		
Less than grade 12	**18 (34.6)**	**11 (10.2)**
Graduated grade 12	**15 (28.9)**	**24 (22.2)**
Post-secondary	**19 (36.5)**	**73 (67.1)**
Marital Status, n (%)		
Married	**29 (55.8)**	**90 (83.3)**
Single (never married, divorced, or widowed)	**23 (44.3)**	**18 (16.7)**
Ethnicity, n (%)		
Caucasian	42 (80.8)	93 (86.1)
Asian	3 (5.8)	6 (5.6)
African Canadian	0	2 (3.5)
Indigenous	3 (5.8)	5 (4.6)
Other	4 (7.7)	2 (1.9)
Dwelling location, n (%)		
Urban	32 (61.5)	81 (75.0)
Rural	20 (38.5)	27 (25.0)
If travelling by car, how many hours would it take you to drive from your home to the Manitoba Prostate Centre? n (%)		
<1 hour	**35 (67.3)**	**93 (86.1)**
1–2 hours	**10 (19.2)**	**11 (10.2)**
>2 hours	**7 (13.5)**	**4 (3.7)**
Comorbidities, n (%)		
0	9 (17.3)	28 (25.9)
1–2	20 (38.5)	60 (55.6)
3 or more	23 (44.2)	20 (18.5)
Median BMI (IQR)	27.1 (25.1, 30.3)	28.3 (24.7, 30.7)
Median pre-biopsy prostate-specific antigen (PSA), ng/mL (IQR)	**10.1 (7.5, 14.8)**	**8.7 (6.1, 12.4)**
Biopsy result		
Negative	16 (30.8)	37 (34.3)
Positive	36 (69.2)	71 (67.1)
Risk level among individuals with a positive biopsy result**		
Low	4 (11.1)	7 (9.9)
Intermediate	16 (44.4)	36 (45.7)
High	16 (44.4)	28 (39.4)
Mean REALM-SF score* ± SD	6.4±1.2	6.6±0.7
REALM-SF score, n (%)		
<7	18 (34.6)	32 (29.6)
7	34 (65.4)	76 (70.4)

Bolded values indicate a statistically significant difference between groups (p<0.05). *Possible range of 0–7. **Risk levels are cancer risk groups defined using prostate-specific antigen test results, clinical stage and Gleason scores. SD: standard deviation; BMI: body mass index; IQR: interquartile range; REALM-SF: The Rapid Estimate of Adult Literacy-Short Form Questionnaire.

Table 2. Prostate cancer knowledge assessment for individuals with a confirmed positive prostate cancer biopsy result (non-metastatic), stratified by yearly household income level (n=79)

Characteristic	Low income	Higher income	p
n (%)	25 (31.7)	54 (68.4)	
Prostate cancer knowledge assessment			
"Based on your last encounter with the doctor, what is your diagnosis?" n (%) correct	19 (76.0)	49 (92.5)	0.07
"What is your Gleason score?" n (%) correct	5 (20.0)	22 (40.7)	0.07
"What is your risk category?" n (%) correct	6 (24.0)	11 (20.4)	0.7
Prostate cancer treatment options			
"Are you aware of your treatment options?" n (%) yes	18 (72.0)	40 (74.1)	0.8

Table 3. Treatment decision type among individuals with a positive biopsy result (n=98)*

	Low income	Higher income
Total, n (%)	35 (35.7%)	63 (64.2%)
Surgery	6 (17.1)	18 (28.6)
Radiation therapy	15 (42.9)	29 (46.0)
Active surveillance	7 (20.0)	12 (19.1)
Watchful waiting/denied standard treatment	7 (20.0)	3 (4.8)
Other (high-intensity focused ultrasound)	0	1 (1.6)

p=0.1 for all values. *Excluding individuals who were diagnosed with metastatic cancer (n=6); and whose treatment decision type was not available (n=3).

We found 33.3% of the patients with low household incomes have experienced some level of difficulty paying for healthcare or related expenses even prior to their prostate cancer diagnosis. We also found that the time required to travel for treatments was an important consideration to patients with low household incomes. There is also an additional financial burden associated with travel, including costs for transportation and lodging.[19] This may be more impactful to patients living outside of urban centers, where all prostate cancer is centralized. While the lower-income group acknowledged these perceived barriers, they also indicated that they have not avoided getting the services, equipment, or medications they have needed because of it. Presumably, lower-income patients previously absorbed the financial burden associated with their medical care

Table 4. Ranking of patient values for individuals with a confirmed positive prostate cancer biopsy result, stratified by yearly household income level (n=79)

	Low income	Higher income	p
Total, n (%)	25 (31.7)[a]	54 (68.4)[b]	
Patient values: "When considering prostate cancer treatment, what is important to you?" n (%)			
Staying away from regular visits to doctors and hospitals			
Not important	11 (45.8)	36 (66.7)	0.2
A little important	6 (25.0)	10 (18.5)	
Very important	7 (29.2)	8 (14.8)	
Emotional side effects of treatment			
Not important	7 (30.4)	12 (23.5)	0.6
A little important	3 (13.0)	12 (23.5)	
Very important	13 (56.5)	27 (52.9)	
Being able to take care of myself after treatment			
Not important	2 (8.3)	6 (11.1)	0.3
A little important	1 (4.2)	0	
Very important	21 (87.5)	48 (88.9)	
Chance that the prostate cancer returns			
Not important	2 (8.3)	2 (4.0)	0.7
A little important	2 (8.3)	4 (8.0)	
Very important	20 (83.3)	44 (88.0)	
Bladder side effects of treatment			
Not important	2 (8.3)	4 (7.6)	0.2
A little important	0	7 (13.2)	
Very important	22 (91.7)	42 (79.3)	
Sexual side effects of treatment			
Not important	8 (33.3)	13 (25.0)	0.8
A little important	5 (20.8)	12 (23.1)	
Very important	11 (45.8)	27 (51.9)	
Bowel side effects of treatment			
Not important	4 (17.4)	8 (14.8)	0.9
A little important	5 (21.7)	11 (20.4)	
Very important	14 (60.9)	35 (64.8)	
Being a burden to my spouse, family and/or friends			
Not important	6 (25.0)	7 (13.2)	0.05
A little important	0	9 (17.0)	
Very important	18 (75.0)	37 (69.8)	
Being able to remain in my own home			
Not important	2 (8.7)	3 (5.8)	0.3
A little important	1 (4.4)	0	
Very important	20 (87.0)	49 (94.2)	
Additional years of life			
Not important	1 (4.4)	2 (3.8)	0.5
A little important	3 (13.0)	3 (5.7)	
Very important	19 (82.6)	48 (90.6)	

[a]Item responses may add to less than 25 because of missing data.
[b]Item responses may add to less than 54 because of missing data.
Bolded values indicate a statistically significant difference between groups (p<0.05).

Table 4 (cont'd). Ranking of patient values for individuals with a confirmed positive prostate cancer biopsy result, stratified by yearly household income level (n=79)

	Low income	Higher income	p
Total, n (%)	25 (31.7)[a]	54 (68.4)[b]	
Out-of-pocket expenses associated with treatment			
Not important	2 (8.7)	21 (38.9)	**0.001**
A little important	3 (13.0)	15 (27.8)	
Very important	18 (78.3)	18 (33.3)	
Loss of income due to treatments and/or recovery			
Not important	16 (69.6)	32 (62.8)	0.8
A little important	2 (8.7)	4 (7.8)	
Very important	5 (21.7)	15 (29.4)	
Time away from work			
Not important	17 (77.3)	31 (63.3)	0.3
A little important	1 (4.6)	8 (16.3)	
Very important	4 (18.2)	10 (20.4)	
Time required to travel for treatments			
Not important	9 (37.5)	39 (73.6)	**0.004**
A little important	3 (12.5)	6 (11.3)	
Very important	12 (50.0)	8 (15.1)	
Reported level of shared decision making preferred, n (%)			
At least some degree of patient-physician shared decision making preferred	19 (79.2)	48 (92.3)	0.1
Prefer physician make the final decision	5 (20.8)	4 (7.7)	

[a]Item responses may add to less than 25 because of missing data. [b]Item responses may add to less than 54 because of missing data. Bolded values indicate a statistically significant difference between groups (p<0.05).

Table 5. Socioeconomic barriers to care for individuals with a confirmed positive prostate cancer biopsy result, stratified by yearly household income level (n=79)

	Low income	Higher income	p
n (%)	25 (31.7)[a]	54 (68.4)[b]	
In the past 12 months, how often have you had difficulty paying for health services, equipment, or medications that you needed?			
Always	0	0	0.02
Often	1 (4.2)	0	
Sometimes	6 (25.0)	5 (9.3)	
Rarely	1 (4.2)	0	
Never	16 (66.7)	49 (90.7)	
In the past 12 months, how often did you NOT get the services, equipment, or medications you needed due to cost?			
Always	0	0	0.7
Often	0	0	
Sometimes	1 (4.2)	1 (1.9)	
Rarely	0	1 (1.9)	
Never	23 (95.8)	52 (96.3)	
In the past 12 months, did you work for a job or business (including part-time jobs, seasonal work, contract work, self-employment, or any other paid work) regardless of the hours worked?			
Yes	6 (25.0)	33 (61.1)	**0.008**
No	16 (66.7)	19 (35.2)	
Unable to work	2 (8.3)	2 (3.7)	
In the past 12 months, how often did you find it difficult to get healthcare services because of lost income from taking time off work?*			
Always	0	0	1.0
Often	0	0	
Sometimes	0	1 (3.1)	
Rarely	0	1 (3.1)	
Never	7 (100.0)	30 (93.8)	
In the past 12 months, how often did you find it difficult to get healthcare services because it was difficult to get time off work?*			
Always	0	0	1.0
Often	0	0	
Sometimes	0	3 (9.1)	
Rarely	0	0	
Never	7 (100.0)	30 (90.9)	

*Among individuals who are currently employed. [a]Item responses may add to less than 25 because of missing data. [b]Item responses may add to less than 54 because of missing data. Bolded values indicate a statistically significant difference between groups (p<0.05).

when necessary but if given the choice, may select a treatment option that has less associated financial requirements.

The term 'financial toxicity' refers to the harms and burdens placed on the patient by treatment costs, both direct and indirect.[20] Financial toxicity been shown to be a risk factor for worse oncological outcomes, including death.[21,22] The relationship between financial toxicity and disparate health outcomes is not completely understood, and the role it plays in a universal healthcare systems is even less known. Our group previously explored the concept that socioeconomic status (SES) may be influencing treatment decisions for patients diagnosed with localized prostate cancer.[23] For men with localized prostate cancer, household income as a surrogate for SES was independently associated with the treatment received (surgery vs. radiation). This suggests that there may be unique considerations that patients are faced with relative to their financial status. Opportunity cost in the form of missed work may be a reality for patients undergoing both surgery or radiation-based treatments.[8] The lost income and increased expenses from surgery, however, would largely be upfront and more immediate due to the inherent recovery period. The immediate income lost from surgery could possibly stand as a barrier for those without sufficient financial reserves. Indirect costs from radiation could theoretically be spread out into smaller portions over multiple shorter treatments. Additionally, since radiation is an

outpatient procedure, many patients may be able to maintain employment through treatment. Interestingly, there was no difference in concerns related to loss of income or time away from work in our study between the two income groups. This may be explained by the finding that patients with lower household incomes were older in age and less likely to be currently working. These patients may be relying more on fixed budgets, and less able to bear immediate out-of-pocket costs.

In our prospective study, most patients with low household incomes considered out-of-pocket expenses very important when considering different treatment options. This aligns with the findings of a qualitative study published in 2018 from Saskatchewan, Canada, which followed prostate cancer patients as they made treatment decisions to learn more about their experiences.[24] The study identified financial concerns as a subtheme under the broader themes of practical concerns and anxiety. The authors suggested that some patients avoided treatments due to feasibility rather than personal preference, and that for some patients, financial situation represented a major concern.[24]

While our study did not identify a statistically significant difference in health literacy levels between the income groups, we did identify that more than a third of the patients overall had health literacy levels that were less than a grade nine reading level and may thus struggle with provided information.[25] Importantly, patients generally want to be part of their treatment decisions.[26] Limited knowledge and poor health literacy may impair the ability of patients to take part in shared decision-making. Additionally, current available prostate cancer patient material does not include information on time required away from work for recouperation or possible areas where expenses may be incurred, which thus presents an opportunity for improvement. If patients had increased transparency regarding possible additional expenses (or lost income-generating abilities) associated with treatment, they may be able to plan for this and select the treatment they truly prefer.

Strengths and limitations

This study has several strengths. The centralized intake process at the Manitoba Prostate Centre ensures the capture of a broad cross-section of the patient population, including from both urban and rural settings. This study also had a very high participation rate, with 91.4% of patients initially approached choosing to participate. At the same time, our findings must be interpreted in the context of its limitations.

Our study was likely limited by power to show differences in actual treatment selection. The recruitment for our study was also done during the COVID-19 pandemic, which may introduce unique considerations. Economic stresses may be more pronounced during this time, particularly in the lower-income group, which may affect responses. Further, virtual visits were implemented by most institutions, which would help to reduce travel associated costs to clinic appointments but may come at the expense of reduced comprehension of health information over virtual platforms. Importantly, even through the pandemic, patients are still inherently required to travel for their actual cancer treatments (surgery with hospitalization vs. multiple outpatient visits for RT). This highlights that even in a virtual healthcare system, there will always remain out-of-pocket expenses for cancer care that would disproportionately affect lower-income status patients.

CONCLUSIONS

Our study found that patients with lower household incomes have different treatment values and decision-making considerations than those with higher economic capacity. These findings should be considered when framing discussion with patients, as well as when constructing decision aids and patient information material designed to facilitate patient-centered care.

COMPETING INTERESTS: Dr. Tangri is a medical affairs consultant for Bayer, AstraZeneca, BI-Lilly, Janssen, Otsuka, Pulsedata, Renibus, and Tricida; has received research grants (to his institution) from AstraZeneca, Bayer, BI-Lilly, Janssen, Otsuka, and Tricida; and owns stock or stock options in Clinpredict, Klinrisk, Quanta, and Tricida. Dr. Patel is a consultant for and has received honoraria from Boston Scientific. Dr. Nayak is a speaker for Astellas and is participating in clinical trials supported by TerSera and Zenflow. The remaining authors do not report any competing personal or financial interests related to this work.

This paper has been peer-reviewed.

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