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The impact of management option on out-of-pocket costs and perceived financial burden among men with localised prostate cancer in Australia within 6 months of diagnosis

Daniel Lindsay[A,B,*] (*PhD, Senior Research Officer*), Penelope Schofield[C,D,E] (*PhD, Professor*), Doreen Nabukalu[A] (*PhD student*), Matthew J. Roberts[E,G,H] (*MBBS, PhD, FRACS (Urol), Consultant Urologist*), John Yaxley[B,F,I] (*MBBS, FRACS (Urol), Urological Surgeon*), Stephen Quinn[J] (*PhD, Associate Professor*), Natalie Richards[D] (*BNurs, Research Nurse*), Mark Frydenberg[K,L] (*MBBS, FRACS, FAICD, Professor*), Robert Gardiner[B,F,G] (*MBBS, Emeritus Professor*), Nathan Lawrentschuk[M,N,O] (*MBBS, PhD, FRACS, Professor*), Ilona Juraskova[P] (*PhD, Professor*), Declan G. Murphy[E,Q] (*MBSS, FRACS (Urol), Professor*) and Louisa G. Gordon[A,B,R] (*PhD, Professor*)

For full list of author affiliations and declarations see end of paper

***Correspondence to:**
Daniel Lindsay
Health Economics, Population Health Department, QIMR Berghofer Medical Research Institute, 300 Herston Road, Herston, Brisbane, Qld 4006, Australia
Email:
Daniel.lindsay@qimrberghofer.edu.au

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ABSTRACT

Objective. This study aimed to quantify the out-of-pocket (OOP) costs and perceived financial burden among Australian men with localised prostate cancer in the first 6 months after diagnosis, by primary management option. **Methods.** This cost-analysis quantified OOP costs using administrative claims data and self-reported survey data. Financial burden was assessed using the COmprehensive Score for financial Toxicity–Functional Assessment of Chronic Illness Therapy (COST-FACIT) tool. Participants were recruited into a randomised control trial from public or private treatment centres in Victoria and Queensland. Generalised linear models were used to predict OOP costs and COST-FACIT scores. **Results.** Median total OOP costs within 6 months of diagnosis for 256 Australian patients with localised prostate cancer was A$1172 (A$343–2548). Up to 50% of the sample reported A$0 costs for most medical services. Compared with those managed with active surveillance, men having active treatment had 6.4 (95% CI: 3.2–12.7) times greater total OOP costs. Management option, higher Gleason score at diagnosis and having multiple comorbidities were significant predictors of higher OOP costs. Overall high scores on the COST-FACIT indicated low levels of financial burden for the entire sample. **Conclusion.** Largely attributable to being managed with active surveillance, Australian men diagnosed with localised prostate cancer reported relatively low OOP costs and financial burden in the first 6 months post-diagnosis. Together with clinical outcomes, clinicians can use this up to date evidence on costs and perceived financial burdens to assist localised prostate cancer patients and their families make informed decisions about their preferred management option.

Keywords: active surveillance, active treatment, clinical guidelines, financial burden, health economics, health services research, out-of-pocket costs, prostate cancer.

Introduction

Prostate cancer is the second most commonly diagnosed cancer in men worldwide.[1] A high proportion of cases are diagnosed with localised disease,[2] with a low likelihood of disease progression. Evidence-based clinical guidelines recommend active surveillance (AS), which includes ongoing monitoring through imaging, routine biopsies, prostate specific antigen (PSA) testing and annual digital rectal examination, for managing those with localised, low-risk prostate cancer and a life expectancy of ≥10 years. Active treatments such as radical prostatectomy or radiation therapy are appropriate for higher-risk disease.[3–5]

Understanding what out-of-pocket (OOP) costs are faced by patients may be the deciding factor for prostate cancer treatment choice where multiple options exist with similar outcomes. Long-term survival is similar between men managed by active treatment or AS,[6,7] but AS may initially incur lower OOP costs compared with active treatment.[8–10] Patients managed with active treatment may experience side-effects such as incontinence and sexual dysfunction.[11,12] Alternatively, being managed with AS may produce anxiety and distress due to a low but possible chance of cancer progression,[13,14] and greater future medical expenses (associated with subsequent treatments) compared to having active treatment.[15]

In an Australian study, approximately 20% of men with prostate cancer stated treatment costs caused a great deal of distress, with greater impacts reported by recently diagnosed men.[9] Gordon *et al.* did not use a validated measure of financial toxicity and used a self-reported measure of OOP costs only.[9] Other Australian research quantifying prostate cancer costs does not consider how they may differ by management option.[16–18] This study overcomes these limitations by using validated measures of financial toxicity and more comprehensive real-world data on initial OOP costs for localised prostate cancer by management option.

The *Navigate* randomised control trial (RCT) assessed the impact of an online treatment decision aid on uptake of AS for first-line management.[19] In this RCT, data on quality of life, financial toxicity, healthcare service use and OOP costs were collected from over 250 Australian men recently diagnosed with prostate cancer. Using data from the *Navigate* RCT, we quantified the OOP costs and perceived financial burden in the first 6 months after a localised prostate cancer diagnosis, by AS versus active treatment groups.

Methods

Study design

Eligible participants for the *Navigate* RCT included men diagnosed with prostate cancer in the last 3 months who had not made a treatment decision and were clinically eligible for AS. Recruitment occurred between May 2017 and May 2021 from treatment centres in Victoria (four public, one private) and Queensland (two public, one private).[19] Participants were identified by their treating clinician/nurse or study site investigator using clinic lists, could self-refer or be referred to the study team by their treating physician.[19] Location of healthcare delivery (i.e. public or private treatment centre) was not able to be identified for all participants. Ethical approvals for the *Navigate* RCT (ACTRN: 12616001665426) were received by the Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC/16/PMCC/114), the QIMR Berghofer Medical Research Institute Human Research Ethics Committee (P2293) and Services Australia (MI5900). Study reporting adhered to STROBE recommendations.[20]

Data collection

Socio-demographic and patient-reported outcomes data from the *Navigate* RCT were collected at baseline, 1-, 3- and 6-months follow-up.[19] Clinical information on PSA level and Gleason score were collected at baseline while management option (i.e. no treatment, AS, surgery, radiotherapy or brachytherapy) was self-reported by participants at 1-month follow-up. 'No treatment' may have been chosen because participants had not yet decided on their treatment option or did not want to receive treatment. First-line surgery, radiotherapy or brachytherapy were collectively classified as 'active treatment'.

We created the Rx-Risk Comorbidity Score to determine participant's comorbidities based on their prescribed Pharmaceutical Benefits Scheme (PBS) medicines.[21] Malignancy was coded as 0, as cancer was the primary disease for participants. The Rx-Risk score is a valid measure of comorbidity in outpatient cohorts.[21]

Cost measures

Health service claims data under the Medicare Benefits Scheme (MBS) and PBS were extracted from March 2017 to October 2021 and covered different durations for each participant due to rolling study recruitment. The MBS and PBS are part of Australia's universal healthcare system which subsidises medical services and pharmaceuticals for Australian citizens and permanent residents.[22] Each participant had at least 6 months of complete MBS and PBS data extracted, including item number and description, cost to the individual (i.e. the difference between the amount the provider charges and the rebate paid by the government) and item category.

Separately to the MBS and PBS data, we also captured self-reported OOP costs incurred in the last 3 months. These costs were assessed using 13 questions at 3- and 6-months follow up, and summed to quantify OOP costs over the first 6 months after diagnosis. Costs covered in the self-reported measure included co-payments for medical services and indirect costs such as accommodation and parking (Supplementary Table S1). To minimise double counting, participants were asked to estimate how much they spent on services related to prostate cancer care excluding those already covered by Medicare or other third parties.

The COmprehensive Score for financial Toxicity–Functional Assessment of Chronic Illness Therapy (COST-FACIT) was used for assessing financial toxicity at 6 months.[23] This measure contains 11 questions assessing the respondent's financial situation and stress experienced due to cancer during the past 7 days. Overall scores range between 0 and 44, with lower scores suggesting greater financial toxicity. The COST-FACIT

has been used to identify individuals who are at risk of or currently experiencing financial toxicity,[23] and is a reliable and validated tool for measuring financial toxicity in Australian cancer outpatients.[24]

Statistical analysis

Total OOP costs relating to MBS and PBS services ('direct costs') were calculated by summing the costs for services claimed. If a participant reported not using an MBS or PBS service, they were assigned a cost of $0. Direct OOP costs are for all healthcare services, not just those specific to prostate cancer, because differentiating between those clearly applicable to prostate cancer or other conditions was not possible. All direct costs were inflation-adjusted to 2023 using the health group component of the Consumer Price Index and are presented in Australian dollars (A$).[25] A total OOP cost was created by summing the self-reported and direct OOP costs.

Demographic and clinical information of the final sample at baseline were reported using descriptive statistics. Median and interquartile range (IQR) per person and total number of medical services claimed and direct OOP costs were quantified, as well as median (IQR) per person and total self-reported OOP costs. To account for right-skewed data, generalised linear models using the gamma family and log link function predicted direct, self-reported and total OOP costs using sociodemographic and clinical factors. Factors significantly influencing costs ($P < 0.05$) in univariate analyses were used in multivariate models. The main outcome for these cost analyses was the rate ratio, interpreted as a cost ratio, or the difference in OOP costs between those managed with AS or active treatment. Using the same process outlined above, generalised linear models using the Gaussian family and log link function predicted total COST-FACIT scores.

Missing data ($n = 7$ missing management option, $n = 13$ missing self-reported OOP costs) were identified as missing completely at random. Multiple imputation was performed with 50 sets using chained equations with predictive mean matching (Supplementary File S1).[26] All analyses were undertaken in Stata v17 (StataCorp, College Station, TX, USA).

Results

Of the 302 participants in the *Navigate* RCT, 46 did not consent to release their MBS and PBS data, leaving 256 participants for analysis. Differences between those who did and did not consent to provide their MBS and PBS data are shown in Supplementary Table S2. Participant's mean age was 66 years (s.d. = 7.5), three-quarters were born in Australia and 82% were married. Almost half of the sample had completed tertiary education, while just over a third were retired (Table 1). For the total sample,

Table 1. Demographic and clinical information for study participants ($n = 256$).

Variable	Level	*n* (%)
Age (mean (s.d.)), range (years)		66 (7.5), 46–82
Study group	*Navigate* intervention	134 (52)
	Usual care	122 (48)
Management option	Active surveillance	220 (86)
	Active treatment	16 (6)
	No treatment	20 (8)
Referral location	Public treatment centre	93 (36)
	Private treatment centre	78 (31)
	Unknown[A]	85 (33)
Referral type	Treatment centre	141 (55)
	Clinician referred	83 (32)
	Self-referral	32 (13)
Country of birth	Australia	188 (73)
	Other	68 (27)
Employment status	Employed	152 (60)
	Retired	97 (37)
	Unemployed	7 (3)
Highest education completed	Secondary/primary schooling	75 (29)
	Trade/TAFE college	55 (22)
	Tertiary education	126 (49)
Marital status	Married/de facto	211 (82)
	Other	45 (18)
Annual household income (A$)	Prefer not to say	51 (20)
	$0–37 000	44 (17)
	$37 001–80 000	55 (21)
	$80 001–180 000	61 (24)
	Over $180 000	45 (18)
PSA level (mean (s.d.)), range[B]		5.4 (3.1), 0.13–26
Gleason score[C]	3 + 3 = 6	192 (75)
	3 + 4 = 7 or 4 + 3 = 7	64 (25)
Number of comorbidities (mean (s.d.)), range		1.9 (1.5), 0–8

s.d., standard deviation; TAFE, technical and further education; PSA, prostate-specific antigen.

[A]Unknown indicates referral from clinicians working in both private and public treatment centres or participants who self-referred into the study.

[B]PSA levels ≥10 are indicative of intermediate risk prostate cancer.[3,4]

[C]Gleason scores of 6 are categorised as Grade Group 1 prostate cancer, which is typically low-risk prostate cancer. Gleason scores of 7 are categorised as Grade Group 2 prostate cancer and are more indicative of intermediate risk prostate cancer.[4]

the majority were managed with AS (86%), had a Gleason score of 3 + 3 = 6 (75%) and an average PSA at diagnosis of 5.4 μg/L (s.d. = 3.1) (Table 1). Of the 16 men managed with active treatment, 13 (81%) had a surgical procedure. Individuals with Gleason scores of 3 + 4 = 7 or 4 + 3 = 7 were more likely to have active treatment (56%) compared to those having no treatment (30%) or managed by AS (22%), $P = 0.01$ (not shown).

Overall, participants incurred total direct OOP costs of just over A$320 000 in the first 6 months after diagnosis, or median A$665 per person (Table 2). Five out of six men with total direct OOP costs ≥A$5000 had a radical prostatectomy. Half of all participants reported zero OOP costs for all health services except for specialist visits (Table 2). Those reporting costs for specialist visits were significantly more likely to be referred from private centres, were more educated and had higher Gleason scores at diagnosis (Supplementary Table S3). For those reporting total self-reported costs of ≥A$5000 ($n = 11$), median direct costs were A$3366 (IQR = A$2263–12 705) compared to A$982 (IQR = A$118–1405) for those with self-reported costs of <A$5000 ($n = 245$). Three-quarters of participants paid total OOP costs of up to A$2575 in the 6 months following a prostate cancer diagnosis, with the remainder spending greater than this amount.

For participants managed with active treatment compared to those managed with AS, direct OOP costs were

Table 2. Service use and OOP costs in the first 6 months post-diagnosis, by service type ($n = 256$).

Service type	Number of services used		OOP cost (A$)	
	Median (IQR) per person	Sum	Median (IQR) per person	Sum
MBS services				
GP visits	2 (1–4)	745	$0 ($0–46)	$9098
Specialist visits	1 (0–2)	384	$67 ($0–190)	$30 583
Other prof attendances	2 (0–4)	706	$0 ($0–26)	$13 550
Imaging	1 (0–2)	401	$0 ($0–67)	$20 328
Pathology	6 (2–10)	1875	$0 ($0–139)	$26 163
Therapeutic procedures	1 (0–4)	670	$0 ($0–810)	$185 534
Other MBS[A]	0 (0–0)	90	$0 ($0–0)	$1106
Total MBS	17 (10–25)	4985	$460 ($33–1341)	$289 172
Medicines				
Total PBS	4 (0–14)	2065	$61 ($0–164)	$31 517
Total MBS/PBS services	24 (13–39)	7050	$665 ($121–1569)	$320 688
Self-reported costs				
Medications (prescription and non-prescription)			$0 ($0–90)	$19 342
GP visits			$0 ($0–40)	$8338
Specialist visits			$74 ($0–300)	$71 584
Hospitalisations (for treatment and complications)			$0 ($0–0)	$132 967
Medical tests (e.g. PSA and ultrasounds)			$0 ($0–0)	$34 794
Transport costs (e.g. fuel, bus, taxi, parking)			$0 ($0–60)	$13 829
Accommodation costs			$0 ($0–0)	$3950
Other costs[B]			$0 ($0–0)	$11 810
Total self-reported OOP			$200 ($26–1100)	$342 773
Total costs			$1172 ($343–2 548)	$660 820

OOP, out-of-pocket; MBS, Medicare Benefits Schedule; IQR, interquartile range; GP, general practitioner; PBS, Pharmaceutical Benefits Scheme; PSA, prostate-specific antigen.

[A]Other MBS services included miscellaneous diagnostic procedures, services provided by a practice nurse/register/nurse practitioner, COVID-19 allied health telehealth services, allied health services, psychological therapy services and focused psychological strategies.

[B]Other self-reported costs included costs for medical equipment and supplies, ambulance services, home and self-care assistance, home modifications (e.g. plumbing, ramps), special food and other costs.

5.1 (95% CI: 2.7–9.5) times greater, self-reported OOP costs were 8.8 (95% CI: 4.0–19.6) times greater and total OOP costs 6.9 (95% CI: 3.8–12.5) times greater in the first 6 months after diagnosis ($P < 0.05$ for all, Table 3). In multivariate models, total OOP costs were 6.4 (95% CI: 3.2–12.7) times greater for individuals undergoing active treatment compared to those managed with AS ($P < 0.001$, Table 4). Higher Gleason score at diagnosis and a higher number of comorbidities consistently predicted greater OOP costs. Management option remained the strongest predictor of costs even when adjusting for these factors.

Participants who completed the COST-FACIT ($n = 231$) had an average score of 32.9 (s.d. = 8.4) and a median score of 34 (IQR = 27–40). Only nine (4%) participants had COST-FACIT scores of ≤15 (i.e. high financial toxicity). Higher COST-FACIT scores (lower financial burdens) were significantly related to greater direct costs ($P = 0.022$), while lower COST-FACIT scores were significantly related to lower self-reported OOP costs ($P < 0.001$). In unadjusted models, men who were younger, had lower levels of completed education, lower household income and higher self-reported costs had significantly greater perceived financial difficulty. Management option had no significant effect on perceived financial burden (Table 5). All statistically significant predictors in unadjusted models (except for education level) were significant predictors in the adjusted model (Table 5).

Discussion

Australian men with newly diagnosed localised prostate cancer reported median OOP costs of $1172 over 6 months post-diagnosis and mostly reported low levels of financial difficulty. After adjusting for clinical and sociodemographic factors, self-reported, direct and total OOP costs were approximately 6–7 fold greater 6 months after diagnosis for individuals who were managed with active treatment compared to AS. Despite the significant differences in OOP costs, management option had no significant impact on perceived financial difficulties.

Our study confirms previous findings from the United States,[8] adding to the evidence-base for significantly lower initial OOP costs for those managed with AS compared to active treatment. With evidence indicating similar survival between those managed by AS and active treatment,[6,7] and men having greater side-effects after active treatment,[11,12] the initial lower costs for those managed by AS provide further support for its use as the primary management option for localised prostate cancer.[3–5]

By assessing financial difficulties using a validated measure (COST-FACIT), we fill a significant gap regarding the financial burdens initially experienced by Australian men with localised prostate cancer.[27] Respondents reported low levels of financial difficulties, suggesting a diagnosis of localised prostate cancer has minimal impacts on short-term financial wellbeing. This may be because of the low OOP costs reported in this study. A relatively high proportion of the sample were employed, well educated, married and reported a high household income, suggesting respondents may have had the economic means to deal with the OOP costs for managing their cancer.

Management option had no significant influence on perceived financial burden. Potentially, men experiencing greater financial difficulty chose AS knowing they would incur lower OOP costs than if they had active treatment. Future research on larger samples are required to confirm this. Costs for participants with higher Gleason scores, indicating intermediate-risk prostate cancer, and/or comorbidities at diagnosis were significantly higher than those with low-risk cancer and/or no comorbidities, yet these factors were not predictive of greater financial difficulties. This suggests that the presence of high OOP costs may not always align with poorer financial wellbeing.

The relationship between OOP costs and financial wellbeing found here may be due to the structure of the Australian healthcare system, which allows private clinicians to set their own fee for service while those treated in the public system are likely bulk-billed.[22] Individuals who are financially well off may be more likely to be managed in private practice, while those unable to afford such care are treated in the public system, potentially having minimal impact on financial wellbeing.

Together with the short- and long-term health consequences associated with each management option, presenting up to date information around OOP costs and perceived financial burdens in decision making tools such as *Navigate* allows patients and their families to make informed, evidence-based decisions around management options, potentially reducing treatment regret. Clinicians can use our findings to discuss financial aspects of management options for localised prostate cancer, with research indicating that financial aspects of treatment are important to cancer patients but not commonly discussed.[28,29] Management options such as AS that can reduce costs for individuals remain a priority and may increase patient willingness to choose this option. An increased uptake of AS may lead to reductions in potentially unnecessary radical treatments with significant side effects and greater cost savings for the Australian healthcare system.

Our study is limited by the small numbers of individuals having active treatment, particularly radiation therapy (<10%). The high number of individuals managed with AS in this study reflects management trends for localised prostate cancer in Australia.[30] Private health insurance status and whether health care was received at public or private treatment centres, both of which are factors known to influence OOP costs and financial difficulties in Australians with cancer,[9,17,31,32] were not fully captured in this study so were not included in analyses. The short follow up period of this study reduces the likelihood of capturing disease progression, which may cause additional expenses for those initially managed with AS. Future studies should

Table 3. Unadjusted generalised linear models predicting OOP costs in the first 6 months post diagnosis ($n = 256$).

Factor	Level	Estimated marginal means, in A$ (s.e.)	Direct OOP Cost ratio (s.e.)	95% CI	Estimated marginal means, in A$ (s.e.)	Self-reported OOP Cost ratio (s.e.)	95% CI	Estimated marginal means, in A$ (s.e.)	Total OOP Cost ratio (s.e.)	95% CI
Age in years			1.03 (0.01)	0.99–1.1		1.01 (0.1)	0.96–1.1		1.02 (0.1)	1.0–1.1
Management option	AS	$1002 (87)	REF		$912 (197)	REF		$1915 (226)	REF	
	No treatment	$876 (156)	0.9 (0.2)	0.6–1.3	$522 (161)	0.6 (0.2)	0.3–1.2	$1398 (223)	0.7 (0.1)	0.5–1.1
	Active treatment	$5162 (1597)	5.1 (1.6)	2.7–9.5**	$8062 (2772)	8.8 (3.6)	4.0–19.6**	$13 224 (3664)	6.9 (2.1)	3.8–12.5**
Study group	*Navigate* intervention	$1435 (260)	REF		$1272 (289)	REF		$2707 (515)	REF	
	Usual care	$1087 (125)	0.8 (0.2)	0.5–1.2	$1380 (434)	1.1 (0.4)	0.5–2.3	$2467 (467)	0.9 (0.2)	0.5–1.5
Country of birth	Australia	$1335 (174)	REF		$1438 (341)	REF		$2774 (432)	REF	
	Other	$1024 (218)	0.8 (0.2)	0.5–1.3	$1064 (336)	0.7 (0.3)	0.3–1.6	$2089 (516)	0.8 (0.2)	0.4–1.3
Employment	Employed	$1227 (171)	REF		$1560 (416)	REF		$2787 (493)	REF	
	Unemployed/retired	$1291 (239)	1.1 (0.2)	0.7–1.7	$1015 (238)	0.7 (0.2)	0.3–1.3	$2306 (455)	0.8 (0.2)	0.5–1.4
Education	Secondary/primary	$1282 (358)	REF		$1233 (403)	REF		$2515 (711)	REF	
	Trade/TAFE	$921 (113)	0.7 (0.2)	0.4–1.3	$784 (157)	0.6 (0.2)	0.3–1.4	$1705 (212)	0.7 (0.2)	0.4–1.2
	Tertiary	$1380 (183)	1.1 (0.3)	0.6–2.0	$1644 (477)	1.3 (0.6)	0.6–3.1	$3024 (551)	1.2 (0.4)	0.6–2.3
Marital status	Married/de facto	$1330 (166)	REF		$1446 (320)	REF		$2776 (415)	REF	
	Other	$890 (167)	0.7 (0.2)	0.4–1.04	$837 (186)	0.6 (0.2)	0.3–1.1	$1727 (282)	0.6 (0.1)	0.4–0.96*
Household income	$0–37 000	$759 (129)	REF		$1438 (870)	REF		$2197 (905)	REF	
	$37 001–80 000	$988 (250)	1.3 (0.4)	0.7–2.4	$729 (179)	0.5 (0.3)	0.1–1.8	$1716 (401)	0.8 (0.4)	0.3–2.0
	$80 001–180 000	$1301 (374)	1.7 (0.6)	0.9–3.3	$1687 (487)	1.2 (0.8)	0.3–4.4	$2988 (810)	1.4 (0.7)	0.5–3.6
	Over $180 000	$1753 (336)	2.3 (0.6)	1.4–3.8**	$1974 (994)	1.4 (1.1)	0.3–6.4	$3727 (1140)	1.7 (0.9)	0.6–4.6
Gleason score	3 + 3 = 6	$1084 (160)	REF		$821 (151)	REF		$1905 (284)	REF	
	3 + 4 = 7 or 4 + 3 = 7	$1758 (286)	1.6 (0.4)	1.1–2.5*	$2892 (935)	3.5 (1.3)	1.7–7.3**	$4650 (1052)	2.4 (0.7)	1.4–4.1**
PSA level			0.93 (0.1)	0.9–0.98*		0.93 (0.1)	0.9–0.99*		0.93 (0.2)	0.9–0.98**
Number of comorbidities			2.6 (0.8)	1.5–4.6**		3.6 (0.2)	1.5–8.4**		1.4 (0.1)	1.2–1.7**
COST-FACIT			1.02 (0.1)	1.01–1.04*		0.94 (0.1)	0.9–0.98**		0.98 (0.1)	0.95–1.01

s.e., standard error; CI, confidence interval; OOP, out-of-pocket; REF, reference category; AS, active surveillance; TAFE, technical and further education; PSA, prostate specific antigen; COST-FACIT, COmprehensive Score for financial Toxicity–Functional Assessment of Chronic Illness Therapy.

*P sig at <0.05.

**P sig at <0.01.

Table 4. Adjusted generalised linear models predicting OOP costs in first 6 months post diagnosis ($n = 256$).

Factor	Level	Estimated marginal means, in A$ (s.e.)	Direct OOP		Estimated marginal means (s.e.), in A$	Self-reported OOP		Estimated marginal means, in A$ (s.e.)	Total OOP	
			Cost ratio (s.e.)	95% CI		Cost ratio (s.e.)	95% CI		Cost ratio (s.e.)	95% CI
Management option	AS	$1120 (93)	REF		$1021 (234)	REF		$2207 (309)	REF	
	No treatment	$943 (212)	0.8 (0.2)	0.5–1.3	$707 (271)	0.7 (0.3)	0.3–1.5	$1546 (341)	0.7 (0.2)	0.4–1.2
	Active treatment	$6479 (2125)	5.8 (2.0)	3.0–11.3**	$7617 (2604)	7.5 (3.2)	3.2–17.5**	$14 141 (4253)	6.4 (2.2)	3.2–12.7**
Marital status	Married/de facto	$1534 (176)	REF		$1682 (368)	REF		$3273 (486)	REF	
	Other	$1320 (306)	0.9 (0.2)	0.6–1.3	$1047 (342)	0.6 (0.2)	0.3–1.3	$2445 (560)	0.7 (0.2)	0.5–1.2
Gleason score	3 + 3 = 6	$1299 (165)	REF		$1059 (215)	REF		$2363 (336)	REF	
	3 + 4 = 7 or 4 + 3 = 7	$2008 (293)	1.5 (0.3)	1.1–2.1**	$2704 (897)	2.6 (1.0)	1.2–5.5*	$4965 (1195)	2.1 (0.6)	1.2–3.7*
PSA			0.95 (0.3)	0.91–1.0		0.94 (0.1)	0.9–1.0		0.95 (0.1)	0.91–0.99*
Number of comorbidities			1.9 (0.5)	1.1–3.2*		1.8 (0.7)	0.8–4.0		2.0 (0.6)	1.1–3.6*
COST-FACIT			1.03 (0.1)	1.01–1.04**		0.96 (0.1)	0.92–0.99*		0.99 (0.1)	0.97–1.02

s.e., standard error; CI, confidence interval; OOP, out-of-pocket; AS, active surveillance; REF, reference category; PSA, prostate specific antigen; COST-FACIT, COmprehensive Score for financial Toxicity–Functional Assessment of Chronic Illness Therapy.

*P sig at <0.05.

**P sig at <0.01.

Table 5. Generalised linear models predicting total COST-FACIT scores for men with localised prostate cancer ($n = 231$).

Factor	Level	Estimated marginal means (s.e.)	Unadjusted values		Estimated marginal means (s.e.)	Adjusted values	
			Ratio (s.e.)	95% CI		Ratio (s.e.)	95% CI
Age in years			1.01 (0.01)	1.001–1.01*		1.01	1.0–1.01**
Management option	Active surveillance	32.9 (0.6)	1.02 (0.1)	0.9–1.1			
	No treatment	33.8 (2.0)	1.05 (0.1)	0.9–1.2			
	Active treatment	32.2 (1.7)	REF				
Study group	*Navigate* intervention	33.6 (0.8)	REF				
	Usual care	32.2 (0.8)	0.96 (0.1)	0.9–1.02			
Country of birth	Australia	32.6 (0.7)	0.96 (0.1)	0.9–1.02			
	Other	33.9 (0.8)	REF				
Employment	Employed	32.3 (0.7)	0.96 (0.1)	0.9–1.02			
	Unemployed/retired	33.8 (0.8)	REF				
Education	Secondary/primary	31.1 (1.1)	0.9 (0.1)	0.8–0.96**	32.0 (1.1)	0.94 (0.1)	0.9–1.02
	Trade/TAFE	30.4 (1.1)	0.9 (0.1)	0.8–0.95**	31.7 (1.2)	0.9 (0.1)	0.9–1.01
	Tertiary	35.0 (0.7)	REF		34.1 (0.8)	REF	
Marital status	Married/de facto	33.0 (0.6)	REF				
	Other	32.2 (1.4)	0.97 (0.1)	0.9–1.1			
Household income	$0–37 000	31.0 (1.5)	0.83 (0.1)	0.8–0.94**	29.7 (1.5)	0.8 (0.1)	0.7–0.91**
	$37 001–80 000	32.5 (1.0)	0.88 (0.1)	0.8–0.95**	31.5 (0.9)	0.8 (0.1)	0.8–0.92**
	$80 001–180 000	32.6 (1.0)	0.88 (0.1)	0.8–0.96**	33.9 (1.1)	0.91 (0.1)	0.8–0.99*
	Over $180 000	37.0 (1.0)	REF		37.3 (1.2)	REF	
Gleason score	3 + 3 = 6	32.7 (0.6)	0.99 (0.1)	0.9–1.1			
	3 + 4 = 7 or 4 + 3 = 7	33.4 (1.1)	REF				
PSA level			1.01 (0.01)	0.99–1.02			
No. comorb			0.99 (0.01)	0.9–1.1			
Direct costs			1.0 (0.01)	0.99–1.0			
Self-reported costs			0.99 (0.01)	0.99–0.99**		0.99 (0.01)	0.99–0.99**

Note: s.e., standard error; CI, confidence interval; OOP, out-of-pocket; REF, reference category; PSA, prostate specific antigen; COST-FACIT, COmprehensive Score for financial Toxicity-Functional Assessment of Chronic Illness Therapy.
*P sig at < 0.05.
**P sig at < 0.01.

examine costs over a longer time period. Strengths of this study include quantifying direct medical costs with administrative data and indirect costs through self-report, providing a comprehensive measure of real world OOP costs, as well as using a validated tool for assessing financial toxicity. As we included men with localised prostate cancer from multiple Australian states, the results are reasonably generalisable to the Australian context.

Conclusion

Australian men diagnosed with localised prostate cancer and managed by AS have relatively low levels of OOP costs in the initial 6 months following diagnosis, contributing to overall low levels of financial difficulty. The Australian guideline recommendations of AS for localised prostate cancer provides an opportunity to reduce the immediate costs of cancer.

Supplementary material

Supplementary material is available online.

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Author affiliations

[A]Health Economics, Population Health Department, QIMR Berghofer Medical Research Institute, 300 Herston Road, Herston, Brisbane, Qld 4006, Australia.

[B]Faculty of Medicine, The University of Queensland, Qld, Australia.

[C]Department of Psychology, Swinburne University of Technology, Melbourne, Vic., Australia.

[D]Behavioural Science Unit, Peter MacCallum Cancer Centre, Melbourne, Vic., Australia.

[E]Peter MacCallum Department of Oncology, The University of Melbourne, Melbourne, Vic., Australia.

[F]Department of Urology, Royal Brisbane and Women's Hospital, Qld, Australia.

[G]Centre for Clinical Research, The University of Queensland, Qld, Australia.

[H]Department of Urology, Redcliffe Hospital, Qld, Australia.

[I]Wesley Urology Clinic, Wesley Hospital, Qld, Australia.

[J]Department of Health Science and Biostatistics, Swinburne University of Technology, Melbourne, Vic., Australia.

[K]Department of Urology, Cabrini Institute, Cabrini Health, Vic., Australia.

[L]Department of Surgery, Monash University, Melbourne, Vic., Australia.

[M]EJ Whitten Foundation Prostate Cancer Research Centre, Epworth HealthCare, Melbourne, Vic., Australia.

[N]Department of Surgery, University of Melbourne, Melbourne, Vic., Australia.

[O]Department of Surgery, Royal Melbourne Hospital, Melbourne, Vic., Australia.

[P]Centre for Medical Psychology and Evidence-based Decision-making (CeMPED), School of Psychology, University of Sydney, Sydney, NSW, Australia.

[Q]Division of Cancer Surgery, Peter MacCallum Cancer Centre, Melbourne, Vic., Australia.

[R]School of Nursing and Cancer and Palliative Care Outcomes Centre, Queensland University of Technology, Qld, Australia.