MEN'S EXPERIENCES ON ACTIVE SURVEILLANCE: FROM DIAGNOSIS TO DISCONTINUATION

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THESIS DECLARATION

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Megan McIntosh

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THESIS ABSTRACT

Over 1.4 million men were diagnosed with prostate cancer worldwide in 2020. Due to increased early testing and detection, higher numbers are being diagnosed with low risk, localised prostate cancer. Active surveillance is the recommended treatment option for patients with low risk, localised prostate cancer, as it provides patients the opportunity to delay definitive treatments until clinically necessary whilst actively monitoring progression. However, there is no global consensus on eligibility criteria, best practice for management, or triggers for discontinuation, and therefore uptake, practice, and patient experiences may vary greatly across clinics and countries. In order to (a) understand patient experiences during active surveillance, (b) inform changes to active surveillance management that align with the needs of patients, and (c) identify critical research areas, consideration of the individual, social and ecological factors that influence patient experiences is required. To reach this aim, this thesis includes four studies using a range of methodologies to investigate patient experiences from diagnosis to active surveillance discontinuation. A fifth study focusing on enhancing methodology in this research domain is also included. Study One used qualitative methods to explore patient and partner experiences after low risk localised prostate cancer diagnosis as they navigated the treatment decision between active surveillance and definitive treatment. Study Two systematically reviewed the literature on patients' unmet supportive care needs during active surveillance. Data for studies Three and Four were collected together using a mix of methodologies (quantitative survey and qualitative interviews). Given the outcomes of the systematic review (Study Two), in Study Three we investigated the unmet supportive care needs and psychological wellbeing of patients during active surveillance. In Study Four, we explored the personal and/or medical reasons patients discontinue active surveillance and move to definitive treatment. Finally, Study Five was a randomised trial embedded within Studies Three and Four to examine the influence of different unconditional monetary incentives on survey response rates. This body of research demonstrated that whilst patients on active surveillance generally report positive experiences and outcomes, a significant proportion report unmet supportive care needs across informational, sexual, physical, psychological, and patient

care domains. Patients on active surveillance frequently report experiencing fear of cancer progression, appear to be greatly influenced by a variety of factors when navigating treatment decision (both at diagnosis and prior to discontinuation), and report uncertainty about active surveillance and their future. In addition, we observed that prostate cancer patients are no more likely to respond to long surveys when provided a larger unconditional monetary incentive ($20AUD) than a smaller unconditional monetary incentive ($10AUD). Further research to inform the development of supportive care interventions which directly address patient needs, align with their preferences, and consider their perspectives, is essential for improving active surveillance uptake, adherence, and overall experience for both patients and their partners/close allies. Doing so will require a strong engagement in research, which may be improved by using a variety of engagement strategies such as unconditional incentives, though further research is required.

LIST OF PUBLICATIONS CONTAINED IN THIS THESIS

Published Journal Articles

1. **McIntosh M**, Opozda MJ, Evans H, Finlay A, Galvão DA, Chambers SK, Short, CE. A systematic review of the unmet supportive care needs of men on active surveillance for prostate cancer. Psycho-oncology. 2019;28(12):2307–22. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/pon.5262

2. **McIntosh M**, Opozda MJ, Short CE, Galvão DA, Tutino R, Diefenbach M, Ehdaie B, Nelson C. Social ecological influences on treatment decision-making in men diagnosed with low risk, localised prostate cancer. European Journal of Cancer Care. 2022 (in press)

3. **McIntosh M,** Opozda MJ, O'Callaghan M, Vincent AD, Galvão DA, Short CE. Why do men leave active surveillance? A mixed methods study on reasons men with prostate cancer stop active surveillance. Psycho-Oncology. 2022;1-11. Available from: https://doi.org/10/1002/pon.5947

Articles Submitted For Publication / Under review

1. **McIntosh M,** Short CE, O'Callaghan M, Vincent AD, Galvão DA, Opozda MJ. A mixed methods investigation of unmet needs and psychological wellbeing during active surveillance for prostate cancer. Supportive Care in Cancer. 2021

2. **McIntosh M,** Opozda MJ, O'Callaghan M, Vincent AD, Galvão DA, Short CE. Impact of different unconditional monetary incentives on PROMS survey response rates in men with prostate cancer: a 2-arm randomised trial. BMC Research Methods. 2022

Conference Presentations

1. **McIntosh, M**, Opozda, MJ, Evans, H, Finlay, A, Galvão DA, Chambers, SK, Short, CE. A systematic review of the unmet supportive care needs of men on active surveillance for prostate cancer (poster presentation, M. McIntosh). Cancer Survivorship Conference 2019, Sydney, Australia, 28-29 March.

2. **McIntosh, M**, Opozda MJ, O'Callaghan M, Vincent A, Galvão DA, Short, CE. Why do men leave active surveillance? Protocol for a mixed methods investigation to identify predictors of non-adherence to active surveillance for prostate cancer patients (poster presentation, M. McIntosh). Psycho-Oncology Co-operative Research Group Scientific Meeting 2019, Adelaide, Australia, 10 November.

3. **McIntosh, M**, Opozda, MJ, Evans, H, Finlay, A, Galvão DA, Chambers, SK, Short, CE. A systematic review of the unmet supportive care needs of men on active surveillance for prostate cancer (poster presentation, M. McIntosh). Clinical Oncology Society of Australia Annual Scientific Meeting 2019, Adelaide, Australia, 12-14 November.

4. **McIntosh, M,** Opozda, MJ, Evans, H, Finlay, A, Galvão DA, Chambers, SK, Short, CE. A systematic review of the unmet supportive care needs of men on active surveillance for prostate cancer (poster presentation, M. McIntosh). Florey Postgraduate Research Conference 2021, Adelaide, Australia, 22 September.

AS	Active surveillance
AUA	American Urological Association
BPH	Benign prostatic hyperplasia
CALD	Culturally and linguistically diverse
CaPSURE	Cancer of the Prostate Strategic Urologic Research Endeavour
DRE	Digital rectal examination
DVA	Department of Veterans' Affairs
EBRT	External beam radiation therapy
GAP3	Movember Global Action Plan Prostate Cancer Active Surveillance initiative
ISUP	International Society of Urological Pathology
JBI	Joanna Briggs Institute
LUTS	Lower urinary tract symptoms
Mp-MRI	Multiparametric magnetic resonance image
MSK	Memorial Sloan Kettering Cancer Centre
MUSIC	Michigan Urological Surgery Improvement Collaborative
NCCN	National Comprehensive Cancer Network
OR	Odds ratio
PCa	Prostate cancer
PCOR-ANZ	The Prostate Cancer Outcome Registry – Australia and New Zealand
PCOR-Vic	The Prostate Cancer Outcome Registry – Victoria
PRIAS	Prostate Cancer Research International Active Surveillance
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSA	Prostate Specific Antigen
SA-PCCOC	South Australian Prostate Cancer Clinical Outcomes Collaborative
SEM	Social Ecological Model
USCNs	Unmet supportive care needs
VAS	Visual analogue scale
WW	Watchful waiting

THESIS STRUCTURE

This thesis is presented in the format of thesis by publication. Chapter One provides background information related to the research, followed by Chapter Two which presents the overall research aims, and research aims specific to each publication. Chapters Three to Seven present the five research papers, presented as published works (Chapters Three, Four, Six) or in manuscript format (Chapter Five and Seven). These chapters are formatted according to the journals in which they have been submitted to or published in, and therefore formatting and reference styles may differ. Finally, Chapter Eight summarises the overall findings and provides clinical implications and future research directions. Tables and figures are numbered consecutively within each chapter, and appendices relevant to each chapter are located at the end of the thesis.

1.   CHAPTER ONE:

INTRODUCTION

1.1   Prostate cancer

1.1.1   *Epidemiology*

In 2020, just over 1.4 million men[*] were diagnosed with prostate cancer[1]. It is the second most diagnosed cancer in men worldwide (after lung cancer), accounting for 14.1% of all new cancer cases in males[1]. Prostate cancer is also the most commonly diagnosed cancer in males in 112 countries, including Australia and the United States[1]. Yet, considerable advances in detection and treatment methods have resulted in improved survival rates worldwide, with Australia and the United States reporting 5-year survival rates of 95.5%[2] and 98%[3] respectively.

The use of widespread prostate specific antigen (PSA) screening to detect prostate cancer in higher-income countries is likely the reason incidence rates in these countries are considerably higher[4]. Recognised risk factors for prostate cancer include advanced age, family history, and certain conditions or genetic mutations[1]. Other probable risk factors which may increase the risk of prostate cancer include smoking, obesity, poorer access to healthcare, and other behavioural differences (e.g., poorer nutrition, physical inactivity, etc)[1].

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[*] Individuals who do not identify as men or males may also be diagnosed with prostate cancer. The term 'men' is used in this thesis to refer to individuals with the physical capability of being diagnosed with prostate cancer rather than a gender identity.

1.1.2   Symptoms and diagnosis

Prostate cancer may not cause any noticeable symptoms, especially in its early stages. Advanced stages of prostate cancer may cause symptoms including[5]:

- Incontinence (i.e., trouble urinating or urinating often, especially at night)
- Blood in the urine or semen
- Erectile dysfunction
- Pain or discomfort in the pelvis/surrounding areas.

However, these symptoms may also be evidence of other health issues, such as benign prostatic hyperplasia (BPH), lower urinary tract symptoms (LUTS), or prostatitis[5].

There is no one, single test for prostate cancer. Rather, the cancer is usually diagnosed through a series of tests and examinations. A rise in PSA level is often the first sign; however, it is also associated with non-cancerous conditions including BPH and LUTS. PSA is a protein created by cells in the prostate gland and is found both in semen and blood[6]. A PSA test measures the units (nanograms per millilitre, ng/mL) of PSA in the blood, with a higher reading indicating a higher chance of prostate cancer. The American Cancer Society states that generally, a PSA level <4 ng/mL indicates a very low chance of prostate cancer; a PSA between 4-10 ng/mL indicates a 1 in 4 chance of prostate cancer; and >10 ng/mL indicates a ≥50% chance[6]. In addition to PSA testing, a digital rectal examination (DRE) to feel for abnormalities around the prostate may also be performed.

Abnormal PSA and DRE results generally suggest a confirmatory prostate biopsy needs to be performed to determine whether cancer is present[7]. Additionally, a multiparametric magnetic resonance image (mp-MRI) may be performed to assist in determining whether a biopsy is required to confirm the presence of cancer[7]. Prostate biopsies are typically performed transrectally or through the perineum[7]. Although necessary to determine the presence of cancer, both procedures are invasive and have been associated with adverse effects, including infection, rectal bleeding, erectile dysfunction, and incontinence[8].

1.1.3   Staging, grading, and risk

Upon confirmation of prostate cancer through a biopsy, the cancer is assigned a clinical stage and grade. Clinical stage is determined by the tumour size, whether the cancer is localised to the organ or spread to lymph nodes, and metastases[9]. Stage groups 1-2 are generally considered to be localised prostate cancer, and stages 3-4 reflect advanced stages of prostate cancer[10].

Grade refers to the likelihood of the cancer advancing or spreading. Typically, the grade is determined by a Gleason score. This is the sum of two numbers attributed to a type of pattern of the cancer cells taken from the biopsy. The first number reflects the cancer cells in the largest area of the tumour, and the second number reflects cancer cells in the second largest area. Originally, Gleason scores were grouped into the following grades: Low (Gleason scores 2-6), Intermediate (Gleason score 7), and High (Gleason scores 8-10). However, this grading system was revised in 2014 by the International Society of Urological Pathology (ISUP), to help improve patient communication and understanding[11]. The ISUP system now categorises Gleason scores in five possible grades (see Table 1).

Table 1: ISUP Prostate Cancer Grading System

Grade Group	Gleason Score/s
Grade Group 1	Gleason score ≤ 6
Grade Group 2	Gleason score $3 + 4 = 7$
Grade Group 3	Gleason score $4 + 3 = 7$
Grade Group 4	Gleason score $4 + 4 = 8$; $3 + 5 = 8$; $5 + 3 = 8$
Grade Group 5	Gleason score $9 - 10$

The most common overall prostate cancer risk stratification is the National Comprehensive Cancer Network (NCCN) which determines risk using PSA, clinical stage, and Gleason score/ISUP grade[12]. Levels are categorised into very low risk, low risk, intermediate risk (favourable and unfavourable), high risk, and very high risk[12] (see Table 2).

Table 2: NCCN Prostate Cancer Risk Classification

Risk Group	Clinical Features	
Very low risk	Has all of the following: • Clinical stage T1c • Grade group 1 • PSA < 10 ng/mL • Fewer than three biopsy cores with cancer (≤ 50% cancer in each core) • PSA density[±] < 0.15 ng/mL/g.	
Low risk	Has all of the following (but does not qualify for very low risk): • Clinical stage T1 – T2a • Grade group 1 • PSA < 10 ng/mL	
Intermediate risk	Has all of the following: • No high-risk or very high-risk group features • Has one or more of: • Clinical stage T2b-T2c • Grade group 2 or 3 PSA between 10-20 ng/mL	Favourable intermediate risk: • 1 intermediate-risk factor • Grade group 1 or 2 • < 50% positive biopsy cores Unfavourable intermediate risk: • 2 or 3 intermediate-risk factors • Grade group 3 • ≥ 50% positive biopsy cores
High risk	Has no very high-risk features and has 1 of the following: • T3a, or • Grade group 4 or 5, or • PSA > 20ng/mL	
Very High risk	Has at least one of the following: • Clinical stage T3b-T4 • Primary Gleason pattern 5 • Grade group 4 or 5 with > 4 biopsy cores with cancer	

[±] PSA density measures the amount of PSA compared to the size (in grams) of the prostate.

Whilst the incidence of prostate cancer has been rising due to increased accessibility and use of early detection tests such as the PSA test, the majority of men are diagnosed with low to intermediate risk, localised prostate cancer, with low risk of metastases and prostate-specific mortality[12]. According to state-based Australian data, approximately 24% of localised tumours identified are considered low risk[13], a proportion which is expected to increase over time considerably[13]. Given this, this thesis will largely focus on the experiences of men diagnosed with very low and low risk, localised prostate cancer.

1.1.4   Treatment options

Prostate cancer treatment options are dependent on the stage and grade of the disease, as well as age at diagnosis and other health comorbidities. Many available treatments commonly cause unpleasant

short- and/or long-term side effects. Common treatment options for all stages of prostate cancer are briefly outlined below, followed by a deeper discussion on active surveillance, the recommended treatment for patients diagnosed with localised, low risk prostate cancer.

1.1.4.1 Expectant Management Options

Active Surveillance

Active surveillance is a management strategy which involves closely monitoring the cancer through regular PSA tests, biopsies, mp-MRIs and DREs to identify disease progression. Active surveillance is considered the best available treatment option for men diagnosed with very low risk and low risk prostate cancer and may be considered for men with favourable intermediate risk prostate cancer[14]. Associated side effects include risk of infection from repeat biopsies[8], as well as psychosocial impacts (e.g., anxiety)[15].

Watchful Waiting

Although similar in concept to active surveillance, watchful waiting is a management strategy intended for men with limited life expectancy (< 5-10 years), as the aim is to monitor and manage the disease and symptoms, rather than monitor with curative intent[16]. Repeat biopsies are rarely performed. Similar to active surveillance, minimal side effects are associated with watchful waiting as no physical intervention is conducted. Some patients may experience psychosocial impacts, such as anxiety[17].

1.1.4.2 Definitive Treatments

Prostatectomy

Prostatectomy involves the complete removal of the prostate gland and is a recommended treatment for patients with localised disease (i.e., Stage 1-2), who are low or intermediate risk. Prostatectomies are the most common approach to treating localised prostate cancer[18]. There are two main types of

prostatectomy; radical retropubic prostatectomy and laparoscopic robot-assisted prostatectomy[18]. Whilst the latter approach is a less invasive option, there is considerable ongoing debate as to whether their outcomes differ[18]. In a large randomised controlled trial involving over 300 patients, no differences in urinary function or sexual function were found at 12 weeks post-operation in patients who received either the radical retropubic prostatectomy or a laparoscopic robot-assisted prostatectomy[18]. However, patients who received a laparoscopic robot-assisted prostatectomy did experience less blood loss during surgery, less post-operative pain when doing normal activities, and less distress at 12-weeks, compared to patients who had a radical retropubic prostatectomy[18]. The most common side effects of prostatectomy (regardless of type) include urinary incontinence and erectile dysfunction[18,19].

Radiotherapy

Radiotherapy, or radiation treatment, is appropriate for patients across all stages of prostate cancer (very low risk to very high risk), though it is typically used in conjunction with other treatments (such as radical prostatectomy and hormone therapy) in later stages[19]. There are two main types of radiation used in prostate cancer treatment, external beam radiation therapy (EBRT) and brachytherapy[19]. In EBRT, radiation beams are focused on the prostate or tumour from outside the body. Brachytherapy involves the temporary or permanent insertion of radioactive pellets or seeds directly into the prostate. Radiation treatment has been associated with fewer long-term side effects (e.g., urinary incontinence and erectile dysfunction) than radical prostatectomy. However, side effects including bowel issues (radiation proctitis), urinary issues (radiation cystitis), fatigue, and lymphedema are often reported[20,21].

Hormone Therapy

Hormone therapy, commonly referred to as androgen deprivation therapy, aims to reduce testosterone to castrate levels to control prostate cancer progression. Hormone therapy is often reserved for patients with high or very high risk (i.e., Stage 3-4) prostate cancer or recurrent prostate cancer and is often used in combination with radiation treatments or chemotherapy[22]. There are many side effects

associated with this treatment type, including erectile dysfunction, genital shrinkage, hot flushes, breast tissue tenderness and growth, osteoporosis, loss of muscle mass, weight and fat mass gain, fatigue, and depression[20,23,24].

Chemotherapy

Chemotherapy is typically reserved for high to very high risk prostate cancer when the disease has spread outside the prostate (i.e., metastatic disease), and is typically used if hormone therapy has not been effective[25]. Side effects include hair loss, mouth sores, loss of appetite, nausea, increased infection risk, and fatigue[19].

1.2   Active surveillance

An increase in PSA testing in the 1990s led to dramatic increases in early detection of prostate cancer[26]. Up until this point, the majority of prostate cancers were treated with curative intent, resulting in increased strain on the healthcare system as well as reduced quality of life for patients experiencing treatment side-effects[27]. Active surveillance has since become a recommended method of disease management to prevent this overtreatment, whilst allowing patients to receive curative intervention when clinically necessary[27]. Active surveillance has become standard practice in recent years. However, with still no global consensus on eligibility criteria, best practice for management, or triggers for discontinuation, uptake and practice vary greatly across clinics and countries[28–30].

1.2.1   Eligibility for active surveillance

Eligibility guidelines for active surveillance have been published by many organisations including the NCCN, American Urological Association (AUA), and the European Association of Urology[26,30] (see Table 3).

Table 3: Overview of Active Surveillance Guidelines

Organisation	Title	Country
American Urological Association	Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline (2017)[14]	USA
The National Comprehensive Cancer Network	NCCN Guidelines Version 1.2022 Prostate Cancer (2021)[31]	USA
European Association of Urology	EAU Guidelines: Prostate Cancer (2021)[32]	Europe
National Institute for Health and Clinical Excellence	Prostate Cancer: diagnosis and management (2019)[33]	UK
Prostate Cancer Foundation of Australia and Cancer Council Australia	Clinical Practice Guidelines for PSA testing and early management of test-detected prostate cancer (2015)[34]	Australia

According to the 2017 AUA guidelines, active surveillance is an appropriate treatment option for men diagnosed with very low risk and low risk, localised prostate cancer and may be offered to selected patients with favourable intermediate risk, localised prostate cancer[14]. The majority of guidelines appear to follow this recommendation (including those from Australian organisations such as the Prostate Cancer Foundation of Australia[34]). However, differences in eligibility criteria are often found, particularly in large cohort studies[26], which often directly inform such evidence-based guidelines. The suitability of active surveillance for patients diagnosed with intermediate risk prostate cancer is often debated and further longitudinal research is required to determine its efficacy and safety in this population[35].

1.2.2 *Uptake of active surveillance in Australia and worldwide*

Given men diagnosed with low risk prostate cancer are eligible for either active surveillance or definitive treatments, treatment decision making can become overwhelming and confusing. Often the final decision is left to the patient after their doctor has provided the relevant information and recommendations[36]. Factors reported to influence the decision between active surveillance and definitive treatment include the patient's age, comorbidity, fear of cancer, pressure from family and friends, and recommendations and preferences of the doctor[29]. Over time the proportion choosing active surveillance has increased dramatically. A study from Cancer of the Prostate Strategic Urologic Research Endeavour (CaPSURE), a registry which accrues patient data across 45 urology practices in the United States, reported treatment trends in prostate cancer between 1990 and 2013. Overall use of

active surveillance in low risk prostate cancer patients was found to have increased from 14% in 2009 to 40% in 2013, and in men aged 75 years or older, uptake was as high as 96%[37]. In Australia, a similar uptake has been reported. The Prostate Cancer Outcome Registry – Victoria (PCOR-Vic), which captures up to 85% of patients diagnosed with prostate cancer in that state, reported that between 2009 and 2013, approximately 60% of patients diagnosed with low risk prostate cancer received either active surveillance or watchful waiting[38].

1.2.3   *Expected clinical outcomes of active surveillance*

There has been extensive research on the efficacy of active surveillance as a treatment option for men with low risk, localised prostate cancer. Studies comparing active surveillance to definitive treatments have found no significant difference between the groups in prostate cancer specific deaths and deaths from any cause[21]. However, active surveillance cohorts generally have higher rates of disease progression[21], though this is to be expected given progression serves as the indicator for pursuing definitive treatments. Risk of infection and sepsis due to having repeat biopsies is an uncommon but reported risk of active surveillance[39].

1.2.4   *Management of patients on active surveillance*

Active surveillance management involves patients having regular, accurate disease staging tests, including routine PSA tests and DREs, a confirmatory biopsy, and surveillance biopsies and MRIs thereafter[26,28]. The timeline for these follow-up events is at the discretion of the healthcare providers, though the majority of guidelines agree that PSA testing should occur every 3-6 months, DREs every 6-12 months, a repeat biopsy at 12 months and every 1-4 years thereafter based on clinical progression indications[26,28]. An overview of guidelines from the major organisations is outlined in Table 3. Notably, the guidelines from the Prostate Cancer Foundation of Australia and Cancer Council Australia[34], which have not been revised since 2015, do not recommended a specific protocol for active surveillance due to a lack of clinical evidence[34].

Table 3: Active surveillance guidelines of international organisations

Organisation	PSA	DRE	First repeat Biopsy	Additional repeat biopsies	mpMRI
American Urological Association[14]	Every 3-6 months	At 3-6 months	At 12 months	Every 3 - 5 years	Not specified
National Comprehensive Cancer Network[31]	Every ≥ 6 months	At 12 months	At 12 months	Every 1 - 4 years	At 12 months
European Association of Urology[32]	Every 6 months	At 12 months	If evidence of progression is detected on PSA, DRE and/or mpMRI.	If evidence of progression is detected on PSA, DRE and/or mpMRI.	If required, perform prior to confirmatory biopsy.
National Institute for Health and Clinical Excellence[33]	Every 3 months in 1st year, and every 6 months thereafter	At 12 months	If evidence of progression is detected on PSA, DRE and/or mpMRI.	If evidence of progression is detected on PSA, DRE and/or mpMRI.	At 12 and 18 months

Timing and frequency of repeat biopsies and the use of mp-MRI is the main point of difference between clinical guidelines. Given the main non-cancer related risks of active surveillance derive from biopsy complications[8,26], and men on active surveillance often report discomfort and desire to avoid biopsies when possible[29], determining the frequency of repeat biopsies to maintain patient satisfaction whilst enabling accurate disease monitoring is essential. This is especially important as compliance with active surveillance management protocols is often poor[40]. In an Australian cohort study of active surveillance patients two years after diagnosis, only 54% had undergone at least one repeat biopsy, 38% had undergone no repeat biopsies, and only 37% had undergone at least three PSA tests[40]. In the United States, a Michigan Urological Surgery Improvement Collaborative (MUSIC) study reported that among men who remained on active surveillance after two years, only 31% complied with the management protocol as outlined by the National Comprehensive Cancer Network[41]. In the Prostate Cancer Research International Active Surveillance (PRIAS) study of more than 100 centres across 17 countries, an estimated 81% of patients on active surveillance had their first repeat biopsy at approximately 12 months post-diagnosis[42]. Finally, it has also been reported that 25% of patients who undergo a prostate biopsy will be disinclined to undergo a repeat biopsy[43], particularly if the patient experienced complications[44].

As an alternative, the utilisation of mp-MRI scans in place of repeat biopsies has been suggested. Research is still ongoing to determine the role of mp-MRIs in the management of active surveillance, though their use in identifying men suitable for active surveillance has been well-established[45]. The use of mp-MRI to investigate disease progression and thus avoid repeat biopsy has already been recommended in clinical guidelines[26] based on emerging evidence that its use decreases the number of men required to undergo repeat biopsies to detect disease progression, reducing patient burden[45]. Significant limitations of the use of mp-MRI in active surveillance management include increased healthcare costs[46], high risk of false results[45], a need for access to equipment, and inconsistent image quality and interpretation[45]. Clearly, further investigation to establish a management protocol which is not burdensome to patients, encourages compliance, and is effective in detecting progression and facilitating access to definitive treatment, is required.

1.2.5   Discontinuing active surveillance

Ideally, patients will discontinue active surveillance when disease progression is identified that results in adverse disease reclassification (i.e., moving from a lower-risk to a higher-risk category) which warrants intervention with definitive treatment[14]. Adverse reclassification may be due to a higher Gleason score, lesion growth identified by an mp-MRI scan, and/or a rise in PSA level[14]. Given the aim of active surveillance is to monitor disease progression in order to maintain the window of opportunity to receive definitive treatment if needed, it is not uncommon for patients to discontinue active surveillance. In the 10-year follow-up report by the PRIAS study, 52% of patients discontinued active surveillance within five years, and 73% within ten years[47]. Similarly, in the 10-year follow up report by the ProtecT study (which randomised patients in the United Kingdom diagnosed with low risk, localised prostate cancer to receive active surveillance, radical prostatectomy, or radiotherapy), 55% of patients randomised to active surveillance had received definitive treatment within 10 years[21].

Whilst the majority of men appear to discontinue active surveillance because of disease progression and/or risk reclassification, there is evidence to suggest some patients transition for other reasons. For

instance, the Movember Global Action Plan Prostate Cancer Active Surveillance initiative (GAP3) 2018 report found that across their consortium, 12% of men had discontinued active surveillance without evidence of disease progression within five years of diagnosis[48]. In the PRIAS 10-year report, 5% of patients discontinued due to anxiety or patient request (without disease reclassification), and a further 12% discontinued for other unspecified reasons (without disease reclassification)[47]. Very few publications have explored reasons for active surveillance discontinuation without disease progression from patient perspectives. One mixed-methods study by Berger et al[49] identified that 9% of the sample (103/1,159 on active surveillance) from the Johns Hopkins database had discontinued active surveillance without disease progression[49]. Their quantitative results suggested that men who discontinued without progression were more likely to be younger (aged 40-60 years) and have a PSA level between 4 and 10 ng/mL. Qualitative interviews (N=14) in this study found that men who discontinued without disease progression experienced uncertainty regarding their treatment, found biopsies uncomfortable, feared cancer progression, distrusted diagnostic tests, and were influenced by their partners and/or family[49]. Whilst these results are useful in understanding men's reasons for discontinuing active surveillance without disease progression, they are limited in generalisability in several ways. First, as the perspectives from men currently on active surveillance and those who did experience disease progression were not explored, it is unclear whether men with disease progression also consider personal reasons for discontinuation. Furthermore, this study recruited from one university care centre that has an established active surveillance care service which provides ongoing and frequent support for their patients on active surveillance[49]. Unmet needs for accessible and appropriate support may be a contributing factor to men's decision to leave without disease progression. In fact, unmet informational needs and a desire for additional support have been reported by men on active surveillance[50–52]. Given that the concept and practice of active surveillance has also evolved considerably over the last 20 years and that advances in technology have improved diagnosis and management, it is also imperative to consider how active surveillance is managed and experienced by men in more recent times[53].

1.3 Issues faced by patients eligible and on active surveillance

Exploring the experiences and challenges of active surveillance requires consideration across multiple, interacting levels spanning the individual, social, and broader environment. Ecological models of development and behaviour, such as Bronfenbrenner's ecological systems theory (also known as the Social Ecological Model)[54] are commonly used in health research to assist in contextualising the causal pathways between these multilevel factors of health and behaviour, thereby guiding the development and implementation of supportive care interventions and aid in improving patient care. As an extension of the traditional Biomedical Model, which purported that health and behaviour is solely influenced by biological mechanisms, and later Engel's Biopsychosocial Model[55], which expanded the biomedical model to also consider the influence of the psychosocial contexts of individuals, the Social Ecological Model (SEM) further incorporates higher-order social influences, such as community, organisation, and policy level influences[54,56].

Bronfenbrenner's original ecological systems theory proposed individuals are embedded within four interacting levels: the microsystem (immediate environment), the mesosystem (settings in which one actively participates), the exosystem (wider social/organisational setting), and the macrosystem (cultural belief systems and governing policies). An overview is illustrated in Figure 1. Whilst Bronfenbrenner originally articulated the theory to explore human development[54], it has since been used extensively in healthcare research to facilitate knowledge exploration and intervention design which targets individual, social, organisational/community, and public policy factors[57]. Importantly, the model acknowledges that levels are interactive and reinforcing, and therefore creating sustainable health improvements relies on the consideration and targeting of all multifaceted levels[58]. Below, we have utilised the SEM to assist in contextualising the issues faced by patients diagnosed with low risk, localised prostate cancer who are eligible for or on active surveillance, and gaps in knowledge which require further research to improve patient care.

Figure 1: The Social Ecological Model
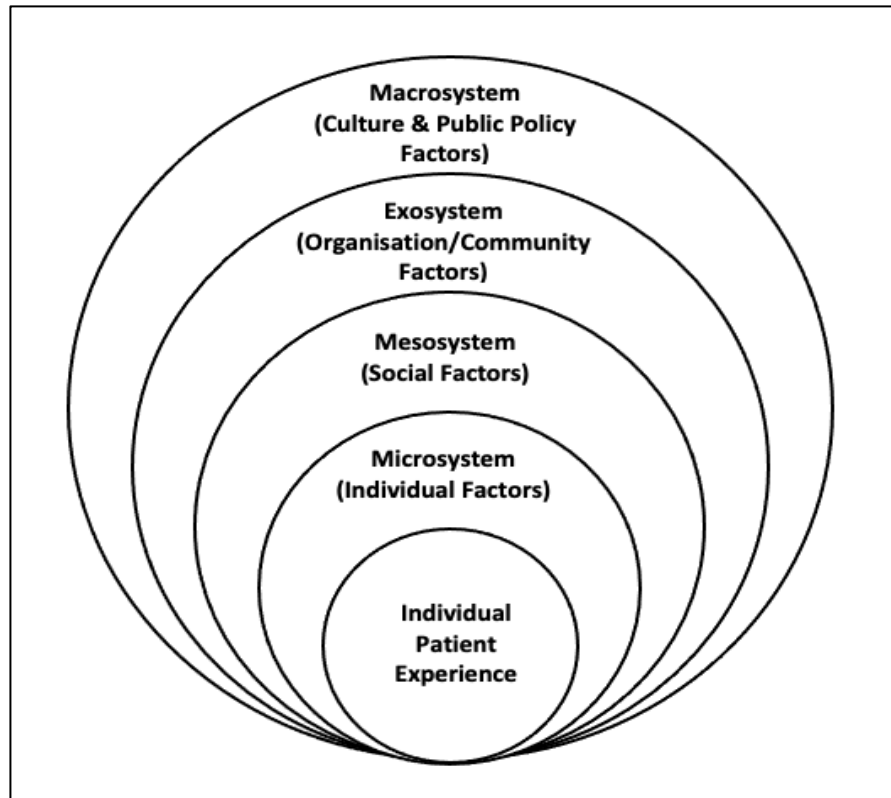
1.3.1   Individual level factors influencing active surveillance experiences

1.3.1.1   Health status and demographics

Outside of the patient cancer characteristics, individual factors such as age, family history of prostate cancer, and education level have been found to influence the uptake of active surveillance, though findings are often inconsistent. Findings suggest that older men are more likely than younger men to choose active surveillance over definitive treatment and are more likely to stay on active surveillance, with qualitative findings suggesting that younger patients feel more capable of handling definitive treatment side effects while still relatively young and healthy[59,60]. It has also been reported that patients with a family history of prostate cancer are reportedly less likely to choose and adhere to active surveillance[61,62]. In regards to education, inconsistent findings on the influence of higher education in uptake of active surveillance and adherence have been reported, with some studies finding higher education can act either as a barrier or facilitator[29]. Acknowledgement of these factors

and their interactions with other levels within the SEM is important when designing clinical recommendations and supportive care services to ensure these are considerate of patient individual differences.

1.3.1.2   Anxiety and mental health

The impact of active surveillance in comparison to definitive treatments on quality of life is unclear. In general, research suggests active surveillance has no greater threat on psychological wellbeing, health-related quality of life, and anxiety when compared to active treatments, and is associated with a greater quality-adjusted life expectancy[42,63,64]. However, recent research has found that men on active surveillance experience more fear of cancer progression than those who have had definitive treatment[65], and qualitative research regularly reports that men on active surveillance experience anxiety, fear of progression, and uncertainty, particularly before follow-up appointments[61,66–68]. Furthermore, whilst depression and anxiety are comparable between men on active surveillance and men post-definitive treatment, men on active surveillance may experience greater anxiety both at diagnosis and over time[69]. These varying results are often attributed to research methodological limitations such as insufficient sample sizes, recruitment from cancer centres specialising in active surveillance monitoring, lack of study comparison groups, and inappropriately timed data collection[70]. Further research to understand psychological wellbeing, especially anxiety and uncertainty, and how it influences the uptake, experience, and adherence to active surveillance, is essential in order to appropriately address these issues through supportive care interventions.

1.3.2   Social level factors influencing active surveillance experiences

1.3.2.1   Social pressure to have treatment

Research suggests men are more likely to adhere to active surveillance if they are married/partnered, attended support groups, and feel they receive adequate social support[29]. However, research has also found that partners of men diagnosed with prostate cancer prefer definitive treatments over active

surveillance[71,72], and men have reported receiving pressure from family/partners to have definitive treatments after diagnosis[49,73]. Whilst research has investigated the role of partners in treatment decision-making after the cancer diagnosis, further investigation of the influence of partners, family, and others on the patient's active surveillance experience and treatment decision-making is required.

1.3.2.2 Vicarious experiences of prostate cancer

As previously mentioned, men with a family history of prostate cancer are reportedly more likely to choose definitive treatments over active surveillance[61,62]. Initial research indicates that vicarious experiences of prostate cancer and treatment experiences may influence treatment preferences and adherence to active surveillance[74,75]. For instance, in a qualitative study by Xu et al[75], anecdotal experiences of prostate cancer from friends/family influenced patient treatment preferences, especially in deciding which treatments to avoid. In another qualitative study, participants on watchful waiting and active surveillance justified their choice of active surveillance by referencing the adverse side effects from definitive treatments experienced by their friends or family members[74]. Participants also referred to others they knew who had experienced positive outcomes after deferring definitive treatment[74]. However, the extent to which patients on active surveillance are influenced by the stories or experiences of other prostate cancer patients (from friends, family, or those in the media) who experience adverse outcomes, such as metastases, has not be widely explored.

1.3.3   Organisation and Community level factors influencing active surveillance experiences

1.3.3.1   Doctor Recommendations and Biases

Research on patients recently diagnosed with prostate cancer has consistently demonstrated that the treating doctor's opinion and treatment recommendation is the largest influence on the patient's treatment choice[29]. For instance, Davison and Goldenberg[64] found that the urologist's treatment recommendation had the strongest influence on the treatment choice in men diagnosed with low risk, localised prostate cancer. Similarly, in a cohort study by Gorin et al[76], 73% of participants on active surveillance said the greatest influence on their treatment decision was their doctor's treatment

recommendation. However, the doctor's recommendation and treatment preferences or biases can also be a barrier to patients choosing active surveillance. For instance, one study found that although urologists discussed active surveillance as a treatment option with 72% of their patients diagnosed with localised prostate cancer, in patients with low risk disease it was only recommended 25% of the time at initial consultation, and 16% of the time in a second opinion consultation[77].

The quality and amount of information provided by doctors about active surveillance may also vary considerably between doctors, which may be an issue given this has also been identified to significantly influence the uptake of active surveillance[78,79]. Furthermore, research has often identified that patients diagnosed with prostate cancer, including those who chose active surveillance, have strong desires for receiving more information on their treatment options, treatment side effects, and general information on prostate cancer[51]. Awareness of the considerable influence the doctor has on their patient's treatment choice and overall experience is essential when developing and modifying supportive care interventions and services for men diagnosed with low risk, localised prostate cancer.

1.3.3.2   Access to supportive care and services

Cancer-related supportive care was first defined by Fitch in 1994 as *"the provision of the necessary services for those living with or affected by cancer to meet their physical, emotional, social, psychological, informational, spiritual, and practical needs during the diagnostic, treatment, and follow-up phases, encompassing issues of survivorship, palliative care and bereavement"*[80]. This framework is based upon psychological constructs of human needs, cognitive appraisal, and coping and adaption, and posits that if an individual's needs remain unmet during their care, they will experience emotional distress and difficulties[80].

Up to 80% of men with prostate cancer have unmet informational, psychological, sexual, and practical supportive care needs[81,82]. A large systematic review by Paterson et al[81] reported that men with prostate cancer often experience a range of unmet needs across all domains: physical (e.g., to

address urinary symptoms, hot flushes, fatigue, sexual issues), psychological (e.g., help dealing with anxiety, uncertainty, fear of recurrence, concerns about the future), practical and daily living (e.g., around financial support, early retirement/unemployment concerns), and informational/health systems (e.g., access to information which adequately explains treatments and side effects, receiving test results, information and referral for psychological care options, and information/referral for complementary medicine).

Whilst the supportive care needs of men with prostate cancer in general have been well documented, no studies have summarised the specific unmet supportive care needs of men on active surveillance. Understanding the particular unmet needs of men on active surveillance is important as their treatment protocol is entirely different to that of patients undergoing definitive treatments. Unlike men receiving definitive treatment immediately upon diagnosis, men on active surveillance may experience more long-term support needs, and if these remain unmet, it may significantly impact the physical and psychological burden they experience, potentially causing them to re-think their treatment plan. It is currently unclear the extent to which unmet needs experienced by prostate cancer patients are also experienced by men on active surveillance, and the magnitude of this issue.

1.3.4   *Macro level factors influencing the active surveillance experience*

1.3.4.1   Management of active surveillance and clinical guidelines

Recognised clinical guidelines for active surveillance eligibility criteria, management protocol, and discontinuation criteria are inconsistent and vary considerably[26,28,30]. These inconsistencies may impact patient experiences and lead to increased patient uncertainty and potentially poor active surveillance management (i.e., inconsistent follow-up or irregular follow-up which does not identify disease progression in a timely manner)[30,83]. Global consensus on clinical guidelines for active surveillance is required and will need more high-quality research, especially longitudinally to investigate experiences and patient needs over time. In the meantime, consideration for the potential

influence of inconsistent clinical guidelines and practices on the uptake of active surveillance, experiences during active surveillance, and discontinuation is essential.

1.4   Addressing research recruitment challenges

In order to successfully explore men's experiences on active surveillance and acquire data which is reliable, valid, and representative of the population, we need to consider implementing strategies which can ensure patient participation in research. Men are often viewed as a difficult group to recruit for in psychological research[84], particularly in psycho-oncology[85–88]. Given that quantitatively assessing men's experiences, preferences and needs from their own perspectives will predominantly rely on utilising multiple self-report measures, identifying strategies to reduce participant burden and encourage participation is vital. Many strategies to increase response rates and participation in questionnaire-based research, such as providing incentives (e.g., monetary, lottery-style, prize draws), following up non-responders, personalisation techniques and priming participants[89], have been identified and studied. However, research to identify which engagement strategies will be most effective in boosting response rates to questionnaires in prostate cancer research is required. Utilising existing research projects to explore this may simultaneously reduce participant burden and increase knowledge output. Conducting trials within other research studies is a recommended research method for increasing evidence-based knowledge which evaluates or explores the effectiveness of researcher strategies or approaches[90]. Conducting a study to investigate which engagement strategies are most effective in boosting men's participation in research will not only help to ensure the studies within this thesis recruit representative samples, but will inform future research studies recruiting prostate cancer patients for questionnaire-based research.

1.5   Conclusions

The experiences of prostate cancer patients who are diagnosed with low risk, localised prostate cancer requires more research to best ascertain (a) what, if any, supportive care services and management

protocols are required to improve patient experiences and outcomes, and (b) how best to address these areas. To effectively improve the overall active surveillance experience, consideration of not just the individual and social level influences are required; instead, a broader approach which considers the individual, social, community, and policy level influences is needed[54]. This will require the use of both quantitative and qualitative methodologies in order to gather data which is both representative of the population and rich in detail, particularly from the patient perspective. To identify how best to inform the development of supportive care interventions for men on active surveillance and make effective changes in the management of these patients, the follow gaps in the literature will need addressing:

1. Exploration of effective recruitment strategies to increase prostate cancer patients' engagement in research.

2. Investigation of the social-ecological influences on the uptake of active surveillance in men diagnosed with low risk, localised prostate cancer, given this is the recommended treatment option for men diagnosed with this risk-level.

3. Summarisation of existing literature investigating the unmet supportive care needs of men on active surveillance, to ascertain what needs are unmet, the magnitude of these needs, and whether these needs are similar to patients after definitive treatment for prostate cancer.

4. Identification and exploration of the social-ecological factors which influence the discontinuation of active surveillance, to understand how to address these influences to ultimately improve selection of patients for active surveillance, active surveillance experiences, and adherence to active surveillance.

The aims of this thesis, including the aims of each chapter, are outlined in Chapter 2.

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2 CHAPTER TWO:

RESEARCH AIMS AND THESIS OUTLINE

2.1 Thesis Aims

This thesis aims to explore the experiences of men diagnosed with low risk, localised prostate cancer as they navigate through decision-making phases for treatment at diagnosis (i.e., whether to commence active surveillance) and whilst on active surveillance (i.e., whether to continue on active surveillance or discontinue to have definitive treatment). By understanding men's experiences both on and off active surveillance, we hope to inform the development of support and enhance existing support services according to men's needs and preferences, and ultimately improve the overall experience of active surveillance as a treatment option for men with low risk, localised prostate cancer. This thesis also aims to advance research methodology in future studies by examining the efficacy of recruitment strategies to encourage prostate cancer survivors to participate in supportive care research. To reach these aims, five research studies were conducted, each with its own specific aims.

2.2 Thesis Outline and Chapter Aims

2.2.1 Paper 1 (Chapter Three): Decision Making In Men Diagnosed With Early Stage Prostate Cancer And Their Close Allies – A Qualitative Exploration

In this qualitative paper, men diagnosed with low risk, localised prostate cancer who were eligible for active surveillance (as well as some partners) were recruited after their treatment decision (i.e., between active surveillance and definitive treatment) had been made. This study aimed to explore the range of perceived influences on treatment decision-making in this group, and to examine the decision-making processes they had used. Interviews with patients and partners were conducted separately in order to discover their individual experiences, treatment preferences, and needs.

2.2.2 Paper 2 (Chapter Four): A Systematic Review Of The Unmet Supportive Care Needs Of Men On Active Surveillance For Prostate Cancer

To understand men's experiences and inform the development of support services men need while on active surveillance, we performed a systematic review identifying (a) the unmet supportive care needs experienced by men during active surveillance; (b) factors found to predict, relate to, or influence men's unmet supportive care needs during active surveillance; and (c) gaps in the literature and the quality of available evidence.

2.2.3 Paper 3 (Chapter Five): Men's Unmet Supportive Care Needs During Active Surveillance: A Mixed Methods Investigation

The prior systematic review highlighted a paucity of quantitative research using validated measures to measure the supportive care needs of men on active surveillance. Therefore, we next conducted a study using a quantitative survey and qualitative interview data to measure and explore the unmet supportive care needs and mental wellbeing of men who were currently or had previously been on active surveillance after diagnosis of prostate cancer.

2.2.4 Paper 4 (Chapter Six): Reasons Men Transition From Active Surveillance To Treatment: A Mixed Methods Investigation

Patient perspectives on their reasons for discontinuing active surveillance is a largely unexplored area and may help to inform the development and provision of supportive care services to improve active surveillance management. In this study, we used quantitative survey and qualitative interview data to identify and explore the reasons men leave, or consider leaving, active surveillance and transition to treatment.

2.2.5 *Paper 5 (Chapter Seven): Impact of different unconditional monetary incentives on PROMS survey response rates in men with prostate cancer: a 2-arm randomised trial*

Increased research engagement by prostate cancer survivors is essential for ensuring the wider population's experiences, needs, and preferences are represented in the literature. This randomised trial within a case-control cross sectional study was conducted to evaluate the effect of offering different unconditional incentive amounts on response rates in a cross-sectional study of men diagnosed with prostate cancer. The study aimed to determine whether (a) response rates to different relatively large unconditional incentive amounts would vary, and (b) patient characteristics (e.g., age, marital status) would vary in those who did respond to the different incentive amounts.

2.2.6 *Discussion and Conclusions (Chapter 8)*

In this final chapter, the findings of this thesis are summarised and discussed in line with existing literature. The strengths of the overall thesis and the individual research studies are illustrated, alongside the limitations of the thesis and its findings. Finally, future directions for research and recommendations for practice are outlined in detail, through the lens of the social ecological model.

3   CHAPTER THREE:

SOCIAL ECOLOGICAL INFLUENCES ON TREATMENT DECISION-MAKING IN

MEN DIAGNOSED WITH LOW RISK, LOCALISED PROSTATE CANCER

3.1   Statement of Authorship

Title of paper	Social ecological influences on treatment decision-making in men diagnosed with low risk, localised prostate cancer
Publication status	Accepted for publication in the European Journal of Cancer Care
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<u>Principal Author</u>

Name	Megan McIntosh
Contribution to paper	Analysed data, wrote and revised manuscript as per co-author and review feedback, acted as corresponding author.
Overall percentage (%)	70%
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.
Signature and date	10/11/2021

By signing the Statement of Authorship, each co-author certifies that:

- The candidate's stated contribution to the publication is accurate (as detailed above);
- Permission is granted for the candidate to include the publication in the thesis; and
- The sum of all co-author contributions is equal to 100%, less the candidate's stated contribution.

Co-author name	Chris J Nelson
Contribution to paper	Principal investigator on grant, developed protocol, oversaw data collection, provided feedback and advice on manuscript drafts.
Signature and date	19/10/2021

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Contribution to paper	Assisted in data analysis and provided feedback and advice on manuscript drafts.
Signature and date	04/11/2021

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Contribution to paper	Assisted in data analysis and provided feedback and advice on manuscript drafts.
Signature and date	24/08/2021

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Contribution to paper	Provided feedback and advice on manuscript drafts.
Signature and date	15/09/2021

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Contribution to paper   Assisted in data analysis and provided feedback and advice on

                          manuscript drafts.

Signature and date   21/10/2021

Co-author name   Michael Diefenbach

Contribution to paper   Acted as PI on grant, produced protocol, provided feedback and

                          advice on manuscript drafts.

Signature and date

                                                                          19/10/2021

Co-author name   Behfar Ehdaie

Contribution to paper   Provided feedback and advice on protocol and manuscript drafts.

Signature and date

                                                                          20/10/2021

Social ecological influences on treatment decision-making in men diagnosed with low risk, localised prostate cancer

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3.2 Abstract

Objective: Individuals diagnosed with low risk, localised prostate cancer (PCa) face a difficult decision between active surveillance (AS) and definitive treatment. We aimed to explore perceived influences on treatment decision-making from the patient and partner's perspectives.

Methods: Patients (and partners) who met AS criteria and had chosen their treatment were recruited. Semi-structured individual interviews were conducted via telephone to explore experiences of diagnosis, impact on patient lifestyle, experiences with physicians, treatment preferences/choice, treatment information understanding and needs, and overall decision-making process. Interviews were audio recorded, transcribed verbatim, and analysed using Reflexive Thematic Analysis.

Results: Twenty-four male patients (18 chose AS) and 12 female partners participated. Five themes relating to social-ecological influences on treatment choice were identified; 1) Partner support and direct influence on patient treatment choice, 2) Patient and partner vicarious experiences may influence treatment decisions, 3) The influence of the patient's life circumstances, 4) Disclosing to wider social networks: friends, family, co-workers and 5) The importance of a good relationship and experience with physicians. Additionally, two themes were identified relating to information patients and partners received about the treatment options during their decision-making process.

Conclusions: A range of individual and social influences on treatment decision-making were reported. Physicians providing treatment recommendations should consider and discuss the patient and partner's existing beliefs and treatment preferences and encourage shared-decision making. Further research on treatment decision-making of partnered and non-partnered PCa patients is required. We recommend research considers social ecological factors across the personal, interpersonal, community, and policy level.

3.3 Introduction

Prostate cancer (PCa) is one of the most commonly diagnosed cancers in men worldwide (Sung et al., 2021). The majority of patients are diagnosed early with low to intermediate risk PCa, with a low risk of metastases and PCa-specific mortality (Albertsen, 2015). In 2017, the American Urological Association (AUA) (Sanda et al., 2018) recommended that individuals diagnosed with very low or low risk PCa (localised to prostate, PSA <10, Gleason score ≤6) be treated with active surveillance (AS). AS involves regular monitoring of the cancer (through PSA testing and biopsies) to detect progression. However, as there is currently no widespread consensus on the most effective frequency for monitoring procedures nor triggers for definitive treatment, management is often at the discretion of treating physicians (Bruinsma et al., 2016; Kinsella, Helleman, et al., 2018). Definitive treatments with curative intent, such as prostatectomy or radiation, may also be appropriate for low-risk patients depending on patient preference and clinical factors (Sanda et al., 2017). However, definitive treatments can cause varying degrees of significant, potentially long-lasting physical side-effects including erectile dysfunction and incontinence (Hamdy et al., 2016). AS therefore allows patients to delay or avoid definitive treatments and their associated side-effects until clinically necessary (Chen et al., 2016). The lack of both clear treatment recommendations and clarity regarding expected outcomes from different treatments can result in a more difficult and distressing treatment decision-making process for patients (Owens et al., 2019).

A variety of factors have been found to influence patients' decisions on which treatment to undergo and when (Kinsella, Stattin, et al., 2018). Both quantitative and qualitative research suggests patient treatment decisions are prominently influenced by their physician's recommendations (Brooks et al., 2018; Feldman-Stewart et al., 2011; Kinsella, Stattin, et al., 2018). Research has also explored the role of romantic partners in the decision-making process, given they often attend clinical appointments with the patient and assist in treatment decision-making (Zeliadt et al., 2011). Emerging evidence suggests partners also experience anxiety related to their partners PCa, and potential outcomes and tend to favour definitive treatments over AS (Couper et al., 2006; Srirangam et al., 2003). However,

prior qualitative research has often interviewed couples together (which may preclude participants from sharing information), and therefore their individual experiences, treatment preferences, and needs requires further research (Stewart et al., 2021). There is also emerging evidence that patients may be influenced by opinions beyond their partner's when making treatment decisions (Berry et al., 2003). For example, one study comparing the use of online versus face-to-face support groups in PCa survivors found that men participating in online support groups were more likely to use peer support for treatment decision making and more often revised their treatment choice after consulting their support group (Huber et al., 2018). Another study reported that patients who involved close allies (i.e., friends or family in who the patient confides and whose opinion the patient considers important) in the decision-making process were more likely to choose definitive treatment over AS (Reamer et al., 2017). However, much of this research reflects treatment preferences and decision-making experiences prior to the 2017 AUA recommendations. Gaining an updated understanding of the range of influences on treatment decision-making now, with AS a more common and recommended option (Sanda et al., 2017), is important for informing development of effective decision-making support strategies for physicians to utilise with patients and their partners/close allies. Contextualising these factors through the lens of a theoretical model which extends beyond the individual and social levels, such as the social-ecological model (SEM), may be beneficial (Bronfenbrenner, 1979). The SEM proposes individual behaviour and decision-making is influenced by the interaction of personal, interpersonal, community, and policy/society levels, and is commonly used in cancer research (Beesley et al., 2008; McIntosh et al., 2019; Mitchell, 2011; Woods et al., 2006).

The present study used separate interviews with patients and their partners/close allies to explore the range of perceived social-ecological influences on treatment decision-making and examine decision-making processes after a low risk PCa diagnosis.

3.4   Methods

3.4.1   Study design

This qualitative study was part of a mixed methods investigation into decision-making by patients with low risk PCa and their partners/close allies. Patients were recruited from the urology clinic at [cancer centre], a private cancer hospital in New York, United States. The quantitative part of the study used patient-reported outcomes to investigate decision-making pre- and post-treatment decision by patients diagnosed with low risk PCa who met criteria for AS, and their partners or close allies. The results from the quantitative part will be reported elsewhere (manuscript in preparation). The present study is the qualitative part of the mixed methods study, comprising semi-structured interviews with a subset of participants after their treatment decision had been made. This study followed COREQ criteria for qualitative research (Tong et al., 2007). See supplementary material for checklist. The larger mixed methods study received ethics approval from the Memorial Sloan Kettering Cancer Center (MSK).

3.4.2 Participants

To be eligible to participate in the present study, patients and partners/close allies needed to have participated in the first part of the study and have made and disclosed their treatment decision to study staff. Partners/close allies could participate in the interviews regardless of patient involvement in this study. Patient inclusion criteria for the first part of the study included meeting eligibility criteria for AS at MSK (Gleason score of ≤ 6 or clinical stage $\leq$T1c; and PSA level <10ng/mL; and biopsy indicated <3 positive cores with $\leq 50\%$ cancer in each core; or documented physician discussion of AS as a treatment option), English proficiency, aged 18+ years, no history of other cancers (except for non-melanoma skin cancer), and no significant psychiatric or cognitive disturbance (as assessed by chart review) that would preclude providing informed consent or participation. Partners/close allies were eligible if they were viewed by the participating patient as being their partner/close ally, proficient in English, and aged 18+ years.

3.4.3 Procedure

Participants were invited to participate in an interview once the patient had disclosed their treatment choice to study staff. The first 102 participants in the main study (N=66 patients and N=36

partners/close allies) who disclosed their treatment choice were invited to participate in qualitative interviews. In total, 33 patients and 15 partners agreed to participate and were interviewed. No close allies participated. Nine patients and three partners were found ineligible for AS during interviews and analysis and were therefore eliminated from the study. All interviews occurred via telephone and were audio-recorded and transcribed verbatim. Transcribed interviews were not returned to participants for comment/correction. Interviews were semi-structured and aimed to explore experiences of diagnosis, impact on patient lifestyle, experiences with physicians, treatment preferences/choice, treatment information understanding and needs, and overall decision-making process (see supplementary material for interview guides). Interviewers also kept field notes during interviews. All participants were interviewed once by a female research staff member (N=4, all with Bachelor/Masters degrees in related fields) who had prior interview experience or had received training. Interviewers had no prior relationship with the participants outside of study interactions. Interviews lasted an average of 26 minutes with patients and 23 minutes with partners.

3.4.4   Analysis

Transcribed interviews were analysed by the research team MM, CES, RT using reflexive thematic analysis (Braun & Clarke, 2013). Analysis was conducted in NVivo version 12 (QRS International Pty Ltd., 2020) and Microsoft Word. This process involved both MM and RT each independently conducting a close reading of all transcripts and identifying initial codes. MM, RT, and CS then analysed the same five transcripts (three patients and two partners) to identify and combine coding and create themes. Transcripts were then re-analysed using those themes by MM and RT. Finally, themes were formally defined, summarised, and supported by extracts from the transcripts. A thematic map was also created, reviewed, and refined by all authors to illustrate the themes. As per Braun and Clarke's reflexive thematic analysis approach, data saturation was not the intention of recruitment and data analysis (Braun et al., 2019). Rather, we endeavoured to recruit and interview a high volume of eligible participants (aiming for N=20 patients and N=10 partners/close allies) to ensure a broad and meaningful exploration of participants experiences.

3.5 Results

3.5.1 Participants

Interview data from N=36 participants were included in the analysis (N=24 male patients and N=12 female partners). The average patient was 59 years old, Caucasian (83%), had a college degree or higher (83%), was employed (79%), had chosen AS for their treatment option (75%), and were married (88%). Patients were interviewed on average 48 days after reporting their treatment decision to the study staff. Partners were on average 60 years old, had a college degree or higher (75%), were employed (50%), Caucasian, married (both 100%), and were partner to a patient who had chosen AS (67%). See Table 1 for a complete breakdown of participant demographics.

Table 1: Participant Demographics

	Patients (n=24)	Partners (n=12)
Age: Mean (SD)	59.6 (6.2) years	59.9 (5.5) years
Treatment choice: % (N)		
Active surveillance	75.0% (18)	66.7% (8) *
Prostatectomy	20.8% (5)	8.3% (1) *
Cryotherapy	4.2% (1)	25.0% (3) *
Days since treatment decision: Mean (SD)	47.8 (37.4)	59.3 (47.4) *
Ethnicity: % (N)		
Caucasian	83.3% (20)	100% (12)
African American	4.2% (1)	0%
Other	12.5% (3)	0%
Education: % (N)		
Completed high school	16.7% (4)	25.0% (3)
Completed college	83.3% (20)	75.0% (9)
Current employment: % (N)		
Employed	79.2% (19)	50.0% (6)
Retired or unemployed	20.8% (6)	50.0% (6)
Marital status: % (N)		
Single/divorced/separated	12.5% (3)	0
Partnered (married, defacto)	87.5% (21)	100% (12)

* Indicates the disclosed treatment choice of the patient in the partner-patient dyad.

3.5.2 Overview of themes

A thematic map is presented in Figure 1. Participants described a variety of factors as influencing treatment preferences and choice. Five major themes were identified related to influences on the treatment decision: "Partner support and direct influence on patient treatment choice", "Patient and

partner vicarious experiences may influence treatment decisions", "The influence of the patient's external circumstances", "Disclosing to wider social networks: friends, family, co-workers" and "The importance of a good relationship and experience with physicians". Two further themes were identified related to additional considerations during the decision-making process: "Learning about PCa and treatments" and "Weighing up the risk and benefits of treatment options". Extracts from the transcripts to support each theme are presented in Table 2.

Figure 1: Thematic Map of Themes
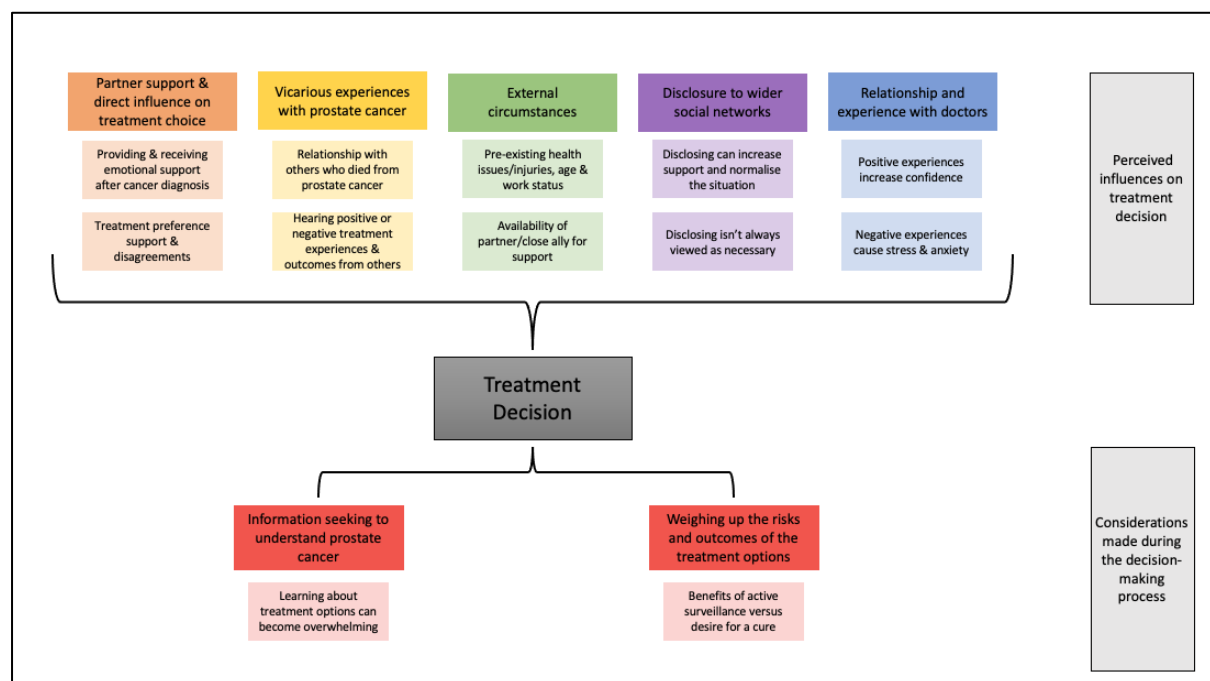
3.5.3   *Partner support & direct influence on the treatment choice*

3.5.3.1   Partner support and influences on the patient and the decision

Patients described receiving emotional and practical decision-making support from their partners. For many this meant attending appointments together, sharing new knowledge learnt from their own research or friends, family, or co-workers, and discussing treatment options. Partners felt it was their responsibility to provide emotional and practical support whenever possible to the patient. Whilst many patients felt the treatment decision was solely theirs, they wanted their partner to support their

choice and considered their concerns and opinions when making their decision. Often, partners deliberately withheld expressing their treatment preference until the patient had expressed theirs.

3.5.3.2   Partner disagreement about treatment choice

Not all participating partners supported the treatment choice that had been made. Dissatisfaction with treatment choice was particularly prevalent when the patient had chosen AS. Many partners expressed a preference for prostatectomy, believing it to be the 'gold standard' treatment option, and felt concerned the patient was risking their health if they chose AS. Consequently, patients found the decision-making process difficult when their partner disagreed with their preferences or choice.

3.5.4   *Patient and partner vicarious experiences may influence treatment decision*

The influence of vicarious PCa treatment experiences on the decision-making process was significant. Participants who had directly or indirectly known others with PCa often considered those people's treatment experiences whilst weighing up their own treatment options. Patients and partners who knew others that had negative experiences with a particular treatment often reported an aversion towards it, especially when that person had died. On the other hand, those who had known others to have a positive experience with a particular treatment felt reassured of its safety and effectiveness. For some, another's positive treatment experience heavily influenced their own treatment preferences.

3.5.5   *The influence of the external circumstances*

The decision-making process and treatment preference were sometimes affected by external circumstances. Some patients had other health issues or injuries at the time of diagnosis. Several patients delayed their treatment decision-making due to external circumstances such as separation, working overseas, or undergoing their own medical treatment. Some patients felt choosing AS and delaying definitive treatment was necessary as they were still working, which would be difficult with treatment-related side effects.

3.5.6   *Disclosure to wider social networks: friends, family, co-workers*

3.5.6.1   Disclosing can increase support and normalise the situation

Deciding whether to share their diagnosis and discuss treatment options with others was another decision for participants. Many who discussed the diagnosis and treatment preferences with others, such as friends, family, or co-workers, explained that it helped them connect to others currently going through a similar experience, bringing feelings of normalisation, hope, and support.

3.5.6.2   Disclosing isn't always seen as necessary

However, some patients chose not to share their diagnosis and treatment choice with others, thereby deliberately limiting potential outside influences on the decision-making process. This was most often mentioned by patients who chose AS.

3.5.7

3.5.8   *The importance of a good relationship and experience with physicians*

3.5.8.1   Positive experiences increase confidence

Feeling comfortable, confident, reassured, and well-informed about the physician's treatment recommendation and expertise was noted by participants as essential for a positive experience with their physician, which decreased decision-making difficulty. Participant's reported positive experiences with their physician when their physician had taken time to explain the different treatment options, appeared confident in their treatment recommendation, and rechecked or performed additional diagnostic tests. Patients who chose AS often mentioned their physician's calm attitude and reassurance provided participants with confidence in the treatment option and their decision.

3.5.8.2   Negative experiences cause stress and anxiety

Several patients reported having negative experiences with their diagnosing physician. In such circumstances, patients reported it had made their decision-making more difficult and confusing. Physicians who had not provided the desired amount of information or reasoning for their treatment recommendation, appeared uninformed or biased, had not followed-up with the patient in a timely manner, did not consider the patient's treatment preferences, and who were seen as lacking compassion were viewed poorly by the participants and often led them to pursue a second opinion. These experiences prolonged the treatment decision-making process and caused stress, anxiety, and frustration.

3.5.8.3   Seeking a second opinion can assist decision-making

Approximately half of the participants mentioned the importance of getting a second opinion regarding their diagnosis, often from an [cancer centre] physician, to assist in their decision-making. Often the desired outcome from the second opinion was to support the first recommended treatment, to learn about or get support for other treatment options, or because they had an unsatisfactory experience with their first physician. Participants often mentioned the credibility and well-known reputation of [cancer centre] and for many this had a considerable influence on their decision-making. A treatment recommendation from [cancer centre] was considered credible and trustworthy, and increased participants' confidence in their treatment decision.

3.5.9   Learning about PCa and treatments

3.5.9.1   Learning about PCa and treatments is essential, but sometimes overwhelming

Learning about PCa was an essential step for participants in their decision-making process. Most participants, especially those without prior knowledge of PCa, began researching and seeking information once the shock of the diagnosis had passed. Participants sought information to better understand their diagnosis, test results, the different treatment options and their side-effects, to

investigate physicians and their clinical expertise, and to read other patients' experiences. In general, participants felt they had access to enough information about PCa and their treatment options, and receiving information often made them feel calmer and in more control. However, it was also noted that too much information or conflicting opinions could be overwhelming and had the potential to confuse and delay decision-making.

3.5.9.2 Information sources used

Patients and their partners sought information from multiple sources, including the internet (e.g., hospital websites, information found via Google searches, and YouTube videos), physicians and nurses, books, newsletters, research papers, radio, and online discussion groups. Many noted the importance of specifically looking for information from credible sources. Participants reported that other patients or partners of patients who had PCa were also valuable sources of information. For some, this was accessed by attending support groups or looking to celebrity accounts of their experiences.

3.5.10 Weighing up the risks and benefits of the treatment options

3.5.10.1 Avoiding the side effects of definitive treatments

Most patients favoured AS because it delayed definitive treatment and its associated side effects until necessary, allowing them to maintain their health and vitality for as long as possible. The potential side effects of definitive treatments weighed heavily on patients' minds and was often reported as being their main reason for choosing AS. Patients who chose AS frequently viewed the potential long-term side effects of definitive treatment as burdensome and hoped to completely avoid treatment altogether because of this.

3.5.10.2 Making a treatment decision can take time

After diagnosis and being told their treatment options, participants reported deliberately taking their time to gather second opinions and research treatments. For some, AS was a relatively simple choice; many were accepting of the protocol and were relieved when their physicians and the diagnostic tests supported the treatment option. Delays in treatment decision-making were usually due to weighing up the potential negatives of AS (e.g., fear of progression, regular biopsies, potential treatment regret) against the potential negatives of definitive treatment (e.g., experiencing short- and long-term side effects, taking time off work to recover), rather than a focus on the possible benefits of either option. Others were simply overwhelmed.

3.5.10.3 Strong desire to remove or treat the cancer

Some patients who elected to undergo definitive treatment were open-minded about going on AS, but the desire to act was too overwhelming. Others reported being strongly opposed to AS, due to distrust in its ability to detect progression.

Table 2: Illustrative Quotes Extracted from Transcripts

Partner support & Direct Influence on Treatment Choice

Partner support and influences on the patient and the decision.
- *"I have to be sensitive to her feelings as well. We've been married 38 years already… So we've always come to some kind of decision together or at least we try to accept each other's opinion. And, and it was important to me that she accept why I wanted to do this and understood it, and I think she finally did."* Participant 1008, Patient, AS.

Partner disagreement about treatment choice.
- *"I'm feeling the same thing that, what I've always heard, with cancer, you need to take care of it, you know, time is the essence. You take care of it fast, and you do whatever you can to get rid of it. And to me, it's like surgery. That's where the cancer is. You get rid of the prostate, and you're done. Um, but for him, it wasn't that, you know, that clear-cut process. So it's been a little frustrating for me, because we're really not on the same page as far as how we'd approach treatment"* Participant 2017, Partner.
- *"My wife actually had a very strong opinion and, and we were surprisingly once again on different sides of the table about it. And it wasn't until she came around to my side, which made my decision a lot easier because then I knew that she was supportive and understood it."* Participant 1008, Patient, AS.

Patient and partner vicarious experiences may influence treatment decision

- *"I've heard cases from all extremes, as I'm sure you all have. I've heard cases of, '[the prostatectomy] was no problem. I did it and within two months I was fine and I'm so glad I did it'. And I've heard other cases of people who years later are still dealing with the side effects and have said, 'I would never do it again'. I've heard both experiences."* Participant 1002, Patient, AS.
- *"I won't say it's the sole reason, but it's one of the main reasons that I made the decision to do the surgery. I just looked at it and said, you know what? I don't know that I can go day-to-day and not know, okay, what if it progresses and it steps out of the host organ, and all of a sudden, now I'm like my brother where he was sick and let it go and let it go and let it go, and then he all of a sudden was faced with a stage four advanced disease that there was nothing he could do about it."* Participant 1207, Patient, Prostatectomy.
- *"I guess I always thought because I had a close friend of mine that had prostate cancer and he had surgery that I always thought in the back of my mind that that was the option I would take."* Participant 1138, Patient, Prostatectomy.

The influence of the external circumstances

- *"The biggest difficulty for me is that my wife hasn't been available for me… The problem was I got diagnosed at a time when my wife is out of the country, she's working overseas… The biggest problem I have in dealing with the whole thing is not the condition itself, but how I was going to let my wife know about it"* Participant 1021, Patient, AS.
- *"[If] they told me that there wouldn't be really any side effects to the surgery I would have had it taken out already…At my age I can't, I can't live with the incontinence… I'm working and I just can't live with it."* Participant 1010, Patient, AS.

Disclosure to wider social networks: friends, family, co-workers

Disclosing can increase support and normalise the situation
- *"Then when you find out how many people are indeed experiencing the same thing… then it becomes a big support network and I think that's extremely helpful as well because you, you each share information as you learn new things, because you can't obviously catch everything that's out there in the world and… now you're getting your friends letting you know, hey, do you know about this? Have you heard about that?"* Participant 1008, Patient, AS.

Disclosing isn't always seen as necessary
- *"I internalized a lot of it. That's just the way that I am. I don't like to worry [people], even as close as my wife and my children. I initially just kept it from them to be honest with you. I mean I let my wife know right out of the gate. I think I called her as soon as I got into the parking lot. But for example, my mother to this day doesn't know. She's just elderly and she has some health issues herself… I don't feel that it's necessary for her to even know about it at this point… I really didn't tell a lot of people before my wife initially and that's just the way that I function, I guess. I try to resolve things. I don't like to worry other people until I know exactly what's going on."* Participant 1127, Patient, AS.

The importance of a good relationship and experience with physicians

Positive experiences increase confidence
- *"He comes across as very confident, competent, knowledgeable, and just makes me—gave me a confidence level that for now I don't need to worry. See you in six months."* Participant 1002, Patient, AS.

Negative experiences cause stress and anxiety
• *"I felt that initially out of the gate at the initial urologist I was not given any information whatsoever. And that added to a lot of my stress. I can understand why some people may not want to know. To be honest with you, I understand it, but that's not how I--that's not my process."* Participant 1127, Patient, AS.
Seeking a second opinion can assist decision-making
• *"I have a lot of friends that went through different types of cancer, not only prostate cancer, but also other kinds of cancer. So obviously you're familiar with the facility. You're familiar with their reputation. You're getting word of mouth as far as the quality and it is where you want to be. I feel confident going there."* Participant 1127, Patient, AS.
Learning about PCa and treatments
Learning about PCa and treatments is essential, but sometimes overwhelming
• *"I felt there was enough information out there. And at times, there's almost too much information. Okay, I know what I know. And there always seems to be another piece of information you can find. And at some point, you just have to cut the turmoil and say, I'm going to make a decision on what I know… Sometimes it's too much. Sometimes it absolutely can be too much information."* Participant 1034, Patient, Prostatectomy.
Information sources used
• *"I didn't want to read the nonsense and the noise that would be on the Internet. I tried to find good articles and good data to help me make the decision."* Participant 1245, Patient, Prostatectomy.
• *"Well there's just so much news out there. There's been so many, you know, famous people what have had it, um, that, you know, immediately I went on the web and started reading about, you know, their stories."* Participant 1014, Patient, AS.
Weighing up the risks and benefits of the treatment options
Avoiding the side effects of definitive treatments
• *"That was really the main concern about why I'm leaning towards active surveillance right now, because I'm 55 years old, I'm young – in my mind I'm young – and things are fine physically, so why should I – why do I risk complications when nothing's really a problem right now"* Participant 1021, Patient, AS.
Making a treatment decision can take time
• *"There are so many options, and it's almost like there are too many options. I almost wish it was more cut and dry, and the doctor would say this is the way to do it, and this is the best way, the only way, and you have to do it now. Um, the fact that there are so many options and so many opinions, and that you have time… it gets very confusing."* Participant 2017, Partner.
Strong desire to remove or treat the cancer
• *"I thought that the term active surveillance was kind of marketing bullshit, frankly. Let's, let's sit and wait and hope nothing bad happens. And, and I guess that's a philosophy that I can't ever embrace. For me, it was like saying, oh, I have a hole in my roof. Let's not repair it now. Let's repair it in ten years and hope it doesn't get any worse. That's not, that's not who I am."* Participant 1348, Patient, Prostatectomy.

3.6 Discussion

This study aimed to investigate patients' and partners' perceived influences on treatment decision-making after a low risk, localised PCa diagnosis. Patients and partners discussed a range of influences, particularly social influences, on treatment decision-making. Immediately after diagnosis participants relied strongly on the opinions of medical professionals to drive their treatment choice. However, participants' treatment preference was also influenced by prior knowledge and vicarious experiences of PCa journeys. Whilst patients ultimately made their own treatment decision, both patients and partners acknowledged the importance of discussing the options and gaining support for the chosen treatment from each other. However, many partners in the study expressed disappointment

or dissatisfaction with the patient's choice of treatment. These findings have implications for medical professionals regarding communicating with patients and partners after diagnosis and during the treatment decision-making phase.

Healthcare and health promotion has been criticised for focusing largely on influencing factors related to the individual, while ignoring contextual factors that can influence health and health-related behaviours (Golden & Earp, 2012). We therefore utilised the social-ecological model (SEM) to assist in contextualising our results across the various levels outlined by the SEM (Bronfenbrenner, 1979). Our study showed participants were strongly influenced by personal (pre-existing knowledge of PCa treatments and preferences), interpersonal (vicarious experiences of PCa, partner support and treatment preferences, relationship/experiences with physicians) and community/organisational factors (physician expertise and [cancer centre] reputation). Some of these factors have been previously identified in the literature. For instance, the process of information-seeking and weighing the benefits/consequences of AS versus definitive treatments has been previously described (Kinsella, Stattin, et al., 2018). Research has similarly established that physicians' attitudes towards AS, the level of trust forged with the patient, and the amount of information they provide are considered influential by patients when making their PCa treatment decision (Kinsella, Stattin, et al., 2018). In our study, patients and partners emphasised that trust and the quality of their relationship with physicians was essential for confidence in treatment recommendations and their treatment choice. Participants were particularly satisfied with their physicians when they openly disclosed biases regarding particular treatments, provided clear and thorough information, were well-informed of recent research, listened to the preferences and worries of the patient, provided ample appointment time, offered reassurance and compassion, and conducted further testing where appropriate. Physician attitude towards AS and their comfortability in managing patients who are delaying treatment until further disease progression occurs, has likely improved significantly since the AUA updated their treatment guidelines in 2017 (Sanda et al., 2018). Since the early 2000's, AS uptake has steadily increased as it becomes a more refined protocol (Kinsella, Helleman, et al., 2018). For instance, uptake of AS in the United States between 1990-2010 was approximately 10%, and increased to 40%

by 2013 (Cooperberg & Carroll, 2015). Given the AUA treatment guidelines were again updated in 2017, it is not surprising that 75% of patients in the present study selected AS for their treatment. Participants in the present study may have been further influenced by the reputation of [cancer centre], given it is considered to specialise in AS management.

Another example of influential interpersonal factors was vicarious experiences of PCa, whether direct (e.g., family member or friend) or indirect (e.g., co-workers and celebrities), which helped participants learn about possible treatment outcomes. Participants usually eliminated treatment options if they heard several negative experiences with a treatment, whether or not it was relevant to their own situation and clinical factors. Participants who knew of others on AS whose cancer had progressed before definitive treatment was performed were considerably more sceptical of its safety. The influence of this interpersonal factor has been previously identified (Xu et al., 2011); however, our study also found participants were similarly influenced towards treatments by positive vicarious experiences. Influence from celebrity experiences with PCa and treatments was also identified. Research has demonstrated that celebrity endorsement of cancer screening can increase the likelihood of participation – one study found that in a sample of 87 men aged 50+ who had been exposed to a celebrity endorsement of PSA testing, 31% of participants reported they were now more likely to undergo PSA testing (Larson et al., 2005). Whilst caution is needed, it may be beneficial for PCa public health messaging to harness the effects of such interpersonal influences, by including stories from celebrities and other public figures when disseminating information on PCa. Furthermore, it is important that physicians providing treatment recommendations and information are aware of the interaction and effect such factors can have on treatment preferences. Providing clear, tailored, and evidence-based information, and exploring the patient's reasons for their choice of treatment may help physicians uncover and counter any unhelpful biases or misconceptions. This aligns with recommendations for medical professionals to utilise a shared decision-making care model (Kane et al., 2014), which urges patients and health professionals to engage in mutual sharing of information, preferences, and needs (Kane et al., 2014). The utilisation of this model has been strongly recommended by oncology researchers as part of patient-cantered care. Its use can result in increased

patient confidence in treatment decisions, satisfaction with treatment, and trust in providers (Kane et al., 2014).

On another interpersonal level, the experience of partners in the decision-making context was also explored. Some partners in the study expressed dissatisfaction with the patient's choice of treatment, particularly when the patient had chosen AS. Given patients desired and placed significant importance in having their partner support their treatment choice, further research into partners' treatment preferences will assist understanding how to best communicate information and provide support to both in the dyad. Little research has investigated partner's treatment preferences after a PCa diagnosis, though prior research and the present study suggest partners often favour curative treatments over AS (Couper et al., 2006; Reamer et al., 2017; Srirangam et al., 2003). Whilst partners were generally understanding of the patient's final decision no matter their choice of treatment, some expressed feelings of anxiety and worry about the patient's health and safety on AS. Partners of men with PCa often report significant levels of anxiety and depression, and research even suggests that partners may experience more psychological distress compared to the patient (Chambers et al., 2013; Couper et al., 2006; Resendes & McCorkle, 2009). However, much of this research occurred prior to the 2017 AUA recommendations for AS as the best-available treatment option for low-risk patients. Given AS recommendations and uptake rates have since increased, further investigation on spousal psychological distress is required. In particular, research which explores treatment preference disagreements and how this is navigated by the couple and their physicians is required. Again, the utilisation of a shared decision-making model, considering *both* patient and their partner's views and preferences, is recommended.

In light of these findings, some limitations should be considered. This study was originally intended to investigate both partner and close ally experiences, as little research has explored the involvement and influence on treatment decision-making of non-romantic close allies in men diagnosed with PCa. Unfortunately, we were unable to recruit close allies to this study. Furthermore, no individuals in non-heterosexual relationships choose to participate in this study. Understanding the influence of close

allies and exploring the experiences of non-heterosexual individuals are critical areas for future research. An additional limitation is that this was a single-site study, and many participants had the same treating physician (almost 30% of patients shared the same physician, with the remaining patients spread across an additional six physicians). All physicians involved were urologists. Notably, no patients involved in the interviews chose radiotherapy as their treatment, despite this being one of the treatment types generally discussed and recommended as a curative treatment approach. Lastly, participants were predominantly Caucasian and were highly educated, and therefore results may not be reflective of patients with lower social-economic status and minority ethnicities. Research has suggested that compared to Caucasian men, African American men have higher PCa incidence (particularly with higher grades/stages), have higher PCa mortality rates, and have differences in treatment preferences/choice (Badal et al., 2020; Desantis et al., 2016; Kan et al., 2018).

Treatment decision-making in PCa, especially when patients are diagnosed with low risk, localised PCa, can be a complex process, as often patients and their partners are faced with several treatment options and no clear 'right' answer. Our study highlights that treatment preferences were influenced by pre-existing knowledge of vicarious experiences of PCa via friends, co-workers, and public figures in the media, as well as by physician recommendations. Treatment decision-making appears to become far more complex when patients and partners are exposed to either positive or negative vicarious experiences, and when there are disagreements between patient and partner about the preferred treatment. These results align with the SEM, which suggests decision-making, and behaviour, is influenced by the interaction of personal, interpersonal, community and policy/society factors (Bronfenbrenner, 1979). In practice, physicians should be aware of these interacting factors and employ a shared decision-making care model. Specifically, physicians should discuss with their patients (and partner/close ally) the various treatment option, seek to understand their treatment preferences, and address any existing biases and misconceptions, whilst ensuring they provide evidence-based, tailored information and recommendations.

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4 CHAPTER FOUR:

A SYSTEMATIC REVIEW OF THE UNMET SUPPORTIVE CARE NEEDS OF MEN

ON ACTIVE SURVEILLANCE FOR PROSTATE CANCER

4.1 Statement of Authorship

Title of paper	A systematic review of the unmet supportive care needs of men on active surveillance for prostate cancer.
Publication status	Published in Psycho-Oncology
Publication details	McIntosh M, Opozda MJ, Evans H, Finlay A, Galvão DA, Chambers SK, Short, CE. A systematic review of the unmet supportive care needs of men on active surveillance for prostate cancer. Psycho-oncology. 2019;28(12):2307–22.

Principal Author

Name	Megan McIntosh
Contribution to paper	Developed protocol, conducted searches and paper retrieval, appraised extracted literature, wrote and revised manuscript as per co-author and review feedback, acted as corresponding author.
Overall percentage (%)	80%
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.
Signature and date	
	10/11/2021

Co-Authors

By signing the Statement of Authorship, each co-author certifies that:

- The candidate's stated contribution to the publication is accurate (as detailed above);
- Permission is granted for the candidate to include the publication in the thesis; and
- The sum of all co-author contributions is equal to 100%, less the candidate's stated contribution.

Co-author name	Camille E Short
Contribution to paper	Provided guidance, assistance, and critical feedback throughout all stages of this research.
Signature and date	24/08/2021

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Contribution to paper   Assisted in quality appraisal and provided critical feedback on
                                  manuscript.

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A systematic review of the unmet supportive care needs of men on active surveillance for prostate cancer

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4.2 Abstract

Objective: Understanding the unmet supportive care needs of men on active surveillance for prostate cancer may enable researchers and health professionals to better support men and prevent discontinuation when there is no evidence of disease progression. This review aimed to identify the specific unmet supportive care needs of men on active surveillance.

Methods: A systematic review following PRISMA guidelines was conducted. Databases (Pubmed, Embase, PsycINFO, and CINAHL) were searched to identify qualitative and/or quantitative studies which reported unmet needs specific to men on active surveillance. Quality appraisals were conducted before results were narratively synthesised.

Results: Of the 3,613 unique records identified, only eight articles were eligible (five qualitative and three cross-sectional studies). Unmet Informational, Emotional/Psychological, Social, and 'Other' needs were identified. Only three studies had a primary aim of investigating unmet supportive care needs. Small active surveillance samples, use of non-validated measures, and minimal reporting of author reflexivity in qualitative studies were the main quality issues identified.

Conclusions: The unmet needs of men on active surveillance is an under-researched area. Preliminary evidence suggests the information available and provided to men during active surveillance is perceived as inadequate and inconsistent. Men may also be experiencing unmet psychological/emotional, social, and other needs; however, further representative, high-quality research is required to understand the magnitude of this issue. Reporting results specific to treatment type and utilising relevant theories/models (such as the social ecological model) is recommended to ensure factors which may facilitate unmet needs are appropriately considered and reported.

4.3 Background

Prostate cancer (PCa) is one of the most prevalent cancers in men worldwide[1,2]. The majority of men diagnosed with PCa are classified as having localised, low-to-intermediate risk disease, and receive active treatment immediately upon diagnosis[3,4]. Active treatments for low risk PCa include radical prostatectomy and radiation, which often cause significant and ongoing side effects (including erectile, urinary, and rectal dysfunction) that can reduce quality of life[5]. Alternatively, men with low risk, localised PCa may commence active surveillance (AS). AS involves closely monitoring biological markers of the disease (through regular prostate specific antigen tests, biopsies, magnetic resonance imaging, and digital rectal examinations) until progression is detected, wherein the patient is offered curative treatments[6]. According to the American Urological Association/American Society for Radiation Oncology/American Society of Urologic Oncology, AS is recommended as the best available option for patients with very low risk PCa, and as a preferable option for patients with low risk PCa[7,8]. Research suggests that AS poses no greater threat to patient mortality or wellbeing than active treatments[9–12] when recommended and adhered to correctly. However, there is some concern men on AS experience psychological burdens[13–16], which may contribute to AS non-adherence[17]. Emerging research suggests approximately 10%-20% of men transition from AS to treatment without evidence of disease progression[18–20]. Empowering men to adhere to AS until they are medically recommended to transition to treatment requires consideration of their unmet supportive care needs.

According to the Supportive Care Framework[21], needs that remain unmet may continue to cause the patient emotional distress or difficulty, thus negatively impacting their wellbeing[21–24]. Measures of unmet needs, such as the Supportive Care Needs Survey[25], seek to identify the extent to which support needs have been met, thereby assisting in the improvement of support, resources, and services[22]. Studies evaluating PCa supportive care needs have recently been synthesised in comprehensive reviews. These reviews suggest up to 80% of PCa survivors experience at least one unmet supportive care need[26–28], including physical needs (e.g., addressing urinary symptoms)[27], social needs (e.g., unable to participate in social activities due to side-effects)[27], and informational needs (e.g., poor

information on treatments and side effects)[28]. While these reviews are informative, they have focused predominantly on men who have received curative treatments. Given AS does not involve any immediate intervention, the unmet needs of men on AS may significantly differ from those receiving curative treatments. Therefore, a deeper review of the unmet needs reported by men on AS is warranted, as is investigation of factors that may influence or explain these unmet needs. Together, this information may assist in the development of evidence-based interventions to support men on AS.

The present study aims to systematically review the literature to (1) Identify the unmet supportive care needs experienced by men during AS; (2) Identify factors, which may predict, relate to, or influence men's unmet supportive care needs during AS; and (3) Identify gaps in the literature and assess the quality of available evidence.

4.4   Methods

This systematic review has been conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[29]. The review protocol was registered a priori with PROSPERO (ID # CRD42018097177).

4.4.1   Eligibility criteria

Studies which met the following pre-determined criteria were included for review: (1) sample included men currently on AS for PCa and reported results specific to those men; (2) explored unmet supportive care needs of men on AS; (3) available in English; and (4) original research utilising a qualitative and/or quantitative design. Grey literature (e.g., dissertations, protocol papers or conference abstracts) was considered only if it met the above criteria and final results were available. Studies which reported men as being on 'watchful waiting' (WW) were considered as this term is often confused and used interchangeably with AS in the literature. However, such studies were only included if the participants were actually on AS rather than WW. This was established either by

contacting study authors or when the provided definition of WW actually reflected AS (e.g., 'deferred' or 'delayed' treatment). Although very similar to AS, WW is often reserved for men with limited life expectancy (≤5 years), as the aim is to monitor and manage the disease, rather than monitor with curative intent [7,9]. Studies were excluded if they: (1) explored supportive care needs of men deciding whether to commence either AS or curative treatment, and/or (2) if the sample of men on AS also included men with metastatic disease, high-risk disease, or those whose treatment information was not available, and the AS-related results were not reported separately. Additionally, studies which only reported on quality of life or those that compared patient outcomes (e.g., urinary symptoms, anxiety) across treatment types were excluded as such measures only identify the prevalence or existence of an issue, rather than whether these issues are being adequately addressed.

4.4.2 Operational definition of unmet supportive care needs

The Supportive Care Framework[21] was utilised to operationalise the unmet supportive care needs domains investigated. The framework identifies six domains of need: physical, informational, emotional/psychological, social, spiritual, and practical. Systematic reviews on the supportive care needs of cancer survivors have used similar justifications and definitions[22,27].

4.4.3 Search strategy

The following electronic databases were searched: PubMed, Embase, PsycINFO, and CINAHL. Boolean logic search strategies were created, piloted and refined with the assistance of a medical research librarian from The University of Adelaide. Search terms related to "prostate cancer" AND "active surveillance" AND "supportive care needs" were incorporated into a systematic search strategy tailored for Pubmed and adapted for the remaining databases (Appendix 1: Search Strategy). As there were no database headings (e.g., MeSH) for unmet supportive care needs in the included databases, related keywords and free text were included in the search. Previous systematic reviews investigating the supportive care needs of men with PCa were referred to when constructing the

search strategy[27,28]. All searches were conducted by a single author (MM) and were run from database inception to July 2018.

4.4.4 *Study selection and data extraction*

Identified articles from each database were imported and managed in Endnote. After removing duplicate records, the titles and abstracts of remaining publications were reviewed against the eligibility criteria by one author (MM; Figure 1). Full-text versions of the potentially eligible studies were then reviewed and screened against the eligibility criteria the same author (MM). Those deemed to meet eligibility criteria were then also checked for eligibility by a second reviewer (HE). There were no disagreements to resolve.

Separate qualitative and quantitative data extraction forms were developed. Each form captured the following information regarding each study: study design, aims, hypotheses, population and setting, data collection and methods, measurements, participants, raw results/author conclusions, and evidence of supportive care needs characterised by domain. The form was reviewed and revised by MM, CES and MO before being pilot tested by MM on one quantitative and two qualitative articles (one of which was included in the review) and adjusted where necessary. Data from all included studies were then extracted by one author (MM).

4.4.5 *Quality appraisal*

Quality appraisal of the included literature was conducted using the Joanna Briggs Institute (JBI) checklists for prevalence and qualitative studies[30,31]. The appraisals were conducted independently by two researchers (MM and AF), and discrepancies were resolved by consensus with a third reviewer (CES).

4.4.6   Data synthesis

This review utilised thematic synthesis to analyse and report the results. Thematic synthesis involves three key stages: (1) line-by-line coding of primary study results; (2) organisation of codes into descriptive themes; and (3) development of analytical themes[32]. Results from each of the included studies were organised under the relevant supportive care need domain and then subsequently analysed to identify the key themes.

4.5   Results

4.5.1   Study selection & characteristics

The searches identified 3,613 unique records, of which 3,574 were excluded after reviewing titles and abstracts (Figure 1). Of the remaining 39 studies, eight met eligibility criteria and were included for review: five qualitative studies[33–37] and three cross-sectional studies[38–40]. Study characteristics can be found in Table 1. Three studies were from the United States[33,34,40], two from Canada[36,38], and one each from the United Kingdom[35], Sweden[39] and Australia[37]. Sample sizes of AS patients in cross-sectional studies ranged from three to 431 (M=169, SD=229.6), and in qualitative studies ranged from four to 37 (M=20.8, SD=11.2). The majority of studies (5/8) recruited men via their treating physicians. While one study[40] reported their patients were on WW, this was included as the authors' definition of AS ("deferred treatment") appeared to more closely reflect AS.

4.5.2   Quality appraisal

Only three of the studies included had a primary aim of investigating unmet supportive care needs[33,34,40], and only two of these looked specifically at AS patients[33,34]. A detailed summary of the quality appraisal results can be found in Appendix 2. Whilst the overall quality of the three cross-sectional studies was good based on their primary aims, some limitations were identified in relation to our reviews aims; particularly regarding the representation of men on AS and the validity of the unmet need measures. One study[38] did not use a validated measure to assess unmet needs, and the two

others[39,40] did not assess or report the validity or reliability of their unmet needs measure. Sample size was also an issue in the cross-sectional studies. Adequate sample size was determined by both the number of men on AS in the study, and whether the study reported a sample size calculation. None of the studies reported a sample size calculation, and Boberg et al's[40] study included only n=3 men on AS in their sample.

In the five qualitative studies, congruity was consistently shown between the research methodology used and the philosophical perspective, research question, data collection method, analysis, and interpretation of results. The conclusions drawn in the studies flowed logically from the results presented. However, detail on reflexivity and researcher bias was insufficiently provided across all studies. For instance, information on the authors research experience/background and the possible effects this may have had on their analysis was rarely disclosed. Finally, two studies did not report whether saturation was reached[34,37], though the use of quotes to represent participant voices was adequate across studies. These limitations should be considered when interpreting the results.

Figure 1: PRISMA Flow Diagram
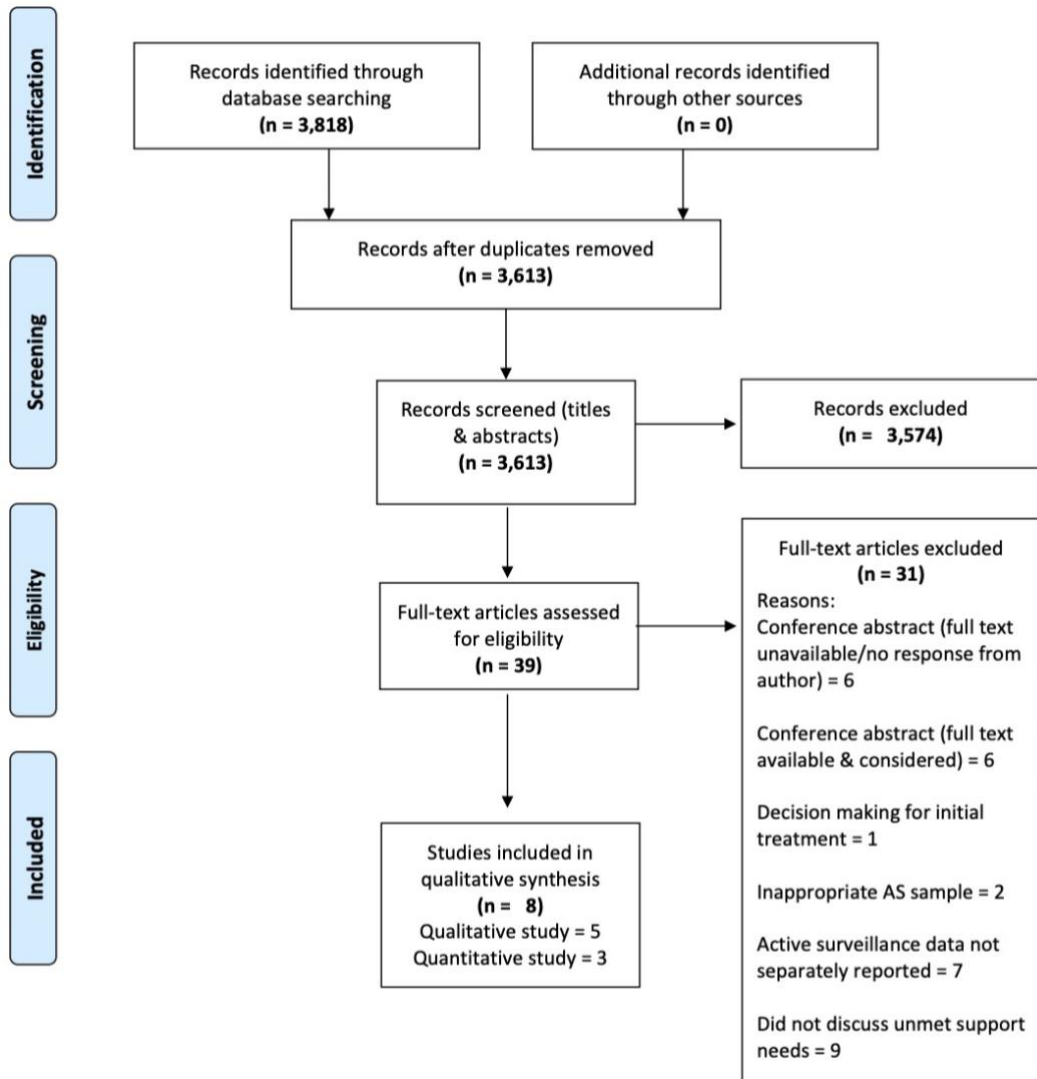
Table 1: Study Characteristics

Source (Author & Year)	Location	Sample Characteristics				Study Aims	Study Design & Method	Recruitment source & method	Data Related to Unmet Needs
		Participants	Age of men on AS (mean and/or range)	Time since diagnosis of men on AS (mean or range)	Time on AS (mean and/or range)				
Bergengren et al, 2018 [39]	Sweden	*Mixed sample* Total *N* = 1288 (PCa patients diagnosed with low risk PCa and treated with RP, RT, or AS). Total *N* on AS = 431	*M* = 64	7 years (all patients diagnosed in 2008 and surveyed in 2015)	7 years (all AS patients still on AS at time of survey).	Investigate the overall satisfaction with healthcare among men with low risk PCa across 3 treatment options (RP, RT, or AS), as well as identify possible explanatory factors for their satisfaction.	Quantitative; cross-sectional study utilising a paper-based survey.	Eligible men identified on National Prostate Cancer Register of Sweden were invited to participate via letter. Response rate = 1288/1720 (74.9%)	Survey included EPIC-26 measure and 49 study-specific questions. All results reported by treatment type (AS, RP, RT). One study-specific item related to unmet needs: "Information on treatment" with response options (a) little/no, (b) moderate, (c) substantial. Missing data for this item reported as n=16 (3.5%) for men on AS.
Boberg et al, 2003 [40]	USA	*Mixed sample* Total *N* = 204 (men treated for PCa) Total *N* on AS = 3 (note, term WW was used)	NP *Of men treated for PCa: M = 66.2*	NP *Of men treated for PCa: M = 21.2 months*	NP	Identify the needs of men diagnosed and treated for PCa, as well as assess their perceived level of importance.	Quantitative; cross-sectional study utilising a paper-based survey.	Men recruited from 3 health-care clinics. Clinic identified eligible men and were subsequently sent the survey.	Survey included 135 items (all study-specific; no validated measure) aimed to identify unmet needs and assess importance. Two items specific to AS/WW and unmet needs:

								Response rate = 233/500 (46%)	"If you chose 'watchful waiting' (deferred treatment', support dealing with fear of leaving cancer in your body", and "If you chose 'watchful waiting' (deferred treatment), support in dealing with fears of 'doing nothing for now'"
Davison et al, 2011 [38]	Canada	*AS only sample* *N* on AS = 73	≤ 60: *N* = 22 61 – 70: *N* = 37 > 70: *N* = 14	≤ 5 years since diagnosis: *N*= 64 > 5 years since diagnosis: *N* = 9	All on AS at time of survey.	Identify the role men diagnosed with PCa assume when making treatment decisions in regard to commencing AS, as well as the factors that affect this decision and the resources they desired to access while on AS.	Quantitative; cross-sectional study utilising a paper-based survey.	Treating physicians identified eligible men, who were subsequently sent the study information and survey. Response rate = 73/121 (60%).	Of the 3-part survey, only results from Part 3 ('Need for additional support during AS') were reviewed as it was specific to unmet needs. This section included 7 items and responses were recorded across a 5-point Likert scale (0=not at all, 4=a great deal).
Avery et al, 2014 [35]	U.K.	*Mixed sample* Total *N* = 89 (PCa patients, men at risk of PCa, partners, stakeholders) Total *N* on AS = 15	NP *Of men diagnosed with PCa: M = 66.5*	NP *Of men diagnosed with PCa: 7-42 months*	NP	Explore patient, partner, and stakeholder views about diet, and their motivations and barriers to dietary change in men at elevated risk, and those diagnosed with PCa.	Qualitative; Interviews with patients and partners. Focus groups with stakeholders.	Participants were purposefully sampled from sample pools of 3 different studies managed by the research team. Stakeholders	The following themes were analysed (AS specific results/quotes were made explicit when identifying unmet needs): • Perceived relationship between PCa treatment and dietary change

								were recruited from local hospitals, academic institutions, and primary care practices. Response rates were NP.	• Interest in dietary advice and information following diagnosis Interview questions were not made available.
Kazer et al, 2011 [34]	USA	*AS only sample* *N* on AS = 7	*M* = 70 years Range = 65 - 79 years	NP	NP	Explore the psychosocial and educational needs of men on AS for PCa.	Qualitative; focus groups with men on AS.	Men on AS were identified by urologists and provided with study information. Those interested contacted the research team to organise to attend a focus group. Number of men approached was NP.	All themes were analysed for this review. Themes: • Sources of support • Sources of information • Disease monitoring/vigilance • Myths, misinformation, FAQs • Health promotion and taking charge
Loeb et al, 2018 [33]	USA	*Mixed sample* Total *N* = 61 (AS patients, healthcare providers) *N* on AS = 37	*M* = 66 Range = 48 - 84	NP	NP	Explore perceptions of existing information sources and identify recommendations for additional resources (particularly those which utilise	Qualitative; focus groups with men on AS, semi-structured interviews with healthcare providers.	Men on AS were identified via electronic records at 2 clinics and screened for eligibility. Those eligible were mailed an invitation to participate.	All themes were analysed: Themes: • More information on PCa • More information on AS • More information on alternative management options

					social and digital media).			*N* invitations mailed = 235 (response rate = 15.74%)	• Greater variety of resources • More social support and interaction • Verified integrity of information
Mroz et al, 2013 [36]	Canada	*AS only sample* *N* on AS = 25	*M* = 86 Range = 48 – 77	< 1 year: *N* = 13 1-2 years: *N* = 9 > 2 years: *N* = 3	All on AS at time of interview.	Explore and describe the connection between masculinity and patients' perspectives of male patient-physician communication whilst on AS for PCa.	Qualitative; semi-structured interviews.	Participants were recruited from the Vancouver Prostate Centre and the British Columbia Cancer Agency. Eligible men were invited to participate by their treating physicians. *N* invitations sent = 45 (response rate = 55.56%)	The following themes were included in analysis as they identified unmet needs: • Positioning risk in diagnosis with 'benign' cancer • Dazed and silent • The devil in the detail
O'Callaghan et al, 2014 [37]	Australia	*Mixed sample* Total *N* = 35 (men diagnosed with PCa, partners). *N* on AS = 20 (*N* = 9 men	NP *Of whole sample:* *≤ 50: N = 1* *51-60: N = 6* *61-70: N =11*	NP	*M* = 22 months Range = 3 – 96 months	Explore patient and partner experiences of treatment decision making following PCa diagnosis and their experiences of AS when it was the recommended option.	Qualitative; semi-structured interviews.	Men were recruited via urologists. Patients were purposefully sampled according to various characteristics (ages,	The following themes were included in analysis as they identified unmet needs after the decision to commence AS was made: • Information was satisfactory, contradictory,

| | | received treatment after 3 months on AS) | *71+: N = 3* | | | | | treatment choice, time on AS, reason for ceasing AS, socio-demographic background, rural/urban dwelling).

N invitations sent = 85 (response rate = 41.18%).

An unspecified number of invitations were sent out after initial data collection to men with 'less evident' characteristics. | stressful, and/or misunderstood
• AS stressors encompass illness uncertainty, monitoring stressors, and inconsistent information |

Abbreviations: PCa = Prostate cancer; AS = Active surveillance**;** WW = Watchful waiting**;** RP = Radical prostatectomy**;** RT = Radiotherapy**;** NP = Not provided.

4.5.3   Unmet supportive care needs of men on active surveillance

Unmet needs were identified in the following domains: informational, emotional/psychological, social, and 'other'. These needs are discussed in turn below.

4.5.3.1   Informational

Seven of the reviewed studies (two cross sectional; five qualitative) identified unmet informational needs[33–39]. Thematic analysis revealed two key themes, which explored to men's unmet informational needs; (1) existing information was inadequate, and (2) existing information was inconsistent and confusing.

4.5.3.2   Existing information available/provided to men on active surveillance is inadequate.

Unmet information needs were commonly attributed to inadequate information being provided or available to men on AS. Information on PCa, signs of progression, future treatment options, and adjuvant treatments (such as diet and exercise) were reported as inadequately provided by the treating physicians and/or unavailable to patients[33–37]. For instance, one man in Loeb et al's study explained he wanted to "*know what progresses the cancer*" as he currently felt "*ignorant about the whole thing*"[33]. Several participants in the qualitative studies also reported that information regarding AS was too limited[33,34,36,37]. Loeb et al[33] noted men often needed more information regarding the follow-up protocol, such as the ideal frequency and reason for performing tests. Mróz et al[36] suspected several men in their study had utilised the interviews to get information on AS. Additionally, several men in Kazer et al's[34] study felt information on AS was difficult to find, as one explained; "*when I was in my peak of information seeking, I couldn't find information about [active surveillance]; I could not [find] anything meaningful*". This suggests existing information may be perceived as inadequate in regard to both quantity and quality.

Inadequate information was also discussed in two of the cross-sectional studies [38,39]. Bergengren et al[39] reported that 26.1% of the men on AS (*N* = 431) reported receiving little to no information regarding their treatment options. Similarly, Davison and Goldenberg[38](N =73) found 55% of men on AS reported a great deal of unmet need on information about future treatment options. In addition, 27% of participants reported a great deal of unmet need on receiving information on non-traditional treatment options, and 26% reported a great deal of unmet need in relation to receiving information on eating a 'prostate-friendly diet'[38].

4.5.3.3   Existing information available to men on active surveillance is confusing & inconsistent.

Participants in four qualitative studies reported that information on PCa and AS was contradictory, confusing, overwhelming, and inconsistent[33,34,36,37]. Those in Loeb et al's[33] study were often confused by their prognosis and the purpose/results of tests. One man stated, "*there's a lot of jargon, and it's putting all the pieces together. Remembering what the Gleason score is. All I remember is that it exists and higher is bad*"[33]. In Mróz et al's[36] study, lack of specificity regarding their prognosis resulted in confusion and sometimes left men wondering if they actually had cancer. Confusion was also reported by patients on the difference between AS and watchful waiting[33,36]. Both the researchers and participants attributed this confusion to the inconsistency of information, especially those from differing sources. For example, men in Loeb et al's[33] investigation suggested the most trustworthy websites were those sponsored by their urologists' clinic/hospital, as they believed these might more closely align with their doctor's views and advice; "*it's more likely that your doctor will be aware of what's on that website and in a better position to respond to questions from that website as opposed to just the popular press in general*"[33]. Men in Mroz et al's[36] study also reported that inconsistent information and recommendations "*was not only confusing it was stressful*", suggesting unmet informational needs may have led to additional unmet emotional/psychological needs.

4.5.4 Emotional/Psychological

One qualitative study discussed men's unmet emotional and psychological needs whilst on AS[37]. O'Callaghan et al[37] found that a lack of emotional support coupled with unmet informational needs appeared to contribute to feelings of depression, irritability, anxiety, fear, worry, embarrassment, and stress in men on AS[37]. For instance, one man summed up his AS experience as "*death, dying*", awaking some mornings "*really depressed*"[37].

Two of the quantitative studies explored unmet psychological/emotional needs[38,40]. In Boberg et al's[40] study (*N*=3), some need was reported for support dealing with fears associated with AS. Specifically, these men rated their level of unmet need and perceived importance on a Likert scale (0-10) for two items. Results showed that for receiving support to deal with the fear of leaving cancer in the body, the level of unmet need was rated 4.3/10, and the level of importance was rated 7.8/10. The second item measured unmet needs and importance for support to deal with fears of 'doing nothing' for now to treat their cancer (unmet need = 4.2/10; importance = 7.5/10). Davison and Goldenberg's[38] survey (*N* = 73) reported that 49.3% of men in their study reported some unmet need (from very little to a great deal) regarding accessing web-based anonymous support groups for men on AS. Additionally, 50.7% reported some need for separate support groups for men on AS[38]. In relation to factors which may influence unmet needs, Davison and Goldenberg[38] found that compared to men with none or little anxiety symptoms, men experiencing greater anxiety reported that having adequate access to formal and informal support from other men on AS and receiving adequate information on future treatment options, was important for them (all *p* < 0.05).

4.5.5 Social

One quantitative study reported unmet social needs. Davison and Goldenberg[38] (*N* = 73) found that 59% of men had some level (very little to a great deal) of unmet need to socialise with other men on AS . However, only 4% reported a great deal of need in this area. This suggests that whilst this unmet need may not be strongly endorsed; socialising with other men on AS is certainly desired by some.

4.5.6   Other

Two studies identified unmet needs in relation to strategies for self-managing health. In Kazer et al's[34] qualitative study, one man expressed a need for a monitoring tool specially for tracking his PSA results. The authors proposed that by implementing disease-self management strategies, men's self-efficacy over their treatment may be enhanced. Davison and Goldenberg[38] ($N = 73$) identified that 20.8% of men strongly desired to participate in exercise programs for men on AS. It was not reported whether the men were currently exercising or if programs were offered.

4.6   Discussion

The aim of this systematic review was to identify and summarise the unmet supportive care needs of men on AS, identify factors that may contribute to unmet needs, and highlight the research gaps of this area. Of the 3,613 studies identified, only eight explored men's unmet needs during AS, reflecting the infancy of this area of research. This preliminary evidence suggests men on AS may have a variety of unmet needs, particularly informational. However, these findings are largely based on qualitative work that is not intended for generalisation. Further, no cross-sectional study explored unmet needs utilising a supportive care framework, well-validated measures, or unmet needs over time, therefore limiting the findings. Lastly, none of the cross-sectional studies included a control group, and none utilised a mixed methods approach within a single study, which would better facilitate triangulation of the data[41]. Consequently, the magnitude of the issue of unmet needs in AS is unknown, and further research utilising large, representative samples is required to measure prevalence. Many of these issues have also been identified in previous systematic reviews of unmet needs in PCa[27,28] patients who have undergone treatment. Understanding men's unmet needs during AS may assist researchers and health professionals in empowering men to adhere until treatment is medically necessary. With approximately 10-20% of men who begin AS discontinuing without disease progression[18–20], interventions that considers men's experiences and unmet needs are required.

Due to the limited research exploring the unmet needs of men on AS, identifying the factors that may be contributing to onset of these needs is difficult. Further investigation of these factors may best be done utilising a theoretical model, such as the social ecological model (SEM)[42]. The SEM is often adapted for use in health research to facilitate the exploration of how human behaviour and experience is influenced by the interaction of personal, social, community, and societal/policy levels (see Figure 2). The SEM has been used in the cancer context previously, for instance, to identify predictors of screening for PCa in African-American men[43,44] and to identify correlates of social-ecological factors and unmet needs in gynaecological cancer survivors[45]. In this context, we can use the SEM to hypothesise factors outside the biomedical area which may contribute to the identified unmet needs for men on AS, such as social or community factors, which may be essential given men on AS spend little time in-hospital or at clinics receiving cancer care. In doing so we can simultaneously summarise the available literature and identify research gaps.

Figure Two: Social-ecological model of the interactive factors which may influence the unmet supportive care needs of men on AS, adapted from Bronfrenbrenner[42].
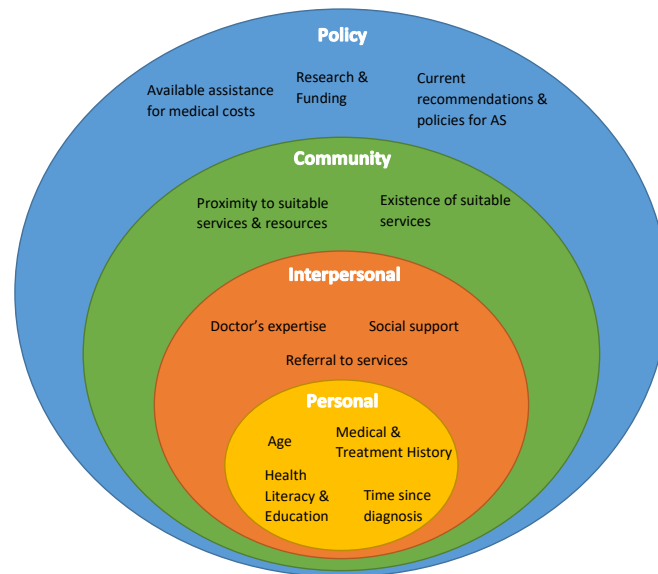
In this model, the outer level is composed of policy factors, such as current AS recommendations proposed by research and organisations (e.g., PRIAS[7]), research funding from industry, and government bodies that determine what assistance is available for medical costs, and services available with respect to socio-economic status. The community level includes existence of and access to suitable services that address key unmet needs, such as allied health professionals (e.g., psychologists, exercise physiologists), support groups, medical specialists (e.g., prostate cancer nurse), and so on. The interpersonal level comprises of factors which are influenced by our social relationships. For men on AS, this may be their urologists and other medical professionals, and their family/friends. Finally, personal factors may include age, medical history, income, time since diagnosis, education, and other lifestyle or individual factors (e.g., experiencing unrelated significant events). Importantly, these factors can interact to influence each other.

According to the reviewed literature in our study, unmet informational needs appear to be the most reported need in men on AS. This unmet need was discussed in seven of the eight studies included in our review (two cross-sectional, five qualitative)[33–39]. We identified two major themes within this domain; (1) Existing information is inadequate, and (2) Existing information is confusing/inconsistent. Information regarding PCa, AS, treatment options, and healthcare recommendations was perceived as confusing, inconsistent between providers/resources, and/or inadequately available or provided to men. Similar informational needs were also reported as unmet in systematic reviews for PCa survivors across treatments[27,28], and in a recent mixed-methods paper investigating psychological impact of AS[46].

These unmet informational needs may occur for a variety of reasons, which can be categorised according to the SEM. For instance, personal factors such as health literacy may influence a patient's ability to seek out and understand information regarding AS from various resources. If the information is perceived as confusing or inadequate, this may contribute to unmet informational needs if not properly addressed. Research has suggested PCa patients may find it difficult to locate high quality information online, due to both their ability to search for the information and the lack of gold-standard information being readily available[47]. Interpersonal factors, such as their doctor's expertise, and community factors such as the availability of resources/services, may further contribute unmet informational needs. Finally, unmet informational needs may be influenced by policy-level factors such as the inherent uncertainty regarding the most suitable cancer grade for AS. Whilst AS is generally recommended for men with low risk, localised disease, there is often no clear consensus, and therefore the adoption and practice of AS varies greatly across countries and urological communities[48].

Unmet emotional/psychological needs were reflected in men's fears/worries associated with cancer, feelings of uncertainty in relation to AS and unmet information needs, and the accessibility of appropriate support groups/resources specific to men on AS[37,38,40]. While research comparing men on AS to men who have received curative PCa treatment generally show that depression and anxiety are comparable and scores decrease over time, recent research suggests anxiety may be higher in men on AS[49]. In line with this recent research, the present analysis suggests some men may be inadequately supported psychologically/emotionally. Addressing unmet emotional/psychological needs again will require the consideration of the social-ecological factors which may contribute, including personal factors (e.g., pre-existing health issues) and community factors such as the existence and availability of appropriate support (e.g., support groups for AS).

Lastly, unmet social and 'other' needs were identified in our review. Social needs included a desire for socialisation with other men on AS[50]. Other needs included a desire for exercise programmes and

cancer tracking tools[34,38]. Again, these unmet needs may exist due a combination of social-ecological factors, such as community (i.e., existence/access to support groups and exercise programmes) and social (i.e., relationships with family/loved ones). However, limited evidence for these unmet needs was found and therefore the magnitude of the issue is uncertain. Further exploration into exercise programmes is particularly recommended given the increasing evidence that exercise may slow PCa progression[51,52], the majority of men with PCa are inactive[53], and exercise may assist in supporting men physically, psychologically, and socially[54]. Evidence suggests men on AS would be interested in receiving exercise-based support[55]. Such programmes are currently being researched[56], but are not yet widely available.

Other systematic reviews of unmet needs in PCa identified a number of social, physical, spiritual, and practical needs which were not investigated or identified by the studies in our review[27,28]. Furthermore, a study investigating the unmet psychosexual needs of PCa patients found that the men on WW (n=4) experienced unmet psychosexual needs (e.g., healthcare providers discussing sexual health) and unmet social needs (e.g., support available for partners/family)[57]. It is unclear the extent to which unmet needs on AS and WW are similar, though given the similarities in treatment method consideration of these unmet needs should be given to these findings. In addition, social-ecological factors found to influence unmet supportive care needs in cancer survivors also require consideration. For instance, evidence suggest poor social support[22], time since diagnosis[58], rural locality[22], time since the last clinical appointment[22] and experiencing unrelated significant/distressing events[59] may predict greater unmet needs in cancer patients' post-treatment.

4.6.1 Clinical implications

It is clear from our review that further research into the unmet needs of men on AS is required to both identify the magnitude of the issue and to investigate whether the hypothesised factors influence men's unmet needs. We recommend future research in this area do so utilising a theoretical model (such as the SEM) a priori, to ensure factors outside the biomedical area considered and

contextualised effectually. Meanwhile, it is essential health care professionals ensure they provide clear evidence-based information to their patients on AS. Furthermore, healthcare professionals must re-check patient needs and provide referrals to allied health services where possible, to ensure needs outside of their area of expertise are addressed. This is especially important as research suggests it is common to overlook referrals to allied health services during cancer care. For instance, less than 20% of men with PCa are referred to exercise physiologists/specialists[60,61]. On a larger scale, it may be beneficial for prostate and/or cancer registries, hospitals, and other large health services to include patient-reported outcome measures, including unmet supportive care needs and psychological wellbeing. Some registries and large trials have already incorporated measures to assess psychological wellbeing (ProtecT study[62]) and health-related quality of life (PCOR-ANZ[63]). However, the measurement of unmet needs in particular is recommended both to assist health professionals to address these unmet needs, and to assist researchers and policy-makers by gathering representative data which can be used in the development of multidisciplinary, comprehensive interventions.

4.6.2   *Study strengths and limitations*

This review has strengths and weakness that should be considered when reflecting on the findings. Whilst other systematic reviews have summarised the unmet needs of PCa patients, this is the first to specifically focus on the particular needs of men on AS. Understanding the unique challenges and needs of this group is likely to be important for minimising overtreatment, promoting adherence, and optimising wellbeing. Our systematic review aligned with the PRISMA[29] guidelines, recommend future research directions utilising an established theoretical model[42], and has made suggestions for enhancing current practice for health professionals managing men on AS. The review was registered a priori, involved several reviewers to screen and analyse the data, and utilised standardised quality assessment tools. However, our findings were limited due to the nature of available evidence and that many studies did not report findings specific to men on AS despite including them in their sample. Future research would benefit from separately examining the experiences and needs of men undergoing different PCa treatments, in order to better tailor recommendations and support.

4.6.3 Conclusions

While the unmet needs of men on AS are still somewhat unclear, preliminary evidence suggests the information available and provided to men during AS is often perceived as inadequate and inconsistent. Men may also be experiencing unmet psychological/emotional, social, and other needs during AS. To address current knowledge gaps, it is recommended that unmet needs among men on AS are explored in a representative sample using a validated measure, and that possible determinants of unmet needs be assessed and explored in line with the SEM. Based on currently available evidence, the provision of clear, consistent, and comprehensive information provided to men on AS is encouraged to address unmet informational needs.

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5 CHAPTER FIVE:

MEN'S UNMET SUPPORTIVE CARE NEEDS DURING ACTIVE SURVEILLANCE: A MIXED METHODS INVESTIGATION

5.1 Statement of Authorship

Title of paper	A mixed methods investigation of unmet needs and psychological wellbeing during active surveillance for prostate cancer
Publication status	Submitted to Supportive Care in Cancer
Publication details	Submitted as: McIntosh M, Short CE, O'Callaghan M, Vincent AD, Galvão DA, Opozda MJ. A mixed methods investigation of unmet needs and psychological wellbeing during active surveillance for prostate cancer. Supportive Care in Cancer. 2021 (under review)

<u>Principal Author</u>

Name	Megan McIntosh
Contribution to paper	Developed protocol, conducted data collection and analysis, wrote and revised manuscript as per co-author and reviewer feedback, acted as corresponding author.
Overall percentage (%)	80%
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.
Signature and date	10/11/2021

By signing the Statement of Authorship, each co-author certifies that:

The candidate's stated contribution to the publication is accurate (as detailed above);

Permission is granted for the candidate to include the publication in the thesis; and

The sum of all co-author contributions is equal to 100%, less the candidate's stated contribution.

Co-author name	Camille E Short
Contribution to paper	Provided guidance, assistance, and critical feedback throughout all stages of this research.
Signature and date	24/08/2021

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Contribution to paper	Provided guidance, assistance, and critical feedback throughout all stages of this research.
Signature and date	04/11/2021

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Contribution to paper	Assisted in protocol and recruitment logistics and provided critical feedback on manuscript drafts.
Signature and date	27/10/2021

Co-author name	Andrew D Vincent
Contribution to paper	Assisted in protocol and analysis and provided critical feedback on manuscript drafts.
Signature and date	29/10/2021

Co-author name	Daniel A Galvão
Contribution to paper	Provided guidance, assistance, and critical feedback throughout all stages of this research.
Signature and date	15/09/2021

A mixed methods investigation of unmet needs and psychological wellbeing during active surveillance for prostate cancer

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5.2 Abstract:

Purpose: While prostate cancer survivors experience unmet supportive care needs (USCNs) after definitive treatments, no study has measured USCNs during active surveillance (AS). This study aimed to identify and explore the USCNs and psychological wellbeing of AS patients using both quantitative and qualitative methods.

Methods: Patients 18+ years diagnosed with prostate cancer, who had been on AS for ≥6 months, were invited to complete a survey measuring USCNs, general and prostate cancer specific anxiety, and depression. A purposefully selected subset was also interviewed to explore USCNs and how needs during AS were addressed. Semi-structured interviews were transcribed verbatim and thematically analysed.

Results: One hundred and three participants (n=47 currently on AS, n=54 on/had subsequent treatment, n=2 ceased all care) completed the survey, and 33 were also interviewed. Although most USCNs were considered low/moderate, 20% of participants reported high unmet informational needs around receiving information about monitoring and their test results. USCNs related to patient care (e.g., access to services in rural areas or after hours) and sexuality were also discussed in interviews. Anxiety, depression, and prostate cancer specific anxiety were generally very low. Fear of cancer progression/recurrence was the highest scoring prostate cancer specific worry and was frequently mentioned by interview participants.

Conclusions: While unmet needs, anxiety and depression were generally low, one in five patients during AS experience unmet needs in psychological, physical, patient care, information, and sexual domains. Health professionals should be aware of common USCNs and offer appropriate support to address potential needs.

5.3 Introduction

5.3.1 Background

Active surveillance (AS) is the recommended treatment option for people with low risk prostate cancer [1]. It involves routine surveillance of biological markers of the disease through the use of prostate specific antigen (PSA) testing, digital rectal examinations, biopsies, and magnetic-resonance imaging (MRI) [1]. Transition to treatment is recommended upon identification of disease progression that constitutes reclassification [2]. Despite these recommendations and increased use of AS worldwide [2], there is no global consensus for AS initiation criteria, best practice for surveillance/follow-up, or triggers for intervention. As such, uptake and protocols vary greatly across clinics and countries [3–5]. This lack of consistency and consensus for best practice may impact patient's experiences, needs, and adherence during AS.

Approximately 12% of patients who begin AS will discontinue without evidence of disease progression, for largely unknown reasons [6], though factors such as anxiety, fearing mortality, and pressure from family/friends may contribute [4, 7]. Approximately 4-17% and 6-8% of patients on AS report generalised anxiety and depression, which is similar to rates among those who have definitive treatment [8–10]. However, much of this research has been conducted on samples recruited from cancer centres which specialise in AS management. Research which has recruited from a wider population has indicated that patients on AS consistently report high scores on anxiety and depression measures, which may actually increase over time [11]. Fear of progression may be a particular concern, as it is commonly reported in patients on AS [12–15] and is higher in patients on AS than in those who have undergone definitive treatment [16]. Persistent fear of progression during AS and ongoing anxiety may lead patients to discontinue AS prematurely to receive definitive treatments in an attempt to gain control of their health and disease [11].

Unmet supportive care needs may also contribute to discontinuation of AS, either directly or indirectly by negatively impacting psychological wellbeing [17–19]. A recent systematic review [20]

suggests that patients on AS may experience a variety of unmet needs, most commonly related to inadequate and/or inconsistent information. However, only eight studies (five qualitative and three cross-sectional) were included in the review and the cross-sectional studies did not assess USCNs using a validated measure [20], such as the Supportive Care Needs Survey [21]. Just three of the studies had a primary aim of identifying unmet supportive care needs in patients on AS. Therefore, USCNs experienced by patients on AS, and their magnitude, are largely unknown, as is the extent of and ways in which unmet needs influence discontinuation of AS.

Understanding patient's experiences and needs during AS is essential for targeting support, to inform future research on issues faced by AS patients, and potentially improve compliance to AS management when appropriate.

5.3.2   Aims

This study aimed to measure and explore the USCNs and psychological wellbeing of patients currently or who had previously been on AS after a prostate cancer diagnosis. Both quantitative and qualitative methods will be used given the limited research to date and to allow potential identification of unmet needs not included in validated measures. Additionally, it may help us explore the methods patients have utilised to address unmet needs and which of these methods patients felt were successful.

5.4   Methodology

5.4.1   Sample

Participants were recruited as part of a larger case-control study designed to examine social-ecological factors associated with discontinuing AS [22]. The larger study, in which we had intended to recruit from multiple states in Australia, was paused due to COVID-19. Quantitative data collection

from South Australia was completed prior to COVID-19. As such, this sub-study includes cross-sectional data from the South Australian participants.

Eligible participants were identified and recruited through the South Australian Prostate Cancer Clinical Outcomes Collaborative (SA-PCCOC), which captures 90% of all diagnosed prostate cancer survivors in the state [23]. All eligible cases (individuals who had left AS and received definitive treatment without evidence of significant disease progression), and four matched controls (individuals still on active surveillance or who had received definitive treatment following adverse risk reappraisal, as clinically recommended) were invited to participate in the study (N=270) based on a sample size calculation for the main study.

Eligibility criteria for the survey were: diagnosed with prostate cancer between January 2014 and October 2019, commenced AS after diagnosis, on AS for at least six months (could still be on AS or since received further treatment), 18+ years old. Patients were deemed ineligible if insufficient registry data was available to determine their treatment(s). Participants who completed the survey and provided their contact information on the consent form were considered for interviews and were selected using purposeful sampling [24]. Predetermined selection criteria were based on responses to the survey in regard to anxiety, depression, prostate specific anxiety, USCNs, rural/regional location, and reasons for or considering AS discontinuation (see Appendix E). Ability to participate in a telephone interview in English was also required.

5.4.2   Procedure

Ethics approval was obtained from Southern Adelaide Local Health Network (HREC/19/SAC/88).

5.4.2.1   Survey

They survey could be completed on paper, online, or via phone. Following eligibility screening, two pilot tests on the survey were conducted. The first assessed survey readability. Feedback was provided

by four prostate cancer patients and two health professionals and adjustments to the survey were made accordingly. The second pilot test assessed response rate in a random sub-sample (n=32) prior to the main mail-out. Six completed surveys (18.8%) were returned. Given this low rate, changes were made in line with established methods for increasing response rates (i.e., use of a priming letter and unconditional monetary incentive) [25]. The remaining eligible participants (n=238) were mailed the priming letter and one week later, the survey package (containing information sheet, consent form, survey, reply-paid envelope, and unconditional incentive). If no response was received after two weeks, a reminder letter was mailed. Participant demographics, clinical data, and treatment information were retrieved from SA-PCCOC.

5.4.2.2   Interviews

Interviews were semi-structured and aimed to explore experiences on AS, USCNs, and psychological wellbeing (anxiety and depression) during AS (see Appendix F for interview guide). Participants were interviewed via phone, and interviews were audio recorded and transcribed verbatim. Interviews lasted on average 31 minutes (range 15-63 minutes). We invited all participants who met sampling criteria; as per Braun and Clarke's recommendations [26], thematic saturation was not considered the primary aim of recruitment.

5.4.3   Outcome measures

Validated measures (see Table 1) were used to assess USCNs, general and prostate cancer-specific anxiety, and depression. Demographic information was also assessed using standard items. Additional measures were included in the survey to assess potential predictors of adherence to AS (e.g., physical activity, coping strategies) and will be reported elsewhere.

Table 1: Survey Measures

Variable	Measure	Description and scoring
Unmet supportive care needs	Supportive Care Needs Survey – Short Form(Boyes et al., 2009).	This measure contains 34 items to assess unmet needs across five domains: Physical & Daily Living, Psychological, Health System & Information, Patient Care & Support, and Sexuality. Items are measured on a revised, validated(Schofield et al., 2012) 4-point Likert Scale, where 1=no need, 2=low need, 3= moderate need, 4=high need.
Anxiety and depression	Patient Health Questionnaire for Depression and Anxiety (Kroenke et al., 2009).	Assesses anxiety and depression using 4 items (two each for anxiety and depression), across a 4-point Likert scale (0= not at all; 5=nearly every day). Total scores in each domain of 3 or above indicate clinical threshold levels of anxiety/depression.
Prostate cancer-specific anxiety	Memorial Anxiety Scale for Prostate Cancer(Roth et al., 2003).	Includes three sub-scales (general prostate cancer anxiety, anxiety related to PSA testing, and fear of recurrence/progression), with items measured across a 5-point Likert scale (0= not at all; 5=nearly every day).

5.4.4   Analysis

5.4.4.1   Quantitative analyses

Descriptive statistics for demographics, USCNs, anxiety, depression, and prostate cancer-specific anxiety were calculated in R [27]. In analysis, USCN categories were collapsed into none/low need and moderate/high need.

5.4.4.2   Qualitative analyses

Transcripts were analysed using Braun and Clarke's reflexive thematic analysis method [26]. This involves six key steps: familiarisation, coding, creating themes, revising themes, defining themes, and writing. Authors MM and MJO independently read and coded all transcripts. Both MM and MJO have experience in qualitative research and thematic analysis. MM and MJO discussed codes, and then all transcripts were re-analysed by MM to ensure all data was considered. Themes were then created, revised, and formally defined. Finally, themes were summarised with quotes from the transcripts, and refined by all authors.

5.5 Quantitative results

5.5.1 Participants

One hundred and three participants returned a completed survey (38% response rate). Of these, forty-seven were currently on AS, and fifty-four had received further treatment. Two participants indicated they had ceased all treatment and follow-up care. Most participants were married (83%), retired (64%), had completed post-secondary education (70%), and lived in a major city (71%; Table 2).

Table 2: Participant Demographics

Demographics	All Participants (N = 103)	Qualitative Sub-sample (N=33)
Age in years: M (SD)	68.8 (6.5)	69 (6.3)
Age range: years	52-80	54-80
Treatment status at time of survey: N (%)		
Previous definitive treatment	54 (52.4%)	19 (57.6%)
Still on active surveillance	47 (45.6%)	14 (42.4%)
Ceased all treatment	2 (1.9%)	0 (0%)
Years on active surveillance: M (SD)	2.6 (1.3)	3.1 (1.5%)
Marital status: N (%)		
Single	3 (2.9%)	0 (0%)
Married/de facto/partnered	86 (83.5%)	27 (81.8%)
Divorced/separated	9 (8.7%)	4 (12.1%)
Widowed	5 (4.8%)	2 (6.1%)
Employment: N (%)		
Full time	17 (16.5%)	3 (9.1%)
Part time	12 (11.6%)	6 (18.2%)
Retired	66 (64.1%)	20 (60.6%)
Unemployed	5 (4.9%)	2 (6.1%)
*Other**	3 (2.9%)	2 (6.1%)
Highest education completed: N (%)		
Primary	3 (2.9%)	0 (0%)
Secondary	27 (26.2%)	7 (21.2%)
Vocational education/training/trade qualifications	36 (35.0%)	12 (36.4%)
University	36 (35.0%)	14 (42.4%)
Location: N (%)**		
Very remote	0 (0%)	0 (0%)
Remote	5 (4.9%)	3 (9.1%)
Outer regional	11 (10.7%)	6 (18.2%)
Inner regional	14 (13.6%)	3 (9.1%)
Major city	73 (70.9%)	21 (63.6%)

* Employment ("Other"): Participants did not indicate at which level of employment they held (full time or part time) but did indicate they were 'self-employed'.
** Location was determined by postcode and classified using the Australian Statistical Geographical Classification – Remoteness Area Framework.

5.5.2 Unmet supportive care needs

An overview of the USCNs by domain is presented in Table 3. Moderate-high unmet needs were most common in the Health System and Information domain (e.g., being given written information about care, being informed of treatment side effects, informed of tests and monitoring results, provision of information and support from hospital staff), and Sexuality domains (e.g., changes in sexual feelings, relationships, and receiving sexual health information). Over one-fifth of participants (21.6%) reported moderate-high unmet needs regarding fear of the cancer spreading (Psychological domain). Very few participants reported moderate-high unmet needs in the Physical and Daily Living and the Patient Care and Support domains. A complete summary of needs is presented in Table 4.

5.5.3 Psychological wellbeing

Anxiety, depression, and prostate-specific anxiety were minimal. Only four (3.9%) and five (4.9%) participants met clinical thresholds for anxiety and depression, respectively (Table 3).

Table 3: Scores for Anxiety, Depression and Supportive Care Needs

Measure / Domain	All Participants (N=103)		Still on Active Surveillance (N=47)		Underwent Definitive Treatment (N=54)	
	M (SD)	Range	M (SD)	Range	M (SD)	Range
Anxiety and Depression (PHQ-4)						
Anxiety	0.6 (1.1)	0 – 5	0.5 (0.9)	0 – 4	0.6 (1.2)	0 – 5
Depression	0.6 (1.1)	0 – 6	0.5 (0.9)	0 – 4	0.6 (0.3)	0 – 6
Supportive Care Needs (SCNS)						
Physical	1.2 (0.3)	1 – 2.4	1.1 (0.3)	1 – 2.4	1.2 (0.3)	1 – 2.4
Psychological	1.6 (0.6)	1 – 3.3	1.5 (0.6)	1 – 3.3	1.6 (0.6)	1 – 3.1
Sexual	1.8 (0.9)	1 – 4	1.5 (0.8)	1 – 4	1.9 (0.9)	1 – 4
Care	1.3 (0.5)	1 – 3.6	1.2 (0.4)	1 – 2.2	1.4 (0.5)	1 – 3.6
Informational	1.8 (0.9)	1 – 4	1.6 (0.8)	1 – 3.6	2.1 (0.9)	1 – 4
Prostate Cancer Anxiety (MAXPC)						
Prostate cancer	0.6 (0.6)	0 – 2.8	0.6 (0.6)	0 – 2	0.7 (0.7)	1 – 2.3
PSA	0.1 (0.4)	0 – 3	0.1 (0.3)	0 – 1.3	0.1 (0.5)	0 – 3
Recurrence	0.7 (0.7)	0 – 3	0.7 (0.7)	0 – 3	0.7 (0.7)	0 – 2.8

Table 4: Unmet Supportive Care Needs Experienced During Active Surveillance

Unmet Need	Total N	None/Low need		Moderate/High need	
		N	%	N	%
Physical & Daily Living					
Lack of energy/tiredness	101	94	93.1	7	6.9
Not being able to do things you used to do	102	98	96.1	4	3.9
Pain	102	99	97.1	3	2.9
Work around the home	102	101	99.0	1	1.0
Feeling unwell a lot of the time	101	101	100.0	0	0.0
Psychological					
Fears about the cancer spreading	102	80	78.4	22	21.6
Worry that the results of treatment are beyond your control	102	82	80.4	20	19.6
Concerns about the worries of those close to you	102	84	82.4	18	17.6
Uncertainty about the future	102	85	83.3	17	16.7
Learning to feel in control of your situation	102	87	85.3	15	14.7
Keeping a positive outlook	102	90	88.2	12	11.8
Feelings about death and dying	102	91	89.2	11	10.8
Feeling down or depressed	102	93	91.2	9	8.8
Anxiety	102	94	92.2	8	7.8
Feelings of sadness	102	94	92.2	8	7.8
Sexuality					
Changes in sexual feelings	102	77	75.5	25	24.5
Changes in your sexual relationships	99	75	75.8	24	24.2
Being given information about sexual relationships	99	78	78.8	21	21.2
Patient Care & Support					
Reassurance by medical staff that the way you feel is normal	100	90	90.0	10	10.0
More choice about which cancer specialist you see	97	90	92.8	7	7.2
Hospital staff acknowledging, and showing sensitivity to, your feelings and emotional needs	98	92	93.9	6	6.1
More choice about which hospital you attend	100	94	94.0	6	6.0
Hospital staff attending promptly to your physical needs	99	94	94.9	5	5.1
Health System & Information					
Being informed about the monitoring of the cancer	100	61	61.0	39	39.0
Being informed about your test results as soon as feasible	100	64	64.0	36	36.0
Being adequately informed about the benefits and side-effects of treatments before you choose to have them	99	68	68.7	31	31.3

Being informed about things you can do to help yourself to get well	100	69	69.0	31	31.0
Having one member of hospital staff with whom you can talk to about all aspects of your condition, treatment, and follow up	100	70	70.0	30	30.0
Being treated like a person not just another case	99	70	70.7	29	29.3
Being treated in a hospital or clinic that is as physically pleasant as possible	99	70	70.7	29	29.3
Being given written information about the important aspects of your care	100	80	80.0	20	20.0
Being given information (written, diagrams, drawings) about aspects of managing your illness and any side effects at home	100	80	80.0	20	20.0
Being given explanations of those tests for which you would like explanations	100	81	81.0	19	19.0
Having access to professional counselling (e.g., psychologist, social worker, counsellor, nurse specialist) if you, family, or friends need it	100	81	81.0	19	19.0

5.6   Qualitative results

5.6.1   Sample

Thirty-three of the 37 eligible participants were interviewed (N=4 could not be contacted or declined to participate). At the interview, 14 were still on AS and 19 had received further treatment since being on AS. Most were married (82%), retired (61%), completed post-secondary education (79%), and lived in a major city (64%), see Table 2. Nine (27%) participants lived in an outer regional or remote area, four (12%) met clinical thresholds for anxiety and/or depression, five (15%) reported experiencing prostate-specific anxiety (in at least one of the subscales), and 13 (39%) reported a moderate-high unmet need in at least one domain.

5.6.2   Overview of themes

Participants generally reported minimal USCNs and anxiety regarding their prostate cancer. Three overarching themes were identified. The first, "Unmet needs on AS", explores the unmet needs discussed by participants, and includes four sub-themes of specific unmet needs identified. The

second theme, "How needs were addressed during AS", details the methods participants used to address needs and why they did not feel they experienced unmet needs after their cancer diagnosis. The final theme, "Hindsight is 20/20", explores the perspectives of participants who had since received definitive treatments on their unmet needs during AS. Illustrative quotes relevant to each theme/subtheme are presented in Table 5.

5.6.3   Unmet needs of patients during AS

5.6.3.1   Informational needs

Some participants identified topics they would have liked more information on during AS. One participant expressed a desire for more information and visual depiction of the prostate and its functions. Additionally, several participants expressed uncertainty about their understanding of test procedures (e.g., biopsy and PSA), their safety and efficacy, and their effect on their overall health. Another participant described the lack of understanding of AS and prostate cancer treatment options in his (ethnic minority) culture. This participant explained needing to keep his diagnosis and treatment private due to the stigma associated with cancer in his culture and community. The participant reported a need for increased information dissemination about AS and prostate cancer to minority communities in Australia and overseas.

5.6.3.2   Physical and sexuality needs

Participants regularly mentioned that a physical difficulty, such as erectile dysfunction and urinary incontinence, was the first symptom investigated that led to their prostate cancer diagnosis. Most participants had spoken to their urologist and/or general practitioner (GP) regarding these issues, and whilst some experienced improvements, for others they continued throughout AS.

5.6.3.3   Patient care and support needs

A more holistic form of healthcare (addressing full-body health) within AS follow-up appointments was desired by several participants. Participants wanted care to address ongoing physical symptoms (such as incontinence or erectile dysfunction), and to check for other health issues in blood tests, not just PSA levels. These participants expressed wanting a doctor who was compassionate and considered their whole health, rather than just their prostate cancer.

Most rural participants felt their experience and needs during AS were not significantly affected by their location. However, many acknowledged that long-distance travel could be difficult due to urinary incontinence or pain after a biopsy. Several participants also mentioned that AS would be easier if they could have biopsies and MRIs in hospitals closer to home. Furthermore, accessing support services was reported as more difficult when living rurally, due to confidentiality concerns, work schedules, or distance.

5.6.3.4   Psychological needs and anxiety

Whilst most participants reported experiencing very little or no anxiety in regard to their cancer, some felt anxious or worried before their appointments while waiting for test results. Participants described worrying that their cancer had progressed and would require treatment, or in some cases, that the cancer had metastasised and it was too late for treatment.

Several participants described feeling uncertain about staying on AS due to the inability of doctors to predict outcomes. Participants expressed a desire to receive objective recommendations and information specific to their diagnosis and expected future outcomes. Sometimes this uncertainty and unclear future left participants feeling anxious and worried.

5.6.4   *How needs were addressed during AS*

Information and support regarding prostate cancer and AS provided by the primary prostate cancer doctor was regularly described as sufficient for the patient's needs. Many reported they did not feel the need to access additional support from practitioners such as psychologists, dietitians, or prostate cancer nurses. Participants often confirmed they would be comfortable asking for referrals for additional support if they desired it.

Many participants reported seeking additional information via "Dr. Google", research papers, prostate cancer-related programs on television, textbooks, and prostate cancer or cancer websites (e.g., Cancer Council). Others found it beneficial to speak to other prostate cancer survivors or friends who were also medical professionals to discuss their experiences, seek support, or ask questions, particularly regarding definitive treatments.

Several men in the study had been members of the Australian Defence Force and held a Department of Veteran Affairs (DVA) healthcare card, providing them with financial support for cancer treatment, among other healthcare benefits [28]. Participants explained that holding a DVA card improved their experience and reduced their USCNs as it enabled them to access cancer treatment and other support services for free or at a discounted rate.

Many of the participants in the study reported experiencing very little to no anxiety or unmet psychological needs regarding their cancer, the AS protocol, or the future during AS. Participants attributed their comfortability and lack of anxiety/depression to having trust and a good relationship with their doctor, having adequate access to information and support, and because they experienced minimal or no physical AS symptoms. Maintaining a positive outlook and objectivity was also considered to aid in reduced anxiety and worry.

5.6.5   *Hindsight is 20/20*

For participants no longer on AS, reflecting on their unmet needs during AS helped them identify areas which they, in hindsight, thought would have helped to improve their AS experience. This was especially the case for psychological support – several participants had begun seeing a psychologist after undergoing definitive treatment and wished they had done so sooner. Similarly, some participants felt they may have had fewer unmet needs post-definitive treatment if they had accessed health professionals, such as a dietician, prostate cancer nurse, exercise physiologist, or physiotherapist, whilst on AS.

Table 5: Illustrative Quotes for each theme/subtheme

Unmet needs of patients during AS

Informational Needs
- *"If urology showed us models that showed prostates in various stages and that sort of thing that would probably help people to understand what's, what's being done, and why it's being done and how it's being done and so forth"* Participant 10433, Active Surveillance
- *"No, I didn't get a chance to talk to somebody, you know, especially in my community. No, no one I know who has got cancer, prostate cancer. And the issue they have, you know, we still have that stigma. Not to talk about it... So that lack of awareness in my [ethnicity] community is still there"* Participant 9160, Definitive Treatment

Physical and Sexuality Needs
- *"And I think I raised it with a GP, but my GPs at that time were ladies and whether they were reluctant to do anything to take that up, or whether they just didn't think it was very important. That has become more of a significant issue for me in more recent years. I have to say, but having said that, my wife has very severe back pain. And is, you know, there really wouldn't be much opportunity for that side of life anyway."* Participant 13235, Definitive Treatment

Patient Care and Support Needs
- *"Maybe a little bit more time, perhaps with the actual urologist maybe would be good or, or one that speaks, and I don't mean this badly, but one who's perhaps a little bit more GP orientated, a little bit better bedside manner, rather than just the medical side of things."* Participant 14695, Active Surveillance
- *"Oh yeah. That was really bad. And then if they want to do anything for country people, it would be to organise biopsies to be done in regional, country hospitals because it's not rocket science really."* Participant 9107, Active Surveillance

Psychological Needs and Anxiety
- *"Then the worry comes at the time that the numbers you know, when you keep going back to your PSA tests, and to see the results, you're hoping like hell, the numbers are gonna work out to be right, you know?"* Participant 16058, Definitive treatment/s
- *"Um, I won't say anxiety, but the uncertainty was annoying. And this goes back to this grey area I keep talking about. Besides that, just that uncertainty... you couldn't get the degree of facts-based support that I would have been, you know, that I'm entirely comfortable with. So that causes some anxiety."* Participant 15132, Definitive Treatment

How needs were addressed during AS

- *"Mostly I relied on the discussions with the doctor himself, or herself... The communication between them provided everything I needed really. Basically, it was, there was nothing that I wasn't unclear about that, or had concerns about, or any needs that were unmet."* Participant 13959, Definitive Treatment
- *"Pretty private dude. And I have my connections, friends and family who are, in in the systems and medical business side. It wasn't like I was out here by myself trying to work out what to do next. I had pretty good information. I didn't feel the need for anything other than my family support"* Participant 9107, Active Surveillance
- *"It's very important thing, it's a lot of worry off your mind... one thing I didn't have to worry about was funding for all that, all the, the treatment. You know, for either biopsy or the proctectomy, and the follow up treatments, all those things. All that was funded by [the department of veterans affairs]. So I was very, very fortunate that that happened."* Participant 16058, Definitive treatment
- *"But there hasn't been any sort of anxiety about that as such. At all, you know, when the test comes up, I've just been taking it in my stride. Because I think I trust the urologist."* Participant 10421, Active Surveillance

Hindsight is 20/20

- *"I don't think I was shocked by not having [a referral to a prostate cancer nurse or physiotherapist]. But I think that there would be value, in retrospect, in having a service like that offered for men and their partners."* Participant 13235, Definitive treatment

5.7   Discussion

Despite research demonstrating that 80% of patients experience USCNs after definitive prostate cancer treatments [29], and over 35% experience at least one USCN 15 years post-diagnosis [30], no research has used validated measures to explore and identify the USCNs of patients on AS. Given the unique management style AS provides to patients diagnosed with low risk, localised prostate cancer (which is the most common prostate cancer diagnosis [31]), understanding the needs of these patients is imperative for providing them with adequate care, support, and information. This is the first study to identify and measure the USCNs of patients on AS using a validated measure, which was further supported by qualitative interviews. Within our sample, USCNs were reported across all domains, with moderate-high needs most commonly in informational, sexual, and patient care needs. However, average unmet needs per domain were reflective of low-moderate levels. In addition, our sample reported low levels of anxiety (general and prostate cancer-specific) and depression. Ways in which healthcare practitioners might address the USCNs mentioned by participants are summarised in Table 6.

Table 6: Unmet Needs by Supportive Care Needs Domains

Need domain	Unmet need	Recommendations to address unmet need
Health System & Information	Information on prostate cancer, diagnosis, treatment options	Continue with provision of verbal and hard-copy information dissemination, referrals to online information, and support groups. Ensure information is up to date.
	Information on prostate anatomy	Doctors/nurses to provide explicit information on prostate. Include this information on handouts.
	Understanding test results and purpose of test	Doctors to provide specific information on patients tests results & purpose of tests, as well as resources for general overviews.
	Awareness of prostate cancer in minority communities	Health professionals to consider cultural influence on knowledge/preferences during appointments. Advocate for information dissemination by public health services about prostate cancer screening & treatment to minority communities.
Patient Care & Support	Financial support to access services and support	Lobbying for wider Medicare and pharmaceutical benefit coverage of treatments related to prostate cancer. Encourage use of available services through Medicare, Department of Veterans, etc. for increased support.
	Social support	Doctors/nurses provide information on support groups. Provision of support groups for patients on active surveillance. Involve spouse/partner where applicable.
	Difficulty accessing services due to rurality	Doctors to utilize telehealth where possible (especially for short check-up appointments) for rural patients. Consideration of appointment times for rural patients who must travel.
	Accessing holistic healthcare	Doctors/health professionals to utilise multi-disciplinary healthcare services and coordinate ongoing care with services.
	Accessing out-of-hours services (for patients working full-time or shiftwork)	Increased provision of after-hours psychological, support, and healthcare services for patients in rural areas, working full time, or working shiftwork. Potential for online provision of services.
Psychological	Uncertainty of AS (is it safe?)	Health professionals to collaborate & employ standardised AS protocols and explain this clearly to patients. Advocation for national & global AS protocol guidelines.
Sexual	Addressing erectile incontinence and other symptoms on intimacy with partner	Doctor/nurse to specifically ask patients about sexual functioning & effect on intimacy with partner – offer support/referral if desired.
Physical	Urinary incontinence and erectile dysfunction	Doctor to routinely check for signs of existing issue. Considerations for patients traveling long-distances.

Just over 20% of the sample reported moderate-high unmet needs in at least one item across information, sexuality, psychological, and patient care domains. Unmet informational needs were the most common; participants reported a desire for written information about AS care, treatment options and side effects, and receiving test results and explanations for these results. Similar unmet informational needs are often reported by prostate cancer patients after definitive treatments [29, 32],

and were the most common reported need in a systematic review on USCNs in patients on AS [20]. Several unique unmet informational needs were identified in our qualitative analysis. Unmet needs related to the desire for information specific to the role and functioning of the prostate and the ways in which it is affected by prostate cancer treatments and tests was mentioned by one participant. Another participant discussed unmet informational needs regarding the awareness of prostate cancer (i.e., treatment options including AS and definitive treatments) in his minority ethnicity community. In line with recent recommendations for practitioners working with prostate cancer survivors [33], these unmet informational needs may be addressed through an increased focus on disseminating information on men's health and prostate cancer to primary care providers, community workers, and prostate cancer survivors and their families, especially those living in rural/remote areas and people from culturally and linguistically diverse (CALD) backgrounds. Ensuring messaging is consistent, readily available, evidence-based, culturally appropriate, and takes into account existing health literacy and preferences for information is essential for reducing unmet informational needs [33].

Sexuality needs were the second most common moderate-high USCN by patients in the present study. Information on addressing sexual function and intimacy issues is a common unmet need for patients post-definitive treatment, given that erectile dysfunction is a common side effect of most prostate cancer treatments [19]. The present study has identified that, like patients after definitive prostate cancer treatment, patients on AS may also require information and support regarding their sexuality and sexual function. Similar again to USCNs seen after definitive treatments [29, 32], physical unmet needs relating to urinary incontinence were also reported by participants on AS. Health practitioners with patients on AS must ensure they provide information and support and routinely check-in with patients to identify if additional support or information regarding sexuality or physical function is required.

Finally, although generalised and prostate cancer-specific anxiety scores were generally low across participants, over 20% of participants reported fear of cancer progression as an unmet psychological

need while on AS. Feelings of fear, worry, and uncertainty were also regularly discussed by participants in interviews. Participants described feeling concerned and fearful of the cancer spreading too quickly, negating their ability to cure the cancer with definitive treatments. Previous research has demonstrated that fear of progression and anxiety, whilst generally low and similar to levels reported by patients after definitive treatment, are experienced by patients on AS [8, 34, 35]. Psychological unmet needs and fear of progression may be combatted by reducing unmet informational needs (e.g., providing clear and consistent information about AS, test results, treatment options, and triggers for definitive treatment) and routinely discussing psychological wellbeing and providing referrals to psychological or other services when applicable. This is especially vital given that several participants in the present study reported difficulties in accessing support services due to their rural location or work schedules. Furthermore, many participants in the study who had since received definitive prostate cancer treatment shared that in retrospect, additional psychological support, access to a prostate cancer nurse, or referrals to a dietician or exercise physiologist may have been beneficial during AS to improve their experience and anxiety/fears.

5.7.1   Limitations and future research

Several limitations should be considered when interpreting these results. The original case-control study (which intended to recruit from multiple Australian states) was unable to proceed due to COVID-19 shutdowns. Consequently, our sample size was considerably lower than originally planned and prevented us from statistically investigating predictors of higher USCNs. Further research with larger samples is therefore required to understand the extent of USCNs in patients on AS both in Australia and worldwide. With no global AS protocol and wide variations in healthcare services and systems, research is also to determine whether unmet needs differ by location. While our findings suggest that patients from culturally and linguistically backgrounds may experience unique USCNs after prostate cancer diagnosis, as we only recruited participants who could communicate fluently in English, these results are limited, and further investigation is needed.

5.7.2 Conclusions

This cross-sectional study is the first to measure and explore the USCNs experienced by patients during AS using a validated measure and interviews. While unmet needs, anxiety and depression were generally low, one in five patients during AS experience unmet needs in psychological, physical, patient care, information, and sexual domains. To reduce unmet needs, including anxiety and fears of cancer progression, and potentially prevent AS discontinuation prematurely, it is essential that health professionals provide consistent and clear information, and enquire about their patient's needs and psychological wellbeing regularly.

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6   CHAPTER SIX:

REASONS MEN TRANSITION FROM ACTIVE SURVEILLANCE TO TREATMENT:

A MIXED METHODS INVESTIGATION

6.1   Statement of Authorship

Title of paper	Why do men leave active surveillance? A mixed methods study on reasons men with prostate cancer stop active surveillance.
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Name	Megan McIntosh
Contribution to paper	Developed protocol, conducted data collection and analysis, wrote and revised manuscript as per co-author and reviewer feedback, acted as corresponding author.
Overall percentage (%)	80%
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.
Signature and date	10/11/2021

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By signing the Statement of Authorship, each co-author certifies that:

The candidate's stated contribution to the publication is accurate (as detailed above);

Permission is granted for the candidate to include the publication in the thesis; and

The sum of all co-author contributions is equal to 100%, less the candidate's stated contribution.

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Contribution to paper	Assisted in protocol and recruitment logistics and provided critical feedback on manuscript drafts.
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Contribution to paper	Assisted in protocol and analysis and provided critical feedback on manuscript drafts.
Signature and date	29/10/2021

Why do men leave active surveillance? A mixed methods study on reasons men with prostate cancer stop active surveillance

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6.2 Abstract

Objectives: To explore the personal and/or medical reasons patients on active surveillance (AS) have, or consider having, further definitive treatment for their prostate cancer. Research suggests up to 50% of patients on AS will discontinue within five years, though reasons for discontinuation from the patient's perspective is under-explored.

Methods: Prostate cancer patients who were or had been on AS for at least six months were recruited. A questionnaire assessed reasons for receiving/considering definitive treatment and the extent to which reasons were personal or medical. Clinical information was extracted from a state-level population registry. A subset of participants were interviewed to further explore questionnaire responses.

Results: One-hundred and-three individuals completed the survey; 33 were also interviewed. Fifty-four survey participants (52%) had discontinued AS for definitive treatment. Common reasons for discontinuation were evidence of disease progression, doctor recommendation, desire to act, and fear of progression. Many participants who considered or had treatment reported weighing medical and personal factors equally in their decision. Interview participants described strongly considering any amount of disease progression and personal factors such as fear of progression, family concerns, and adverse vicarious experiences when deciding whether to pursue treatment.

Conclusion: Both medical and personal factors are considered when deciding whether to discontinue AS. Identifying predictors of discontinuation is essential for informing supportive care services to improve AS management.

6.3 Introduction

Active surveillance (AS) is the recommended best-available treatment option for individuals with low risk prostate cancer [1]. It involves routine surveillance of biological markers of the disease through prostate specific antigen (PSA) tests, digital rectal examinations (DRE), biopsies, and magnetic-resonance imaging (MRI) [1]. Transition to definitive treatment (e.g., prostatectomy or radiotherapy) is generally recommended upon significant disease progression which results in risk reclassification [1]. Currently, there is no globally-recognised criterion of initiation, follow-up procedures, or triggers for intervention; therefore, AS practices vary greatly across clinicians and countries [2].

Approximately 50% of patients discontinue AS within five years, the majority of which with evidence of significant disease progression [3,4]. Whilst AS discontinuation rates are commonly reported [4–6], the extent to which discontinuation is triggered by disease progression and/or other personal reasons requires further research, especially from the patient perspective. Emerging research suggests this decision may be influenced by both medical (e.g., disease progression, doctor recommendation) and personal reasons (e.g., anxiety, pressure from family), at least for some people [6–8]. For instance, in a cohort study, Lang et al [8] reported that in those who had transitioned from AS to definitive treatment at 3 years post-diagnosis, 69% had done so for medical reasons, 31% for a mix of personal and medical reasons, and 8% for solely personal reasons. However, this study only illustrated personal reasons as either 'spousal encouragement' or 'unspecified' [8]. A more fine-grained understanding of the personal reasons men transition to definitive treatment is needed to assist in targeting supportive care interventions, thereby encouraging adherence and improved mental wellbeing. In this study, a mixed-methods approach was used to identify and explore the reasons men discontinue or consider discontinuing AS to receive definitive treatment.

6.4 Methodology

6.4.1 Sample

Participants for this study were sampled from a larger case-control study designed to examine social-ecological factors associated with discontinuing AS. Unfortunately further recruitment from other Australian states was unable to proceed due to COVID-19 [9]. Given data collection from South Australia had already been completed, the present study reports this cross-sectional data. Participants were recruited through the South Australian Prostate Cancer Clinical Outcomes Collaborative (SA-PCCOC), which captures 90% of all diagnosed prostate cancer survivors in the state [10]. SA-PCCOC identified patients eligible using the following criteria: diagnosed with prostate cancer between January 2014 and October 2019, initially monitored through AS for at least six months, 18+ years old, and had consented to be contacted for research projects through SA-PCCOC. As per the original case-control design, participants were then identified as either cases (patients identified as transitioning to treatment with weak evidence of disease progression) or controls (patients currently on active surveillance or patients who had transitioned with strong evidence of disease progression), and were matched 1:4. This resulted in N=270 eligible participants for recruitment. In the present study, participants were not analysed according to their case/control status. A recruitment flowchart is presented in Figure 1.

Eligibility criteria for interviews included: completed survey, provided contact information on the returned consent form, had access to a telephone, and spoke English.

Figure 1: Participant Recruitment Flow Chart

Participant Recruitment Flow Chart

```
         ┌─────────────────────────────┐
         │ Eligible patients identified on │
         │      SA-PCCOC registry       │
         │           N = 527            │
         └─────────────────────────────┘
                      │
                      ▼
         ┌─────────────────────────────┐
         │ Eligible patients categorised as │
         │  case/control, and matched 1:4  │
         │         N = 54 cases         │
         │        N = 216 controls       │
         └─────────────────────────────┘
                      │
                      ▼
         ┌─────────────────────────────┐
         │    Invited to participate in     │
         │       research study          │
         │           N = 270            │
         └─────────────────────────────┘
            │                      │
            ▼                      ▼
┌─────────────────────────┐   ┌─────────────────────────┐
│   Non-responders = 151  │   │ Responded to survey = 103 │
│ Responded but self-identified │   └─────────────────────────┘
│   as ineligible = 16    │                 │
└─────────────────────────┘                 ▼
                             ┌─────────────────────────┐
                             │ Invited to interview = 37 │
                             └─────────────────────────┘
                                          │
                                          ▼
                             ┌─────────────────────────┐
                             │     Interviewed = 33     │
                             └─────────────────────────┘
```
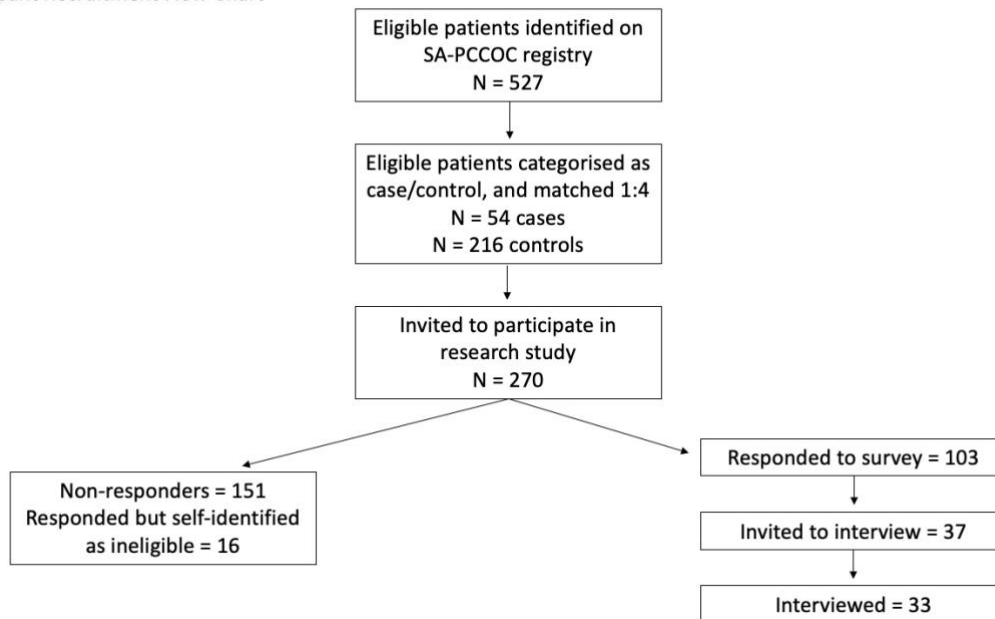
6.4.2 Evidence of disease progression in sample

Disease progression was determined using the following clinical information at diagnosis and follow-ups: Gleason Score, PSA test results, and Biopsy results (i.e., positive cores identified). We classified participants into three categories, indicating the level of evidence available indicating significant disease progression had occurred; Strong, Moderate, and Weak. See supplementary material (appendix 1) for specific criteria.

6.4.3 Survey

Following identification of eligible participants through SA-PCCOC, pilot testing on the survey was conducted. The survey underwent two separate pilot tests for (a) readability and (b) response rate prior to dissemination of the final version. In the readability pilot, the survey was reviewed by four prostate cancer survivors and two health professionals, and adjustments were made based on their feedback. Changes to the study procedure (including the provision of unconditional monetary incentives to all remaining participants) and survey length were made given the outcomes of the response rate pilot test, which was conducted with N=32 eligible participants.

Following pilot testing, remaining eligible participants (n=238) were sent the study materials. Reminder letters were sent to non-responders two weeks later. Surveys completed on paper, or the phone were entered into RedCap [11,12], which also hosted the online version of the survey. Additional clinical data was retrieved from the SA-PCCOC database for participants who completed the survey, including demographics and treatment information.

6.4.3.1 Survey measures

The present study examined survey responses on men's reasons for transitioning from AS to definitive treatment, or if still on AS, the reasons they had considered having definitive treatment. Fifteen items were assessed on a 5-point Likert scale ranging from 1 (doesn't apply to me) to 5 (strongly applies to me). In analysis, categories were collapsed into three categories; Doesn't apply, Minimally/Somewhat applies, and Very-much/Strongly applies. See Table 2 for all items. The main reason for treatment/considering treatment was also assessed on a visual analogue scale (VAS), where 0 indicated purely personal reasons and 100 indicated purely medical/clinical reasons. These items were informed by previous literature [7,13] and purpose-written by the research team (see supplementary material appendix 2). The full survey also included validated measures and purpose-written questions on demographics, anxiety, depression, coping strategies, physical activity, social support, supportive care needs, their relationship with doctors, and their experiences on AS. Findings related to these measures will be reported elsewhere.

6.4.3.2 Survey Analysis

Descriptive statistics for demographics, considering treatment, reasons for undergoing definitive treatment, and main reason for undergoing treatment were calculated in R [14].

6.4.4 Interviews

Participants were sampled using Criterion-I purposeful sampling technique. This involves identifying and selection participants according to predetermined criterion of importance, which enables researchers to deepen the understanding of results from information-rich cases [15]. Participants with VAS scores under 70, had considered leaving active surveillance, were located in outer

regional/remote areas, and had reported higher scores of anxiety, depression, and unmet supportive care needs were prioritised for interview selection. All participants were interviewed by lead author MM (who had prior qualitative research experience). Interviews were semi-structured, and followed a topic guide (see supplementary material appendix 3) which explored experiences on AS, reasons for treatment or considering treatment, and treatment experiences. Interviews were audio recorded and transcribed verbatim, taking an average 31 minutes to complete. Braun and Clarke have recommended thematic saturation should not be the primary aim of sample size calculations and recruitment when conducting thematic analysis [16]. Rather, all participants who met elibility and sampling criteria were invited to ensure richness of data to address the research questions.

6.4.4.1 Interview Analysis

Transcripts were analysed using Braun and Clarke's reflexive thematic analysis method [16,17]. This involves six key steps: Familiarisation, Coding, Create Themes, Revise Themes, Define Themes, Writing. The Familiarisation and Coding steps were performed by MM and MJO, who both have experience in qualitative research and thematic analysis. All transcripts were then re-analysed by MM and themes were created. MM and MJO then revised and formally defined the themes, and a thematic map was created to illustrate the relationship between themes. Themes and the thematic map were reviewed and finalised by all authors. Results were written with transcript excerpts to illustrate the findings.

6.5 Results

6.5.1 Participants

One hundred and three participants completed the survey and consent form (38% response rate). The average participant was married (83%), retired (64%), had completed post-secondary education (70%), and lived in an Australian state capital city (71%). See Table 1 for complete breakdown of demographics.

Of the 103 participants, 53 (51%) participants had discontinued AS and since undergone definitive treatment, and 48 (47%) participants were currently on AS. In patients who had discontinued AS, 11 had strong evidence of progression, 19 moderate evidence, and 23 weak evidence of progression. Two participants reported on the survey they had ceased all treatments and were not attending any follow-up for their cancer, however both participants received a repeat biopsy. Approximately 61% of participants received a repeat biopsy an average of 17 months after diagnosis.

The average time on AS was 2.1 years (SD=1.3) for those who had since undergone treatment, and 3.3 years (SD=1.1) for those currently on AS. Thirty percent of those currently on AS (n=14) reported that they had considered discontinuing to have definitive treatment. The average time for those currently on AS who had considered leaving was 4 years (SD=0.9), versus 4.3 years (SD=0.9) for those who had not considered discontinuing.

6.5.2 Reasons for leaving active surveillance

The most common reasons participants who went onto have definitive treatment endorsed to have very much or strongly influenced their decision included a rise in PSA level (70%), receiving a doctor's recommendation to have further treatment (60%), a change in Gleason score (63%) or change in repeat biopsy results (70%), experienced fear of cancer progression (18%), or had a strong desire to do something to cure the cancer (51%). Few people reported comorbidities or anxiety strongly influenced their decision. See Table 2 for a complete overview.

Tables were produced to examine the reasons for leaving AS by level of disease progression evidence (strong, weak moderate; see supplementary material appendix 4). In brief, average scores endorsing medical reasons were marginally higher among those with highest levels of evidence for disease progression. Similarly, participants with weaker evidence for progression more strongly endorsed personal reasons, though again differences were marginal.

Table 1: Participant Demographics and Clinical Information

	All participants (n=103)	Treatment (n=53)	Active Surveillance (n=48)
Age at diagnosis: Mean (SD)	64.5 (6.6)	63.7 (7.1)	65.4 (5.6)
Age at diagnosis range: years	48 - 75	48 - 75	49 - 74
Time on active surveillance: Mean years (SD)	2.5 (1.4)	2 (1.2)	3.2 (1.1)
Current Treatment Status: N (%)			
Had treatment	53 (51.4%)	-	-
On active surveillance	48 (46.6%)	-	-
*Ceased all treatment with no follow-up care**	2 (1.9%)	-	-
Treatment Type: N (%) **			
Prostatectomy	-	33 (62.3%)	-
Radiation	-	23 (43.4%)	-
Other (e.g., Hormone Therapy)	-	2 (3.8%)	-
Marital status: N (%)			
Single	3 (2.9%)	3 (5.7%)	0
Married / De facto/Partnered	86 (83.5%)	42 (79.2%)	43 (89.6%)
Divorced/Separated	9 (8.7%)	5 (9.4%)	3 (6.3%)
Widowed	5 (4.9%)	3 (5.7%)	2 (4.2%)
Employment: N (%)			
Working (full or part time)	32 (31%)	14 (26.4%)	17 (35.4%)
Retired	66 (64.1%)	35 (66%)	30 (62.5%)
Unemployed	5 (4.9%)	4 (7.6%)	1 (2.1%)
Education: N (%)			
Primary	3 (2.9%)	0	3 (6.3%)
Secondary	27 (26.2%)	16 (30.2%)	11 (22.9%)
Vocational Training/Education	36 (35%)	16 (30.2%)	18 (37.5%)
University	37 (35.9%)	21 (39.6%)	16 (33.3%)
Location***: N (%)			
Remote	5 (4.9%)	2 (3.7%)	3 (6.4%)
Outer regional	11 (10.7%)	6 (11.1%)	4 (8.5%)
Inner regional	14 (13.6%)	4 (7.4%)	9 (19.1%)
Major city	73 (70.9%)	42 (77.8%)	31 (66%)
Diagnostic Biopsy Type: N (%)			
Transperineal	21 (20.4%)	12 (22.6%)	8 (16.7%)
Transrectal Ultrasound (guided)	30 (29.1%)	15 (28.3%)	14 (29.2%)
Transurethral resection of prostate	12 (11.7%)	3 (5.7%)	9 (18.8%)
Not reported	40 (38.8%)	23 (43.4%)	16 (33.3%)
Received repeat biopsy: N (%)	63 (61.2%)	30 (56.6%)	31 (64.6%)
Time between diagnostic and repeat biopsy: Mean months (SD)	17.4 (12.7)	18.5 (12.2)	16.5 (13.6)
Repeat Biopsy Type: N (%)			
Transperineal	36 (57.1%)	17 (56.7%)	18 (58.1%)
Transrectal Ultrasound (guided)	21(33.3%)	9 (30%)	12 (38.7%)
Transurethral resection of prostate	4 (6.4%)	3 (10%)	1 (3.2%)
Not reported	2 (3.2%)	1 (3.3%)	0
MRI conducted (prior/post diagnosis): N (%)	68 (66%)	39 (73.6%)	27 (56.3%)

* The two participants who reported they 'ceased all treatment with no follow-up care' were not grouped into the active surveillance or treatment categories, though their demographics have been included in the total sample.

* * Some participants received more than one treatment, therefore the percentage does not equal 100.

* * * Location determined by postcodes and classified using the Australian Statistical Geographical Classification – Remoteness Area framework [27].

Table 2: Reasons for Treatment in participants who had undergone definitive treatment after active surveillance

Reason Item	N	Doesn't apply. N (%)	Minimally/Somewhat applies. N (%)	Very much/Strongly applies. N (%)	Mean (SD)
Medical reasons					
PSA increase	50	2 (4%)	13 (26%)	35 (70%)	4 (1)
Doctor recommendation	48	4 (8.3%)	10 (20.8%)	34 (70.8%)	3.9 (1.2)
Biopsy	46	6 (13.1%)	11 (23.9%)	29 (63%)	3.6 (1.3)
Gleason score increase	45	12 (26.7%)	6 (13.3%)	27 (60%)	3.3 (1.6)
DRE	44	37 (84.1%)	3 (6.8%)	4 (9.1%)	1.4 (1)
Medical comorbidities	43	32 (74.4%)	7 (16.3%)	4 (9.3%)	1.6 (1.2)
Personal Reasons					
Desire to act	47	13 (27.7%)	10 (21.3%)	24 (51.1%)	3.2 (1.6)
Fear of cancer	44	28 (63.6%)	8 (18.2%)	8 (18.2%)	1.9 (1.3)
Pressure from others	46	29 (63%)	10 (21.7%)	7 (15.2%)	1.9 (1.3)
Uncertainty	40	27 (67.5%)	9 (22.5%)	4 (10%)	1.7 (1.1)
Anxiety	45	34 (75.6%)	10 (22.2%)	1 (2.2%)	1.4 (0.8)
Tired of waiting	42	33 (78.6%)	7 (16.7%)	2 (4.8%)	1.4 (0.9)
Inconvenient protocol	43	39 (90.7%)	4 (9.3%)	0 (0%)	1.1 (0.4)
Depression	43	39 (90.7%)	4 (9.3%)	0 (0%)	1.1 (0.5)

6.5.3   Balance of medical and personal reasons impacting decision making

Figure 2 displays the VAS scores for people who discontinued AS to undergo definitive treatment (N =44, 10 missing) and those who have considered ceasing AS for definitive treatment (N =11, 3 missing). The majority of participants reported both personal and medical reasons influenced decision making, but to varying degrees. Among those who had received treatment, almost half had a VAS indicating their main reason for AS discontinuation was medically and personally balanced (i.e., VAS score of 50) or was tipped towards personal (i.e., VAS of 0 - 50). Another third had a VAS score indicating reasons were predominantly medical (i.e., VAS score of 90+). In participants still on AS, many indicated their desire for treatment was medically and personally balanced (VAS score of 50) or trended towards predominantly medical reasons (VAS scores of 75+).

When analysed by disease progression (in participants who had discontinued AS), average VAS scores were generally higher in the 'Strong' progression group (M = 72.8, SD = 22.1) versus the Moderate (M = 65.6, SD = 25.7) and Weak (M = 69, SD = 30.6) groups.

Figure 2: Visual Analogue Scale Scores reflecting reasons for having/wanting definitive treatment in Participants
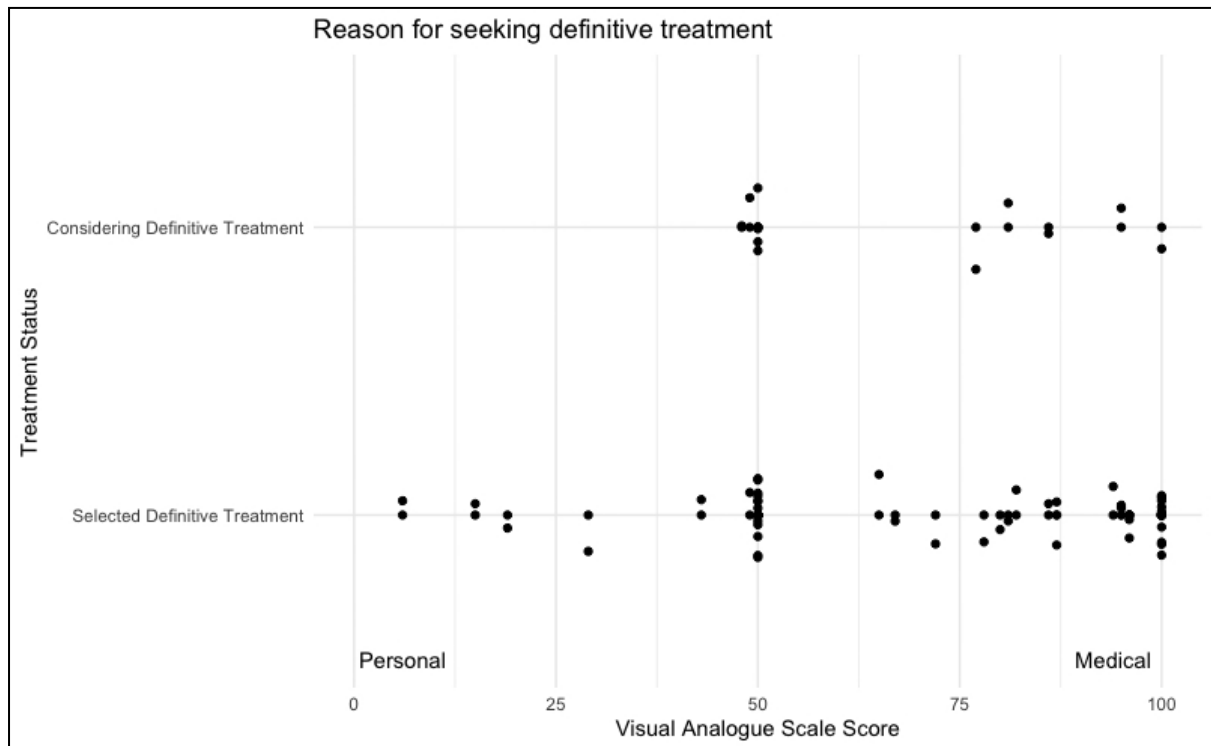
6.5.4 Qualitative sample

Thirty-three participants were interviewed. Of these, 10 (30.3%) were still AS at the time of the interview (although one had a prostatectomy upcoming). The remaining 23 interviewees (69.7%) had left AS and had undergone definitive treatment for their prostate cancer. Most interview participants were married (82%), retired (61%), educated beyond high school (79%), and lived in a major city (64%).

6.5.5 Overview of themes

Men discussed a wide range of reasons they considered or had transitioned off AS to have definitive treatment. Ultimately, most participants were primarily motivated by medical reasons, though their decision was significantly supported or influenced by personal reasons. We identified three major themes: "Disease progression indicates need for action", "A desire to act now", and "Fear, worry, and uncertainty". We did not note any major differences in themes between patients' post-treatment and those still on AS, and as such results are reported together. Participants' reasons for treatment are

illustrated in a thematic map (see Figure 3), with the larger ovals depicting reasons more often
discussed by participants, and the smaller ovals reflecting reasons less commonly discussed.

Figure 3: Thematic Map of Themes
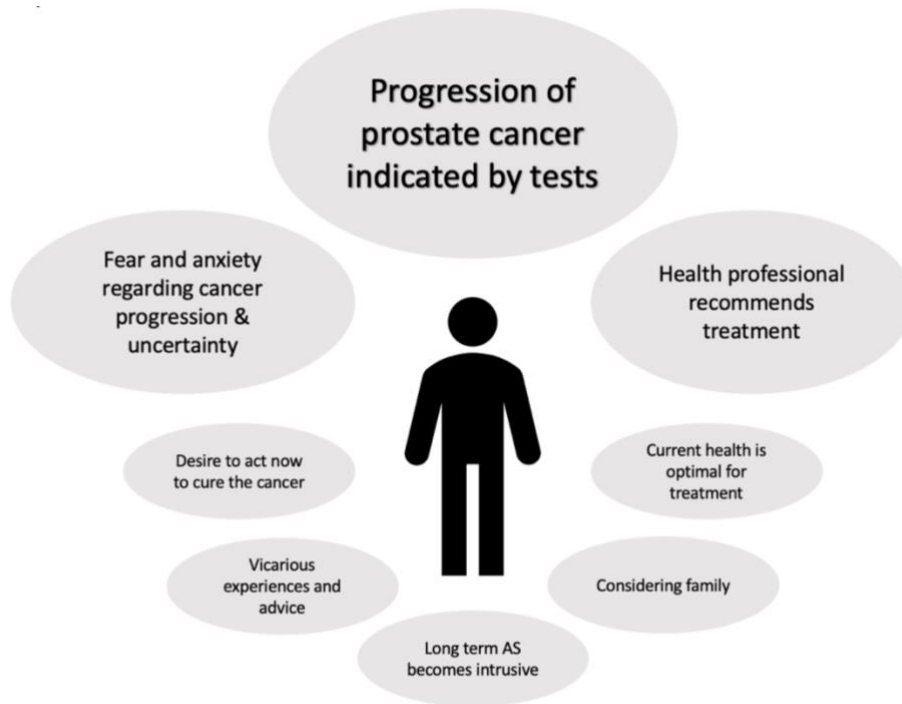
6.5.5.1   Disease progression indicates need for treatment.

By far the most common reason participants stated they had or considered having treatment was
because their doctor made the recommendation to do so. Some participants noted they sought advice
from several doctors before making the decision to transition from AS to treatment.

"I did toy with the idea, you know, should I wait another 12 months. And he advised it wouldn't be a
good idea" P16058, Prostatectomy

Participants also explained that any disease progression identified from PSA, Gleason, MRI, or biopsy
results often prompted them to discuss treatment options with their doctor. In almost all cases,
participants considered any level of progression to be the first reason they considered and underwent
definitive treatments. Men on AS said they would seek definitive treatments if or when tests indicated
the cancer had progressed, irrespective of if this level constituted disease reclassification.

"I've gone from having a low PSA to quite a high PSA, my PSA started fluctuating... So there was obviously something happening… When we got to the serious decision-making stage... I'm thinking, you know, at least to take [Dr M's] advice to explore what surgery options are open to me." P15132, Prostatectomy.

6.5.5.2 A desire to act now

"Well, I mean, cancer is not good in your body, and it can spread. So I think the sooner you get rid of it, the better. That's my opinion." P14774, Active Surveillance but scheduled for Prostatectomy.

Several participants expressed a clear and intense desire to seek definitive treatments as soon as possible after diagnosis. For some, this was not offered or recommended at diagnosis and patients were advised to wait until the cancer had progressed further. In other circumstances, although progression was detected doctors advised participants that they could remain on AS. However, some participants viewed the doctor's mention of progression and having provided the option to undergo treatment as a reason to have definitive treatment and felt staying on AS would be risky. Despite being eligible for AS, participants often felt that having definitive treatments would provide more control over outcomes and were fearful that the cancer would progress outside the prostate.

"This why I was pushing the doctor to do something like surgery. But before then it was just too small. He went active surveillance. For me, I was always pushing, no no, I don't want that. Remove it please." P9160, Prostatectomy, Radiation, and Hormone Therapy.

Some participants who had been on AS for several years expressed that their decision to have treatment was also influenced by the nature of AS follow-up. The regular tests, particularly annual biopsies, and mental load of continuing to watch for disease progression, became tiring and inconvenient for participants over time.

"I almost got tired, I guess. I guess of having nine years of just sitting there wondering what's going on. Mentally I was just done." P15132, Prostatectomy.

Several patients also mentioned that their decision to transition off AS and pursue definitive treatment was influenced by the state of their current health, such as their age, fitness, and life expectancy.

Participants felt that seizing the opportunity to have treatment while they were still 'young and healthy' would assist their recovery.

"And it, ah, occurred to me that if I was going to do anything, I might as well do it now. While I'm still reasonably active and so forth, and could recover, I would hope. Without too much difficulty."

P10433, Brachytherapy.

6.5.5.3 Fear, worry, and uncertainty

Participants often reported ongoing fears that the cancer would progress undetected, and they could be at risk of metastases or dying. It was common for participants to fear that delaying treatment was risky, as their PSA test might increase suddenly and it would be 'too late' to treat or cure the cancer. Ongoing anxiety or concerns that progression would occur too quickly were common reasons why participant sought or had considered treatment.

"I thought, my wife and I discussed it quite a lot… she was really concerned. And I guess I was concerned as well a little bit that, yeah it was internal, which was okay, so it was contained within the prostate, but there was always that fear… if it does get out and gets into your system elsewhere, I knew it could take off pretty quickly. And then you're, you know, you're fighting a bigger battle. It's probably best to get it done before it goes." P14835, Prostatectomy.

Participants also discussed the influence that other people's experiences with prostate cancer had on their desire for treatment. Negative vicarious experiences of prostate cancer and hearing 'horror stories', whether directly from friends or family or indirectly online or via the media, was described as a reason participants had experienced fears of progression and desired treatment as soon as possible. Delaying treatment by remaining on AS in such cases was viewed as riskier than having treatment and avoiding the consequences that they had heard others had experienced.

"Keeping in mind though, that an old friend of mine got prostate cancer at about the same age as I did and said 'oh nah, I'm not worried about it. You die with it rather than from it'. But eight years later, he was dead from it. So I've always had in the back of my mind. You know, keep an eye on it. What I'm trying to say, I think it's been, It's been at the back of my mind and a little bit concerning"

P15005, Active surveillance but scheduled for Prostatectomy.

Participants also explained they chose to have treatment often because they wanted to ensure they would continue to be around for their family, and that having definitive treatment would reduce their family's worry.

"During that period, it was horrible, you know, I was a little bit depressed you know, knowing that I'd been diagnosed with this. And we have a big family, my children are still young. How am I meant to leave them if I die, earlier like this?" P9160, Prostatectomy, Radiation, and Hormone Therapy.

6.6   Discussion

This study investigated the reasons people transition, or consider transitioning, from active surveillance to definitive treatments. Results indicate that the reasons patients decide to leave AS are more complex than the literature often suggests.

Previous literature reporting rates of AS discontinuation often categorise participants according to progression criteria available on cancer registries [4,6], and have rarely explored participants' own perspectives of reasons for discontinuation, nor considered the extent to which personal reasons influence those with evidence of disease progression. This may actually hinder health professionals from providing support to patients questioning when to transition to definitive treatment. Our results suggest that patients on AS often consider a variety of medical and personal factors when deciding whether to continue on AS or undergo definitive treatment, regardless of strength of evidence for disease progression. Evidence of disease progression, regardless of whether it meets criteria for disease reclassification, is considered strongly by men as a reason to pursue definitive treatment. In addition, we found patients may still consider and pursue treatment irrespective of whether the doctor states such progression warrants intervention. Participants in this study described feeling anxious when any evidence of cancer progression was detected. Cancer progression, or the fear of it, prompted participants to consider their future and the impact that delaying definitive treatment could have on their own health and their family. Fear of cancer recurrence is a significant issue for people with a cancer history, and several successful interventions have been developed [18,19]. Lessons from this literature may be useful to address fear of cancer progression in this population, whilst dispelling

common misconceptions regarding prostate cancer and treatment (e.g., prostate cancer progresses rapidly) and promoting positive vicarious experiences of AS.

Several of the personal reasons, such as fear of progression and family pressure, have been identified in previous research [7,8,13]. Significant research has reported low levels of anxiety in men on AS, which often reduces or remains stable over time [20–23]. However, much of this research recruited patients from cancer centres which specialise in AS, which may have resulted in improved AS management and greater acceptance from both patients and doctors. Recent research conducted with patients from non-specialist AS cancer centres have found men on AS experience more fear of cancer progression and generalised anxiety (immediately and long-term) than those who have definitive treatment [24,25]. Further research is required to provide a more representative understanding of distress in AS patients, with consideration of crucial time-points (e.g., prior to treatment choice and follow-up appointments.

6.6.1 Study Limitations

Despite our novel findings, the limitations must be considered. The original case-control study, which was paused due to COVID-19, planned to recruit from multiple Australian states. The intended larger sample size would have enabled investigation into predictors of AS discontinuation. Despite this, we were able to recruit 103 participants into the study and collected both quantitative and qualitative data. In addition, the registry does not collect data on education or marital status, and the representativeness of our sample in regard to the registry population was difficult to determine. However, our sample is similar to the registry population in terms of age and location [26]. Finally, our study did not recruit participants whose primary language was not English, therefore results may not be generalisable to patients from culturally and linguistically diverse backgrounds.

6.6.2 Conclusion & Clinical Implications

Our mixed-methods investigation of the reasons men on AS undergo or consider having definitive treatment indicates that both clinical factors and personal factors are strongly considered by patients

during this process. Identifying predictors of discontinuing AS with and without evidence of disease progression or risk reclassification may further assist health professionals in targeting patients for support during the first few years on AS, when emotional distress and discontinuation rates are higher. Lessons from interventions targeting fear of cancer recurrence may be useful for guiding the development of supportive care interventions to address fear of cancer progression in this population. However, additional strategies to target other personal reasons, such as family pressure and negative vicarious experiences, are also expected to be useful.

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7   CHAPTER SEVEN:

IMPACT OF DIFFERENT UNCONDITIONAL MONETARY INCENTIVES ON

SURVEY RESPONSE RATES IN MEN WITH PROSTATE CANCER: A 2-ARM

RANDOMISED TRIAL

7.1   Statement of Authorship

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Name	Megan McIntosh
Contribution to paper	Established protocol, conducted data collection and analysis, wrote and revised manuscript as per co-author and reviewer feedback, acted as corresponding author.
Overall percentage (%)	80%
Certification	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.

Signature and date   10/11/2021

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Contribution to paper   Provided advice and feedback on the protocol, data analysis, and
                        manuscript drafts.

Signature and date   15/09/2021

Impact of different unconditional monetary incentives on survey response rates in men with prostate cancer: a 2-arm randomised trial

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7.2 Abstract

Background: Men are often viewed as a difficult group to recruit for psychological research, including in psycho-oncology. Whilst research has demonstrated the effectiveness of small monetary incentives for encouraging research participation, little research has examined different large unconditional incentive amounts. Larger unconditional incentives may result in increased participation of men in psychological research. This randomised study within a case-control trial of men diagnosed with early-stage prostate cancer aimed to investigate whether (a) response rates to a 30-minute questionnaire completed via mail, online, or phone would vary with different unconditional incentive amounts, and (b) demographics would vary in those who responded within the different incentive groups.

Methods: We conducted this randomised study within a case-control cross-sectional study aiming to identify the social-ecological factors influencing treatment discontinuation in prostate cancer patients. A total of 238 participants from the cross-sectional study were randomised to receive one of two unconditional incentives (n=121 received AUD\$10, n=117 received AUD\$20) with the study materials (consent form and survey).

Results: Overall, 113 (47%) responded; n=61/121 (50.4%) in the AUD\$10 group, and n=52/117 (44.4%) in the AUD\$20 group. No evidence of a difference was found in response rates by incentive group (odds ratio 1.27, 95% CI=0.76-2.12, p=0.36). Additionally, there were no evident differences in the demographics of the responders vs. non-responders within each incentive group (all p>0.05).

Conclusions: Unlike previous research, we were unable to show that higher monetary incentives were more effective for increasing response rates. An AUD\$20 unconditional incentive may be no more effective than a lesser amount for encouraging prostate cancer survivors to participate in research involving long questionnaires. Future research should consider the cost-benefits of providing large

unconditional incentives, as non-responses will result in lost resources perhaps better utilised in other engagement strategies.

7.3   Background

Prostate cancer is responsible for a large burden of disease worldwide[1]. It is highly prevalent and associated with significant and long-term morbidity[2]. To ensure high-quality care for patients, and thus reduce disease burden, a greater understanding of patient experiences and unmet needs is essential, especially from the patient perspective. In recent years, psychological studies focusing on patient reported outcomes, such as anxiety and quality of life, have been encouraged in order to inform disease management[3]. However, men are often viewed as a difficult group to engage in psychological research[4], particularly in psycho-oncology[5–8]. While emerging evidence suggests that men with prostate cancer frequently experience unmet physical, social, and informational supportive care needs[9,10], much of the research to date is qualitative or has relatively small or unrepresentative samples (e.g., recruited participants from only one clinic/hospital). Men have varying health-related needs and preferences[11] and high response rates and representative samples are essential to reflect this variability.

Research into understanding cancer patients' supportive care needs and experiences has traditionally relied on participant completion of self-reported validated questionnaires[5,10]. A number of strategies that have been shown to generally improve response rates in paper-based survey research may also be beneficial in recruiting men to these types of studies. Incentives are a potentially important area to investigate in regard to improving recruitment rates in men's supportive care survey studies. In a large systematic review by Edwards et al[12] (N=481 trials) that evaluated the effects of 110 different strategies on response rates to postal surveys, odds of response were significantly higher when monetary incentives were utilised, compared to offering no incentive (odds ratio (OR) 1.87; 95% CI 1.73-2.04). Of the 481 randomised controlled trials included, 94 (involving 160,004 participants) evaluated the effect of a monetary incentive. Monetary incentives can either be conditional on

response (e.g., mailed out to the participant after they submit a completed survey), or unconditional (e.g., mailed out to the participant with the study materials). Unconditional (versus conditional or non-monetary) monetary incentives have been shown to be the most effective for increasing response rates across a range of populations[12,13]. Edwards et al found the odds of postal response increased when unconditional monetary incentives are provided (OR 1.61, 95% CI 1.36-1.89), compared to using conditional monetary incentives[12]. However, there is currently limited guidance for researchers on what amount constitutes an effective monetary incentive, and whether this varies by factors such as participation burden and participant characteristics. Social exchange theory posits the level of monetary incentive needs to be weighted against the burden of the task[14]. If a research incentive is perceived as too high, the participant may be more likely to view it as an economic exchange (rather than a social exchange), resulting in a reduced likelihood of response[14]. Though Edwards et al[12] did find that responses to postal surveys are slightly higher when a larger incentive is used (odds ratio 1.26, 95% CI 1.14-1.39), much of the research to date has compared conditional and unconditional incentive amounts of around AUD$10 or less, or outcomes using different incentive types (such as monetary amounts versus lottery-style prize draws).

Additionally, emerging research suggests gender differences for monetary incentives in response rates may exist. In a Canadian study by Boulianne[15], men were more responsive to a web-based survey on community attachment and engagement when provided a higher unconditional incentive (CAD$10, equivalent to AUD $10 at the time of the Boulianne study), and women were more responsive with a lower unconditional incentive (CAD$5). However, participants in this study were first-year university students, and these incentive amounts may not be sufficient for paper-based questionnaires of significantly longer length containing personal, health-related questions. Little research has compared larger unconditional monetary incentives (e.g., AUD$10 and over)[16–18], especially in predominantly male cancer populations[15,19].

We aimed to evaluate the effect of offering different unconditional incentive amounts on response rates in a case control study of men diagnosed with prostate cancer. In particular, we aimed to determine whether (a) response rate would vary by different relatively large unconditional incentive amounts, and (b) patient characteristics (e.g., age, marital status, employment status, education level) would vary in those who responded within the different incentive groups.

7.4 Methods

7.4.1 Study setting & procedure

We conducted a randomised study within a case-control cross-sectional study aiming to explore the social-ecological reasons why prostate cancer patients discontinued active surveillance without evidence of disease progression[20]. Conducting trials within other research studies is a recognised method for increasing evidence-based knowledge and evaluating or exploring the effectiveness of various approaches to conducting research in a resource efficient way[21]. This sub-study is linked to recruitment for the case-control study. Recruitment was intended to occur through two state-based prostate cancer registries in South Australia and Victoria. Our target sample size for the case-control trial was 450 participants (i.e., 90 case-control groups). Using registry data, men were pre-identified as 'cases' (those who had received curative treatment without evidence of disease progression according to predefined criteria) or 'controls' (those still on active surveillance or those who had received treatment with signs of disease progression, as clinically recommended) and matched on a 1:4 ratio. The matching ratio was based on the assumption that the response rate among controls would be lower (estimated as 50%) than cases (estimated as 75%), and that a ratio of 1:4 for our sample size would give a probability of 0.94 of having at least 1 of 4 controls for each case.

Unfortunately, due to COVID-19, we were unable to conduct the Victorian arm of the study. As such, all potential participants were contacted through the South Australian Prostate Cancer Clinical Outcomes Collaborative (SA-PCCOC), which captures approximately 90% of newly diagnosed prostate cancer patients in South Australia every year[22]. Recruitment involved SA-PCCOC mailing

study materials on our behalf. The study materials included an information statement, consent form, a hard-copy of the survey and a return envelope. An eligibility form was also included. Based on the social-ecological model[23], the survey consisted of 18-pages incorporating validated and researcher-devised measures. Participants could complete and return a hard copy of the survey, access an online version by typing in a link noted on the study materials or call the research team to complete it over the phone. This was to accommodate participant preferences and access needs. A pilot test (N=32 controls) was conducted to assess the probable response rate to the research participation request. Six of the 32 responded (19% response rate). Therefore, alterations to the materials and protocol were made in an attempt to boost the response rate. As recommended by Edwards et al[12], we reduced the survey length (by two pages), sent all participants a priming letter two weeks prior to study materials, and provided unconditional incentives in the form of a gift card redeemable at thousands of Australian stores (either AUD$10 or AUD$20). Gift card allocation was randomised. The survey took approximately 30 minutes to complete. Participants who had not responded after two weeks were mailed a reminder letter. The main study was registered on ANZCTR in February 2020 (trial #12620000170921), and this sub-study was registered retrospectively in March 2022 (trial 12622000556741).

7.4.2 *Sample size*

Based on the target sample for the main study and the expected effective sizes of unconditional incentives [12] we anticipated we would have reasonable power ($> 80\%$) to detect expected differences in response rates (OR 1.9) between the two groups. However, we were unable to recruit sufficient numbers to the main trial. With Victoria having approximately four times the population of South Australia we anticipated recruiting approximately 75% of our sample from Victoria. With the South Australian registry only, we were only able to invite 270 potential participates to complete the study (consisting of 54 case-control groups).

7.4.3 *Participants*

Participants were 18+ years old, had been diagnosed with prostate cancer between January 2014 and October 2019, were able to communicate in English, and had been on active surveillance for at least six months immediately following their prostate cancer diagnosis.

7.4.4 Randomisation

The allocation sequence was generated by the study statistician (AV) who was blinded to the study participants. The randomization was clustered by the main study case-control group (excluding 32 controls who participated in the pilot), with clusters being block randomized using random block length 2 or 4. Of the 238 participants invited to participate, 121 were allocated the AUD$10 incentive and 117 were allocated the AUD$20 incentive.

7.4.5 Outcome measures & data collection.

The primary outcome was the proportion of responders. Responders were defined as those who either (a) completed and returned a survey (i.e., participants) or (b) did not complete and return the survey but did complete and return a form that had been included with the survey on which individuals could indicate their ineligibility for the case-control study due to having never been on active surveillance ("Never on Active Surveillance" form). Packages returned to sender and returned blank questionnaires were not counted as responses. The secondary outcome was differences in demographic variables in responders within each incentive group. This self-reported information was sourced from the completed surveys (marital status, employment status, and education level) and the SA-PCCOC registry (postcode, diagnosis information, and age). Survey data were collected via mail, online or phone in February – March 2020, and is available on Figshare[25]. Data collected by mail and phone was entered into RedCap, a secure, web-based software platform[26] that also hosted the online version of the survey. Information recorded regarding surveys sent, received, reminders sent, and responses were tracked in Excel[30] and RedCap[26] on a secure University of Adelaide network.

7.4.6 Blinding:

Participants were not advised of the differing incentive amounts included in the survey packages. Author MM was not blind to conditions after group allocation, as she was responsible for facilitated recruitment, material dissemination, and analysis for both the survey and interviews.

7.4.7   *Statistical methods*

Descriptive statistics to illustrate participant demographics were performed. Mixed-effects logistic regression with matched groups as the random effect was used to compare differences in response rates between the two incentive groups. To compare differences in demographics by incentive group responders, Pearson's chi-square analyses (for categorical variables) and Welch's two-sample T tests (for continuous variables) were used. The significance level was set at 0.05 (two-sided). All analyses were completed in R[27].

7.5   **Results**

7.5.1   *Response rate*

A CONSORT diagram of the recruitment process is shown in Figure 1. In brief, 238 participants from the SA-PCCOC registry were invited to participate in the current study. A total of 113 (47%) responded, with 97 completing and returning a valid survey and a further 16 responding to report that they were ineligible for the study as they had never been on active surveillance.

Figure 1: CONSORT diagram
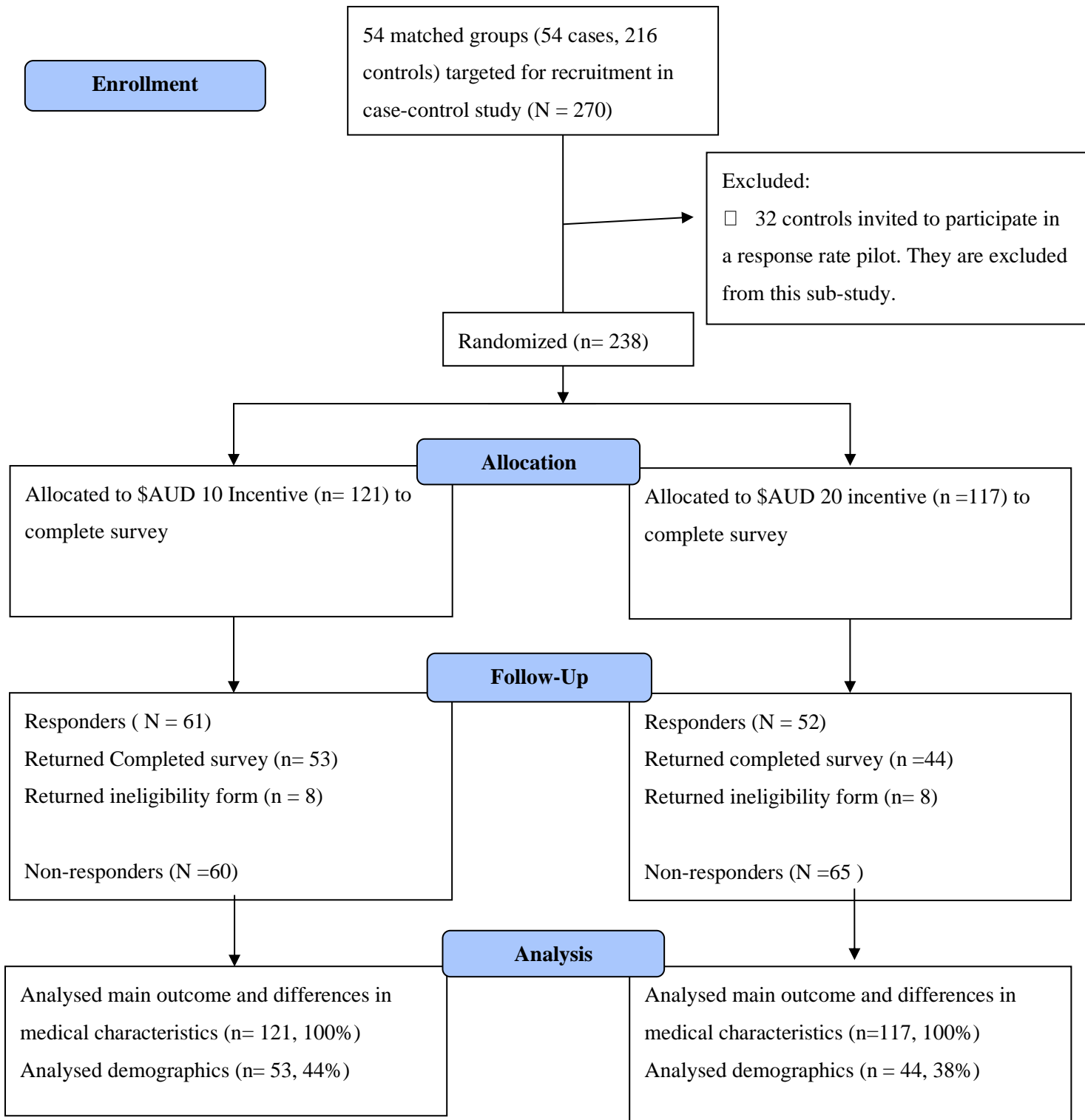
7.5.2   *Responders*

Demographic information on the responders, by incentive group, is presented in Table 1. This information on non-responders was not available, as it was collected within the survey. Clinical characteristics of all randomised participants (N=238), sourced from the SA-PCCOC registry, are shown in Table 2. The average eligible responder was 64 years old, married/partnered (84%), not currently working (71%), had completed post-high school education (69%), and lived in a major South Australian city (71%).

Table 1: Demographics of eligible* responders

Demographic Variable	All eligible responders (n=97)	$10 eligible responders (n=53)	$20 eligible responders (n=44)	p-value
Age: M (Sd)				
Mean age in years	64.4 (6.7)	65.7 (6)	62.8 (7.3)	0.55
Current Treatment Status: N (%)				0.64
Underwent curative treatment	51 (52.6)	29 (54.7)	22 (50)	
On active surveillance or ceased all treatment	46 (47.4)	24 (45.3)	22 (50)	
Relationship status: N (%)				0.13
Partnered/married	81 (83.5)	47 (88.7)	34 (77.3)	
Single/divorced/widowed	16 (16.5)	6 (11.3)	10 (22.7)	
Employment: N (%)				0.38
Currently working (full- or part-time or self-employed)	28 (28.9)	16 (30.2)	17 (38.6)	
Not in paid work (e.g. retired, unemployed)	69 (71.1)	37 (69.8)	27 (61.4)	
Highest Education: N (%)				0.34
Primary or high school	29 (29.9)	18 (34.0)	11 (25.0)	
Post-high school	67 (69.1)	35 (66.0)	33 (75.0)	
Location**: N (%)				0.75
Major city	69 (71.1)	37 (69.8)	32 (72.7)	
Regional or remote area	28 (28.9)	16 (30.2)	12 (27.3)	
Time Since Diagnosis: M (Sd)				
Mean years since diagnosis	2.9 (1.2)	2.8 (1.1)	3.1 (1.3)	0.15

*This table only includes eligible responders, as ineligible responders (i.e., the N=16 who completed the "Never on Active Surveillance" form) were not asked to provide demographic information.

* Location is determined by residential postcode and classified using the Australian Statistical Geographical Classification – Remoteness Area framework [29].

Table 2: SA-PCCOC Patient Information for all randomised participants

	All Participants (N=238)	All Responders (N=113)	All Non-responders (N=125)
Age at diagnosis: M (Sd)			
Mean age (years)	64 (7.3)	64.8 (6.6)	63.4 (7.8)
Current Treatment Status: N (%)			
Underwent curative treatment	98 (41.2%)	46 (40.7%)	52 (41.6%)
On active surveillance or ceased all treatment	140 (58.8%)	67 (59.3%)	73 (58.4%)
Time Since Diagnosis: M (Sd)			
Mean years since diagnosis	3.1 (1.3)	2.9 (1.2)	3.2 (1.4)
Time on active surveillance: M (Sd)			
Mean months on active surveillance	22.7 (13)	22.8 (13.5)	22.7 (12.6)

7.5.3   Difference in responses between AUD$10 and $20 incentives

In the AUD$10 group, n=61/121 (50.4% response rate) responded, and n=52/117 (44.4%) responded in the AUD$20 group. There was no significant difference in response rates to the different incentives (OR=1.27, 95% CI=0.76 – 2.12, *p*=0.37).

7.5.4   Demographic differences between incentive groups

Respondents allocated to the AUD $20 incentive reported higher rates of being single or divorced and higher rates of post-high-school education compared to respondents to the AUD $10 incentive. However, no statistically significant differences in any of the demographic and health variables (age at diagnosis, marital status, employment status, education level, region/location, and days since diagnosis) were observed between responders to the two different incentives (all *p*>0.05).

7.6   Discussion

In order to produce generalisable research that is demographically and clinically representative of the target population, researchers must use effective recruitment strategies to ensure a high response rate[12]. Offering unconditional monetary incentives can significantly increase response rates across a range of populations[12]. This trial attempted to incentivise survey participation by men diagnosed with prostate cancer, as they are generally an under-represented cohort in mixed-gender psycho-oncology

research due to low response rates[4–8]. This study evaluated the impact of two different unconditional incentive amounts (AUD$10 versus AUD$20) on response rates to a lengthy, personal, health-related questionnaire (when used in conjunction with pre-notification and follow-up). The response rate was approximately 6% higher in the $AUD 10 unconditional incentive group than in the $AUD 20 unconditional incentive group. In line with Social Exchange Theory, this may suggest that the $AUD 20 unconditional incentive was perceived as too high. However, the difference was not statistically significant. Unfortunately, the study likely wasn't powered to detect differences of this magnitude, which makes the null findings difficult to interpret. These findings are in contrast to previous research suggesting that higher monetary incentive amounts result in higher response rates, though that research was primarily evaluated lower incentive amounts (i.e., under $10AUD), and was not specific to male cancer survivors[12]. It is also noteworthy that our overall response rate of 47% was lower than previous studies that have recruited prostate cancer patients from SA-PCCOC[24], and other research investigating conditional versus unconditional response rates in prostate cancer patients[19]. This may be due to the fact that participation in this study may have involved greater burden (16 written pages total survey, approximately 30 minutes to complete, including personal questions on mental and physical health) than in many other studies. Data collection also overlapped with the beginning of the COVID-19 pandemic in Australia, which also may have impacted response rates.

Overall, this study found an AUD$20 unconditional incentive was not superior to a AUD$10 unconditional incentive for increasing response rates to a relatively long questionnaire on cancer experiences and unmet needs in prostate cancer survivors. Observational research intending to offer incentives to boost participation rates must also consider the cost benefit of the strategy. If incentives are unconditional, as in the present study, non-responses will result in lost funds perhaps better spent on other effective engagement strategies. Edwards et al (2009) found that odds of response were significantly higher when strategies such as pre-notification of the study (OR 1.45; 95% CI 1.29-1.63) and follow-up contact (1.35; 95% CI 1.18-1.55) were used. Whilst these strategies were utilised in the present study, we are unable to determine their effect on response rates as these were used with all

participants. Future research may consider exploring this and other strategies previously found to be effective, such as providing another copy of the questionnaire when attempting to follow up non-responders[12]. Where sample sizes allow, studies may also consider utilising a factorial design, which would enable analysis of the individual and interactive effects of different strategies[28].

7.7   Conclusions

Conducting trials within studies is a recognised method for identifying effective procedures in the conduct of research (such as the effectiveness of engagement strategies)[21]. In line with social exchange theory, future research should consider whether engagement strategies are balanced to the required tasks in order to be effective. Despite our relatively small sample of prostate cancer survivors, the results suggest that larger monetary unconditional incentives (i.e., over \$10) may not be superior to lower incentive amounts (i.e., \$10 or less) in this population. Monetary savings by using equally effective smaller incentives would allow valuable resources to be utilised on other strategies to increase engagement and responses in psycho-oncology research. Further research may be needed to generalise these findings to populations not represented in our sample (e.g., prostate cancer patients with metastatic disease).

7.8   References

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8 CHAPTER EIGHT:

DISCUSSION & CONCLUSIONS

8.1 Overview of thesis and principal findings

This body of research aimed to explore the experiences and influences on patients diagnosed with low risk, localised prostate cancer, from diagnosis to discontinuation. A range of methodologies were used to identify, summarise, and explore patient experiences, knowledge gaps, and areas for further research, with the aim of informing interventions to improve active surveillance uptake, experiences, patient outcomes, and adherence. This research explored a variety of issues from the patient perspective using both quantitative and qualitative methods: perceived influences on treatment choice, unmet supportive care needs, and reasons for discontinuing active surveillance. It also summarised existing literature in a systematic review to inform further research and conducted a randomised trial to understand how to better recruit prostate cancer survivors into research. Overall, this thesis provides a comprehensive account of the experiences of patients on active surveillance throughout their cancer journey, from diagnosis to discontinuation. Below, a more detailed overview of the findings from each research chapter is provided.

8.1.1 *Chapter Three: Decision making in men diagnosed with early-stage prostate cancer and their partners/close allies – A qualitative study*

In this qualitative study, we aimed to investigate factors perceived to influence the treatment decision for patients eligible for active surveillance. We interviewed 24 male patients (most of who had chosen active surveillance as their treatment) and 12 female partners of men eligible for active surveillance and found that both patients and their partners can be influenced by a range of social-ecological factors when making their treatment choice. Participants strongly considered other people's experiences with prostate cancer and treatments (both positive and negative experiences), their doctor's treatment recommendation and level of expertise, and their family/spouse's treatment

preferences. The results suggest that to reduce treatment decision regret and uncertainty associated with decision-making, doctors should employ a shared decision-making model which considers the patient and partner's existing beliefs and preferences. However, further research on treatment decision-making by partnered and non-partnered prostate cancer patients is required and may best be done through the lens of the social-ecological model, which recognises such behaviour can be influenced by an interaction of personal, interpersonal, community, and policy factors.

8.1.2   *Chapter Four: A systematic review of the unmet supportive care needs of men on active surveillance for prostate cancer*

This systematic review aimed to summarise the literature on the unmet supportive care needs of men on active surveillance, to help inform the development of supportive care interventions targeting areas of need. Of the 3,613 unique records identified, only eight studies (five qualitative and three cross-sectional quantitative) met eligibility criteria and were included in the review. The literature suggests informational needs are the most common unmet need experienced by men on active surveillance; the information available and provided to men during active surveillance is perceived as inadequate and inconsistent. The results also showed that men may also be experiencing other unmet needs, including psychological and social needs; however, further representative, high-quality research is required to understand the magnitude of this issue. Given the limited research available, the review was unable to identify factors associated with or predictive of unmet supportive care needs in active surveillance patients. In order to do so, it was recommended that research utilise existing theoretical models, such as the social ecological model, to ensure factors which may facilitate unmet needs are appropriately considered and reported.

8.1.3 Chapter Five: Men's unmet supportive care needs during active surveillance: a mixed methods investigation

Given the outcome of the systematic review, this study aimed to report on the unmet supportive care needs (and psychological wellbeing) of patients during active surveillance, from the perspectives of patients both currently on active surveillance and those who had discontinued. We recruited 103 participants (n=47 currently on AS, n=54 subsequent treatment, n=2 ceased all care), all of whom completed a survey. Thirty-three of the 103 participants also participated in a semi-structured interview. In general, unmet supportive care needs across all domains (informational, psychological, sexual, physical, patient care/support) were moderately low, however just over 20% of the sample reported having high unmet informational needs related to receiving information about their monitoring and test results. Unmet needs related to patient care (e.g., access to services/treatment in rural towns or after-hours) and sexuality were also commonly discussed. In regard to mental wellbeing, general and prostate cancer specific anxiety, and depression scores were low. However, higher fear of prostate cancer progression scores were reported and this fear was also frequently mentioned in interviews. To better support patients who may require more support without increasing patient and service provider burden doctors should be aware of common unmet supportive care needs and offer support when appropriate to address potential needs. Further research to identify factors predictive of or associated with unmet supportive care needs is recommended to assist health professionals to target patients who would benefit from support.

8.1.4 Chapter Six: Reasons men transition from active surveillance to treatment: a mixed methods investigation

Reasons for discontinuing active surveillance, particularly from the patient's perspective, is an under-explored area. In this study, we aimed to explore patient's own reasons for (or considering) discontinuing active surveillance. This study included 103 participants, 47 of whom were still on active surveillance at the time of the survey. All participants completed a survey, and 33 also completed semi-structured interviews. Results indicated that patients commonly discontinue or

consider discontinuing active surveillance for a mix of personal and medical reasons. Common reasons for discontinuation were evidence of disease progression, doctor recommendation, having a desire to act, and fear of progression. Interestingly, patients frequently considered any level or amount of disease progression, rather than a clinically significant level, as a reason to consider treatment. Other personal reasons such as fear of progression, family concerns, and adverse vicarious experiences were also reported to influence patients' desire to discontinue active surveillance. Further research to identify predictors of discontinuation, as well as interventions to address the influence of personal factors (such as fear of progression and vicarious experiences), may assist health professional in providing support to those considering treatment in the absence of clinically significant progression.

8.1.5   *Chapter Seven: Impact of different unconditional monetary incentives on PROMS survey response rates in men with prostate cancer: a 2-arm randomised trial*

In this randomised trial, embedded within the planned case-control study, we sought to investigate the effect of different unconditional monetary incentive amounts on survey response rates in men with prostate cancer. Men are a heterogenous group with varying health-related needs and preferences, and are often viewed as a difficult group to recruit for psychological research, including in psycho-oncology. Whilst studies have demonstrated the effectiveness of monetary incentives for encouraging research participation, little research has examined different large unconditional incentive amounts, despite emerging evidence that larger unconditional incentives may result in increased participation by men in psychological research. We aimed to investigate whether higher and lower unconditional monetary incentives would lead to differing response rates, and if responder demographics would vary within the different incentive groups. Of the 238 participants randomised to receive one of two unconditional incentives (AUD$10 or AUD$20), 50.4% in the $10 group, and 44.4% in the $20 group responded. No statistically significant difference was found in response rates by incentive group, nor were there differences in the demographics of the responders within each incentive group. These results suggest that larger unconditional incentives (e.g., AUD$20) may be no more effective than a

lesser amount for encouraging prostate cancer survivors to participate in research involving long, personal questionnaires. Though our study findings are limited by a smaller than expected sample size. Future research should consider the cost-benefits of providing large unconditional incentives, as non-responses will result in lost resources perhaps better utilised in other engagement strategies.

8.2   Strengths of the research

The research contained within this thesis employed diverse and rigorous research methods which optimised research outputs while placing minimal impact on participants. This included the conduct of a high-quality systematic review, original research which recruited from a state-based registry, a qualitative study with participants recruited from a leading international cancer centre, and a randomised trial conducted within a study. All research followed the relevant research guidelines (CONSORT[1], PRISMA[2], COREQ[3], and STROBE[4]).

Three of the five research papers included in this thesis (Chapters Five, Six, and Seven) utilised data and recruited patients from SA-PCCOC, a large, state-based prostate cancer registry that captures approximately 90% of all patients diagnosed with prostate cancer in South Australia[5]. Patient registries are an extremely useful resource in healthcare research as they comprehensively obtain patient data across various specific outcomes which can be utilised for scientific, clinical, and policy purposes[6]. Patient registries can benefit a range of stakeholders. For instance, clinicians can utilise registry information to collect patient data in a comprehensive and cohesive manner, thereby producing an accurate, real-world depiction of the disease outcomes and treatment practices across patients. Hospitals and other healthcare practices may also use patient registries to analyse whether their own patient care is consistent with evidence-based guidelines and to inform proposed changes to practice and policy[7]. Importantly, researchers can utilise patient registries to either analyse previously collected data or for recruitment purposes, which may assist in providing a more representative sample and generalisable results, as patient characteristics are likely to differ across practices, clinicians, and locations[8]. Our research, which sampled from SA-PCCOC, was therefore more likely

to be representative of all South Australian prostate cancer patients than previous studies that have often only recruited from one hospital or practice.

Three out of the five studies (Chapters Three, Five and Six) included in this thesis focussed on understanding active surveillance from the perspectives of patients. Unlike previous registry-based cohort studies which predominantly utilise data collected by the registry to describe patient outcomes, this research explored patient experiences from their own perspectives, through the use of validated questionnaires and qualitative methods. Furthermore, our systematic review (Chapter Four) summarised predominantly qualitative literature, further illustrating the needs and experiences of patients from their own perspectives. Understanding the experiences, needs, and perspectives of patients is imperative when informing and designing patient-centred supportive care services and patient management guidelines. Patient-centred care, which considers patient preferences, needs, and values, and aims to ensure patient values guide clinical decisions, is a widely recommended approach in oncology, and its use has been associated with increased satisfaction with care, greater job satisfaction in healthcare workers, increased quality of care, and greater quality of life and wellbeing of patients[9].

In order to provide a thorough overview of the experiences of patients on active surveillance, this thesis included research on several time-points during the cancer journey: early after diagnosis, during active surveillance, and after discontinuation. In doing so, this research has provided a solid foundation for further research across all stages of active surveillance, including longitudinal research. For instance, further research into identifying and exploring the unmet supportive care needs of men on active surveillance is recommended, including to compare unmet needs in men on active surveillance with other treatment groups, explore whether unmet needs change across the cancer trajectory and at what timepoints, and identify what social-ecological factors are associated with or predict increased unmet needs. Understanding unmet needs in men on active surveillance in such

ways will enable the development and provision of targeted supportive care services when they are needed most, thereby placing less burden on patients and the healthcare system.

It has long been recommended that health research and public health interventions consider the interaction between individuals and their environment. This may be effectively understood through the lens of a theoretical model, such as the social-ecological model, to contextualise factors influencing behaviour and health outcomes[10]. According to the theory underpinning this model, interventions to enable sustainable health improvements will be most effective when factors across the five social-ecological levels (i.e., individual, social, community, organisation, and policy), are targeted[10]. This thesis utilised the social ecological model to assist in identifying and contextualising areas in which further research and support for patients on active surveillance may be required. The use of theoretical models to drive health research can assist in the prevention of research repetition, enable wider consideration of factors that may influence health and behaviour, assist in the organisation of knowledge, and help guide the development of interventions[11]. The social ecological model has been utilised within several of the research papers within this thesis to both summarise and contextualise the results, as well as inform future areas of research and supportive care strategies.

Finally, several study-specific strengths must be mentioned. Our systematic review (Chapter Four) is the first we are aware of to summarise the unmet supportive care needs of active surveillance patients. This research identified a clear need for further research utilising validated questionnaires to assess unmet supportive care needs. Given this finding, a validated measure of unmet supportive care needs was included in our survey (used in the studies presented in Chapters Five and Six). Given this study was the first of its kind to reliably assess unmet supportive care needs of active surveillance patients, the findings have global significance and are likely to be useful to inform further research and interventions to improve active surveillance management. Additional study strengths have been outlined in their respective chapters.

8.3   Limitations of the research

The findings of this research should be interpreted within its limitations. This section will outline the limitations associated with the overall thesis; study-specific limitations have been outlined in their respective chapters.

Firstly, the COVID-19 pandemic had a considerable impact on this research and the study designs. For instance, our research presented in Chapters Five and Six had originally aimed to identify predictors of discontinuing active surveillance and had planned recruitment from both South Australian and Victorian prostate cancer registries. The original study was a case-control matched design, where cases (patients who received definitive treatments after active surveillance without evidence of disease progression/risk reclassification) and controls (patients either currently on active surveillance or those who had definitive treatment after active surveillance with evidence of disease progression/risk reclassification) in multiple Australian states were to be recruited and matched on a 1:4 ratio. Unfortunately, the COVID-19 pandemic resulted in the need to halt recruitment before we could begin at the Victorian registry, thereby significantly reducing the number of eligible participants. This reduced sample size resulted in an inability to perform higher-level analyses to identify factors predicting and associated with active surveillance discontinuation. Fortunately, recruitment and data collection in South Australia had already been completed prior to recruitment was halted. As such, we proceeded with a cohort study to analyse the validated measures contained within the survey, along with qualitative interviews to further explore these findings. This research provides an excellent foundation for further research to extend these findings accordingly.

Secondly, the research within this thesis largely contains cross-sectional research. Whilst this provides an important overview of the experiences, needs, and preferences of patients from their current perspective, it does not reflect changes in patient experiences, needs and preferences over time. Longitudinal research of the active surveillance experience to assess social-ecological variables influencing patient experiences (such as unmet needs, anxiety, and fear of cancer progression) across

the patient journey is needed to inform the provision of supportive care services at critical time-points (e.g., after diagnosis and prior to follow-up testing). Existing longitudinal research on prostate cancer patients has demonstrated that mental health (e.g., depression, general anxiety, and prostate-cancer specific anxiety, uncertainty)[12], quality of life[13], and adjustment (e.g., avoidance thoughts, fight against cancer attitudes)[14] may improve or remain stable over time, although increased undesirable symptoms have been reported by patients prior to follow-up active surveillance testing[12]. Further longitudinal research which utilises a mixed-methods approach, explores outcomes from patient perspectives, and considers the timing of data-collection to ascertain at which points during active surveillance additional support would be best offered and delivered is recommended[12].

Finally, we were unable to determine the proportion of participants in this research from culturally and linguistically diverse (CALD) backgrounds and who identify as gay, bisexual, intersex, or transgender, and therefore could not identify whether results differed by these factors. Further research which takes such factors into account is required, especially given Australia is a multi-cultural society, and differences in prostate cancer outcomes between CALD or minority groups and the general population have been identified in the United States[15–18]. Whether similar differences exist in Australian populations is yet to be determined. Furthermore, the extent to which family and social factors, such as family and spousal pressure, influence the experience of active surveillance in non-heterosexual couples and single patients, needs to be determined.

8.4   Implications for practice and future research directions

This thesis has used a range of research methods which has elucidated novel findings, strengthens previous research, and provides a foundation for further research to build upon to better understand and support men during their time before, during, and after active surveillance. Furthermore, many of our findings can directly inform and be implemented into the daily practice and management of patients on active surveillance. Only a small body of research had previous examined the experiences and outcomes of men on active surveillance, and a significant proportion of these had reported results

from mixed patient samples (e.g., combining participants on active surveillance, watchful waiting, and after definitive treatment), did not use validated measures, had not considered use of theoretical frameworks to inform and guide their research, or did not investigate the patient's perspective. The original research in this thesis sought to address these knowledge gap to inform the development of patient-centred supportive care services which cater to the needs of patients on active surveillance, and provide internationally-relevant information which can inform future research and the management of patients during active surveillance. Improving active surveillance management, outcomes, and patient experiences will ultimately require a multi-level approach to address the individual, social, and wider environmental and policy factors. Through the lens of the social ecological model, the following sub-sections outline areas of further research and practice that are recommended to build upon the findings illustrated in this thesis. As depicted in Figure 1, a range of research areas, interventions, and recommendations for practice across all levels in the social ecological model (individual, social/community, organisation, and public policy) are encouraged.

Figure 1: Future Research and Practice Directions through a Social-Ecological Lens
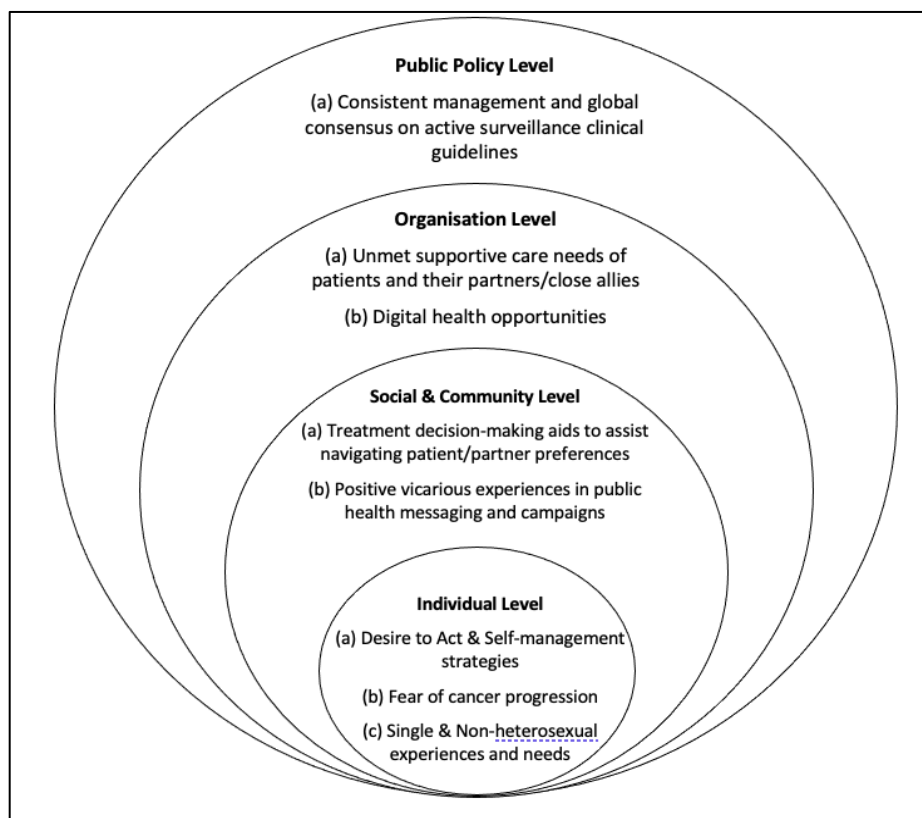
8.4.1 Targeting the individual level

8.4.1.1 Addressing patient desire to act through self-management interventions

As illustrated in Chapter Six, our research found that one of the personal reasons men leave, or consider leaving active surveillance, is a desire to take action to cure their cancer. However, for patients whose disease is not progressing (or is slowly progressing but still considered low risk), taking steps to cure or remove the cancer may be unnecessary and potentially detrimental to their health. To fulfil the needs of patients during active surveillance who desire to take actionable steps to take control of their health and cancer, we recommend further research be conducted to identify effective opportunities for patients to practice health self-management. Offering patients opportunities to have greater control over important aspects of their health may alleviate desires to act and seek definitive treatments before this is medically necessary[19]. One potentially effective strategy is physical activity and exercise prescription, as these can both assist in improving the physical and mental health of patients, whilst potentially slowing disease progression[20]. Research has already demonstrated that patients on active surveillance would welcome exercise support as part of their management, and when it is provided, patients have found it beneficial to their overall health and wellbeing[21]. Exercise may be a particularly effective self-management strategy for men on active surveillance, as unlike traditional support (e.g., psychological therapy), exercise and physical activity is aligned with masculine values (e.g., strength) and action-orientated coping strategies[20]. In a study of prostate cancer patients who had received definitive treatment, physical inactivity was associated with higher levels of distress, anxiety, and more unmet needs[22]. Research is currently being conducted to evaluate this type of intervention in men on active surveillance, to understand the effects of exercise on aerobic fitness, biological outcomes, tumour growth, and psychological wellbeing (including fear of cancer progression)[23]. Other potential self-management strategies to cater to patients' desire for control and action may include psychologically-based self-management interventions which focus on stress reduction, anxiety, and improving lifestyle and nutrition. Very few of these types of interventions have been developed and evaluated for patients during active surveillance[19,24–26], though more are underway[27].

8.4.1.2 Addressing fear of cancer progression

Fear of cancer progression was a common theme throughout the research in this thesis. In almost every study, patients described feeling fearful and worried their cancer was progressing too quickly, suddenly, or silently whilst they were on active surveillance. Given that fear of cancer progression is often experienced during active surveillance, more so than after definitive treatment[28], further research to develop and evaluate effective interventions to address this is required. As briefly discussed in our study on the reasons patients discontinue active surveillance (Chapter Six), drawing from and adapting existing research and interventions addressing fear of cancer recurrence may be a valuable approach. Fear of cancer recurrence in prostate cancer survivors is common; one study reported that over 35% of patients post-prostatectomy experienced high level of fear of cancer recurrence[29]. Furthermore, participants with higher fear of cancer recurrence had lower quality of life scores and reported more symptom burdens[29]. Fear of cancer recurrence has also been reported in partners of cancer patients. For instance, one study found that partners of cancer patients with higher fear of cancer recurrence scores had poorer mental health, general health, and vitality, compared to partners with lower scores of fear of cancer recurrence[30]. Unfortunately, very few interventions specifically designed for patients (and their partners/close allies) dealing with fears of prostate cancer progression or recurrence have been developed and evaluated[31,32], though many do exist for other cancers (particularly women with breast cancer)[33,34]. The adaptation of interventions found effective for improving fear of cancer recurrence and progression in other cancers for men (and their partners/close allies) with prostate cancer and on active surveillance, may be an valuable start in the effort to improve patient outcomes and reduce discontinuation of active surveillance without evidence of disease progression.

8.4.1.3 Understanding the experiences of single men with prostate cancer and non-heterosexual men with prostate cancer

A significant limitation of this research is that the experiences of single or non-heterosexual men with prostate cancer and on active surveillance were not portrayed. This is an under-researched area of

literature in prostate cancer. Given that married men have longer life expectancies and lower disease burdens compared to unmarried men[35], and approximately 3.6% of Australian men describe themselves as gay, bisexual, or another sexual minority orientation[36], research on the experiences of single and non-heterosexual men is required. From both the research contained in the thesis and in the wider literature, it is understood that prostate cancer patients are influenced by the treatment preferences and opinions of their partner, and that partners are more likely to prefer definitive treatments[37–39]. Spouses also provide essential emotional and practical support to patients[40,41]. Whether single men require additional support after their prostate cancer diagnosis and during their time on active surveillance is yet to be widely explored. Research which suggests married men have better prostate cancer outcomes (particularly in regard to prostate cancer specific survival and quality of life), compared to unmarried men, suggests this may be the case[42–46]. In regard to sexuality, the majority of research on partner's experiences of prostate cancer largely reports on female partners of male patients. Whilst specific research with gay and bisexual men with prostate cancer does exist[47–50], recruitment of such patients and reports of their outcomes within large cohort studies is lacking. This is especially problematic as research suggests gay/bisexual men with prostate cancer experience poorer health outcomes, including worse urinary function, dissatisfaction with medical care, and more fear of cancer recurrence[51]. Further research which actively seeks to consider and describe the experiences and needs of single, non-heterosexual men, transgender women, and non-binary people (and their partners where applicable) is required to ensure their needs are equally met.

8.4.2   *Targeting the social and community levels*

8.4.2.1   Treatment decision-making aides to include navigating treatment preference disagreements between patient and their partner/close allies.

As illustrated in Chapter Three of this thesis, our interviews with patients and partners about the treatment decision-making phase after a prostate cancer diagnosis illustrated that treatment decision-making can become even more complex when the patient and their partner/close allies have different

treatment preferences. In order to better support patients and their families/close allies through the treatment decision making phase, the use of treatment decision-making aides (which typically provide a thorough overview of the treatment options and help guide patients to choose the option which aligns with their values and goals), which also address ways in which couples might navigate treatment disagreements, may be very beneficial. Decision-making aides provided to both the patient and their partner/close ally may assist in provided more thorough, balanced, and unbiased information about prostate cancer, treatment options, and treatment side effects. Whilst many treatment decision-making aides have been developed for patients after a prostate cancer diagnosis, two systematic reviews have identified some major limitations in these, including a lack of consideration for patient values/beliefs, inadequate partner/close ally involvement or consideration, incorrect definitions of active surveillance (e.g., no distinction made between active surveillance and watchful waiting), and underuse of theoretical frameworks[52,53]. Treatment decision-making aides in cancer are most effective when they are tailored, interactive, collaborative, and focused on the priorities of the patient, though few interactive decision aides have been developed and implemented[54]. However, a randomised control trial for an online, interactive decision aide for prostate cancer patients and their partners is reportedly underway[55].

Other potential avenues for supporting couples through treatment decision making may include practical changes to practice, such as encouraging partners/close allies of patients to attend medical appointments (to ensure they are exposed to the information provided), providing opportunities for the partner/close ally to voice their concerns and questions, and if necessary, providing recommendations and referrals to additional support (such as psychological support or a prostate cancer nurse). Several accessible support options already exist, including guides for partners of prostate cancer patients (including that published by the Prostate Cancer Foundation of Australia)[56], and in some locations, face-to-face support groups for partners and carers[57].

8.4.2.2 Increased use of positive vicarious prostate cancer experiences in public health messages and campaigns

Given our research has found both prostate cancer patients and their partners are influenced by positive and negative vicarious experience of prostate cancer, we recommend that public health messaging and campaigns specific to prostate cancer promote positive vicarious experiences, particularly in regard to active surveillance. Increasing awareness of active surveillance as a safe treatment option for patients diagnosed with low risk, localised prostate cancer may have significant effect on its uptake and adherence. Promoting and illustrating positive experiences on active surveillance in campaigns such as Movember (a large campaign run in November each year to promote awareness of men's health issues including prostate cancer, testicular cancer, and suicide)[58] and on social media (such as Facebook, Twitter, and Instagram) may be beneficial. In an analysis of social media platforms, Vraga and colleagues[59] found that as very few posts during the Movember campaign mentioned prostate cancer, the campaign may not be translating into greater awareness of prostate cancer, treatment options, or health-positive actions. Increasing awareness and understanding of prostate cancer in the community is particularly important as research has demonstrated that prostate cancer patients (including those on active surveillance, as identified in our systematic review – Chapter Four) often have unmet information needs related to their cancer and treatment[60–63].

8.4.3 Targeting the organisational level

8.4.3.1 Further research to understand and identify the unmet supportive care needs of patients, and their partners/close allies, during active surveillance

Several research directions to understand the supportive care needs of patients and their partners/close allies are warranted given the findings of our research as illustrated in Chapters Four and Five.

Firstly, we recommend longitudinal research be conducted to assess how needs do or do not change over time to ascertain when support is best offered and provided to patients and their partners/close

allies. In a cohort study of prostate cancer patients in New South Wales, over a third of participants reported at least one unmet need 15 years post-diagnosis, demonstrating that prostate cancer patients experience unmet supportive care needs which may not be addressed for years after diagnosis. However, like much of the unmet needs research in prostate cancer, this study did not analyse unmet needs by treatment type, and therefore the specific needs of patients on active surveillance are unknown. Unfortunately, very little longitudinal research on unmet needs in prostate cancer has been conducted, and no study has specifically assessed the unmet needs of active surveillance patients over time from diagnosis.

Secondly, to further extend our findings described in Chapter Five, additional research is required to identify any potential social-ecological predictors of unmet supportive care needs of men during active surveillance. Identifying social-ecological factors such as demographics (e.g., age, location, relationship status), clinical factors (e.g., time on active surveillance, PSA, Gleason score), social/community factors (e.g., social support), and organisational/policy factors (e.g., satisfaction with healthcare, access to services) that may be associated with or predictive of unmet needs will undoubtedly assist in improving the management and care of patients eligible for and during active surveillance.

Finally, as the majority of research in prostate cancer and unmet supportive care needs has combined treatment types and not assessed the needs of patients', partners or close allies, we suggest research be conducted to address this knowledge gap. Understanding whether differences in unmet needs exist between treatment groups is essential for doctors to understand the common unmet needs experienced by their patients and may assist in ensuring patients are provided with appropriate supportive care options. Furthermore, understanding the unmet needs of partners/close allies is essential, as these needs may impact the patient experience, and may be addressable through joint interventions. Research to explore the unmet needs of prostate cancer patients (and their partners/close allies) across Australia has already begun. Colleagues from The Daffodil Centre and I recently secured a grant from

the Prostate Cancer Foundation of Australia to assess the population-based unmet needs of prostate cancer patients and their close allies/partners. This mixed-methods study will explore the prevalence of unmet needs as well as the barriers and facilitators to satisfy unmet needs in these groups (grant reference PIRAYI 1020). Already underway are two systematic reviews, which will identify and summarising the existing literature on (a) the unmet supportive care needs of prostate cancer patients across treatment types, and (b) the unmet supportive care needs of partners/close allies of prostate cancer patients.

8.4.3.2   Opportunities for digital health strategies

Delivering support such as psychosocial assistance (e.g., from allied health professionals), support groups, and information on topics such as prostate cancer, active surveillance, and self-management strategies during active surveillance to patients on or contemplating active surveillance via digital online modalities would likely increase access to services and reduce burden on the healthcare system. Research has routinely demonstrated that support and interventions delivered online are a cost-effective and accessible resource and are generally perceived as an acceptable modality of service provision by prostate cancer patients[21,64,65]. Digital health services that address symptom management, decision-making, follow-up care, as well as palliative care and general survivorship have been successfully developed across a range of cancer types. Given the increasing use of the internet and smartphones, the implementation of digital health services is becoming a feasible solution to address the lack of provision of supportive care services to available to some patients, especially those in remote areas or on lower incomes[66]. Although significant further research is required to assess the acceptability, safety, and efficacy of delivering supportive care services to patients and their partners/close allies after prostate cancer diagnosis, it is recommended that future supportive care interventions consider this mode of delivery.

8.4.4 *Targeting the policy level*

8.4.4.1 Consistent management and use of active surveillance nationally and worldwide.

Underpinning the overall active surveillance experience, from both a patient and physician perspective, is the amount of high-quality research informing the clinical guidelines of care and management. Inconsistent clinical guidelines for active surveillance across practices, organisations, and on an international scale may have serious implications on patient outcomes[66–68]. Results from our research suggest men are influenced by the vicarious experiences of prostate cancer they are exposed to; if a patient on active surveillance hears of another patient on active surveillance receiving a different management strategy, experiencing poor active surveillance management/support, or experiencing adverse outcomes as a result of active surveillance (e.g., clinical intervention is left too late and the cancer metastasises), they may experience increased uncertainty, fear, or anxiety, and may be more inclined to discontinue active surveillance before clinically necessary. The Movember Global Action Plan Active Surveillance project (GAP3), which was launched in 2014, is a promising start to address this issue. The GAP3 initiative aims to (a) create a centralised database of information on active surveillance patients, (b) create and implement globally recognised clinical guidelines for active surveillance selection and monitoring criteria, (c) open and maintain an online platform to provide the latest information on active surveillance research, and (d) reduce the proportion of men who transition to definitive treatment within the first year of active surveillance[69]. Already, the GAP3 initiative has established their database, which is collecting information from patients on active surveillance from 25 hospitals and institutions across 15 countries[70], resulting in a plethora of research publications and further research opportunities[71–76].

8.5   Conclusion

Through a social-ecological lens, this thesis has comprehensively explored the experiences of patients diagnosed with low risk, localised prostate cancer from diagnosis, during active surveillance, and after active surveillance discontinuation. Given the rise of low risk prostate cancer incidence worldwide, and that active surveillance is the best-available treatment option for such patients, understanding the experiences, supportive care needs, and psychological wellbeing of patients (and their partners/close allies) throughout the entire journey on active surveillance is essential. As illustrated in this research, whilst the majority of men on active surveillance report positive experiences and outcomes, a significant proportion report fear of cancer progression, uncertainty on their treatment and future, and unmet supportive care needs across informational, psychological, physical, sexual, and patient care domains. This research sought to understand patient experiences and needs to ultimately inform interventions and changes to management which aim to improve patient experiences and prevent discontinuation without evidence of significant disease progression. Furthermore, this research has identified a range of areas for further research across individual, social, community, organisational, and public policy levels which will continue to improve the active surveillance experience for both patients and their partners/close allies.

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9   APPENDICES

The following appendices contain the supplementary material available for each publication,

organised by each chapter and reference to the supplementary material within the manuscripts.

9.1   Chapter Three

9.1.1   Appendix A – Patient Interview Guide

First of all, thank you for completing the questionnaires and for speaking with me today. I want to just remind you why we are conducting this study. Our objective is to learn from you and other patients more about the decision-making process either for definite treatment or active surveillance. We would first like to start out by having you tell us about when you were first diagnosed with prostate cancer.

1) When were you initially diagnosed with prostate cancer?
2) What kind of information was helpful to you when first learning you had prostate cancer?
3) What were you feeling? (For example: hope, determination, sadness, depression, despair, anger, fear, guilt, other emotions?)
4) How did your partner/close ally react?
5) Have you made any changes to your diet since your diagnosis with prostate cancer?
   a) How long ago did you initiate these changes?
6) Are your priorities the same now as when you were diagnosed with prostate cancer
   a) What is most important to you in your life at this moment? (Travel, family, increasing life span, quality of life, other things?)

I would now like to move on to talking about your feelings and thoughts about your current treatment options and/or decision.

1) How have you decided to approach the management or treatment of your illness?
2) Can you tell us how you made that decision? Specifically, we would like to focus on the communication you had with your doctors. The first series of questions are directed toward doctors outside of Memorial Sloan Kettering:
   a) When your doctor(s) spoke to you, did they discuss the pros and cons?
   b) Which are more important to you?
3) Your doctor discussed different treatment options, are there some that you liked or didn't like? Do you remember pros and cons?

4) Was there information that you really wanted to know or that you really didn't want to know?

5) How much influence did your partner/close ally have when making the decision?

The next series of questions are directed toward doctors at Memorial Sloan Kettering:

1) Did your doctor focus more on your interests and quality of life (as compared to your disease)?

2) Did you learn something new about active surveillance or its safety?

3) If so, can you tell us 3 things that would support active surveillance as described by your doctor?

4) Was there anything that was not clear after your discussion with the doctor?

5) Did you feel the risk of active surveillance was: the same, less, or more than you expected after speaking with your doctor? Please explain.

6) What did your doctor say that made you feel active surveillance was a viable option for managing your cancer, similar to surgery or radiation? Please list.

7) What did you not agree with about what your doctor said regarding active surveillance?

8) Your doctor discussed different treatment options, are there some that you liked or didn't like? Do you remember pros and cons?

9) Was there information that you really wanted to know or that you really didn't want to know?

10) How much influence did your partner/close ally have when making the decision?

11) Did the doctor provide you with a strategy to speak with your family or friends about active surveillance?

12) *If active surveillance:* Do you plan to begin active treatment at a certain point?

13) *If definitive treatment:* When ideally would you begin treatment (or feel like you should have begun treatment if you thought it should have begun already)?
   a) How long did it take to make your decision?
   b) Did you go back and forth between treatment options?
   c) Was there anything that your doctor at Memorial Sloan Kettering said that really impacted your decision the most?

14) What information was helpful to you during the decision making process?
   a) Have you done research such as reading books, looking online?
   b) Have you spoken to other men with prostate cancer and/or rising PSA?
   c) Were you worried about getting more information?
   d) Is it worrisome to get more information, or does it calm you down?
   e) What information influenced your decision the most?

I am now finished with my questions, is there anything else you would like to add, and/or do you have any questions for me? Thank you again for your time and participation in our study.

9.1.2   Appendix B - Partner Interview Guide

First of all, thank you for completing the questionnaires and for speaking with me today. I want to just remind you why we are conducting this study. Our objective is to learn from you and other partners/close allies more about the decision-making process either for definite treatment or active surveillance. We would first like to start out by having you tell us about when _____ (insert name of the patient) was first diagnosed with prostate cancer.

1) When was _____ initially diagnosed with prostate cancer?

2) What kind of information was helpful to you when you first learned about his prostate cancer?

3) What were you feeling? (For example: hope, determination, sadness, depression, despair, anger, fear, guilt, other emotions?)

4) How did he react?

5) Has he made any changes to his diet since he was diagnosed with prostate cancer?

    a) How long ago did he initiate these changes?

6) Are your priorities the same now as when he was diagnosed with prostate cancer?

    a) What is most important to you in your life at this moment? (Travel, family, increasing life span, quality of life, other things?)

The next series of questions are directed toward doctors at Memorial Sloan Kettering:

1) Did his doctor focus more on your husband's interests and quality of life as compared to his disease? (N/A if you were not at his clinic visit)

2) Did you learn something new about active surveillance or its safety from his doctor or from your husband after his visit?

3) If so, can you tell us 3 things that would support active surveillance as described by his doctor or by your husband to you?

4) Was there anything that was not clear after your discussion with the doctor? Or did your husband express to you that something was not clear- please describe?

5) Did you feel the risk of active surveillance was: the same, less, or more than you expected after speaking with his doctor? Please explain. (N/A if you were not at his clinic visit)

6) What did his doctor say that made you feel active surveillance was a viable option for managing your cancer, similar to surgery or radiation? Please list. (N/A if you were not at his clinic visit) (N/A if you were not at his clinic visit)

7) What did you not agree with about what his doctor said regarding active surveillance? (N/A if you were not at his clinic visit)

8) Was there information that you really wanted to know or that you really didn't want to know after speaking with his doctor? (N/A if you were not at his clinic visit)

9) Did the doctor provide you with a strategy to speak with your family or friends about active surveillance?

I would now like to move on to talking about your feelings and thoughts about your current treatment options and/or decision.

10) How has _____ decided to approach the management or treatment of his illness?

11) Can you tell us how he made that decision? Did he consider alternative treatment?
   a) When your doctor was talking to him, did the doctor discuss the pros and cons?
   b) Which are more important to _____?
   c) Which are more important to you?
   d) His doctor discussed different treatment options. Are there some that he liked or didn't like? Do you remember pros and cons? Are there some that you liked and didn't like? Do you remember the pros and cons?
   e) Was there information that you really wanted to know or that you really didn't want to know?
   f) Compared to _____, how much influence did you have when helping him make the decision?

12) If active surveillance: Does he plan to begin active treatment at a certain point?

13) If definitive treatment: When ideally would he begin treatment (or feel like he should have begun treatment if you thought it should have begun already)?

14) How long did it take for _____ to make a decision? Did he go back and forth between treatment options?

15) How long did it take for you to make decision? Did you go back and forth between treatment options?

16) What information was helpful to you during the decision making process?
   a) Have you done research such as reading books, looking online?
   b) Have you spoken to other men with prostate cancer?
   c) Have you spoken to other partners/close allies about prostate cancer?
   d) Were you worried about getting more information?
   e) Is it worrisome to get more information, or does it calm you down?
   f) What information influenced your decision the most?

I am now finished with my questions. Is there anything else you would like to add, and/or do you have any questions for me? Thank you again for your time and participation in our study.

9.2 Chapter Four

9.2.1 Appendix C - Search Strategy

Prostate Cancer	Active Surveillance	Support Needs
MeSH Headings: "Prostatic neoplasms" Titles/Abstracts: 'prostate cancer' OR 'prostate neoplasm' OR 'prostatic cancer' OR 'localised prostate cancer' OR 'indolent prostate cancer'	MeSH Headings: "Watchful waiting" Titles/Abstracts: 'active surveillance' OR 'management' OR 'monitoring' OR 'deferred treatment' OR 'observation' OR 'delay treatment'	MeSH Headings: "needs assessment" OR "Quality of life" OR "Social support" OR "Self-Help groups" OR "Health services needs and demand" OR "Psycho-oncology" OR "Survivorship" OR "Patient satisfaction" OR "Self-management" OR "Activities of daily living" OR "Anxiety" OR "Depression" OR "Uncertainty" OR "Fear" OR "Exercise" OR "Exercise therapy" OR "Healthy lifestyle" OR "Nutritional support" OR "Financial support" OR "Symptom assessment" OR "Lower urinary tract symptoms" OR "Pain" Titles/Abstract: 'Unmet need' OR 'Perceived need' OR 'Supportive care need' OR 'Psychosocial need' OR 'Psychological need' OR 'Physical need' OR 'Information need' OR 'Emotional need' OR 'Social need' OR 'Spiritual need' OR 'Religious need' OR 'Support need' OR 'Psychosocial support' OR 'Psychological support' OR 'Emotional support' OR 'Physical support' OR' Information support' OR 'Spiritual support' OR 'Supportive care needs survey' OR 'Sexual need' OR 'Sexual support' OR 'Supportive care' OR 'Communication support' OR 'Communication need'

	Criterion: Qualitative Studies	Avery et al 2014	Kazer et al 2011	Loeb et al 2018	Mroz et al 2013	O'Brien et al 2011	O'Callaghan et al 2014
1	Is there congruity between the stated philosophical perspective and the research methodology?	Yes	Yes	Yes	Yes	Yes	Yes
2	Is there congruity between the research methodology and the research question/objective?	Yes	Yes	Yes	Yes	Yes	Yes
3	Is there congruity between the research methodology and the methods used to collect data?	Yes	Yes	Yes	Yes	Yes	Yes
4	Is there congruity between the research methodology and the representation and analysis of data?	Yes	Yes	Yes	Yes	Yes	Yes
5	Is there congruity between the research methodology and the interpretation of results?	Yes	Yes	Yes	Yes	Yes	Yes
6	Is there a statement locating the researchers culturally and/or theoretically?	No	No	No	No	No	No
7	Is the influence of researcher on the research, and vice-versa addressed?	No	No	No	No	No	No
8	Are participants, and their voices, adequately represented?	Yes	Yes	Yes	Yes	Yes	Yes
9	Is the research ethical according to current criteria and is there evidence of ethical approval by an appropriate body?	Yes	Yes	Yes	Yes	No	Yes
10	Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?	Yes	Yes	Yes	Yes	Yes	Yes

	Criterion: Prevalence Studies	Boberg et al 2003	Davison & Goldenberg 2011	Bergengren et al 2018
1	Was the sample frame appropriate to address the target population?	Yes	Yes	Yes
2	Were the study participants sampled in an appropriate way?	Yes	Yes	Yes
3	Was the sample size adequate?	No	Unclear	Unclear
4	Were the study subject and the setting described in detail?	Yes	Yes	Yes
5	Was the data analysis conducted with sufficient coverage of the identified sample?	Yes	Yes	Yes
6	Were valid methods used for the identification of the condition?	Yes	No	Yes
7	Was the condition measured in a standard, reliable way for all participants?	Yes	Yes	Yes
8	Was there appropriate statistical analysis?	Yes	Yes	Yes
9	Was the response rate adequate, and if not, was the low response rate managed appropriately?	Yes	Yes	Yes

9.3   Chapter Five

9.3.1   *Appendix E - Participant Selection Criteria for Interviews*

Participants were invited to participate in qualitative interviews if they met any of the following criteria based on responses to the survey:

- Scored a 2 or higher (i.e., indicating the item was experienced 'sometimes' during active surveillance) across any of the three domains (prostate cancer, PSA testing, cancer recurrence) in the prostate cancer specific anxiety measures (MAX-PC).
- Met clinical criteria for anxiety or depression according to the PHQ-4 measure (i.e., score of 3 or above in anxiety or depression).
- Indicated a moderate or high unmet need in any unmet support care need domain (physical, sexual, informational, patient care, or psychological) according to the Supportive Care Needs Survey.
- Lived in an outer regional, remote, or very remote area according to the Australian Statistical Geographical Classification – Remoteness Area Framework
- If they had since received definitive treatment after active surveillance: Indicated a personal reason for discontinuing active surveillance
- If they were still on active surveillance: Indicated, they had considered discontinuing active surveillance to any extent

9.3.2 Appendix F - Interview Questions

Question	Prompts
Can you start by telling me about when you were diagnosed with prostate cancer and began active surveillance?	• How long were you on AS for? • What did you know about AS? • Relationship with doctor?
What was/is active surveillance like for you?	Pros of experience? Cons of experience?
IF APPLICABLE: I can see from the survey you received support from a _____. Can you tell me about this?	• Why did you access this support? • Did someone refer you or suggest this? • Did you find it helpful? • Did you access or use anything else to help you cope during AS?
IF APPLICABLE: I see you live in a regional area, do you have any thoughts about the experience of being on AS/having treatment given you live rurally?	Did this impact your decision to have treatment?
We included some questions about unmet needs in the survey. Is there anything you wish you had during active surveillance that would have improved your experience?	• Information (e.g., about Prostate cancer, AS, treatments) • Psychological help/support • Sexual Health info/support • Help with physical symptoms/issues (e.g., pain, energy, feeling unwell) • Health care (e.g., receiving test results, involvement, access to cancer nurse) • Did any of these unmet needs impact your decision to have treatment?
Did you experience any anxiety during active surveillance in regard to your prostate cancer?	• Fear of progression? • Uncertainty about PSA results/next steps? • Fear of dying? • Did this anxiety impact your decision to have treatment?

9.4 Chapter Six

9.4.1 *Appendix G – Interview Guide*

Question	Prompts
Can you start by telling me about when you were diagnosed with prostate cancer and began active surveillance?	• How long were you on AS for? • What did you know about AS? • Relationship with doctor?
What was/is active surveillance like for you?	Pro's of experience? Cons of experience?
IF APPLICABLE: I see you live in a regional area, do you have any thoughts about the experience of being on AS/having treatment given you live rurally?	Did this impact your decision to have treatment?
IF STILL ON AS:	
Have you ever considered having treatment?	• Why/why not • On survey you said XX, can you tell me about that?
Is there anything you wish you had access to while on AS?	E.g., professional help, information, social support, exercise prescription, etc Would this affect your desire for treatment?
IF TRANSITIONED TO TX:	
I understand you had XX treatment. What made you decide to have XX treatment?	• Did anyone help you make that decision? • Has XX treatment had an impact on your overall health/personal life? • Are you satisfied/dissatisfied with your decision?

Please see below for the relevant sections from the survey used to assess Reasons for Treatment and

Considering Treatment. Please contact the research team for a copy of the entire survey if desired.

Considered Treatment

In this section, participants still on AS were asked whether they had considered having treatment on a

4-point Likert scale (0= No, not at all; 3= yes, very often). The main reason for considering treatment

was assessed on a visual analogue scale (0-100), where 0 indicated purely personal reasons and 100

indicated purely medical/clinical reasons.

1. **Since commencing active surveillance, have you considered having curative**
   treatment for prostate cancer?
   - ☐ No, not at all
   - ☐ Yes, occasionally
   - ☐ Yes, somewhat often
   - ☐ Yes, very often

2. **Men can leave active surveillance for purely medical reasons (e.g., disease**
   progression), purely personal reasons (e.g., cancer related anxiety) or a mix of the
   two. Reflect on your reasons for considering to leave active surveillance to have
   curative treatment, and place and X on the line below which best represents why you
   have considered having treatment:

Personal reason (e.g., Fear of progression)		*Medical reason (e.g., PSA increase*
	├──────────────────────────┤	

Reasons for Treatment

Included items specific to personal reasons (uncertainty regarding test results, fear of cancer progression, depression, anxiety, pressure from family, and advice from others to have treatment, desire to cure/do something) or 'clinical/medical' reasons (PSA or Gleason score increased, changes in biopsy or DRE results, advice from doctors, comorbidity). Items were answered on a five-point Likert scale (1= doesn't apply to me at all; 5= strongly applies to me). This section was only answered by men who had definitive treatment. The main reason for having treatment was assessed on a visual analogue scale (0-100), where 0 indicated purely personal reasons and 100 indicated purely medical/clinical reasons.

1. **Please indicate if any of the following reasons prompted you to have curative treatment for your prostate cancer:**

Reason	Did not apply to me	Minimally applied to me	Somewhat applied to me	Very much applied to me	Strongly applied to me
My PSA (prostate specific antigen) level increased	1	2	3	4	5
My Gleason score increased	1	2	3	4	5
Uncertainty about my test results	1	2	3	4	5
My biopsy showed increased cancer volume	1	2	3	4	5
There was a change in my digital rectal examination	1	2	3	4	5
I had fear of my cancer progression going undetected	1	2	3	4	5
The follow-up protocol was inconvenient (e.g., conflicted with travel plans)	1	2	3	4	5
I experienced depression symptoms	1	2	3	4	5
I experienced anxiety symptoms	1	2	3	4	5

Reason	Did not apply to me	Minimally applied to me	Somewhat applied to me	Very much applied to me	Strongly applied to me
Other symptoms/comorbidities prompted my treatment	1	2	3	4	5
My doctor recommended I have treatment	1	2	3	4	5
I felt pressure from loved ones to have treatment	1	2	3	4	5
I received advice from others with prostate cancer to have treatment	1	2	3	4	5
I had a desire to 'do something' and cure the cancer	1	2	3	4	5
I was tired of waiting for my cancer to progress	1	2	3	4	5
Other reason which strongly applied to me (please describe):					
Other reason (2) which strongly applied to me (please describe):					
Other reason (3) which strongly applied to me (please describe):					

2. **Men may leave active surveillance for purely medical reasons, purely personal reasons or a mix of the two. Consider your reasons for leaving active surveillance. Please place an X on the line below that best represents why you stopped active surveillance to receive active treatment**:

Personal reason (e.g., fear of progression)	⊢————————————————————⊣	*Medical reason (e.g., PSA increase)*