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FACTORS INFLUENCING TREATMENT DECISIONS

FOR MEN WITH PROSTATE CANCER

A thesis submitted in fulfilment of the requirements for the award of the degree

Master of Philosophy

from University of Wollongong

by Timothy Alan Skyring

Faculty of Science, Medicine and Health

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ABSTRACT

The decision-making process for men with early stage prostate cancer is complex and difficult because prostate cancer, despite having a high incidence, has a low mortality and treatments, despite having significant side effects, may not prolong survival with many men dying of non-cancer health issues. There is, therefore, an imperative to treat young, healthy men with aggressive cancers (preventing undertreatment) and avoid treatment of men with low grade cancers and/or a limited life expectancy due to age or comorbidities (avoiding overtreatment). This thesis places the process of decision making as the central locus.

Study A (Chapter 4) was a practice audit of four urology practices and investigated the influence of cancer and non-cancer patient factors (such as age and comorbidities) on the treatment decision-making process. The concordance of the treatment chosen with published guidelines was established and then any possible over- or under-treatments estimated. Our study demonstrated that 80% of patients received treatment concordant with published guidelines; however, for low risk cancers approximately one third of patients received non-concordant treatment. Appropriately, younger patients with few comorbidities and more aggressive cancers were more likely to receive curative treatment.

Study B (Chapter 5) was a survey of 151 men diagnosed with prostate cancer and examined whether there was an association between the extent to which men wished to be involved in the decision-making process, their satisfaction with that process, and their levels of decision regret after treatment. Although one third of men found the decision difficult to make, the majority were satisfied with the decision making process and the level of communication with their clinician and for these men, rates of regret were low. A major finding of the study was that taking an active role in the treatment decision-making process led to greater satisfaction with that process which, in turn, reduced the chance of experiencing regret following treatment.

Study C (Chapter 6) aimed to gain a better understanding of the health literacy of men

newly diagnosed with prostate cancer, the information sources they accessed, how helpful they found these sources, as well as the readability, understandability and actionability of these sources. The major finding was that approximately 20% of men, newly diagnosed with prostate cancer, had inadequate health literacy (HL), and this lower HL correlated with a younger age at leaving school. More than 80% of men used more than four sources of information, but older men, who are typically the group diagnosed with prostate cancer, were shown to access fewer sources, which may limit their ability to be involved in the shared decision-making process. In terms of information sources, men found their primary treating urologist the most helpful source of information and even though the internet was used by approximately half of the study participants, older men were less likely to use the internet as a source of information. The readability and understandability of many information sources was at too high a level and the actionability of these information sources was too low, meaning that men were not empowered to be involved and actually make a decision.

Study D (Chapter 7) assessed the level of health literacy among a broad group of men attending a urological clinic and investigated the concordance between two different published measures of health literacy. We also explored if there was an association between health literacy, cancer literacy and comprehension, and prostate cancer knowledge among this group of men. Similar to the previous study, more than 20% of men were shown to have low health literacy, with low scores specifically in areas relating to seeking and understanding information about their health. There was high concordance between two measures of health literacy and a positive correlation between cancer literacy and comprehension, and both measures of health literacy used in this study.

Our overall conclusion is that the process of decision making for men with prostate cancer is critical, with clinicians needing to assess both the life expectancy of the patient from non-cancer causes and the risk from the cancer if untreated and patients being involved in, and satisfied with, the decision-making process, which we have shown lead to lower rates of post-treatment regret. We also identified that low health literacy, and the low readability, understandability and actionability of available prostate cancer information sources, can potentially interfere with men’s involvement in the decision-making process.

ACKNOWLEDGEMENTS

I wish to acknowledge the support, guidance and encouragement of my supervisors Associate Professor Kylie Mansfield and Professor Judy Mullan. I also thank my wife, Helena, for her forbearance.

STYLE OF THESIS

The style chosen was journal article compilation style as it was important to gather data in a mixed methods approach and have it published in peer reviewed journals. These publications form the ‘backbone’ of the thesis and the narrative is built around them.

LIST OF PUBLICATIONS

1. Skyring TA, Mansfield KJ, Wallace W, Nasir S, Mullan JR. Risk of under- and over-treatment in a group of Australian men diagnosed with prostate cancer (ANZ Journal of Surgery, submitted for publication/under review)
2. Skyring TA, Mansfield KJ, Mullan JR. Factors Affecting Satisfaction with the Decision-Making Process and Decision Regret for Men with a New Diagnosis of Prostate Cancer. Am J Mens Health. 2021 Jul-Aug;15(4):http://doi.org/10.1177/15579883211026812
3. Skyring TA, Mansfield KJ, Mullan JR. Readability, understandability and actionability of written information available for patients diagnosed with prostate cancer. J Health care communication 7(2):7006. (Published Feb 2022) Available from: http://doi.org/10.35248/ipjhcc-7.2.7006
4. Skyring TA, Mansfield KJ, Abbott K, Mullan JR. Health literacy, comprehension and prostate cancer among men. (American Journal of Mens Health, submitted)

DECLARATION AND CERTIFICATION

I, Timothy Alan Skyring, declare that this thesis is wholly my own work unless otherwise referenced or acknowledged. The document had not been submitted for qualifications at any other academic institution.

Timothy Alan Skyring

February 2022

Author contributions

Associate Professor Tim Skyring: Conceptualisation, data curation, formal analysis, writing original draft, and review and editing.

Professor Judy Mullan: Methodology, project administration, supervision, validation, writing review and editing.

Associate Professor Kylie Mansfield: methodology, project administration, supervision, validation, writing-review and editing.

Ethical considerations

Ethics approval has been obtained from the Health and Medical Human Research Ethics Committee (HREC) of the University of Wollongong. Approval number 2016/955 and subsequent amendments

LIST OF ABBREVIATIONS

ABS	Australian Bureau of Statistics
AIHW	Australian Institute of Health and Welfare
ALLSS	Adult Literacy and Life Skills Survey
ANOVA	Analysis of Variance
AUA/ASTRO	American Urological Society/American Society for Radiation Oncology
BHLS	Brief Health Literacy Scale
CCI	Charlson Comorbidity Index
HeLMS	Health Literacy Management Scale
HL	Health Literacy
IRDS	Index of Relative Socioeconomic Disadvantage
MRI	multiparametric Magnetic Resonance Imaging
NCCN	National Comprehensive Cancer Network
PCA	Prostate Cancer
PEMAT	Patient Education Materials Assessment Tool
PSA	Prostate Specific Antigen
QOL	Quality of Life
SEER	Surveillance, Epidemiology and End Results
TCI	Treatment with Curative Intent
TDM-SAT	Treatment Decision-making Satisfaction Scale

TNCI	Treatment with Non Curative Intent
UNESCO	United Nations Educational, Scientific and Cultural Organisation

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CHAPTER 1:

FOREWORD AND THESIS CONTEXT

1.1 *GENERAL INTRODUCTION*

1.1.1 Overview

The overarching aim of this thesis is to explore the factors that influence the decision-making process of men with newly diagnosed prostate cancer.

The discussion surrounding treatment choices for men with prostate cancer poses unique challenges for both clinicians and their patients as it is a common cancer, but one with often a low mortality regardless of treatment chosen, or even with no treatment.[1] Confounding this however, the natural history of a cancer for a particular patient can be difficult to define. In addition, the ability of treatments to change this natural history, and improve survival, can be difficult to prove and all treatments carry moderate risks of significant side-effects.[2-5] The provision of information with high readability to men and an assessment of the health literacy (HL) of those men is critical to establishing a collaborative treatment decision-making process between the patient and the physician.[6] The aim of this process is to identify men for whom treatment with curative intent is required (i.e. men with aggressive cancers); while, avoiding overtreatment in men with low life expectancy due to age or comorbidities, or in those with low grade cancers that are unlikely to progress and cause either morbidity or death.[7,8]

1.1.2 Incidence of prostate cancer

Prostate cancer has a high incidence and remains the most common solid organ cancer diagnosed in Australian men, with an incidence rate of 129 cases per 100,000 persons.[1] This is similar to the incidence rate of 104 cases per 100,000 persons among American men .[9] As a result there is a 1 in 7 chance of an Australian man being diagnosed with prostate cancer by age 85.[1] The Australian Institute of Health and Welfare (AIHW) estimates that in 2021, 16,665 new cases of prostate cancer would have been diagnosed in Australia, representing 23% of all new male cancer diagnoses.[1]

1.1.3 Process of Diagnosis.

In most men there are no symptoms or signs of prostate cancer, and the diagnosis is usually made after a routine blood test measuring the serum Prostate Specific Antigen (PSA).[9] If the PSA is elevated a Multiparametric Magnetic Resonance Imaging (MRI) scan is frequently performed to further estimate the likelihood of cancer.[9] If these results and a digital rectal examination (DRE) of the prostate are *not* reassuring, a prostate biopsy is performed to confirm the diagnosis and to establish the grade or aggressiveness of the cancer. Further scans are then performed to determine the cancer stage, specifically, if there is spread outside the prostate, both locally and at distant sites, such as in bone. Ninety percent of cases are diagnosed when the cancer is still confined to the prostate (clinically localised or early stage prostate cancer), such that treatment with curative intent is possible and needs to be considered.[10,11]

1.1.4 Survival and Mortality.

Survival rates for early stage prostate cancer are high, regardless of the treatment option chosen, with an overall 95% five year survival rate.[1] This means that a man diagnosed with early stage prostate cancer in 2021 has a 95% chance of surviving 5 years and a disease specific survival in excess of 10 years.[1] The AIHW reports that although prostate cancer has a high incidence it is only responsible for 12.7% of cancer deaths, suggesting that in the majority of cases the prognosis for these men is good over a 10-15 year period.[1] The literature suggests that for low grade (non-aggressive) cancers the long term cancer specific survival with no treatment is very high, with comorbidities accounting for most deaths, whereas for high grade (aggressive) cancers deaths due to cancer itself were much higher.[4,12,13] Ultimately, with prostate cancer, we have a cancer that is common, often presents at an early and potentially curative stage but is indolent with long survival with no treatment in many cases and therefore the place of curative treatments is unclear.[3]

1.1.5 Treatment options.

Early stage prostate cancer can be treated conservatively or with curative intent. Conservative treatment can involve active monitoring with deferred curative treatment if the cancer progresses (active surveillance) or in older men, less intensive monitoring to pick up symptomatic progression (watchful waiting).[14] Due to the low mortality of prostate cancer, a no treatment surveillance option is a reasonable one for many older men, especially for those with low grade, non-aggressive cancers, and those with significant comorbidities leading to lower life expectancy.[13] In younger, healthier men, especially those with more aggressive cancer, curative treatment is usually considered.[15] Curative treatment is only considered when staging investigations show no regional or distant spread (metastases), such that the cancer is likely to be confined to the prostate and therefore amenable to local treatment.

Active treatment options, which include radical prostatectomy or radiation therapy, can be associated with significant early and late side effects and complications. Patients with higher grade (more aggressive) cancers, who are younger and fitter are more likely to have surgery recommended, while older patients with more advanced disease will often be recommended to have local radiation therapy to avoid the risks of surgery.[16] Radical prostatectomy has potentially significant in-hospital complications, including blood transfusion and venous thromboembolism, with mortality rates approaching 0.4%.[17] Late complications include significant incontinence requiring intervention (ranging between 2-5% of cases) and erectile dysfunction rates ranging from 25-50% of cases. Radiation therapy, on the other hand, can be associated with low but significant rates of dysuria (painful urination), rectal bleeding and faecal incontinence.[18] These types of long-term genitourinary and sexual complications are particularly distressing to men and may make decisions concerning active treatment difficult and emotionally fraught.[11]

Although most patients have early and potentially curable prostate cancer at presentation, approximately 20% do not present until the cancer is more advanced.[19] These patients may be asymptomatic, but harbour spread of disease to the lymph nodes or distant metastases. When, or if, these metastases become symptomatic they are usually managed with chemical castration (androgen deprivation therapy) to reduce testosterone levels and shrink the cancer, albeit for a limited period of time.[18] In contradistinction to early stage prostate cancer, the 5-year cancer specific survival for patients with distant metastases is 29%.[19] Androgen deprivation therapy also carries the risk of significant side effects, such as hot flushes, gynaecomastia, weight gain and depression, as well as the psychological burden associated with complete loss of libido and erectile dysfunction.[20] For these men, diagnosed with advanced prostate cancer, the treatment options, although significant and life changing, are more straightforward and the decision-making process is, possibly, less complex.

1.1.6 Effect of treatment on the natural history of prostate cancer

If the need for curative treatment is established, the next issue to be considered is whether treatment itself changes the natural history of the cancer and improves survival. Prostate cancer is usually detected by a screening test and survival is long regardless of treatment or no treatment; therefore, the phenomenon of lead time bias may occur such that survival is long after treatment but the time to death from when the cancer actually started is not changed and any improvement in survival is therefore artefactual.[21] The possibility of being cured by a treatment, or alternatively the chance of dying of cancer with no treatment, has a large influence on the treatment decision for early-stage prostate cancer, especially for men themselves.

Immediate treatment with curative intent is considered when the patient is younger and fitter (with a long life expectancy) and the cancer is deemed to be aggressive (high PSA and high grade), such that it is deemed likely to progress (locally or with distant metastases) within that patient's healthy life expectancy.[22]

A randomised controlled trial of 1643 men published in 2016 with mostly low stage, low grade cancer (age range 50-69, mean age 62) by Hamdy et al. compared active treatment to observation for early stage prostate cancer and showed a mortality rate of approximately 1% at 10 years, regardless of treatment option assigned.[2] The trial findings are significant as it involves large numbers of well-matched men followed-up over a long period of time and highlights the generally indolent nature of most prostate cancer, with slow progression and long survival without treatment. This biology makes it difficult to establish that treatment can and does prolong survival. A randomised trial of radical prostatectomy versus no treatment conducted by Wilt et al.,[3] involving 731 participants (mean age 67 years), failed to show a decrease in all cause or prostate cancer-specific mortality for those treated with radical prostatectomy at a median follow-up of 12 years. In this study only 7% of patients died from cancer during the follow-up period with a significant proportion of men dying of non-cancer diagnoses. Co-morbidities can be assessed using the validated Charlson Co-morbidity Index (CCI), which is a strong predictor of overall survival and life expectancy.[23,24] However, for those men with intermediate risk disease in this trial, radical prostatectomy led to less disease progression, lower cancer specific mortality and lower overall mortality. Supporting the findings of Hamdy et al[2] and Wilt et al.[3] on the difficulty of establishing improved survival with treatment, a Swedish trial of surgery versus observation with a 20 year follow-up involving 223 participants (mean age at diagnosis 72 years, range, 41-91 years), was only able to show a 10% reduction in prostate cancer mortality in the surgery group.[12] While this study had a comparative small sample population, its findings do offer support for those of Wilt et al.[3] In contrast, and giving support to the possible curative role of surgery, the randomised trial conducted by Bill-Axelson et al.,[22] involving 695 Scandinavian men younger than 75 years, showed that younger (<65 years) men with higher risk (more aggressive) cancer had a significant (>30%) decrease in all-cause mortality and cancer specific mortality following radical prostatectomy. This study also found that in older men, although there was a reduction in the development of metastases, an improvement in survival was not shown. Contemporary radiation therapy series report similar high survival rates with 5-year disease-free survival rates approaching 95%.[25]

1.1.7 Summary

The treatment decision process therefore, is a complex and difficult one for both patients and physicians with pressure on both to consider curative treatments.[26,27] For many men, because there are no symptoms, the diagnosis comes as a significant shock; consequently, there are high rates of psychological distress, anxiety and cancer fear, all of which complicate the decision about treatment options.[28,29] Understanding the options and making a decision about treatment is difficult for men in the context of a cancer that has high rates of long-term survival with no treatment, and treatment options that are associated with significant side effects and difficult to prove benefits.[2,19] For physicians the complexity of these issues makes presenting treatment options to men with varying degrees of HL complex and difficult.

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CHAPTER 2: REVIEW OF THE LITERATURE RELATING TO FACTORS INFLUENCING TREATMENT DECISIONS FOR MEN WITH PROSTATE CANCER

2.1 INTRODUCTION

The decision about treatment options for newly diagnosed prostate cancer is multifaceted involving both cancer related factors, patient related factors and factors related to the structure of the process. This literature review will first look at these factors in isolation and then attempt to examine how they are interrelated and combine to influence the treatment decision-making process.

Cancer related factors must first be assessed by the physician to allow advice to be given to the patient on the likelihood of the cancer progressing and therefore the need for treatment. Following this assessment, there are multiple patient factors that influence the decision to be considered involving both cognitive value judgements about treatment options by the patient, including level of risk aversion, and an assessment of the life expectancy and comorbidities of the patient by the physician. The structure of the decision-making process, and its success, will be influenced by the HL of the patient; their ability to access, read and understand information, and the extent to which the patient wants to share in the treatment decision.

A narrative literature review was performed using database searches for articles of most relevance. Further to the articles cited in this chapter, additional articles were sourced for each of the empirical studies and included when each of the four manuscripts were prepared.

2.2 CANCER FACTORS

Cancer factors, such as PSA, grade and stage of cancer, as well as an assessment of possible distant spread (metastases) influence the risk of cancer progression with no treatment, and therefore the need for treatment and the likelihood of cure following treatment[1] The likelihood of prostate cancer progressing is directly related to the grade or aggressiveness of the cancer and this can be assessed using validated scoring systems combining PSA, grade and stage of the cancer.[1,2] An American study of 14,156 older men (average age 78 years) showed that for less aggressive (lower grade) cancers, the 10 year cancer specific survival was > 90% with no treatment, and the risk of dying of a competing non-cancer related cause in this period of time was 60%.[3] For aggressive (high grade) cancers, this same study showed that the 10-year cancer-specific survival was 75% and the risk of dying from a non-cancer cause was 50% over that same 10-year period. The combination of the large sample size and the 10-year follow-up period strongly supports the proposition that men with early-stage prostate cancer, and especially older men with low-grade cancer, have a long life expectancy without treatment, and a significant risk of dying of comorbidities, which brings into question the need for active treatment for men with low grade disease. The fact that Cancer Specific Survival was significantly lower for men with high grade disease compared to men with low and intermediate grade disease indicates that the risk of cancer progression is dependent on cancer factors.[3] These findings are supported by the study of Ketchandji et al.[4], which interrogated the Surveillance, Epidemiology and End Results (SEER) database, which followed more than 150,000 men for 20 years post diagnosis and found that for men with low grade and low stage cancer survival is almost equivalent to men without cancer. However, for men with high stage and grade cancer, prostate cancer was the cause of death in 45%, again emphasizing the importance of risk stratification as part of the decision-making process. Notwithstanding the above, in all groups, comorbidity, especially diabetes and cardiovascular disease, remains an important cause of death.

The D’Amico risk stratification (a combination of PSA, cancer grade and stage) allows separation of patients into low, intermediate, and high-risk groups for post treatment PSA rise, which is indicative of treatment failure.[1] This is important not just because it allows better allocation of appropriate treatment but also because the risk groups can be used as a surrogate for measuring the potential aggressiveness of an individual patient’s cancer. These risk groups also correlate with biochemical recurrence, cancer specific survival and overall survival. These risk stratification guidelines have been extended by the American Urological Association (AUA) and the American Society for Radiation Oncology (ASTRO) into four groups for which they have published treatment guidelines[5] The aim of the prostate cancer treatment decision-making process is therefore to offer treatment with curative intent (TCI) with either surgery or radiation to men who will most benefit, usually younger men and those with aggressive cancers (thus avoiding undertreatment), and to avoid overtreatment of those with limited life expectancy due to age or comorbidities, and for those with low grade cancer, by offering treatment with non-curative intent (TNCI) including watchful waiting or active surveilance.[6,7]

2.3 PATIENT FACTORS

There are several patient factors that influence the treatment decision following a diagnosis of prostate cancer. These have been summarised in Figure 2.1

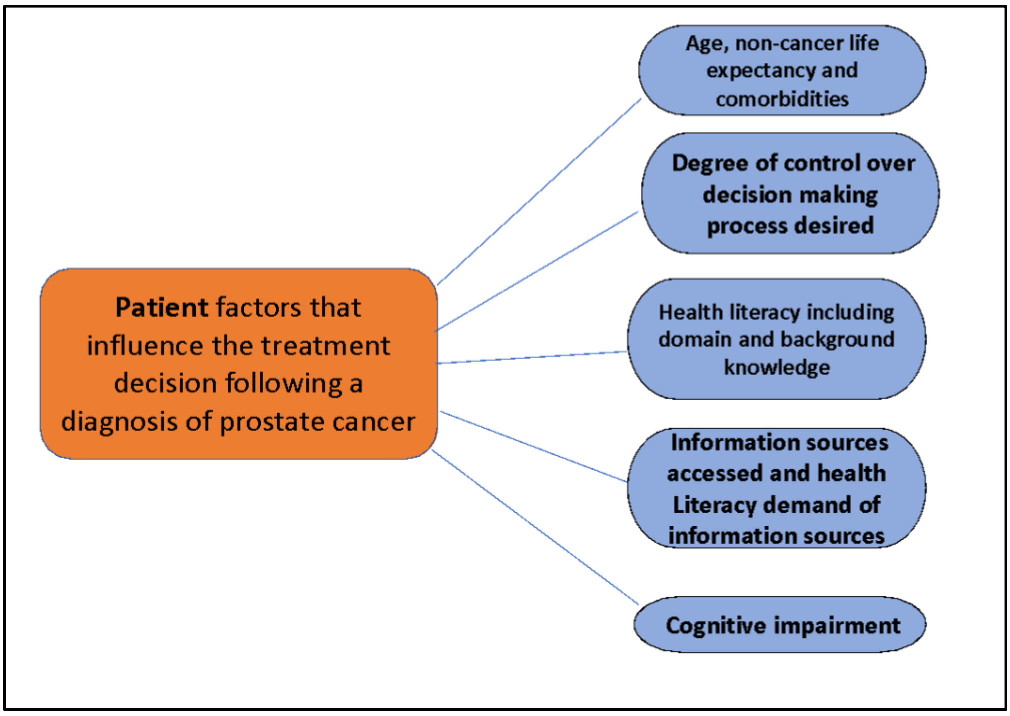

Figure 2.1: *Patient factors that influence the treatment decision following a diagnosis of prostate cancer.*

2.3.1 Organic/Physical factors.

Both the age of a patient and the presence of any chronic health conditions and comorbidities have a significant influence on the treatment decision-making process because they determine both non cancer influenced life expectancy and the risks of undertaking any proposed surgical treatments. To benefit from TCI, it is generally suggested by physicians that men have a life expectancy of more than 10 years.[8] A study from Hall et al.[8] established that the incidence and prevalence of co-morbid conditions, especially cardiovascular disease, cerebrovascular disease, hypertension and diabetes, increases with age, and this has particular significance for the cohort of patients diagnosed with prostate cancer, who tend to be older, with an average age at diagnosis of 65 years. This same study also identified that although cancer grade was the most significant predictor of cancer specific mortality, overall mortality was predicted by both cancer grade *and* comorbidities. To complicate the assessment further, Albertsen et al.[9] have shown that men themselves tend to underestimate their life expectancy without treatment and overestimate the survival benefit associated with treatment. In their study of 19,000 men followed-up for 10 years, and who did not have TCI, survival at 10 years was directly proportional to the Charlson Co-morbidity Index (CCI)[10] which is a validated measure of comorbidities. A score of ≥ 2 is associated with significantly higher mortality. Only 41% of men with a CCI score of 3 were still alive after 10 years compared to 60 percent of those with a CCI score of 0. Physicians, however, also tend to overestimate men's life expectancy and underestimate the effect of co-morbidities on survival. This is demonstrated by a randomised trial of radical prostatectomy versus observation in which one third of men in each arm died of non-cancer related causes within 10 years.[11] Prior to offering a patient a treatment, physicians must assess the patient's non-cancer life expectancy, based both on their age and the presence of comorbidities.[9] This involves the concept of 'competing risk analysis' to determine whether an individual patient is more likely to die of a pre-existing health condition rather than from progression of their prostate cancer.[9,12,13]

Age is ultimately a significant determinant of treatment chosen, with men over the age of 70 unlikely to be recommended to have radical surgery regardless of age.[14] Life tables can be used to predict life expectancy more accurately but even these do not take into account comorbidities and overestimate life expectancy, especially for older men.[15] These studies emphasise the critical role of comorbidities in determining life expectancy for men with prostate cancer. Therefore, in order for active treatment to be recommended it must be shown that the cancer is aggressive, that the treatment will be effective, and the patient will not die of comorbid conditions before they can derive benefit from treatment.

2.3.2 Cognitive factors

2.3.2.1 Degree of patient control over decision-making process

The degree to which patients wish to be involved in the decision-making process, and the extent to which they actually are involved, also contribute to a mutually successful decision.[16] Degner et al.[17(p22)] defined decisional control as “the degree of control an individual wants to assume when decisions are being made about medical treatment.” They highlight that decisional control is different to the need for information, which is related to a desire for enhanced psychological autonomy, but not necessarily a desire to accept responsibility for treatment decisions. Nonetheless, decision-making may be significantly influenced by the patient’s preferences, which may be based on anxiety, fear, and the personal stories of family and other men as well as more factual analysis, and possible cognitive decline.[14] A man’s perception of risks associated with treatment, and the extent to which they feel these risks may affect them personally, especially by interfering with their quality of life, may also affect their treatment decision.[18] Decision-making may also be impeded by the high rates of psychological distress that occur close to diagnosis of prostate cancer, which is at the very time treatment decisions are being undertaken.[19]

It has been established that older persons, males, and those of lower educational achievement are more likely to desire a more passive role in treatment decisions, which may prevent many men with prostate cancer participating fully in the decision-making process.[20] Age at diagnosis is an important factor in treatment decisions for prostate cancer, with the average age at diagnosis being 65 years.[21] Australia, like most developed countries, has an ageing population, such that in 2020 there were 4.2 million Australians over the age of 65, accounting for 16% of the total population.[22] It has been highlighted that increasing age is associated with the tendency to seek less information, make decisions faster, prefer fewer choices, have increased difficulty understanding information, and a focus on emotional aspects when making decisions.[23] These factors may militate against a man's involvement in the decision-making process.

Cognitive impairment will impact upon the decision-making process as it has been shown to impair decision-making ability and there is an increased incidence of cognitive decline with ageing, such that by age 65 one in ten of the population is affected.[24] Dementia and cognitive decline in general are associated with decreased capacity for complex decision-making.[25] Overall, therefore, it appears that older men in particular face a greater number of challenges when it comes to taking part in the decision-making process about their prostate cancer treatment.

2.3.3 Health literacy factors

2.3.3.1 Literacy in general and individual health literacy

Health literacy is another factor that can affect a man's ability to be involved in the shared decision-making process with their physician. Being involved in the decision-making process can provide increased patient control and autonomy, however, for the patients to be involved in this process they need high levels of literacy, in particular HL, or a support person with those skills.[22] As part of this process men need to be able to find, absorb, understand, critically analyse and act upon a large volume of complex information delivered both orally and in written form.[26] In 1957, the United Nations Educational, Scientific and Cultural Organisation (UNESCO) developed a basic description of literacy, defining a literate person as one who "can with understanding both read and write a short simple statement on his (her) life".[27 (p17)] General literacy underpins health literacy with a significant overlap between the two concepts, however the strong health-specific demands involved in health literacy differentiate it significantly.[26] Fifty six percent of Australians have the general literacy level that allows them to cope with everyday life and work.[28] The Adult Literacy and Life Skills Survey carried out by the Australian Bureau of Statistics[29] assessed prose literacy, document literacy, numeracy and problem solving. Forty percent of adults were assessed to be at the minimum level to function in society. Age was strongly associated with literacy levels, with 32% of those between 55 and 65 years old and 17% of those aged 65 to 75 years possessing adequate levels of literacy. This is significant because older men may not have the general literacy skills necessary to read, understand and act on the information that will be presented to them when making a decision about their prostate cancer treatment.

2.3.3.2 Health literacy as one of the 'new literacies'

The terms 'new literacies' or 'multi literacies' were coined to describe literacies such as health literacy (HL), media literacy and information literacy, as well as computer technology literacy, that are increasingly becoming a necessity to function in the 21st century.[30] The key concept is that these are all dynamic literacies involving manipulation of information and problem solving.[31] Nutbeam[26] has noted that these literacies are all content specific, such that even individuals with high general literacy may not be able to apply their knowledge and skills in situations requiring specific content knowledge or in unfamiliar contexts such as health. Nutbeam suggests that HL be defined as the “capacity to acquire, understand and use information in ways which promote and maintain good health”.[26 (p304)] Health literacy is thus a broad construct involving a complex relationship between basic literacy, knowledge, and comprehension.[32]

Comprehension of text requires integration of the literal meaning of the text (the textbase) with prior background knowledge.[33] Both domain knowledge, of a specific and defined field, and background, or general ‘world’, knowledge are critical to this process of constructing meaning, learning, and decision-making.[34] Specific knowledge of a topic has been shown by McCarthy et al.[35] to allow individuals to process information more quickly, recall information more readily and understand information at a deeper level. There is thus a vital interconnection between literacy, knowledge and comprehension, with each being an integral part. It is not just the ability to read labels and follow instructions that is important, but also the capability to access complex health information, interpret advice critically, navigate the healthcare system and communicate with healthcare professionals.[36,37] Nutbeam[26] , proposed a spectrum of HL extending from ‘basic functional’ health literacy through to ‘interactive’ HL, involving seeking and comprehending information and, finally, ‘critical’ HL, which empowers the individual to take control of their own health decisions. The capacity to be engaged, involved in discussions, and ask questions of the physician is a measure of interactive HL, which is critical for men wishing to be actively involved in the decision-making process.[38]

2.3.3.3 Adverse effects of low health literacy

In diverse health situations, lower HL has been shown to be associated with lower levels of knowledge about the health condition, a lack of social empowerment and self-efficacy, i.e., perceived health competence, and significantly worse health outcomes.[28] A 2011 study by Song et al.[39], investigated 1500 American men (median age 63: range 41-79) with clinically localised prostate cancer that was diagnosed within the previous year. In this study, 37% of the study participants were found to have low or intermediate HL which correlated with worse Health-Related Quality-of-Life scores. Similar results were obtained in a smaller study by Kim et al.[40] who surveyed 30 American men (mean age 67.0 years) with newly diagnosed prostate cancer, and noted overall low HL among the participants, which contributed to low prostate cancer knowledge. These adverse effects of low HL extend to the decision-making process and consultation. Several studies have shown that poor HL can negatively affect the successful interaction and communication between patient and physician and, therefore, result in less involvement by the patient in the decision-making process.[41,42] When assessing HL, it is the domains that measure self-efficacy that are the most critical to communication with the physician.[38] Higher levels in these domains give the patient a sense of control and involvement and may lead to improved satisfaction with decisions and improved quality-of-life scores.[38] These studies show that health literacy is critical to patient involvement in the decision-making process for men with a new diagnosis of prostate cancer.

2.3.3.4 Sources of information about prostate cancer utilised and valued by men

The level to which men access, utilise and then choose to trust the multiple sources of information available to them after a diagnosis of prostate cancer may empower them to be involved in the decision-making process and enable them to make an informed decision; nevertheless, access to random and unauthorized information may skew the decision or distort rational decision-making.[43,44] Individual patients differ in the sources from which they choose to seek information and in the degree to which they wish to be involved in the decision-making process.[45] Men may access multiple sources of information and this varied information may be helpful; however, they may also seek out and focus on information that is consistent with their original conceptions or beliefs and avoid conflicting information.[46] In an American study of 260 men (average age 63 years) with localised prostate cancer who were interviewed after the clinician 'information visit', but before treatment, it was highlighted that personal factors such as a man's perception of his age, anecdotes, the cancer histories of other men, and mistaken perceptions that one treatment was superior had a large influence on treatment choice.[14]

In a study confirming the variety of information sources used, Ramsey et al[43] surveyed 804 men with newly diagnosed prostate cancer and identified that, apart from the treating physician, the most used source of information was written literature. In this study, men were found to use an average of five different sources of information including written information, online information, the advice of family and other men with prostate cancer, as well as the opinion of their physician. Supporting the finding of men using multiple information sources, another study of more than 3,000 men with early stage prostate cancer highlighted the critical impact of the availability, quality and usefulness of information in making decisions about prostate cancer treatment·[19] Information directly provided by the physician was used by 93% of men and was found to be the most useful source of information by 33% of the study participants. Websites, which were used by 68% of the study participants, were found to be the most useful by 19% of men. In this study, the Internet was used more often by younger, better educated, and higher income men. Overall, the most critical factor arising from these studies is that the provision of information by the healthcare provider and its understanding by the patient leads to improved patient participation in a consultation and increased satisfaction with the shared decision-making process .[19,44]

2.3.3.5 Health Literacy Demand of information

As discussed in the previous paragraph the accessibility of materials is important, but to be effective in enabling a man to be actively involved in the decision-making process they must be presented in a form that can be read and understood.[45] The complexity and difficulty of the information provided or accessed by men is a measure of the 'health literacy demand'[46]. As reported previously, many people in the community have a low level of general literacy with only 56% of Australians having the general literacy level that allows them to cope with everyday life and work.[28] This has led to the recommendation that health information should be produced at or below an 8th grade reading level.[47] Dalziel et al.[47] assessed the readability of patient information materials provided by the Canadian Urological Association and found that the average grade level required to interpret these texts was 10.5, which is well above the recommended 8th grade level. Similar results were obtained by Leroy et al.[48] in a study of patient education material found on the Internet. They estimated that 60% of the information required college or graduate level reading skills, i.e., 13th grade or higher. The readability of educational materials found in physicians' offices has also been found to be written in technical language and at high reading grade levels.[49]

While readability formulas provide quantitative estimates in grade form of the reading difficulty based on word and sentence difficulty of written information, they do not address comprehension or whether the information provided encourages a response or action[50] It is important, therefore, that information relating to prostate cancer diagnosis and treatment is presented in a way that is understandable for men of average literacy, which will empower them to act on the information.[46] Shoemaker et al.[50] (p396) suggested that materials are "understandable when consumers of diverse backgrounds can process key messages", while materials are "actionable when consumers can identify what they can, or need to, do based on the information presented." Taken together these studies emphasise that for men to be truly involved in the decision-making process it is critical that the health literacy demand of provided written information does not exceed the patient's health literacy skills.

2.3.4 Shared decision-making

Given the complexity and value driven nature of the decision regarding treatment options, a shared decision-making process involving close cooperation and interplay between the patient and physician would seem desirable.[51] Some patients, however, wish to avoid having to make choices and therefore still rate the physician's advice as the most important factor in treatment decision-making, and some physicians do not fully explore the patient's wishes despite the evidence suggesting the importance of patient preference clarification and understanding patient's values.[52,53]

Patients value information which is specific to their individual circumstances rather than 'generic' prostate cancer information and this makes them especially value the information from their primary diagnosing physician; however, this may make them overly dependent on one source of advice.[39] The healthcare system is evolving from a paternalistic one, where health care providers make decisions for patients, to a more collaborative, rights based model, where patients are provided with information and choices about their health.[54] To encompass this change, the concept of 'shared decision-making' has arisen and this has become accepted as the ideal model for patient care, especially in chronic disease states and cancer treatment, where there may be no clearly superior option.[54] Shared decision-making involves the concept of 'patient-centered care', which was defined by the Institute of Medicine report as "care that is respectful of and responsive to individual patient preferences, needs and values", and which ensures "that patient values guide all clinical decisions".[55(p780)] Shared decision-making is critical to the decision-making process for men with prostate cancer, as it is associated with increased patient autonomy, control and competence.[56,23] However, as discussed above, it is older men who are typically diagnosed with prostate cancer, which militates against successful shared decision-making as men in this age group have been shown to desire fewer choices and less information in making decisions.[21,23] Shared decision-making is the ultimate corollary of all the patient and cancer factors discussed above and is the link to factors which assess the success of the treatment decision-making process.

2.4 CONSEQUENCES OF THE TREATMENT DECISION-MAKING PROCESS

2.4.1 Treatment decision-making satisfaction.

Greater patient involvement in the decision-making process has been shown to lead to 'better' decisions (both as defined by researchers and as perceived by patients) and subsequent greater satisfaction with that decision.[57,58] Fischer et al.,[57] in their study of 187 Dutch men (mean age 67.0), established that 80% of their patients desired or preferred to select treatment by themselves or in collaboration with their doctor. This high level of involvement in the treatment decision process led to more than 80% of the total study population being satisfied with the decision-making process. While this was a small sample, undertaken in one location, it does support how critical it is for effective decision-making that the doctor-patient relationship is as equal as possible, and the decision is truly a shared one. Likewise, Orom et al.[59] contend that collaborative and active decision makers displayed less decisional conflict and were more satisfied with their treatment related decision-making. Complex, high stakes, value driven decisions associated with risk, and where value trade-offs and judgements must be made in selecting a course of action, such as the decision regarding treatment options for prostate cancer, can lead to decisional conflict and subsequent lower treatment decision-making satisfaction.[57-59] It can be seen, therefore, that although the decision may be stressful and difficult for men, provided they receive and comprehend information, and are involved actively in the decision-making process, satisfaction with the decision process can be high. Treatment decision-making satisfaction is important in prostate cancer as it has been shown to lead to improved quality of life post-treatment and lower levels of decision regret.[57]

2.4.2 Decisional regret

As there is no 'right' decision concerning the management of prostate cancer, men may feel that they could have made the 'wrong' decision and later wish they had chosen differently leading to regret or 'decision loss'.[60] Zeelenberg[61] (p326) defines regret as "the negative, cognitively based emotion that we experience when realizing or imagining that our present situation would have been better had we acted differently". It differs from the emotion of disappointment because regret involves the individual taking responsibility for the decision and, therefore, there is an element of self-blame as opposed to disappointment, in which the bad outcome can be attributed to circumstances beyond the decision maker's control.[62]

Overall rates of regret post treatment for prostate cancer are low. A survey by Hu et al[63] investigating treatment choice in 96 men (mean age 64 years, mean follow-up 2.8 years) with previously treated prostate cancer uncovered decisional regret in 16% of the study participants. Interestingly, they reported that regretful men were almost twice as likely as non-regretful men to have less than a college education (60% v. 33%, $p=0.05$) and were more likely to have lower current health-related quality of life ($p<0.05$). Regret does not always occur after a 'bad' outcome or when there are significant side effects as a result of the decision made. To illustrate this, although there is a high incidence of clearly negative physical outcomes related to radical prostatectomy, with 30-90% incidence of erectile dysfunction and 5-30% incidence of incontinence at one year postoperatively, Ratcliff et al. [64] reported a 20% decisional regret rate in their study of 145 American men (average age 60.9 years). Supporting this Hoffman et al.[65] in a study of more than 900 men, 15 years post diagnosis, found a 16% incidence of decision regret. Conversely, Wilding et al.[66] in a large United Kingdom study, reported that 63% of men reported some level of decision regret 2-4 years after diagnosis. In that study, higher levels of decision regret were associated with a higher level of side effects and lower involvement in the decision-making process. The correlation of regret and adverse side effects, especially in sexual, urinary and bowel function domains, has been confirmed.[67] Lower rates of decision regret have been found to be associated with the patient feeling informed, having an increased involvement in the decision-making process, using decision aids and being satisfied with the information provided by the clinician.[67-69]

Decision regret, and its prevention, is a critical, measurable variable following medical interventions because higher levels have been shown to lead to lower quality of life scores, adverse health outcomes and negative experiences with the healthcare system. The effect of adverse outcomes on regret, however, can be ameliorated by informed decision-making and the patient being actively involved.

2.4.3 Concordance with guidelines

Clinical practice guidelines are widely used to guide clinicians in treatment by transferring the principles of evidence based medicine into practice.[70] They have been defined as “statements that include recommendations intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options”.[71(p1)] The National Comprehensive Cancer Network® (NCCN) is a not-for-profit alliance of 31 leading cancer centres, based in the United States of America, devoted to patient care, research, and education. The NCCN guidelines are useful because “clinicians and patients must choose the treatment that is most appropriate considering what matters most to the patient. Implicit in the evaluation of each treatment is the efficacy, quality, quantity, and consistency of the evidence supporting the recommendation as well as and expected associated toxicities.”[72(p1)] These guidelines are updated each year and are widely used to guide treatment.

2.4.4 Assessment of potential overtreatment and undertreatment

Improvement in cancer testing, earlier treatment and better treatment have led to improvements in cancer survival but at the cost of increased overdiagnosis, which occurs when a cancer which would never have progressed to cause clinical symptoms, harm or death, (or would have progressed so slowly that the patient dies of other causes first, is diagnosed in the preclinical or latent stage.[73,74] Overdiagnosis occurs more frequently when a cancer has the following characteristics: a long latent stage with low volume of cancer, a long natural history before symptoms become apparent and a screening test to allow early diagnosis.[74,75] Prostate cancer falls into this category as it is found at autopsy in approximately 70% of 70 year old men dying of other causes. A corollary of this is that if a biopsy is performed on an asymptomatic patient there is a high likelihood cancer will be found. This phenomenon leads to what is called ‘stage migration’, or lead time bias, in that treatment given in the latent phase prolongs the time the patient lives with the cancer but does not change the natural history of the cancer and extend survival.[74] Klotz[74] maintains that whether a particular cancer in an individual patient becomes clinically significant depends on the volume and rate of growth of the cancer and the life expectancy of the patient as determined by age and co-morbidities. The CCI is a validated tool to assess comorbidity and is a strong predictor of overall survival and life expectancy.[75] The presence of overdiagnosis can be established when there is an increase in new diagnoses but, despite this, the disease specific mortality of the condition remains stable.[76]

Overtreatment is a corollary of overdiagnosis and occurs when there is “treatment of a disease that if untreated is unlikely to cause symptoms or death”.[76(p2)] Implied in this definition is that the patient undergoes treatment with no benefit but is subject to the potential harms of treatment. Overtreatment is a consequence of overdiagnosis because for an individual patient it is impossible to predict accurately exactly when the cancer will cause harm, so cautiousness and fear of missing when the cancer progresses leads clinicians to recommend treatment earlier than is necessary.

Undertreatment has been less studied but occurs when older, healthy patients with a long life expectancy and an aggressive cancer do not receive curative treatment. For example, Lunardi et al.[77] identified that 16% of men aged between 75 and 85 years with high grade disease and no comorbidities did not receive curative treatment from which they were likely to have benefited. These findings were supported by Bratt et al.[78] who noted that only 10% of men aged 75-80 years with a CCI of zero received radical treatment despite a 52% probability of 10-year life expectancy. In contrast, half of all men younger than 70 years of age with a similar life expectancy received treatment with curative intent. Similar findings were identified in the studies conducted by Schwartz et al.[79] who identified what they described as suboptimal treatment, in that men did not receive potentially curative treatment, in 15% of men with early stage prostate cancer. This was particularly pronounced for healthy men more than 70 years old with high grade cancers in whom they identified 73% suboptimal treatment.

2.5 SUMMARY

This literature review has examined the factors that influence the treatment decision-making process of men with a new diagnosis of prostate cancer. Decision-making is complex as it involves a complex interplay between the biology of the prostate cancer (grade, stage and PSA), the biology of the man concerned (age, comorbidities and life expectancy), and the personal social and demographic factors which influence the decision process. In conjunction with their physician, men must make a decision as to whether treatment is necessary, in the context of a cancer that presents early and progresses slowly, and if treatment is deemed necessary, an acknowledgement that not only may it not prolong survival, it may also have significant long term side effects affecting quality of life.

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CHAPTER 3: CONCEPTUAL FRAMEWORK AND METHODOLOGICAL APPROACH

3.1 CONCEPTUAL FRAMEWORK AND AIMS

A conceptual framework for this thesis and its aims has been developed by the author and is shown in Figure 3.1. This framework places the decision-making process for men with newly diagnosed prostate cancer as the central locus. The decision-making process is impacted by multiple input factors related to the cancer (stage, grade and localization), the patient's physical condition (age, co-morbidities and life expectancy), the patients understanding (health literacy) and, therefore, their ability to contribute to shared decision-making, and also structural factors and guidelines that influence the treatment options available to the individual patient. As part of this, a number of these inputs were examined and correlations with outcomes of the treatment decision-making process, including concordance with published guidelines, degree of over and undertreatment, treatment decision-making satisfaction and decision regret, were investigated.

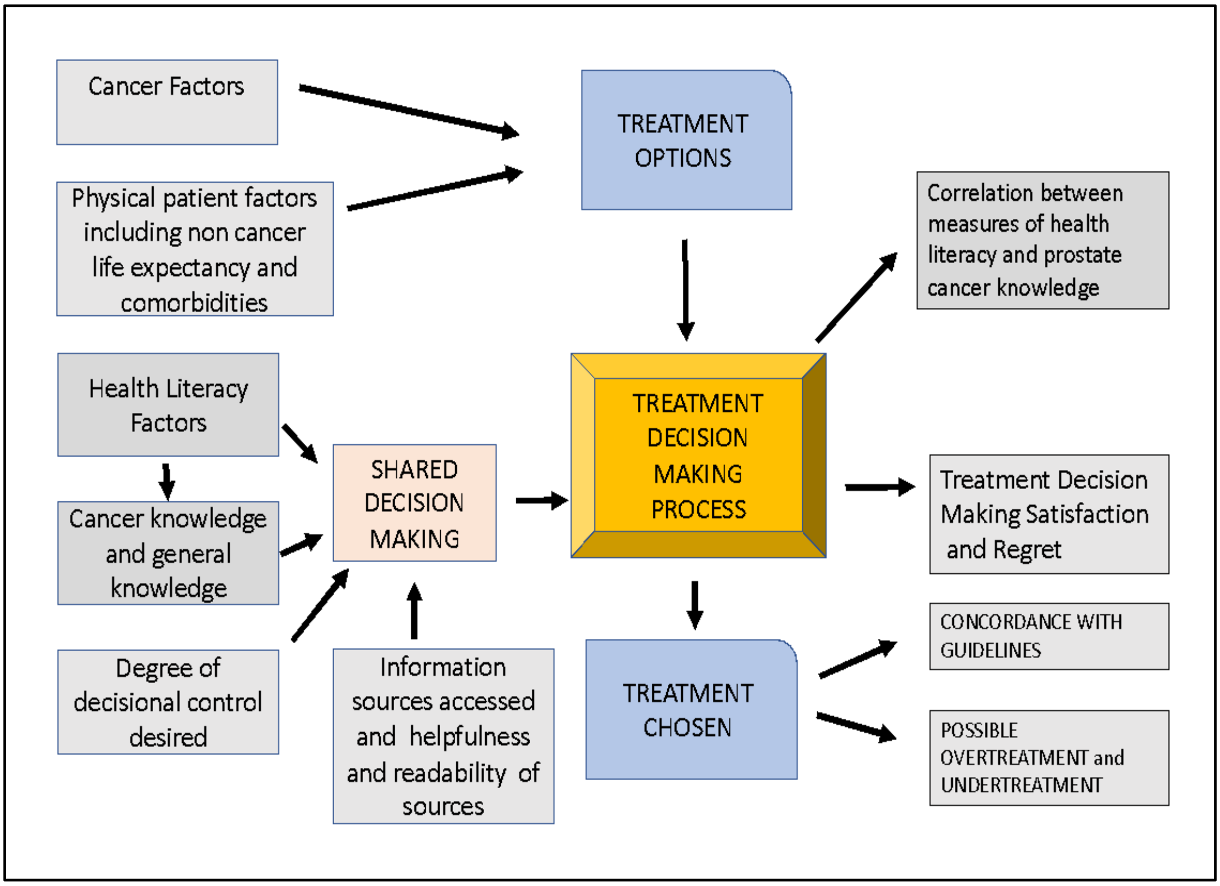

Figure 3.1: *Overall conceptual framework*

Based on the conceptual framework four studies were undertaken. The overarching aim of these studies was to explore the factors that influence the decision-making process of men with newly diagnosed prostate cancer. The decision is complex as it involves an interplay between the biology of the prostate cancer (grade, stage and PSA), the biology of the man concerned (age, comorbidities and life expectancy), and the personal social and demographic factors which influence the decision process. In conjunction with their physician, men must make a treatment decision in the context of a cancer that presents early and progresses slowly and, if treatment is deemed necessary, an acknowledgement that it may not prolong survival and may have significant long term side effects affecting quality of life.

Study A (Chapter 4) aimed to examine how cancer-related factors and patient-related factors (age and comorbidities) influenced treatment decisions in men with a diagnosis of prostate cancer, the concordance of those treatment decisions with the relevant guidelines, and the level of possible under- or over-treatment . There is a paucity of literature on the integration of cancer and non-cancer factors and how they affect the treatment decision-making process, with most studies focusing on cancer factors and the treatment selected rather than the process. There is only one Australian study, which focused mainly on treatment. It found that radiation was less utilised than surgery.[1] The studies conducted by Fowler et al.[2] and Schymura et al.[3] focus on the factors that predict mortality rather than decision-making. Few studies have examined whether treatment follows published guidelines and estimated rates of overtreatment and undertreatment. The hypothesis for Study A was that cancer factors would be the prime determinant of treatment choices but that these choices would be modified by patient factors, and that the majority of men would be treated appropriately. Nonetheless, a proportion of men would not receive concordant treatment.

Study B (Chapter 5) aimed to investigate if there was an association between the extent to which men with a new diagnosis of prostate cancer had wanted to be involved in the decision-making process, their satisfaction with that process, and their levels of decision regret, if any, after treatment. There is contradictory evidence on the relationship between the degree of control a man takes in the decision-making process, either active or passive, and the level of subsequent regret post treatment with studies suggesting an inverse relationship between the degree of involvement and the level of regret.[4,5] There is a gap in the literature examining the link between involvement in the decision-making process and satisfaction with that process, and then the relationship between decision-making satisfaction and subsequent regret.[6-9] Study B hypothesized that men who took an active role in the decision-making process would be more satisfied with that process and would experience less treatment regret.

Study C (Chapter 6) aimed to collect HL data on a group of men with newly diagnosed prostate cancer. Based on the literature it was hypothesized that a proportion of these men would have inadequate levels of HL. There is limited published literature on the HL of men with prostate cancer and only one significant study of Australian men.[10] There is also limited published data on the sources of information that men use after a diagnosis of prostate cancer[11,12] and especially on how helpful men find this information. The Australian study by Hyde et al.[13] focused more on the unmet psychological and sexual support needs of men in the year after treatment and confirmed that multiple sources of information were used by most men. To our knowledge there is no published Australian literature on the readability, understandability and actionability of the information available to men (the health literacy demand) after a diagnosis of prostate cancer so Study C sought to clarify these issues. It was hypothesized that the literature available to men would be understandable and readable and, therefore, useful as a source of information but that it would not be actionable and would not help men in the decision-making process.

Study D (Chapter 7) aimed to provide further HL information on a wider group of men attending a urology clinic and to further investigate the baseline level of cancer knowledge of these men and the complex interconnection between HL and subject specific knowledge, which has been identified in a range of other health conditions[14] but not previously with respect to prostate cancer. There is also little literature that compares different measures of HL used in men with prostate cancer with Study D aiming to rectify this by comparing scores on the Brief Health Literacy Score (BHLS)[15,16] and the Health Literacy Management Scale (HeLMS)[17] in this group of men. Study D aimed specifically to investigate if there was a correlation between two different measures of health literacy and to explore if there was an association between HL; cancer literacy and comprehension; and prostate cancer knowledge. We hypothesized that men with low levels of HL would also have lower levels of cancer literacy and comprehension and lower levels of prostate cancer knowledge.

3.2 METHODOLOGICAL APPROACH

This thesis is based on four studies that use a quantitative design and follow both an objectivist and a constructivist paradigm.[18] This paradigm assumes a static, measurable, physical and social reality; however, this concept has been modified to a post-positivism approach in which the objective reality exists, is observable and constant but cannot be absolutely validated by research, only strengthened. In contradistinction, a constructivist paradigm accepts multiple perspectives of social reality, which are determined by how an individual interacts with their world.[19] In other words, reality is socially constructed and each person's understanding of their world is valid. In this thesis some variables are fixed and measurable, such as age, number of comorbidities, treatment undertaken, and so an objectivist paradigm is followed. Other factors assessed such as *satisfaction* with the treatment decision-making process, extent to which men *wished* to be involved in the decision-making process and the *degree of regret* experienced after treatment are concepts that depend on the lived experience of the person involved and their interpretation of reality.

All four studies conducted as part of this thesis use both a causal comparative and a correlational design to compare the relationship between groups.[1] A correlational design examines two numerically expressed variables for each individual in a population, which are plotted on a x/y graph. A line of best fit was obtained to predict future individual’s results if only one variable is known. This allowed for the determination of the degree and direction of the relationship between the two variables. These were expressed mathematically using linear regression as the correlation coefficient (r) and the square of the correlation coefficient r^2 which represents the explained variance. The p value was used to indicate the extent to which the deviation of the slope from zero was significant. A causal-comparative design is a quantitative, non-experimental technique used to determine naturally occurring cause and effect relationships.[18]

Study A used a retrospective audit or chart review of men with a new diagnosis of prostate cancer to record demographic data, comorbidities and cancer risk stratification and then determined if there was a correlation with these factors and the chosen treatment. Studies B, C and D used a cross sectional mail-out survey design.[20] This type of study design was chosen because the researcher does not interfere but simply records the data captured. Its success depends on obtaining a representative sample and can be compromised by ‘nonresponse bias’. Questionnaires were used for studies B, C and D as they were deemed to be an efficient and useful way to collect a mix of both demographic data and data about values, experiences, opinions and attitudes.[21]

In addition to the demographic questions used in studies C-D, the questionnaire used in study B included three validated tools: the Control Preference Scale[22] to measure the degree of control men wished to assume when making treatment decisions; the Treatment Decision-Making Satisfaction Scale (TDM-SAT)[23] to assess satisfaction with the treatment decision-making process; and the Decision Regret Scale[24] to assess the level of regret after treatment.

Study C and D used the Brief Health Literacy Questionnaire [25,26] and the Health Literacy Management Scale (HeLMS) [17] to assess the HL of men newly diagnosed with prostate cancer. In addition to the HL tools, study C included questions derived from the validated European Silent Voice survey[27] to investigate information sources men used when making their decision about treatment and how they rated the quality and helpfulness of those information sources. Using an online readability calculator, the information sources in study C were also examined to determine their readability ('Readability Formulas'), and understandability and actionability, using the validated 'Patient Education Materials Assessment Tool for Print Materials' (PEMAT-P).[28]

Study D, compared the HL scores of participants using the Brief Health Literacy Survey (BHLS)[25,26] and the Health Literacy Management Scale (HeLMS),[17] as well as assessing their cancer literacy and comprehension using two Cancer Message Literacy Tests–Reading (CMLT) from the National Cancer Institute.[29] Study D also identified the participants' cancer knowledge by using the Prostate Cancer Knowledge test.[30]

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CHAPTER 4: STUDY A

4.1 Title Page

RISK OF UNDER- AND OVER-TREATMENT IN A GROUP OF AUSTRALIAN MEN DIAGNOSED WITH PROSTATE CANCER

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4.2 FOREWORD AND LINK TO CONCEPTUAL FRAMEWORK OF THESIS

The treatment decision-making process for men with prostate cancer should incorporate a shared decision-making process involving both the patient and the physician. The process begins with an analysis of cancer factors which will determine the natural history of the cancer progression with no treatment and establish whether treatment is needed based on the stage and aggressiveness of the cancer. The decision-making process is then influenced by the life expectancy of the patient based on age and comorbidities to determine if treatment will truly be of benefit. The aim of this study (Study A) was to identify physical patient-related factors (specifically age and comorbidity) and cancer-related factors (PSA, Grade and Stage) that determine the possible treatment options. We also attempted to establish the quality of the decision-making process by assessing both the degree of concordance of treatment with published guidelines and possible overtreatment or undertreatment in this group of men. Figure 4.1 shows a schematic outline of the issues examined in Study A and how they relate to the conceptual framework.

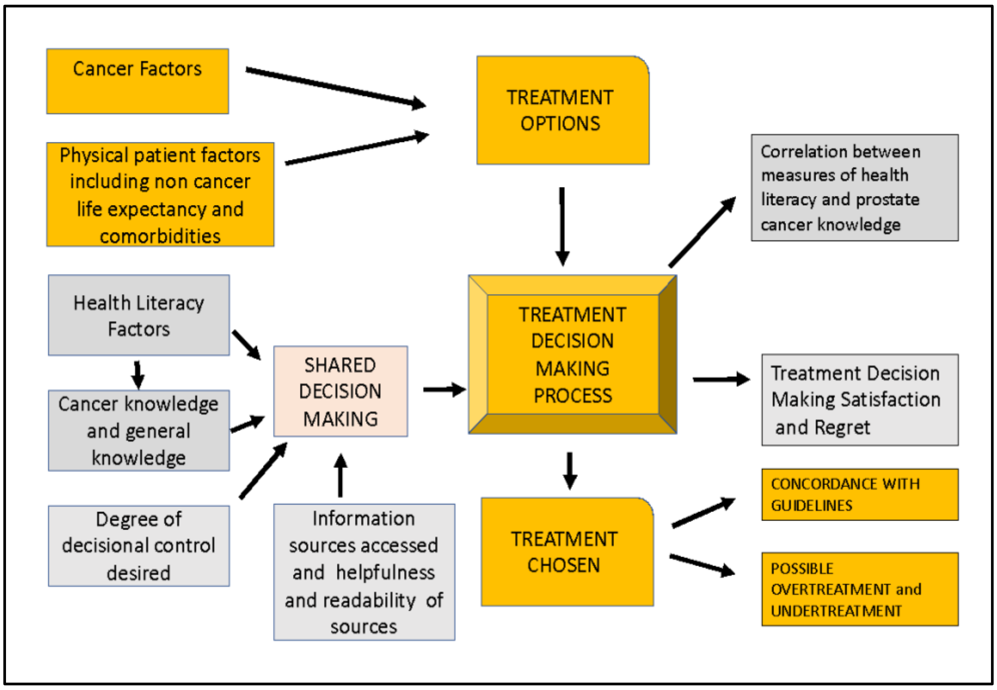

Figure 4.1: *Concept map for Chapter 4 (Study A)*

4.3 ABSTRACT

Background: Patients with newly diagnosed prostate cancer must decide whether to undergo treatment with curative intent or conservative treatment on the background of a cancer where the potential for over-treatment and under-treatment is real.

Methods: The clinical records of 545 men who were diagnosed at four Australian based Urology services, between January 2015 and December 2016, were retrospectively audited for the purposes of this study. Age, comorbidities, and cancer factors were recorded, and patients allocated to risk categories based on cancer factors.

Results: Cancer risk stratification was seen to be a primary determinant of treatment options for an individual patient with Low-Risk patients being more likely to have active surveillance and patients classified as Intermediate or High risk being more likely to have treatment with curative intent (TCI, surgery or radiation). Younger patients and those with lower comorbidities were more likely to be offered surgery. Eighty percent of patients in this study received treatment concordant with the guidelines but 20% of patients were identified as being over-treated and received TCI despite having a limited life expectancy and/or high comorbidities.

Conclusion: The aim in treating men diagnosed with prostate cancer should be to avoid under-treatment in men who are young, healthy and have aggressive cancers by offering TCI. Conversely, over-treatment (unnecessary treatment) should be avoided in men with low-grade cancer or who because of limited life expectancy due to significant comorbidities are likely to die of competing causes rather than from prostate cancer.

Key Words:

Prostate Cancer, Risk Stratification, Screening, Treatment Decision-making, Comorbidity

4.4 INTRODUCTION

The 17,000 Australian men likely to be diagnosed with prostate cancer in 2020 face a difficult decision—the decision about whether to undergo treatment.[1] This decision is difficult due to uncertainty about the risk of progression of cancer (and therefore the need for treatment), as well as the lack of proven efficacy of treatments in improving survival.[2-4] Compounding this difficulty, there is a moderate risk of side-effects from treatment affecting bladder, bowel and sexual function which can lead to adverse effects on physical, psychological and sexual well-being.[5]

Patients diagnosed with can elect to undergo Treatment with Curative Intent (TCI) with either surgery or radiation therapy; or Treatment with Non-Curative Intent (TNCI) including active surveillance, watchful waiting or androgen deprivation therapy.[6] The aim in managing is to avoid both under- and over-treatment.[7] Exact definitions of these terms are difficult and contested, but Loeb et al[7] suggest that over-treatment arises from TCI of a cancer that has been detected due to screening and that would not have been detected clinically or symptomatically in the patient's lifetime.

The imperative, therefore, is to identify and treat men with aggressive who have a long life expectancy, thus avoiding under-treatment in these men.[3] At the same time, clinicians must avoid over-treatment in men with limited life expectancy due to age, those with co-morbidities who are likely to die from other causes, and those who have a low-grade cancer and are therefore at low risk of progression.[8,9] Generally, younger men, with longer life expectancy and aggressive cancer have been shown to benefit significantly from TCI.[10] However, there are also older healthy men with more aggressive cancers who may benefit from TCI but do not receive it.[11-14]

The aim of this study was to examine how cancer-related factors and patient-related factors (age and comorbidities) influenced the initial treatment decision in men with a new diagnosis of . Treatment decisions were then assessed for concordance with the relevant guidelines and possible under- or over-treatment identified.

4.5 METHODS

The clinical records of 545 men who underwent a prostate biopsy at four Australian based Urology services between January 2015 and December 2016. Men were included in the study if the biopsy resulted in their first diagnosis of prostate cancer. Treatment decisions for these men were audited for the purposes of this study. Two of these practices were in metropolitan areas (n= 109 patients, two urologists), one was based in rural NSW (n=99 patients, two urologists) and one in regional NSW (n=337 patients, five urologists). The study was approved by the local Human Research Ethics Committee (HREC approval 2016/955).

4.5.1 Treatment:

Patients were classified according to the treatment they underwent following their diagnosis of prostate cancer. Patients allocated to the TCI group received surgery or radiation therapy. For the purposes of this study, surgery refers to radical prostatectomy, either open or robotic assisted.[15] Radiation therapy refers to treatment with interstitial seeds (brachytherapy) or external beam radiation.

Patients included in the TNCI group included those who as a result of the decision-making process were allocated to receive active surveillance, watchful waiting, or androgen deprivation therapy (ADT).

4.5.2 Patient related factors:

As part of the audit, patient demographic factors such as age, Charlson Comorbidity Index (CCI) and number of medications were recorded.[16, 17] The patient’s age was used to determine overall life expectancy based on the Australian Bureau of Statistics (ABS) life tables.[18] The CCI was chosen because it is a validated tool to assess comorbidity and is a strong predictor of overall survival and life expectancy.[8,16] Additionally, the patients' medical records were examined, and the number of regular medications they were prescribed recorded as a numerical value.

4.5.3 Cancer related factors:

Pathological details including serum Prostate Specific Antigen (PSA), cancer stage and grade were collected from the prostate biopsy report in the patient medical records. The clinical stage (using the 1992 American Joint Commission on Cancer (AJCC) staging system) was obtained either from the Digital Rectal Examination (DRE) findings recorded in the patients file or from the DRE findings recorded at the time of biopsy.[19] The D'Amico risk group incorporates PSA, grade and clinical stage and gives a guide to disease severity and prognosis.[20] These risk groups correlate with biochemical recurrence, cancer specific survival and overall survival.[21,22]. Using the D'Amico risk groups patients were classified into four risk groups developed by the American Urological Association (AUA) and the American Society for Radiation Oncology (ASTRO)[23] (Table 4.1a). Treatments received by patients in this study were compared with these guidelines to determine concordance.

Lunardi *et al.*[24] have developed an algorithm which considers both patient related factors (age and CCI) and cancer-related factors (D'Amico risk group) to determine under- or over-treatment of men with prostate cancer (Table 4.1b).

Table 4.1: Classification of patients into AUA/ ASTRO Risk groups and the Lunardi et al algorithm[23] to determine under- or over-treatment.

Table 4.1a: AUA/ASTRO risk groups

	D'Amico risk group	Grade Group	PSA (ng/ml)	Clinical Stage	Recommended Treatment
Low-Risk	Low	1	<10	T1-T2a	AS
Intermediate-Favourable	Intermediate	1	10 to <20	≤T2b-c	AS or TCI
	Intermediate	2	<10	≤T2b-c	AS or TCI
Intermediate-Unfavourable	Intermediate	2	10 to <20	≤T2b-c	TCI or WW
	Intermediate	3	<20	≤T2b-c	TCI or WW
High-Risk	High	4 or 5	≥20	≥T3	TCI or WW

Table 4.1b: Determination of under- or over-treatment (Lunardi et al algorithm[23])

Treatment	D'Amico risk group	Age	CCI	Over-treatment	Under-treatment
TCI	any	<75	≥2	✓	
TCI	any	>75	≥1	✓	
TCI	Low	65-75	≤1	✓	
None	Intermediate/ high	<75	≤1		✓
None	Intermediate/ high	75-85	0		✓

Abbreviations: AS active surveillance, WW watchful waiting, TCI (Treatment with curative intent) with either surgery or radiation therapy.

4.6 STATISTICAL ANALYSIS

Descriptive statistics were used to provide an overview of respondents' sociodemographic characteristics. To determine if the differences between two groups was significant, when one value (the independent variable) was categorical, and the other numerical and non-parametric (not normally distributed) the Mann- Whitney test was employed as there were 2 categorical groups. When one value was numerical (and normally distributed) and the other categorical an unpaired *t* test was performed if there were two categorical groups. All analysis was performed using Prism 7 for MacOSX (GraphPad Software Inc.).

4.7 RESULTS

4.7.1 Demographics

The average age of the 545 patients included in this study was 67.5 years with a range of 44 to 91 years (Table 4.2). The median PSA was 8.0 ng/ml ranging from 5.6 ng/ml for the Low-Risk group to 12 ng/ml for the High-Risk group. The average CCI for the entire cohort was 0.63 and the average number of medications was 2.9. Over 63.7% of the patients underwent TCI with two thirds of those undergoing surgery. Distribution of patients across the four risk categories is detailed in Table 4.2.

Table 4.2: Audit of the factors affecting patient treatment choices following a diagnosis of prostate cancer.

	Total	**Low risk**	**Intermediate favourable**	**Intermediate unfavourable**	**High Risk**
n (%)	545	111 (20.4%)	148 (27.2%)	120 (22%)	166 (30.4%)
Age (years, mean)	67.5	63.1	66.7	68.9	70.3
Average CCI	0.63	0.55	0.51	0.57	0.85
Number of medications	2.9	2.5	2.8	2.7	3.3
Median PSA	8	5.6	6.9	9.5	12
Treatment with Curative Intent (TCI)					
Total	347 (63.7%)	29 (26.1%)	114 (77%)	89 (74.2%)	116 (69.9%)
Surgery n (%)	213 (39%)	22 (19.8%)	81 (54.7%)	59 (49.2%)	51 (30.7%)
Radiation n (%)	134 (24.6%)	7 (6.3%)	32 (21.6%)	30 (25%)	65 (39.2%)
Treatment with non-curative intent (TNCI)					
Total	198 (36.3%)	82 (73.9%)	35 (23%)	31 (25.8%)	50 (30.1%)
Watchful waiting n (%)	63 (11.6%)	8 (7.2%)	22 (14.9%)	22 (18.3%)	11 (6.6%)
Active surveillance n (%)	88 (16.1%)	74 (66.7%)	10 (6.8%)	4 (3.3%)	0 (0%)
ADT n (%)	47 (8.6%)	0 (0%)	3 (2%)	5 (4.2%)	39 (23.5%)

Concordance with recommended treatments					
Concordance n (%)	440 (80%)	74 (66.7%)	123 (83.1%)	89 (74.2%)	154 (94%)
Non-concordance n (%)	104 (19%)	37 (33.3%)	25 (16.9%)	31 (25.8%)	11 (6.6%)
Non-Concordance, treated with Surgery	22 (19.8%)	22 (19.8%)	0	0	0
Non-Concordance, No treatment	67 (64%)	8 (7.2%)	22 (14.9%)	26 (21.7%)	11 (6.6%)
Non-Concordance, Life expectancy <10 years	15	0	4	8	3
Lunardi estimate of over or under treatment					
Over-treatment n (%)	77 (14%)	10 (9%)	22 (14.9%)	15 (12.5%)	30 (18.1%)
Under-treatment n (%)	45 (8.3%)	0 (0%)	27 (18%)	14 (12%)	4 (2.4%)

The AUA/ASTRO risk stratification was seen to be a primary determinant of treatment options for an individual patient with Low-Risk patients being more likely to have active surveillance and patients classified as Intermediate (Favourable and Unfavourable) or High-Risk being more likely to have TCI (surgery or radiation) (Figure 4.2).

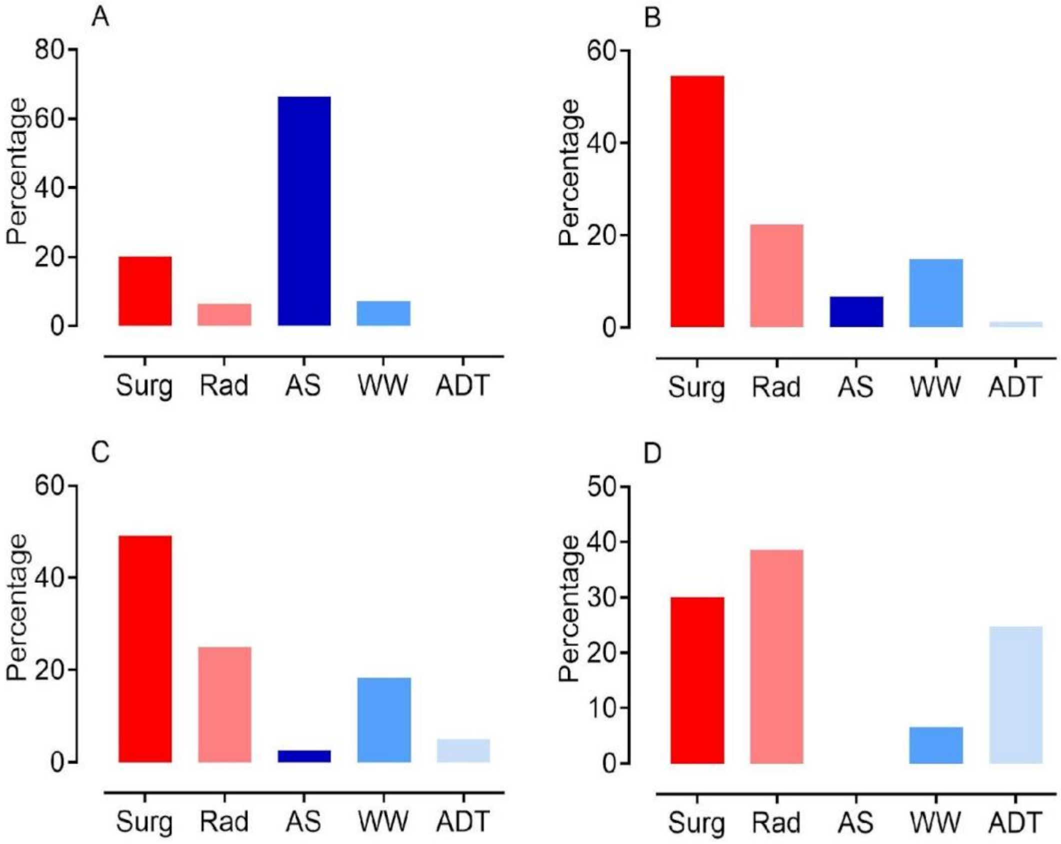

Figure 4.2: *Treatment according to the AUA/ASTRO risk classification. TCI, surgery (Surg) radiation therapy (Rad) is compared with TNCI active surveillance (AS), watchful waiting (WW) and androgen deprivation therapy (ADT) for each of the AUA/AUSTRO risk categories: Low risk (A), intermediate favourable (B), intermediate unfavourable (C) and high risk (D).*

4.7.2 Treatment decisions for patients across all risk groups

Younger patients more likely to be offered surgery (mean age 64.3 years) or active surveillance (mean age 61.8 years) with older patients more likely to be treated with radiation, Watchful Waiting, or ADT. Patients treated with surgery were younger (mean age 64.3years) than those treated with all other treatment options combined (mean age 69.7 years, $P < 0.0001$). Patients treated with surgery also had significantly lower CCI (mean 0.64), when compared to all other patients combined (mean CCI 0.96, $P < 0.0026$) and were on fewer medications (mean number medications 2.3) when compared to all other patients combined (mean number of medications 3.6, $P < 0.0001$) However overall, there was no significant difference in the age of patients undergoing TCI compared to those offered TNCI (Figure 4.3A). Patients with more comorbidities (as indicated by a higher CCI score) were more likely to receive TNCI (Figure 4.3B, $P = 0.0018$). Similarly, patients on more medications were more likely to receive TNCI ($P = 0.0442$, Figure 4.3C).

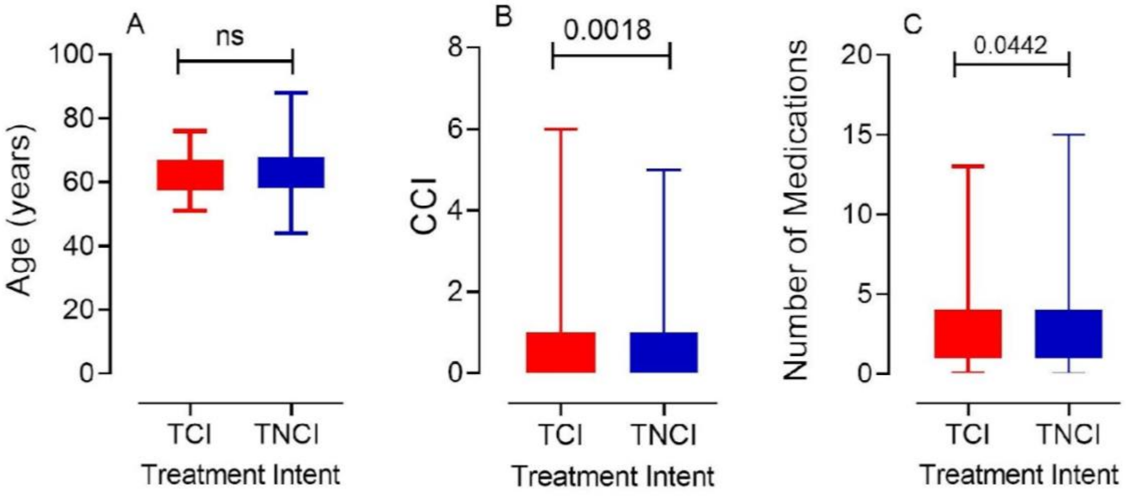

Figure 4.3: *Influence of patient factors including age (A), co-morbidities (B), as indicated by the CCI and number of medications (C) on treatment intent.*

4.7.3 Treatment decisions according to the AUA/ ASTRO risk classification

As seen in Figure 4.2, patients classified as Low-Risk were most likely to undergo active surveillance (66.7% of this group, Table 4.2). This is in concordance with the AUA/ASTRO guidelines (Table 4.1a). Most patients who received a treatment that was not in concordance with the AUA/ ASTRO guidelines received surgery as a TCI option. Taking the Lunardi *et al* algorithm into consideration, 10% of our study population in the Low-Risk group received over-treatment (Table 4.2).[24] All the patients, who received TCI (surgery or radiation) however, did have a life expectancy of >10 years. In patients classified as Low-Risk, there was no difference in age between those who received TCI (mean age 62 years) or TNCI (mean age 63.5 years). Patients who received surgery had significantly lower CCI scores (mean 0.27) than those receiving active surveillance (mean 1.0, $P < 0.0001$).

Of patients in the Intermediate-Favourable risk group 77% were given TCI (55% Surgery, 22% Radiation therapy) (Table 4.2). Patients who received surgery were younger than those who received radiation therapy (mean age 64 years for surgery versus 71 years for radiation, $P < 0.0001$) and those who received TCI were younger (mean age 66 years) than those who received TNCI (mean age 69 years, $P = 0.0285$, Figure 4.4B). Patients who received TNCI were taking significantly more medications (mean 3.7) than those who elected TCI (mean 2.5, $P = 0.0288$). Patients treated with Surgery also had a lower average CCI (0.33) than those who received Radiation therapy (0.87, $P = 0.0350$) but overall, there was no significant difference in the mean CCI of those receiving TCI versus TNCI. The AUA/ASTRO guidelines suggest either TNCI or TCI for patients in the Intermediate-Favourable risk group (Table 4.1a) and concordance was high in this group (83%, Table 4.2). According to the Lunardi *et al* algorithm 15% of patients in this intermediate favourable risk group were judged to have been overtreated either because they had a high CCI or because they were over 75 years of age and still received TCI.[24] In this group 18% of patients (n=27) were possibly undertreated.

Of patients in the Intermediate-Unfavourable risk group three quarters in this risk group underwent TCI, with almost 50% receiving surgery and an additional 25% undergoing radiation therapy (Figure 4.1C). Similar to the previous risk group, patients who received surgery were younger (mean age 66 years) than those treated with radiation therapy (mean age 72 years, $P = 0.0027$). Those treated with TCI were younger (mean age 67.5 years) than those in the TNCI group (mean age 72.8 years), $P = 0.0007$, Figure 4.4C). Those receiving TCI were taking fewer medications (mean 2.4) than those receiving TNCI (mean 3.6, $P = 0.0128$). Likewise, patients who received TCI had a lower CCI (mean 0.5) than those receiving TNCI (mean 0.9, $P = 0.0145$) and those receiving surgery had a lower CCI (mean 0.3) than those receiving radiation (mean CCI 0.7, $P = 0.0011$) or Watchful Waiting (mean CCI 1.0, $P < 0.0001$). The AUA/ASTRO guidelines suggest TCI for this group or TNCI if life expectancy is less than 5years (Table 4.1a). Overall, three quarters of patients received treatment that was concordant with the guidelines (Table 4.2). According to the Lunardi *et al* algorithm 12% of the patients (n=14) in this risk group were undertreated and 12.5 % of patients (n=15) were considered overtreated as they received TCI despite having a high CCI score or being 75 years and older.[24]

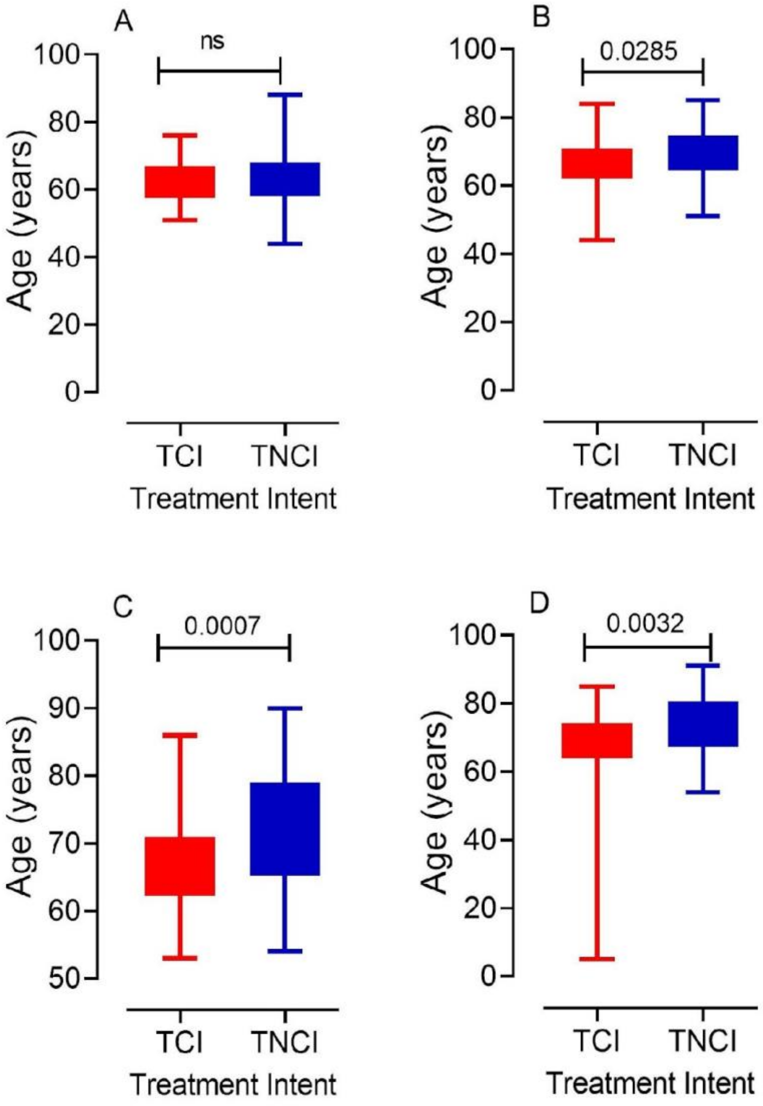

Figure 4.4: *Effect of age on treatment choice in patients classified as low risk (A), intermediate favourable risk (B), intermediate unfavourable risk (C) and high risk (D).*

Of patients in the High-Risk group 70% (n=116) received TCI (31% Surgery, 39% Radiation) (Figure 4.1D). Age influenced the treatment received with patients receiving TCI being younger (average age 68.9 years) compared to those receiving TNCI (Average age 73.7 years, Figure 4.4 D, *P* = 0.0032). Like patients in the intermediate risk groups, patients receiving surgery were significantly younger (mean age 65 years) than those receiving radiation therapy (mean age 72 years, $P < 0.0001$). Patients receiving surgery took fewer medications (mean 2.4) compared to those treated with radiation (mean 3.9, $P = 0.0136$).

The AUA/ ASTRO guidelines suggest TCI or TNCI (watchful waiting) if life expectancy is less than 5 years for patients classified as High-Risk (Table 4.1a). The treatment received by 94% of the patients in this High-Risk group was concordant with the guidelines (Table 4.2). According to the Lunardi *et al* algorithm 18% of patients were potentially overtreated, (Table 4.1b).

4.8 DISCUSSION

The results of our study demonstrate that 80% of patients treated by the participating urologists received appropriate treatment based the AUA/ASTRO guidelines; however, approximately one third of patients classified as low risk were not treated in concordance with the guidelines.[23,25] Similar to the findings of the current study, a Victorian prostate cancer registry study, reported by Wang *et al* , has shown a correlation between cancer risk stratification and treatment options.[26] In their study, 55% of low-risk patients received active surveillance, compared to 66% of the patients in our cohort. The most recent report of the Prostate Cancer Outcomes Registry of Australia and New Zealand which followed more than 10,000 men diagnosed between 2015 and 2017 shows that identical to our study 66% of men with low-risk disease were placed on observation.[27] In that study 85% of men in the intermediate risk group received TCI compared to approximately 75% in our study. Therefore, the patient group from the current study has similar demographics to those in both studies and in particular the risk stratification distribution is similar suggesting that our patient cohort is representative of Australian patients with prostate cancer in general.[26,27] The results of these studies and ours confirm that patients' treatment options are being ab initio appropriately driven by cancer factors.

Once treatment options, based on cancer factors, are established a patient's age and comorbidities will modify these options.[6,28] Overall (across all risk groups), patients in our study who were younger and healthier were more likely to undergo TCI, suggesting that invasive treatments were given to those most likely to benefit. In the current study patients classified in the Low-Risk group receiving TCI had fewer comorbidities than those receiving TNCI. Similarly, for patients classified into the High-Risk group those receiving surgery were on fewer medications than those receiving other therapies, including radiation (a second TCI). These findings concord with an Australian population-based study of men with a new diagnosis of prostate cancer which showed that men who were younger (<60 years old) and with low comorbidities were more likely to receive surgery (radical prostatectomy).[29] It is thus critical to estimate the risk of death from prostate cancer and compare this risk to the risk of death from other causes to avoid the use of TCI in men with limited life expectancy or significant comorbidities.[30] Schymura *et al.'s* study [31] supports this paradigm of treatment with TNCI associated with increasing age, high PSA, low grade cancer and high comorbidity.

Under-treatment should be avoided in men who are young, healthy and have aggressive cancers by offering TCI. Similarly, over-treatment (unnecessary treatment) should be avoided in those with low-grade cancer, or who because of limited life expectancy due to significant comorbidities are likely to die of competing causes, rather than from prostate cancer. Notwithstanding this, older, healthy men with aggressive cancers *may* need to receive treatment.[25] In our study over-treatment was identified in 15% of patients which is slightly lower than the over-treatment rate of 25% reported by Lunardi *et al*.[24] In the current study, like the Lunardi study, patients identified as being over-treated received TCI despite having a limited life expectancy and/or high comorbidities. Daskivich *et al.'s* study of nearly 1500 patients with newly diagnosed low/ intermediate risk showed that the risk of death from prostate cancer over 10 years was only between 5-8% (regardless of the treatment chosen) with

25% of men dying of non-prostate cancer causes.[8] So for many men the risk of dying directly from prostate cancer is low whereas those with a CCI score greater than or equal to 2 have a >75% risk of dying from any cause over 10 years.[25,31] Ultimately comorbidities have a large impact on survival with Frendl's study showing that age at diagnosis, CCI, self-reported general health and smoking to be the most predictive risk factors for mortality.[12] Scores utilising medication use have been shown to be a good measure of comorbidity.[32,33]

Age is significant not just as one factor contributing to life expectancy, but also as an independent risk factor for comorbidity and is therefore rightly a prime determinant of treatment options.[10] In our study patients receiving TCI were significantly younger than those choosing TNCI for the intermediate favourable, intermediate unfavourable and high-risk groups. Clinicians can use the ABS life tables as a crude estimate of life expectancy based on age.[35] However, the life tables do not consider health status or comorbidities and have been shown to overestimate life expectancy significantly, especially in older men, which may contribute to possible overtreatment.[9,10,34] Despite this evidence, Daskivich *et al*. suggest that clinicians tend to emphasise age (and crude estimates of life expectancy) over comorbidities when making treatment decisions.[8] Hoffman *et al*. have confirmed that comorbidity is a more significant determinant of life expectancy than age. [9,14]

While the focus of the discussion until now has been on over-treatment of older men with co-morbidities; conversely, some older men with aggressive cancer may be denied TCI based merely on their age and thus suffer from under-treatment. For older men with high grade disease, the lethality of prostate cancer must not be underestimated, especially for those with fewer comorbidities.[14] In our study 12-18% of men in the intermediate risk groups did not receive TCI despite having no comorbidities suggesting possible undertreatment of this group of men. Lu-Yao has shown that for men with high-risk disease and a life expectancy of greater than 10 years there is a significant risk (> 25%) of prostate cancer specific mortality within that

10-year period, suggesting that active treatment may be beneficial.[11] However, men over 70 are less likely to receive TCI, regardless of cancer grade or CCI, suggesting that age alone, rather than cancer grade or comorbidities, is the prime determinant of treatment options for these men.[35] In Frendl *et al's* study, for men over 65 years old, only 40% of those who died as a result of their had undergone definitive treatment suggesting undertreatment of this group of older men.[12]

4.7 CONCLUSION

The aim in treating men diagnosed with prostate cancer should be to avoid under-treatment in men who are young, healthy and have aggressive cancers by offering TCI. Conversely, over-treatment (unnecessary treatment) should be avoided in men with low-grade cancer or who because of limited life expectancy or significant comorbidities are likely to die of competing causes rather than from prostate cancer. The results of the current study demonstrate that 80% of patients treated by the participating urologists received appropriate treatment based on the AUA/ASTRO guidelines. Ultimately cancer factors should be the prime determinant of treatment options and be modified by life expectancy and comorbidities. Physicians must be careful not to overestimate the lethality of the cancer and underestimate the potential for age and comorbidities to be a more likely cause of death while still offering TCI to those most likely to benefit.

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CHAPTER 5: STUDY B

5.1 Title Page

FACTORS AFFECTING SATISFACTION WITH THE DECISION-MAKING PROCESS AND DECISION REGRET FOR MEN WITH A NEW DIAGNOSIS OF PROSTATE CANCER

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Abbreviations: ADT, Androgen Deprivation Therapy; PSA, Prostate Specific Antigen; TDM-SAT, Treatment Decision-Making Scale.

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5.2 FOREWORD AND LINK TO CONCEPTUAL FRAMEWORK OF THESIS.

In the current paradigm of modern medicine, it is accepted that shared decision-making is the gold standard for all treatment decisions. However, patient participation in the treatment decision-making process is affected by numerous cognitive patient factors, including health literacy (HL) factors and the degree of control the patient choses to exert over the decision-making process will influence the extent to which successful shared decision-making can occur. The level of shared decision-making between patient and clinician has a significant impact on the decision-making process and the success of that process can be assessed by measuring satisfaction with the decision-making process and ultimately by assessing decision regret, as highlighted in Figure 5.1. The aim of Study B was to investigate if there was an association between the extent to which men, with a new diagnosis of prostate cancer, had wanted to be involved in the decision-making process, their satisfaction with that process, and their levels of decision regret after treatment. The effect of the actual treatment chosen on treatment decision-making and regret was also assessed.

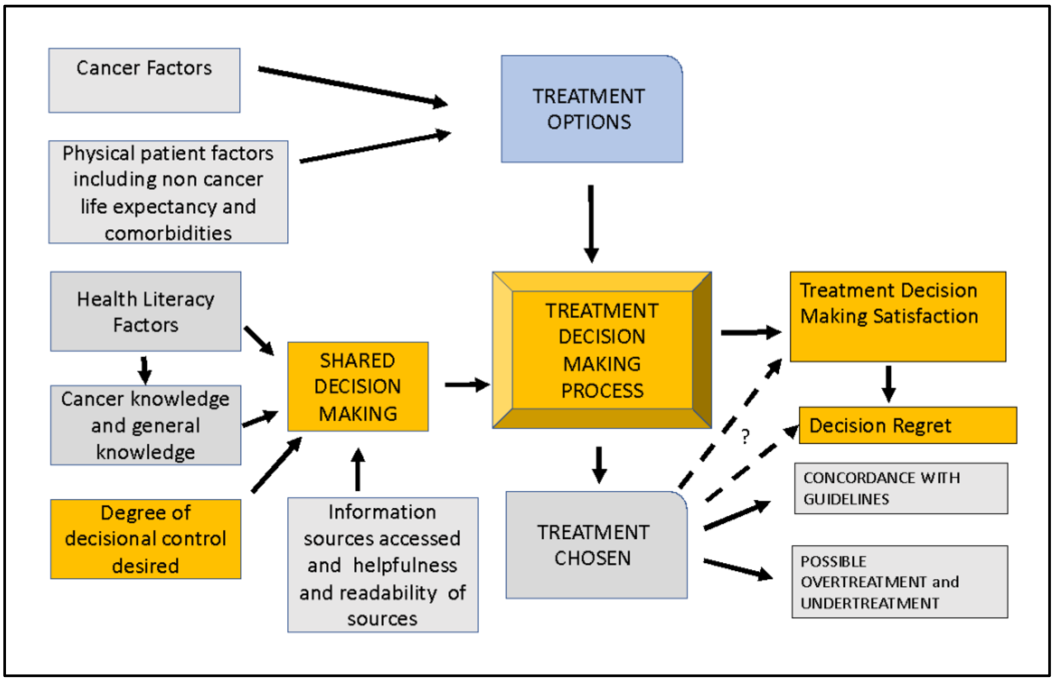

Figure 5.1: *Concept map for Chapter 5 (Study B)*

5.3 ABSTRACT

For men with newly diagnosed prostate cancer the decisions about treatment options are complex and difficult. The aim of this study was to investigate any association between the extent to which men wanted to be involved in the decision-making process, their satisfaction with that process, and their levels of decision regret after treatment. The study population consisted of men diagnosed with prostate cancer at a regional centre in Australia. Men (n=324) were invited to complete a mail out survey which included demographic questions, the treatment chosen, and three validated tools: The Control Preference Scale to measure the degree of control assumed when making decisions about medical interventions; the Treatment Decision-Making Satisfaction Scale (TDM- SAT) to assess satisfaction with the treatment decision-making process; and the Decision Regret Scale to assess the level of regret after treatment. The majority of the 151 respondents (47% response rate) expressed an active decision control preference. There was no correlation between age and the treatment chosen or the degree of control men exerted over the decision-making process. Men who preferred a passive role were less satisfied with the decision-making process than were those who took an active or collaborative approach. A strong inverse correlation was demonstrated between regret experienced and satisfaction with the decision-making process. In conclusion, for men newly diagnosed with prostate cancer, taking an active role in the treatment decision-making process led to greater satisfaction with that process, which in turn reduced their chances of experiencing regret following treatment.

Keywords

Prostatic neoplasms, decision-making, personal satisfaction, patient participation, emotions

5.4 BACKGROUND

Prostate cancer has a high incidence and remains the most common solid organ cancer diagnosed in Australian men, with an incidence rate of 129 cases per 100,000 persons.[1] This rate is similar to the incidence rate of 104 cases per 100,000 persons among American men.[2] Based on these estimates, approximately 17,000 Australian men and 192,000 American men will have been diagnosed with prostate cancer in 2020.[1,2] Although prostate cancer is a commonly diagnosed cancer, the mortality rate is low such that there is a 95% five-year survival.[3] The high incidence and low mortality contribute to a high prevalence of prostate cancer in the male population. Ninety percent of these cases are diagnosed when the cancer is clinically confined to the prostate, such that decisions need to be made about treatment with curative intent (radical prostatectomy or radiation therapy or conservative management (active surveillance or watchful waiting).[4,5]

For all men with a new diagnosis of prostate cancer, the decision to undergo active treatment is difficult because of the potential for treatment-related side effects that can interfere with physical, psychological and sexual well-being.[6,7] This difficulty is compounded by the lack of proven efficacy of prostate cancer treatments in improving survival.[4,8] The decision as to what treatment to pursue following a diagnosis of prostate cancer should be made collaboratively by the treating physician and the patient. Ideally, a patient would make their treatment decision based on a good understanding of their condition and treatment outcomes; however, many patients do not have a good understanding of their treatment choices and are frequently not well informed. In addition patients often make decisions ruled by emotion and intuition rather than reason and fact.[9] The patients' decision may be impacted upon by psychological distress, anxiety and fear often experienced after a cancer diagnosis.[7,10] Physicians should actively involve the patient in the decision-making process by ensuring that they are well informed and providing them with advice about: the need for treatment (based on the risk of the cancer progressing within the patient's life expectancy); the risks associated with treatment choices; and the possible benefits in terms of longer survival.[11-17] Physicians need to be careful not to unduly influence patient decisions and ensure that men are presented with all available treatment options in a neutral and unpressured way.[9] The patient should then consider this advice in light of their personal values and preferences, and their preparedness to trade-off the risk of potential treatment-related side effects for a possible longer survival.[18,19]

Following treatment, there may be a good or bad outcome for the patient which is essentially defined by their consequent 'level of health'.[20] A good outcome entails a low level of side effects associated with treatment and continued good health without any impact on quality of life. A poor outcome will be experienced as lower scores on a cancer focused quality of life scale, poor functional status eg long term side effects of treatment including adverse bladder, bowel and sexual side effects, failure of the treatment to provide cure or poor emotional well-being.[21] So, although a patient may suffer from significant side effects post treatment their response to that outcome can be ameliorated by their satisfaction with, and involvement in, the decision-making process.[22,23]

When a decision about a treatment option is made under conditions of uncertainty, and the patient later considers that there were alternatives, a sense of loss or regret can occur.[24] Decision regret has been defined as a negative emotion involving distress or remorse following a decision.[12] and can result when the outcome of a decision is compared with the likely outcome of an unchosen alternative.[25] Decision regret is characterized by self-blame and a wish to undo the situation which has led to a poor outcome.[26(p10)] In a range of health care settings, both cancer and non-cancer related, lower involvement in the decision-making process has been associated with increased decision regret.[20,27,28] Other factors that may exacerbate decision regret for patients diagnosed with prostate cancer include: pre-treatment anxiety; post-treatment side effects (for example reduction in sexual, bladder and bowel function); higher levels of decisional conflict before choosing the treatment and lower satisfaction with the information provided by the physician.[12,29-31] A 15 year post-treatment study on men with localised prostate cancer found that decision regret was lower among men who had made informed decisions and who were older at the time of diagnosis.[30] These findings are in contrast, to those of a small Taiwanese study which highlighted that there was no association between decision regret and the involvement of men in the decision-making process.[32] Increased levels of decision regret are associated with significant health impacts including lower health related quality of life, poor self-image, negative appraisal of masculinity, increased cancer related distress, overall worse health outcomes and subsequent negative experiences with the health system.[12,20]

As described above, there is some evidence that increased control over the decision-making process leads to increased satisfaction with that process and that a passive role in decision-making is associated with increased decisional regret.[10] However, there is a gap in the literature examining the links between involvement in the decision-making process, satisfaction with that decision-making process and subsequent regret in the same patient population. Therefore, the aim of the current study was to investigate if there was an association between the extent to which men, with a new diagnosis of prostate cancer, had wanted to be involved in the decision-making process, their satisfaction with that process, and their levels of decision regret after treatment.

5.5 METHODS

5.5.1 Study population

The study population consisted of men, with a new diagnosis of prostate cancer, under the care of physicians at a regional center in Australia, between January 2015 and January 2017. There were no specific exclusion criteria, and the study was approved by the Human Research

Ethics Committee of the University of Wollongong, NSW, Australia [HREC2016/955].

5.5.2 Study Measures

The 324 men in the study population were mailed an 18-item written survey and tacit consent was assumed for surveys that were completed and returned via reply paid envelopes. Non-responders were not reminded or contacted further and there were no inducements, financial or otherwise offered. The survey included demographic questions (e.g., age, marital (partner) status, employment status, education level, country of birth, as well as a question about the treatment option chosen. The survey also included three reliable and validated tools: The Control Preference Scale[33], the Treatment Decision-Making Satisfaction Scale[34] and the Decision Regret Scale[27] (Table 5.1.)

Table 5.1: Individual items that make up the survey tools

Control Preference Scale

Items	Response options
Item 1: I made the final treatment decision.	1) I made the final treatment decision.
Item2: I made the final treatment decision after seriously considering my doctors opinion.	2) I made the final treatment decision after seriously considering my doctor's opinion.
Item 3: My doctor and I shared responsibility for deciding which treatment was best.	3) My doctor and I shared responsibility for deciding which treatment was best.
Item 4: My doctor made the final treatment decision after seriously considering my opinion.	4) My doctor made the final treatment decision but seriously considered my opinion.
Item 5: I left all the treatment decisions to my doctor.	5) I left all treatment decisions to my doctor.

Treatment Decision- Making Satisfaction Scale (TDM-SAT)

Items	Response options
Item 1: My treatment decision-making options were clear to me.	1) not at all 2) a little bit
Item 2: It was easy for me to decide on the treatment I chose.	3) somewhat 4) quite a bit
Item 3: I am satisfied with the level of communication I had with my physician about treatment options.	5) to a very great extent
Item 4: Overall, I am satisfied with my treatment decision-making experience.	
Item 5: Overall, I am satisfied with the treatment I chose.	

Decision Regret Scale

Items	Response options
Item 1: It was the right decision.	1) strongly disagree
Item 2: I regret the choice that was made.	2) disagree
Item 3: I would go for the same choice if I had to do it over again.	3) neither agree not disagree 4) agree
Item 4: The choice did me a lot of harm.	5) strongly agree
Item 5: The decision was a wise one.	

The Control Preference Scale consists of 5 items designed to measure the degree of control an individual wants to assume when decisions are being made about medical treatment.[33] It is a graded, agree-disagree response tool in which a respondent endorses an attitude stated to the extent that it matches their own opinions.[35] As part of this scale, we adopted the modification used by Davison et. al.[36] in that response statements were in the past tense and respondents were asked to select the response option that reflects best the role they took in the decision (Table 5.1). Respondents who chose options 1 or 2 were categorized as having an Active role, those that chose option 3 were categorized as having a Collaborative approach, and those that selected options 4 or 5 were categorized as having a Passive role in the decision-making process.[10,18,] This scale was chosen because its reliability has been established with 80% of the decisional preferences of men with newly diagnosed prostate cancer falling into the 'dimension' of the preference scale.[33]

A modification of the Treatment Decision-Making Satisfaction Scale (TDM-SAT)[34] was used to measure satisfaction with the decision-making process. The TDM-SAT contains 5 items on a 5-point Likert scale (Table 5.1) with higher scores, out of a possible 25, indicating greater satisfaction with the decision-making process. The tool has been validated with item total correlations ranging from 0.85 to 0.91 and internal consistency reliability was 0.96.[34]

The final validated and reliable tool included in the survey, was the Decision Regret Scale.[27] This tool asks respondents to reflect on their treatment decision by providing 5 statements requiring responses on a 5-point Likert about the degree to which they agree with the statement (Table 5.1). This scale provides a score out of 100 (0 = no regret; 100 = extreme regret), with a score greater than 25 indicating significant regret[28]. The scale has high internal consistency with Cronbach's Alpha ranging from 0.81 to 0.92. The item total correlations range (for a group of prostate cancer patients) was between 0.50 and 0.67.[28]

5.5.3 Statistical analysis

Descriptive statistics were used to provide an overview of respondents' sociodemographic characteristics, primary treatment option chosen and degree of control they exerted over the decision-making process. Continuous data with 2 numerical variables were analysed using linear regression with p values indicating the extent to which the deviation of the slope from zero was significant (p values <0.05 were taken as significant) and r^2 indicating the 'goodness of fit'. To determine whether the difference between values was significant, when one value was numerical (and normally distributed) and the other categorical, an unpaired t test was performed if there were 2 categorical groups and an ANOVA if multiple categorical groups. However, when the numerical values were non-parametric, to determine if the difference between the values was significant, the Kruskal-Wallis test was used if there were multiple groups and the Mann-Whitney test if only 2 groups. Analysis to determine correlation between the responses from individual tools or items was performed using Prism 7 for MacOSX (GraphPad Software Inc.).

5.6 RESULTS

5.6.1 Participant demographics

In total, 151 men responded to the survey representing a response rate of 47% (151/324). The time since diagnosis of prostate cancer ranged from 70 to 783 days. There was no significant difference between the clinical characteristics of the group that responded to the survey and those that did not (Table 5.2). The median age of the two groups (responders, non-responders) was similar, as was the proportion of participants who had undertaken surgical treatments, as compared to non-surgical treatments (Table 5.2). The mean PSA, % high Grade Gleason score and D'Amico scores (identifying the risk of metastases) was also similar in the two groups (Table 5.2) and all but three of the respondents had clinically localized prostate cancer. Many of the respondents (56%, 84/150) underwent surgery as the primary treatment for their prostate cancer and no association was found between age and the choice of either surgical or non-surgical treatment (p 0.93, Mann-Whitney). The majority (87%, 130/151) of the respondents had a partner and just over half (55%, 83/151) described themselves as being retired. Almost one third of respondents were not born in Australia (26%, 40/151) which is representative of the general population of Australia of whom 30% were born overseas[37] and 9% (14/151) spoke English as a second language. Three quarters of the study respondents had finished high school (75%, 113/151) and one quarter had a university degree (25.2%, 38/151); however, one third (32%, 48/151) of the respondents left school at less than 16 years of age.

Table 5.2: Participant characteristics

	Participants	Non-Responders
Age median mean (range)	66.5 (47-84)	65.6 (50-90)
Cancer related factors		
PSA	8.3 (6.1-11)	7.6 (5.2-13)
% Gleason High Grade	20 (5-70) %	30 (1-80%)
D'Amico Score [a]		
Low	12%	23%
Intermediate	62%	49%
High	26%	28%
Primary treatment		
Surgical	56% (84/150)	44% (91/206)
Non-Surgical		
Radiation	20% (30/150)	19% (40/206)
Androgen deprivation therapy	5% (7/150)	9% (18/206)
No therapy	19% (29/150)	28% (57/206)

[a] *The D'Amico score predicts the 5 year risk of development of metastases post treatment from pretreatment clinical data.*[15] *Patients are divided into 3 groups. Low Risk cancer is defined as a PSA <10 AND a highest Gleason biopsy score of ≤6 AND clinical stage T1/2a, Intermediate Risk cancer is defined as a PSA of ≥ 10 and <20 OR a highest Gleason score of 7 or clinical stage T2b and High Risk cancer is defined as a PSA of ≥20 OR a Gleason score of ≥ 8 OR clinical stage T2c/ T3.*

5.6.2 Degree of Control on the decision-making process

The majority of men who responded to the survey perceived that they had taken an active role in the decision-making process (65%, 97/151), based on their responses to the Control Preference Scale. There was no association between the degree of control men exerted over the decision-making process and age (p 0.57, ANOVA), achieving a university degree (p 0.23, Mann-Whitney) or having a partner (p 0.55, Mann-Whitney). Participants who opted for a passive role in decision-making were more likely to have left school at a younger age compared to those who opted for an active role (Figure 5.2, p = 0.0170, ANOVA).

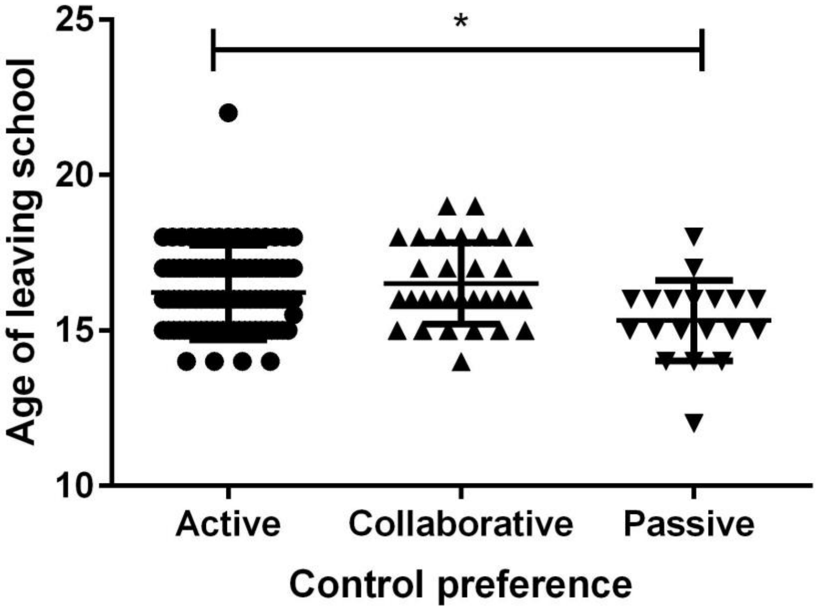

Figure 5.2: *Effect of age leaving school on control preference. Participants who opted for a passive control preference were more likely to have left school at a younger age than those who opted for an active control preference (p 0.017, ANOVA).*

5.6.3 Factors that influence patient satisfaction with the decision-making process

Overall, a high proportion of respondents were satisfied with the decision-making process, with an average TDM-SAT score of 20.8 out of 25. However, one third of respondents did not find it easy to make a decision, as highlighted by their response to TDM-SAT Item 2 (33% scored 3 or less). No correlations were found between the primary treatment and satisfaction with the decision-making process (p 0.61, Kruskal-Wallis). Respondents who had surgical treatment (radical prostatectomy) were just as satisfied as were those who had opted for a non-surgical treatment (Figure 5.3A). No correlation was found between age and satisfaction with decision-making (p 0.57, r2 0.002, linear regression).

An association was found between the respondents' decisional control preference (either active, collaborative or passive) and their satisfaction with the decision-making process. Respondents who had taken a passive role were less satisfied with the decision-making process, as compared to those who had taken an active role (p 0.005, Kruskal-Wallis using Dunn's multiple comparison test) or a collaborative role (p 0.02, Figure 5.3B). These results were confirmed by the responses to TDM-SAT Item 5, which indicted that those who took an active role in the decision-making process showed greater 'satisfaction with the treatment chosen', compared to those that opted for a passive role (p 0.0115, Figure 5.3C).

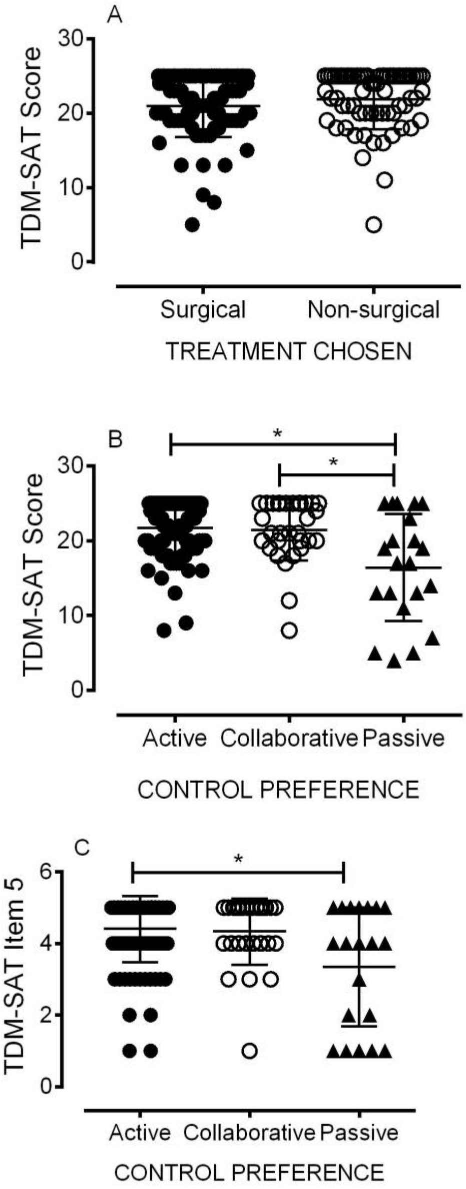

Figure 5.3: *Determinants of decision-making satisfaction (TDM-SAT).*

(p <0.05) Figure 5.3A shows the relationship between the treatment chosen and satisfaction with the decision-making process (non-surgical treatment includes radiation therapy, androgen deprivation therapy and conservative management). Figure 5.3B shows the influence of the degree of control the patient exerted in the decision-making process and satisfaction with the decision-making process as measured by TDM-SAT [21]. Figure 5.3C shows the relationship between control preference and satisfaction with the particular treatment chosen (TDM-SAT item 5)*

5.6.4 Factors that influenced decision regret

According to the decision regret scale, approximately 30% of respondents had scores greater than 25 indicating significant regret. This decision regret is indicated in multiple aspects of the decision regret scale with 30% of respondents indicated that they would not make the same choice if they had to do it over again (Decision Regret Scale, item 3); similarly, 30% indicated that they felt that their choice did them a lot of harm (Decision Regret Scale, item 4). Decision regret was the same regardless of the treatment undertaken (p 0.62, Kruskal-Wallis), with no difference in decision regret among respondents who chose surgical treatment (radical prostatectomy), compared to those who chose non-surgical treatment (p 0.57, Figure 5.4A). The results indicate that decision regret did not vary with age (p 0.49, $r^2$0.003, linear regression) or with length of time since diagnosis (p 0.115, r^2 0.02).

There was a strong negative correlation between decision regret and the total score relating to satisfaction with the decision-making process (TDM-SAT) ($p < 0.0001$, r^2 0.3176, linear regression, Figure 5.5A).

This result suggests that men who were satisfied with the decision-making process were less likely to experience decision regret. A similar strong negative correlation was demonstrated for all 5 components that make up the TDM-SAT scale (Figure 5.5B-F) suggesting that men who were more satisfied with the level of communication with their physician ($p<0.0001$) and who felt that their options were clear ($p<0.0001$) had lower levels of decision regret. Although there was a trend for men with a passive role in the decision-making process to have higher decision regret which did not reach statistical significance (p 0.27, Kruskal-Wallis test, Figure 5.4B).

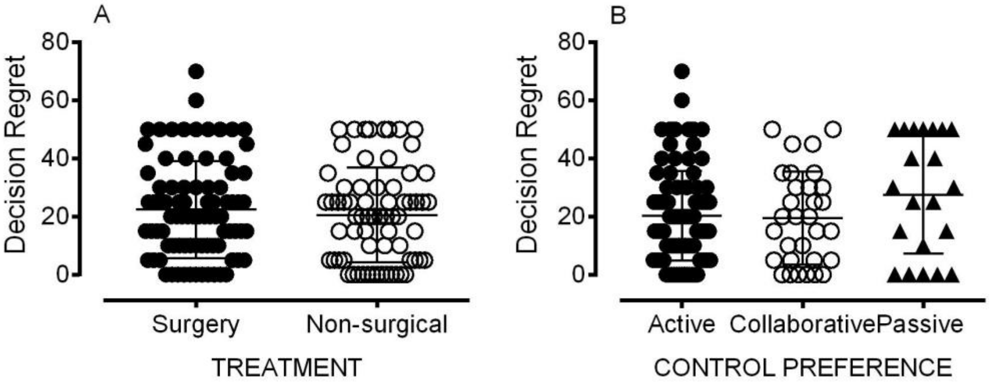

Figure 5.4: *Influence of Decision regret on treatment decisions and control preference. Figure 5.4A shows the relationship between decision regret and the treatment chosen. Figure 5.4B shows the relationship between decision regret and the degree of control the patient exercised over the decision-making process.*

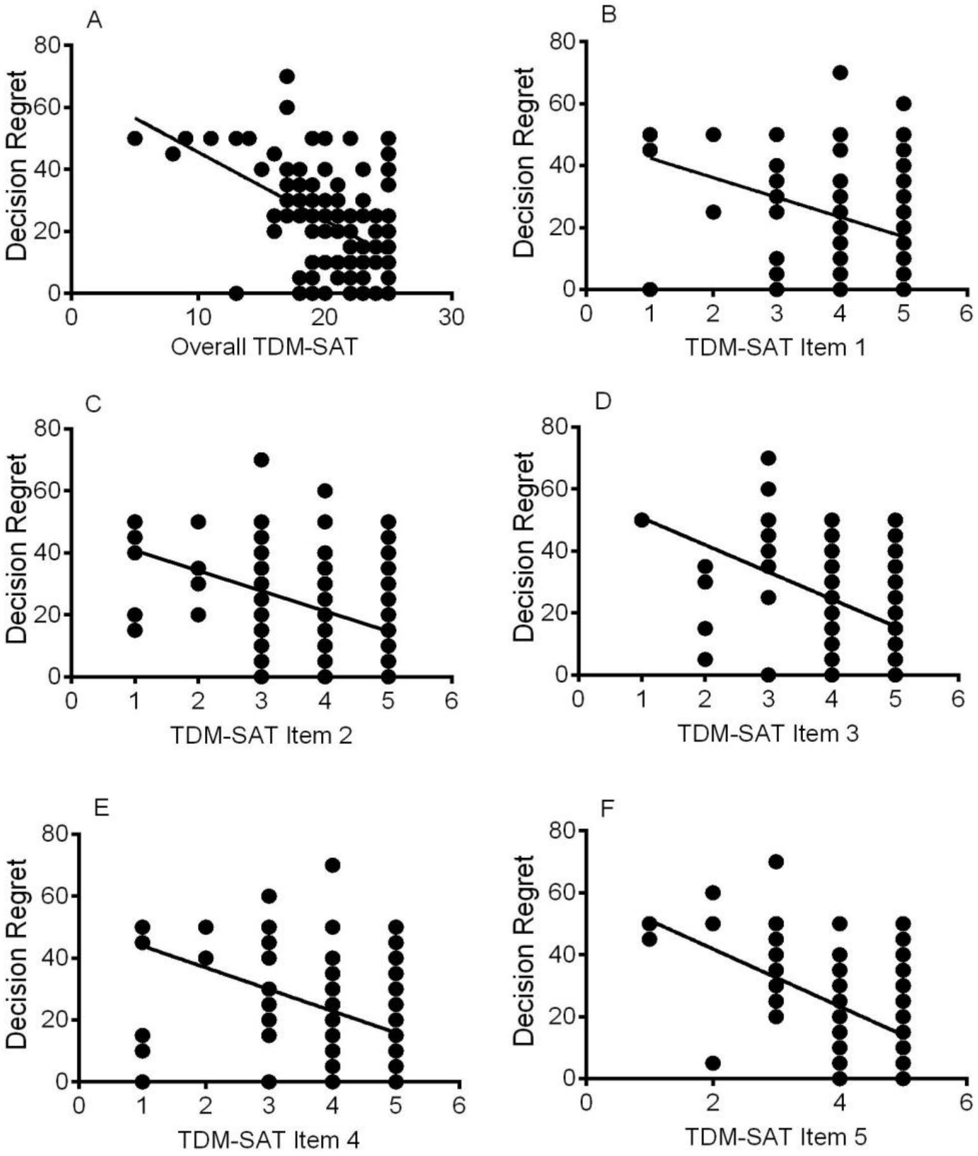

Figure 5.5: *Relationship between decision regret and TDM-SAT*

Figure 5.5A shows *the inverse relationship between regret and satisfaction with the treatment decision-making process (TDM-SAT). Figures 5.5B-F show the correlation between regret and the sub-items in the TDM-SAT scale. Item 1: "My treatment decision-making options were clear to me" (Figure 5.5B, $p<0.0001$, r^2 0.16). Item 2: "It was easy for me to decide on the treatment I chose", (Figure 5.5C, $p<0.001$, r^2 0.24). Item 3: "I am satisfied with the level of communication I had with my physicians about treatment options" (Figure 5.5D, $p<0.0001$, r^2 0.24). Item 4: "Overall I am satisfied with my treatment decision-making experience", (Figure 5.5E, $p<0.0001$, r^2 0.23). Item 5: "Overall I am satisfied with the treatment I chose", (Figure 5.5F, $p<0.0001$, r^2 0.39).*

5.7 DISCUSSION

Treatment decisions following a diagnosis of prostate cancer are complex and difficult for men.[11] This study aimed to better understand three factors that influence this decision-making process: the patient involvement in the decision-making process, the patient satisfaction with the decision-making process, and their level of decision regret following their treatment. The major findings of this study are that increased involvement in the decision-making process correlates with increased satisfaction with that process and that increased satisfaction with the decision-making process then correlates with lower decision regret.

The majority of respondents in this study were men with clinically localized prostate cancer with a median age of 66 years, which is a representative age for men diagnosed with prostate cancer.[4,5] In addition, more than half of the study participants were in the intermediate D'Amico risk group (indicating that they had an intermediate risk of metastases in the 5 years post diagnosis) which is also typical of men newly diagnosed with prostate cancer.[17] Just over half of the respondents underwent a radical prostatectomy as their primary treatment, which is slightly lower than comparable US trends, and almost 20% elected to be managed conservatively, which is higher than US trends.[38] Therefore, the population who responded to the survey are broadly representative of the population of men diagnosed with prostate cancer. One important limitation of the current study is that it was a retrospective study conducted at only a single regional urology practice. The retrospective nature of the study could not be avoided as it is ethically and practically difficult to examine the thought processes of men during the decision-making process. Their satisfaction and regret about these decisions are emotions that can only be judged in retrospect.

Historically, the treatment decision following a diagnosis of prostate cancer has been a paternalistic 'doctor knows best' decision. In the last 20 years there has been a shift in the nature of the physician-patient consultation to a more collaborative, shared decision-making model in which patients are encouraged to take part in the decision regarding their treatment options.[39-41] Shared decision-making has been defined as a process whereby "both parties take steps to actively participate in the process of decision-making, share information and personal values, and together arrive at a treatment decision with shared responsibility".[40(p2)] In the current study, the majority of men reported a preference to take an active role in the decision-making process, which did not differ according to their age. These results are somewhat different to the evidence in the literature which suggests that some men prefer their physician to make decisions on their behalf, especially if they are older.[42-45] It is possible that the high percentage of men with an active involvement in the decision-making process may result from the nature of the survey method used, with men who were actively involved in the decision-making process also more likely to respond to the survey.

Our results demonstrated that men who left school at a younger age were more likely to opt for a passive role in decision-making. These findings are supported by those of a cross-sectional study of 562 men diagnosed with prostate cancer, which reported that more educated men were more likely to prefer a more active role in decision-making.[42-45] The association between lower education level (for which age at leaving school may be a surrogate) and inadequate health literacy is well documented.[46,47] Smith et al.[48] have suggested that lower education and literacy levels may be associated with decreased involvement in the decision-making process. Physicians need to be aware that patients taking a passive role in the decision-making process may simply reflect their lower educational attainment and an underlying (and unappreciated) low health literacy status. A shared decision-making model has been shown to help men, including those with lower education and health literacy levels, to become more actively involved in the decision-making process.[48]

We have reported that men who took a more active role in decision-making had higher satisfaction with the treatment decision-making process and were more satisfied with the treatment chosen. High levels of satisfaction with treatment decisions are important because they are associated with higher quality of life scores and a better self-image post treatment.[10,19,20,34] Increased patient autonomy and collaborative involvement in the decision-making process has been reported to improve satisfaction associated with the decision-making process for men with prostate cancer.[10,18,34]

The current study has established that one third of respondents experienced decision regret following their treatment irrespective of the primary treatment chosen, which is higher than the rates of 15-25% reported in the literature.[28,30,49,50] However, only one of these studies used the Decision Regret Scale, which makes comparing the level of decision regret reported in different studies difficult.[28] The Decision Regret Scale, used in the current study, may overestimate regret due to the nature of the Likert Scale used where a response of "neither agree or disagree" resulted in a Likert score of 3. These indeterminate responses may have then been perceived as possible regret. If we had not included a score of 3 as an indicator of possible regret, then only 17% of respondents would have been recorded as experiencing decision regret. Our results suggest that higher satisfaction with the decision-making process, including subscale factors such as satisfaction with communication from the physician and having clear treatment options, was a major factor contributing to lower decision regret following treatment. This finding supports a 2016 systematic review of general health care decisions (not specifically related to prostate cancer) which reported that higher rates of decision regret among men were associated with lower satisfaction with the decision, increased decisional conflict and less involvement in the decision-making process.[12] Our study has demonstrated an association between an active role in decision-making and increased satisfaction with the decision-making process, as well as an association between increased satisfaction with the decision process and lower levels of regret. However, unlike previous research, which found a direct relationship between patient decision control preference and decision regret, the current study was unable to identify a direct association between these two factors.[20,27]

5.8 IMPLICATIONS FOR PRACTICE

The key finding of this study is that following a diagnosis of prostate cancer men who pursue an active role in their treatment decisions are more satisfied with the decision-making process and subsequently have lower rates of decision regret. We identified that men who took a passive role in decision-making were more likely to have left school at an earlier age. Based on these findings, physicians must recognize the need to increase the active participation of men newly diagnosed with prostate cancer in the decision-making process to help improve satisfaction and reduce decision regret about the treatments chosen. Active participation can be improved by communication skills training for both physicians and patients.[51] Clearly, physicians cannot force patients whose natural proclivity is to adopt a passive role into more active engagement. However, physicians have a responsibility to educate patients about the benefits of a more active involvement in making their treatment decision and to give patients tools to become more actively involved by providing them with key questions to ask.[38,52] Patient involvement in the decision-making process is also dependent on physicians providing information (both verbal and written) that is within the educational and health literacy levels of their patients.[42] The provision of information that is understandable by the patient will empower them to become involved by increasing their knowledge and confidence. It is only by ensuring true shared decision-making at the beginning of a patient's prostate cancer journey that later decision regret and its negative effects on men's health can be avoided.

While outside the scope of this study, future research could examine different approaches to physician-patient communication, in particular the initiation of conversations and the content being discussed. These studies would help to determine which communication approaches afford optimal patient engagement and satisfaction with the decision-making process;

ultimately investing both the physician and patient in minimising decision regret following treatment.

Conflicts of interest

The authors all declare that they have no conflicts of interest regarding the publication of this manuscript.

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CHAPTER 6: STUDY C

6.1 Title Page

READABILITY, UNDERSTANDABILITY AND ACTIONABILITY OF WRITTEN INFORMATION AVAILABLE FOR PATIENTS DIAGNOSED WITH PROSTATE CANCER

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6.2 FOREWORD AND LINK TO CONCEPTUAL FRAMEWORK OF THESIS

The previous study (Chapter 5) identified that for men with a new diagnosis of prostate cancer, increased involvement in the decision-making process was associated with improved satisfaction with that process and the treatment chosen; however, to be involved men must have sufficient HL to read and understand a large volume of complex information. The health literacy demand (including the readability, understandability and actionability of the available information sources) is also critical to allow men to feel they can engage in the decision-making process. Therefore, matching the HL of men with the HL demand of the available information sources is essential for successful shared decision-making and consequently an effective treatment decision-making process (Figure 6.1). The aim of this study was to gain a better understanding of the health literacy of men newly diagnosed with prostate cancer, the prostate cancer information sources they accessed, and how helpful they found these sources, as well as the readability, understandability and actionability of these prostate cancer information sources.

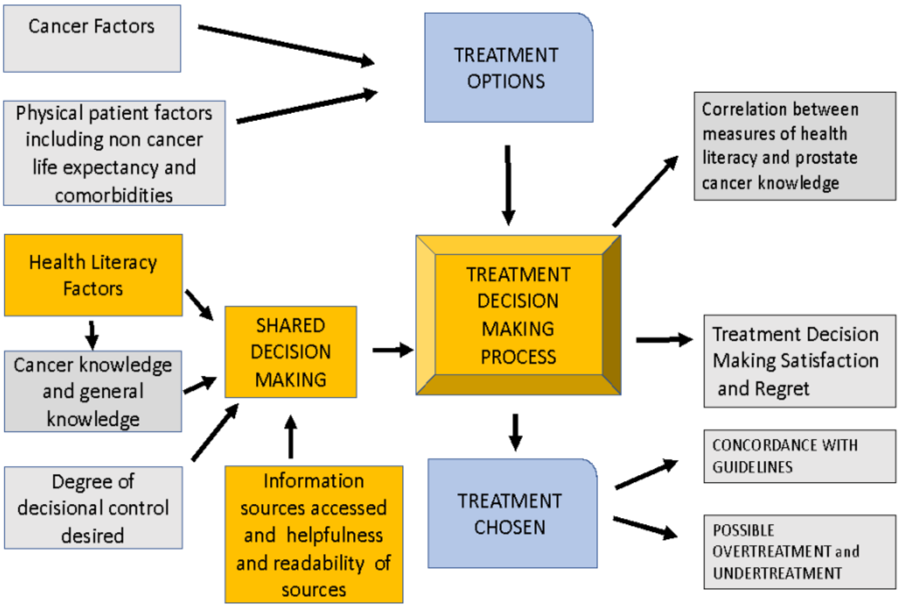

Figure 6.1: *Concept map for Chapter 6. (Study C)*

6.3 ABSTRACT

Context: Following a diagnosis of prostate cancer men need to be able to read, understand and take action based on information accessed if they are to take part in the decision-making process about their treatment options. However much of this information is written at a level beyond the health literacy of this group of men.

Objectives and Design: By means of cross-sectional survey this study investigated the health literacy of men diagnosed with prostate cancer and the information sources they accessed. The readability, understandability and actionability of prostate cancer information sources was also assessed.

Results and Conclusion: Responses were received from 151 men (44% response rate), with a median age of 67 years, 21% with inadequate health literacy and most of whom had chosen surgery as their active treatment (56%). The majority of the respondents (80%) accessed four or more different information sources. Most information sources available were written above the recommended readability level (grade 8 or below) and had low 'actionability' scores (30-50%) which were well below the recommended 70%.

Men newly diagnosed with prostate cancer often access information sources which are difficult to read, understand and take action upon. Clinicians, health authorities and non-government organisations must be made aware of the variable, but overall low, health literacy of men and work with consumer groups to develop good quality information that is readable, understandable and actionable thereby allowing men to have a better understanding of their treatment options and to be more involved in the decision-making process.

Keywords

Prostate Cancer, Health Literacy, Patient Information, Readability and Understandability, Actionability

6.4 INTRODUCTION

Prostate cancer has a high incidence and remains the most common solid organ cancer diagnosed in Australian men, with an incidence rate of 129 cases per 100,000 persons.[1] This is similar to the incidence rate of 104 cases per 100,000 persons among American men. [2] Based on these estimates, approximately 17,000 Australian men and 192,000 American men will have been diagnosed with prostate cancer in 2020.[1,2]

The majority of prostate cancers (approximately 90%) are diagnosed at an early stage, while the cancer is still localised within the prostate, and therefore discussion about curative treatment options between the physician and the patient is required.[2] Treatment options for early stage prostate cancer involve either immediate active treatment, surgery or radiation therapy, or conservative options including a watch and wait approach.[2] Both surgery and radiation therapy can be associated with significant side effects involving bladder, bowel and sexual dysfunction.[3,4] This, and evidence that active treatment may not prolong survival, make the decision about whether to undergo active treatment, and if so which treatment to choose, a difficult one.[5, 6]

To assist with this complex and difficult decision, a collaborative approach between the physician and patient encompassing the principles of shared decision-making is highly recommended.[7] In addition to verbal communication, this often involves the provision of written information. Given the extent of inadequate health literacy in the general population, any written information provided to patients should be clearly written, easy to read and understand[8,9] It is recommended that written information be made available at or below an 8th grade level[10,11] or even perhaps a 5th or 6th grade reading grade[12,13] However, despite these recommendations, available written information about prostate cancer and treatment frequently requires a higher level of health literacy than many men possess.[14,15]

The aim of our study was to gain a better understanding of the health literacy of men newly diagnosed with prostate cancer, the prostate cancer information sources they accessed, and how helpful they found these sources, as well as the readability, understandability and actionability of these prostate cancer information sources.

6.5 METHODS

The study was undertaken in two parts. Part A included an 18-item cross-sectional survey. Part B investigated the readability, understandability and actionability of publicly available written prostate cancer information sources (including those available on the internet), compared to the written prostate cancer information resources provided by the urologist at the time of diagnosis.

6.5.1 Part A: Cross Sectional Survey

A total of 340 men newly diagnosed with prostate cancer attending a Urology clinic, between January 2015 and December 2016, were invited to complete and return by mail an 18-item questionnaire which included demographic questions, health literacy questions and questions about how informative and helpful they found the written prostate cancer information provided to them by the Urologist. This part of the study was approved by the Human Research Ethics Committee at our University (Protocol number 2016/955).

The health literacy questions included in the 18-item cross sectional survey comprised of the validated three item Brief Health Literacy Questionnaire: Question 1: “How often do you have someone help you read hospital materials?”; Question 2: “How often do you have problems learning about your medical condition because of difficulty understanding written information?”; and Question 3: “How confident are you filling out forms by yourself?”[16,17,18] Response options for Questions 1 and 2 included: Always (1), Often (2), Sometimes (3), Occasionally (4) and Never (5). While response options for Question 3 were: Not at all (1), A little bit (2), Somewhat (3), Quite a bit (4) and Extremely (5). The overall Brief Health Literacy Score (BHLS) is the sum of the scores for these three items. A higher score indicates better health literacy with a maximum score of 15 and a combined score of 9 or less indicating inadequate health literacy.[17,19,20,21]

The cross sectional survey also included five questions, adapted from the 'Silent Voice Survey',[22] which asked questions about information sources which were accessed following their prostate cancer diagnosis and how informative/helpful they found these information sources.

6.5.2 Part B: Assessment of readability, understandability and actionability of prostate cancer information

Part B of the study involved a comparison of the readability, understandability and actionability of information sources relating to prostate cancer and treatment options. The health information sources analysed in this part of the study included three patient information sources provided to patients attending the Urology service (Part A). These patient information sources prepared 'in-house' by the urology clinic physicians, included information about 'Open Radical Prostatectomy', 'Robotic Radical Prostatectomy' and 'Pelvic floor exercises for men'. The health literacy demand for these 'in-house' information sources, were compared with the health literacy demand of the Cancer Council of Australia booklet titled 'Understanding Prostate Cancer',[23] as well as the top 50 websites identified by the researchers using 'prostate cancer', 'prostate cancer treatment' and 'prostate cancer treatment side effects' as key word searches in Google (Figure 6.2). These key word search terms were used to identify if there was a difference in the health literacy demand between information found from a generic/basic google 'prostate cancer' search, and that for more complex/higher order concepts such as ‘prostate cancer treatment’ and ‘prostate cancer treatment side effects’. In addition, five websites were chosen by the research team as example websites (Figure 6.2). These example websites were identified using each the Google search terms listed above. These websites are: Prostate Cancer Foundation of Australia, (https://www.prostate.org.au) Cancer Council of Australia, (https://www.cancer.org.au/cancer-information/types-of-cancer/prostate-cancer); Mayo Clinic (http://www.mayoclinic.org/diseases-conditions/prostate-cancer/basics/definition/con-20029597); Movember foundation (https://au.movember.com/mens-health/prostate-cancer) and Wikipedia (https://en.wikipedia.org/wiki/Prostate_cancer)

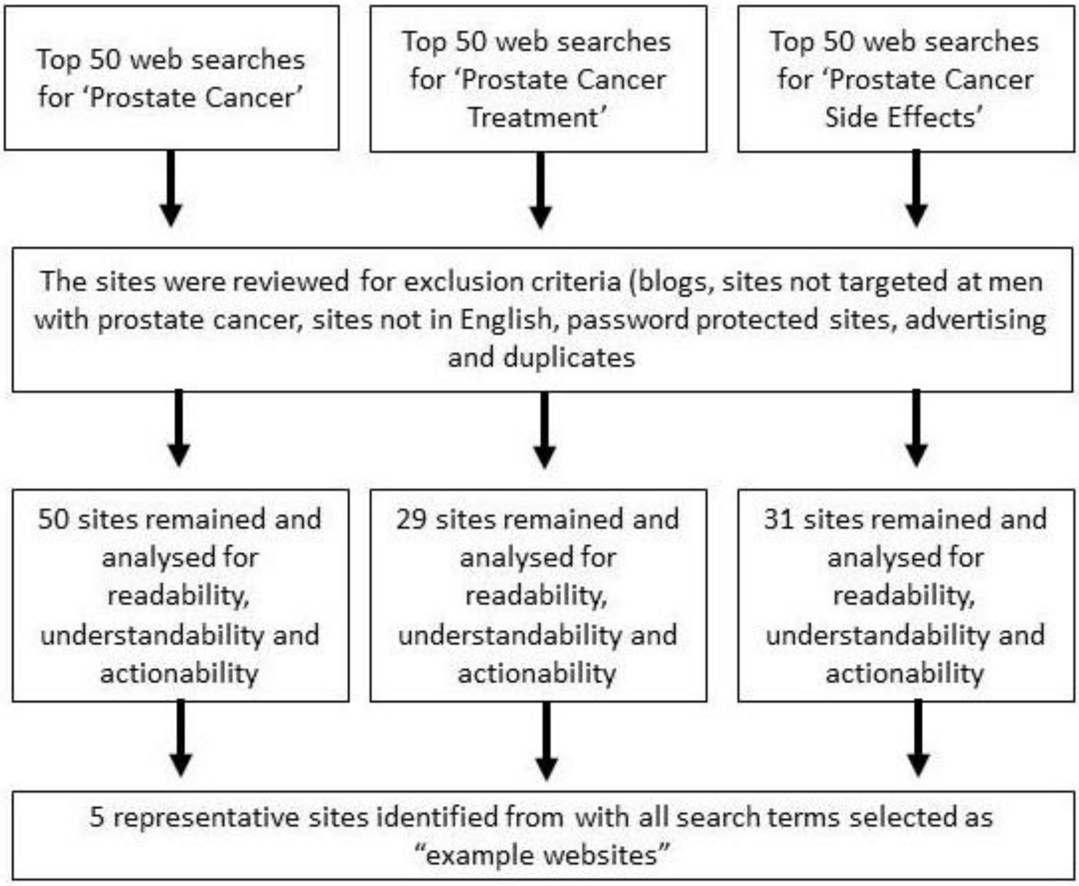

Figure 6.2 *Results of independent word searches using the Google search engine.*

6.5.2.1 Readability

The readability of each of these sources of information was assessed by pasting a sample of the text (at least 300 words) from the handouts, booklets and/or websites into a proprietary online readability calculator 'Readability Formulas'.[24] This calculator provides a 'consensus' grade level required to read the written information by averaging the results of seven validated reading formulas: the Flesch Reading Ease formula, the Flesch Kincaid Grade Level, the Gunning FOG formula, the SMOG Index, the Coleman-Liau Index, the Automated Readability Index and the Linsear Write Formula.

6.5.2.2 Understandability and Actionability:

The understandability and actionability of the different information sources were assessed by using the validated and reliable 'Patient Education Materials Assessment Tool for Print Materials' (PEMAT-P), which has been used in a variety of health care settings.[25,26] This tool gauges the likelihood that the information sources can be understood by people from diverse backgrounds, with varying levels of health literacy, by assessing 19 domains which include: purpose, use of everyday language, use of active voice, set out and logic of information, as well as use of visual cues. The tool also measures actionability, or how easily a person can identify what they need to do based on the information presented, by assessing seven of the 19 domains which include: use of clear steps to next action or response, clearly addressing the user and providing tools, such as checklists to help the user take action. The PEMAT-P scores materials on a scale of 0-100, with higher scores indicating greater understandability and actionability, respectively.[27] The authors of the tool suggest that a score of greater than 70% is indicative of material that is understandable and actionable, respectively.

6.5.3 Statistical Analysis:

In Part A, the Mann Whitney test was used to test for significant differences between the BHLS, the number of information sources used and how informative the respondents found the information sources. An unpaired t test was used to determine if there was any correlation between having a partner, employment status, and the results of the BHLS. The Wilcoxon signed rank test was used to test for significance of relationship between age and internet use. Linear regression analysis was used to test for correlations between age, age of leaving school, the helpfulness of the information sources, and the BHLS.

In Part B, the Kruskal-Wallis test was used to test for significance between the ‘consensus’ grade levels of the different information sources, including those accessed from the internet and also to test for significance of difference between understandability and actionability of the different information sources. All statistical analysis was performed using Prism 7 for MacOSX (GraphPad Software Inc.).

6.6 RESULTS

6.6.1 Part A: Cross Sectional Survey:

Of the 340 eligible participants, 151 (44%) responded to the survey (n=151, response rate 44%) (Table 6.1). The median age of the respondents was 67 years (range 47 to 84 years) and just over half of the respondents had chosen surgery (radical prostatectomy) as their active treatment (56%, 84/151).

Table 6.1: Characteristics and health literacy of the study participants

	Responses
Men having a partner % (n)	87% (130/151)
Currently employed % (n)	32% (48/151)
Describing themselves as retired % (n)	55% (83/151)
Not born in Australia % (n)	27% (40/151)
Education	
Age leaving school (years (range))	16 (12-22)
Finished high school % (n)	75% (113/151)
University degree % (n)	25% (38/ 151)
Health Literacy	
Median Brief Health Literacy Score, (IQR)	11 (3)
Inadequate Health Literacy (BHLS ≤ 9)	21.3%

6.6.1.1 Health Literacy of men newly diagnosed with prostate cancer

The median BHLS was 11, which is consistent with reports in diverse health care settings reporting BHLS medians ranging from 12 to 13.9[18,19] In our study, 21% of men had a BHLS of ≤ 9 indicative of inadequate health literacy (Table 6.1). There was a significant positive correlation between the BHLS and age leaving school (r^2 0.14, P<0.0001) suggesting that staying at school longer is associated with higher health literacy. There was a negative correlation between age and BHLS although this did not reach significance (r^2 0.015, P = 0.13). There was no difference in the BHLS for men who had a partner, compared to those who did not (P = 0.35) and similarly, there was no difference in the BHLS for those who were employed compared to those who had retired (P = 0.27).

6.6.1.2 Information Sources Accessed

Almost all (91%) of the respondents reported being given information by their urologist upon diagnosis of their prostate cancer. The majority of respondents (61-68%) rated the information they were given by their urologist as ‘very informative’, with a much smaller proportion of them (20-22%) rating it as ‘somewhat or very uninformative’. There was no difference in the BHLS among those who found the information informative versus those who found it uninformative.

In addition to the information provided by the Urologist, the majority of respondents (80%) accessed information from four or more different sources, with as many as 45% of them accessing six or more different sources. There was no difference in the number of information sources used by men with adequate health literacy (who used a median of six sources) to those with inadequate health literacy (who used a median of five sources) (P = 0.252). There was however a significant negative correlation between increasing age and the number of information sources accessed ($r^2 = 0.02908$, $p = 0.0369$), indicating that older men accessed fewer information sources.

6.6.1.3 Helpfulness of verbal information sources accessed:

Most men (87%) found talking with their urologist about their prostate cancer and treatment to be very helpful (Table 6.2). However, there was a positive correlation between respondents with higher BHLS (health literacy) and how helpful they found the urologist as a source of information ($r^2=0.0288$, $P=0.0406$), suggesting that those with higher health literacy found the urologist more helpful.

A large proportion of respondents also reported using their general practitioner (72%), family, friends and other men with prostate cancer (60%) as information sources, with many of them (60-70%) finding them to be ‘very helpful’. For the 53% of respondents who reported using their radiation oncologist as an information source, almost all (92.5%) found the radiation oncologist to be ‘very helpful’. There was no correlation between BHLS, and helpfulness of any other individuals used as information sources.

6.6.1.4 Helpfulness of ‘written information sheets’ provided by the treating urologist:

A high proportion (77%) of respondents used the ‘written information sheets’ provided by the urologists (Table 6.2). However, only 71% of them found these to be ‘very helpful’ or ‘vital’ to their decision-making process. There was no correlation between BHLS and the helpfulness of the ‘written information sheets’.

Table 6.2: Heat map of helpfulness of information sources used by men following a diagnosis of prostate cancer.

	UROLOGIST	GP	FAMILY and FRIENDS	OTHER MEN	RADIATION ONCOLOGIST	PRACTICE NURSE	PHARMACIST	WRITTEN INFORMATION SHEETS	INTERNET
Number of respondents that used this source of information (%)	146 (100)	109 (72)	92 (61)	90 (60)	80 (53)	52 (34)	18 (12)	115 (77)	73 (48)
Vital to my decision	62	19	13	14	31	6	1	10	8
Very helpful	65	55	47	48	43	29	6	72	39
Somewhat helpful	14	29	28	25	4	12	8	30	26
Not helpful at all	5	6	4	3	2	5	3	3	0

Note: The darker colours indicate increasing respondents' perception of helpfulness for each source of information.

6.6.1.5 Helpfulness of internet sources of prostate cancer information accessed by men who responded to the survey.

Of the respondents (48%) who reported using the internet as a source of information, many of them (65%) found it to be ‘very helpful or vital’ to making their decision (Table 6.2). Respondents who accessed the internet for information were significantly younger than those who did not report using the internet ($p<0.0001$). However, there was no association between BHLS and how helpful men found the internet.

6.6.2 Part B: Assessment of readability, understandability and actionability of prostate cancer and treatment information.

6.6.2.1 Readability

The consensus reading grade level for the three ‘written information sheets’ provided by the urologists were: grade 11 for the ‘open radical prostatectomy’ information sheet; grade 14.3 for the ‘robotic radical prostatectomy’ information sheet; and grade 12 for the ‘pelvic floor exercises for men’ information sheet (Figure 6.3). The booklet ‘Understanding Prostate Cancer’ prepared by the Cancer Council,[23] had a lower average reading grade level of 10.4 (Figure 6.3). The average reading grade level of the top 50 websites identified using ‘prostate cancer’ as a search term on the ‘Google’ search engine was 8.0. This was significantly lower ($p<0.0001$) than websites identified using ‘prostate cancer treatment’ (average grade level 11.8) and ‘prostate cancer treatment side effects’ (average grade level 11.3) as search terms (Figure 6.3). The readability for the five example websites identified by the researchers is also shown in Figure 6.3.

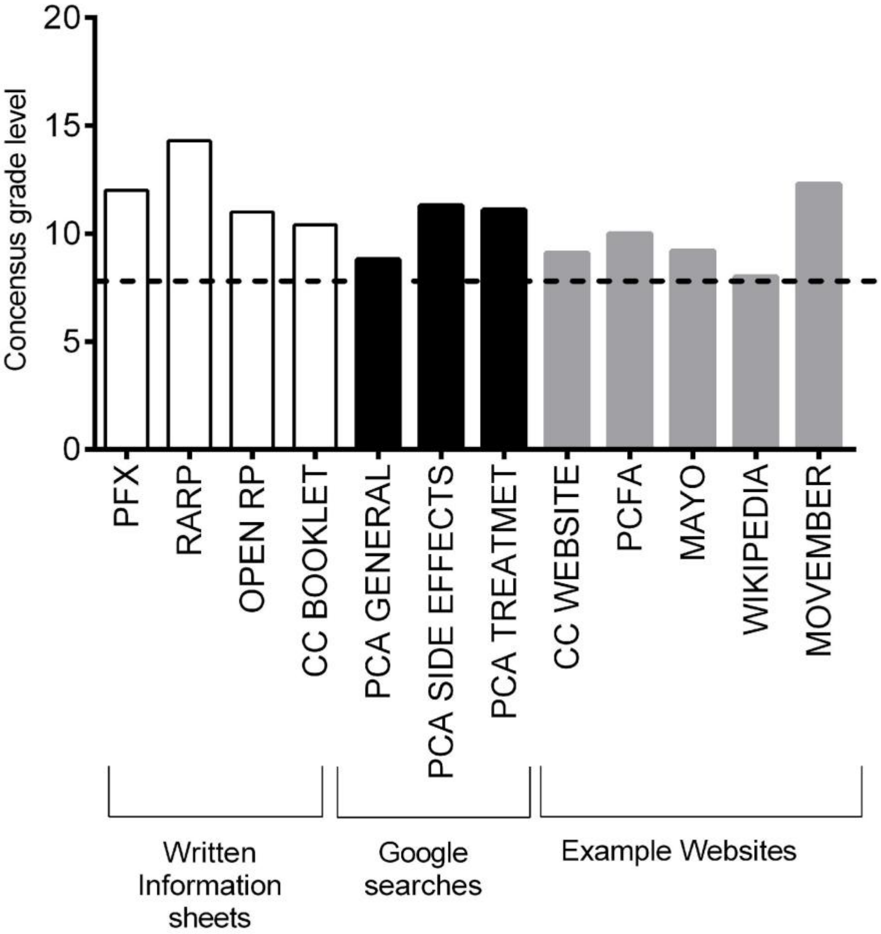

Figure 6.3: *Readability as determined by the consensus grade level of written information sheets, google search results and selected websites.*

The dashed line represents the grade 8 readability level that is recommended in the literature for an information source to be useful to the general population.[11] *Legend: Written information sheets: PFX = Pelvic floor exercises for men, RARP = robotic assisted radical prostatectomy, OPEN RP = open radical prostatectomy, CC BOOKLET = cancer council booklet, Google searches: GENERAL = independent web search by authors for Prostate cancer in general, SIDE EFFECTS = independent web search for Prostate Cancer side effects and TREATMENT = independent web search for Prostate Cancer treatment. Example websites: CC WEBSITE = cancer council website, PCFA = Prostate Cancer Foundation of Australia, MAYO = Mayo Clinic , MOVEMBER = Movember Foundation.*

6.6.2.2 Understandability

The understandability score for the ‘written information sheets’ varied between 71% for the ‘Open Radical Prostatectomy’ information sheet, 44% for the ‘Robotic Radical Prostatectomy’ information sheet and 82% for the ‘Pelvic floor exercises for men’ information sheet (Figure 6.4A). The understandability scores for the Cancer Council of Australia booklet titled ‘Understanding Prostate Cancer’ scored the highest of all written materials analysed for this study at 88%.

The average understandability scores for the top 50 websites identified using the ‘Google’ search engine with the search terms ‘prostate cancer’, prostate cancer treatment’ and ‘prostate cancer treatment side effects’ was 76%, 76% and 72%, respectively (Figure 6.4A). The understandability scores for the example websites ranged from 44 to 83% (Figure 6.4A). Three of the five example websites had understandability scores above 70 %, these were the cancer council website, the website of the Prostate Cancer Foundation of Australia, and the Movember Foundation.

6.6.2.3 Actionability

The actionability scores for the ‘written information sheets’ were 40% for both the ‘Open Radical Prostatectomy’ and the ‘Robotic Radical Prostatectomy’, and 60% for the ‘Pelvic floor exercises for men’ (Figure 6.4B). The actionability score for the Cancer Council booklet was also low at 33% (Figure 6.4B). Similarly, the actionability scores for the top 50 web sites identified by the researchers using the ‘Google’ search engine and the search terms ‘prostate cancer’, ‘prostate cancer treatment’ and ‘prostate cancer side effects’ were low at 13%, 30% and 25% respectively (Figure 6.4B). The actionability scores for four of the five example websites ranged between 0-20% (Figure 6.4B) however the actionability score for the ‘Movember Foundation’ website stood out at 80%.

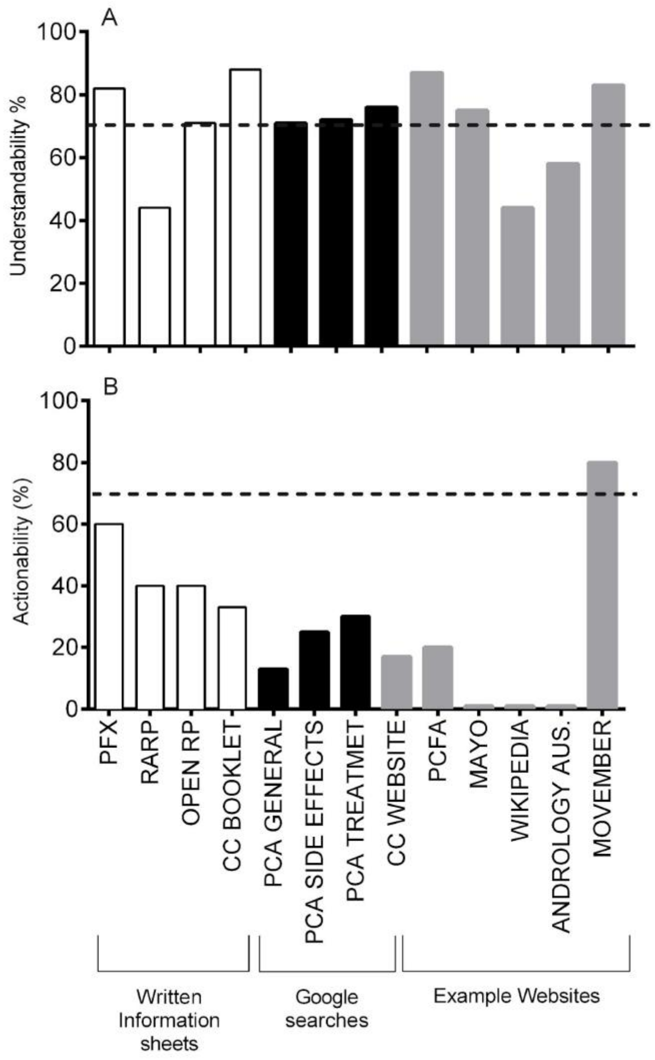

Figure 6.4: *PEMAT-P measure of (A) understandability and (B) actionability of written information sheets, results of the google searches and example websites.*

The dashed line represents the 70% understandability and actionability level that is recommended in the literature for an information source to be useful to the general population.[25,26] *Legend: Written information sheets: PFX = Pelvic floor exercises for men, RARP = robotic assisted radical prostatectomy, OPEN RP = open radical prostatectomy, CC BOOKLET = cancer council booklet, Google web search: GENERAL = independent web search by authors for Prostate cancer in general, SIDE EFFECTS = independent web search for Prostate Cancer side effects and TREATMENT = independent web search for Prostate Cancer treatment. Example websites: CC WEBSITE = cancer council website, PCFA Prostate Cancer Foundation of Australia, MAYO = Mayo Clinic , MOVEMBER = Movember Foundation.*

6.7 DISCUSSION

Our study has identified that approximately 20% of men, newly diagnosed with prostate cancer, had inadequate health literacy which concords with the very limited literature available for men with prostate cancer.[28] This proportion of men with inadequate health literacy is also similar to that reported for men within the same age group from the general population.[8] However, it is important to consider that in studies of this type, the study population who chose to respond to the survey, are self-selecting and it is likely that men with low levels of health literacy would choose not to participate. Therefore, it is likely that the percentage of men in the general population with inadequate health literacy is underestimated in this and other studies.

Our results also highlight that the readability of most information sources available to men with prostate cancer was above that recommended as suitable for the health literacy skill level of the general population.[11] Our study supported this by demonstrating that the information available to men diagnosed with prostate cancer, including the in house 'written information sheets', is at too high a grade level to be read and understood, especially by men with inadequate health literacy. In the current study, men with inadequate health literacy found information provided by the urologist less helpful than those with adequate health literacy. These results, highlight that urologists need to be more aware of providing information, both verbal and written, which addresses the needs of all their patients, including those with inadequate health literacy. Furthermore, we found that the majority of information sources available for men with prostate cancer had actionability scores which were well below the recommended 70%.[26] This may mean that many men would find it difficult to be actively involved in the decision-making process because of their inability to fully comprehend the information needed to communicate with their physicians.

Men receiving a diagnosis of prostate cancer tend to be older,[2,29] as confirmed in our study (median age 67 years) and are less likely to seek health information[30] with our results confirming that older men used fewer sources of information. We also found that higher health literacy levels correlated positively with age at leaving school, which is supported in the literature.[31,32] This suggests that older and less educated men, diagnosed with prostate cancer, may require additional support when trying to engage in the decision-making process about their prostate cancer treatment choices.

Most men in our study, and especially the younger men, were more likely to access multiple sources of information about prostate cancer and its treatment. These multiple sources included verbal information from their urologist, GPs, family and friends, as well as written information supplied by their urologist, the cancer council and the internet. These findings support the evidence from the literature which suggests that men, diagnosed with prostate cancer, will primarily access information provided by their treating physician, as well as information available from other health professionals, the lay literature (e.g., videos and pamphlets), friends with prostate cancer and the internet.[33,34] Treating physicians should therefore be aware that their patients, including those with inadequate health literacy, will be seeking information from multiple sources which may not always be reliable, or evidence based. This may lead to confusion and an impairment of a patient’s ability to take part in the decision-making process. To help address this issue, physicians should suggest reliable and evidence-based information sources to their patients.

The provision of information by the treating physician, and its understanding by the patient, are essential to enable patients to be involved in the decision-making process.[34,35,36] It is important therefore, that information is presented in a way that is understandable for men of all levels of health literacy and empowers them to act on the information.[37] The majority of men, both in our study and in the literature, reported using the material provided by the treating physician as the primary source of information. In our study, the average grade level required to read the ‘written information sheets’ provided by the urologists, the Australian Cancer

Council booklet[23] and the websites identified using ‘prostate cancer treatment’ and ‘prostate cancer treatment side effects’ was above grade 10, that is, they were all above the recommended 8th grade level[10,11] These higher than recommended readability levels, are also evident in the Canadian Urological Association booklet on prostate cancer, which is written at an average grade level of 10.5.[15] Similarly, Choi and associates found that prostate cancer patient education materials were written at a mean grade level of 9.6.[14] In addition to the information provided by the urologist, patients have access to information about prostate cancer online. However, it has been estimated that 60% of the patient education materials available on the internet relating to a broad spectrum of patient health conditions (not specifically prostate cancer) required college or graduate level reading skills i.e., 13th grade or higher.[38] This perhaps indicates the inability of clinicians to appreciate the health literacy limitations of their patients.[18,39]

Our study highlights that while the ‘understandability’ of written patient information was in general good (66-88%, above the recommended 70%), the ‘actionability’ scores were low (30-50%, well below the recommended 70%). While there have been no previous studies regarding the actionability of information relative to prostate cancer our findings concur with those found in studies for other health conditions.[40,41] This low level of actionability of the health related information available on the internet is important because it is not sufficient for men just to be informed about prostate cancer (able to read and understand available information) it is also important for them to be empowered to take action and make decisions about their treatment.

6.7.1 Strengths and limitations:

While the characteristics of our study population are representative of men presenting with prostate cancer generally this is a study from a single urological clinic in a regional town.[2]

However, the health literacy of our study group is similar to that of the general population and the results and messages are therefore generalisable and may be able to be extrapolated to any population especially those of older males.

6.8 CONCLUSION

This study highlights that approximately one quarter of the men, with a new diagnosis of prostate cancer, will have inadequate health literacy. This is of concern given that the majority of the patient information sources are written at too high a grade level and even though many of them were at the recommended level for understandability, almost all of them were well below the level recommended for actionability. This means that despite men accessing multiple information sources men may not have acquired and understood sufficient information to enable them to be fully involved in decision-making about treatment options.

6.8.1 Practice Implications

After a diagnosis of prostate cancer men need to be provided with information that is clear and easy to follow. Clinicians treating patients with prostate cancer must enquire into men's health literacy to ensure they do not overestimate it, and also be aware that approximately half of all men at this age are not regular internet users. Not only must information provided be written so it is understandable for men, it must also enable men to take action and make a decision about treatment. Clinicians, health authorities and non-government organisations must be made aware of the variable, but overall low, health literacy of men and work with consumer groups to develop good quality information that is readable, understandable and actionable. It is interesting that this has been achieved by a charitable non-government organisation (Movember foundation: https://au.movember.com/mens-health/prostate-cancer) by providing brief but readable, understandable and most importantly actionable information, which gives a direct call to men to respond and take action towards a decision.

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CHAPTER 7: STUDY D

7.1 Title page

HEALTH LITERACY, CANCER LITERACY, COMPREHENSIONS AND KNOWLEDGE

AMONG MEN ATTENDING A UROLOGY CLINIC

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7.2 FOREWORD AND LINK TO CONCEPTUAL FRAMEWORK OF THESIS

The previous chapter in this thesis has highlighted the significant proportion (>20%) of men newly diagnosed with prostate cancer who have low HL. It is widely accepted that men cannot read, understand and act on the information they receive if their own HL is less than the HL required to engage with the information. As well as basic HL, to be part of the decision-making process, men need to have an adequate level of cancer literacy and comprehension, and prostate cancer knowledge. Without competence in these areas men may struggle with being true participants in the treatment decision-making process. The aim of study D was to assess the level of health literacy among a broad group of men attending a urological clinic and to investigate the concordance between two different published measures of health literacy. We also aimed to explore if there was an association between HL; cancer literacy and comprehension; and prostate cancer knowledge among this group of men.

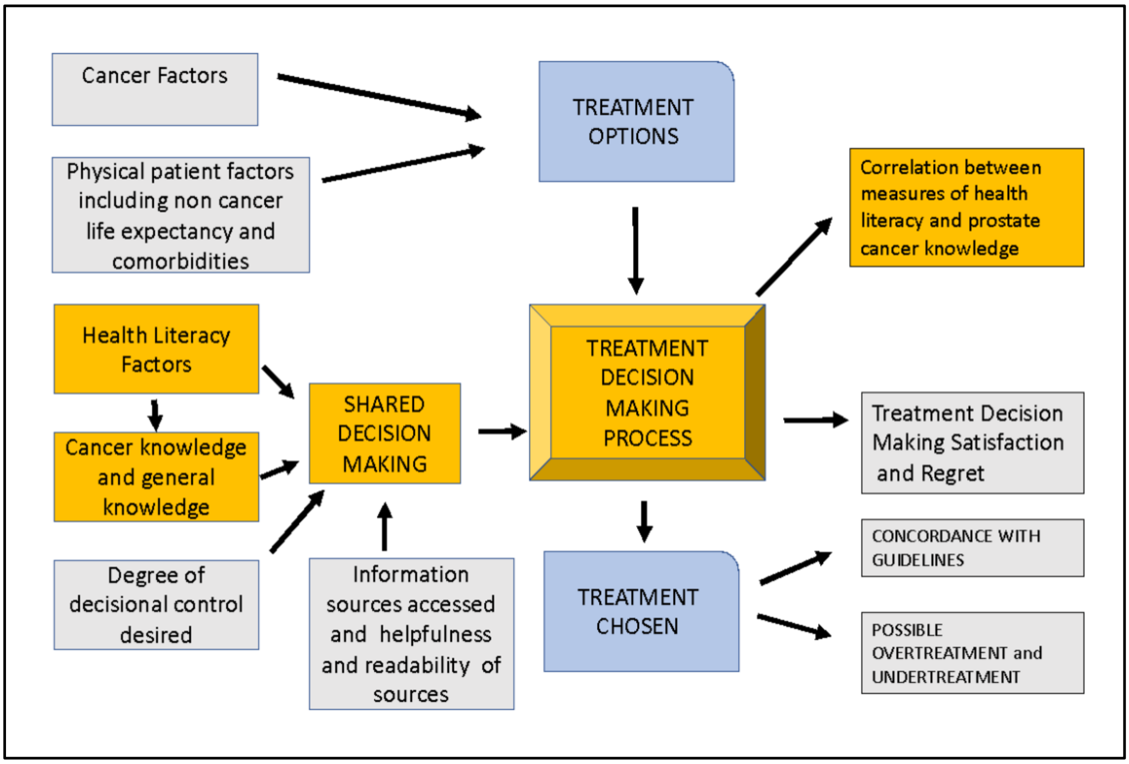

Figure 7.1: *Concept map for Chapter 7. (Study D)*

7.3 ABSTRACT:

Background*:* Background knowledge, adequate health literacy (HL) and comprehension about prostate cancer are essential for men receiving urological treatment to be actively involved in the shared decision-making process and yet little is known about these issues.

Objectives: This study aimed to assess the level of HL among a group of men receiving urological treatment and to investigate if there were any correlations between the two different measures of HL, cancer literacy and comprehension, and prostate cancer knowledge.

Methods: A survey was mailed to 200 men attending a urological clinic. The survey included: demographic questions, two validated tests of HL—the Brief Health Literacy Score (BHLS) and the Health Literacy Management Scale (HeLMS); a test of cancer comprehension—the Cancer Message Literacy Tests Reading (CMLT); and a prostate cancer knowledge test. Descriptive statistics were used to analyse the data.

Results: Surveys from 72 respondents, average age of 65 years, were included in the final analysis. Based on the BHLS, 22% of respondents had inadequate HL and 50% of respondents had inadequate HL in one or more of the HeLMS domains. Overall, the study participants had relatively high cancer literacy, comprehensions, and knowledge. However, for men with inadequate HL, based on the BHLS and the HELMS, there were strong correlations with poor cancer literacy, comprehension, and knowledge.

Conclusion: Our study highlights that many men receiving urological treatment with inadequate HL, require additional support to access health information which they can understand and act on to be part of the shared decision-making process.

Key words:

Health Literacy; Prostate Cancer; Knowledge; Cancer literacy and comprehension.

7.4 INTRODUCTION

Nearly half of all American adults have difficulty understanding and acting on health information.[1] Similarly inadequate health literacy is common in Australia with the Adult Literacy and Life Skills survey from the Australian Bureau of Statistics (ABS) reporting that 46-53% of Australians lack basic literacy skills.[2] This places them below the "minimum required to meet the complex demands of everyday life and work".[2,p5] The results from this survey are even worse for more complex areas of literacy, with 70% of Australian adults having inadequate problem-solving skills.

Modern healthcare places complex demands on the patient with individuals asked to seek information and participate in treatment decisions for themselves and others. This requires a degree of health Literacy (HL) which has been defined as the ability to access, understand, and use health related information to make informed decisions and manage health.[1,]Basic health literacy involves what Nutbeam[4] describes as 'task-based' literacy (the ability to read and write) and is an important first step to 'skill-based' literacy associated with the knowledge and skills required to perform these tasks. This means that even individuals with high levels of general literacy may not be able to apply their knowledge and skills in unfamiliar situations, especially those requiring specific content knowledge, such as healthcare. This skills-based literacy is a prerequisite to the more complex 'interactive HL' which allows participation and control of an individual's healthcare by applying information to changing situations.[5] HL is thus a broad construct involving a complex relationship between basic literacy, knowledge, and comprehension.[6]

Chin and associates[7] have suggested that HL reflects the interplay of cognitive abilities (what they call 'processing capacity') and knowledge, which may be domain specific knowledge. As such, background knowledge of subject matter has been shown to be essential for literacy and especially comprehension of information, including information provided by clinicians during consultations to facilitate shared decision making.[6,7] Therefore, it is important for clinicians to consider HL during their patient interactions because inadequate HL is often associated with less knowledge and understanding of illness management, poorer communication between patient and physician, and decreased ability to take part in shared decision making.[8]

Inadequate HL is also associated with poorer health outcomes and lower self-reported health status.[1,9,10] Previous studies have suggested that inadequate HL is associated with lower socioeconomic status, lower education level and increasing age.[11,12] There is also evidence which suggests that men exhibit lower levels of HL than women, even with respect to male specific health issues.[2,13] Compounding the problem, men have been found to be less able to assess, interpret and apply health information.[14]

The aim of the study was to assess the level of health literacy among a group of men attending a urological clinic and to investigate if there any correlations between two different measures of health literacy, cancer literacy and comprehension, and prostate cancer knowledge.

7.5 METHODS

This study utilised a prospective cross-sectional research design. Patients aged 18 years and over, who were referred to an Australian based urology clinic between February and July 2018 with one of three urological conditions (lower urinary tract symptoms, consideration for vasectomy or follow up after screening for prostate cancer) were invited, by mail, to complete a paper-based survey. Tacit consent was assumed for participants who completed the survey and returned it when they attended their initial urology consultation. The study was approved by the Human Research Ethics Committee of the University of Wollongong, NSW, Australia [HREC2016/955].

7.5.1 Survey Questions

The mailed research survey consisted of demographic questions, two independent HL tools, a cancer literacy and comprehension test, as well as a Prostate Cancer Knowledge test. The demographic questions in the survey included age and residential postcode. The participants' residential postcodes were used to assess their socio-economic (S-E) status using the Socioeconomic Index for Areas (SEIFA), which ranks areas in Australia according to S-E advantage, with lower scores indicating higher S-E disadvantage.[15]

7.5.2 Assessments of Health Literacy

The two health literacy tools included in the survey were the Brief Health Literacy Survey (BHLS)[16] and the Health Literacy Management Scale (HeLMS).[17] The BHLS included three questions: Question 1: "How often do you have someone help you read hospital materials?"; Question 2: "How often do you have problems learning about your medical condition because of difficulty understanding written information?"; and Question 3:"How confident are you filling out forms by yourself?"[16,18,19] Response options for Questions 1 and 2 included: Always (1), Often (2), Sometimes (3), Occasionally (4) and Never (5). While response options for Question 3 were: Not at all (1), A little bit (2), Somewhat (3), Quite a bit (4) and Extremely (5). The overall BHLS score is the sum of the scores for these three items. A higher score indicates better health literacy with a maximum score of 15. Men who scored ≤ 3 answering any of the 3 questions were regarded as having low overall HL.[20,21]

The multidimensional HeLMS tool consists of 29 subjectively rated questions within eight independent domains each of which measures different constructs related to HL (Appendix 1). Five of the eight domains focus on individual abilities: Domain 1, patients' attitude towards health; Domain 2, ability to access and understand health information; Domain 6, ability to communicate with health professionals to get the information they want about their health; Domain 7, ability to be proactive and seek and understand information about their health and Domain 8 on ability to understand and use information to make informed health decisions.[22] The remaining three domains focus on broader factors that influence these abilities: Domain 3, ability to seek social support to manage health; Domain 4 on socioeconomic factors influencing ability to access health care and Domain 5, ability to access GP healthcare services and knowing where to seek health information. For each question in each domain, participants were required to score themselves on a five-point Likert scale, with options varying from 5 "able to do without any difficulty" to 1 "unable to do so". For each domain item scores were averaged and used for data analysis.[22] As previously reported by Jayasinghe[23], an average score of <4, on any domain, was classed as inadequate HL for that domain.

7.5.3 Assessment of Cancer Literacy and Comprehension , and Knowledge

Two Cancer Message Literacy Tests –Reading (CMLT) from the National Cancer Institute were included in the survey to identify the participant's cancer literacy and comprehension.[24] The "Citizens Guide to Radon" and "What do I Need to Learn about Getting Tested for Prostate Cancer?" messages were selected by the authors as being the most appropriate because they provided scenarios, which would resonate with men (Appendix 3). Both CMLTs consisted of a written passage of information (the message) and subsequent statements to test cancer literacy and comprehension. Participants were instructed to read the passage and determine if each corresponding statement was the ‘same’, ‘different’ or ‘not sure.’ For the purposes of analysis, ‘not sure’ was scored as an incorrect answer. There were four statements requiring answers for the “Citizen’s Guide to Radon” (maximum score of four) and three statements requiring answers for “What do I Need to Learn about Getting Tested for Prostate Cancer?” (Maximum score of 3). Higher scores for these messages were assumed to suggest higher cancer comprehension and literacy.

The survey also included the Prostate Cancer Knowledge test.[25] The test is comprised of 14 questions, divided into six domains, assessing knowledge about screening, side effects from treatment, symptoms, risk factors, screening age guidelines and screening controversy(Appendix 3). Each question was recorded to be either correct (1) or incorrect (0). Total correct responses were between 0–14 and in the absence of published cut scores, it was assumed that higher scores indicated higher knowledge levels.

7.5.4 Data Analysis

Descriptive statistics were used to provide an overview of respondents’ sociodemographic characteristics. Continuous data with two numerical variables were analysed using linear regression with p values indicating the extent to which the deviation of the slope from zero was significant (p values <0.05 were taken as significant) and the “goodness of fit” represented by r^2. The Kruskal-Wallis test was used to determine if there were significant differences between multiple groups and the Mann- Whitney test if only two groups were compared. All analysis was performed using Prism 7 for MacOSX(GraphPad Software Inc.).

7.6 RESULTS

Ninety of the 200 mailed surveys were returned by participants (response rate 45%). Eighteen of the 90 responses were incomplete and not included in the final analysis, which included 72 survey responses. Thirty of these men attended the urology clinic for assessment after screening for prostate cancer, twenty-five required assessment of lower urinary tract symptoms and seventeen for consideration of vasectomy.

7.6.1 Demographic details of study participants

The average age of respondents was 65 years (Range: 33–95 years) with 56% (40/72) being over 65 years old. Most of the respondents (40.3%) were in the third decile of the Index of Relative Socio-economic Disadvantage (IRSD)[15] (Table 7.1).

Table 7.1: Relationship between the Index of Relative Socioeconomic Disadvantage (IRSD) and the health literacy of respondents.

IRSD Quintile*	1	2	3	4	5
Number of men in each quintile	7	7	29	14	15
Percentage of men in each quintile	9.7	9.7	40.3	19.4	20.8
Percentage of men with inadequate HL on BHLS (Number of men with inadequate HL)	28% (2)	28% (2)	17% (5)	28% (4)	20% (3)

** IRSD[15] results are recorded as deciles, and we have amalgamated these into quintiles with lower scores indicating higher socioeconomic disadvantage*

7.6.2 Health Literacy Results

Even though the average BHLS score was 12.7 (out of a possible 15), 16 out of the 72 men (22%) were classified as having low HL based on this measure. There was an approximate equal spread of respondents with inadequate HL in each of the SEIFA codes (Table 7.1) indicating that there was no correlation between socio-economic status and HL in this patient population.

The average scores for each of the HeLMS domains are highlighted in Table 7.2. Even though the average score for each domain wase greater than 4 (out of a possible 5), the individual HeLMS domains with the highest proportion of scores of less than 4 (indicative of inadequate HL) were: Domain 1 (patient’s attitude towards their health, 26.4%); Domain 3 (ability to seek social support to manage health, 16.7%); and Domain 7 (ability to be proactive and seek and understand information about their health, 13.9%).[23] Based on the HeLMS criteria 36 (50%) of the respondents were assessed as having inadequate HL in one or more of the eight domains (not visible in Table 7.2). Of the respondents with inadequate HL, 55% (20/36) were aged over 65 years.

Table 7.2: Health Literacy of respondents in each of the eight HeLMS Domains

Health Literacy Focus	HeLMS Domain	Description	Av. HeLMS score	Number of men with inadequate HL in each domain*	% with inadequate HL
Individual	Domain 1	Patient's attitudes towards their health	4.22	19	26.4%
Individual	Domain 2	Ability to access and understand health information	4.58	7	9.7%
Broad	Domain 3	Ability to seek social support to manage health	4.46	12	16.7%
Broad	Domain 4	Socioeconomic factors influencing ability to access health care	4.61	7	9.7%
Broad	Domain 5	Ability to access GP healthcare services and knowing where to seek health information	4.9	1	1.4%
Individual	Domain 6	Ability to communicate with health professionals to get the information they want about their health	4.75	3	4.2%
Individual	Domain 7	Ability to be proactive and seek and understand information about their health	4.49	10	13.9%
Individual	Domain 8	Ability to understand and use information to make informed health decisions	4.73	3	4.2%

* Inadequate HL determined by a HeLMS score <4 in that domain

7.6.3 Cancer Literacy and Comprehension and Prostate Cancer Knowledge

The average score for the two CMLT messages[24] were 85% for Radon and 83% for the prostate cancer messaging test.[25] The average score for the Prostate Cancer Knowledge test among the 72 respondents was 10.9 out of a possible 14 with a median of 11 (range 4–14). Based on these scores it appears that the study participants had relatively high cancer literacy, comprehension, and knowledge scores.

7.6.4 Correlations between Health Literacy, Cancer Literacy and Comprehension

There was concordance between our two measures of HL with a strong correlation between the average score for seven of the eight HeLMS domains and the total BHLS score (Figure 7.2). Only HeLMS Domain 3 (ability to seek social support to manage health) did not correlate with the BHLS scores.

There was a positive correlation between scores on the CMLT (measuring cancer literacy and comprehension) and Domain 2 (ability to access and understand health care information, $p = 0.0128$, $r^2 = 0.8535$), Domain 4 (socio-economic factors influencing ability to access health care, $p = 0.116$, $r^2 = 0.0876$) and Domain 5 (ability to access GP health care services and knowing where to seek health information, $p=0.0025$, $r^2 = 0.0123$) of the HeLMS. There was also a positive correlation between the BHLS score and the CMLT total ($p= 0.0087$, $r^2= 0.0943$).

There was a positive correlation between scores in the Prostate Cancer knowledge test and average scores in Domain 3 (ability to use social support to manage health, $p = 0.013$, $r^2 = 0.085$), Domain 5 (ability to access GP health care services and knowing where to seek health information, $p= 0.048$, $r^2 = 0.055$) and Domain 6 (ability to communicate with health professionals to get the information they want about their health, $p= 0.048$, $r^2 = 0.070$). There was no correlation between the Prostate Cancer Knowledge test and the other HeLMS domains or the BHLS total scores. There was also no correlation between age or SEIFA codes with either of the two HL measures, the CMLT, or the prostate cancer knowledge test. In addition, there was no correlation between CMLT (cancer literacy and comprehension) and the Prostate Cancer Knowledge test scores.

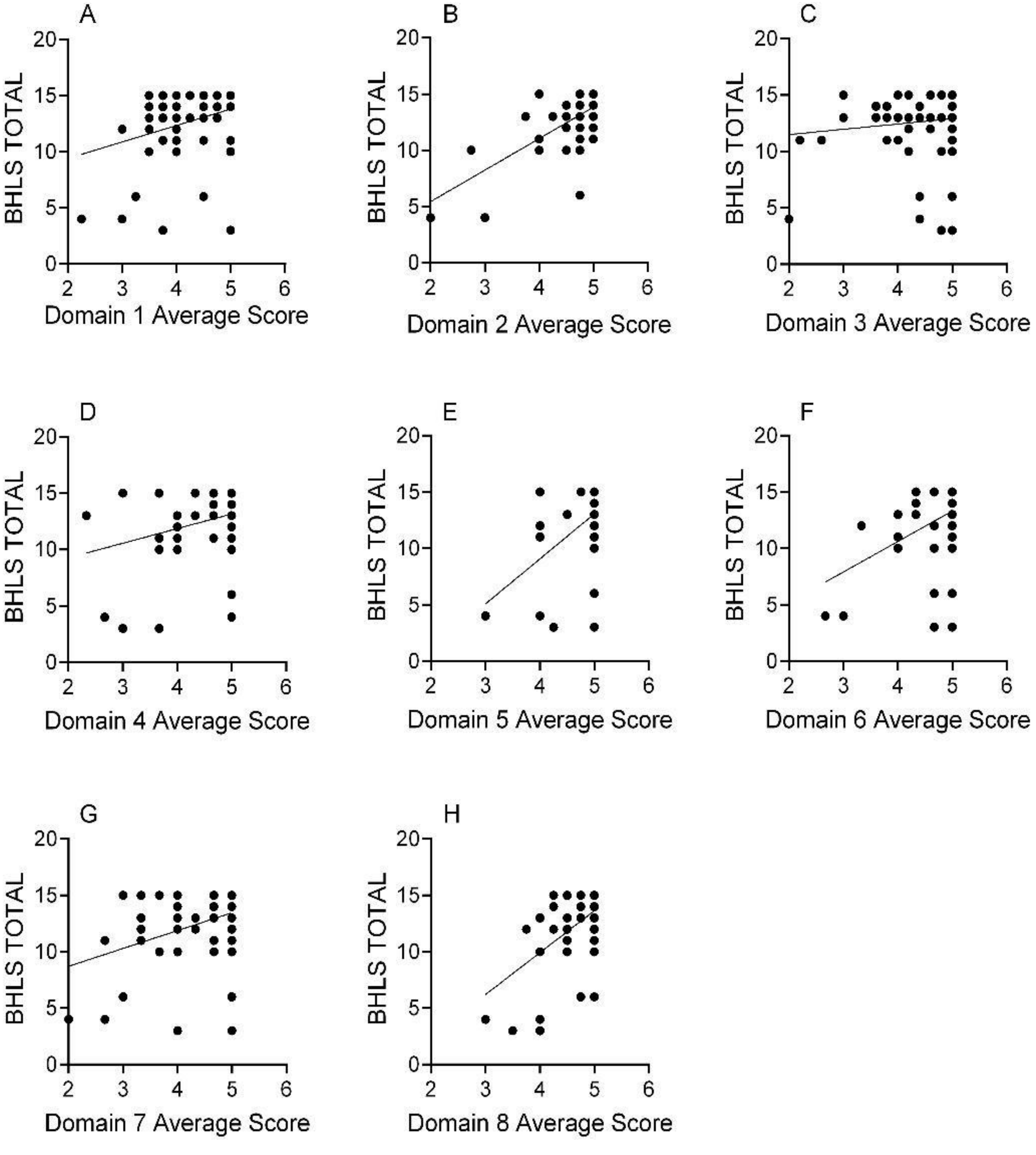

Figure7.2. *Correlation between the BHLS and the average scores for each of the HeLMS Domains. There was strong correlation between BHLS and Domain 1 (A, patients' attitude towards health; p 0.013,* $r^2 = 0.084$*), Domain 2 (B, ability to access and understand health information; p <0.0001,* $r^2 = 0.622$*), Domain 4 (D,*

socioeconomic factors influencing ability to access health care; $p = 0.018$, $r^2 = 0.078$*),* *Domain 5 (D, ability to access GP healthcare services and knowing where to seek health information;* $p <0.0001$, $r^2 = 0.199$*), Domain 6 (F, ability to communicate with health professionals to get the information they want about their health;* $p = 0.0001$, $r^2 =0.194$*) Domain 7 (G, ability to be proactive and seek and understand information about their health;* $p = 0.0009$, $r^2 = 0.146$*) and Domain 8 (H, ability to understand and use information to make informed health decisions;* $p <0.0001$, $r^2 = 0.274$*). The only HeLMS domain that did not correlate with BHLS was Domain 3 (C, Ability to seek social support to manage health;* $p=0.328$, $r^2=0.014$*).*

7.7 DISCUSSION

Our study suggests that at least one fifth of men (22%) presenting to a urology clinic have inadequate HL and that almost half of them men had inadequate health literacy based on the HeLMS domains.[24] Overall, the men in our study had relatively high cancer literacy, comprehension, and cancer knowledge. However, those with inadequate HL were more likely to have lower cancer literacy and comprehension, as well as lower knowledge about prostate cancer.

Our findings regarding the proportion of me with inadequate health literacy concur with evidence in the literature.[17] The highest proportion of those with inadequate HL was identified in the following HeLMS domains: Domain 1, patients' attitudes to their health (26.4%), Domain 3, ability to seek social support and help to manage their health (16.7%) and Domain 7, ability to be proactive in seeking and understanding information about their health (13.9%). These important concepts that measure men's ability to access, understand and apply information to manage their health, appeared to be deficient for a high proportion of our study participants.

This study found that there was a strong positive correlation between the BHLS and seven of the eight HeLMS domains (all except Domain 3, ability to use social support to manage health). These findings are important because busy clinicians can choose to use the three-question BHLS tool[16], which can also be delivered verbally, to quickly ascertain their patient’s HL. Alternatively, they could use the HeLMS,[17] a more comprehensive and time-consuming measure, to identify specific HL domains which can be targeted as part of their patient interactions. Using the HeLMs[17] would allow clinicians to focus more on HL constructs which could help improve their patients’ ability to seek, understand and use health information.

Overall, the cancer literacy and comprehension of the participants in our study had high levels of cancer literacy and comprehension. However, the positive correlations between cancer literacy and comprehension and inadequate HL based on the BHLS and the HeLMS domains that specifically measure ability to seek, understand and access health information and healthcare services, including socio-economic factors (Domains 2, 4 and 5) are major findings. These findings highlight that men with inadequate health literacy have lower cancer literacy and comprehension and would have problems seeking, understanding, and accessing health information and managing their health. Clinicians need to ensure that the information they provide to these men should be easy to read and understand and that they might need to tailor their communications and interactions with these patients to ensure that they can take part in the shared decision-making process. These findings also emphasis the need for clinicians, to be cognisant of the cancer literacy, and comprehension of their male patients, and to ensure that they consider factors such as their emotional state, the nature of the decision being made, and their relationship with the patient, all of which may impact on their ability to take part in shared decision-making.[26]

Previous research has shown that there is a strong and positive correlation between HL and knowledge about a wide variety of health conditions.[27,28] To the best of our knowledge this is one of the first studies which has investigated health literacy and prostate cancer knowledge among men attending a urology clinic. In our study, even though prostate cancer knowledge was high among the study participants, the positive correlations between the participants' prostate cancer knowledge and scores for the HeLMS' Domain 3 (ability to use social support to manage health) and Domain 5 (ability to access GP health care services and knowing where to seek health information) suggest that men with inadequate HL have poorer knowledge about prostate cancer than their counterparts with adequate HL. These men would also struggle to access health information, health care services and social support to manage their health. The positive correlations between the prostate cancer knowledge and the HeLMS Domain 6 (ability to communicate with health professionals to get the information they want about their health) also suggest that men with adequate HL would also have problems communicating with their health professionals. These findings suggest that clinicians can feel confident that patients with adequate HL are able to be involved in the shared decision-making process because they can comprehend and act on information provided to them. However, the same cannot be assumed for men with inadequate HL who would require information and education tailored to their individual needs.

Our study did not find an association between age and social disadvantage with HL, which contrasts with evidence in the literature.[29,30] Perhaps an explanation for this disparity is that the number of participants from low SES groups was limited in our study (with many coming from the middle SES group) and, as a result, our study findings may be limited in terms of their generalisability. Other limitations of this study include the relatively small sample size. Furthermore, men with inadequate HL, and those from non-English-speaking backgrounds may not have been able to respond to the survey questions. In addition to these limitations, the strengths of this study need to be acknowledged. For example, to the best of our knowledge, this is the first time a study has investigated the HL, cancer literacy, comprehension, and prostate cancer knowledge among male urological patients.

7.8 CONCLUSION

Our study highlights that while many men attending urology clinics have adequate HL, cancer literacy and knowledge, at least a fifth of them have inadequate health literacy which negatively impacts on their ability to seek, understand, and access health information to manage their health. Clinicians could use the BHLS or the HeLMS to help identify these men with inadequate HL. While the BHLS is quick and easy to administer, the HeLMS is more comprehensive and provides information about specific HL domains which could be targeted to tailor health information to the needs of these men and thereby help to ensure that they can be part of the shared decision-making process.

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CHAPTER 8:

OVERALL THESIS DISCUSSION AND CONCLUSION

8.1 SYNTHESIS OF KEY FINDINGS

The overarching aim of this thesis was to explore the factors that influence the decision-making process of men with newly diagnosed prostate cancer. This process is critical because it will determine the chance of cure, the risk of experiencing side effects, and ultimately the level of satisfaction men have with the decision, the chosen treatment, and possible decision regret.[1] In helping a man with newly diagnosed prostate cancer to make a treatment decision clinicians must first consider the risk of the cancer progressing and, therefore, the *need* for treatment.[1,2]. This advice will be modified based on patient factors including an estimate of the patient's life expectancy and their risk of death from other non-cancer causes.[3,4] Ultimately, treatment with curative intent should be offered to those that need it, thus avoiding undertreatment, and overtreatment should be avoided in those men with limited life expectancy, or low grade cancer that is unlikely to progress in their life expectancy.[5,6] For men the decision is complicated and emotionally fraught because it involves them having sufficient knowledge of prostate cancer, understanding of the chance of their cancer progressing and, therefore, the threat it poses, acceptance of their life expectancy from comorbidities and age, and combining those issues with their individual preferences to arrive at a decision.

Our research adds to the available literature by showing that cancer risk stratification was the primary determinant of treatment, with low risk patients more likely to be placed on active surveillance and patients with more aggressive cancer more likely to be given treatment with curative intent. In the population group included in this thesis, 66.7% of men with low risk cancer underwent treatment that was concordant with the guidelines, rising to more than 75% for intermediate risk cancer and 94% for high risk cancer. We also demonstrated that these treatment recommendations were appropriately modified by life expectancy and the presence of comorbidities, such that overtreatment rates were approximately 10% for men with low risk cancer, 12-18% for intermediate risk cancer and 18% for high risk cancer. Overall, younger healthier patients with longer life expectancy were more likely to receive TCI, which concords with the findings of two Australian studies.[5,7]

In a model of shared decision-making[8] both the clinician and patient participate in the decision-making process. Men's health literacy, and the degree to which they wished to be involved in the shared decision-making process, also impacted upon the decision-making process. It has been suggested that for the patient, lower education levels and lower levels of health literacy are associated with lower patient participation,[9] and the findings of this thesis support this assertion. A high proportion of men in our study were satisfied with the decision-making process, regardless of age or the treatment undertaken, which concords with the available literature.[10,11] It has been assumed that men, especially older men, tend to be passive participants in the decision-making process;[12,13,14] however, the majority of men in our study expressed a preference to take an active role in this process with these men showing they were more satisfied with the decision-making process and ultimately the treatment chosen.

Nonetheless, approximately 30% of men who participated in our study described significant decision regret. Decision regret is a sense of distress or remorse following a decision characterised by self-blame and a wish to undo the situation that has led to a poor outcome.[15,16] It is critical to prevent regret because it is associated with poorer health outcomes and lower health related quality of life.[12] Results from this thesis have determined that patient satisfaction with the decision-making process was associated with lower rates of decision regret. Patients who felt that their options were made clear to them during the decision-making process also suffered less regret. These findings suggest that greater involvement in the decision-making process will lead to greater satisfaction with that process, the treatment chosen and lower rates of decision regret. Clinicians can help promote patient engagement and satisfaction with the decision-making process by educating patients on how to be more involved: for example, by suggesting questions to prompt discussion and providing literature to patients that is appropriate to their level of health literacy. Not only must men be provided with information but, in order to actively participate in the decision-making process, they need to *understand* the information and it must prompt them to take action, i.e., actually help them to make a decision.

The findings of this thesis have demonstrated that approximately 20% of men have inadequate health literacy, with the level of health literacy correlating inversely with age at leaving school. This level of inadequate health literacy is similar to that previously reported in diverse health care settings.[17,18] Of concern is that our study found that approximately 50% of men had inadequate health literacy in one or more of the HeLMS domains, including Domain 5, which measures their ability to seek healthcare information.

Health literacy has been defined as the ability to access, understand and use health related information to manage health.[19,20] However, it is a complex construct involving relationships between basic literacy, knowledge (both background and domain specific), and comprehension.[21] Inadequate health literacy of a patient is important for clinicians to consider during patient interactions because it is often associated with less knowledge and understanding of illness management, poorer communication between patient and physician, and decreased ability to take part in shared decision-making, including the treatment decision-making process.[22] Our study found correlations between our two measures of health literacy (the BHLS and HeLMS), cancer literacy and comprehension, and cancer knowledge, supporting the need to consider the complex interplay between these concepts when assessing health literacy.

The literature has shown that men use multiple sources of information when making health decisions[23,24] and our study confirmed this with 80% of men using more than four information sources. However, our results also indicated that older men used fewer sources of information than younger men. The treating clinician was the primary source of information for most men in our study, supporting published studies, [23,24] but the patient's level of health literacy correlated with how helpful men found the clinician as a source of information. These results are important because they indicate that clinicians must take the time to assess the health literacy of men and be aware that men with low health literacy may not be able to fully partake in the shared decision making process. In our study, only 48% of men used the Internet as an information source and it was used predominantly by younger men, suggesting that in the older patients diagnosed with prostate cancer (median age in our study 67 years) clinicians cannot depend on men accessing the Internet independently. Furthermore, this thesis argues that the readability levels of most information available to patients, both written and online, is at too high a grade level for men. This is a critical deficiency as access to, and understanding of, information has been shown to be an essential prerequisite to men being involved in the treatment decision-making process.[24,25] Compounding this problem, our study found that the 'actionability' of most information sources was too low so that the resource did not lead men towards an action or response and help them to be involved in the decision. To our knowledge this low actionability has not been previously demonstrated for prostate cancer information.

8.2 IMPLICATIONS FOR PRACTICE

The overall implication for practice arising from this thesis is that the decision-making process, and patient involvement in it, is critical to good care, and clinicians must endeavour to improve the process by increasing a patient's ability to participate. Box 1 highlights the important factors that clinicians should consider in order to involve patients more fully in the decision-making process.

Box 1: Recommendations for clinical practice

Clinicians must:

- *Continue to be vigilant to not overestimate the lethality of an individual man's cancer, or overestimate his life expectancy, when giving advice and thus avoid the risk of overtreatment, as comorbidities are often the cause of death for men with prostate cancer rather than the cancer itself.*
- *Not deny treatment to older men solely based on age if they have an aggressive cancer and are otherwise well with a long life expectancy, i.e. avoid undertreatment.*
- *Work to improve the patient's engagement with, and participation in, the shared decision-making process by, providing or suggesting key questions and themes to discuss as this leads to greater satisfaction with the decision-making process, lower levels of regret and improved QOL.*
- *Be aware of possible low levels of health literacy, especially in older men, and take active steps to enquire into it and then ensure the information provided is readable and understandable to men at their level of literacy so that men have the necessary information to be involved in the shared decision-making process.*
- *Acknowledge that many older men, which includes most men with prostate cancer, tend to seek less information and use fewer sources of information and to respond to this by actively providing appropriate resources.*
- *Evaluate the information available in their practice and that distributed by government bodies and charitable organisations, to ensure they are readable, understandable and actionable.*
- *Be cognisant of the cancer literacy, knowledge, and comprehension of their male patients, as well as factors such as their emotional state, the nature of the decision, and their own relationship with their patient, all of which may impact on patient-centred decisions.*

8.3 STRENGTHS AND LIMITATIONS

8.3.1 Strengths

The major strength of the study was that it examined decision-making as a whole and not just the narrow results of that decision such as which particular curative treatment was undertaken, or patient survival following treatment. To enable this, multiple factors that influenced the decision-making process were examined, for example, age, comorbidity and life expectancy, health literacy, cancer comprehension and knowledge, with the flow-on results emanating out of the process being assessed, for example, treatment decision-making satisfaction, decision regret and concordance with guidelines. As part of this process, gaps in the literature were identified and addressed, especially regarding decision-making for men with prostate cancer. For example, the 'actionability' of information resources, i.e., what do I, as a patient with prostate cancer, actually do now, and the interconnected relationship between cancer knowledge, comprehension and health literacy had not previously been examined. Another strength of this study is that, to the best of our knowledge, this is the first time a study has investigated the health literacy, cancer literacy, comprehension, and prostate cancer knowledge among male urological patients.

8.3.2 Limitations

The main limitation of this thesis was the small sample size for some elements, and for most studies, all patients were recruited from a single practice. However, the demographics of the men who responded (age, health literacy levels), their cancer characteristics, and treatments undertaken were representative of Australian men more broadly, and of those diagnosed with prostate cancer, suggesting that the results could reasonably be extrapolated to a broader population. In addition, due to the nature of the survey tools used, we may have underestimated the true level of low health literacy because the population of men who were able to respond to questionnaires were men of sufficient knowledge and comprehension to allow them to answer surveys comfortably and who may tend to have higher health literacy. Furthermore, the majority of participants were those attending a private urology practice and therefore there were few patients from low socioeconomic groups. We may therefore have underestimated the association between low SE group, age and health literacy. Another potential limitation is the retrospective nature for some aspects of the study. For example, men's reflections on the decision-making process were retrospective but in designing the study we felt that it was ethically questionable to 'intrude' on a stressful and life changing decision (by questioning values and motives etc.) contemporaneously.

8.4 FUTURE RESEARCH

Following on from our finding that increased involvement and control over the decision-making process by men is associated with improved satisfaction with this process, future research could examine different approaches to improve physician-patient communication and engagement in the decision-making process. These interventions are critical as we and other authors have shown that they lead to improved satisfaction with the decision-making process and ultimately less regret post treatment and improved quality of life scores. Techniques to assess treatment satisfaction, immediately after the decision has been made, should be further explored, being mindful not to intrude at a time of high psychological stress.

We have highlighted that the 'actionability' of information available to men is too low, which means it does not actually help them make a decision. Future studies could investigate ways to improve actionability of patient information materials available for men following a diagnosis of prostate cancer.

This thesis has identified that the health literacy of men with prostate cancer is low; consequently, larger scale studies should be performed. A larger cohort of men would allow elucidation of the association between health literacy, age, education level and socio-economic group. We also highlighted the interconnection between domain specific knowledge, comprehension and health literacy, and the exact nature of this relationship should be explored in the future. We know that higher levels of health literacy are associated with improved domain specific knowledge but the exact relationship between health literacy and cancer understanding is not fully understood.

We have reported that comorbidities have a significant effect on life expectancy. Further research is required to establish more reliable and easier to use tools for assessing comorbidities and their effect on non-cancer life expectancy. These would be used by clinicians to determine the need more effectively for treatment with curative intent in men with prostate cancer and thus reduce rates of overtreatment in men who will not benefit.

8.5 CONCLUSION

We have identified that although the majority of men with prostate cancer receive treatment concordant with guidelines, there are significant levels of overtreatment and possible unnecessary treatment. These levels may be lowered by clinicians better assessing the cancer and the risk it poses, as well as the life expectancy of patients, so that men who need treatment are offered it and those who are unlikely to benefit are not. We have highlighted that increased involvement of men in the decision-making process leads to improved satisfaction, which in turn leads to lower rates of decision regret. However, we have identified that approximately one third of men find the decision difficult to make and many men may not have adequate levels of health literacy to be able to read and understand the information they are given or have located themselves). This problem is exacerbated by the low levels of readability and, particularly, actionability of prostate cancer information sources available to men, which may interfere with their ability to be involved in the decision-making process. Physicians must therefore work with men to help improve their engagement in the decision-making process.

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CHAPTER 9 - APPENDICES

APPENDIX 1 - HELMS DOMAINS

Are you able to ?	Without any difficulty	With little difficulty	With some difficulty	Very difficult	Unable to do
DOMAIN 1					
1a. Change your lifestyle to improve your health?					
1b. Make time for things that are good for your health?					
1c. Pay attention to your health needs?					
1d. Find the energy to manage your health?					
DOMAIN 2					
2a. Find health information in a language you can understand?					
2b. Fill in forms eg Medicare?					
2c. Read written information eg leaflets given to you by your doctor					
2d. Read health information brochures found in hospitals at a doctors clinic?					

DOMAIN 3					
3a. Discuss your health with people other than a doctor					
3b. Take a family or friend with you to a doctor’s appointment					
3c. Ask someone to go with you to a medical appointment					
3d. Ask family or friends for help to understand health information					
3e. Know where you can see a Doctor					
DOMAIN 4					
4a. Pay to see a doctor?					
4b. Afford transport to medical appointments?					
4c. Pay for medication you need to manage your health?					
DOMAIN 5					
5a. Do you know where a doctor can be contacted?					
5b. Do you know how to get to a doctor’s appointment?					
5c. Do you know what to do to get a Doctors appointment?					
5d. Do you know where you can see a Doctor?					

DOMAIN 6					
6a.Can you ask a doctor questions to help you understand health information?					
6b. Can you get the information you need when seeing a doctor?					
6c. Are you able to follow up with a doctor to understand information about your health?					
DOMAIN 7					
7a. Are you able to change to a different doctor to get better care?					
7b. Are you able to get a second opinion about your health from a health professional?					
7c. Are you able to look for a second opinion about your health from a health professional?					
DOMAIN 8					
8a. Can you use information from a doctor to make decisions about your health?					
8b. Are you able to follow instructions that a doctor gives you?					
8c. Are you able to carry out instructions that a doctor gives you?					
8d. Are you able to use advice from a doctor to make decisions about your health?					

APPENDIX 2 - KNOWLEDGE ABOUT THE PROSTATE AND PROSTATE CANCER

The following questions assess your knowledge about the prostate and prostate cancer.

Please place a cross (x) in the box to indicate if you think the statement is true or false.

	True	**False**
The prostate is located between the bladder and penis, in front of the rectum.	○	○
If you have brothers or sons they are at higher risk for prostate cancer.	○	○
A man can have prostate cancer without having any pain or symptoms.	○	○
Antibiotics can be used to cure prostate cancer.	○	○
The goal of hormone therapy is to lower the levels of the male hormone, testosterone.	○	○
Surgery or radiation can cure prostate cancer in its early stage.	○	○
Chemotherapy is given to men with early prostate cancer.	○	○
Hormone treatment for prostate cancer can cause hot flashes.	○	○
Prostate cancer treatment can increase your sex drive.	○	○
Radiation treatment of prostate cancer can cause urinary or sexual problems.	○	○
Surgery of prostate cancer can cause urinary or sexual problems.	○	○
Eating soybean products such as tofu and soymilk may lower the risk of prostate cancer.	○	○
Eating tomatoes may decrease the risk of prostate cancer.	○	○
Experts recommend eating at least 2 servings of fruits and vegetables each day	○	○

APPENDIX 3 - CMLT MESSAGES

Reading About Cancer

Please read each of the following short passages about cancer. After each passage, read the statements that follow.

If the statement contains information that is the same or nearly the same as the information in the passage, check the box in the “Same” column.

If the statement contains information that is different from the information in the passage, check the box in the “Different” column.

If you are not sure whether a statement contains content that is the same or different from the passage check the box in the “Not Sure” column, but still take a guess on whether or not the statement is same or different. So if you are not sure, place a check in the box under “Not Sure” and a check under your guess, either “Same” or “Different”.

A Citizen's Guide to Radon

From the US Environmental Protection Agency

Radon is a cancer-causing, radioactive gas.

You can't see radon. And you can't smell it or taste it. But it may be a problem in your home.

Radon is estimated to cause many thousands of deaths each year. That's because when you breathe air containing radon, you can get lung cancer. In fact, the Surgeon General has warned that radon is the second leading cause of lung cancer in the United States today. Only smoking causes more lung cancer deaths. If you smoke and your home has high radon levels, your risk of lung cancer is especially high.

Statements:

	Same	**Different**	**Not Sure**
Radon can't be seen, but it gives off a slightly metallic scent which is detectable to many people	○	○	○
Radon causes more than ten million cancer deaths each year	○	○	○
Radon causes lung cancer and usually contributes to skin and breast cancer	○	○	○
The Surgeon General ranks radon the third leading cause of lung cancer in the United States, after smoking and breathing in fumes from home fires	○	○	○

What do I Need to Learn about Getting Tested for Prostate Cancer?

From A Patient Education Booklet
Isn’t getting the PSA test a simple step?
No, because of what may follow a high PSA test.

- _If your PSA level is high, a prostate biopsy will be recommended.
- _If the biopsy shows cancer, then surgery or radiation therapy will often be recommended.
- _You may end up getting treatments that you really did not need.
- _You may end up getting side effects you did not want.

What happens if the biopsy shows prostate cancer?
If the biopsy shows that you have prostate cancer, then you will need to make some more decisions. You have three options: two active treatments and watchful waiting. Your doctor will talk to you about choosing a cancer treatment. There are two main types of active treatment.

- _Surgery to remove the prostate
- _Radiation therapy of the prostate

Each of these treatments has potential serious side effects:

- _Urinary incontinence (being unable to control flow of urine)
- _Stool incontinence (being unable to control bowel movements)
- _Sexual impotence (being unable to have sex)

These side effects may get better with time. By 5 years after either surgery or radiation therapy, 65 to 80% (65 to 80 out of 100) men will have trouble getting an erection. 5 to 20% (5 to 20 out of 100) will have trouble controlling urine or bowel movements. These active treatments may not be needed. They may not cure many men of cancer.

Another option is:

- Watchful waiting (Wait and See)

Watchful waiting means that you do not get treatment right away. Doctors check your PSA levels and the size of the prostate every few months. If the cancer starts to grow, then you can get treatment. Many doctors do not like to wait and see if the cancer grows. They worry that the cancer may get too big to be cured. They will ask men to choose between surgery and radiation therapy right away. Men may feel pressure from their doctors and families to choose a cancer treatment right away. But the treatment may not help them live longer and may result in serious side effects.

Statements:

	Same	Different	Not Sure
A high PSA test means that a man definitely has cancer	○	○	○
One outcome of a PSA test is that a high PSA can lead to procedures which in turn have undesirable side effects	○	○	○
Men who have surgery tend to live longer and feel better then men who do not get treatment	○	○	○