Copyright Statement

This copy of the thesis/dissertation has been supplied on condition that anyone who consults it is understood to recognize that its copyright rests with its author and that information derived from it may not be published without attribution.

Copyright ownership of theses and dissertations is retained by the author, but the student must grant to TWU royalty-free permission to reproduce and publicly distribute copies of the thesis or dissertation. In circumstances where the research for the thesis or dissertation has been done in conjunction with other policies discussed in The Texas Woman’s University Policy on Intellectual Property, those policies will apply with regard to the author.

No further reproduction or distribution of this copy is permitted by electronic transmission or any other means. The user should review the copyright notice on the following scanned image(s) contained in the original work from which this electronic copy was made.

Section 108: United States Copyright Law

The copyright law of the United States [Title 17, of the United States Code] governs the making of photocopies or other reproductions of copyrighted materials.

Under certain conditions specified in the law, libraries and archives are authorized to furnish a photocopy or other reproduction. One of these specified conditions is that the reproduction is not to be used for any purpose other than private study, scholarship, or research. If a user makes a request for, or later uses, a photocopy or reproduction for purposes in excess of “fair use,” that use may be liable for copyright infringement.

No further reproduction and distribution of this copy is permitted by transmission or any other means.

Texas Woman’s University ©2013.

www.twu.edu
EXPLORING THE RISK OF OVERTREATMENT IN OLDER MEN WITH PROSTATE CANCER: A DESCRIPTIVE ANALYSIS OF ACTIVE SURVEILLANCE

A DISSERTATION
SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY IN THE GRADUATE SCHOOL OF THE TEXAS WOMAN’S UNIVERSITY

COLLEGE OF NURSING

BY
LYDIA T. MADSEN BSN, MSN

DENTON, TEXAS
AUGUST 2014
DEDICATION

For my Dad, John Gilbert Torian (1929-2007). He would have been the proudest man imaginable to tell his friends he had a “Doctor-Nurse, Daughter”
ACKNOWLEDGMENTS

I would like to gratefully acknowledge the many individuals who have assisted me through this developing dissertation. First, I would like to thank my committee chair Dr. Sandra Cesario for her mentoring and unwavering support and encouragement throughout this program. I would also like to thank Dr. Rae Langford and Dr. Judith McFarlane, who served as indispensable members of my dissertation committee. Their support, constructive comments, and suggestions provided valuable direction for my research and writing. I am also grateful to the faculty at Texas Woman’s University, particularly Dr. Lene Symes, who encouraged me to think critically and challenged me to think beyond the apparent. And finally, my thanks to my parents John and Day Torian, my sister, Vivian, my husband John and my children Rachel, Jonathan and Marissa, who consistently help me to see that persistence, hard work and love for family make life a continually evolving adventure.
ABSTRACT

LYDIA T. MADSEN

EXPLORING THE RISK OF OVERTREATMENT IN OLDER MEN WITH PROSTATE CANCER: A DESCRIPTIVE ANALYSIS OF ACTIVE SURVEILLANCE

AUGUST 2014

NCCN guidelines recommend active surveillance as the most appropriate treatment for individuals with disease classified as ‘very low’ risk or ‘low’ risk, to minimize the risk of over-treatment (NCCN Policy Update, 2013). In a senior prostate cancer population, recommendation for active surveillance may be particularly applicable given the risk of death from competing comorbidities.

Disease characteristics, treatment recommendations and treatment decisions were retrospectively examined in a population of senior men, age 75 and older that were newly diagnosed with organ confined prostate cancer. These men presented in a senior multidisciplinary prostate cancer clinic for treatment recommendations and were offered Active Surveillance as treatment. To characterize competing comorbidities, the Adult Comorbidities Evaluation (ACE-27) was retrospectively coded for each patient, in addition to counting comorbidities disclosed during the PME. Patient self-rated health status was also included.
137 men, ages 75 to 88 were included in the analysis. Each patient was seen by a medical oncologist and a radiation oncologist, or by a radiation oncologist and a urologist. After detailed consultation with the multidisciplinary team, patients routinely received either a list of treatment options or a consensus recommendation from the team.

We conclude that the consensus recommendation statement is a highly significant aspect to patients’ selection of active surveillance, with a statistical effect size of 11.7, and that the decision to accept active surveillance is facilitated by the multidisciplinary clinic process.
<table>
<thead>
<tr>
<th>TABLE OF CONTENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Page</td>
</tr>
<tr>
<td>DEDICATION ........................................................................................................ iii</td>
</tr>
<tr>
<td>ACKNOWLEDGMENTS ................................................................................................ iv</td>
</tr>
<tr>
<td>ABSTRACT ............................................................................................................ v</td>
</tr>
<tr>
<td>LIST OF TABLES .................................................................................................. xi</td>
</tr>
<tr>
<td>LIST OF FIGURES ................................................................................................ xii</td>
</tr>
<tr>
<td>Chapter</td>
</tr>
<tr>
<td>I. INTRODUCTION .................................................................................................... 1</td>
</tr>
<tr>
<td>Problem of Study .................................................................................................. 2</td>
</tr>
<tr>
<td>Rationale for the Study ....................................................................................... 3</td>
</tr>
<tr>
<td>Theoretical Framework ....................................................................................... 4</td>
</tr>
<tr>
<td>Assumptions .......................................................................................................... 5</td>
</tr>
<tr>
<td>Research Question ................................................................................................ 6</td>
</tr>
<tr>
<td>Definition of Terms ............................................................................................. 6</td>
</tr>
<tr>
<td>Limitations ............................................................................................................. 9</td>
</tr>
<tr>
<td>Summary ............................................................................................................... 10</td>
</tr>
<tr>
<td>II. REVIEW OF LITERATURE: AN INTEGRATIVE REVIEW OF NURSING RESEARCH ON ACTIVE SURVEILLANCE IN AN OLDER PROSTATE CANCER PATIENT POPULATION ......................................................... 11</td>
</tr>
<tr>
<td>Abstract ............................................................................................................... 11</td>
</tr>
<tr>
<td>Scope of this Review ........................................................................................... 15</td>
</tr>
<tr>
<td>Summary of Research Review ............................................................................ 16</td>
</tr>
<tr>
<td>Existing Models of Care for Nursing Practice ............................................... 22</td>
</tr>
<tr>
<td>Gaps in Nursing Research .................................................................................. 23</td>
</tr>
<tr>
<td>Conclusions and Implications for Future Nursing Research ........................... 24</td>
</tr>
<tr>
<td>Summary ............................................................................................................... 26</td>
</tr>
<tr>
<td>References ............................................................................................................ 27</td>
</tr>
</tbody>
</table>
### III. METHODOLOGY

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting</td>
<td>33</td>
</tr>
<tr>
<td>Population and Sample</td>
<td>33</td>
</tr>
<tr>
<td>Protection of Human Subjects</td>
<td>34</td>
</tr>
<tr>
<td>Instruments</td>
<td>34</td>
</tr>
<tr>
<td>Data Collection Process</td>
<td>35</td>
</tr>
<tr>
<td>Treatment of Data for Analysis</td>
<td>36</td>
</tr>
</tbody>
</table>

### IV. EXPLORING THE RISK OF OVERTREATMENT IN OLDER MEN WITH PROSTATE CANCER: A DESCRIPTIVE ANALYSIS OF ACTIVE SURVEILLANCE IN A MULTIDISCIPLINARY PROSTATE CANCER CLINIC SETTING

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>37</td>
</tr>
<tr>
<td>Background</td>
<td>41</td>
</tr>
<tr>
<td>Methods</td>
<td>42</td>
</tr>
<tr>
<td>Sample</td>
<td>43</td>
</tr>
<tr>
<td>Measures</td>
<td>43</td>
</tr>
<tr>
<td>Demographic/Psychosocial Measures</td>
<td>43</td>
</tr>
<tr>
<td>Disease Characteristics</td>
<td>44</td>
</tr>
<tr>
<td>Health Status Measures</td>
<td>44</td>
</tr>
<tr>
<td>Analysis</td>
<td>45</td>
</tr>
<tr>
<td>Results</td>
<td>45</td>
</tr>
<tr>
<td>Discussion</td>
<td>46</td>
</tr>
<tr>
<td>Clinical Trial Enrollment</td>
<td>48</td>
</tr>
<tr>
<td>Limitations</td>
<td>50</td>
</tr>
<tr>
<td>Implications for Research and Practice</td>
<td>51</td>
</tr>
<tr>
<td>Conclusions</td>
<td>51</td>
</tr>
<tr>
<td>References</td>
<td>60</td>
</tr>
</tbody>
</table>

### V. RECOMMENDATIONS FOR FUTURE STUDY

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective Data for Providers</td>
<td>65</td>
</tr>
<tr>
<td>A Qualitative Exploration of the Patient Experience</td>
<td>65</td>
</tr>
<tr>
<td>Active Surveillance Monitoring Standardization</td>
<td>67</td>
</tr>
<tr>
<td>Conclusion</td>
<td>67</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>68</td>
</tr>
</tbody>
</table>

### APPENDICES

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. An Integrative Review of Current Nursing Research on Active Surveillance in a Senior Prostate Cancer Patient Population</td>
<td>77</td>
</tr>
</tbody>
</table>
B. IRB Approval Forms ................................................................. 89

C. Publication Release Letter ..................................................... 93

D. Verification of Chapter IV Submission .................................... 98
LIST OF TABLES

Table | Page
--- | ---
1. Demographic and Clinical Characteristics of the Population (N=137) | 52
2. Univariate Logistic Regression Assessing Association with Choosing Active Surveillance | 56
3. Multivariate Logistic Regression Assessing Association with Choosing Active Surveillance | 58
# LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Summary Letter Provided to Patients at the Completion of the Multidisciplinary Prostate Cancer Clinic</td>
<td>54</td>
</tr>
<tr>
<td>2.</td>
<td>AS Offering Method [Menu or Consensus (written)] &amp; Patient Decision by Year</td>
<td>55</td>
</tr>
</tbody>
</table>
CHAPTER I
INTRODUCTION

Prostate cancer is the most commonly diagnosed non-cutaneous cancer in men and second only to lung cancer as the cause of male cancer mortality in the United States. An estimated 238,590 cases were diagnosed in 2013, with a projected 29,720 deaths (CDC/SEER Statistics, 2013). A disease of aging, the Center for Disease Control (CDC) projects that almost eighteen percent of new diagnoses will occur in the 75 - 84 age population with four percent diagnosed after age 84 (CDC/SEER Statistics, 2013). Seventy percent of deaths due to prostate cancer occur after age 75 (UTPSTF, 2012, Droz, Balducci, Bolla… & Sternberg, 2010). To add an additional level of complexity, although nearly twenty-two percent of new diagnoses will occur in the senior population, an estimated 30-50 % of these cases are considered ‘over diagnosis’ of potentially indolent cancers that are often amendable to management with an active surveillance approach (Hegarty & Bailey, 2011, UTPSTF, 2012).

The Unites States Census Bureau estimates there are currently 21 million men age 65 and older increasing to 35.7 million within the next 25 years. With this expected trajectory, prostate cancer management in a senior population of men will assume increasing importance (Konety, Sharp, Raut & Williams, 2008). Screening guidelines for prostate cancer vary particularly in a senior population and when cancer is detected, the difficulty with estimating life expectancy impacts treatment recommendations.
Although the diagnosis of prostate cancer that is classified as low-risk, asymptomatic, disease comprises approximately half of those diagnosed each year, about ninety percent of those diagnosed patients currently go on to receive some type of curative intervention. Such treatment approaches often occur because of physician and/or patient uncertainty and discomfort with non-intervention approaches such as active surveillance (Davison & Goldenberg, 2011).

Active surveillance is a treatment alternative to surgery or radiation in patients with low-risk, low-volume disease. This treatment approach involves the cooperative, intentional and prescribed monitoring of prostate cancer with a clearly defined strategy for intervention in patients who exhibit signs of disease progression by either a rapid, sequential prostate specific antigen (PSA) blood level increase, or an increase in pathologic Gleason score or volume of disease, after systematic routine biopsy (Madsen & Symes, 2013). Recent policy update by the National Comprehensive Cancer Network (NCCN) recommends active surveillance as the most appropriate treatment for individuals with disease classified as ‘very low’ risk or ‘low’ risk, to minimize the risk of over-treatment (NCCN Policy Update, 2013).

**Problem of Study**

This study is designed to describe the disease and contextual characteristics seen in a senior cohort of men, recently diagnosed with prostate cancer, who seek treatment recommendations in a multidisciplinary prostate cancer clinic setting.
Rationale for the Study

According to the U.S. Preventative Services Task Force, (USPSTF), neither screening nor treatment trials show benefit in men older than 70 years (USPSTF, 2012) so treatment and screening guidelines recommend limiting treatment for prostate cancer in male populations that have a projected life expectancy of less than 10 years. Individual medical co-morbidities and potential impact on health status are additional considerations for the senior male population. Although screening and treatment guidelines are familiar to health care providers, the population of seniors routinely request and expect screening along with treatment recommendations when prostate cancer is detected. However, active surveillance has not historically been used as a treatment recommendation in the majority of practices. With a diagnosis of prostate cancer in the senior population, treatment recommendations must also take into consideration both individual comorbidities and disease characteristics when deciding which patients may best be served by a recommendation for active surveillance versus a treatment intervention recommendation from the health care team. Finally, although current screening guidelines discourage screening and diagnosis after age 75, with the exception of aggregate SEER data, there is limited information in the literature; no studies to date detail the clinical and contextual characteristics of the senior population diagnosed and pursuing treatment recommendations, which should frequently include active surveillance, after being counseled on all appropriate treatment options.
Theoretical Framework

Decision Theory is the guiding framework for this research. Brim et al (1962) describes five sequential steps: identification of the problem, obtaining necessary information, producing possible solutions, evaluating the solutions and selecting a strategy. These steps encompass the decision-making process individuals work through on a routine basis and are the steps associated with obtaining and weighing critical information to move forward with a health-related treatment decision. Resnick (1987) proposes that decision-making routinely involves choices that the decision maker will always rank by ‘preferred outcomes’. Weighing the information on outcomes results in determining some decisions as potentially ‘better’ than others; otherwise decisions are not needed. To move forward with a decision, decision theory posits that the gathering of options with subsequent preferential ranking are the essential steps to any decision making process.

The aspect of decision theory relational to ‘decision under ignorance’ (Petersen, 2009, Resnik, 1987) will guide the examination of data obtained from a senior cohort of men, newly diagnosed with prostate cancer, who have received treatment recommendations in a multidisciplinary prostate cancer clinic setting. Peterson (2009) details this aspect of decision theory as internal deliberations that reach a conclusion that one specific ‘alternative’ choice is perceived as the one that will result in the best possible outcome. The intent of this research is to identify variables and contextual differences associated with active surveillance, as a treatment offered and subsequently
chosen, during the decision-making process. This study will examine the physiologic-
physical and demographic factors, at the time of clinical interaction, to assess what
factors or individual patient characteristics such as age, education, marital status, and
health status may appear to influence the decision to accept active surveillance as a
treatment versus active treatment.

Assumptions

The assumptions relevant to this investigation are drawn from the assumptions in
decision theory that relate to an individual’s exploration of decision-making. The first
assumption in decision theory is that the determination of what options are available must
occur (Petersen, 2009). Patients presenting to the MPCC are given detailed information in
the clinical process to meet this assumption. The second assumption is that formalization
of the decision problem requires information about ‘acts, states and outcomes’ (Petersen,
2009); this assumption is met in the MPCC as detailed information provided in this
format includes probabilities or outcome statistics and arguably assists the patient from
moving from a state of ‘decision under ignorance’ to ‘decision under risk’ because of
knowledge gained from the MPCC team regarding current statistics and literature on
active surveillance versus active treatment. Educational and clinical information
provided to each patient encompasses both quality of life aspects in addition to disease
management to move the patient from the inability to weigh the choices available for
treatment to an informed understanding of the various probabilities associated with
treatments.
**Research Question**

Do treatment recommendation variables, health related variables, and demographic variables serve as predictors for whether male patients, 75 years and older and diagnosed with organ-confined prostate cancer, who receive treatment recommendations in a multidisciplinary prostate cancer clinic, ultimately choose active surveillance versus active treatment?

**Definition of Terms**

For this study the following terms and definitions are applicable to the study population:

Three categories of independent variables and one dependent variable will be examined in this study. The independent variables are categorized by treatment choices, health related concerns and demographic information. The treatment recommendation variable examines treatment choices offered to the male participants by a multidisciplinary prostate cancer team and are categorized as those patients offered an array of treatment choices including active surveillance as opposed to those who were given a consensus recommendation for active surveillance. Groups were further sub-classified by whether the recommendations were oral or written.

Treatment recommendation variables were classified as yes or no as a treatment choice and may include, radiation therapy, delivered either externally as photons, proton beam, or with brachytherapy seed implants, surgery or hormone therapy. Patients in this study were all offered active surveillance as a treatment choice.
Independent variables include the following:

1. Age, in years, at the time of prostate cancer diagnosis,
2. Risk Status of low risk, intermediate risk or high risk, as defined by National Comprehensive Cancer Network (NCCN) and compiled from clinical stage by digital rectal exam (DRE), as recorded in the electronic medical record at the time of clinic consultation, Prostate specific antigen (PSA) lab value at the time of diagnosis, and Gleason Stage as recorded in the electronic medical record and confirmed by University of Texas M.D. Anderson Cancer Center Pathologist’s report.
3. Number of comorbidities listed in the electronic medical record within the primary medical exam at the time of clinic evaluation,
4. Number of prostate cancer treatment options offered at the time of clinic consultation,
5. Number of clinical trials the patient consented to participate in at the time of clinic consultation,
6. Marital status at the time the patient presented for the clinic consultation
7. Education level as recorded by the patient in the electronic medical record at the time of clinic consultation
8. Primary team recommendation if one was offered as a consensus recommendation, at the time of clinic consultation, and as noted in either the electronic medical record as a patient letter or verbal consensus recommendation,
9. Patient’s self-described health rating, as recorded in the electronic medical record at the time of clinic consultation
10. Adult Comorbidity Evaluation (ACE-27) rating, based on comorbidities recorded in the electronic medical record at the time of the clinic consultation.

Other key terminology is defined as follows

1. Organ-confined prostate cancer is defined as disease still contained within the capsule of the prostate and by physical exam and staging x-rays presumed to be localized to the prostate.

2. A multidisciplinary prostate cancer clinic (MPCC) is a specialized clinic format providing detailed counseling and treatment recommendations by team consisting of a urologic surgeon and radiation oncologist and an advanced practice nurse or a medical oncologist, radiation oncologist and advanced practice nurse. The purpose of this specialized clinic format is to provide detailed assessment of the patient’s disease state, his health status with resulting recommendations and education regarding most appropriate treatment options based on clinical stage of disease, Gleason grade, patient’s age and current health status for each patient seen in the clinic. The patients receive a time intensive educational format consultation by specialist in active surveillance as a treatment, or radiation-based options.

3. Treatment choices
   a. Active surveillance is a treatment alternative to surgery of radiation in patients with low-risk, low-volume disease which involves the cooperative, intentional and prescribed monitoring of prostate cancer with a clearly defined strategy for intervention in patients who exhibit signs of disease progression by either a rapid,
sequential prostate specific antigen (PSA) blood level increase, or an increase in pathologic Gleason score or volume of disease, after systematic routine biopsy (Madsen & Symes, 2013).

b. Radiation therapy is a treatment selection which may include either brachytherapy; seed implant treatment for prostate cancer, or external beam radiation therapy delivered as either proton therapy or photon therapy.

c. Hormone therapy is a systemic treatment option for prostate cancer that consists of suppressing testosterone production in males with a routinely administered intramuscular injection of a luteinizing hormone releasing hormone (LHRH) agonist.

**Limitations**

Limitations of the proposed study include the following:

1. Patients presenting to the multidisciplinary prostate cancer clinic were self-selected by individual, self-initiated referral which may reflect either increased personal or family support structure or higher levels of socio-economic status.

2. Increasing exposure from media or friends, on the management of prostate cancer, may have influenced patients’ decisions to pursue an active surveillance strategy independent of the physician team recommendation. Variations in how treatments were offered also exist; most patients received a letter detailing treatment recommendations, some with a written consensus statement from the team, some with just a verbal consensus statement.
Determining the best method for relaying recommendations within this patient cohort may not be possible.

3. The physicians and APN providing treatment recommendations administer care in an academic university setting and are salaried. Without financial incentive to actively treat patients, enrollment numbers for active surveillance may be higher than the community standard where active surveillance is time-intensive with a low economic yield.

Summary

Prostate cancer is a frequently diagnosed disease that is often amendable to treatment by an active surveillance management strategy, particularly in a senior population. However, limited information currently exists in medical and nursing literature regarding disease and contextual characteristics of senior men who are offered and select active surveillance as a treatment option within a multidisciplinary prostate cancer clinic. This research study is intended to add to the current body of knowledge on the characterization of senior prostate cancer patients who are both appropriate and accepting of an active surveillance monitoring strategy, so subsequent research may be tailored to delineate the needs and experiences of this senior population.
ABSTRACT

Purpose/Objectives: This literature review summarizes the current state of nursing science in an elderly patient cohort diagnosed with prostate cancer and managed with active surveillance as the treatment strategy.

Data Sources: Nursing research publications from 2003 through March 2012 which address prostate cancer patients undergoing an active surveillance treatment management strategy were included in this review.

Data Synthesis: A paradigm shift in the recommendation to consider active surveillance is apparent in the literature. Since 2003, active surveillance has become a more frequent
recommendation for the management approach of low-risk, small volume prostate cancers. Current nursing science provides data on decision-making and the uncertainty associated with active surveillance, however minimal information is available which specifically addresses the needs of the aging population with prostate cancer. Additionally, the trajectory of adaptation has only been preliminarily identified within the body of nursing science; the actions that promote or obstruct successful adaptation to active surveillance as a treatment approach require in-depth study.

**Conclusions:** Active surveillance has timely relevance for the aging population while providing a potential means to judiciously allocate medical resources and expenses within the healthcare delivery system. The nurse researcher in partnership with the APN should proactively address the multifaceted needs of this patient population.

**Implications for Nursing:** Active Surveillance, as a program of cooperative, intentional and prescribed monitoring of the disease with a clearly defined strategy for management, is ideally suited for nursing research into adaptation, education and management of chronic disease processes while advancing the role of advanced practice nurse.
Prostate cancer is a common diagnosis in the aging male population; in the US alone, 1 in 6 men will receive that diagnosis during their lifespan (American Cancer Society, 2012). Over the past three decades the detection of prostate cancer has evolved from a clinically detected advanced disease where cure was unlikely, to the PSA blood test era of the late 1980’s which allowed for increased screening and detection of treatable disease. The use of the PSA blood test helped identify at-risk men who subsequently underwent prostate biopsy. Thus, detection of localized disease with a substantial decrease in the numbers of men dying of prostate cancer has evolved into the current era in which a large percentage of prostate cancers are detected as indolent cancers that may never manifest as clinically significant (Thompson & Klotz, 2010).

The detection of disease classified as an insignificant or indolent cancer creates a dilemma for both the practitioner and patient. Current statistics reflect that even when Gleason score and volume of cancer are classified as both low risk and low volume and therefore unlikely to impact mortality, a staggering 90% of these patients will still go on to receive a definitive treatment in the form of either a radiation-based treatment or surgery (Thompson & Klotz, 2010). The impact on quality of life on those treated patients is also significant; the most common side effects of erectile dysfunction, incontinence or persistent bowel and bladder irritative symptoms are consistently reported throughout the literature. The risk of treatment side effects may vary from less than 10 percent to more than 60 percent of treated patients (Hugosson, Stranne, &
A treatment option under increasing consideration as an alternative to a surgical or a radiation based treatment for the patient with low-risk, low volume disease is active surveillance. Active surveillance is a program of cooperative, intentional and prescribed monitoring of the prostate cancer, with a clearly defined strategy for intervention management reserved for patients who exhibit sign of disease progression by either a rapid, sequential PSA increase or an increase in Gleason score or volume of disease after systematic, routine biopsy (Madsen & Symes, 2012). Although active surveillance remains an evolving treatment option, current data suggests that the risk of death related to prostate cancer at 10 years within this treatment category is 3% (Thompson & Klotz, 2010, Albertsen, 2011, Klotz, Zhang, Lam, Nam, Mamedov, & Loblaw, 2010).

The recommendation to consider active surveillance in a low-risk, low volume disease is even more compelling within the senior population of 75 years of age and older (Konety, 2009). Members of this population frequently present with competing morbidities that increase the risk of death from alternate causes (Roberts, Albertsen, Shao, Moore, Mehta, Stein, & Lu-Yao, 2011) while maintenance of quality of life also remain a priority (Hayes, Ollendorf, Pearson, Barry, Kantoff, Stewart, … & McMahon, 2010, Stangelberger, Waldert, & Djavan, 2008). The economics of overtreatment in the low-risk population in the current climate of health care reform must also be a consideration. Therefore, the topic for this review is an exploration of the current state of
nursing science in the cohort of elderly patients, defined as 75 years of age and older, who are diagnosed with prostate cancer and managed with active surveillance as the treatment strategy.

**Scope of this Review**

A comprehensive literature search was conducted using the search term combination of ‘active surveillance’, ‘prostate cancer’, ‘nursing’ and ‘elderly’ or ‘aged’ to identify articles with the terms in the title, as key words or within the abstract. The databases accessed were Ovid MEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and SCOPUS. The time limitation imposed ranged from 2003 to 2012; literature preceding 2003 solely addressed watchful waiting, a variation of a non-intervention strategy that conceptually differs from active surveillance as an approach to disease management. Both qualitative and quantitative research, in addition to review publications which referenced a population of 75 and older, was the focus of this literature search. The results obtained through the age limitation were restrictive; only two retrieved publications dealt solely with the senior population. When nursing articles that contained elder populations undergoing active surveillance were included, ten additional articles and one abstract were eligible for review. Secondary sources of information from the identified articles were also reviewed for possible inclusion. One article from 2003 and one from 2004 were included because, although the treatment strategy was called watchful waiting, the defined monitoring approach clearly met the definition for active surveillance.
Thirteen nursing research publications, one review, and one abstract with a primary focus on active surveillance in the prostate cancer population, published between the years of 2003 through March 2012, are summarized in Appendix A. The greatest increase in active surveillance as a nursing research topic was in recent years; two nursing articles were published in 2003, two published in 2004 and one published in 2007. The remaining ten were published in 2009, 2010 and 2011. Described studies included in this review were a mixture of both qualitative and randomized quantitative studies that characterized and addressed the current needs of the prostate cancer patient currently engaged in an active surveillance treatment management strategy.

**Summary of Research Review**

Hegarty & Bailey (2011) provide a review of the evolution of active surveillance as a prostate cancer treatment option; they note the incidence of over-diagnosis of prostate cancer to currently range from 30 – 50% of screen-detected cancers. This statistic emphasizes a common observation in the literature; the over-diagnosis of prostate cancer translates to overtreatment and treatment-related side effects. Over diagnosis and overtreatment may ultimately result in an effort to control cancers that are statistically predicted to remain indolent without intervention (Klotz, 2010, Thompson, 2011, Lawrentschuk, & Klotz, 2011, Abrahamsson, 2009). Coupling those observations with the reported rate of as high as 19% decisional regret (Birnie & Robinson, 2010), among patients who proceeded with a surgical or radiation-based treatment, supports the rationale for exploring treatment options and educating patients on the likelihood of disease progression in their lifetime. An interpretive, descriptive, qualitative study by
Davison, Oliffe, Pickles, & Mroz, (2009) identified factors that enhanced decision-making for the patient when offered active surveillance as a treatment option. This group concluded that the treatment team recommendation to consider active surveillance, coupled with the education associated with both the disease state and the active surveillance monitoring plan, were the most influential factors in decision-making for the patient and family. Davison and Goldenberg (2011) recently re-examined the decision-making process in men currently on active surveillance based on their prior findings. A survey, developed as follow-up to a qualitative study conducted by Ollife, Davison, Pickles, & Mroz, (2009), evaluated 73 men in a descriptive cross-sectional survey study to ascertain key elements of the patients’ decision process. The survey results revealed that the urologist’s recommendation, the risk to urinary function with interventional treatment, and the age at diagnosis, were key factors that influenced the decision to participate in an active surveillance program. Of particular interest was the finding that 82% of the participants in the survey reported being comfortable and 90% reported decision satisfaction with an active surveillance approach, with the majority (55%) not reporting anxiety about cancer progression while on observation (Davison & Goldenberg, 2011). These finding indicate the need for greater exploration regarding the structure and the support offered to patients in their program.

Wallace-Kazer (2003, 2010, 2011, & 2011) conducted several research studies within the active surveillance patient population throughout the period covered in this review. An initial exploration by Wallace in 2003 was a descriptive, quantitative survey study that examined the variables of uncertainty and quality-of-life in 19 men with
prostate cancer undergoing a watchful waiting/active surveillance treatment strategy. The mean age of the study population was 76 years of age. Increasing uncertainty accompanied by the perception of danger or risk was a primary finding indicating that professional nursing should target the development of patient education materials and interventions designed to address the risk of increasing uncertainty and anxiety associated with monitored but untreated cancer. Although a small study population, the findings establish that uncertainty results in a perception of danger which then impacts QOL measures. This team’s research has subsequently built on these findings and extended the focus on uncertainty and the management of that feeling within the theoretical framework of Uncertainty in Illness Model (UIT); Mishel’s middle range nursing theory originally proposed in 1988 and revised in 1990. Mishel’s UIT theory is an established framework for the prostate cancer patient population undergoing active surveillance as treatment because of the documented, persistent uncertainty associated with monitoring known disease (Bailey, Wallace & Mishel, 2007, Wallace, 2003). An abstract from Bailey, Wallace, Landerman, Albala, Polascik, & Robertson, (2009) provides preliminary data on a senior population of 8, with the average age of 75.4 to evaluate the psychosocial trajectory of men during a 24 month period of active surveillance monitoring. Although final results were not available for review, the abstract identified time intervals for implementation of nursing interventions directed at decreasing patient uncertainty. A follow-up focus group study by Wallace-Kazer, Bailey, Colberg, Kelly & Carroll (2011) identified the psychosocial and educational needs of men undergoing active surveillance as treatment for prostate cancer. The mean age of the focus group was 70 with seven
men participating in the discussions. The findings support the consistent observation in
the literature that men may not have adequate information and access to appropriate
educational resources on active surveillance as a treatment; the internet was their primary
source of information. Wallace-Kazer et al. (2011) also found in this focus study that men
did not use traditional support structures or family as a means to verbalize uncertainty,
 anxiety or concern. Ervik, Nordoy, & Asplunds’ (2010) research findings echoed the
patients perceived lack of support structures. Although this study population also
included men receiving endocrine therapy, both active surveillance and endocrine therapy
patients expressed a need for concrete information regarding their expected disease
trajectory. Notable also were the findings that patients routinely remarked that short
meeting times with health care providers added to their sense that additional support and
education about disease was not provided in the time increments necessary to decrease
personal anxiety and uncertainty related to their disease (Ervik, et al. 2010). The aspect of
patient uncertainty was examined by Ollife, Davison, Pickles, & Mroz, (2009) in a
qualitative study assessing self-managed uncertainty in men participating in active
surveillance. The study revealed that in the absence of a formal, structured program to
address the uncertainty that men experience with an active surveillance disease
management approach; participants self-manage uncertainty be either
compartmentalizing the disease by solitary ‘stoicism’, or commit to proactively
addressing disease uncertainty with complementary interventions such as diet
modifications (Ollife et al. 2009).
Bailey, Wallace, Latini, Hegarty, Carroll, Klein, & Albertsen (2011) reported on a secondary analysis conducted to test reliability of the Mishel Uncertainty in Illness Scale - Community form in four cohorts of men undergoing active surveillance for prostate cancer. The intent of this secondary analysis was the validation of a survey tool used to measure uncertainty within the active surveillance population. The validation of the tool lays the preliminary foundation work needed to develop future uncertainty management interventions. The authors Wallace-Kazer, Bailey, & Whittemore (2010) continue the exploration of management of uncertainty within the active surveillance treatment population with a proposed expansion of the Uncertainty Management Intervention (UMI); an intervention developed by Mishel for breast and prostate cancer patients. Their stated intention was to test the intervention tool in the active surveillance population as a means to assist this cohort of men. The intended outcome of the proposed intervention would be to provide a better understanding of the expected trajectory of disease by reframing it as a chronic condition rather than an impending threat, while providing tools directed at self-support (Wallace-Kazer, Bailey, & Whittemore, 2010). A follow-up to the proposed UIM intervention was most recently reported as a pilot study by Wallace-Kazer, Bailey, Sanda, Colberg & Kelly (2011) to provide preliminary data and confirm feasibility of an internet intervention designed to assist a senior population of men to self-manage disease related concerns and subsequently improve quality of life perceptions. The results demonstrated both feasibility and positive impact trends when the intervention was implemented in a pilot population of nine men with a mean age of 72.
The necessity to accurately educate patients and offer supportive program to patients is not trivial; the demonstrated outcome of unaddressed uncertainty often translates to a sense of urgency to intervene (Thompson, & Klotz, 2010, Wallace, 2003, Hegarty & Bailey, 2011, Albertsen, 2011, Roberts, et al, 2011). This is particularly valid in an anxious or neurotic personality as reported by Van den Bergh, Essink-Bot, Roobol, Wolters, Schroder, Bangma, & Steyerberg, (2009) and predicts for risk of an inclination to treat indolent prostate cancer, thus highlighting the need to explore priorities with individual patients. The exploration of individual treatment priorities allows for the possibility to frame treatment decision-making within the context of a well-educated patient who understands outcome statistics and self-identified quality of life priorities.

To address the needs of both education and support, Walsh-Scura, Budin & Garfing (2004) conducted a pilot study to evaluate the effectiveness of telephone support intended to enhance adaptation to a prostate cancer diagnosis. Of the 17 patient participants, 10 were treated with active surveillance/watchful waiting. A comprehensive battery of symptom experience survey instruments were used to assess functional, social, physical and emotional well-being during the 4 time-points of assessment throughout the 12 month study. The prospective, randomized trial evaluated telephone support plus mailed standard educational materials versus mailed standard educational materials. Although findings did not reach statistical significance, there was a noted trend toward positive adaptation in the group that participated in the telephone support arm of the study. Bailey, Mishel, Belyea, Stewart & Mohler (2004) also conducted a telephone
intervention intended to evaluate the effectiveness of a program directed at assisting men to cognitively reframe perception of their disease state and manage uncertainty. A Watchful Waiting Intervention (WWI) was tested in a convenience sample of 39 men with a mean age 75.4 years, who completed the study. The experimental group (n=19) received five weekly calls, lasting an average of 13 minutes, while the control group (n=19) received standard care follow-up which was not described in detail. Growth Through Uncertainty Scale (GTUS), Profiles of Mood States Profile - Short Form (POMS-SF), and Cantril’s Ladder quality of life measurements were made at enrollment and 10 weeks after enrollment in both groups. Quality of life ratings and the new view of life subscale of GTUS were significantly better in the intervention group than in the control arm. The POMS-SF differed on the confusion subscale with the intervention group showing significant improvement, p=.04 (Bailey, et al., 2004).

Existing Models of Care for Nursing Practice

Active surveillance is an accepted nursing care practice model that is supported by the utilization of two theoretical frameworks in nursing research. Mishel’s Uncertainty in Illness Theory (UIT) and the Roy Adaptation Model (RAM) both lend structure and a framework for the current body of nursing research in men participating in an active surveillance management strategy. Bailey, et al., (2004, 2007, 2011) and Wallace-Kazer (2003, 2010, 2011) provide substantive research findings documenting the existence of uncertainty in the active surveillance population. Nursing interventions with proposed timelines have been explored as means to avert or decrease the uncertainty of living with known disease. Oliffe et al., (2009) and Davison et al., (2009, 2011) have explored
patients’ decision-making and self-managed uncertainty aspects of active surveillance under the model for UIT. Using RAM as the theoretical framework, Walsh-Scura’s (et al., 2004), nursing intervention facilitates adaptation to a prostate cancer diagnosis with emphasis on the multidisciplinary assessment of the patient and the surrounding environment from a nursing perspective. Focusing on the human potential for conscious awareness and choice (Roy, 2009), two factors directly related to the concept of active surveillance, the applicability of RAM in this population as a theoretical framework is also apparent. Particularly in the aging population the often chronic, complex disease process of cancer requires multidisciplinary care, assessment and a holistic involvement which are hallmarks of nursing care and evaluable within a RAM theoretical framework.

**Gaps in Nursing Research**

Active surveillance as a treatment option continues to evolve. Initially described as watchful waiting, a treatment for individuals with multiple co-morbidities or seniors with a limited lifespan, it is now recognized as an underutilized treatment option for low-risk, low volume disease patients of all ages. Prior nursing research on watchful waiting as a treatment option does exist. However, active surveillance research, as the restructured approach for non-intervention has had limited although increasing interest within the nursing science community. As more prostate cancer is classified as disease amendable to observation rather than treatment, the impetus for increased nursing research becomes more pronounced. The National Institutes of Health (2011) State of Science Conference Report is a call for nursing action; the stated need for patient characteristics to be measured with standardized instruments and incorporated into the
decision making of patients under consideration for active surveillance should alone compel greater nursing engagement. The apparent need to characterize patients’ baseline anxiety, in addition to attitudes about quality of life measures must be evaluated to not only select appropriate candidates for active surveillance as a treatment approach but to also tailor patient education and long-term expectations regarding disease management. A general consensus on the most appropriate time gaps and monitoring strategies for this cohort of patients is also needed (NIH, 2011). Collaboration with physician colleagues, with a goal for the establishment of a monitoring algorithm, could provide a foundation for research and eventual establishment of an evidence-based practice. Additionally, the literature consistently reports that the recommendation to consider active surveillance is inconsistent and dependent on the practitioner making the original diagnosis (NIH, 2011, Gorin, Soloway, Eldefraway, & Soloway, 2011, Davison et al., 2009). Therefore, given the opportunity to advance the education of patients who are recommended to pursue active surveillance treatment in combination with long-term care management of these patients, similar to care management in the survivorship arena, research in this area should become a nursing priority.

**Conclusions and Implications for Future Nursing Research**

In recent years there has been a paradigm shift in the recommendation to consider active surveillance. Prior to 2003, this treatment approach was routinely reserved for a small subset of elderly men in which a medical ‘watchful waiting’ strategy was employed (American Cancer Society, 2012). Since 2003, active surveillance has become a more frequent recommendation for the management approach of low-risk, small volume
prostate cancers. A significant shift from the prior approach to not intervene under most circumstances is now relayed to the patient as a plan of monitoring; however the lack of detailed education and assurance is now well documented in the nursing literature as the primary cause of patient uncertainty and anxiety (Bailey et al., 2011, Wallace, 2003, Oliffe et al., 2009, Ervik et al., 2010, Kazer et al. 2010, van den Bergh et al. 2009, Kazer et al. 2011, Kazer et al. 2011).

Current nursing science has explored issues related to both decision-making and the uncertainty associated with active surveillance as a treatment process for a prostate cancer diagnosis. However, there is minimal information available that specifically addresses the aging population with this disease. And although quality of life is routinely emphasized as an endpoint in clinical trials, senior adults are consistently underrepresented in clinical trials enrollment (Puts, Monette, Girre, Wolfson, Monette, Batist & Bergman, 2010). The development of a follow-up algorithm, in combination with sequential follow-up quality of life measurements in the senior population would provide a valuable source of research data.

Cooperberg, Carroll & Klotz (2011) address the economics of active surveillance in the observation that ‘active surveillance is labor intensive and reimbursed relatively poorly’. Their conclusion is that the economics associated with active surveillance in combination with perceived risk of an undetected, clinically significant disease influences both the provider and the patient to pursue more aggressive treatment than may frequently be unwarranted (Cooperberg et al. 2011). Corcoran, Peele & Benoit (2010)
also address the economics associated with active surveillance but from a different perspective. The findings that active surveillance is a cost effective method of prostate cancer treatment in a select group of men give support to the argument that this treatment strategy has a timely relevance when considered through the lenses of both the aging population and the need to judiciously allocate medical resources and associated expenses within the healthcare delivery system. Both perspectives give support to the argument for use of an advanced practice nurse to monitor this patient cohort, following an established algorithm, while providing the time intensive, educational support required to assist the patient in their management of a disease. Providing patient education by the advanced practice nurse presents patient value at two levels. First, it provides the opportunity to assess and address quality of life measures as patients live with disease and second it is an educational opportunity to teach patients about coping skills and interventions to manage stress, uncertainty and fear. The challenge for nursing is how best to assist patients diagnosed with prostate cancer, that pursue observation rather than an interventional treatment, so that they can comfortably coexist with the cancer untreated. An additional area of nursing science is to identify the trajectory of adaptation; what actions promote and what actions obstruct successful adaptation.

**Summary**

Multiple and varied nursing research opportunities are apparent for the population of prostate cancer referred to treatment monitoring by active surveillance. The development and implementation of a monitoring algorithm would be a timely endeavor
based on the recent NIH recommendations. Current research by nurse scientists reflect the need to develop and implement patient and family education programs that address anxiety and associated uncertainty of the disease state. Qualitative and quantitative studies to assess the short and long-term adaptation of active surveillance as a treatment strategy are also areas of opportunity for nursing to clarify and promote active surveillance as an advanced practice nursing strategy in the prostate cancer population. Both a progressively aged population in combination with diminished health care resources increasingly tasks the advanced practice nurse with the responsibility to monitor and manage patient populations that, as opposed to an active intervention or procedure, may instead require increased time, extensive education and support and a holistic approach to care management. Active Surveillance, as a program of cooperative, intentional and prescribed monitoring of the disease with a clearly defined strategy for management, is ideally suited for nursing research into adaptation, education and management of chronic disease processes while advancing the role of an advanced practice nurse.

References


American Cancer Society. (2012). Retrieved from

http://www.cancer.org/Cancer/ProstateCancer/DetailedGuide/prostate-cancer-key-statistics


CHAPTER III

METHODOLOGY

This research is designed to provide a detailed characterization of a senior population of men, recently diagnosed with prostate cancer, that receive recommendation and education associated with active surveillance as treatment, and those that pursue it as a treatment.

This non-experimental descriptive study was designed to predict treatment decisions made by the patient participants using treatment recommendation variables, health related variables and demographic variables.

Setting

The study will be a secondary data review and analysis from an existing database. The dataset is de-identified and contained within a double password protected computer system. Analysis will be conducted with SPSS on a password protected desktop computer.

Population and Sample

Men, age 75 years & older, diagnosed with organ-confined prostate cancer, who received treatment recommendations in a multidisciplinary prostate cancer clinic (MPCC) between the years of 2004 through 2012, and were offered active surveillance as a treatment option and proceeded with active surveillance, a radiation-based treatment, cryotherapy, or surgery as their treatment choice. The sample of 137 men is a subset of an
IRB approved protocol for data collection of patients seen in a multidisciplinary prostate cancer clinic at the University of Texas M.D. Anderson Cancer Center.

Protection of Human Subjects

The sample is a subset of an existing IRB-approved protocol of patients seen in a multidisciplinary prostate cancer clinic at the University of Texas M.D. Anderson Cancer Center. IRB approval for analysis of this subset has also been obtained through Texas Woman’s University for dissertation research. Patient data, included in the existing dataset, has been assigned a number and de-identified following standard protection of human subject guidelines. In compliance with the current rules and regulations of the Institutional Review Board, approval for the utilization and protection of human subjects has been obtained from Texas Woman’s University and The University of Texas M.D. Anderson Cancer Center. As per the protocol specifics, patient confidentiality will be preserved as no effort will be made to contact patients in the context of this protocol. All findings will be reported as aggregate data with no reference to individual patient information.

Instruments

To characterize this senior population, the existing database will be analyzed for a relationship between clinical variables at the time of diagnosis, which includes the risk status of the patient of low-risk, intermediate-risk or high risk disease, as defined by NCCN guidelines and compiled based on PSA value, Gleason Score and clinical DRE, patient’s age, marital status, education, treatment selected, number of treatments offered as recommended treatments or as a consensus team recommendation, if one was offered. The number of co-morbidities recorded in the primary medical evaluation will also be
included to examine if a relationship between patient health status and treatment recommendations exists. Because, significant practitioner variability between recorded comorbidities may exist, the Adult Comorbidity Evaluation (ACE-27), retrospectively scored for each patient, will be used to standardize the individual assessment of each patient’s comorbidities. This instrument has established prior use in both head & neck and prostate oncology populations. Published psychometrics demonstrated a positive predictive value of the ACE-27 instrument to predict morbidity of 62.1%, and a negative predictive value of 76.5%. Instrument sensitivity was 61.6% and specificity at 70.9% (Thomas, Neby, Balagopal, Preethi, & Sebastian, 2010). Additionally, a self-rated perception of health status by the patient, obtained at the time of initial assessment is included to examine the patient perception of current health state within the context of disease and demographic characteristics. The number of clinical trials accepted is also included, although the data on number of clinical trials offered is not available.

**Data Collection Process**

A list of patients seen in the multidisciplinary clinic has been maintained by both the GU business center and by MDACC Medical Informatics. Patient information including demographic information, patient characteristics such as age, tumor characteristics such as tumor stage, grade and PSA lab values, treatment recommendations and treatment completed is currently maintained in a password protected, de-identified database, and will be reviewed by the PI of this study.
The target subset of patients in the database of patients, age 75 years and older will be analyzed for patient characteristics as they related to treatments offered and treatment decisions in relation to active surveillance.

**Treatment of Data for Analysis**

The primary outcome is participant decision to participate in active surveillance versus an alternative active treatment choice for prostate cancer. Variables which were thought to influence this decision were identified and examined using logistic regression.

Descriptive statistics were generated to describe and characterize the study cohort.
CHAPTER IV
EXPLORING THE RISK OF OVERTREATMENT IN OLDER MEN WITH PROSTATE CANCER: A DESCRIPTIVE ANALYSIS OF ACTIVE SURVEILLANCE IN A MULTIDISCIPLINARY PROSTATE CANCER CLINIC SETTING

To Be Submitted for Publication

Lydia T. Madsen
Jeri Kim
Brian Chapin
Sandra Cesario
Rae Langford
Judith McFarlane
Bryan Fellman
Karen E. Hoffman
Deborah A. Kuban

ABSTRACT

Purpose/Objectives: Exploration of variables associated with the decision to select active surveillance in a senior prostate cancer population.

Design: Secondary data review and analysis.
Setting: Senior multidisciplinary prostate cancer clinic.

Sample: 137 recently diagnosed prostate cancer patients, age 75 to 88 who received active surveillance as an option or consensus team recommendation.

Methods: Retrospective review of disease characteristics, psychosocial and demographic variables and health status variables.

Main Research Variables: Independent variables were categorized by disease risk group, health-status measures and demographic/psychosocial information. Dependent variable was treatment decision.

Findings: 137 men, ages 75 to 88 were included in the analysis. Age (OR = 1.2; p = 0.038), number of treatments offered (OR = 0.2; p < 0.001), and active surveillance offer type (OR 11.7; p < 0.001) impacted treatment decision. Older patients and those that received written documentation of the recommendations were more likely to choose active surveillance. Subjects offered more treatments (3-5) were less likely to choose active surveillance. In the final reduced model, number of treatments offered (OR = 0.1; p = 0.006) and active surveillance offer type (OR 7.2; p = 0.003) were significantly associated with the decision to accept active surveillance.

Conclusions: This clinic facilitated consensus recommendation and senior patients were routinely accepting of the team recommendation when it was offered in this setting.

Implications for Nursing: Senior patients accept active surveillance when part of a comprehensive strategy to educate and provide consensus team recommendations.
Development of an algorithm for management of the senior population that incorporates the use of an advanced care practitioner is recommended.
Prostate cancer is the most commonly diagnosed non-cutaneous cancer in men and second only to lung cancer as the cause of male cancer mortality in the United States. A disease of aging, an estimated 238,590 cases were diagnosed in 2013, with the Center for Disease Control (CDC) projecting almost eighteen percent of new diagnoses occurring in the 75 - 84 age population. An additional four percent of these cancer diagnoses are estimated to occur after age 84 (CDC/SEER Statistics, 2013). Approximately 30-50% of these newly diagnosed cases however, are considered ‘over diagnoses’ of potentially indolent cancers that may be amendable to management with an active surveillance approach (Hegarty & Bailey, 2011, UTPSTF, 2012).

Recent policy update by the National Comprehensive Cancer Network (NCCN) recommends active surveillance as the most appropriate treatment for individuals with disease classified as ‘very low’ risk or ‘low’ risk, to minimize the risk of over-treatment (NCCN Policy Update, 2013). Active surveillance is a treatment alternative to surgery or radiation in patients with low-risk, low-volume prostate cancer; the cooperative, intentional and prescribed monitoring of known disease with a clearly defined strategy for intervention in patients who exhibit signs of disease progression by either a rapid, sequential prostate specific antigen (PSA) blood level increase, or an increase in pathologic Gleason score or volume of disease, after systematic routine biopsy (Madsen & Symes, 2013).

In a senior population, prostate cancer is a commonly diagnosed disease often amendable to treatment by an active surveillance management strategy when classified as low-risk. However, limited information currently exists in medical and
nursing literature regarding the disease and contextual characteristics of a senior population of men who are offered and select active surveillance as a treatment option. Therefore, the aim of this research was to explore disease characteristic variables, demographic psychosocial measures and health status variables of a senior population offered active surveillance in a multidisciplinary prostate cancer clinic. The research question under examination was: Do treatment recommendation variables, health related variables, and demographic variables serve as predictors for whether male patients, 75 years and older and diagnosed with organ-confined prostate cancer, who receive treatment recommendations in a multidisciplinary prostate cancer clinic, ultimately choose active surveillance versus active treatment?

**Background**

The Unites States Census Bureau currently estimates that the 21 million men age 65 and older will increase to 35.7 million within the next 25 years. With this expected trajectory, prostate cancer management in a senior population of men will assume increasing importance (Konety, Sharp, Raut & Williams, 2008). Screening guidelines for prostate cancer vary, particularly in a senior population, and when cancer is detected, the difficulty with estimating life expectancy impacts treatment recommendations. Treatment and screening guidelines further recommend limiting treatment for prostate cancer in male populations that have a projected life expectancy of less than 10 years (Walz, Gallina, Saad,…& Karakiewicz, 2007); according to the U.S. Preventative Services Task Force, (USPSTF), neither screening nor treatment trials show benefit in men older than 70 years (USPSTF, 2012). Individual medical co-morbidities and the potential impact on
health status is an additional consideration in the senior population (Konety, 2009). However, although screening and treatment guidelines are familiar to health care providers, the population of seniors continues to increase, and routinely request screening, evaluation and when diagnosed, treatment recommendations for their prostate cancer. Therefore, the diagnosis of prostate cancer, particularly in a senior population, requires consideration of both individual comorbidities and disease characteristics when deciding which patients may best be served by an active surveillance versus a treatment intervention recommendation from the health care team; active surveillance may be a more frequent consideration given the increasing risk of death from competing comorbidities (Daskvich, Fan, Koyama,…& Penson, 2013, Gosney, 2005).

**Methods**

A secondary data review and analysis was conducted from an existing database of patients seen and offered treatment recommendations in a multidisciplinary prostate cancer clinic in a NCI designated Cancer Center.

Three categories of independent variables and one dependent variable were examined. The independent variables were categorized by disease risk group, health-status measures and demographic /psychosocial information. The dependent variable was treatment decision and stratified as patients either offered a menu of treatment choices by the multidisciplinary prostate cancer team which included active surveillance as opposed to those who were given a team consensus treatment recommendation. Groups were further stratified by whether the recommendations were oral or written.
Treatment recommendation variables were classified as yes or no as a treatment choice offered and included, radiation therapy, delivered either externally as photons, proton beam, or with brachytherapy seed implants, surgery or hormone therapy. All patients in this subset analysis were offered active surveillance as a treatment choice.

Sample

One hundred and thirty seven men, 75 years of age and older, with non-metastatic, localized prostate cancer were seen in the MPCC from 2004 to 2012 at MD Anderson Cancer Center and offered active surveillance. Each patient evaluated in the MPCC was self or physician-referred, recently diagnosed (within 6 months) with localized disease, and had not yet received definitive treatment. The primary outcome was treatment decision when active surveillance was a treatment offered.

Measures

The covariates evaluated for association with the decision to pursue active surveillance as the treatment were categorized as demographic/psychosocial measures, prostate cancer risk group, and health status measures.

Demographic/Psychosocial Measures

Demographic and psychosocial measures included marital status, education level and age. Visit year was evaluated as both a continuous and a categorical variable. Marital status was also obtained based on patient report. Educational status was obtained at initial assessment and recorded as reported by the patient on the new patient intake
form. The number of clinical trials in which patients agreed to participate was also included, although the number of trials offered to patients was not recorded.

**Disease Characteristics**

Prostate cancer risk group was categorized using current National Comprehensive Cancer Network (NCCN) criteria as low-risk disease of clinical tumor (T) stage T1a-T2a, Gleason score ≤ 6, and PSA < 10.0 ng/ml. Intermediate risk disease was clinical tumor stage T2b or T2c or Gleason 7(3+4) or 7(4+3), or PSA >10.0 ng/ml to 20.0 ng/ml. High-risk disease was clinical tumor stage T3-4, or Gleason score ≥ 8 (4+4) or PSA > 20 ng/mL (NCCN, 2013).

**Health Status Measures**

To characterize current health status and competing comorbidities, the Adult Comorbidities Evaluation (ACE-27) (Thomas, Neby, Balagopal, Preethi, & Sebastian, 2010) was retrospectively coded for each patient in addition to counting comorbidities by the number listed on the primary medical exam (PME) at the time of initial evaluation in the multidisciplinary prostate cancer clinic. An additional assessment for patient health was the patient self-assessment score of health which we included as the patient self-rated health status; this measure was obtained from the intake form, as completed by the patient at the initial visit.
Analysis

Descriptive statistics were generated to describe the demographic and clinical characteristics of the population. Covariates evaluated for an association with acceptance of active surveillance included age, prostate cancer risk group, educational status, marital status, number of treatments offered, method recommendations were offered, year of evaluation, and comorbidities at the time of treatment decision.

Univariate logistic regression models were conducted to determine if subjects were more likely to choose active surveillance based on specific variables of interest. Results are reported as odds ratios (OR) and adjusted OR (AOR) with 95% confidence intervals. P-value less than 0.05 was considered statistically significant. A multivariable logistic regression model was conducted and then reduced using backward selection techniques; only variables significant at the alpha = 0.05 level were included in the final model.

Results

The total number of patients included in the analysis was 137. Table 1 includes the demographic and clinical characteristics of the population. The average age of the population was 78.4 and the majority was Caucasian (84.7%). Age (OR = 1.2; p = 0.038), number of treatments offered (OR = 0.2; p < 0.001), MPCC letter, and active surveillance offer type (OR 11.7; p < 0.001) were significantly associated with the decision for active surveillance. Older patients and those that received written documentation of the recommendations were more likely to choose active surveillance.
Subjects who were offered more treatments (3-5) were less likely to choose active surveillance. No variables were significant in the multivariate model. In the final reduced model, number of treatments offered (OR = 0.1; p = 0.006) and active surveillance offer type (OR 7.2; p = 0.003) were significantly associated with the decision to accept active surveillance as treatment.

**Discussion**

The University of Texas M.D. Anderson Cancer Center’s multidisciplinary prostate cancer clinic (MPCC) opened in 2004 in the Genitourinary Center. A senior multidisciplinary prostate cancer clinic, for patients 75 years of age and older with newly diagnosed with prostate cancer was opened in 2008, following the same care format, but more tailored to specifically address the needs of the senior population. All patients meet with a specialist team comprised of either a urologist and radiation oncologist or a medical oncologist and radiation oncologist, in addition to an advanced practice registered nurse during the course of one morning. The clinic process format is designed to provide detailed education to patients, in addition to allowing time for discussion and concluding with recommendations for patient-specific treatment options. At the completion of each clinic visit, patients receive both verbal and written (Figure 1) detailed recommendations for treatment. When patients receive a consensus recommendation from the multidisciplinary team, it is written into the comment section on page 2 of the letter.

The Center noted a significant increase in acceptance of active surveillance as a treatment option in this clinic; particularly when it was offered as a consensus
recommendation. These findings mirror those of Davison & Goldberg (2011), Ollife, Davison, Pickles and Mroz (2009) and Gorin, Soloway, Eldefraway, and Soloway, (2011), that patients are primarily influenced and accepting of active surveillance as treatment based on the treating physician’s recommendations. We believe that the high level of acceptance for active surveillance, without significant correlations associated with perceived health status, comorbidities, or disease risk categorization, can be attributed to the structure of the multidisciplinary clinic which incorporated a collaborative approach to recommending treatment at the time of each specialists’ consultation, in a clinic designed for long counseling visits, in which all treatment options are discussed while providing detailed patient education on the appropriateness of why that treatment was offered. These findings confirm recently reported success for patient acceptance of active surveillance by Aizer, Paly, Zietan…& Efstathiou (2013) when provided in a multidisciplinary prostate cancer clinic. However, we also found that this population is significantly receptive to the consensus recommendation (p<0.001), particularly when the patient received this in writing. We hypothesize that in a setting in which much information and detail is shared, the written document is a powerful statement for the patient to refer back to for clarification in addition to a document he can show and share with family members.

Current nursing research also validates the concept that detailed patient education facilitates an increased acceptance of active surveillance as a prostate cancer treatment option in men with low-risk or very low-risk disease (Davison & Goldenberg, 2011,
Davison, Oliffe, Pickles, & Mroz, 2009, Oliffe, Davison, Pickles, & Mroz, 2009). A multidisciplinary clinic setting provides detailed education and guidance regarding the option of active surveillance, particularly to a senior population. This treatment setting may be a key factor to patient counseling because although prostate cancer may be classified as a low-risk, asymptomatic disease in approximately half of those patients diagnosed each year, more than ninety percent of those diagnosed patients currently go on to receive some type of curative intervention (Thompson & Klotz, 2010, Cooperberg, Broering & Carroll, 2010.). Such treatment approaches often occur because of physician and/or patient uncertainty and discomfort with non-intervention approaches such as active surveillance (Davison & Goldenberg, 2011).

Clinical Trial Enrollment

We also note that 58.4% (n=80) of this study cohort enrolled in at least one or more clinical trials. This study did not delineate the types of trials in which patients enrolled, however as a large academic university, we have previously reported on a process to incorporate discussion of clinical trials into the clinic discussion and recommendations (Madsen, Kuban, Davis…& Hoffman, 2014). Patients in this cohort were receptive to participate beyond the national average for seniors participating in clinical trials.

Providing detailed, disease specific counseling and recommendations in a multidisciplinary setting designed to accommodate lengthy counseling-specific visits, in addition to collaborative decision-making were the factors we believe contributed to
patient and family acceptance of the consensus recommendation. Physician recommendation of active surveillance is known to facilitate patient acceptance of this treatment strategy (Davison & Goldberg, 2011, Ollife, Davison, Pickles and Mroz, 2009). Additionally, patient participation in a collaborative approach to decision-making is also a factor which enhances both acceptance and long-term compliance to the treatment plan (Ollife, Davison, Pickles and Mroz, 2009).

Factors beyond patient education may have also been instrumental to acceptance of active surveillance as a treatment recommendation; Davison et al (2009) noted in their descriptive study that the more renowned the referring specialist is, the easier it was for the men to be confident with the recommendation. We believe that the letter detailing the recommendations in writing, in addition to the team consensus statement and the accessibility of the treatment team, subsequent to the visit may impact patient comfort with the recommendation.

Prostate cancer is more common among older men than younger men, and we noted that this cohort of older men were likely to participate in clinical trials. With nearly 60 percent of new cancers and more than 70 percent of cancer deaths occurring in the 65 and older population,( Smith, Reeve, Bellizzi, 2008, Siegel, Naishadham, & Jemal, 2012) advances in prostate cancer treatment are dependent on a representative sample of an older population in clinical trials. Future prostate cancer trials should continue to be inclusive and directed at enrollment for the 65 and older population; the multidisciplinary
format which incorporated trial recommendations appears to facilitate increased senior
clinical trial enrollment.

**Limitations**

The authors acknowledge several study limitations. Patients presenting to the multidisciplinary prostate cancer clinic were self-selected by individual, self-initiated referral which may reflect either increased personal or family support structure or higher levels of socio-economic status. Active surveillance has also continued to gain momentum over time as a reasonable treatment strategy for patients that meet the criteria for ‘low risk’ disease. Increasing exposure from media or friends, on the management of prostate cancer, may therefore have influenced patients’ decisions to pursue an active surveillance strategy independent of the physician team recommendation. During the course of this data collection, it should also be noted that variations in how treatments were offered also exist; most patients received a letter detailing treatment recommendations, some with a written consensus statement from the team, some with a verbal consensus statement only. Determining the best method for relaying recommendations within this patient cohort may not be possible.

Finally, it may be notable that the physicians and APRN providing treatment recommendations are salaried and administer care in an academic university setting. Without financial incentive to actively treat patients, enrollment numbers for active surveillance may be higher than the community standard where active surveillance is time-intensive with a low economic yield.
Implications for Research and Practice

Recommendations for research are further exploration into the facilitators and deterrents for senior patients exploring treatment recommendations for active surveillance. Although we found a high level of acceptance for active surveillance as a treatment, data exists that surveillance as treatment, even in a senior population, continues to be an underutilized treatment option (Cooperberg, Broering & Carroll, 2010).

Conclusions

The Senior MPCC format facilitated the process for a consensus recommendation and patients were routinely accepting of the team recommendation when it was offered in this setting. The results of this subset analysis provide support for the recommendation to develop a comprehensive strategy to educate and make consensus team recommendations to senior patients about the most appropriate, disease-specific treatments for prostate cancer based on current NCCN guidelines for active surveillance. Additionally we recommend that comprehensive, upfront evaluation of health-related factors be taken into consideration when making treatment recommendations to this senior population. Finally, we recommend that the community consider instituting an algorithm type approach to management of the senior population that incorporates the use of an advanced care practitioner, able to educate and monitor patients within a comprehensive, holistic disease management strategy.
Table 1: Demographic and Clinical Characteristics of the Population (N=137)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AGE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>137</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>78.4</td>
<td>3.1</td>
</tr>
<tr>
<td>Median (Min – Max)</td>
<td>78</td>
<td>74.5-88</td>
</tr>
<tr>
<td><strong>Risk Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Risk</td>
<td>60</td>
<td>43.8</td>
</tr>
<tr>
<td>Intermediate Risk</td>
<td>72</td>
<td>52.6</td>
</tr>
<tr>
<td>High Risk</td>
<td>5</td>
<td>3.6</td>
</tr>
<tr>
<td><strong>Comorbidities: number in PME</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>137</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>3.6</td>
<td>1.9</td>
</tr>
<tr>
<td>Median (Min – Max)</td>
<td>3</td>
<td>0-12</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>117</td>
<td>85.4</td>
</tr>
<tr>
<td>Single, widowed, divorced</td>
<td>20</td>
<td>14.6</td>
</tr>
<tr>
<td><strong>Educational Level</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not graduate HS</td>
<td>8</td>
<td>7.0</td>
</tr>
<tr>
<td>HS Graduate</td>
<td>20</td>
<td>17.4</td>
</tr>
<tr>
<td>Some College</td>
<td>18</td>
<td>15.7</td>
</tr>
<tr>
<td>College Graduate</td>
<td>31</td>
<td>27.0</td>
</tr>
<tr>
<td>Advanced Degree</td>
<td>38</td>
<td>33.0</td>
</tr>
<tr>
<td><strong>Number of Treatments Offered</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>29</td>
<td>21.2</td>
</tr>
<tr>
<td>2</td>
<td>33</td>
<td>24.1</td>
</tr>
<tr>
<td>3</td>
<td>38</td>
<td>27.7</td>
</tr>
<tr>
<td>4 or 5</td>
<td>37</td>
<td>27</td>
</tr>
<tr>
<td><strong>Self-Described Health</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unavailable Info</td>
<td>18</td>
<td>13.1</td>
</tr>
<tr>
<td>Excellent</td>
<td>17</td>
<td>12.4</td>
</tr>
<tr>
<td>Very Good</td>
<td>44</td>
<td>32.1</td>
</tr>
<tr>
<td>Good</td>
<td>45</td>
<td>32.8</td>
</tr>
<tr>
<td>Fair</td>
<td>13</td>
<td>9.5</td>
</tr>
<tr>
<td>ACE-27 Comorbidities Score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>None</td>
<td>12</td>
<td>8.8</td>
</tr>
<tr>
<td>Mild</td>
<td>82</td>
<td>59.9</td>
</tr>
<tr>
<td>Moderate</td>
<td>38</td>
<td>27.7</td>
</tr>
<tr>
<td>Severe</td>
<td>5</td>
<td>3.6</td>
</tr>
<tr>
<td>Active Surveillance Offered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Choice Menu</td>
<td>89</td>
<td>65</td>
</tr>
<tr>
<td>Consensus Recommendation</td>
<td>48</td>
<td>35</td>
</tr>
</tbody>
</table>
Figure 1: Summary Letter Provided to Patients at the Completion of the Multidisciplinary Prostate Cancer Clinic

Dear Mr. ____________:

Thank you for choosing The University of Texas MD Anderson Cancer Center Multidisciplinary Prostate Cancer Clinic for your treatment consultation and recommendations. Dr. ____________, Urologist, and Dr. ____________, Radiation Oncologist saw you in the clinic today, ____________, 2013. These doctors and their staff are referred to as your team.

The team has reviewed your medical history, biopsy, X-ray and lab tests and the results of your physical exam. The doctors recommend the following treatment options, in no particular order, for your prostate cancer:

- **Surgery**
  - Open, retropubic radical prostatectomy (removal of the prostate)
  - Robotic prostatectomy (less invasive procedure to remove the prostate)
  - With unilateral/bilateral nerve-sparing
  - Recommended Clinical Trials

- **Radiation Therapy**
  - External beam radiation therapy
  - Proton therapy
  - Brachytherapy (seed implant)
  - With hormone therapy of _____ months duration
  - Recommended Clinical Trials

- **Active Surveillance (also called watchful waiting)**
  - Recommended Clinical Trials

- **Cryotherapy (freezing of the prostate gland)**
  - Recommended Clinical Trials

- **Hormone Therapy Alone**

**About Clinical Trials**

Clinical trials are research studies that involve people. The main purpose of a clinical trial is to find a better way to prevent, diagnose or treat a disease. Clinical trials are part of a long, careful research process. Patients who participate in a clinical trial receive drugs, procedures or therapies that have already been researched in successful laboratory, animal, and/or human studies. All patients who participate in clinical trials are volunteers. They can choose to stop their participation in a clinical trial at any time.

Clinical trials are important to develop new treatments for cancer. Many of today’s standard cancer treatments are based on the results of previous clinical trials. MD Anderson Cancer Center is committed to improving the treatment outcome of every cancer patient. If there is a clinical trial that would be applicable to your treatment recommendation, it has been listed after the treatment (above).
Figure 2: AS Offering Method (Menu or Consensus (written) & Patient Decision by Year

- **AS offered**
  - Menu
  - Written

  \[ p = 0.23; \text{p-value} = 0.007 \]

- **AS chosen**
  - AS Not Chosen
  - AS Chosen

  \[ p = 0.26; \text{p-value} = 0.002 \]
Table 2: Univariate Logistic Regression Assessing Association with Choosing Active Surveillance

<table>
<thead>
<tr>
<th>Effect</th>
<th>AS not chosen (n = 42)</th>
<th>AS chosen (n = 95)</th>
<th>OR</th>
<th>95% LB</th>
<th>95% UB</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, Mean (SD) Min - Max</td>
<td>77.6 (2.2) 74.7 - 84.0</td>
<td>78.8 (3.4) 74.5 - 88.0</td>
<td>1.2</td>
<td>1.0</td>
<td>1.3</td>
<td><strong>0.038</strong></td>
</tr>
<tr>
<td># Comorbidities, Mean (SD) Min - Max</td>
<td>3.4 (1.6) 1.0 - 8.0</td>
<td>3.7 (2.0) 0.0 - 12.0</td>
<td>1.1</td>
<td>0.9</td>
<td>1.4</td>
<td>0.315</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Widowed, single, or divorced</td>
<td>3 7.1</td>
<td>17 17.9</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married or significant other</td>
<td>39 92.9</td>
<td>78 82.1</td>
<td>0.4</td>
<td>0.1</td>
<td>1.3</td>
<td>0.113</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not graduate HS</td>
<td>2 5.6</td>
<td>6 7.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HS graduate</td>
<td>8 22.2</td>
<td>12 15.2</td>
<td>0.5</td>
<td>0.1</td>
<td>3.1</td>
<td>0.459</td>
</tr>
<tr>
<td>Some college</td>
<td>2 5.6</td>
<td>16 20.3</td>
<td>2.7</td>
<td>0.3</td>
<td>23.4</td>
<td>0.376</td>
</tr>
<tr>
<td>College graduate</td>
<td>10 27.8</td>
<td>21 26.6</td>
<td>0.7</td>
<td>0.1</td>
<td>4.1</td>
<td>0.693</td>
</tr>
<tr>
<td>Advanced degree</td>
<td>14 38.9</td>
<td>24 30.4</td>
<td>0.6</td>
<td>0.1</td>
<td>3.2</td>
<td>0.526</td>
</tr>
<tr>
<td>Disease risk group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>17 40.5</td>
<td>43 45.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermediate</td>
<td>24 57.1</td>
<td>48 50.5</td>
<td>0.8</td>
<td>0.4</td>
<td>1.7</td>
<td>0.537</td>
</tr>
<tr>
<td>High</td>
<td>1 2.4</td>
<td>4 4.2</td>
<td>1.6</td>
<td>0.2</td>
<td>15.2</td>
<td>0.691</td>
</tr>
<tr>
<td>ACE 27</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>4 9.5</td>
<td>8 8.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>24 57.1</td>
<td>58 61.1</td>
<td>1.2</td>
<td>0.3</td>
<td>4.4</td>
<td>0.774</td>
</tr>
<tr>
<td>Moderate/Severe</td>
<td>14 33.3</td>
<td>29 30.5</td>
<td>1.0</td>
<td>0.3</td>
<td>4.0</td>
<td>0.960</td>
</tr>
</tbody>
</table>

56
### Self-described health

<table>
<thead>
<tr>
<th></th>
<th>Unavailable info</th>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5</td>
<td>11.9</td>
<td>13</td>
<td>13.7</td>
<td>reference</td>
</tr>
<tr>
<td>Excluded because this level predicted outcome perfectly</td>
<td>7</td>
<td>16.7</td>
<td>10</td>
<td>10.5</td>
<td>0.6</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>33.3</td>
<td>30</td>
<td>31.6</td>
<td>0.8</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>26.2</td>
<td>34</td>
<td>35.8</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>11.9</td>
<td>8</td>
<td>8.4</td>
<td>0.6</td>
</tr>
</tbody>
</table>

### Number of treatments offered

<table>
<thead>
<tr>
<th></th>
<th>1 – 2</th>
<th>3 – 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8</td>
<td>34</td>
</tr>
<tr>
<td>Number of treatments</td>
<td>19.1</td>
<td>81.0</td>
</tr>
<tr>
<td>offered</td>
<td>54</td>
<td>41</td>
</tr>
<tr>
<td></td>
<td>56.8</td>
<td>43.2</td>
</tr>
<tr>
<td></td>
<td>reference</td>
<td>reference</td>
</tr>
</tbody>
</table>

### Clinical trials

<table>
<thead>
<tr>
<th></th>
<th>None</th>
<th>consented to one trial</th>
<th>consented to 2 trials</th>
<th>consented to 3 trials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>16</td>
<td>14</td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>Clinical trials</td>
<td>38.1</td>
<td>33.3</td>
<td>26</td>
<td>4</td>
</tr>
<tr>
<td>Number of treatments</td>
<td>41</td>
<td>26</td>
<td>21</td>
<td>7</td>
</tr>
<tr>
<td>offered</td>
<td>43.2</td>
<td>27.4</td>
<td>22.1</td>
<td>7.4</td>
</tr>
<tr>
<td></td>
<td>reference</td>
<td>reference</td>
<td>reference</td>
<td>reference</td>
</tr>
<tr>
<td></td>
<td>&lt;0.001</td>
<td>0.468</td>
<td>0.535</td>
<td>0.365</td>
</tr>
</tbody>
</table>

### MDCC letter in scanned documents

<table>
<thead>
<tr>
<th></th>
<th>no letter in scanned documents</th>
<th>letter reflects consensus recommendation</th>
<th>letter with choice menu; no consensus</th>
<th>Opted for AS and did not wish to see radiation doc for consensus/may or may not have received letter</th>
<th>No letter/verbal consensus documented in PME to pursue AS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>23</td>
<td>4</td>
<td>12</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>MDCC letter in scanned documents</td>
<td>54.8</td>
<td>9.5</td>
<td>28.6</td>
<td>0.0</td>
<td>7.1</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>30.5</td>
<td>25.3</td>
<td>13</td>
<td>15.8</td>
</tr>
<tr>
<td></td>
<td>14.7</td>
<td>11.9</td>
<td>3.3</td>
<td>13.7</td>
<td>15.8</td>
</tr>
<tr>
<td></td>
<td>reference</td>
<td>reference</td>
<td>reference</td>
<td>excluded*</td>
<td>reference</td>
</tr>
<tr>
<td></td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.015</td>
<td>0.003</td>
<td>0.003</td>
</tr>
</tbody>
</table>

### AS offered

<table>
<thead>
<tr>
<th></th>
<th>Menu</th>
<th>Consensus</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>39</td>
<td>3</td>
</tr>
<tr>
<td>AS offered</td>
<td>92.9</td>
<td>7.1</td>
</tr>
<tr>
<td>Number of treatments</td>
<td>50</td>
<td>45</td>
</tr>
<tr>
<td>offered</td>
<td>52.6</td>
<td>47.4</td>
</tr>
<tr>
<td></td>
<td>reference</td>
<td>reference</td>
</tr>
<tr>
<td></td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*excluded from model because this level predicted outcome perfectly
Table 3. Multivariate Logistic Regression Assessing Association with Choosing Active Surveillance

<table>
<thead>
<tr>
<th>Effect</th>
<th>Multivariate</th>
<th></th>
<th>Reduced model</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Effect OR 95%</td>
<td>p-value</td>
<td>Effect OR 95%</td>
<td>p-value</td>
</tr>
<tr>
<td></td>
<td>LB UB</td>
<td></td>
<td>LB UB</td>
<td></td>
</tr>
<tr>
<td>Age, Mean (SD) Min - Max</td>
<td>1.2 0.9 1.5</td>
<td>0.153</td>
<td>0.9 0.6 1.3</td>
<td>0.536</td>
</tr>
<tr>
<td># Comorbidities, Mean (SD) Min - Max</td>
<td>0.9 0.6 1.3</td>
<td>0.536</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Widowed, single, or divorced</td>
<td>reference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married or significant other</td>
<td>0.3 0.0 3.1</td>
<td>0.301</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not graduate HS</td>
<td>reference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HS graduate</td>
<td>0.1 0.0 1.0</td>
<td>0.054</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>2.3 0.1 48.0</td>
<td>0.599</td>
<td></td>
<td></td>
</tr>
<tr>
<td>College graduate</td>
<td>0.1 0.0 1.5</td>
<td>0.097</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advanced degree</td>
<td>0.3 0.0 3.7</td>
<td>0.358</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease risk group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>reference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermediate</td>
<td>0.4 0.1 1.5</td>
<td>0.164</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>0.2 0.0 4.7</td>
<td>0.284</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE 27</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>reference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>0.6 0.1 5.2</td>
<td>0.635</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate/Severe</td>
<td>0.3 0.0 4.0</td>
<td>0.388</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-described health</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unavailable info</td>
<td>reference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excellent</td>
<td>0.3 0.0 8.4</td>
<td>0.443</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very Good</td>
<td>0.6 0.0 13.4</td>
<td>0.763</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>2.2 0.1 48.9</td>
<td>0.619</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------------</td>
<td>-------</td>
<td>-------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td></td>
<td>Fair</td>
<td>1.1</td>
<td>0.0</td>
<td>48.5</td>
</tr>
<tr>
<td><strong>Number of treatments offered</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 – 2</td>
<td>reference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 – 5</td>
<td>0.3</td>
<td>0.1</td>
<td>1.1</td>
<td>0.064</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clinical trials</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>reference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>consented to one trial</td>
<td>0.2</td>
<td>0.0</td>
<td>1.2</td>
<td>0.079</td>
</tr>
<tr>
<td>consented to 2 trials</td>
<td>0.3</td>
<td>0.1</td>
<td>1.7</td>
<td>0.177</td>
</tr>
<tr>
<td>consented to 3 trials</td>
<td>5.4</td>
<td>0.2</td>
<td>138.4</td>
<td>0.308</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MDCC letter in scanned documents</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no letter in scanned documents</td>
<td>reference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>letter reflects consensus recommendation</td>
<td>4.6</td>
<td>0.2</td>
<td>129.6</td>
<td>0.369</td>
</tr>
<tr>
<td>letter with choice menu; no consensus</td>
<td>6.5</td>
<td>1.2</td>
<td>34.3</td>
<td>0.028</td>
</tr>
<tr>
<td>Opted for AS and did not wish to see radiation doc for consensus/may or may not have received letter</td>
<td></td>
<td></td>
<td></td>
<td>excluded*</td>
</tr>
<tr>
<td>No letter/verbal consensus documented in PME to pursue AS</td>
<td>3.1</td>
<td>0.3</td>
<td>35.1</td>
<td>0.367</td>
</tr>
<tr>
<td><strong>AS offered</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Menu</td>
<td>reference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Written</td>
<td>9.8</td>
<td>0.5</td>
<td>197.6</td>
<td>0.138</td>
</tr>
</tbody>
</table>

*excluded from model because this level predicted outcome perfectly
References


Senior Adult Oncology. In: NCCN Clinical Practice Guidelines in Oncology; 2010.


http://www.uspreventiveservicestaskforce.org/prostatecancerscreening/prost atefinalrs.htm

U.S. Census Bureau (2012).  
http://www.census.gov/population/projections/data/national/2012/summ arytables.html
CHAPTER V

RECOMMENDATIONS FOR FUTURE STUDY

The research conducted for this dissertation was intended to add to the body of knowledge regarding the characteristics of senior men, recently diagnosed with prostate cancer who seek treatment recommendations in a multidisciplinary prostate cancer clinic in a NCI designated Cancer Center. A secondary data analysis on patients, ages 75 and older and recently diagnosed with prostate cancer and offered active surveillance was conducted, with the intent to better characterize this population.

Age, the manner in which treatment recommendations were conveyed to the patient, and the number of treatment recommendations offered, were all significant factors in the patient’s decision to choose or not choose active surveillance. Marital status or educational characteristics, risk group, comorbidities, and self-rated health status did not influence treatment decisions.

The conclusions from this secondary data analysis, are that the Senior Multidisciplinary Prostate Cancer Clinic (SMPCC) format facilitates the process for making rational, thoughtful treatment recommendations. It was also notable that this population was receptive to a consensus treatment recommendation; patients
were routinely accepting of the team recommendation when it was offered in this setting.

**Objective Data for Providers**

The complexities associated with appropriate treatment recommendations for prostate cancer treatment is magnified in the senior patient population because of the additional consideration of health related co-morbidities. Follow-up recommendations are that a systematic adoption of prospectively evaluating, measuring and scoring co-morbidities with an instrument such as the Adult Comorbidities Score (ACE-27) be adopted. Additional research studies into the prospective use of this tool at the initial assessment visit, also has potential to serve two purposes. First, to more objectively characterize the patient, thus providing information regarding baseline health issues that may impact provider treatment recommendations and second, to serve as an instructive instrument to review health risks that influence treatment recommendation acceptance as a tool for a more personalized medicine approach to treatment recommendations.

**A Qualitative Exploration of the Patient Experience**

Future considerations for study would include a qualitative exploration of why senior men choose active surveillance; although the lengthy consultation format for the multidisciplinary setting was successful in influencing patients to consider active surveillance as the treatment recommendation at this center, further research is needed to identify what aspects of the consultation were beneficial and which aspects were unnecessary or superfluous.
An additional recommendation would be an exploration of concerns and issues that patients are able to identify after the initial consultation; specifically whether patients elicited further opinions from other practitioners, family & friends? Was there any recurring or varying level of uncertainty notable during routine activities as the time passed before the next follow-up for active surveillance monitoring? Was there a follow-up time frame that was comfortable for this patient population? Was individual patient anxiety increasing or diminishing over time in relation to the diagnosis, particularly as they remained in active surveillance under routine supervision? Were there facilitators to confidence in the decision to remain on active surveillance?

Future investigation, should also include a companion analysis of the senior patient, ages 75 and older not offered active surveillance; to explore the acceptance of other therapies offered to patients. Additional exploration in this cohort may provide evidence for the multidisciplinary prostate cancer clinic format to validate consistency in this cohort’s acceptance of consensus recommendations for treatment.

Quality of life concerns, specific to the senior population should be explored; quality of life is routinely emphasized as an endpoint in clinical trials, however, although seniors are historically the most burdened population for cancer diagnosis, senior adults are consistently underrepresented in clinical trials enrollment (Puts, Monette, Girre, Wolfson, Monette, Batist & Bergman, 2010).
Active Surveillance Treatment Standardization

Finally, the development and deployment of an active surveillance algorithm for monitoring patients should be developed and consistently used in the community practice setting. The economics of active surveillance are that this treatment is known to be both labor intensive and reimbursed relatively poorly (Cooperberg, Carroll & Klotz, 2011) However, the use of an advanced practice registered nurse to monitor and educate this patient cohort, following an established treatment monitoring algorithm, would be a rational, cost effective alternative to physician supervision, while additionally providing the educational support patients require for management of their disease (Madsen & Symes, 2013).

Conclusion

The rapidly changing health care environment presents opportunity to re-evaluate the role that the advanced practice registered nurse represents in health care teams. Seniors have increasingly healthy, longer life projections and although it is well-documented that a significant percentage of this population’s prostate cancer can often be observed rather than in need of an interventional treatment, this population has multiple yet unmet needs. By partnering with physician colleagues, to manage the senior population with often many competing comorbidities, advanced practice registered nurse can work with nurse scientists to maximize the APRN role in patient management while contributing to the science of care for this ever expanding population.
REFERENCES


doi:10.3109/0284186X.2010.526634


doi:10.1097/NCC.0b013e3181d1c8ea


Klotz, L. (2010). Active surveillance for prostate cancer: Patient selection and management. *Current Oncology, 17*(Suppl. 2), S11–S17. doi:10.3747/co.v17i0.713


Konety, B.R. (2009). Prostate specific antigen screening and active surveillance in


Unpublished manuscript.

Madsen, L.T. & Symes, L. (2013). An integrative review of nursing research on


doi:10.1002/cncr.10390


Senior Adult Oncology. In: NCCN Clinical Practice Guidelines in Oncology; 2010.
Thompson, I., & Klotz, L. (2010). Active surveillance for prostate cancer. JAMA, 304, 2411–2412
http://www.uspreventiveservicestaskforce.org/prostatecancerscreening/prost atefinalrs.htm
U.S. Census Bureau (2012).
http://www.census.gov/population/projections/data/national/2012/summaryt ables.html


APPENDIX A

AN INTEGRATIVE REVIEW OF CURRENT NURSING RESEARCH ON
ACTIVE SURVEILLANCE IN A SENIOR PROSTATE
CANCER PATIENT POPULATION
<table>
<thead>
<tr>
<th><strong>AUTHOR &amp; DATE</strong></th>
<th><strong>DESIGN</strong></th>
<th><strong>SAMPLE CHARACTERISTICS / SETTING</strong></th>
<th><strong>EVALUATED INTERVENTION</strong></th>
<th><strong>STUDY CONCLUSION &amp; NURSING IMPLICATIONS</strong></th>
<th><strong>LIMITATIONS</strong></th>
<th><strong>COMMENTS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bailey, et al. (2004)</td>
<td>Randomized, Descriptive, quantitative intervention study</td>
<td>Convenience sample of 39 men, mean age 75.4, from a urology practice on the Southeast coast of US.</td>
<td>Intervention group (n=19) received 5 weekly calls, control group (n=19) received standard care F/U. Growth Through Uncertainty Scale (GTUS), Profiles of Mood States Profile - Short Form (POMS-SF), and Cantril’s Ladder quality of life measurements made at enrollment &amp; at 10 weeks.</td>
<td>Quality of life ratings and the new view of life subscale of GTUS significantly better in the intervention group. POMS-SF differed on the confusion subscale – with intervention group significant improved, p=.04.</td>
<td>Small study sample with an average enrolment in active surveillance program for 51 months at time of study.</td>
<td>Study design should evaluate nursing intervention at time of initial active surveillance enrollment for a multitude of reasons.</td>
</tr>
<tr>
<td>Bailey, et al. (2007)</td>
<td>Qualitative, descriptive study</td>
<td>Purposeful sample of 10 men ranging from 64 to 88 years of age, within 12</td>
<td>Detailed, single interviews to explore concerns of older men</td>
<td>Additional evidence support that a program of active</td>
<td>Small sample size, significant age range might</td>
<td>A follow-up interview 6 to 12 months later would</td>
</tr>
</tbody>
</table>
months of prostate cancer diagnosis, from a urology practice on the Southeast coast of US.

undergoing a surveillance program.

surveillance contributes to patient uncertainty about disease state.

Study findings provide means to expand Mishel’s Uncertainty of Illness Model and devise nursing interventions to address uncertainty in this population.

influence findings.

provide additional information or support for findings.

<p>| Bailey, et al. (2009) | Descriptive, repeated measure, survey study (Abstract) | Convenience sample of 8 men, mean age 75.4, from one tertiary medical center Urology practice. | Repeated measures, survey study to assess psychosocial trajectory in men undergoing active surveillance using telephone interview and Profiles of Mood | Preliminary data; provides indications for appropriate timing to initiate and expound on nursing education and intervention in regard to | Small group, preliminary data. | No follow-up data located in search by author or topic. |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Study Design</th>
<th>Sample Population</th>
<th>Methodology</th>
<th>Findings</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bailey, et al. (2011)</td>
<td>Secondary data analysis</td>
<td>Four convenience samples of men (total N= 42), mean age of 76.6 with low-risk cancer and undergoing active surveillance. Sample #1 - N=10, Sample #2 - N=19, Sample #3 - N=5, Sample #4 - N=8.</td>
<td>Secondary analysis to test and evaluate the reliability of Mishel Uncertainty in Illness Scale - Community Form (MUIS-C) for use in active surveillance cohort of men with prostate cancer.</td>
<td>Confirmation by Cronbach’s alpha (.908) that full MUIS-C was a valid and reliable instrument for measuring uncertainty in men undergoing active surveillance for treatment management of low-risk prostate cancer.</td>
<td>Small, varied populations pooled for a secondary analysis. MUIS –C and Mishel Uncertainty in Illness theoretical framework provide foundation for future exploratory studies.</td>
</tr>
<tr>
<td>Davison, et al. (2009)</td>
<td>Interpretive, descriptive, qualitative design</td>
<td>25 patients, mean age of 66, on active surveillance with low-risk disease.</td>
<td>Identify and describe decision making factors for men considering active surveillance for most influential factors influencing agreement for active surveillance.</td>
<td>Small sample size and urban setting with extensive experience in active.</td>
<td>Nurses must be familiar with appropriate treatment options for</td>
</tr>
<tr>
<td>Davison, (2011)</td>
<td>Cross-sectional descriptive study. (Follow-up survey analysis based on results of 2009 Qualitative study)</td>
<td>73 men; survey of men, mean age of 64.5, who elected to participate in AS in the past 10 years, with confirmed low-risk disease.</td>
<td>Cross-sectional descriptive study; survey sent to 121 men; 73 (60%) elected to participate. Average age was 64.5 at time of diagnosis. To examine process of decision-making in patients currently under treatment for low-risk prostate cancer with active surveillance.</td>
<td>Physician’s recommendation most important influencing factor in decision. 82% comfortable with decision, 90% satisfied with decision to be on active surveillance. 55% report not anxious about cancer progression during active surveillance.</td>
<td>Limited by un-validated survey questionnaire and pool of patients from one clinic. Extended range of treatment length should also be a consideration.</td>
</tr>
<tr>
<td>Ervik, et al. (2010).</td>
<td>Qualitative, exploratory study.</td>
<td>Mixed population of 10 participants; 3 on active surveillance, 7 on androgen ablation.</td>
<td>Exploratory study to describe patient cancer perceptions and experiences when a curative treatment intervention is not recommended.</td>
<td>Patients felt they had inadequate information about disease process. Limited time with care provider added to the sense of uncertainty. Spouses were primary means of emotional support.</td>
<td>Limited by small sample size and mixed population; active surveillance patients potentially have differing concerns than those on androgen ablation.</td>
</tr>
<tr>
<td><strong>Hedestig, et al. (2003).</strong></td>
<td>Qualitative, phenomenological – hermeneutic approach</td>
<td>Seven patients, ranging in age 62-69, selected from Swedish database.</td>
<td>In-depth interview to explore the meaning of being a male living with untreated prostate cancer.</td>
<td>Patients felt isolated and uncertain related to prognosis; ‘living with a constant threat’ although known to have localized disease and were instrumental in choice for active surveillance. Concerns regarding sexual problems; interpreted by patients as both a burden a consequence of prostate cancer.</td>
<td>Small study group results not generalizable but provides data for a follow-up nursing intervention.</td>
</tr>
<tr>
<td><strong>Hegarty, et al. (2011).</strong></td>
<td>Review article</td>
<td>Literature review of evolution of Active Surveillance as a treatment option – 2001-2011.</td>
<td>Review on current science of active surveillance as treatment option in prostate cancer.</td>
<td>‘The nurse has an important role in supporting men on the active surveillance journey’.</td>
<td>None noted; a comprehensiv e review from nursing perspective.</td>
</tr>
<tr>
<td>Wallace - Kazer, et al. (2010).</td>
<td>Proposal for expansion of a theory based intervention</td>
<td>Patients with a low-risk prostate cancer diagnosis participating in active surveillance.</td>
<td>Proposal to expand Mishel’s Intervention to Self-Manage Uncertainty Associated with Prostate Cancer (UMI) to the active surveillance population of patients.</td>
<td>Not yet implement; presented as a proposal with scientific rationale and theoretical framework.</td>
<td>None noted</td>
</tr>
<tr>
<td>Study</td>
<td>Design and Setting</td>
<td>Methods</td>
<td>Findings</td>
<td>Limitations</td>
<td>Implications</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Wallace-Kazer, et al. (2011).</td>
<td>Qualitative, exploratory, focus group study</td>
<td>Qualitative, exploratory study of 7 active surveillance participants ≥ 65 years of age; mean age of 70.</td>
<td>Participants had insufficient education about their disease and the internet was the primary source of information, men did not use traditional means of support such as groups, spouses or extended family.</td>
<td>Small sample size limits generalizability.</td>
<td>Senior population used internet to gather information and monitor/compare disease status.</td>
</tr>
<tr>
<td>Wallace-Kazer, et al. (2011).</td>
<td>Pilot study; single-subject design</td>
<td>9 patients, mean age 72, on active surveillance.</td>
<td>Confirmed intervention feasibility, showed positive trends in regard to intervention impact and had overall good acceptability by patient population.</td>
<td>Small sample size limits generalizability.</td>
<td>Well-designed pilot study to test feasibility of intended internet intervention.</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Sample Description</td>
<td>Study Design and Findings</td>
<td>Supporting Evidence</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-------------------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td>Oliffe, JL, et al. (2009)</td>
<td>Descriptive, qualitative study</td>
<td>Convenience sample of 25 men, mean age 68, with a low-risk prostate cancer diagnosis participating in active surveillance.</td>
<td>Qualitative, exploratory study to explore uncertainty and self-management strategies in men who are on an active surveillance/watchful waiting treatment approach for low-risk prostate cancer. Participants self-manage uncertainty by either compartmentalizing the disease by solitary ‘stoicism’, or commit to proactively addressing disease uncertainty with complementary interventions such as diet modifications. Self-selected convenience sample population could bias findings. Confirms existing data that patients require more education and support of disease process.</td>
<td>Supports Mishel’s use of Uncertainty on Illness theoretical framework for the active surveillance patient.</td>
<td></td>
</tr>
<tr>
<td>Walsh Scura, et al. (2004).</td>
<td>Prospective, randomized pilot study with supplemental qualitative information gathering.</td>
<td>17 men, mean age 66, with newly diagnosed, clinically localized prostate cancer.</td>
<td>17 men with clinically localized prostate cancer randomized to receive telephone support in addition to mailed educational materials for 12 months (experimental) vs. mailed educational materials (treatment) alone. Impact of telephone support on physiologic, emotional,</td>
<td>No statistical significance between experimental and treatment group although qualitative interview supported use of telephone support in assisting men to adapt during the 12 months post treatment.</td>
<td>Pilot study (small group) in combination with mixed methods (qualitative and quantitative) may impact statistical results.</td>
</tr>
</tbody>
</table>
functional and social adaptation to diagnosis and treatment was assessed with FACT-CA, Symptom Experience Scale-Prostate, and Relationship Change Scale in addition to qualitative interviews.
APPENDIX B
IRB APPROVAL FORMS
0107602

April 16, 2014

Lydia Madsen

Houston, TX

Dear Ms. Madsen:

I have received and approved the prospectus entitled *Patient Characteristics of Men, 75 Years and Older, Diagnosed with Organ-Confined Prostate Cancer, Who Receive Treatment Recommendations in a Multidisciplinary Prostate Cancer Clinic (MPCC)* for your Dissertation research project.

Best wishes to you in the research and writing of your project.

Sincerely yours,

Ruth A. Johnson, Ph.D.
Associate Dean of the Graduate School

kjb

cc:  Dr. Sandra Cesario, Nursing, Houston
     Dr. Brenda Binder, Interim Associate Dean, Nursing, Houston
STUDY MODIFICATION REQUEST

Principal Investigator: Madsen, Lydia  Protocol #: 17414  Campus: Houston

Title of Study:
Patient characteristics of men, 75 years and older, diagnosed with organ-confined prostate cancer, who receive treatment recommendations in a multidisciplinary prostate cancer clinic (MPCC)

Description of Modification Requested:
Title Change ONLY, based on recommendation of the Dissertation Committee, to the following title:
Exploring the Risk of Overtreatment in Older Men with Prostate Cancer: A Descriptive Analysis of Active Surveillance.

List of Attachments:

Corrected Application with amend...

Approved by the Texas Woman's University Institutional Review Board
Date: [signature]
August 07, 2013

Ms. Lydia T. Madsen
College of Nursing
6700 Fannin Street
Houston, TX 77030

Dear Ms. Madsen:

Re: Patient characteristics of men, 75 years and older, diagnosed with organ-confined prostate cancer, who receive treatment of recommendations in a multidisciplinary prostate cancer clinic (MPCC) (Protocol #: 17414)

The above referenced study has been reviewed by the TWU Institutional Review Board (IRB) and was determined to be exempt from further review.

Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any unanticipated incidents. If you have any questions, please contact the TWU IRB.

Sincerely,

[Signature]

Carolyn Kelley, PT, DSc, NCS
Institutional Review Board - Houston

cc. Dr. Karen Lyon, College of Nursing - Houston
    Sandra Cesario, PhD, College of Nursing - Houston
    Graduate School
APPENDIX C
PUBLICATION RELEASE LETTER
Madsen, Lydia T

From: Mike Minjock <mminjock@ons.org>
Sent: Monday, May 19, 2014 9:03 AM
To: Madsen, Lydia T
Subject: RE: Permission Request for Publication as portion of Dissertation

Dear Lydia,

After reviewing the additional information you have provided, we grant you permission to submit your article as part of your dissertation. Please make sure that the your submission clearly indicates the source of the article, including author(s), journal name, article name, year of publication, and volume, issue, and page numbers. If you have any other questions, please let me know.

Sincerely,

Mike Minjock
Production & Permissions Manager, Publishing
Oncology Nursing Society
125 Enterprise Drive
Pittsburgh, PA 15275-1214
+1-412-856-6251 (phone)
+1-412-856-6193 (fax)
mminjock@ons.org

From: Madsen, Lydia T [mailto:lmadsen@mdanderson.org]
Sent: Friday, May 16, 2014 4:40 PM
To: Mike Minjock
Subject: RE: Permission Request for Publication as portion of Dissertation

Hi Mike,

I believe that to have access to Proquest, the Library must have a subscription and then subsequently able to access a dissertation; I do not think it is generally available.

However, because this is so new to me and because I have the ability to access my information through either M.D. Anderson Cancer Center or Texas Woman’s University, I thought perhaps this screen shot (see below) might best answer your question.

Alternately, here is my question: if I am not able to put my article into my dissertation as it was published, are you able to tell me the extent of change I must make to the content so that I do not plagiarize myself? Thank you so much for responding so quickly to my previous query. I am planning to do my final defense next month and I am trying to determine if I need to re-write my entire review/Chapter 2 or if I can salvage much of it because of the publication concerns.

Kind regards,

Lydia Madsen
From: Mike Minjock [mailto:mmijnock@ons.org]
Sent: Friday, May 16, 2014 3:25 PM
To: Madsen, Lydia T
Subject: RE: Permission Request for Publication as portion of Dissertation

Dear Lydia,

Thank you for your request. Could you please tell me if your ONF article will or would eventually become available on the open internet due to its prospective publication as part of the dissertation via ProQuest. That is, we would be more than happy to grant permission as long as the article would not become freely available on the internet. Please let me know. I apologize for my lack of knowledge related to the ProQuest dissertation service.

Sincerely,

Mike Minjock
Production & Permissions Manager, Publishing Oncology Nursing Society
125 Enterprise Drive
Pittsburgh, PA 15275-1214
+1-412-869-6251 (phone)
+1-412-869-6163 (fax)
mmijnock@ons.org

Pharmacology Update:
Integrating Advances Into Practice
Register Now!
June 27 – 9 am – 6:15 pm ET

From: Madsen, Lydia T [mailto:lmadsen@mdanderson.org]
Sent: Friday, May 16, 2014 8:51 AM
To: pubpermissions
Cc: scesario@mail.twu.edu; Madsen, Lydia (LMadsen@mail.twu.edu)
Subject: Permission Request for Publication as portion of Dissertation
Importance: High
Dear Oncology Nurse Forum Publisher,

I would like to deposit the full text of the following article in my dissertation to meet the graduate requirements at Texas Woman's University, Denton, Texas.

CHAPTER II (Review of the Literature) SUBMITTED FOR PUBLICATION

An integrative review of nursing research on active surveillance in a senior prostate cancer patient population


Lydia T. Madsen, MSN, RN, AOCNS & Lene Symes, Ph.D.

I am contacting you as the publisher in order to seek your permission to include this article as a chapter in my dissertation. The requested permission extends to any future revisions and editions of my dissertation and to the prospective publication of my dissertation by ProQuest through its UMI® Dissertation Publishing business. I would be grateful if you could return this email to me with your permission to use the aforementioned article.

I have also attached your permissions request form as per your online instructions.

Yours sincerely
Lydia T. Madsen
Ph.D. Nursing Student
Texas Woman's University

imadsen@mdanderson.org
imadsen@twu.edu

This message (and any associated files) is intended only for the use of the individual or entity to which it is addressed and may contain information that is confidential, subject to copyright or constitutes a trade secret. If you are not the intended recipient you are hereby notified that any dissemination, copying or distribution of this message, or files associated with this message, is strictly prohibited. If you have received this message in error, please notify us immediately by replying to the message and deleting it from your computer. Messages sent to and from us may be monitored. Internet communications cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. Therefore, we do not accept responsibility for any errors or omissions that are present in this message, or any attachment, that have arisen as a result of e-mail transmission. If verification is required, please request a hard-copy version. Any views or opinions presented are solely those of the author and do not necessarily represent those of the company.

This message (and any associated files) is intended only for the use of the individual or entity to which it is addressed and may contain information that is confidential, subject to copyright or constitutes a trade secret. If you are not the intended recipient you are hereby notified that any dissemination, copying or distribution of this message, or files associated with this message, is strictly prohibited. If you have received this message in error, please notify us immediately by replying to the message and deleting it from your computer. Messages sent to and from us may be monitored. Internet communications cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. Therefore, we do not accept responsibility for any errors or omissions that are present in this message, or any attachment, that have arisen as a result of e-mail transmission. If verification is required, please request a hard-
copy version. Any views or opinions presented are solely those of the author and do not necessarily represent those of the company.
APPENDIX D
VERIFICATION OF CHAPTER IV SUBMISSION
Madsen, Lydia T

From: onbehalfof-vkattouf-ons.org@maruscripcentral.com on behalf of vkattouf@ons.org
Sent: Monday, June 23, 2014 7:51 PM
To: Madsen, Lydia T
Subject: Manuscript Entitled EXPLORING THE RISK OF OVERTREATMENT IN OLDER MEN WITH PROSTATE CANCER: A DESCRIPTIVE ANALYSIS OF ACTIVE SURVEILLANCE IN A MULTIDISCIPLINARY PROSTATE CANCER CLINIC SETTING

Dear Ms. Madsen:

Your manuscript, "EXPLORING THE RISK OF OVERTREATMENT IN OLDER MEN WITH PROSTATE CANCER: A DESCRIPTIVE ANALYSIS OF ACTIVE SURVEILLANCE IN A MULTIDISCIPLINARY PROSTATE CANCER CLINIC SETTING," has been received by the Oncology Nursing Forum and is assigned to identification number ONF-2014-0716. As soon as all required electronic author understanding forms have been completed, it will be sent to reviewers for consideration for publication. Please allow 4-6 weeks for the review. The Oncology Nursing Forum accepts manuscripts only if the material has not been published elsewhere and is not being considered for publication by any other journal.

Thank you.

Sincerely,
Oncology Nursing Forum Editorial Office