

**DEFINING THE ADVANCED PRACTICE NURSING ROLE  
IN ADVANCED PROSTATE CANCER:  
APPLICATION OF A SYSTEMATIC PATIENT-FOCUSED APPROACH**

By

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TITLE: Defining The Advanced Practice Nursing Role in Advanced Prostate Cancer:  
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## **ABSTRACT**

### **Defining the Advanced Practice Nursing (APN) Role in Advanced Prostate Cancer: Application of a Systematic Patient-Focused Approach**

#### ***Purpose***

To identify priorities for defining an APN role in advanced prostate cancer. The principles of participatory action research and knowledge of APN were used to adapt two role implementation frameworks to provide a patient-focused approach to role development. Two studies were conducted; the first to examine health related quality of life (HRQL) and health problems across a continuum of prostate cancer care; and the second to examine the prevalence and impact of mental health disorders on HRQL and health care costs.

#### ***Patients and Methods***

Study one involved five groups of patients with prostate cancer receiving care at a comprehensive cancer centre including: Early Stage Newly Diagnosed (E-NEW), Early Stage On Treatment (E-RX), Early Stage Receiving Follow-up Care (E-FLP), Advanced Hormone Sensitive (A-HS), and Advanced Hormone Refractory (A-HR). 631 patients attending clinic appointments were approached and 551 (87%) participated in the study. HRQL was examined using the Functional Assessment of Cancer Therapy-Prostate scale. Patients identified priority health needs using a checklist of possible health problems. Regression analysis was used to identify patient characteristics that predicted HRQL.



A sample of 99 consecutive patients with advanced prostate cancer at the same cancer centre participated in Study two. Participants completed a questionnaire assessing mental health disorders, HRQL, and health costs through a telephone interview.

### ***Results***

A-HS patients experienced HRQL and health problems similar to patients with early stage disease. A-HR patients had significantly poorer HRQL ( $p < 0.001$ ), more severe health problems, and different priority needs compared to other groups. In addition to urinary and sexual function, common health problems across patient groups related to comfort, coping, fatigue, and decreased physical ability. Disease status, prostatic specific antigen, and a history of mental health problems were modest predictors of poor HRQL. 19% of patients with advanced prostate cancer were found to have a mental health disorder. The presence of anxiety and/or depression was associated with significant declines in HRQL. Higher health care costs were observed in patients with mental health disorders and those receiving palliative care.

### ***Conclusions***

In applying a patient-focused approach, new opportunities for defining the APN role and improving care delivery in advanced prostate cancer were identified. The supportive care role of the APN involving early intervention and health promotion across the continuum of prostate cancer care was envisioned for key foci related to prostate cancer health, mental health, and functional capacity. Recommendations for developing the clinical and non-clinical aspects of the APN role in advanced prostate cancer are provided along with recommendations for future research.

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*“Keep the Faith....*

*When the Mind is Ready, a Teacher Appears”.\**

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\* An old Zen expression. From: S. Gordon & H. Brecher (1990). *Life is Uncertain...Eat Dessert First*. New York: Doubleday.

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## CHAPTER 1: INTRODUCTION

### Advanced Practice Nursing: A Proposed Strategy for

#### Meeting the Health Needs of Patients With Advanced Prostate Cancer

*“So, perhaps nursing and society alike have sung enough of the sad songs to itself and it is time for a joyful song, transforming ‘what might have been’ and has not been, into what ‘might be’ for all of our future” (Jean Watson, 1995, p. 81).*

This thesis is about defining an advanced practice nursing role for patients with advanced prostate cancer receiving care at a regional cancer centre. There is consensus among Canadian patients, families, and health care providers that new approaches to care and the delivery of health care services are required for those affected by prostate cancer, especially related to palliative and supportive care health needs (Fitch, Johnson, Gray, & Franssen, 1999; Gray et al., 1997; National Prostate Cancer Forum [NPCF], 1997). As the most common cancer in men and the second leading cause of male cancer-related deaths, prostate cancer poses an enormous burden on the Canadian health care system (National Cancer Institute of Canada [NCIC], 2001). The incidence of prostate cancer has doubled in the past 30 years and continued increases are anticipated over the next two decades (Levy, Gibbons, Collins, Perkins, & Mao, 1993; NCIC, 2001). Introducing a new advanced practice nursing role has been identified as a potential strategy for achieving patient health goals and meeting the increasing health care service demands of this rapidly growing cancer population.

The term advanced practice nursing (APN) refers to a specific field of nursing which includes a variety of specialized roles such as clinical nurse specialists, primary

care nurse practitioners, and acute care nurse practitioners. Advanced practice nurses function in an expanded capacity and intervene at several levels including that of the patient, organization, nursing profession, and broader health care system (American Nurses Association [ANA], 1995; Brown, 1998; Styles & Lewis, 2000). This broad definition of APN reflects the challenge the nursing profession has experienced in defining the roles that make up this unique field of nursing. APN roles are the chameleon of the nursing profession, continually evolving in response to the changing health needs of society and demands of health care systems. As a result there is no agreement within the nursing profession regarding a singular definition of *advanced nursing practice* or one view of what advanced practice nurses do.

The Canadian Nurses Association's Framework ([CNA], 2000) provides the definition of *advanced nursing practice* for this thesis. The CNA (2000) defines *advanced nursing practice* (ANP) as "...an umbrella term. It describes an advanced level of nursing practice that maximizes the use of in-depth nursing knowledge and skill in meeting the health needs of clients (individuals, families, groups, populations or entire communities). In this way ANP extends the boundaries of nursing's scope of practice and contributes to nursing knowledge and the development and advancement of the nursing profession" (p. 1).

The Canadian Association of Nurses in Oncology ([CANO], 2002) expands on this definition to define the *advanced oncology* nurse as a "...Registered Nurse, prepared with a minimum of a Master's degree in nursing, who has acquired in-depth knowledge and clinical experiences in oncology" (p. 61). *Advanced oncology nursing roles*

encompass five domains of practice including: direct patient care, education, research, organizational leadership, and scholarly/professional development (CANO, 2002).

There is growing interest in the use of APN roles because of the flexibility they offer in the delivery of health care services and ability to address increasingly complex health problems and respond to a more comprehensive range of health needs (Alcock, 1996; Dunn & Nicklin, 1995). There is also an expanding body of literature documenting the benefits of APN roles for patient and health care systems outcomes. Two meta-analyses have demonstrated that primary care nurse practitioners provide equivalent care to that of physicians with respect to assessment, diagnostic accuracy, and health outcomes (Brown & Grimes, 1995; Horrocks, et al., 2002). These studies also found that primary nurse practitioner care was associated with higher patient satisfaction and better quality of care related to patient education, communication, and documentation of records. In acute tertiary care settings, seven randomized controlled trials of APN transitional care for high risk and/or complex patient populations, have consistently demonstrated improved patient outcomes and decreased health care costs compared to traditional medical care alone (Brooten et al., 2002).

In randomized controlled trials of patients with breast cancer, advanced lung cancer, and prostate or bladder cancer, those who received APN care also demonstrated improved outcomes related to mental health, quality of life, performance status, symptom management, patient satisfaction, and reduced health care costs compared to conventional medical care (Bredin et al., 1999; Corner, Plant, A'Hern, & Bailey, 1996; Faithfull, Corner, Meyer, Huddart, & Dearnaley, 2001; Helgesen, et al., 2000; Moore et al., 2002;

Ritz et al., 2000). For patients with prostate cancer, APN roles have also been found to be safe and have equivalent medical outcomes compared with conventional care (Faithfull, et al., 2001; Helgesen et al., 2000).

Health care planners and decision-makers are considering implementing new APN roles for a variety of cancer populations in an effort to meet the rising demand for cancer care at a time when there is a shortage of health care providers with oncology expertise (Cancer Care Ontario [CCO], 2001; Fitch & Mings, 1999; Systemic Therapy Program [STP], 1999). Continued growth in the demand for cancer services is expected over the next 10 years due to the rising incidence of cancer associated with an aging population, the increasing complexity of treatment, and advances in technology (Cancer Care Ontario [CCO], 2001b; NCIC, 2001). Thus, APN roles are also being viewed as part of a long-term human resource strategy for ensuring future capacity in meeting the health needs of patients affected by cancer.

In Canada, the majority of cancer and non-cancer related APN roles have evolved from physician replacement/support models and are found in acute tertiary care settings rather than ambulatory regional and/or community cancer centres where most patients with prostate cancer are likely to receive the bulk of their care (Dunn & Nicklin, 1995). As a result, there has been limited experience in developing and evaluating specialized oncology APN roles in outpatient settings. The implementation of new APN roles is also challenged by the lack of consensus within the nursing profession regarding scope of APN roles and the developmental state at which national standards for education, role

expectations, or competencies currently exist (Alcock, 1996; CANO, 2002; CNA, 2000; Howlett & Tamlyn, 1998).

Studies evaluating the introduction of new APN roles identify several factors related to role autonomy, role clarity, role functions, and educational preparation that can inhibit development of the full potential and optimal utilization of these roles (Beal, Steven, & Quinn, 1997; Centre for Nursing Studies [CNS], 2001; Dunn & Nicklin, 1995; Irvine et al., 2000; Irvine, Sidani, & McGillis Hall, 1998; Woods, 1998). These data suggest that a more systematic approach to role development and use of strategies to support the introduction of APN roles is required. There is also a need for APN role development and evaluation to focus on patient needs and health care systems issues (Irvine et al., 1998; Dunn & Nicklin, 1995).

There is significant morbidity associated with prostate cancer; yet limited research in defining the APN role to address these issues. A recent Canadian survey indicates that a large proportion of men with prostate cancer have unmet needs related to information, sexual function, pain, treatment side effects, urinary incontinence, and emotional well-being (Fitch et al., 1999; Gray et al., 1997). This study, as the first of its kind in Canada, provides important information and insight into the supportive care needs of men with prostate cancer. However, its generalizability is limited by non-random sampling resulting in an under representation of patients with advanced disease and those receiving care at cancer centres.

Despite improved methods for screening and early detection, at least 20% of patients have advanced disease at the time of diagnosis and about 30% of early stage

patients subsequently develop metastatic disease (Landis, Murray, Bolden, & Wingo, 1999; Levy et al., 1993). This population of prostate cancer patients is perceived to have more severe, intensive, and complex health care needs and requires a greater number of health care services compared to patients with localized disease. Aggressive supportive care is required to manage symptoms related to bone metastases and soft tissue disease including pain, fatigue, cachexia, and urinary and bowel obstruction (Esper & Redman, 1999; Fossa et al., 1990; Kornblith et al., 1994).

There is need for research to better understand the impact of prostate cancer on the individual and family, and to improve the delivery of supportive and palliative care services (NPCF, 1997). A substantial proportion of unmet needs for patients affected by prostate and other types of cancer relate to practical, psychosocial, coping, and information needs rather than disease or treatment issues (CCS, 1990; Daiter, et al, 1988; Fitch et al., 1999; Gray et al., 1997; Houts et al., 1986; Guadagnoli & Mor, 1991; Wingate & Lackey, 1989). Patients with advanced prostate cancer may also experience greater psychological distress and be at higher risk for developing mental health problems (Breitbart, Bruera, Chochinov, & Lynch, 1994; Cassileth et al., 1984; Roth et al., 1998).

The overall purpose of this thesis is to utilize a systematic patient-focused approach to defining an APN role for patients affected by advanced prostate cancer and who are receiving care at a regional cancer centre. The main premise of this thesis is that the APN role should be developed within the context of a supportive care framework that involves an emphasis on patient health and quality of life, rather than a physician replacement model focused on disease and illness. Opportunities for APN to impact on

patient and health care system outcomes lie within a role focused on maximizing health and well-being that is complementary to existing health care provider roles (Corner, 1996; Pinelli, 1997; Watson, 1995; 1999). A second assumption of this thesis is that the supportive care role of the APN for patients with advanced prostate cancer may require a strong mental health focus.

The CCO Model of Supportive Care provided the background for framing the development of the APN role and specific thesis objectives (Fitch et al., 1994). In this model, Supportive Care is defined as the “provision of the necessary services as defined by those living with or affected by cancer to meet their physical, social, emotional, informational, psychological, spiritual, and practical needs during the pre-diagnostic, diagnostic, treatment, and follow-up phases of cancer care, encompassing issues of survivorship, palliation, and bereavement” (Fitch, 1994, p. 15). Key aspects of this model are the multidimensional nature of health care needs, recognition of the uniqueness of needs for individual patients and families, and the change in needs across the cancer continuum.

The specific objectives of this thesis are to:

1. Develop a framework to guide the development of an APN role for patients with advanced prostate cancer based on an analysis of the current literature regarding the implementation and evaluation of new APN roles.
2. To identify, describe, and compare health related quality of life (HRQL) and patient perceptions of priority health problems across the continuum of care for patients with prostate cancer who receive care at a regional cancer centre.



3. To identify, describe, and examine the prevalence of mental health problems and potential relationship between mental health, HRQL, and health care costs for patients with advanced prostate cancer.
4. To define, from a patient perspective, targeted priorities for the APN role related to advanced prostate cancer, and to provide recommendations for future role development, implementation, and evaluation.

### **Thesis Outline**

This thesis contains four manuscripts representing my work on defining a patient focused APN role for advanced prostate cancer. The manuscript in Chapter 2 provides an analysis and summary of the literature related to the introduction of new APN roles. Six issues impacting on APN role development and implementation are identified including: confusion regarding APN terminology; failure to clearly define APN roles and goals; role emphasis on physician replacement/support; underutilization of APN role domains; failure to address environmental elements that undermine APN role; and limited use of evidence-based approaches to guide the development, introduction, and evaluation of APN roles. Recommendations for improving the future introduction of APN roles are identified.

In Chapter 3, the manuscript outlines the PEPPA Framework, developed to provide a patient-focused, evidence-based, and participatory process for implementing and evaluating APN roles. Two existing frameworks for the introduction of APN and other health care provider roles are adapted to create a new framework designed to

overcome known barriers to role implementation. The principles of participatory action research (PAR) also directed the construction of the PEPPA Framework.

Chapters 4 and 5 are manuscripts for two studies that endeavour to operationalize one component of the PEPPA Framework; an assessment of the health problems experienced by patients with advanced prostate cancer. This evaluation of health problems is undertaken from the perspective of patients as one of many stakeholder groups relevant to the current model of prostate cancer care at a regional cancer centre.

The study summarized in Chapter 4 examines health related quality of life across the continuum of prostate cancer care for five distinct groups of patients. The aim of this study was to examine the health problems of patients with advanced stage disease within the context of a continuum of prostate cancer care from the time of diagnosis to palliation. Patient perceptions of priority health problems are also identified. The study identifies that there are common health concerns affecting patients with prostate cancer regardless of their stage of disease or exposure to prostate cancer treatment. However, patients with advanced hormone refractory prostate cancer have uniquely different and more severe health problems related to most aspects of HRQL, including emotional well-being compared to patients with early stage or advanced hormone sensitive disease.

In Chapter 5, HRQL and the psychological well-being of patients with advanced prostate cancer are examined in more detail. This study estimated the prevalence of mental health disorders and explored relationships between mental health, HRQL, and health care costs. A small but substantial number of patients (19%) were identified as

having a major affective or anxiety disorder. Patients with mental health problems were also more likely to have poorer HRQL and generate higher health costs.

The thesis concludes with Chapter 6 and a synthesis of the results from the two quality of life studies. Based on these data, a model of supportive care for patients with advanced prostate cancer is proposed and identifies targeted patient health needs as the foundation for developing an APN role for advanced prostate cancer. The results of these studies are discussed in relation to the PEPPA Framework and recommendations for the introduction and evaluation of APN roles in prostate cancer care are provided.

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## CHAPTER 2

### Preamble

Spitzer (1978) identified that the introduction of new health care provider roles is a complex process and proposed an evidence-based approach, similar to that for evaluating new drug therapies, to guide role implementation and evaluation. While this approach can be applied to the introduction of any health care provider role, it does not address role implementation challenges unique to Advanced Practice Nursing (APN). Chapter I indicated that several factors related to role autonomy, role clarity, role functions, and educational development represent barriers to successful APN role implementation (Beal et al., 1997; Centre for Nursing Studies, 2001; Dunn & Nicklin, 1995; Irvine et al., 2000; Irvine et al., 1998).

This chapter provides an in-depth analysis of the literature regarding APN implementation and evaluation and identifies strategies for promoting the successful introduction of new APN roles. The chapter is a reformatted manuscript that has been submitted for publication to the Journal of Advanced Nursing. Six recurring themes posing barriers to APN role implementation were identified from the literature. Recommendations for the future introduction of APN roles are discussed and provide the basis for the development of the conceptual framework in Chapter 3. These recommendations and the framework were then used to inform the process for developing an APN role for patients with advanced prostate cancer.

### **Contributions**

This manuscript was a major component of my thesis work. I originated the idea, reviewed and analyzed the APN literature, and wrote the manuscript.

As a member of my thesis committee, Alba DiCenso reviewed and provided comments on the content and format of the draft manuscript. Dr. DiCenso has applied and revised Spitzer's framework for the introduction and evaluation of the primary care nurse practitioner and neonatal nurse practitioner roles in Ontario. Her experience in conducting research on the development and evaluation of APN roles, and insight and feedback on the manuscript were invaluable.

In her role as my thesis supervisor, Gina Browne reviewed and provided comments on several draft copies of the manuscript. As an advanced practice nurse in the field of mental health, her insight into the complementary benefits of the APN role provided additional strength to the paper.

Janet Pinelli is a member of the graduate nursing faculty at McMaster and is a neonatal nurse practitioner. She has published extensively regarding the development and evaluation of neonatal nurse practitioner roles and is involved at the national level in research regarding APN role development. In addition to providing comments on the draft manuscript, my discussions with Dr. Pinelli were helpful in clarifying the terminology used to describe APN roles.

**Advanced Practice Nursing Roles Part I:**

**Issues Influencing Role Development, Implementation, and Evaluation**

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## **Abstract**

### ***Aim of the Paper***

The purpose of this paper is to identify and clarify six issues influencing the introduction of advanced practice nursing (APN) roles. These issues include the: confusion regarding APN terminology, failure to clearly define APN roles and goals, role emphasis on physician replacement/support, underutilization of all APN role domains, failure to address environmental elements that undermine APN roles, and limited use of evidence-based approaches to guide the development, introduction, and evaluation of APN roles.

### ***Rationale/Background***

The restructuring of health care systems in many countries has led to substantial increases in the different types and number of APN roles. The extent to which these roles truly reflect advanced nursing practice is often unclear. The misuse of APN terminology, inconsistent titling and educational preparation, and misguided interpretations regarding the purpose of APN roles pose barriers to developing the full potential of APN roles and their impact on the health of society. Role conflict, role overload, and variable stakeholder acceptance are frequently reported problems associated with the introduction of APN roles.

### ***Conclusions***

Recommendations for the future introduction of APN roles can be drawn from the analysis of six key issues impacting on APN role development, implementation, and evaluation. These recommendations include the need for a collaborative, systematic, and

evidence-based process designed to: provide data to support the need and goals for a clearly defined APN role, support a nursing orientation to advanced practice, promote full utilization of all APN role domains, create environments that support APN role development, and provide ongoing evaluation of APN roles related to pre-determined outcome based goals.

***Keywords:*** advanced nursing practice, advanced practice nursing, role barriers, role implementation, role evaluation, conceptual framework/model.

## **Introduction**

Advanced practice nursing (APN) represents the future frontier for nursing practice and professional role development. APN is a way of thinking and viewing the world that enables questioning and exploration of current practices, creation of new nursing knowledge and skills, and more effective delivery of nursing and health care services (Patterson & Haddad, 1992; Davies & Hughes, 1995; Elliot, 1995; Sutton & Smith, 1995). Therefore, continued development of APN roles is of paramount importance for society and the nursing profession.

In this first paper of a two part series, six issues affecting APN role development, implementation, and evaluation are discussed and recommendations for the future introduction of APN roles are identified. A brief summary of the current global context of APN roles sets the stage for discussion. Lack of clarity regarding the fundamental nature and scope of APN roles is a central barrier to APN role implementation. Confusion regarding APN roles is evident by misuse of terms, inconsistent titling and educational preparation, and varied interpretations about the purpose of APN roles (Dunn & Nicklin, 1995; Woods, 1997; Brown, 1998; Styles & Lewis, 2000). In addressing this issue, APN and advanced nursing practice are defined and distinguished as two important concepts relevant to the successful introduction of APN roles. These concepts provide the foundation for addressing five other issues related to the: lack of clearly defined APN roles and goal expectations, role emphasis on physician replacement and support, underutilization of the full scope of APN role domains, managing APN environments, and the limited use of research and evidence-based approaches to guide the introduction

of new APN roles (see Table 1). The second paper will describe a research framework for developing and evaluating APN roles.

**Table 1**

*Issues Affecting APN Role Development, Implementation, and Evaluation*

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- \*Confusion regarding APN terminology.
  - \*Failure to define APN roles based on systematic identification of needs and goals.
  - \*APN role emphasis on physician replacement or support rather than a nursing orientation to practice and delivery of patient-centred care.
  - \*Underutilization of the full scope of APN role domains related to practice, education, professional development, and organizational leadership.
  - \*Failure to address environmental elements that undermine APN role development and implementation.
  - \*Limited use of research and evidence-based approaches to guide the systematic development, implementation, and evaluation of APN roles.
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*The Global Context of Advanced Practice Nurse Roles*

The United States is a recognized leader in the introduction of four types of APN roles including clinical nurse specialists, nurse midwives, nurse anaesthetists, and nurse practitioners (Sutton & Smith, 1995; Woods, 1997; Hamric, 2000). In the last decade, North America has witnessed an unprecedented increase in the numbers and types of new APN roles such as acute care nurse practitioners, advanced practice case managers, and clinical nurse specialists/nurse practitioners. The influx of new APN roles has occurred predominantly in acute tertiary care settings (Keane & Richmond, 1993; Dunn & Nicklin, 1995; Alcock, 1996; Pinelli, 1997; Pulcini & Wagner, 2001). Similar trends in APN role

development have been documented in the United Kingdom, Australia, and Taiwan (Elliot, 1995; Dillon & George, 1997; Offredy, 1999; Chen, 2001; White, 2001). The introduction of new APN roles reflects the continued development of the nursing profession, and other factors such as specialization, rapid advances in complex medical treatment and technology, health care restructuring, and physician shortages have heightened the demand for APN expertise. Increasing demand for APN is expected to continue well into the 21<sup>st</sup> century with further expansion of roles in ambulatory and community health settings (Alcock, 1996).

Despite the importance and demand for this higher level of nursing practice, the literature identifies that there are many challenges to the successful implementation and optimal utilization of APN roles (Dunn & Nicklin, 1995; Beal, Steven, & Quinn, 1997; Woods, 1998; Irvine et al., 2000; Centre for Nursing Studies [CNS], 2001). Preliminary results of an international survey on APN roles indicate variability in role autonomy, prescriptive authority, role functions, educational preparation, and extent to which these roles have been evaluated (International Council of Nurses [ICN], 2001). Thus, it is unclear how many of these roles truly reflect advanced practice.

### ***Confusion Regarding APN Terminology***

One strength of APN roles is the extent to which they can be shaped in response to complex and changing health care systems needs and demands for greater flexibility in the delivery of health care services. This strength also presents a challenge to those responsible for defining and introducing new APN roles. While variability among APN roles is both expected and desirable, consistency in relation to core characteristics is



important for advanced nursing practice to occur. However, even within the nursing profession there is confusion regarding the terminology or key concepts used to describe APN roles (Alcock, 1996; Styles & Lewis, 2000; Clinical Nurse Specialist Interest Group [CNSIG] of Ontario, 2002). Several authors have noted that the terms *advanced practice nursing* and *advanced nursing practice*, are used as interchangeable or synonymous concepts in the nursing literature (Brown, 1998; Canadian Nurses Association [CNA], 2000; Styles & Lewis). Yet understanding the differences in these concepts is necessary for both defining and supporting the development and implementation of the full potential of APN roles.

Advanced practice nursing is a broad term used to describe the whole field of a specific type of nursing (advanced nursing practice) which includes a variety of roles, such as clinical nurse specialists and nurse practitioners (American Nurses Association [ANA], 1995a; Brown, 1998). APN represents a field of nursing much like oncology nursing is a specific field of nursing, involving a variety of roles focused on the care of patients with cancer. Styles and Lewis (2000) provide a helpful analogy in which the field of APN is a pyramid with a foundational base or factors that support the apex or *raison d'être*, which is advanced nursing practice or what nurses do in the role. In this context, APN includes but is more than advanced nursing practice. APN includes the environment in which the roles exist, factors that influence the purpose and nature of these roles, and the necessary resources, structures, and supports that permit advanced nursing practice to take place.

As the “practice component” or what advanced practice nurses do, advanced nursing practice refers to nursing practice that extends beyond the traditional scope of nursing, maximizes the use of nursing knowledge and skill in meeting patient health needs, and contributes to the development and advancement of the profession (ANA, 1995a; CNA, 2000). A variety of models of advanced nursing practice have been developed from different clinical, conceptual, and philosophical perspectives to articulate role domains, core values, competencies, and characteristics of advanced practice. The primary focus of all models of advanced nursing practice is advanced clinical practice involving direct nurse-patient-family interaction focused on the assessment and management of human responses to actual or potential health problems (Calkin, 1984; Ackerman, Norsen, Martin, Wiedrich, & Kitzman, 1996; Dunphy & Winland-Brown, 1998; Hamric, 2000; CNA, 2000).

In addition to clinical practice, advanced nursing practice includes four other role domains broadly related to education, research, professional development, and organizational leadership (Canadian Association of Nurses in Oncology [CANO], 2001). How these domains are labelled or defined varies among different models of advanced nursing practice. Advanced practice is another term that refers to advanced nursing practice and should not be confused with advanced clinical practice which refers only to one role domain or the direct clinical care of patients (Brown, 1998).

An inherent function of advanced nursing practice is that of change agent. The Synergy Model identifies eight domains of nursing practice across three spheres of influence (patient/family, nursing, health systems) for clinical nurse specialist roles in

critical care settings (Moloney-Harmon, 1999). It is the “synergistic” effect or interaction among role domains related to clinical judgement, clinical inquiry, facilitator of learning, collaboration, systems thinking, advocacy/moral agency, caring practices, and response to diversity across the three spheres of influence that results in achievement of optimal patient and family health goals.

The Strong Model defines the flexible role of acute care nurse practitioners involving five domains of practice including direct comprehensive care, support of systems, education, research, and publication and professional leadership (Ackerman et al., 1996; Mick & Ackerman, 2000). This framework recognizes that to ‘operationalize the role to its full potential some aspect of each role domain must be incorporated into practice’ (Ackerman et al., p. 69). However, the specific nature of each role domain will reflect patient, practitioner, academic, and systems needs unique to practice settings.

Three characteristics distinguish advanced nursing practice from basic nursing practice: specialization or provision of care for a population of patients with complex, unpredictable, and/or intensive health needs; expansion or acquisition of new knowledge and skills and role autonomy that extends beyond the traditional scope of nursing practice; and advancement which includes both specialization and expansion (American Nurses Association [ANA], 1995b).

The concept of advancement is less well defined but is characterized by ‘the integration of broad theoretical, research-based, and practical knowledge that occurs as part of graduate education in nursing’ (ANA, 1995b, p. 14). As such, advancement involves more than specialization and/or expansion. Additional characteristics of

advancement can be drawn from the existing literature (Table 2). Advancement is demonstrated through ‘professional activity that moves forward the nursing care provided to society’ (Davies & Hughes, 1995, p. 160). Professional activities may include developing new nursing knowledge, evaluating nursing interventions, enhancing the nursing role in new models of care delivery, or facilitating change in health care policies and practices. Advancement or progress in the development of nursing practice requires a commitment to the fundamental values of the profession. These values are reflected in a nursing orientation to practice that is patient-centred, health focused, and holistic (McMahon, 1992; Watson, 1995; Chinn & Kramer, 1999).

**Table 2**

*Characteristics of Advancement in Nursing Practice Roles*

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- \*Integration of practical, theoretical, and research knowledge (ANA, 1995b).
  - \* Includes but is not limited to specialized or expanded clinical knowledge, skills, and role autonomy (ANA).
  - \*Purposeful actions designed to improve patient health that are guided by the synthesis of role competencies related to practice, education, research, professional development, and organizational leadership (Calkin, 1984; Davies & Hughes, 1995; Hamric, 2000).
  - \*Commitment to a nursing orientation to practice that is patient-centred, health focused, and holistic.
  - \*Professional activities that move forward the nursing care provided to society (Davies & Hughes).
- 

Models of advanced nursing practice indicate that advancement is more than the integration of practical, theoretical, and research knowledge (Calkin; Ackerman et al.,

1996; Moloney-Harmon, 1999; Mick & Ackerman, 2000). Advancement involves purposeful actions designed to improve patient health that are guided by the integrated application of knowledge and skills from multiple role domains related to practice, education, research, professional development, and organizational leadership (Ackerman et al., 1996; Moloney-Harmon). Davies and Hughes (1995, p. 160) refer to this integration of role domains as the ‘synthesis’ of competencies. Similarly, advancement can be said to occur when advanced nursing practice role domains “function synergistically to produce a whole that is greater than the sum of its parts” (Hamric, 2000, p. 58). As such, advanced clinical practice does not occur in isolation of other role domains and vice versa. Advanced nursing practice role domains both inform and are guided by each other. Acquisition of specialty or expanded knowledge and skills related to clinical practice is not indicative of advanced practice unless clinical practice is also supported by knowledge, skills and activities of other role domains that enhance the contribution of nursing in meeting identified patient health needs. Therefore, nursing roles that extend beyond the traditional scope of nursing practice but are designed to provide clinical care only, represent expanded but not advanced nursing practice.

These characteristics of advancement suggest that APN roles require a high level of critical thinking and analysis to acquire and synthesize the depth and breadth of knowledge and skills necessary for each role domain. Graduate nursing education combined with specialty practice experience provides the level of preparation necessary to fulfil advanced nursing practice role functions (ANA, 1995a; CNA, 2000; CANO, 2001).

There have been fewer efforts to define APN or the foundational factors that support advanced nursing practice. Models of APN provide a useful framework for role development, implementation, and evaluation because environmental elements and foundational factors affecting the operationalization of APN roles are identified. Two models by Hamric (2000) and Brown (1998) consider APN environments. These frameworks were developed for different purposes but have complementary concepts reflecting the current literature on advanced nursing practice and identify similar categories of core competencies related to clinical and professional leadership, consultation, expert guidance and coaching, research, collaboration, and ethical decision-making.

The goal of Hamric's (2000) framework is to assist practitioners in managing environmental elements to promote successful APN role implementation including: organizational structure and culture, business aspects, policy-making procedures, reimbursement and payment mechanisms, outcome evaluation and performance improvement, marketing and contracting, and regulatory and credentialing mechanisms. Pre-requisites for APN roles include graduate education, certification, and patient-focused practice.

Brown's (1998) framework is designed with a broader focus on the field of APN rather than individual practitioners and can be utilized to guide the development of health care policies, educational curricula, role descriptions, and research programs related to APN. Three inter-related concepts including role legitimacy, APN, and outcomes, are influenced by multiple environments. Role legitimacy is similar to Hamric's (2000)

concept of primary criteria in which graduate education, certification, and licensure are the foundation for advanced practice. Role competencies are viewed as a product of graduate education. APN involves ‘professional health care activities’ related to clinical practice, management of health care environments, and involvement in broad health care discourse (Brown, 1998, p. 161). Outcomes of APN can be evaluated in relation to the patient, health care, nursing, and the individual practitioner. Environmental elements that impact on APN include society, the health care economy, local conditions, the nursing profession, and the advanced practice nursing community such as educational institutions, specialty organizations, and informal social networks among advanced practice nurses.

These frameworks illustrate the importance of conceptualizing APN beyond the practice role. APN occurs within a variety of environmental systems that range in context from the broad view of society to local, organizational, and individual perspectives. Outcomes associated with APN roles are not simply a function of the advanced practice nurse, but the relationships among the nurse, APN, and environmental elements. APN environments could also be viewed from the national and global social, political, and economic environments in which nursing, APN, and health care systems exist. For example, the Nurse Practitioner/Advanced Practice Network (NP/APN) established by the International Council of Nurses [ICN] (2001), connects advanced practice nurses from around the world and works to provide nurses and other key stakeholders with resources and evidence-based data to support the global development of APN roles.

### ***Failure To Define APN Roles Based on Systematic Identification of Needs And Goals***

Many new APN roles are initiated at the organizational or local level in response to specific issues rather than well defined goals resulting from a systematic needs assessment and clear understanding of APN roles (Dunn & Nicklin, 1995; Alcock, 1996; Howlett & Tamlyn, 1998; Centre for Nursing Studies [CNS], 2001). In the absence of clearly defined needs and goals, APN roles become shaped by individual expectations of managers, health care providers, or nurses in the role resulting in wide variations in the interpretation and utilization of APN roles. Inexperience with APN roles can lead to misinterpretation and subsequent underutilization of the role (Dillon & George, 1997). Lack of role clarity and inconsistent expectations contribute to implementation problems associated with role conflict, role overload, and variable stakeholder acceptance of APN roles (Beal et al., 1997; Knaus, Felten, Burton, Fobes, & Davis, 1997; Woods, 1998; Kleinpell-Nowell, 1999; Irvine et al., 2000; Sidani et al., 2000; CNS, 2001). Inconsistencies among APN roles across and within organizations related to role purpose, titling, scope of practice, educational preparation, funding, and reporting mechanisms represent major barriers for role evaluation and threaten the long term sustainability and integration of APN roles within health care systems (Dunn & Nicklin; Alcock; Howlett & Tamlyn).

### ***The Role Emphasis on Physician Replacement or Support***

The introduction of APN roles is often characterized by an emphasis on physician replacement or support rather than a nursing orientation to practice focused that is complementary to existing models of care delivery. Physician shortages have been the



driving force behind the development of primary care and acute care nurse practitioner roles (Spitzer, 1978; Mitchell-DiCenso, Pinelli, & Southwell, 1996; Knaus et al., 1997; Munding, 1999). A survey of Canadian teaching hospitals indicates that 46% of new APN roles were developed to provide physician replacement or support, while less than 21% of new APN roles were established in response to patient and family health needs (Dunn & Nicklin, 1995). A nursing orientation to practice and participation in nursing practice activities may decline as APN roles become more medically driven (Beal et al., 1997; Irvine et al., 2000). Patient-centred, health focused, and holistic care are hallmarks of a nursing orientation to practice. A nursing orientation to practice is also important for developing confidence in nursing practice skills and knowledge (Thibodeau & Hawkins, 1994). Thus, when the primary focus of APN roles is not defined in relation to patient health needs as described in models of advanced nursing practice, the nursing components of the role may become less valued and visible.

The emphasis on physician replacement and support rather than the complementary role of APN has necessitated evaluation studies focused primarily on comparing nurses and physicians related to patient outcomes associated with medical care (Sibley et al., 1975; Mitchell et al., 1991; Brown & Grimes, 1995; Munding et al., 2000; Horrocks, Anderson, & Salisbury, 2002). As a result, less is known about the unique contributions of the nursing practice components of APN roles as they are introduced into new health care settings. Despite these limitations, recurring themes from evaluation studies indicate that the value added component of APN roles extends beyond the transfer of medical functions. For example in primary care, two meta-analyses have

demonstrated that nurses and physicians provide equivalent care related to assessment and diagnostic accuracy and achieve similar health outcomes (Brown & Grimes, 1995; Horrocks et al., 2002). However, nurse practitioner care was also associated with higher patient satisfaction and enhanced quality of care related to patient education, communication, and documentation of records.

Positive outcomes have also been demonstrated in acute tertiary care settings where advanced practice nurses have been compared to traditional care practices. A series of studies involving high risk populations, evaluated the impact of a Transition Model of Nursing Care in which advanced practice nurses provided continuous care between home and hospital (Brooten et al., 1986, 1988, 1994; York et al., 1997; Naylor et al., 1999). High risk geriatric, neonatal, and obstetric patients randomized to APN care demonstrated reduced hospital lengths of stay, lower re-admission rates, decreased overall health care costs, increased health promotion behaviours, and higher satisfaction with care.

In oncology settings, randomized trials have found that APN care is associated with improved quality of life compared to standard medical care. Newly diagnosed women with breast cancer experienced lower levels of uncertainty, decreased mood disturbances, and greater improvement in perceptions of overall quality of life (Ritz et al., 2000). Two studies evaluated the effectiveness of APN care designed to treat patient and problem-focused health needs related to breathlessness in advanced lung cancer (Corner, Plant, & Warner, 1995; Corner, Plant, A'Hern, & Bailey, 1996; Bredin et al., 1999; J. Corner, personal communication, 2002). Patients randomized to nurse led clinics

received individually tailored, holistic, and multi-dimensional strategies designed to enhance levels of physical function, tolerate reduced lung capacity, and cope with the functional disability and psychological distress associated with breathlessness. When compared to patients randomized to traditional supportive care, patients in the APN group demonstrated lower levels of depression, improved physical symptoms including decreased breathlessness, and enhanced performance status despite a poor prognosis and/or evidence of progressive disease.

These studies suggest that the value added component of APN roles involves a nursing orientation to practice that is characterized by the delivery of coordinated, integrated, holistic, and patient-centred care that is designed to maximize health, quality of life, and functional capacity. Opportunities to make significant improvements in patient and health care systems outcomes may occur when the introduction of APN roles represents a new and complementary approach to patient care rather than a singular focus on role replacement or the transfer of role functions from one health care provider to another. The focus on patient needs not only results in improved patient outcomes and satisfaction with care, but leads to more efficient and effective use of health care services.

#### ***Underutilization of The Full Scope of APN Role Domains***

A third issue involves the underutilization of the full scope of APN role domains and thus the extent to which roles are truly advanced. Time demands associated with clinical practice and medical role functions, in addition to insufficient administrative support, are frequently reported as role obstacles to providing organizational leadership and participating in education and research activities (McFadden & Miller, 1994;

Sanchez, Lee, & Bosque, 1996; Beal et al., 1997; Irvine et al., 2000; Sidani et al., 2000). As the Strong Model suggests, the time allocated for each domain may vary among different APN roles (Ackerman et al., 1996). However, a balance between clinical and non-clinical role activities is required. It is through the culmination of clinical and non-clinical role activities that advancement occurs both in relation to the APN role and the nursing profession.

The APN model of care for breathlessness in lung cancer described previously is an excellent example of advancement and the need for nursing roles that extend beyond clinical care. Developing and evaluating new models of nursing care and nursing interventions require opportunity for professional development, reflective and scholarly work, and collaboration with other advanced practice nurses and nurse researchers (Plant, Bredin, Krishnasamy, & Corner, 2000; Corner et al., 1995). Integrating new practices into existing models of care requires strategies to effect systems change, disseminate research results, and educate nurses and other health care providers to support the new model of care. Other APN role activities such as educating and mentoring new nurse graduates and advanced practice nurses are important for developing a nursing orientation to practice, recruiting and retaining nursing staff, and promoting safe and effective nursing care.

This synthesis of role competencies as described by Davies and Hughes (1995) is a constant challenge and struggle for many advanced practice nurses. Woods (1997) quite rightly questions whether the implementation of all role domains is a utopian view of APN. Advanced practice nurses indicate that they value the non-clinical aspects of

their role and that these activities contribute to role satisfaction (McMillan, Heusinkveld, & Spray, 1995; Sanchez et al., 1996; Mick & Ackerman, 2000; Sidani et al., 2000).

Frustration arises when planned non-clinical activities leading to improvements in care delivery are constantly neglected or negated as a result of external pressures to provide clinical care. Unclear role expectations contribute to APN role strain when participating in non-clinical role activities. Less attention may be paid to defining how the non-clinical aspects of APN roles can be utilized to meet broader patient, nursing, health care provider, organizational, and health care systems needs. As a result, clearly defined and achievable goals related to education, research, professional development, and organizational leadership are not identified and strategies to support the implementation of these role activities are not employed. Health care systems are better served through the efficient use of the full range of knowledge, skills, and expertise afforded by APN roles. Over the long term, even APN roles in which clinical practice assumes 80-90% of day to day activities will have better opportunity to impact on broader health care issues, with focused and time sensitive goals related to non-clinical activities.

#### ***Failure to Address Environmental Elements That Undermine APN Roles***

Social, economic, and political issues internal and external to practice settings determine formal or informal policies and practices which impact on foundational factors necessary to support APN roles. Brown (1998) identifies that graduate education, licensing, and credentialing are prerequisites for APN role legitimacy and define subsequent scope of practice and role competencies. Yet foundational factors such as licensing and regulations that control diagnostic and prescriptive authority, patient

referrals, hospital privileges, and re-imbursement are frequently reported as environmental barriers to APN role autonomy and thus expansion of nursing roles (Martin & Hutchinson, 1999; Sidani et al., 2000; Lynch, Cope, & Murphy-Ende, 2001).

A recent Canadian study of primary care nurse practitioner (PCNP) roles illustrated the importance of environmental assessments that include analysis of health care policies and stakeholder perceptions of APN roles (CNS, 2001). This study observed that the legitimacy of PCNP roles was compromised by the lack of consistent policies and legislation to support expanded practice. The resulting variation in educational preparation and access to graduate education has led physicians and nurses to question the knowledge, skills, and thus competency of PCNPs in some settings. Scope of practice and full utilization of PCNP roles were also restricted by legislation and physician resistance particularly in settings where there is a higher concentration of physicians (CNS). These barriers result from failure to develop APN roles that are complementary to the existing model of care and failure to implement policies that address fee-for-service issues and physician concerns regarding loss of income. Alternative reimbursement or payment options that provide incentive for collaborative relationships among physicians and PCNPs are required.

Several studies report that the legitimacy, scope of practice, and effectiveness of APN roles can be impaired by the absence of appropriate organizational structures (Ostwald, Abanobi, & Kochevar, 1984; McFadden & Miller, 1994; Sanchez et al., 1996; Beal et al., 1997; Martin & Hutchinson, 1999; Irvine et al., 2000). Examples of these organizational structures include reporting mechanisms that support role development

and a nursing orientation to practice, adequate reimbursement, policies that support autonomous scopes of practice, and practical resources such as office space, clerical support, and communication technology.

Since the implementation of APN roles is often not based on a comprehensive assessment of environmental factors both internal and external to practice settings, the system's readiness for the role and potential obstacles are not identified and strategies to facilitate role implementation are not addressed (Dillon & George, 1997; Martin & Hutchinson, 1999). Key stakeholders at multiple levels within APN environments must participate in developing and planning the implementation of APN roles in order to minimize barriers, facilitate systems entry, and promote integration of the role.

***Limited Use of Research and Evidence-Based Approaches to Guide The Systematic Development, Introduction, and Evaluation of APN Roles***

Similar to new health interventions, the introduction of new health care provider roles, such as advanced practice nurses, should be based on evidence documenting the need and effectiveness of the role (Spitzer, 1978). Only a few reports document this degree of rigour related to wide scale implementation of new APN roles such as primary care and neonatal nurse practitioners (Spitzer; Mitchell, Patterson, Pinelli, & Baumann, 1995; Mitchell-DiCenso et al., 1996).

At the organizational level, variability among roles and lack of pre-determined outcome based goals have resulted in few formal or comprehensive evaluations of APN roles. Lack of pre-determined outcomes results in varied stakeholder perceptions regarding indicators of success and prevents prospective evaluation of outcome data.

Evaluation often involves performance appraisals of the individual in the role and does not account for the impact of environmental elements on role effectiveness. Most APN roles function within the context of health care teams and/or collaborative care models. Evaluation of APN roles must also consider the roles and responsibilities of other members of the health care team in meeting patient, organizational, and health care systems needs. In the absence of efficiency and effectiveness data, APN roles are vulnerable to further role restrictions or elimination, particularly in unstable organizational, political, economic, and health care systems environments (McFadden & Millar, 1994). On-going evaluations of APN roles and interventions are essential for continued development of the role and new nursing knowledge and skills.

#### ***Recommendations for The Introduction of Future APN Roles***

These six common and inter-related issues suggest that the introduction and evaluation of APN roles warrant greater attention to the concept of advancement, attributes of APN roles, and environmental elements impacting on APN roles. Continued efforts of the nursing profession and APN community to further define advanced nursing practice and to work with stakeholders to eliminate confusion regarding APN roles is required. Most importantly, patient needs must be the primary driver for developing new APN roles.

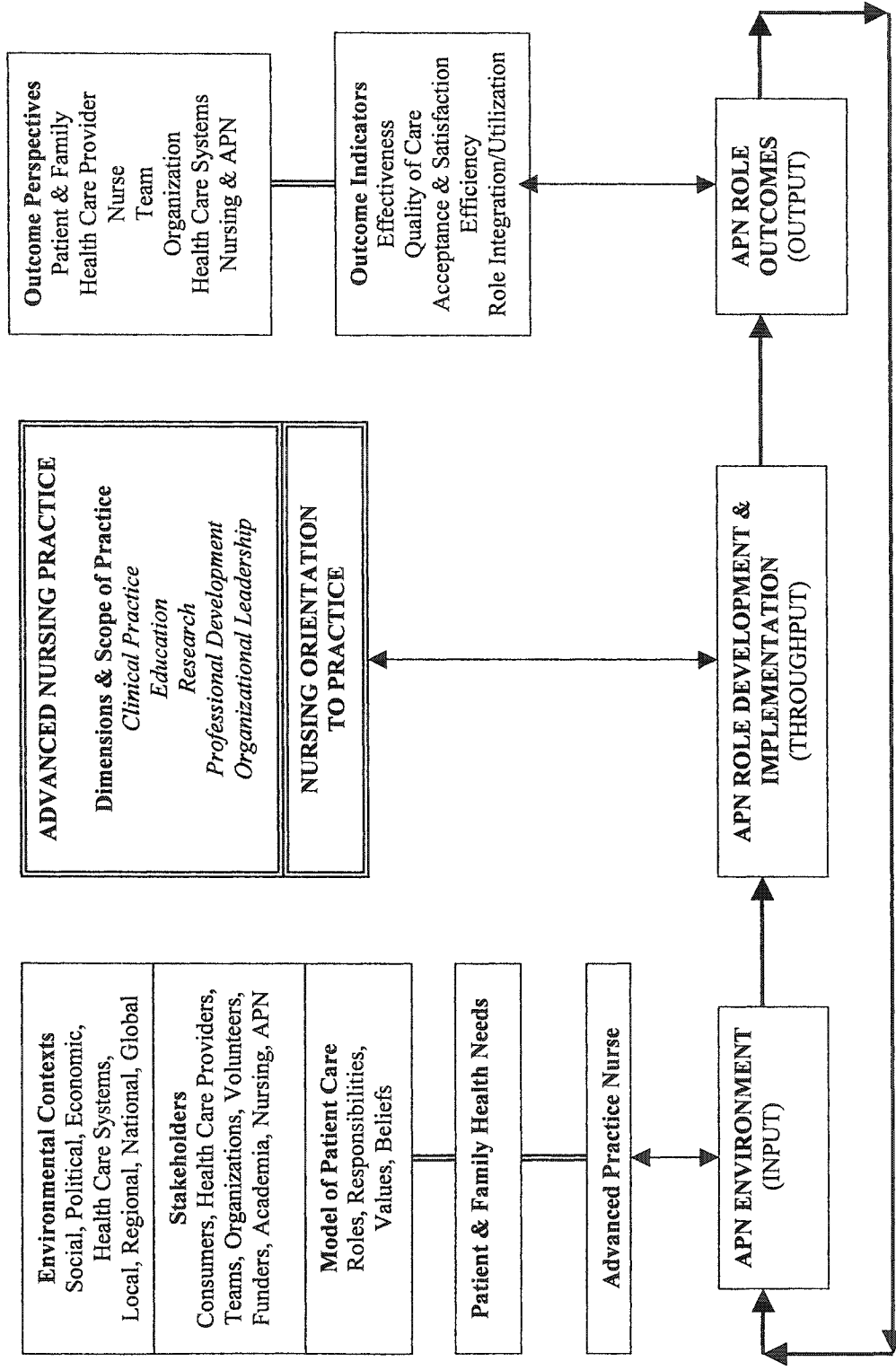
Figure 1 outlines key concepts related to APN role development, implementation, and evaluation. Within this systems model, elements of the APN environment are the inputs into APN role development and implementation. As Brown (1998) and Hamric



(2000) identified, a variety of environmental factors impact on APN roles and outcomes. Elements of APN environments include the local, regional, national, and global contexts of large systems including social, political, economic, and health care systems. Within each of these systems there are key stakeholders who have a direct and/or indirect impact on the delivery of health care services and current models of patient care. Within the practice environment, the current model of patient care is defined by stakeholder roles and relationships, and is influenced by stakeholder values, beliefs, and experiences with APN. The combination of environmental contexts, systems stakeholders, and model of care leads to factors that are facilitators or barriers to how the APN role is developed and implemented. APN roles are also defined and influenced by the health needs of patients and families who are the focus of the current model of care. Characteristics of the advanced practice nurse, such as educational preparation, credentials, role experience, confidence, interests, and values also impact on successful role implementation (Brown, 1998; Hamric, 2000).

The throughput component of the model concerns how the APN role is defined and developed. This involves the processes, steps, and strategies used to identify, organize, coordinate, integrate, and manipulate inputs from APN environments in order to promote role facilitators and eliminate role barriers. The goal is to support a nursing orientation to practice and optimize the use of all dimensions and full scope of advanced nursing practice related to clinical practice, education, research, professional development, and organizational leadership. The success of these efforts can be measured by the outputs or outcomes of the APN role. Outcomes of APN role

**Figure 1 Concepts Related to the Development, Implementation, and Evaluation of Advanced Practice Nursing Roles**



development and implementation include a range of indicators related to effectiveness, quality of care, acceptance, satisfaction, efficiency, integration, and utilization and can be measured from a number of patient/family, advanced practice nurse, health care provider, team, organizational, nursing, and APN perspectives (Spitzer, 1978; Mitchell-DiCenso et al., 1996; Brown, 1998).

This model demonstrates that the introduction of APN roles occurs within the context of complex and inter-related social environments. Successful role implementation is dependent upon the extent to which systemic barriers within these environments are identified and influenced to support APN roles. Thus the process for introducing APN roles must include strategies to promote social change within environments that is consistent with the fundamental nature of APN and conducive to the full implementation and integration of APN roles at multiple levels. Recommendations for the future introduction of APN roles include the need for a collaborative, systematic, and evidence-based process designed to:

- provide sufficient data to support the need and identify goals for a clearly defined role;
- support the development of a strong nursing orientation to advanced practice characterized by patient-centred, health focused, and holistic care;
- promote full utilization of the broad range of APN knowledge, skills, and expertise in all role domains and scope of practice;
- create environments that support APN role development with the health care team, practice setting, and broader health care system; and
- provide ongoing and rigorous evaluation of APN roles related to pre-determined outcome based goals.

### **Conclusions**

In this paper, definitions and models of advanced nursing practice and advanced practice nursing have provided the foundation for describing six issues and recommendations for enhancing the introduction and evaluation of APN roles. In Part II of this two part series, a research framework focused on the throughput component of the systems model will be proposed. In this framework, steps for developing, implementing, and evaluating APN roles are defined and specific strategies for addressing the six issues are incorporated. The goal of the framework is to promote the most efficient and effective use of APN roles through systematic and evidence-based control and management of APN environments.

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## **CHAPTER 3**

### **Preamble**

This chapter involves a reformatted manuscript submitted for publication to the Journal of Advanced Nursing. The manuscript applies recommendations from Chapter 2 to adapt two existing frameworks regarding the introduction and evaluation of new health care provider and advanced practice nursing roles. The principles of participatory action research (PAR) as a social change and evidence-based process guided the development of the new framework. At each stage of the process, strategies to promote effective decision-making, minimize potential role barriers, and strengthen facilitators for successful APN role development and implementation are identified.

**Advanced Practice Nursing Roles Part II:**

**The PEPPA Framework**

**A Participatory, Evidence-Based, Patient-Focused, Process for  
Advanced Practice Nursing Role Development, Implementation, and Evaluation.**

Denise Bryant-Lukosius

McMaster University

## **Abstract**

### ***Aim of the Paper***

This paper describes a patient- focused, evidence-based, and participatory process for developing, implementing, and evaluating advanced practice nursing (APN) roles (PEPPA Framework).

### ***Rationale/Background***

Despite the growing demand for advanced practice nurses, there are limited data to guide the successful implementation and optimal utilization of APN roles. The PEPPA Framework is an adaptation of two existing frameworks and is designed to overcome role implementation barriers through knowledge and understanding of APN roles and environments. The principles of participatory action research (PAR) directed the construction of the new framework.

### ***Conclusions***

The process for implementing and evaluating APN roles is as complex and dynamic as the roles themselves. The PEPPA Framework is shaped by the underlying principles and values consistent with APN, namely a focus on addressing patient health needs through the delivery of coordinated care and collaborative relationships among health care providers and systems. Engaging environmental stakeholders as participants in the process provides opportunity to identify the need and mutually shared goals for a clearly defined APN role. The process promotes increased understanding of APN roles and optimal utilization of the broad range of APN knowledge, skills, and expertise in all role domains and scope of practice. The planning and implementation steps in the

process aid in creating environments to support APN development and long term integration into health care systems. The goal directed and outcome based process also provides the basis for prospective ongoing evaluation and improvement of both the APN role and delivery of health care services.

***Key words:*** advanced practice nursing, participatory action research, evidence-based practice, patient focused care, role barriers, role implementation, role evaluation

## Introduction

Over the last decade, increasing demand for health care services, shortages of trained health care providers, and the need for cost containment have triggered worldwide efforts to develop more efficient and effective health care delivery systems. In many countries, health care restructuring has included the introduction of new types and increased numbers of advanced practice nursing (APN) roles (Dunn & Nicklin, 1995; Chen, 2001; Duffy, 2001; Pulcini & Wagner, 2001; White, 2001). APN is a broad term used to describe a specific field of nursing that includes a variety of roles such as clinical nurse specialists, acute care nurse practitioners, nurse midwives, nurse anaesthetists, and primary care nurse practitioners (American Nurses Association [ANA], 1995).

In Part I of this two part series, a review of the APN literature identified six inter-related issues relevant to the introduction and evaluation of APN roles (Bryant-Lukosius, DiCenso, Browne, G., & Pinelli, 2002). Recommendations for introducing APN roles included the need for a collaborative, systematic, and evidence-based process designed to:

- provide sufficient data to support the need and identify goals for a clearly defined role;
- support the development of a strong nursing orientation to advanced practice characterized by patient-centred, health focused, and holistic care;
- promote full utilization of the broad range of APN knowledge, skills, and expertise in all role domains and scope of practice;
- create environments that support APN role development within the health care team, practice setting, and broader health care system; and
- provide on-going and rigorous evaluation of APN roles related to pre-determined outcome based goals.

This paper responds to these recommendations by proposing a framework outlining a process and strategies for guiding the successful development, implementation, long term integration, and evaluation of APN roles. This framework builds largely on the work of Dunn and Nicklin (1995), who identified key steps for hospitals to consider when introducing new APN roles, and the work of Spitzer (1978) who outlined a strategy for introducing new health professionals.

The steps proposed by Dunn and Nicklin (1995) include: identify patient needs; collaborate with physicians; determine types of positions; define scope of practice; set standards and develop protocols; provide educational programs; evaluate impact; and determine future positions. Details for implementing these steps were not provided. The framework is closely aligned with nursing and is consistent with the models of advanced nursing practice in which patients and patient health needs are the primary focus of APN roles (Calkin, 1984; Ackerman, Norsen, Martin, Wiedrich, & Kitzman, 1996; Moloney-Harmon, 1999; Hamric, 2000). The nursing profession is also responsible for determining operational definitions that distinguish expanded and advanced practice nursing roles, developing a model of advanced nursing practice, defining roles and scope of practice, setting standards, establishing educational programs, and evaluating outcomes (Dunn & Nicklin). Organizations can then apply this information to make decisions about how APN roles can be best utilized to meet patient health needs.

The Spitzer (1978) Framework uses an evidence-based approach in which the introduction of new health care provider roles is viewed as a complex process similar to that for evaluating new drugs and other therapeutic health interventions. The Framework

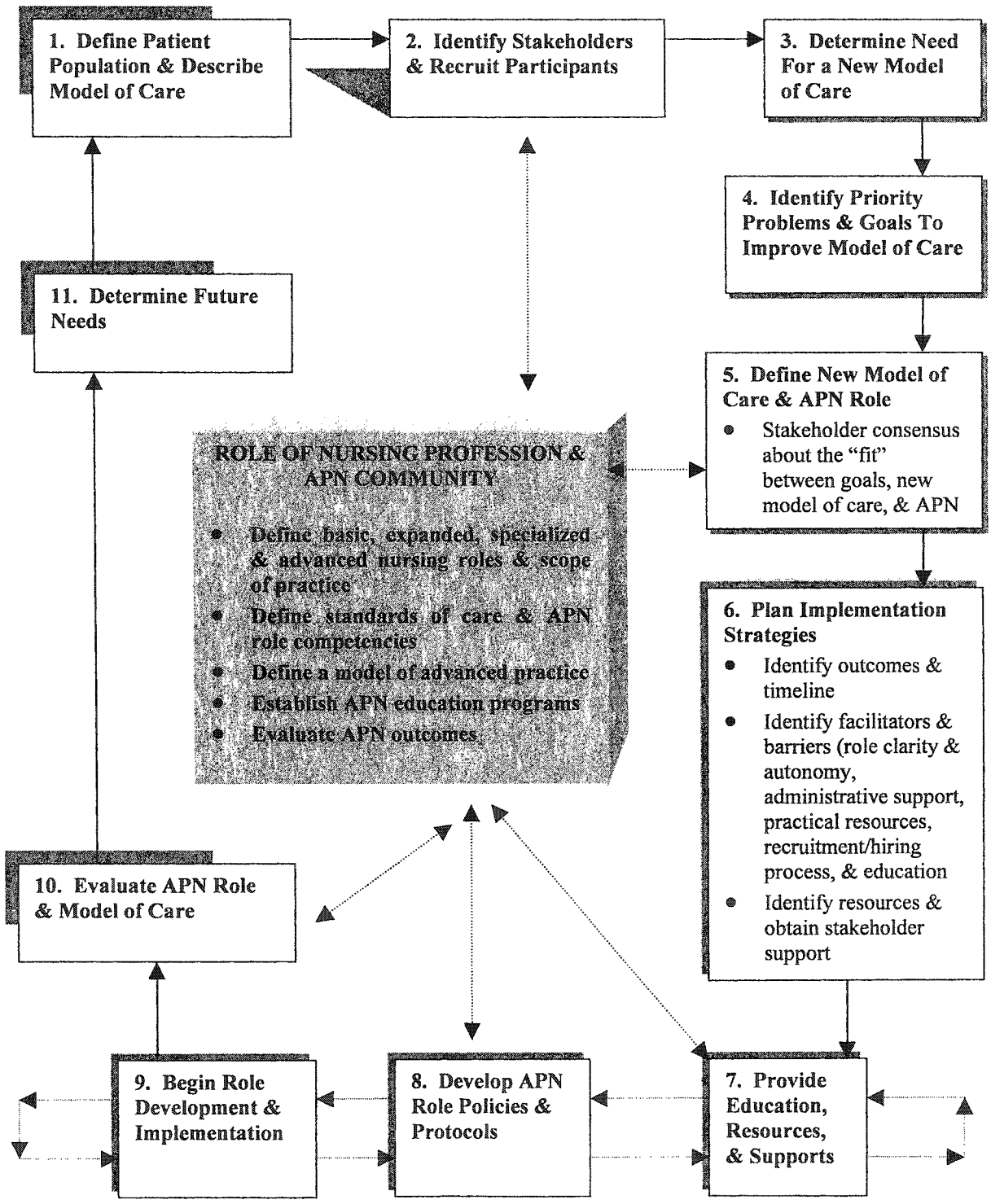


includes the following steps: establish the need for a new approach to patient care; define the new role; evaluate the safety, effectiveness, and economic efficiency of the new role; determine the impact of the new role on quality of care, patient acceptance and satisfaction; evaluate health care provider satisfaction; determine the extent of role transfer if the functions of one health care provider are assumed by the new role; and provide long term surveillance to monitor changes in performance. Spitzer's Framework was revised to include the development and evaluation of educational programs specific to the new role (Mitchell-DiCenso, Pinelli, & Southwell, 1996).

The amalgamation of these two frameworks provides a more comprehensive structure addressing several of the recommendations for implementing APN roles such as: providing a systematic and evidence-based approach to the development of an APN role that is based on patient needs; incorporating nursing standards and scope of practice as the foundation for role delineation; supporting the development of the role through educational programs consistent with role definitions; and rigorously evaluating the role. Missing from the merged frameworks is a comprehensive range of strategies to overcome the systemic barriers to APN roles that can be drawn from knowledge and understanding of advanced nursing practice and APN environments.

The following adaptation of the merged frameworks, named the PEPPA Framework, strives to address implementation issues specific to APN roles. PEPPA stands for a Participatory, Evidence-Based, Patient-Centred, Process, for APN Role Development, Implementation, and Evaluation (Figure 1). The principles of participatory action research (PAR) informed the construction of the new framework. As a process of

Figure 1 *The PEPPA Framework: A Participatory, Evidence-Based, Patient-Focused Process For Advanced Practice Nursing (APN) Role Development, Implementation, and Evaluation*



systematic inquiry, PAR challenges the status quo. PAR provides a democratic process for involving individuals in organizations, education systems, communities, or underdeveloped countries in promoting health and social change (Foote Whyte, 1991; Smith, Pynch, & Lizardi, 1993; Deshler & Ewert, 1995). In the PEPPA Framework, the principles of PAR can be applied to promote more equitable distribution of power in APN environments and thus enhance the contributions of nurses, patients, and other stakeholders in APN role development. Principles of PAR relevant to APN role development and implementation include: active participation in praxis or cycles of reflection-action; value what people know and believe by using their present reality as a starting point and building on it; collective investigation, analysis, learning, and conscious production of new knowledge; collective action in using this new knowledge for managing, improving, or solving problem situations; and evaluating the impact of these actions (Deshler & Ewert; Bowling, 1997; Smith, 1997).

Spitzer (1978) emphasizes the well thought out collection of data to establish the need for new health care provider roles. Factors to consider include population-to-practitioner ratio, demand and utilization of health care services, unmet patient needs, and patient acceptance and satisfaction with care. In the PEPPA Framework, the needs assessment is patient oriented as recommended by Dunn and Nicklin (1995) and moves beyond issues of supply and demand to the identification of additional environmental factors that affect the delivery of patient care and potential introduction of APN roles.

APN does not occur in isolation but within organizational and health care systems environments (Brown, 1998; Hamric, 2000). Most advanced practice nurses also work

collaboratively within formally or informally established sub-systems or multi-disciplinary teams. Within these environments are key stakeholders who have a direct or indirect impact on practice settings and the current model of patient care. The current model of patient care is defined by stakeholder roles and relationships and is influenced by stakeholder values, beliefs, and experiences with APN. These relationships create environmental conditions that can facilitate or obstruct APN role development. Hamric stresses the importance of controlling and managing environmental conditions to support APN role development. Therefore, the process for introducing a new APN role should include an assessment of how well the existing model of care or relationships among patients, health care providers, and the delivery of health care services within teams, organizations, and the broader health care system, is able to meet identified patient health needs.

***Step 1: Define Patient Population and Describe Current Model of Care***

In the first step, the patient population and stage along the continuum of care are clearly defined. The current model of care is determined by mapping out how patients and families enter the health care system and interact with health care providers and health care services over a specific period or continuum of care. While the patient is the central core of the model of care, the focus of relationships and interactions can be defined from a team, organizational, and/or geographic perspective. For example, in considering an APN role for patients with prostate cancer, the population could be limited to individuals with advanced disease. The stage along the continuum of care could begin

at the time of referral to the medical or radiation oncology team, cancer centre, or regional palliative care program and continue until the patient's death.

***Step 2: Identify Stakeholders and Recruit Participants***

Crucial steps involve identification of key stakeholders from the model of care and selection of stakeholder members or the participants to be involved in the process. Stakeholders are individuals or groups who have direct or indirect involvement in the current model of care. Examples of stakeholders include patients and families, patient advocacy groups, volunteer agencies, health care organizations, the health care team, health care providers, professional associations, support staff, health care administrators, educators, and government agencies involved in health policy and funding. Each stakeholder represents vested interests, values, perceived power, and expectations in relation to the current model of care. The principle assumption of the Framework is that all stakeholders, regardless of their role, have the capacity to reflect, learn, inform and work to promote change within the model of care (Deshler & Ewert, 1995; Smith, 1997). Stakeholder participation at the onset of the process is critical for ensuring commitment to and providing practical support for planned changes to the model of care.

For the remaining discussion, participants will refer to stakeholder members selected for involvement in this process to determine the need for change within the model of care and potential introduction of an APN role. The term *participant* rather than *stakeholder* is used to reflect the active role these individuals play in defining the tasks and working as a planner, learner, researcher, and decision-maker throughout each step of the process. As implied, participants require commitment to the "common good"

or the broader objective to optimize patient care and thus are more than representatives of a stakeholder group.

Factors to consider when recruiting participants include: their willingness and ability to invest the time and energy necessary to fully participate in the process, and ability to articulate and communicate stakeholder issues (Gray, Fitch, Greenberg, & Shapiro, 1995; Smith, 1997). The makeup of participants and representative stakeholder groups will impact on decisions made throughout the process and will ultimately shape the APN role and subsequent outcomes. Participants should represent a broad range of stakeholder players and decision-makers who would affect or be affected by changes to the model of care and the possible introduction of an APN role. Finding the right balance of both composition and numbers of participants can be a challenge. If the range of participants is too narrow or over-represented by one stakeholder group, the scope of ideas and possibilities for change may be limited. Too many participants can be a barrier to consensus decisions and meaningful changes to the model of care.

From an APN standpoint, the composition of participants must ensure a balance between medical and other stakeholder viewpoints. Evaluations of APN roles suggest that optimal patient and health care system outcomes may be achieved when APN roles have a strong nursing orientation to practice (Bryant-Lukosius et al., 2002). If so, models of care involving APN roles must reflect values consistent with a nursing orientation to practice. In many health care environments this would require substantial movement from the traditional medical model of care focused on illness toward a patient-focused, holistic, and integrated model of care designed to promote optimal health and quality of

life. Paradigm shifts of this nature can occur when participants with varied and opposing viewpoints, have the opportunity to express opinions, are perceived as valid and valuable contributors, and are involved in determining consensus decisions.

The process for defining a patient-focused model of care must include patients and families as important stakeholders. Patients are active participants in their own health and self-care and are experts regarding their health care needs (Gray, 1992). Families are frequently the primary providers of home care and patient support. Patients and families are uniquely positioned not only to identify strengths and limitations but strategies and solutions for improving the existing model of care. Patients involved in health care planning can provide a balance between medical and administrative viewpoints, increase awareness about the human dimension of health care, and identify inefficiencies and lack of coordination among health care services (Gray et al., 1995).

There is stakeholder confusion and often misleading interpretations about the purpose of APN roles (Dunn & Nicklin, 1995; Alcock, 1996; Howlett & Tamlyn, 1998; Canadian Nurses Association [CNA], 2000). Some stakeholders, such as patients or community agencies, may have no experience with APN roles. Involving APNs and members of professional nursing associations who are knowledgeable about APN roles, as full participants or consultants to the process, can be helpful for educating participants about APN roles and how these roles may fit within a new model of care. Professional nursing associations are also invaluable for addressing role implementation issues related to APN role standards, competencies, licensing, education, mentorship, and outcomes. In addition, a central mandate of nursing and therefore, nurse participants, is to advocate for

changes to the health care system that reflect the interests of patients and families (ANA, 1995; Canadian Association of Nurses in Oncology [CANO], 2001).

A final consideration for this step is determining who will facilitate the process. Like the external researcher in PAR, the facilitator is not an objective observer or consultant but an active participant in the process (Deschler & Ewert, 1995). An important role of the facilitator is promoting equitable and valued involvement of all participants. The challenge is guiding and harnessing participant discussion such that the range of experiences, issues, needs, and conflicts can be elicited and yet still move the group forward to determine mutually shared goals and actions (Gray, 1992; Smith et al., 1993; Soltis-Jarrett, 1997). In order to achieve these objectives, the facilitator requires expert group process and transformational leadership skills. The facilitator must also have the support of participants and be perceived as a credible, legitimate individual with commitment to participants as a whole rather than any one specific agenda (Bowling, 1997). Therefore, participant involvement in selecting the facilitator would be an asset to the process.

### ***Step 3: Determine Need For A New Model of Care***

During this step, the strengths and limitations of the current model of care in meeting patient health needs are determined. The first task is to ensure that the participants agree on the model of care as defined in step one. The input of participants with varied experiences may lead to a more complete understanding of the current model of care and identification of additional stakeholders.



Clarity regarding the range and priority of patient health needs is also essential.

Group discussion and activities address the following questions:

- What are the identified health needs of patients/families?
- What are the context and consequences of these health needs?
- What factors contribute to these health needs?
- What are stakeholder perceptions of these needs?
- What more information about patient/family health needs is required?
- What sources and methods can be used to acquire this new information? (Smith et al., 1993).

Determining patient health needs requires clear definitions distinguishing health problems (e.g. prostate cancer) from health needs (e.g. information about prostate cancer treatment). A need is a subjective expression of goals or desires or the identification of something missing that is necessary to maintain balance or well-being (Maslow, 1970; Alderfer, 1972; Endicott, 1997), whereas a health problem may or may not be associated with specific health needs requiring intervention. Moreover, APN roles are focused on the assessment and management of human responses or needs resulting from actual or potential health problems (ANA, 1995; Endicott).

The health care literature and institutional or national health care databases may provide information regarding patient health needs. Morbidity and mortality rates can provide estimates of preventable or treatable problems and as such are indirect measures of health needs or goals to improve health. Some examples include physical and psychosocial function, disability days, death rates, and healthy years of lost life (Tugwell,

Bennett, Sackett, & Haynes, 1985). Patient perceptions of health-related quality of life (HRQL) also provide an indirect measure of health needs (Harrison, Juniper, & Mitchell-DiCenso, 1996).

In the absence of existing data, methods to identify patient needs and stakeholder perceptions of these needs, such as surveys, focus groups, or in-depth interviews could be employed. Patients and families often have more than one health need, but not all needs have the same frequency, severity or significance in terms of impact on health or quality of life. Determining priority health needs aids in focusing the needs assessment on the most important health issues.

Once needs are identified, a similar process occurs to determine the extent to which the model of care is meeting patient health needs. Participant discussions and data collection activities focus on identifying met and unmet patient health needs, and on understanding the contexts and consequences of these needs across the model of care. In this manner, patient/family, health care provider, and health care system issues and factors contributing to unmet patient health needs are identified. Stakeholder perceptions and other data may identify a variety of issues related to the availability, accessibility, acceptability, awareness, appropriate use, and affordability of health care services. Indicators to evaluate the health care system's human resource capacity in meeting demands for health care services include patient volume and acuity, health care provider/consumer satisfaction, and changes in the quantity, distribution, or roles of health care providers (Mitchell-DiCenso et al., 1996; Spitzer, 1978).

#### ***Step 4: Identify Priority Problems and Goals***

Data analysis is an on-going process throughout the needs assessment. Collectively, participants seek answers to, “What does this new information mean? and “What additional information is required?”. As a result, individual participants and the group as a whole develop a more complete understanding of patient needs, appreciation of and respect for each other’s roles, and the strengths and limitations of the current model of care. Misconceptions are identified and clarified, and common issues and concerns are recognized. Shifts in traditional power structures occur when participants are connected by mutual understanding and shared interests (Smith, 1997). This enables the group to move forward and establish consensus regarding the following questions:

- What are the gaps or problems in meeting patient health needs within the current model of care?
- How are these gaps or problems related?
- What are the most important problems and why?
- What are the goals or what can be accomplished by resolving these problems?

Categorizing patient health needs and health care delivery problems into groups or themes helps to identify and analyze problems resulting from similar or related factors. When several problems in meeting patient health needs are identified, not all can be resolved at once. Establishing priorities can focus and coordinate efforts to achieve maximum improvement in the model of care. There is no cookbook type strategy or criteria to guide consensus decisions regarding priority problems. Formal methods such as delphi technique, consensus panels, or nominal group process can be used for developing consensus regarding health care services (Bowling, 1997). Regardless of the

approach, consensus decisions by participants should be informed by broad stakeholder input. Secondly, priority problems should reflect patient priority needs. High participant agreement on priorities is also important for on-going commitment to problem resolution. Factors to consider in determining priority needs include: the urgency to prevent harmful patient consequences; temporal issues related to short or long term goals or the necessary sequencing of events; magnitude of potential impact on the health of the patient population; and extent to which other stakeholders within the model of care will benefit from problem resolution.

Goal identification allows the participants to look ahead into the future and determine what they hope to accomplish through efforts to resolve priority problems in meeting patient health needs. Thus, goal identification provides the foundation for identifying measurable outcomes to evaluate the new model of care and potential introduction of the APN role. Goal identification also provides direction for determining the next steps or actions.

***Step 5: Define the New Model of Care and APN Role***

During this step the need for modifications to the current model of care and potential introduction of an APN role are addressed through the following questions:

- What new care practices and care delivery strategies can be employed to achieve identified goals? What is the quality of the data to support the introduction of these changes?
- Are changes to current roles and responsibilities within the model of care required to implement new care practices and care delivery strategies?
- Are these role changes sufficient or is there a need for additional knowledge, skills, and expertise provided by an alternative health care provider role?

- If so, would the addition of an APN role enhance our ability to meet identified health needs and goals related to the model of care? How do we know this?
- How well does an APN role “fit” within this new approach or model of care?
- What are the advantages/disadvantages of an APN role compared to alternative health care provider roles?

The potential for generating the depth and breadth of strategies to improve the model of care is strengthened because patient health needs have been examined from multidimensional viewpoints. For example, in a hypothetical assessment of prostate cancer patients undergoing prostatectomy, a priority problem is increased hospital re-admissions for urinary sepsis. Negative consequences include prolonged post-operative recovery, increased costs, and cancellation of other surgeries due to lack of beds. Contextual factors include lack of pre- and post-operative patient education about self-care of urinary catheters, increased age of patients at greater risk for complications, and reduced access to home care services. Possible strategies to reduce the incidence of urinary sepsis include: providing education programs to improve patient knowledge and self-care skills; targeting high risk (elderly) patients; establishing criteria and assessing patient readiness for discharge; and improving home care support and post-operative follow-up care. Implementing only one strategy, such as pre-op education, will limit the impact on reducing urinary sepsis as other contributing factors are not addressed.

A proposed new model of care evolves from participant discussion regarding what is the most appropriate care, who are the most appropriate health care providers, and how and when they will be involved in implementing new care practices and goal related strategies. This discussion requires a review of the literature regarding evidence-based

care practices (e.g. prevention of urinary sepsis post-prostatectomy) and understanding of the knowledge, skills, and expertise each role has to offer in relation to each strategy.

Necessary changes to existing roles and responsibilities are identified along with potential gaps in skill sets and numbers of health care providers. When the current skill mix or complement of health care providers is insufficient, alternate health care providers such as APN roles are considered in relation to patient needs, goals, and new approaches to care. In the prostate cancer scenario, participants would determine the additional expertise an APN role would provide related to patient self-care education, urinary sepsis prevention, discharge assessment and planning, and post-operative follow-up care.

APN definitions, competencies, and statements regarding scopes of practice tend to be broad rather than concrete in order to accommodate the flexible, expandable, and specialized nature of these roles. Common characteristics establish the core foundation of APN roles, but each role has features unique to the specific model of care. In an effort to minimize role confusion, it is important to identify and clarify participant perceptions of APN roles in relation to these core components. Members of the nursing profession who are knowledgeable about APN can assist participants in translating and applying this information to the model of care. A review of literature relevant to APN, the patient population, and model of care may provide examples of functions and benefits of an APN role. An informed decision about introducing an APN role requires a broad vision of the role in relation to the model of care.

The “fit” or consistency between identified goals and strategies and definitions of APN roles, competencies, and scope of practice are also evaluated. Specialization,

expansion, and advancement are basic criteria for an “advanced” nursing role (ANA, 1995; Bryant-Lukosius et al., 2002). To what extent will these criteria be fulfilled within the role? Of particular importance is the degree to which all domains will be utilized, the need for skills and role autonomy beyond the traditional scope of nursing, and extent of role overlap with other health care providers. Another consideration is the compatibility of values underlying the proposed changes to the model of care and values associated with APN. The primary focus of the role should be on the delivery of continuous, coordinated care designed to improve the health and wellness of the patient population. These issues and decisions to introduce a new APN role involve careful evaluation of the strengths and limitations of alternate nursing and health care provider roles (Mitchell-DiCenso et al., 1996). For example, is the range, complexity, unpredictability, or intensity of unmet patient health needs such that they could be managed with the expertise of a basic, expanded, or specialized nurse rather than advanced practice nurse? Increased participant awareness regarding APN and other health care provider roles may result in further review and revision of goals and strategies for improving the model of care.

Once the decision to introduce a new APN role is confirmed, participants work on defining the precise nature of the role specific to the new model of care related to practice, education, research, professional development, and leadership. This task may require greater involvement of stakeholders and those who have had experience with similar APN roles. For instance, the development of the neonatal nurse practitioner role in Ontario, Canada involved surveys of medical directors, head nurses, directors of

nurses, staff nurses, and physicians from neonatal intensive care units across the province (Hunsberger et al., 1992). Neonatal nurse practitioners, physicians, and head nurses from American and Canadian centres who had already implemented the role were also surveyed. Respondents indicated the importance and relevance of specific activities for each APN role domain. These data enabled participants to achieve consensus about explicit activities and time allocated to each dimension of the APN role. Identifying stakeholder perceptions and preferences in defining the APN role enhances the likelihood of role acceptance and optimal implementation of the role within the model of care and broader health care system. Barriers to role implementation may also be identified.

The next task involves defining the relationship between the new APN role and other health care providers or stakeholders. For example, how would the physiotherapist, occupational therapist, and home care nurse work with the APN to improve the self-care skills of post-prostatectomy patients? The model of care is refined and finalized as the roles and responsibilities of the APN and stakeholders are clarified and defined in relation to identified goals. Through this process, stakeholder accountability for achieving goals is determined and issues related to autonomy, team work, collaboration, communication, reporting mechanisms, and reimbursement are addressed. Professional nursing standards provide guidelines for establishing role qualifications including level of experience, education, and credentials. This stage concludes with completion of a well defined APN role position description specific to the new model of care.



### *Step 6: Plan Implementation Strategies*

The purpose of this step is to plan implementation strategies to ensure system readiness for the APN role. Key questions to address during this step include:

- What goal related outcomes are expected from the introduction of an APN role and other changes to the model of care? When will these outcomes be achieved?
- What are the facilitators and barriers to APN role development and implementation?
- What strategies are required to maximize role facilitators and minimize role barriers?
- What resources and stakeholder support is required for role development and implementation?

The planning process is dependent on a clear understanding of outcomes and expectations. Thus, planning begins with developing an outline of the evaluation including identification of goal related outcomes for each domain of the APN role and other changes to the model of care, and the timeline for achievement. Depending on the model of care and APN role, strategies may be required to address implementation issues both within and across health care systems or organizations. Structural discounting or marginalization of the APN role occurs when organizations are not prepared to support role implementation (Martin & Hutchinson, 1999). As primary investors in the process, participants play an active role in developing and executing the implementation plan.

An important aspect of planning is identifying supports and strategies to facilitate optimal APN role development, and anticipating and preventing potential barriers to role implementation. Role clarity and autonomy, administrative support, and practical resources are frequently identified as APN role facilitators and/or barriers and thus

warrant particular attention during the planning stage. The recruitment and hiring process and providing education necessary to support the APN role are other essential role facilitators. The following discussion briefly outlines some strategies to consider for each of these important aspects of APN role development and implementation.

### ***Role Clarity and Autonomy***

In previous frameworks, the focus of education has been on developing the knowledge and skills of the advanced practice nurse (Dunn & Nicklin, 1995; Mitchell-DiCenso et al., 1996). In this framework, education also involves increasing understanding about the APN role across the model of care. Role ambiguity is a frequently reported barrier to APN role implementation (Dunn & Nicklin; Knaus, Felten, Burton, Fobes, & Davis, 1997; Woods, 1998; Irvine et al., 2000). Members of stakeholder groups and other individuals such as patients/families, medical residents, students, support staff, department managers, and volunteers, who were not participants in defining the APN role, should receive information about and have opportunity to clarify role expectations.

While the position description outlines the specifics of role autonomy, planning involves determining structures required across the model of care and related work environments to support APN authority, collaborative and independent practice, and clinical decision-making. These features of role autonomy are critical to the APN role. Role autonomy enables full implementation of the role and permits APNs to be creative, flexible, and immediately responsive to individual patient needs, when and wherever they occur across the model of care (Wood, 1998; Irvine et al., 2000). Role autonomy is also

an important aspect of APN role satisfaction (Beal, Steven, & Quinn, 1997; Sidani et al., 2000). Planning for role autonomy is important for APN functions extending beyond the traditional boundaries of nursing practice. At legislative and health care systems levels, planning may involve gaining regulatory approval and establishing the appropriate credentialing process for expanded role activities. At the organizational level, processes may be required to facilitate documentation of patient care, prescriptive and diagnostic authority, and patient referral to and from other health care providers and services. These issues can be addressed through the development of organizational policies related to clinical privileges and medical directives that outline APN role autonomy, authority, and accountability (Kinney, Hawkins, & Hudman, 1997; Knaus et al., 1997; Irvine et al., 2000; Sidani et al., 2000).

#### ***Administrative and Practical Resources and Supports***

Administrative support from leaders who are knowledgeable about APN roles is crucial for successful role implementation and ongoing professional role development (McFadden & Miller, 1994; Kinney et al., 1997; Knaus et al., 1997). An important function of the administrator is to promote systems entry for the individual within the new role. APNs, particularly those who are new to the role and/or organization, report difficulty in navigating and negotiating their roles within complex health care systems (Knaus et al.; Irvine et al., 2000). Planned orientation activities, heightening the profile of the APN role, facilitating introductions, delegating leadership responsibilities, initiating participation in relevant practice, education, and/or research committees, and

demonstrating commitment to organizational policies and practices that support APN are examples of strategies to support systems entry.

Substantial learning occurs during the first year of role implementation, especially related to clinical knowledge and skill development (Knaus et al., 1997; Kleinpell-Norwell, 1999; Sidani et al., 2000). Administrators can promote APN role development through: regular contact, support, and evaluation of progress; creating mentor relationships; and establishing APN networks and working groups. Collaborating with university schools of nursing provides APNs with opportunities to: evaluate and improve their own practice through education of graduate students, participate in research, and utilize faculty as resources (McFadden & Miller, 1994).

Administrative commitment to the APN role involves providing practical resources and supports necessary to perform the role (Ostwald, Abanobi, & Kochevar, 1984; McFadden & Miller, 1994; Sanchez, Lee, & Bosque, 1996; Martin & Hutchinson, 1999). Practical resources include adequate office and clinical examination space, audiovisual equipment, and communication and computer technology. Practical support includes assistance with clinical procedures and clerical work, access to statistical consultants, and educational opportunities.

The optimal reporting structure for APN roles remains unclear and may depend on the unique features of the role and time allocated to clinical and non-clinical activities. Currently, the APN may report to a physician, a nursing or non-nursing director, or both medical and nursing directors (Sidani et al., 2000; McFadden & Miller, 1994). Nursing administrative and physician support are important for APN role development and

satisfaction (McFadden & Miller; Beal et al., 1996; Woods, 1998; Irvine et al., 2000). Nurse administrators and physicians often have competing expectations regarding the APN role. As such, dual reporting to a nursing and medical director may be an effective strategy for maximizing role support and resolving role conflicts.

### *APN Education*

Graduate education is the minimum level of preparation required for APN roles (ANA, 1995; CNA, 2000; CANO, 2001). In planning new APN roles, one must consider the availability and types of existing graduate nursing programs, and extent to which specialty-based clinical knowledge and skills required for the roles are a focus of these programs. Regional or national models of care requiring substantial numbers of APNs to address current and future health service needs, may necessitate the development of specialty-focused nursing education programs. Such was the case in developing the primary care and neonatal nurse practitioner roles in Ontario (Mitchell-DiCenso et al., 1996; Adrusyszyn, van Soeren, Spence Lashinger, Goldenberg, & DiCenso, 1999).

For models of care needing fewer APN roles, developing specialty graduate programs may not be feasible. Many APNs acquire specialty knowledge and skills through apprenticeships, in-house education programs, or on the job training. There are drawbacks to these kinds of education as the sole means of developing specialty-based expertise including: variable quality and consistency; lack of existing practice standards; incomparability to other APN roles for evaluation; lack of academic credit, limited impact on career advancement; and non-transferability of skills to other settings. Physicians are often the primary educators in apprenticeship programs and as such,

nursing practice issues may not be addressed. Linking with graduate nursing education programs to provide periodic post-graduate certificate or diploma courses may be one strategy to enhance education for APN roles specific to a model of care. In countries such as Canada where there is a paucity of specialty graduate nursing education programs, it may be beneficial to send incumbent APNs to programs in other countries. At the very least, role specific APN education programs, should utilize APN expertise and be guided by professional nursing standards. The effectiveness of education programs in preparing APNs for their roles should also be evaluated (Mitchell-DiCenso et al., 1996).

#### ***Recruitment and Hiring Process***

There are many aspects to consider during the recruitment and hiring process (Ingram & Crooks, 1991). One priority is to evaluate the compatibility between goals and expected outcomes of the APN role and applicant goals, expectations, qualifications, and expertise. The selection committee should also include a variety of stakeholders and staff working directly with the APN.

#### ***Steps 7, 8, And 9: Initiate Implementation Plan***

As the framework illustrates, implementation is a continuous process with movement among three components related to: 1) education, resources, and supports; 2) APN role standards, policies, and protocols; and 3) role development and implementation. Movement among components is dependent upon the stage of role development and on-going performance evaluation. A frequently neglected but critical feature of this stage is recognition that full implementation of the APN role occurs over

time. Hamric and Taylor (1989) identified seven phases of clinical nurse specialist (CNS) role development. Each phase has specific development tasks and needs for different types of resources and support. Full implementation of the APN role was characterized by self-confidence, a high level of advanced practice, role expansion, continuous acceptance of challenges, and congruence between personal and organizational goals. For novice CNSs, transition to this phase took 3 to 5 years (Hamric & Taylor). Woods (1998) also found that the practice environment and degree of patient dependency on medical and nursing interventions may influence how new APN roles are developed and implemented.

APNs and administrators need to be aware of the characteristics and significance of different stages of role development. Movement through the stages is dependent on regular performance evaluations and communication between the APNs and administrator(s) so that supports and resources necessary for achieving development tasks are provided. The first year is associated with several stages of role transition, multiple developmental tasks, and opportunities for role development (Brown & Olshansky, 1997; Woods, 1999). Establishing key systems structures to support role development should be a priority prior to the introduction of the role.

When legislation does not keep pace with the expansion of APN roles beyond the traditional scope of nursing, medical directives can bridge the gap in supporting APN role autonomy and clinical decision (Vlasic et al., 1998; Irvine et al., 2000; Sidani et al., 2000). The onus for developing medical directives often falls to the APN and is an important task during the first year of role implementation. This task enables the APN to

gradually ease into the role, establish confidence and credibility, and can promote knowledge and skill development, particularly for new APN graduates. Forming multidisciplinary groups to work with the APN to develop medical directives can facilitate collaborative relationships within the model of care (Vlasic et al.).

***Step 10: Evaluate APN Role and New Model of Care***

APN role evaluation involves assessing the impact of the new model of care and the APN role itself, in achieving identified goals. This approach attempts to avoid limitations of past evaluations in detecting differences in outcomes related to APN roles, when the impacts of the APN environment or factors beyond the control of the APN are not considered. High quality care depends on three essential elements: structure, process and outcomes (Sidani & Braden, 1998). Structure includes factors related to resources, the physical and organizational environment, and characteristics of health care providers and patients. Process refers to the types of services and when and how care is provided. Outcomes are the changes or results of care. Inclusion of the model of care will enable identification of how the roles, relationships, and resources within the model of care impact on expected outcomes. Comparative evaluations could involve pre- and post-assessments of the model of care with and without the APN role, or comparisons to similar models of care without an APN role. An evaluation of the characteristics of the model of care may also identify elements that facilitate or inhibit APN role development and implementation.

Several authors have applied the structure-process-outcome framework to develop models for evaluating APN roles (Grimes & Garcia, 1997; Byers & Brunell, 1998; Irvine,



Sidani, & McGillis Hall, 1998). Structural elements relevant to the APN include experience, knowledge, skills, and education. The process component of the APN role relates to specific functions of each role domain including practice, education, research, and organizational and professional leadership. APN processes can be further defined in terms of independent, dependent, and inter-dependent role functions (Irvine et al., 1998). APN outcomes are affected by both structure and process factors.

Most research evaluating APN roles has involved comparisons to physicians. As a result, only the impact of medical and not nursing related aspects of the role, are evaluated (Ingersoll, McIntosh, & Williams, 2000; Kleinpell-Norwell, 2001). This narrow evaluation can be averted by selecting goal directed outcomes salient to each role domain and specific to the APN role (Burns, 2001; Minnick, 2001). Outcomes are more likely to be relevant to the APN role when patient needs have driven the identification of goals and the role delineation process. Patient-centred outcomes are thought to be more responsive to nursing interventions (Grimes & Garcia, 1997).

Selecting outcomes sensitive to APN interventions is a major challenge, and may contribute to studies reporting no differences in outcomes related to APN roles. Recent efforts have focused on identifying and categorizing nurse sensitive outcomes (Hill, 1999; Urden, 1999; Van der Bruggen & Groen, 1999; Ingersoll et al., 2000; Dayhoff & Lyon, 2001; Kleinpell-Norwell, 2001). This literature reflects an emphasis on clinical practice outcomes compared to other APN role domains such as education or research. Common measures relate to cost, satisfaction, clinical findings and symptoms, functional status, and quality of life. One article summarizes outcomes relevant to three spheres of

APN influence; the patient, nursing, and organizations/health care systems (Dayhoff & Lyon). Kleinpell-Norwell (2001) provides an excellent summary of resources for identifying reliable and valid outcome measures relevant to APN.

Formal planning for evaluation should begin prior to introducing the role so that baseline data can be collected. To maintain objectivity, it is preferable that the evaluator not be a stakeholder from within the model of care (Grimes & Garcia, 1997). The timing and focus of evaluation are also important considerations. Initial comprehensive evaluations of the APN role and model of care should focus on outcomes related to safety and efficacy, acceptance and satisfaction, costs, and role transfer (Mitchell-DiCenso et al., 1996). Given the extent of role development occurring during the first year of implementation, these evaluations should not occur until after this time period.

Brooten and Naylor (1995) identify that the amount of exposure to a nursing intervention is an important consideration in APN role evaluations. Lack of significant change in APN outcomes may not mean that the role is ineffective but that dose or intensity of exposure to the nurse is too weak. Revisions to the APN role might consider identifying patient needs requiring a stronger dose of nursing such as increased frequency of phone calls or more follow-up visits. The model of care could also be modified to eliminate barriers that restrict the nurse dose.

In addition to formal evaluations, the APN has a responsibility for monitoring the impact of the role and her/his own performance. This should include collection of prospective data relevant to identified goals for each role domain related to clinical practice, education, research, professional development, and organizational leadership.

On-going evaluation is important for individual development within the role and to detect and minimize potential barriers to role implementation. APNs have found that establishing a reporting system documenting activities relevant to goal-directed outcomes demonstrated the diversity of their work, was crucial to maintaining their position, and provided the evidence to support the establishment of new APN roles (McFadden & Miller, 1994). Strategies include maintaining daily records of activities and time spent on each role domain such as the number of referrals and types of patients seen, staff programs provided, number and types of consultations, development of care maps, scholarly presentations and publications, contributions to committees and organizational initiatives, and participation in research (Dayhoff & Lyon, 2001). Activities are then linked to specific outcomes such as prevention of complications, staffing patterns and practices, length of stay, costs, and re-admission rates. Feedback on performance and process related elements of the role such as personal, peer, staff, and patient satisfaction, should also be documented.

***Step 11: Determine Future Needs***

Mechanisms for annual monitoring and long term surveillance of the model of care and the APN role are also required (Mitchell-DiCenso et al., 1996). Continuous change within APN environments can impact on the safety, satisfaction, and sustainability of the role. Advances in treatment and technology can impact on patient health needs and health care policies or funding can influence the delivery of health care services. Thus, the process for APN role development, implementation, and evaluation is

iterative. Long term evaluations should include the opportunity to revisit each stage of the PEPPA Framework and make appropriate changes to the APN role and model of care.

### ***Strengths and Limitations of the PEPPA Framework***

This Framework utilizes a health oriented, patient focused, participatory, and stakeholder driven process as a strategy for overcoming obstacles to full implementation and integration of APN roles. The strength of the PEPPA Framework is illustration of the complexity and inter-relatedness of each step of APN role development, implementation, and evaluation. Introducing APN roles requires thoughtful planning and decision-making and is a lengthy and time consuming process.

This strength is also a potential drawback in that the framework and perceived effort and resources required may appear overwhelming. However, what the model demands is commitment to each step in the process as a method for ensuring successful implementation of the APN role. The depth and scope of the process can be tailored to meet temporal and resource restrictions when defining the patient population and model of care. For example, limiting the patient population to one patient group at one point in the care continuum and restricting the model of care within a team rather than a region narrows the scope of the process. The number of subsequent stakeholders will also be reduced. The needs assessment can be limited to one or two rather than multiple patient needs. The evaluation design can also be practical and feasible to achieve, while maintaining methodological rigor. Establishing limits on the scope of the process will narrow comprehensiveness of care and potential impact of the new model of care and APN role. However, recognizing and responding to environmental constraints will

enhance the likelihood that priority goals for the APN role will be achieved. Future efforts could focus on expansion of the APN role to a broader population of patients, range of needs, and continuum of care.

The underlying principles of the framework related to PAR and the focus on patient health needs are consistent with the central mandate of nursing and the type of collaboration and partnerships associated with APN roles. These same principles and values often conflict with the bureaucratic and disease focused nature of health care systems and may pose barriers to applying the framework. However, a lack of willingness on the part of stakeholders to invest in the process may be an indicator of a health care environment that is not yet ready for an APN role or change within the model of care.

Incorporating the model of care extends the potential impact of the framework beyond that of individual health care provider roles to include coordination and integration of health care services. Consistent utilization of this framework may have useful research applications and facilitate comparisons of APN roles in a variety of settings. Some examples include: identification of patient populations and models of care for which the APN role has the greatest impact; identification of APN sensitive outcomes across role domains, identification of additional role facilitators and barriers; and further development in defining APN roles and scopes of practice.

### **Conclusions**

The process required for the successful implementation of APN roles is as complex and dynamic as the roles themselves. The PEPPA Framework articulates steps

and strategies for role implementation that are relevant to APN and APN environments. Engaging stakeholders as participants in the process provides opportunities to establish the need and identify mutually shared goals for a clearly defined APN role. The Framework promotes increased understanding of APN roles and optimal utilization of the broad range of APN knowledge, skills, and expertise. Effective planning and implementation strategies create environmental conditions necessary to support APN role development and long term integration. The goal-directed and outcome based process also provides the basis for on-going prospective evaluation and thus continued improvement of both the APN role and delivery of health care services.

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## **CHAPTER 4**

### **Preamble**

This chapter is an expanded version of a manuscript that will be submitted for publication. In Chapter 2 it was proposed that the value added benefit of APN roles related to patient health outcomes and health care costs results from roles that are patient-centred, health focused, and complementary to pre-existing models of care. In Chapter 3, the PEPPA Framework was outlined; beginning steps of this process involve identifying patient health needs as the basis for determining the need for and primary focus of new APN roles. This expanded manuscript describes a study designed to identify patient health needs as an initial step for defining an APN role specific to patients with advanced prostate cancer. A cross-sectional survey was used to examine HRQL and the types of health problems experienced by five groups of patients representing the continuum of prostate cancer care provided at the Hamilton Regional Cancer Centre. In this manner the health needs of patients with advanced prostate cancer were identified within the context of the whole illness experience from the time of diagnosis to palliation.

Our results indicate that patients with advanced hormone refractory prostate cancer have different health needs than those with early stage and advanced hormone sensitive disease. Recommendations for defining the APN role for these populations of prostate cancer patients are provided and supportive care research priorities for improving the health and quality of life of patients with prostate cancer are identified.

### **Contributors**

The idea for this study evolved from my Nursing Fellowship in malignant urology at the Hamilton Regional Cancer Centre and was a primary component of my thesis work. I conceived the original idea, developed the proposal, and obtained funding for this study. I was responsible for all stages of study implementation including obtaining ethics approval and selection and development of data collection methods. I supervised and directed data collection, data management and analysis, interpreted the data, and wrote the manuscript.

My thesis supervisor, Gina Browne provided overall guidance for the project, had input into the study design, methods, and data analysis, and reviewed and provided comments on the draft manuscript.

As the Director of the Supportive Care Research Unit at the Hamilton Regional Cancer Centre, Tim Whelan provided feedback on the study design and methods, was a member of the consensus panel involved in defining the five groups of patients with prostate cancer included in this study, and provided research staff who collected and entered the data.

Alba DiCenso is a member of my thesis committee who provided guidance regarding the data analysis and reviewed and provided feedback on the draft manuscript.

Amiram Gafni is a member of my thesis committee who provided feedback on the draft manuscript.

Alan Neville was a clinical consultant prior to and during the study, provided feedback on the original proposal, was a member of the consensus panel that defined the

five groups of patients with prostate cancer, and reviewed and provided comments on the draft manuscript.

Jinka Sathya was as a clinical consultant prior to and during the study, was a member of the consensus panel that defined the five groups of patients with prostate cancer, and reviewed and provided comments on the draft manuscript.

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**Quality of Life in Prostate Cancer:  
Evaluating Health Related Quality of Life and Priority Health Problems  
as the Foundation for Supportive Care**

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## Abstract

### *Purpose*

To examine health related quality of life (HRQL) and patient health problems across the continuum of prostate cancer care.

### *Patients and Methods*

Patients with prostate cancer receiving care at a university affiliated comprehensive regional cancer centre in southern Ontario, Canada were categorized into five different groups representing the continuum of care based on stage of disease and treatment status including: Early Stage Newly Diagnosed (E-NEW), Early Stage On Treatment (E-RX), Early Stage Receiving Follow-up Care (E-FLP), Advanced Stage Hormone Sensitive (A-HS), and Advanced Hormone Refractory (A-HR). Over a 4-month period, 631 patients attending scheduled clinic appointments were approached, and 551 (87%) participated in the study. HRQL was examined using the validated Functional Assessment of Cancer Therapy-Prostate (Total FACT-P) scale. Regression analysis was used to identify patient characteristics that predicted HRQL. Using a checklist of possible health problems, patients identified priority needs for improving their health.

### *Results*

The A-HR group had significantly poorer HRQL compared to the other patient groups ( $p < 0.001$ ) at baseline assessment. Patients with advanced cancer were more likely to have a history of mental health problems. Prostatic specific antigen (PSA), disease status (patient group), and history of mental illness were negatively associated

with and accounted for the greatest variance (18%) in HRQL ( $p < 0.0001$ ). Types of severe health problems and importance of health problems varied among groups.

Patients with early stage and A-HS disease had priority health needs related to sexual function, urinary frequency, urinary incontinence, and other treatment side effects.

Newly diagnosed patients with early stage disease also had priority needs related to emotional well-being and information. Pain, fatigue, decreased physical activity, and urinary frequency were priority concerns for the A-HR group.

### ***Conclusions***

Patients with advanced hormone refractory prostate cancer have significantly poorer HRQL, experience more severe health problems, and have different priority health needs compared to other patient groups. Disease status, PSA and history of mental health problems were modest predictors of HRQL. Further research to examine the extent and impact of mental health problems across the continuum of prostate cancer is required.

Given the differences in HRQL and health needs, the focus of supportive care interventions will differ for patients with advanced hormone refractory prostate cancer compared to those with other stages of disease.

## Introduction

Improving supportive and palliative care in prostate cancer has been identified as a priority among patients, families, and health care providers (National Prostate Cancer Forum [NPCF], 1997). Ontario cancer programs have sought to improve access to and delivery of curative prostate cancer treatment through expansion of radiation oncology services and coordination of medical treatment among urologists and radiation oncologists (Cancer Care Ontario [CCO], 2001). However, systematic development and integration of collaborative and coordinated supportive care services have not yet occurred. The introduction of an advanced practice nursing role, to improve the supportive care provided to patients with advanced stage prostate cancer, is being considered by one Ontario regional cancer program.

Several qualitative studies and a Canadian survey identify that supportive care issues related to information, treatment decision-making, treatment side effects, coping, incontinence, and sexual function are concerns for men with predominately newly diagnosed and/or localized prostate cancer (Butler et al., 2001; Fitch Johnson, Gray, & Franssen, 1999; Gray et al., 1997a; Heyman & Rosner, 1996; Moore & Estey, 1999). However, the supportive care needs of patients with prostate cancer may vary in terms of stage of disease, type of treatment, and time since diagnosis. Patients with advanced prostate cancer may have different supportive care needs related to having an incurable illness or to problems associated with metastatic disease such as fatigue, pain, cachexia, and urinary and bowel obstruction (Esper & Redman, 1999; Fossa et al., 1990; Kornblith et al., 1994; Tannock et al., 1996). Access to and quality of cancer care services, and

ability to meet patient needs are often influenced by local, geographical, and social issues (Gray et al., 1997a; Mackillop, Zhang-Solomans, Groome, Paszat, & Holowaty, 1997). Thus simple application of large national surveys as the basis for development of local and regional services may limit opportunities to address needs that are unique to specific communities.

Till (1994) identifies that measuring HRQL is a useful strategy for assessing patient needs and guiding the development of new health care programs. HRQL is subjective and determined by the patient's appraisal of and satisfaction with their current level of physical, emotional, and social well-being in comparison to the norm or expectations for health (Cella & Bonomi, 1995). Patient health needs and potential gaps in the delivery of health care services may be defined by discrepancies in appraisal and health expectations. Variations in baseline HRQL scores may identify differences in supportive care needs across heterogeneous groups of patients (Till, 1994).

In prostate cancer, HRQL has been utilized as an outcome indicator in clinical trials and other studies to evaluate or compare the impact of specific treatments particularly for localized disease (Galbraith, Ramirez, & Pedro, 2001; Henke Yarbro & Estwing Ferrans, 1998; Joly et al. 1998; Litwin et al, 1995; Madalinska et al, 2001; Wei et al., 2002). There are few studies evaluating HRQL among patients with early and advanced prostate cancer and none which specifically compare patients with hormone refractory disease (Borghede, Karlsson & Sullivan, 1997; Esper et al., 1997; Helgason et al., 1996; Lubeck et al., 1999). Conclusions regarding differences in HRQL in prostate cancer among studies with different stage and treatment specific populations are

hampered by the use of different HRQL instruments and small sample sizes. In addition, the study of prostate cancer specific problems often involves comparison of selected items relevant to the stage of disease or treatment under evaluation (Braslis, Santa-Cruz, Brickman, & Soloway, 1995; Fowler et al., 1995; Helgason et al., 1996; Tannock et al., 1996). Thus, evaluation of HRQL is not always comprehensive and limits full comparison of HRQL across stage specific patient groups. One study involving small sample groups found that patients with advanced disease had poorer quality of life related to physical, functional, and prostate cancer well-being compared to patients with early or localized disease (Esper et al., 1997). Specific problems impacting on differences in HRQL between the patient groups were not reported.

Historically, the delivery of health care services has been driven by health care providers' perceptions of priorities and patient needs. However, patients and health care providers often have differing viewpoints about patient needs (Bunston & Mings, 1995; da Silva, Reis, Costa, & Denis, 1993; Larson, Viele, Coleman, Dibble, & Cebulski, 1993). Patient priorities regarding supportive care health needs in prostate cancer have not been systematically explored. The focus of this study is on determining patient perceptions of their HRQL and supportive care health needs related to prostate cancer across the continuum of care from the time of diagnosis through to palliation. The specific objectives of this study are to:

1. Identify and compare patient perceptions of HRQL across the continuum of prostate cancer care.

2. Identify the most frequent and severe health problems negatively affecting HRQL across the continuum of prostate cancer care.
3. Identify patient perceptions of priority health problems across the continuum of prostate cancer care.
4. Inform the development of the supportive care role of the advanced practice oncology nurse for patients with advanced prostate cancer.

As one stage of a comprehensive needs assessment process, the information gained from this study will contribute to the development and evaluation of supportive care interventions and health care delivery strategies specific to prostate cancer patients.

## **Methods**

### ***Setting***

The Hamilton Regional Cancer Centre (HRCC) is one of nine regional cancer centres in Ontario, Canada and is responsible for providing comprehensive cancer care services for a population of 2.2 million people in the central west region of the province. Within this region, there are approximately 750 new diagnoses and over 200 deaths related to prostate cancer each year (Cancer Care Ontario, 1998). This compares with a national incidence of 17,000 new cases and 4,200 deaths annually (National Cancer Institute of Canada [NCIC], 2000). Prostate cancer patients are referred to the HRCC by family physicians and community urologists primarily for radiation and/or medical treatment.

*Sample*

A panel involving a clinical nurse specialist, medical oncologist, and two radiation oncologists identified five groups of patients with prostate cancer receiving care at the HRCC who were at different points along the continuum of care. Early stage patients included all those with T1 to T3 disease according to the Tumour-Node-Metastasis (TNM) staging classification system and were categorized into three different groups based on their treatment status. Early stage newly diagnosed patients (E-NEW) were those who had not yet begun treatment. Early stage on treatment (E-RX) patients were those receiving initial or post-prostatectomy treatment and included those who were up to 2 months post treatment. Early stage follow-up (E-FLP) patients were more than 2 months post treatment and receiving surveillance care only. All patients with T4 or metastatic disease were considered to have advanced stage disease and were categorized into two groups: hormone sensitive (A-HS) and hormone refractory (A-HR). The A-HS group included patients who were newly diagnosed prior to treatment and those receiving initial treatment or treatment for recurrent disease. Recurrent disease was defined as three consecutive rises in the PSA level following complete response (PSA < 1.0) to curative therapy. Hormone refractory disease was characterized by a progressive rise in the PSA level following a response to androgen suppression therapy. Patients in the A-HR group included those receiving surveillance care, mitoxantrone chemotherapy with or without prednisone, palliative radiation, or other pain and symptom management measures.

Eligible patients included those who provided written informed consent, were able to understand English, and had the physical and cognitive abilities to complete a self-report questionnaire.

The sample size was determined in order to detect a 2-point difference in quality of life subscale scores and a 7 to 10 point difference in total quality of life scale scores, between patient groups (power = 90%). A total of 84 patients per group was required. Recruitment of patients for a specific category stopped once accrual surpassed 100 subjects.

### *Procedure and Instruments*

The study received ethics approval from the participating regional cancer centre and local ethics review board (Appendix B). The health records of patients with prostate cancer who had scheduled appointments at the HRCC, were screened by trained research assistants to ascertain study eligibility and to categorize patients into one of the five pre-defined groups. The principal investigator audited the eligibility information of study participants to ensure correct assignment to each patient group. Research assistants approached patients at the time of their clinic appointment for study participation and obtained informed consent (Appendix C).

### *Demographic Data*

Research assistants abstracted the following information from health records: age, marital status, living situation, time since the diagnosis of prostate cancer, stage of disease at diagnosis, prostate specific antigen (PSA) level, current and previous prostate cancer treatment, and co-morbid conditions (Appendix D). PSA levels were documented



only in patients who had these tests completed as part of routine clinical care within a 2-week period prior to or following their appointment.

### *Quality of Life*

General and prostate cancer specific measures were used to evaluate HRQL. The Functional Assessment of Cancer Therapy Scale or FACT-G (version 4) is a 27-item general cancer quality of life instrument with four subscales related to physical, social, emotional, and functional well-being (Cella et al., 1993). In addition to scores for each subscale, a cumulative score across all domains can be calculated. FACT-G utilizes a likert-type scale measuring from 0 to 4, with higher scores representing greater health or well-being.

FACT-G has well-established psychometric properties and has been utilized in a wide range of cancer populations (Bonomi et al., 1996; Cella, 1997; Weitzner et al., 1995; Yu et al., 2000). Test-retest correlation coefficients are high ranging from 0.82 to 0.92 (Cella et al., 1993). FACT-G has demonstrated ability to discriminate differences in quality of life related to disease, performance status, and hospitalization status in a variety of cancer populations (Cella et al., 1993). Esper et al. (1997) reported that FACT-G discriminated between stages of disease and changes in PSA levels for three sample populations of patients with prostate cancer. The internal consistency of FACT-G was acceptable for most subscales with Cronbach alpha coefficients ranging from 0.71 to 0.84 (Esper et al., 1997). However, lower estimates of internal consistency (Cronbach's alpha 0.62-0.64) were found for one subscale in each of the three samples related to emotional,

social, or physical well-being. Internal consistency for total FACT-G was high (Cronbach's alpha 0.85-0.87).

The Functional Assessment of Cancer Therapy – Prostate Cancer (FACT-P version 4) is a 12-item prostate cancer specific quality of life scale. When used in combination with FACT-G it is called Total FACT-P (Appendix E). FACT-P assesses problems related to weight loss, appetite, pain, comfort, body image, bowel function, urinary symptoms, and sexual function and uses the same rating and scoring method as FACT-G. FACT-P was developed and tested in combination with FACT-G (FACT-P version 2) by Esper et al. (1997) in three populations of patients with prostate cancer. Internal consistency for Total FACT-P was high with Cronbach's alpha coefficients of 0.87 to 0.89. Lower levels of internal consistency were found for the 12-item prostate cancer scale (FACT-P) with Cronbach's alpha ranges of 0.65 to 0.69. While the validity and reliability of FACT-P is less well established than the FACT-G, it does discriminate patients by stage of disease, performance status, and PSA levels. FACT-P was also sensitive to changes in performance status and PSA levels over time (Esper et al., 1997).

#### ***Frequency and Severity of Health Problems***

Severe health problems were defined as any Total FACT-P item in which patients scored 0 to 1 out of 4 (using reversed scores for negatively worded questions), indicating poor HRQL. For each item, the percentage of patients who rated it between 0 and 1 was determined for the study sample and for each patient group.

### *Priority Health Problems*

The final item in the questionnaire was designed to identify patient perceptions of priority health problems (Appendix F). To capture a broad range of supportive care health needs, potential health problems related to fatigue and physical, social, emotional, functional, and prostate cancer well-being were identified from a variety of HRQL instruments including the FACT-Anemia, FACT-G, FACT-P, and European Organization for Research and Treatment of Cancer Care Quality of Life Questionnaire (EORTC-QLQ-C30). Additional health problems not addressed in these instruments related to the side effects of radiation and hormone therapy, urinary function, treatment and disease information, practical support, and finances were identified from the prostate cancer research literature (Borgehede & Sullivan, 1996; Davison & Degner, 1997; Davison, Degner, & Morgan, 1995; Litwin et al., 1995). A total of 38 potential health problem items were identified. Respondents were asked to identify the three most important problems, which if addressed would improve their health.

The reliability and validity of the priority problem question was not established. The questionnaire was pilot tested by 20 prostate cancer patients who were asked to provide feedback on the acceptability, clarity, length, and completeness of the questionnaire. Minor modifications were made to the questionnaire format but not to questionnaire items. The entire questionnaire took approximately 20 minutes to complete. Within a week of completion, questionnaires were reviewed for completeness and research assistants called respondents at home to gather any missing data.

### *Statistical Analysis*

Descriptive statistics in the form of percentages or mean scores were used to describe patient characteristics, HRQL scores, and priority problems. Group differences related to patient characteristics involving continuous variables such as mean age, years since diagnosis, and PSA were evaluated using analysis of variance (ANOVA). Chi-square was used to evaluate group differences related to selected categorical variables including marital status, living arrangements, co-morbidity, and stage at diagnosis. For tests of differences related to patient characteristics, the alpha level was set at a more conservative alpha level of 0.01 to minimize the risk of type one error associated with multiple comparisons.

The internal consistency (Cronbach's alpha) of FACT-G and Total FACT-P subscales and scales for the study sample was assessed using the SPSS Reliability Analysis Program. Mean subscale scores for physical, social, emotional, functional, and prostate cancer well-being were calculated by summing the scores for each item in the subscale. The total score for FACT-G is the sum of subscale scores for physical, social, emotional, and functional well-being. Total FACT-P is the sum of FACT-G and the prostate cancer subscale. At the time of data analysis, reverse scoring is used for negatively worded questions so that high scores always represent better quality of life. According to Cella (1997), FACT scales are considered to be an acceptable indicator of patient quality of life as long as the overall item response rate is greater than 80% (e.g. 22 of 27 FACT-G items) and 50% for subscale items (e.g. 7 of 12 prostate subscale items).

Prorated scores were used when some items were missing ( $[\text{sum of scores for each item}] \times [\text{number of items in subscale} / [\text{number of items answered}]]$ ).

The primary analysis of this study involved comparisons of HRQL. ANOVA was used to test for differences in mean HRQL subscale and total scale scores among the five groups. For this analysis, the alpha level was adjusted to 0.007 (0.05/7 comparisons of HRQL) in an effort to reduce the risk of type one error associated with multiple testing. When differences occurred, Scheffé's method of post hoc comparison was used to identify the pairs of patient groups with significantly different mean scores of HRQL (Casella & Berger, 2002; Kleinbaum & Kupper, 1978). Confidence intervals around mean group differences in HRQL were calculated.

Two, 7, and 10 point differences between groups on FACT subscales, FACT-G scale, and Total FACT-P scale scores respectively were defined a priori as clinically important differences in HRQL for this study. These point differences have been found in other studies to be indicative of clinically important differences in HRQL when compared to performance status (Cella, et al., 1995; Lee et al., 2000; McQuellon et al., 1997). Specifically, an increase or decrease of 2 or 3 points on subscales was associated with the same directional movement of one level of performance status as measured by the Eastern Oncology Cooperative Group (ECOG) performance status scale (Cella et al., 1995). In clinical trials, a one level difference in performance status is thought to be clinically important with respect to the impact of cancer therapies. Other studies have also found that clinically important differences occurred with similar changes in likert scale scores (Jaeschke, Singer, & Guyatt, 1989; Neymark et al., 1998).

Stepwise multiple regression was used to determine the extent to which specific patient and prostate cancer related characteristics were predictors of HRQL as measured by the Total FACT-P. Patient related characteristics included in this analysis were age, marital status, living arrangement, number of co-morbid conditions, and history of mental illness. In addition to patient group, prostate cancer related characteristics included in the regression analysis were PSA level, stage of disease at diagnosis, years since diagnosis, and treatment status (receiving or not receiving treatment for prostate cancer).

To identify the most frequent and severe health problems affecting HRQL, the percentage of patients who rated each Total FACT-P item as 0 or 1 out of 4, indicating poor HRQL was determined for each group. Priority health problems or the problems patients reported as being the most important for improving their health were identified through frequency counts (percentages) for the study sample and each patient group.

## **Results**

### ***The Sample***

Accrual took place over a 4-month period from June to September 1999. Of 947 patients screened, 631 were approached and 551 (87%) agreed to participate in the study. Less than 13% declined participation (n = 42) or were unable to complete the questionnaire (n = 35). Three patients were subsequently found not to have prostate cancer or had a history of prostate cancer but were referred for treatment other than for prostate cancer. An additional 316 patients were screened but not approached for study participation because the patient missed his appointment (n = 27), the research assistant

was unavailable (n = 47), or the patient's disease stage category was already filled (n = 242).

The expected sample size of 84 patients per group was achieved in all but the E-NEW group. Accrual of newly diagnosed patients was hampered by reduction in referrals over the summer months when the study took place, and transfer of patients to other centres due to a backlog of patients waiting for radiation treatment. The number of subjects in each group includes: E-NEW (69), E-RX (134), E-FLP (128), A-HS (110), and A-HR (110).

### *Demographic Data*

Table 1 summarizes the characteristics of the study sample and the five patient groups. The study sample consists of older men with a mean age of 71.47 years. The majority of men were married and living with their spouse or other family members. Co-morbidity was high with 87.7% of men reporting other health problems in addition to prostate cancer. The most frequently reported co-morbid conditions were hypertension (28.3%), cardiac conditions (25.6%), arthritis (14.3%), and diabetes (11.6%). Except for observation or surveillance care, radical radiation therapy and hormone therapy were the most frequently reported current or past treatments. Less than 12% of the sample population had previously undergone prostatectomy and only 3% had received iridium implants.

There were no differences among the groups related to marital status, living arrangements, or the presence of co-morbidity. Except for a history of mental illness, there were also no differences related to types of co-morbid conditions among the groups.

**Table 1 Characteristics of Study Sample and Comparisons of Group Differences**

Characteristics	Total N = 551	E-NEW N = 69	E-RX N = 134	E-LP N = 128	A-HS N = 110	A-HR N = 110	Test (df)	P *
<b>Age</b> Mean Years (SD)	71.47 (6.94)	70.20 (6.80)	68.99 (7.33)	72.14 (5.98)	73.80 (5.81)	72.16 (7.65)	F = 8.94 (4, 446)	< 0.001
<b>Married %</b>	81.9	78.3	88.1	74.2	81.8	85.5	$\chi^2 = 24.32$ (16)	0.03
<b>Live with Family %</b>	83.5	82.6	88.8	76.6	82.7	86.4	$\chi^2 = 14.10$ (8)	0.078
<b>Comorbidity %</b>	87.7	87.0	86.6	87.5	89.1	88.2	$\chi^2 = 0.418$ (4)	0.981
<b>Mental Illness %</b>	7.8	5.8	3.7	4.7	9.1	16.4	$\chi^2 = 16.65$ (4)	0.002
<b>Years Since Diagnosis</b> Mean (SD)	3.07 (3.11)	0.26 (0.23)	0.88 (0.97)	3.02 (2.05)	4.82 (2.80)	5.82 (3.66)	F = 107.60 (4, 446)	< 0.001
<b>Stage at Diagnosis %</b>								
I	21.3	41.8	23.1	28.1	13.0	5.1	$\chi^2 = 229.49$ (12)	< 0.001
II	48.6	55.2	56.0	55.5	54.6	18.4		
III	19.3	3.0	20.9	16.4	22.2	28.6		
IV	10.8	0	0	0	10.2	48.0		
<b>PSA ug/L</b> Mean (SD)	66.46 (229.70)	16.61 (26.66)	3.76 (7.10)	2.45 (4.51)	12.34 (40.67)	261.39 (423.18)	F = 29.92 (4, 434)	< 0.001



**Table 1 continued Characteristics of Study Sample and Comparisons of Group Differences**

Characteristics	Total N = 551	E-NEW N = 69	E-RX N = 134	E-FLP N = 128	A-HS N = 110	A-HR N = 110	Test	P*
<b>Current Therapy (%)</b>								
assessment	12.8	100	0.8	0	0.9	0.9	not assessed	not assessed
observation	48.4	0	34.6	100	51.9	30.9	assessed	assessed
iridium implant	0.2	0	0.8	0	0	0		
radical radiation (RT)	7.1	0	28.6	0	0	0		
radical RT + hormones	5.3	0	21.1	0	0.9	0		
hormones only	16.5	0	13.5	0	44.5	22.7		
orchidectomy	0.4	0	0	0	0	1.8		
mitoxantrone chemotherapy	3.3	0	0	0	0	16.4		
palliative RT *	0.5	0	0	0	0.9	2.7		
pain/symptom management	5.5	0	0.6	0	0.9	24.5		
<b>Previous Therapy (%)</b>								
none	12.7	97.1	0.7	1.6	2.6	3.6	not assessed	not assessed
completed assessment	86.4	4.3	98.5	97.7	98.2	98.2	assessed	assessed
observation	2.7	0	1.5	1.6	2.7	7.3		
prostatectomy	11.6	0	14.2	10.2	15.5	13.6		
iridium implant	2.5	0	0	4.7	4.5	2.7		
radical radiation (RT)	45.2	0	26.1	69.5	78.2	35.5		
radiation RT & hormones	7.8	0	10.4	11.7	7.3	5.5		
hormones alone	18.7	0	6.0	6.3	10.0	69.1		
orchidectomy	13.6	0	0.7	0	10.9	56.4		
mitoxantrone chemotherapy	3.6	0	0	0	0	18.2		
palliative RT	7.1	0	0	0	0	35.5		
pain/symptom management	4.5	0	0	0.9	0.9	21.8		

Note. E-NEW: Early stage new diagnosis, E-RX: Early stage > 2 months post treatment, E-FLP: Early stage > 2 months post treatment, A-HS: Advanced stage hormone sensitive, A-HR: Advanced stage hormone refractory. \* Radical RT = external beam radiation ≥ 6,000 cGy over 30 to 45 fraction \*Palliative RT includes strontium and/or external beam radiation < 6,000 cGy  
Significance at p = 0.01, significant values are bold

There were statistically significant differences among the five groups related to age, years since diagnosis, stage at diagnosis, and PSA. Selected post hoc comparisons (Scheffé) showed that the E-RX group was younger than E-FLP ( $p = 0.007$ ), A-HS ( $p < 0.0001$ ), and A-HR ( $p = 0.01$ ) groups. The A-HR group also had significantly higher levels of PSA compared to the other groups ( $p < 0.0001$ ). Patients with advanced stage disease were more likely to have a documented history of mental health problems compared to patients with early stage disease ( $\chi^2 = 12.34$ ,  $df = 1$ ,  $p = 0.0004$ ).

Observed differences in other prostate cancer related characteristics reflect the continuum of prostate cancer care and confirm that study participants were assigned to the correct group. E-NEW and E-RX patients were less than 1 year, E-FLP patients were 3 years, and advanced stage patients were more than 4 years post diagnosis. A greater proportion of men in the A-HR group had stage IV disease at diagnosis, while the majority of men in other groups had stage II disease at diagnosis. However, the E-NEW group did have fewer patients with stage III disease at diagnosis compared to the other early stage groups. E-NEW patients had not received any past or current therapy, and E-FLP patients were being monitored only. E-RX, A-HS, and A-HR patients had or were receiving stage appropriate therapies.

#### ***FACT-G and Total FACT-P***

The internal consistency of FACT-G and Total FACT-P in this study population was high with Cronbach's alpha coefficients for subscale and total scales ranging from 0.72 to 0.90. Overall, there was only 10% missing data for Total FACT-P and every subject met and most subjects exceeded criteria for completeness of data for all subscales

and total FACT scales. Therefore, the FACT-G and Total FACT-P results reported are believed to accurately reflect these measures of HRQL for this study sample.

Table 2 summarizes the mean scores for HRQL and differences in HRQL among the five groups. For all early stage and the A-HS groups, mean FACT-G and Total FACT-P scores are relatively high, indicating good HRQL<sup>1</sup>. The highest mean scores for FACT-G and Total FACT-P were observed in the E-FLP group, while the A-HR group had the lowest mean scores. There were statistically significant differences in physical, emotional, functional, and prostate cancer well-being across the five groups, but no differences related to social well-being. Group differences were also identified related to FACT-G and Total FACT-P mean scores.

Table 3 summarizes post hoc comparisons of statistically significant ( $p \leq 0.05$ ) differences in HRQL between groups. These differences in HRQL were also clinically important as demonstrated by mean group differences all greater than the pre-determined cut points for clinical significance (e.g. 2, 7, and 10 point difference in subscales, FACT-G, and Total FACT-P scores). There were two differences among the early stage and A-HS groups. E-FLP patients had better emotional well-being compared to E-NEW patients and E-NEW patients had better prostate cancer well-being compare to A-HS patients. The A-HR group had poorer HRQL with significantly lower mean scores for physical, functional, and prostate cancer well-being, FACT-G, and Total FACT-P compared to all early stage and the A-HS groups. E-RX, E-FLP, and A-HS groups also had higher mean scores or better emotional well-being compared to the A-HR group but

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<sup>1</sup> When total scale scores for FACT-G and FACT-P are divided by the total number of scale items, average scores for the early stage and A-HS groups are greater than 3 out of 4, indicating good overall HRQL.

**Table 2 Comparison of Health Related Quality of Life (HRQL) Scores and Disease Status**

HRQL	Total N = 551	E-NEW (N = 69)	E-RX (N = 134)	E-FLP (N = 128)	A-HS (N = 110)	A-HR (N = 110)	F test (df)	P **
<b>Physical</b> 0-28*	24.33 (4.40)	25.94 (3.57)	24.51 (4.28)	25.96 (2.70)	24.28 (3.87)	21.27 (5.45)	23.30 (4, 546)	< 0.001
<b>Social</b> 0-28*	21.63 (5.32)	22.08 (6.05)	21.44 (5.41)	21.75 (5.27)	20.89 (5.36)	22.20 (4.70)	1.043 (4, 546)	0.38
<b>Emotional</b> 0-24*	19.18 (4.27)	18.34 (4.20)	19.97 (4.29)	20.53 (2.91)	19.53 (3.64)	16.80 (5.12)	15.169 (4, 546)	< 0.001
<b>Functional</b> 0-28*	20.86 (6.16)	22.09 (6.03)	21.95 (5.94)	22.00 (6.42)	20.67 (5.054.9)	17.61 (6.14)	11.298 (4, 546)	< 0.001
<b>Prostate Ca</b> 0-48*	33.91 (7.64)	37.16 (6.70)	34.68 (7.96)	35.85 (6.64)	33.05 (6.80)	29.53 (7.72)	16.602 (4, 546)	< 0.001
<b>FACT-G</b> 0-108*	85.97 (14.49)	88.30 (14.04)	87.94 (14.47)	90.28 (12.36)	85.42 (12.81)	77.64 (15.42)	14.305 (4, 546)	< 0.001
<b>Total FACT-P</b> 0-156*	119.86 (20.39)	125.46 (19.36)	122.63 (20.60)	126.12 (17.13)	118.44 (17.94)	107.10 (20.98)	17.782 (4, 546)	< 0.001

Note. E-NEW = Early Stage-New Diagnosis, E-RX = Early Stage-On Treatment, E-FLP = Early stage > 2 Months Post Treatment, A-HS = Advanced Hormone Sensitive, A-HR = Advanced Hormone Refractory. FACT-G = Physical + Social + Emotional + Functional Subscale Scores. Total FACT-P = FACT-G Score+ Prostate Cancer Subscale Score.  
\*Score Range, higher scores signify better HRQL. \*\*P significant at 0.007

Table 3

*Post hoc Comparisons of Mean Group Differences in HRQL (Scheffé Method)*

HRQL	Comparison Groups	Mean Difference (SE)	P **	95% CI around mean difference
<b>Physical Well-Being</b>	E-NEW and A-HR	4.60 (0.62)	< 0.0001	2.73 to 6.60*
	E-RX and A-HR	3.23 (0.52)	< 0.0001	1.61 to 4.86
	E-FLP and A-HR	4.68 (0.53)	< 0.0001	3.04 to 6.32*
	A-HS and A-HR	3.00 (0.55)	< 0.0001	1.30 to 4.70
<b>Emotional Well-Being</b>	E-RX and A-HR	3.17 (0.52)	< 0.0001	1.55 to 4.78
	E-FLP and E-NEW	2.18 (0.60)	0.012	0.31 to 4.06
	E-FLP and A-HR	3.73 (0.52)	< 0.0001	2.09 to 5.36*
	A-HS and A-HR	2.72 (0.54)	< 0.0001	1.03 to 4.41
<b>Functional Well-Being</b>	E-NEW and A-HR	4.48 (0.91)	< 0.0001	1.66 to 7.30
	E-RX and A-HR	4.34 (0.76)	< 0.0001	1.98 to 6.70*
	E-FLP and A-HR	4.39 (0.77)	< 0.0001	2.00 to 6.77*
	A-HS and A-HR	3.06 (0.80)	0.006	0.58 to 5.54
<b>Prostate Cancer Well-Being</b>	E-NEW and A-HS	4.10 (1.11)	0.009	0.66 to 7.54
	E-NEW and A-HR	7.63 (1.11)	< 0.0001	4.19 to 11.06*
	E-RX and A-HR	5.15 (0.93)	< 0.0001	2.27 to 8.03*
	E-FLP and A-HR	6.32 (0.94)	< 0.0001	3.41 to 9.22*
	AHS and A-HR	3.52 (0.97)	0.012	0.51 to 6.54
<b>Total FACT-G</b>	E-NEW and A-HR	10.66 (2.12)	< 0.0001	4.09 to 17.22
	E-RX and A-HR	10.30 (1.78)	< 0.0001	4.80 to 15.80
	E-FLP and A-HR	12.64 (1.79)	< 0.0001	7.08 to 18.19*
	A-HS and A-HR	7.76 (1.86)	0.002	2.00 to 13.53
<b>Total FACT-P</b>	E-NEW and A-HR	18.36 (2.95)	< 0.0001	9.22 to 27.49
	E-RX and A-HR	15.53 (2.47)	< 0.0001	7.88 to 23.18
	E-FLP and A-HR	19.01 (2.50)	< 0.0001	11.28 to 26.75*
	A-HS and A-HR	11.33 (2.59)	0.001	3.31 to 19.35

Note. \* Clinically Important Differences in HRQL where the lower boundary of CI is greater than cut point for clinically significant difference (mean difference of  $\geq 2.0$  for subscales; mean difference of  $\geq 7.0$  for Total FACT-G; and mean difference of  $\geq 10.00$  for Total FACT-P).

\*\*p significant at 0.05

there were no differences in emotional well-being between the E-NEW and A-HR groups.

The results of the stepwise multiple regression analysis examining patient characteristics as predictors of HRQL as measured by Total FACT-P are summarized in Table 4. Three variables accounted for 18% of the variance in HRQL. PSA, disease status (advanced hormone refractory disease), and history of mental health problems were negatively associated with Total FACT-P and contributed to 10%, 5%, and 3% of the variance in HRQL respectively. In other words, high PSA and advanced hormone refractory disease, were modestly predictive of poor HRQL. A history of mental health problems alone was also predictive of poor HRQL.

**Table 4**

***Results of Stepwise Regression to Determine Predictors of HRQL (Total FACT-P)***

<b>Model</b>	<b>R</b>	<b>R<sup>2</sup></b>	<b>Adjusted R<sup>2</sup></b>	<b>Beta</b>	<b>t</b>	<b>Significance</b>
PSA ug/L	.322	.103	.101	-.322	-6.523	.000
PSA ug/L	.393	.154		-.244	-4.802	.000
Disease Status			.150	-.239	-4.710	.000
PSA ug/L	.434	.189		-.261	-5.227	.000
Disease Status				-.205	-4.072	.000
Mental Health			.182	-.188	-3.938	.000

Note. Disease Status refers to Advanced Hormone Refractory (A-HR).

### *Frequency of Severe Health Problems*

For each FACT subscale, the most frequently reported and severe health problems where patients had scored items 0 or 1 out of 4 indicating poor quality of life, were identified. Severe health problems affecting more than 20% of subjects in a patient group are summarized in Table 5. Although the frequency of severe health problems varies from group to group, there were similar problems affecting patients across all groups.

Severe lack of energy or fatigue was the most common problem affecting physical well-being across all groups, but occurred more frequently in the E-RX, A-HS, and A-HR groups. Dissatisfaction with their sex life was a serious concern for more than 36% of patients in all groups. Approximately 20% or more of patients in each group were dissatisfied with how they were coping and E-NEW and A-HR patients were more likely to report severe anxiety or worry that their cancer may get worse. A-HR patients also experienced more severe problems in all aspects of functional well-being. Inability to work including work at home, discontent with their quality of life, and lack of enjoyment were the most problematic for the A-HR group.

Inability to have an erection was the most frequently reported and severe prostate specific problem ranging from 37% in the E-NEW group to 94% in the A-HR group. The prevalence of erectile dysfunction increased sharply with exposure to prostate cancer treatment and advanced stage of disease. Problems related to a decreased sense of male self-image or masculinity also occurred more often in the advanced stage groups. Urinary frequency was a severe problem for a third or more of E-RX and advanced stage patients. Significant pain and pain that limited activity affected a greater number of

Table 5

**Total FACT-P - Most Frequently Reported and Severe Problems (Score 0-1)**

Subscale & Items	E-NEW N = 69 %	E-RX N = 134 %	E-FLP N = 128 %	A-HS N = 110 %	A-HR N = 110 %	ALL N = 551 %
<b>Physical</b>						
Lack energy	10.0	18.7	13.2	20.4	36.1	20.0
<b>Social</b>						
(Dis)satisfied with sex life	36.7	65.4	55.2	74.7	83.6	64.0
<b>Emotional</b>						
(Dis)satisfied with own coping	26.5	17.3	26.0	19.4	21.8	21.8
Worry about cancer getting worse	18.8	9.7	3.9	10.0	30.9	13.8
<b>Functional</b>						
Unable to work, even at home	5.9	14.2	13.4	15.5	39.4	18.2
(Dis)content with quality of life	10.1	11.9	9.4	10.0	27.3	13.8
Enjoy usual fun activities	8.7	10.4	10.3	9.2	28.2	13.5
<b>Prostate Cancer</b>						
Able to have/maintain an erection	37.3	68.3	67.2	87.1	94.1	72.8
Urinary Frequency	14.5	33.8	15.7	27.1	37.3	26.6
Significant Pain	11.6	8.7	17.2	25.5	37.6	22.5
(Dis)satisfied with comfort level	18.6	23.5	20.2	21.9	24.3	21.9
Feel like a man	14.5	17.7	19.7	22.1	30.8	21.2
Pain Limits Activity	4.3	9.8	11.8	19.3	23.6	14.2
Good Appetite	13.0	11.9	10.2	8.2	20.90	12.7
Bowel Problems	8.7	9.0	3.9	5.6	19.1	9.1

Note. E-NEW= Early Stage-New diagnosis; E-RX= Early Stage-On Treatment; E-FLP= Early Stage > 2 Months Post Treatment; A-HS = Advanced Stage-Hormone Sensitive; A-HR= Advanced Stage- Hormone Refractory.  
FACT-P= FACT-G (physical, social emotional & functional well-being) + Prostate Subscale



advanced stage patients. However, about 20% of patients in all groups were dissatisfied with their current level of comfort. Severe bowel problems occurred less frequently, affecting less than 10% of patients in the early stage and A-HS groups. A higher proportion (19%) of patients in the A-HR group experienced severe bowel problems.

### *Priority Problems*

The majority of subjects (74%) in all groups were able to identify three health problems that were a priority for improvement. Less than 8% of the sample identified no priority problems. Table 6 summarizes the most frequently reported priority problems affecting about 15% or more of the entire sample. Sexual function, physical activity, fatigue, urinary frequency, urinary incontinence and pain were the most frequently identified priority problems, but the importance of these problems varied among the groups.

**Table 6**

### *Most Frequently Reported Priority Health Problems for Study Sample*

Priority Problems	E-NEW(%)	E-RX(%)	E-FLP(%)	A-HS (%)	A-HR(%)	ALL (%)
Sexual Function	18.8	36.6	39.8	33.6	19.4	31.0
Physical Activity	14.3	17.2	14.8	15.5	30.9	18.5
Fatigue	13.0	13.4	21.0	11.8	31.8	18.5
Urinary Frequency	15.9	20.9	9.4	19.1	20.9	17.2
Urinary Incontinence	17.4	17.2	13.3	11.8	13.6	14.5
Pain	5.8	9.0	10.9	11.8	31.8	14.2

Note: E-NEW = Early Stage New Diagnosis, E-RX = Early Stage on Treatment, E-FLP = Early Stage Post Treatment Follow-Up, A-HS = Advanced Hormone Sensitive, A-HR = Advanced Hormone Refractory.

Table 7 summarizes the most frequently reported priority problems for each patient group. Sexual function remained the top priority problem for all early stage and the A-HS groups, while improving pain, fatigue, and activity level were a priority for more than one third of A-HR patients. Surprisingly, fatigue was more likely to be a priority for E-FLP patients compared to other early stage or A-HS patients. The E-NEW group also had distinctly different priority needs. They were more concerned about improving their overall sense of well-being and were the only group to identify problems related to mood and the need for more information regarding disease and/or treatment, as important concerns. The E-RX and A-HS groups had similar priority problems related to urinary symptoms and physical activity. The need to minimize treatment related side effects was also more likely to be reported by these two groups. Rectal discomfort likely resulting from radiation therapy was a concern for E-RX patients while relief from hot flashes was a priority need for A-HS patients who were more likely to be receiving hormone therapy. Improving their level of physical activity was a similar priority for the E-RX, E-FLP, and A-HS groups. There was some variation in the importance of improving urinary continence and urinary frequency across the groups. Early stage patients were more likely to identify urinary incontinence as a priority concern, while urinary frequency was important for about 20% of all but the E-FLP group.

**Table 7**

***Most Frequently Reported Priority Health Problems For Each Patient Group***

E-NEW (%)	E-RX (%)	E-FLP (%)	A-HS (%)	A-HR (%)
Sexual Function (18.8)	Sexual Function (36.6)	Sexual Function ( 39.8)	Sexual Function (33.6)	Pain (31.8)
Overall Well-Being (18.8)	Urinary Frequency (20.9)	Fatigue (21.1)	Urinary Frequency ( 19.1)	Fatigue (31.8)
Urinary Incontinence (17.4)	Urinary Incontinence (17.2)	Sexual Desire (18.0)	Hot Flashes (15.5)	Physical Activity (30.9)
Information About Disease/Treatment (17.4)	Physical Activity (17.2)	Physical Activity (14.8)	Physical Activity (15.5)	Urinary Frequency (20.9)
Urinary Frequency (15.9)	Rectal Discomfort (14.2)	Urinary Incontinence (13.3 )	Sleeping (15.5)	Sexual Function (19.1)
Mood (14.5 )				Sleeping (15.5)

Note. E-NEW= Early Stage Newly Diagnosed, E-RX- Early Stage On Treatment, E-FLP= Early Stage > 2 months post treatment, A-HS= Advanced Hormone Sensitive, A-HR= Advanced Hormone Refractory

## Discussion

### *Comparison of Results To Other Studies*

Differences in patient categories do not permit comparison of HRQL results for all five patient groups, but some comparisons can be made with the results reported by Esper et al. (1997). In this study, one group involving 34 patients with hormone refractory prostate cancer, is comparable to the A-HR group. Mean subscale scores for these groups are similar in both studies related to physical, social, emotional, functional, and prostate cancer well-being. Esper et al. (1997) found that early stage (T0/T1, T2) patients had significantly higher total scores or better quality of life related to physical, functional, and prostate cancer related well-being compared to advanced stage (T3/T4) patients. However, our study suggests that the majority of clinically important differences in these domains of HRQL occur between early stage (T1 to T3) and advanced stage (T4) patients who are hormone refractory and not advanced stage (T4) patients with hormone sensitive disease.

Litwin et al. (1995) used the FACT-G (version 2) to evaluate differences in HRQL among three treatment groups of early stage patients (prostatectomy, radical radiation, observation) and a comparison group of healthy patients who did not have prostate cancer. The prostate cancer patient groups were, on average, 4 years post diagnosis and are most similar to the E-FLP group. Mean total subscale scores for the treatment groups related to physical, social, and functional well-being are similar to those of the E-NEW, E-RX, E-FLP, and A-HS groups. No differences related to physical,

social, emotional, and functional well-being were identified among treatment groups and the healthy comparison group (Litwin et al, 1995).

In a recent study, FACT- G and FACT-P (version 4) mean scores for patients with stage T1 to T3 prostate cancer who were 20 to more than 30 months post treatment (brachytherapy, external beam radiation, or radical prostatectomy) were compared to age matched controls with no prior history of cancer (Wei et al., 2002). Mean FACT-G and prostate cancer subscale scores for patients who had received external beam radiation and who are most similar to the E-FLP group, are consistent with mean scores reported for the E-FLP group in our study. Wei et al. (2002) found that only patients who had received brachytherapy had poorer HRQL related to prostate cancer well-being compared to the control group. Mean FACT-G scores for the control group are similar to mean FACT-G scores for the E-NEW, E-RX, E-FLP, and A-HS groups. The control group's mean score for prostate cancer well-being is somewhat higher than those in our study for all except the E-NEW group.

The studies by Litwin et al. (1995) and Wei et al. (2002), suggest that general cancer HRQL for all patient groups in our study except those with advanced hormone refractory disease, may be similar to age matched controls with no history of cancer. Men with early stage prostate cancer disease who have received treatment and those with advanced disease may have poorer prostate cancer specific HRQL compared to men with no history of prostate.

In both Esper's et al (1997) and Litwin's et al. (1995) studies, no differences related to emotional well-being were found between groups of patients categorized either

by stage of disease and/or treatment. However, our study found that patients with advanced hormone refractory disease had significantly poorer levels of emotional well-being compared to other groups except those with newly diagnosed early stage disease. Early stage newly diagnosed patients also had poorer emotional well-being compared to early stage patients who were post treatment. These data suggest that disease and treatment circumstances along the continuum of prostate cancer impact on emotional well-being. Heyman and Rosner (1996) also found that newly diagnosed patients with prostate cancer had greater emotional needs compared to post treatment patients. The greater proportion of E-NEW and A-HR patients with severe symptoms of anxiety is consistent with other reports in the cancer literature. Higher levels of anxiety and psychological distress associated with the uncertainty of a new cancer diagnosis have been well documented (Cassileth et al., 1984; Ford, Lewis, & Fallowfield, 1994; Grassi & Rosti, 1996; Van't Spijker, Trijsburg, & Duivenvoorden, 1997). Increased psychological morbidity has also been associated with declining physical function in advanced stages of cancer such as that experienced by A-HR patients (Breitbart, Bruera, Chochinov, & Lynch, 1995).

The proportion of patients in the E-NEW group with erectile dysfunction (37%) is consistent with pre-treatment prevalence rates reported in other studies. Erectile dysfunction in pre-treatment prostate cancer populations varies from 21% to 53% with lower prevalence rates reported prior to prostatectomy compared to patients waiting for radiation treatment or those with advanced disease (Joly et al., 1998; Madalinska et al., 2001; Perez et al, 1997; Schroder et al, 2000). Patients eligible for prostatectomy tend to

be younger with fewer health problems and thus are less likely to have erectile difficulties (Fowler, Barry, Lu-Yao, Wasson, & Bin, 1996; Fransson & Widmark, 1996; Madalinska et al., 2001; Wei et al., 2002). Thus the pre and post treatment rates of erectile dysfunction for patients with early stage disease in our study, who for the most part have been referred for radiation therapy, may be higher compared to early stage patients who are followed by urologists in the community and undergo radical prostatectomy.

The increased frequency of erectile dysfunction in the E-RX, E-FLP, A-HS, and A-HR groups is consistent with other studies demonstrating declining sexual function following treatment for prostate cancer in both early stage and advanced disease (Galbraith et al., 2001; Helgason, et al., 1996; Litwin et al., 1995; Lubeck et al., 1999; Wei et al., 2002). As in our study, problems with urinary function have been reported following treatment for early prostate cancer (Henke Yarbro & Estwing Ferrans, 1998; Litwin et al., 1995; Wei et al., 2002). Urinary problems in advanced prostate cancer are not well evaluated. Fossa et al. (1990) found few patients had urinary problems, while da Silva (1993) found that 36% of patients with advanced disease had urinary problems prior to treatment. Our findings indicate that urinary frequency in particular is significant problem in patients with advanced hormone sensitive and hormone refractory prostate cancer.

### ***Study Strengths and Limitations***

Strengths of this study include the high response rate, the relatively large sample size for most patient groups, and completeness of HRQL data. While the internal consistency of Total FACT-P for this large sample of patients is high, further evaluation

of the psychometric properties of the study questionnaire examining patient priority health needs is required. Non-random sampling and difficulty in accruing E-NEW patients due to reduced referrals and transfer of E-NEW patients to other cancer centres during the study period, may limit the generalizability of the study results. The study results may also not be generalizable to patients who are not referred to the cancer centre but receive care for prostate cancer in the community.

The differences in HRQL between the E-FLP and A-HR group are robust with the lower boundary of the 95% confidence intervals around mean group differences larger than the a priori identified cut points for clinical significance (Table 3). Similar results were observed for the 95% confidence intervals around mean differences between the E-NEW and A-HR groups related to physical and prostate cancer well-being, and between the E-RX and A-HR groups related to functional and prostate cancer well-being. For all other group differences between the A-HR and early stage or A-HS groups, the cut point for clinical significance falls within the 95% confidence interval and suggests that while the A-HR group does have poorer HRQL, further studies using large sample sizes are required to confirm these results.

Information regarding co-morbid conditions was collected from patient health records. Therefore it is possible that reporting bias contributed to the greater number of patients with advanced stage disease identified as having a history of mental health problems. Patients with advanced prostate cancer may be more willing to report mental health problems or health care providers may be more likely to assess and document



mental health problems in patients with advanced prostate cancer compared to those with early stage disease.

Bowel problems are a common treatment related side effect in early stage prostate cancer (Galbraith et al., 2001; Henke Yabro & Estwing Ferrans, 1998; Litwin et al., 1995). Few patients in the E-RX or E-FLP groups had severe bowel problems. The FACT-P does not examine the specific nature or a complete range of bowel problems. It may be that this cursory evaluation contributed to the underreporting of bowel problems in our study. However, patients did not identify bowel problems as a priority concern.

A final limitation of this study is the lack of a comparison or control group. Men with prostate cancer may have similar health problems and experience the same general HRQL as men without prostate cancer. Lack of a control group makes it impossible to determine the extent to which HRQL and health problems such as decreased physical activity, fatigue, and sleep difficulties that are common among older men, are related to prostate cancer alone.

### ***Implications for Practice***

In spite of substantial co-morbidity and prostate cancer related health problems, the majority of men with early stage and advanced hormone sensitive prostate cancer can expect to enjoy good quality of life for several years following the diagnosis of prostate cancer. Patients with advanced hormone sensitive disease experience a quality of life that is similar to early stage groups and may be comparable to general HRQL experienced by healthy non-prostate cancer control groups reported in other studies. This is important and reassuring information that should be shared with patients and families affected by

prostate cancer. The frequency of severe health problems and importance of health problems related to emotional well-being, information, fatigue, and treatment specific side effects vary at different time points for patients with early stage and A-HS disease. However, these patient groups have common priority needs for improving their health related to sexual function, urinary frequency, urinary incontinence, and physical activity.

In contrast, men with advanced hormone refractory prostate cancer experience significantly poorer HRQL and have multiple severe health problems. These patients also have different priority needs. Erectile dysfunction occurs most frequently for men in this group, but problems related to pain, fatigue, and decreased physical activity are identified more often as a priority for improving their health. Fossa et al. (1990) also found that decreased physical ability, fatigue, and pain were major problems for men with advanced hormone refractory prostate cancer. Given these differences in health needs, the focus of supportive care programs and interventions in advanced prostate cancer will differ for those with hormone sensitive and hormone refractory disease.

Patients with early stage and advanced hormone sensitive prostate cancer may benefit from an APN role that can provide episodic supportive care for health problems occurring at different pre-treatment, during treatment, and post treatment stages. Patients with advanced hormone refractory prostate cancer are more likely to benefit from an APN role that can provide ongoing supportive care to assess and manage the multiple, new, and worsening health problems associated with progressive disease. APN roles in non-cancer settings that focused on patients with high risk and/or medically complex health problems such as those with advanced hormone refractory prostate

cancer, have been found to improve patient outcomes and reduce health care costs when compared to conventional care alone (Brooten et al., 2002). Aspects of the APN role which may contribute to these positive outcomes include in-depth knowledge and skill, continuity of patient care across systems, and the ability to manipulate or manage health care systems in order to meet patient health needs (Brooten et al., 2002).

The APN role should also be designed to prevent and/or minimize the severity of prostate cancer related health problems. In this study, pain, fatigue, and decreased physical activity followed by urinary frequency and sexual function were the priority concerns for patients with A-HR prostate cancer. Targeting nursing interventions for these specific prostate cancer related problems might lead to improvements in HRQL.

A similar patient and problem focused approach to care was evaluated in three randomized controlled trials related to breathlessness in advanced lung cancer (Bredin et al., 1999; Corner et al., 1995; Corner et al., 1996; Moore et al., 2002). Patients randomized to advanced practice nursing care (APN) received nursing interventions focused on improving levels of physical function, ability to tolerate reduced lung capacity, and coping with the functional disability and psychological distress associated with breathlessness. When compared to patients randomized to conventional care, patients in the APN group demonstrated lower levels of depression, improved physical symptoms including decreased breathlessness, and improved performance status despite having a poor prognosis and/or evidence of progressive disease (Bredin et al., 1999; Corner et al., 1995; Corner et al., 1996; Moore et al., 2002). These studies also suggest

that a holistic approach that considers the psychological impact of advanced prostate cancer and related problems may benefit overall health and quality of life.

A surprising finding was the extent of severe pain and discomfort reported by early stage patients, especially those in the E-NEW and E-FLP groups who had not been exposed to or were not currently receiving treatment. Disease and treatment related problems such as urinary frequency or dysuria, rectal irritation, breast swelling and tenderness, and hot flashes may be sources of discomfort. One longitudinal study suggests that pain may be a prolonged symptom for some patients, like the E-FLP group, who have been treated with radiation (Galbraith, Ramirez, & Pedro, 2001). The same study also found that physicians greatly underestimated the frequency and/or severity of discomforting long-term treatment side effects such as dysuria and pelvic pain. Dissatisfaction with comfort level was similar among all patient groups, suggesting that regardless of the cause, there is room for improvement in the assessment and management of pain across the continuum. A Canadian survey also found that 15% of prostate cancer patients had problems with pain management and only 62% felt that they had received adequate help for this problem (Gray et al., 1997a).

An interesting finding was that fatigue was reported more frequently as an important concern for E-FLP patients and not other early stage and A-HS groups, although fewer E-FLP patients reported severe symptoms of fatigue. The reason for this is unclear. Fatigue has been reported for early stage patients treated with external beam radiation, but it usually resolves within 6 months of completing therapy (Monga, Kerrigan, Thornby, & Monga, 1999).

PSA level was found to be negatively associated with and a modest predictor of HRQL. Other studies have also found that higher or increasing levels of PSA were associated with poorer HRQL (Esper et al., 1997; Wei et al., 2002). High levels of PSA are not the direct cause of poor quality of life, but provide an indicator of disease activity. In advanced hormone refractory prostate cancer, PSA level does not always provide an accurate indication of the extent or burden of disease, especially in patients with non-PSA producing tumours (Carduci, DeWeese, & Nelson, 1999; Newling et al., 1997; Tannock et al., 1996; Petrylak, 1999). Therefore, PSA level alone should not be used to identify patients at risk for increasing symptoms and poor quality of life. Other signs of progressive disease such as new sites of bone or soft tissue metastasis, increasing pain, and decline in performance status may be additional indicators for those at risk for poor HRQL (Newling et al., 1997; Petrylak, 1999).

### ***Implications for Research***

The prevalence of mental health problems in prostate cancer has not been well established. However, the higher proportion of patients with advanced stage disease who had a history of mental health problems is consistent with the cancer literature reporting higher rates of anxiety and depression in patients with advanced disease (Breitbart, Bruera, Chochinov, & Lynch, 1995). Our study findings suggest that mental health problems contribute to poor HRQL. Poorer HRQL and increased health care costs are associated with mental health problems in other chronic illnesses (Browne et al. 1993; Hosaka et al., 1999; McDaniel et al., 1995). Further research to determine the extent, risk

factors for, and impact of mental health problems on HRQL and other health outcomes across the continuum of prostate cancer care is warranted.

In this study, patient group or disease and treatment status along the continuum of prostate cancer care, PSA level, and history of mental health problems were modest predictors of HRQL. Therefore these patient and disease related factors do not explain a large proportion of the variance in HRQL. Studies evaluating specific prostate cancer treatments suggest that the extent to which health problems impact on day-to-day activities may influence HRQL. For example, urinary problems including incontinence, frequency, and/or burning associated with either prostatectomy or radiation, have a greater negative impact on overall quality of life and physical, psychological, and social well-being than loss of sexual function (Braslis et al., 1995; Fowler et al., 1995; Joly et al., 1998). Future research should continue to identify modifiable patient, disease, and treatment factors that contribute to poor HRQL across the continuum of prostate cancer care. This information could then be used to further define and evaluate the effectiveness of interventions designed to improve health and quality of life.

There is limited research evaluating the effectiveness of APN roles or nursing interventions in prostate cancer care. One randomized controlled trial found that nurse specialist care was similar to usual medical follow-up care with respect to patient satisfaction, medical safety, and number of interventions (Helgeson et al., 2000). Costs for outpatient care were lower in the nurse specialist group. Although nurse specialist care was not clearly defined, this study suggests that with respect to medical outcomes, follow-up care provided by enhanced nursing roles is feasible, safe, and potentially cost-

effective. Future research should evaluate the impact of the unique contribution of the supportive care role of the advanced practice nurse on a variety of patient, health care provider, and health care systems outcomes. There is also need for research to develop and evaluate nursing interventions specific to the supportive needs of patients with prostate cancer at different time points along the continuum of care. Current research is limited to descriptive evaluations of support groups and a few comparative studies of interventions related to treatment decision-making and coping with radiation therapy in early stage prostate cancer (Davison & Degner, 1997; Gray, Fitch, Davis, & Phillips, 1997; Gregoire, Kalogeropoulos, & Corcos, 1997; Johnson, Fieler, Wiasowicz, Mitchell, & Jones, 1997).

### **Conclusions**

This study examined differences in HRQL across the continuum of prostate cancer care. In both early and advanced stage prostate cancer, problems related to sexual function, urinary frequency, and urinary incontinence would be an important focus for the APN role and supportive care interventions. In early stage and advanced hormone sensitive prostate cancer, other health needs related to emotional well-being, information, and treatment side effects vary along the continuum of care. These patients may benefit from an APN role designed to provide episodic care for severe or distressing health problems at different time points. However, patients with advanced hormone refractory prostate cancer have significantly poorer HRQL and have different health needs compared to patients with early stage or advanced hormone sensitive disease. This patient group requires an APN role that provides continuous care with a stronger

emphasis on alleviating distressing symptoms related to pain, fatigue, and decreased level of physical activity.

Patients with advanced prostate cancer were more likely to have a history of mental health problems compared to patients with early stage disease, and those with mental health problems had poorer HRQL. Thus the assessment and management of mental health problems may be an important role for advanced practice nurses working with patients with prostate cancer, especially those with advanced disease. Future research must evaluate the impact of supportive care role of the advanced practice nurse and problem focused nursing interventions designed to improve the health and quality of life for patients with prostate cancer.



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## CHAPTER 5

### Preamble

This chapter is an expanded version of a manuscript that will be submitted for publication. In Chapter 1 it was hypothesized that the supportive care role of the APN may require a strong mental health focus. The unmet needs of patients with prostate and other types of cancer often relate to psychosocial issues (CCS, 1990; Fitch et al., 1999; Gray et al., 1997). Mental health problems are also associated with poorer HRQL and higher health care costs in cancer and chronic illness (Creed et al., 2002; McDaniel et al., 1995). The study results in Chapter 4, indicating that a history of mental health problems was a modest but negative predictor of HRQL, lends some support to the idea that mental health is an important supportive care issue. A history of mental health problems also occurred more frequently in advanced rather than early stage prostate cancer.

Thus, in this manuscript I describe a study that focuses on a more in-depth examination of mental health problems in advanced prostate cancer. The main focus of the study was to determine the prevalence of mental health disorders and their impact on HRQL. A second aim of the study was to examine the impact of mental health disorders on health care costs. In keeping with the CCO Model of Supportive Care (Fitch et al., 1994) and the concept that health needs vary across the continuum of care, the relationship between the status of advanced stage of disease (e.g. hormone sensitive, hormone refractory, and palliative) and health care costs was also examined.



### **Contributors**

The impetus for this study evolved from my Nursing Fellowship in Malignant Urology at the Hamilton Regional Cancer Centre and was a major component of my thesis work. I conceived the original idea, developed the proposal, obtained funding, initiated the study, screened for and identified study participants, supervised and directed the collection, management, and analysis of data, interpreted the data, and wrote the manuscript.

Gina Browne provided overall guidance for the project as my thesis supervisor, contributed to development of the study design and methods, advised the data analysis, provided staff and resources to implement the study, and reviewed and provided comments on the draft manuscript.

Amiram Gafni is a member of my thesis committee who provided direction for the analysis of economic data, and reviewed and provided comments on the draft manuscript. Alba DiCenso is a member my thesis committee who provided advice regarding data analysis, and reviewed and provided comments on the draft manuscript. Alan Neville was a clinical consultant for the project, provided input into the proposal, and reviewed and provided comments on the draft manuscript. George Browman is a member of my thesis committee who reviewed and commented on the manuscript.

This study received funding from the Hamilton Health Sciences Research Fund and was supported by the Hamilton Regional Cancer Centre, and the System-Linked Research Unit on Health and Social Service Utilization (Appendix G).

**The Prevalence of Mental Health Disorders and their Relationship to Health Related Quality of Life and Health Care Costs in Advanced Prostate Cancer**

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## **Abstract**

### ***Purpose***

The primary purpose of the study was to determine the prevalence of mental health disorders in advanced prostate cancer and explore differences in health related quality of life (HRQL) for men with and without a mental health disorder. The secondary focus was to examine differences in health care costs for advanced prostate cancer patients with and without a mental health disorder. The relationship between disease status and health care costs was also examined.

### ***Patients and Method***

A sample of 99 consecutive patients with advanced prostate cancer receiving care at a regional cancer centre in south central Ontario, Canada participated in this descriptive study. Through telephone interviews, study participants completed a questionnaire assessing mental health, HRQL, and health care costs.

### ***Results***

Nineteen percent of patients were identified as having a mental health disorder. Patients receiving palliative care for end stage disease were more likely to have a mental health disorder. The presence of anxiety and/or depression was associated with significant declines in HRQL. Higher health care costs were observed in patients with mental health disorders and those receiving palliative care.

### ***Conclusions***

Mental health problems in advanced prostate cancer are associated with poorer quality of life and higher health care costs. Opportunities to improve quality of life in

advanced prostate cancer may require a pro-active approach to supportive care with greater emphasis on health promotion and mental health as an integral component of prostate cancer care. Future efforts are required to develop and evaluate the effectiveness and efficiency of mental health and supportive care programs in prostate cancer.

## Introduction

The need to improve the delivery of palliative and supportive care services has been identified as an important research priority by patients, families, and health care providers (National Prostate Cancer Forum, 1997). Effective supportive care is of particular importance to men with advanced stage disease, many of whom will live with their cancer well beyond the traditional 5 year mark for cancer survival (Johansson, Holmberg, Johansson, Bergstrom, & Adami, 1997; Mettlin, Murphy, McGinnis, & Menck, 1995). Despite improved methods for screening and early detection, at least 20% of patients have advanced disease at the time of diagnosis and about 30% of early stage patients subsequently develop metastatic disease (Landis, Murray, Bolden, & Wingo, 1999; Levy, Gibbons, Collins, Perkins, & Mao, 1993).

Perhaps the greatest gap in knowledge regarding the supportive care of patients with advanced prostate cancer relates to the extent and consequences of psychosocial problems. It is well known that patients with cancer have higher rates of depression compared to the general population (Sellick & Crooks, 1999; Van't Spijker, Trijsburg, & Duivenvoorden, 1997). However, other factors such as age, gender, stage of disease, and hormonal treatment may have important psychological implications for patients with advanced stage prostate cancer. Increasing age is associated with lower psychological morbidity in the general community and cancer populations (Cassileth et al., 1984; Harrison, Maguire, & Pitceathly, 1995; Patten, 2000; Van't Spijker, Trijsburg, & Duivenvoorden, 1997). Thus age may be a protective factor for patients with prostate cancer, the majority of whom are over the age of 64 years (Ellison et al., 1998).

Compared to women, men also report less psychological distress related to daily or chronic illness (Bird & Rieker, 1999; MacIntyre, Hunt, & Sweeting, 1996; Mirowsky, & Ross, 1995). However, increased psychological morbidity is associated with advanced stages of cancer and declining physical function (Breitbart, Bruera, Chochinov, & Lynch, 1995; Cassileth et al., 1984). One screening study found that men, with predominantly advanced stage prostate cancer, did report significant psychological distress (Roth et al., 1998). High anxiety and severe symptoms of depression were reported respectively in 33% and 15% of patients receiving outpatient care.

Hormonal therapies and their effect on mood, sexual function, sexuality, and body image may increase the risk for psychological problems. Orchiectomy is associated with poorer emotional well-being compared to medical androgen suppression therapy (Cassileth et al., 1992; Chodak et al., 1995). Patients receiving hormone therapy also experience greater fatigue and psychological distress compared to those who elect to delay treatment (Herr, Kornblith, & Ofman, 1993). Total androgen suppression therapy involving orchiectomy plus flutamide results in poorer emotional well-being compared to orchiectomy plus placebo (Moinpour et al., 1998). Case study reports describe a potential relationship between Luteinizing Hormone Releasing Hormone (LHRH) analogues and major depression (Rosenblatt & Mellow, 1995).

The assessment and management of psychological problems in prostate cancer is confounded by the tendency for men to not report symptoms or seek assistance and for health care providers to underestimate the severity and impact of disease and treatment complications (da Silva et al., 1993; Fossa et al., 1990; Harrison et al., 1995; Litwin,

Lubeck, Henning, & Carroll, 1998). Failure to treat psychological problems can have negative consequences for both the individual and the health care system. For example, in studies of chronic illness other than cancer, poor adjustment rather than disease severity is associated with increased use of health care services without improvement in quality of life or health status (Browne et al., 1993; Creed et al., 2002). Depression in chronic illness may also be associated with decreased length of survival, increased hospital length of stay, and poorer quality of life (Hosaka, Aoki, Watanabe, Okuyama, & Kurosawa, 1999; McDaniel, Musselman, Porter, Reed, & Nemeroff, 1995). In medical populations, depression is highly associated with poor treatment compliance (DiMatteo, Lepper, & Croghan, 2000). Mood disorders such as depression and dysthymia are also associated with increased use of health care services in primary care settings (Browne et al., 2002; Hall, 1995). There is scant research regarding the relationship between mood disorders, adjustment to illness, quality of life, and use of health care services in cancer populations.

The primary purpose of this comparative, descriptive study was to examine the prevalence and consequences of mental health disorders in advanced stage prostate cancer for patients receiving outpatient care. The information gained from this study will guide the development of supportive care initiatives and identify research priorities relevant to the mental health needs of men with advanced prostate cancer. The specific questions addressed in this study of patients with advanced prostate cancer receiving care at a regional cancer centre are:

1. What is the prevalence of mental health disorders?

2. What are the differences in HRQL between men with and without a mental health disorder?
3. What are the differences in health care costs for men with and without a mental health disorder?
4. Do other factors such as disease severity affect health care costs?

It is hypothesized that poorer HRQL and higher health care costs will be found in patients with advanced prostate cancer who have a mental health disorder compared to those with no mental health disorder.

## **Methods**

### ***Setting***

The Hamilton Regional Cancer Centre (HRCC) is one of nine cancer centres in Ontario, Canada and is responsible for providing comprehensive cancer care services for a population of 2.2 million people in the central west region of the province. Within this region, there are approximately 750 new cases and over 200 deaths related to prostate cancer each year (Cancer Care Ontario, 1998). Nationally, there are 17,000 new cases and 4,200 deaths per year (National Cancer Institute of Canada, 2000). Approximately 200 patients with advanced stage prostate cancer are referred to the HRCC each year by family physicians and community urologists for radiation and/or medical treatment.

### ***Sample and Sample Size Justification***

Reports of the prevalence of anxiety and depression in cancer populations range from 10 to 40% (Derogatis, et al., 1983; Parle, Jones, & Maguire; 1996; Sellick & Crooks, 1999). Using the statistical equation for determining prevalence



( $N = pq \times [z \text{ alpha} / \text{error}]^2$ ), 81 subjects were required to detect a 30% prevalence of mental health disorders with a 95% confidence interval and an error rate of 10% (Katchigan, 1986; Machin, Campbell, Fayers, & Pinol, 1997). Eligible patients included all those with localized (D1) or distant (D2) metastatic prostate cancer who could communicate in English, had the physical and cognitive abilities to complete a questionnaire, and who provided informed consent.

### *Procedure and Instruments*

The study received ethics approval from the participating regional cancer centre and local ethics review board (Appendix H). All eligible patients who were receiving regular follow up care or treatment in a medical oncology clinic over a 1-year period from September 1999 to August 2000, were invited to participate in the study. Subjects were identified from clinic appointment schedules. Prior to telephone contact, patients received a letter describing the study (Appendix I). The letter included a telephone number to call if the patient did not want to participate in the study. Patients who did not call over the next 1-week period were contacted by the research assistant. At the time of initial telephone contact, the research assistant reviewed the purpose of the study, emphasized the patient's free choice to participate in the study, and answered any questions regarding the study. Consenting patients completed a questionnaire at a subsequent telephone or face-to-face interview that was scheduled at their convenience. The same research assistant completed all interviews and had previous training and experience in conducting similar surveys in other studies. Depending on participant responses, the interview took 30 to 60 minutes to complete.

### ***Demographic Data***

Using a data template, demographic information related to age, marital status, living arrangements, education, employment, income, and other concurrent illnesses were recorded from patients at the time of the interview (Appendix J). Additional information related to stage of disease, past and current prostate cancer treatment, and time since diagnosis was obtained from the patient's health record (Appendix K).

### ***Mental Health***

There is no universally accepted method or ideal instrument for screening for mental health disorders in advanced cancer (Lloyd-Williams, 2001; Stiefel, Trill, Berney, Olarte, & Razavi, 2001). The controversy relates to the use of inclusive or exclusive methods where confounding symptoms, particularly for depression are also common problems associated with advanced cancer. For exclusive measures, symptoms such as fatigue and weight loss are replaced with non-somatic symptoms such as depressed appearance or social withdrawal (Endicott, 1984; Booth, Kirchner, Hamilton, Harrell, & Smith, 1998a). Higher estimates of depression and number of false positive cases have been found using instruments based on inclusive DSM-III-R criteria compared to those excluding somatic symptoms (Booth et al., 1998a; Lynch, 1995; Uchitomi et al., 2001). Inclusive methods have fewer false negative rates and may be more likely to identify serious cases of major depression (Stiefel et al., 2001; Wilson, Chochinov, de Fay, & Brietbart, 2000). Given that the under-diagnosis of mental health disorders in advanced cancer is recognized as a common and serious problem associated with significant

morbidity, the inclusive approach to screening using a structured diagnostic interview was utilized in this study (Appendix L).

In addition to well-established psychometric properties for use in the general population these instruments assess for mental health disorders utilizing rigorous and conventional diagnostic criteria. Structured interviews also reduce the risk of interviewer variability by ensuring that all subjects are asked the same questions (Lewis & Araya, 2001). In contrast to methods evaluating symptoms of psychological distress, structured diagnostic interviews are the preferred research instruments for use in cancer populations for determining the prevalence of mental health disorders and distinguishing psychiatric syndromes from potentially less severe symptoms (Lynch, 1995; McDaniel et al., 1995; Wilson et al., 2000).

The University of Michigan Composite Diagnostic Interview (UM-CIDI) is a structured diagnostic interview based on the American Psychiatric Association DSM-III-R criteria (Kessler et al., 1994). It is a modified version of the CIDI established by the World Health Organization for large epidemiologic studies. This instrument is designed to be implemented by trained interviewers, who are not clinicians, through face-to-face or telephone interviews and utilizes a computerized scoring system to determine the probability of having a psychiatric disorder (Robins et al., 1988). The UM-CIDI and its short form version have been utilized in a number of American and Canadian national surveys and are considered to be one of the best methods for identifying major psychiatric disorders (Kessler et al., 1994; Patten, 2000). Field tests have documented good inter-rater reliability, test-retest reliability, and validity in medically well

populations in a variety of settings and across multiple cultures (Wittchen et al., 1991; Wittchen, 1994). In medically ill patients, the UM-CIDI with and without exclusions has demonstrated good agreement for current ( $\kappa = 0.57$  and  $0.56$ ) and lifetime ( $\kappa = 0.54$  and  $0.49$ ) diagnoses of depression when compared with the criterion standard or physician administered Structured Clinical Interview for DSM-III-R (Booth et al., 1998a).

The Short Form version of the UM-CIDI (CIDI-SF), designed to provide quick screening of eight common psychiatric disorders, was utilized in this study (Kessler, McGongale, Andrews, Mroczek, Ustun, & Wittchen 1998). An important consideration was the need to minimize the length of the interview and respondent burden for this elderly and potentially frail population of cancer patients. The CIDI-SF takes only 10 minutes to complete compared to 30 to 60 minutes for the UM-CIDI. The major change in the CIDI-SF from the original CIDI was the elimination of redundant questions that did not contribute to determining the probability of a psychiatric diagnosis for each of 8 stem questions. Recall of symptoms was also limited to the previous 12 months and worst symptoms in the past two weeks rather than lifetime episodes (Kessler et al, 1993). The wording of some questions has also been simplified based on recommendations from other studies. These revisions are thought to minimize response bias and the underreporting of mood disorders in the elderly due to decreased working memory capacity (Knauper & Wittchen, 1994).

A summary of psychiatric disorders evaluated by the CIDI-SF and corresponding stem questions are found in Appendix M. Endorsement of the stem question leads to

additional screening questions and a score is calculated related to the endorsement of the stem question and the number of symptoms meeting specific diagnostic criteria (Kessler et al., 1993; Kessler et al., 1998). The scores are associated with a probability for CIDI caseness or the probability that a respondent would meet full diagnostic criteria if given the complete CIDI interview. Each disorder has a pre-determined optimal cut-off point for probable and non-probable cases (Appendix N).

Further evaluation of the validity of the CIDI-Short Form is in progress.

Although the short form version uses the same but fewer questions as the CIDI, it is possible that this new format may result in different responses. However, when compared to the full CIDI, the short form version demonstrates high sensitivity (86%-100%), specificity (94%-99%), positive predictive value (75%-99%), and negative predictive value (87%-100%) for all eight psychiatric disorders (Kessler et al., 1998).

### *Quality of Life*

The Total Functional Assessment of Cancer Therapy-Prostate Cancer (Total FACT-P, version 4) is a 39 item quality of life instrument that includes five subscales related to physical, social, emotional, functional, and to prostate cancer well-being (Appendix E). The psychometric properties of the Total FACT-P have been established in an earlier study involving patients with prostate cancer (Esper et al., 1997). Internal consistency (Cronbach's alpha coefficient) is satisfactory, ranging from 0.62 to 0.83 for all subscales. Esper et al. (1997) also found that the Total FACT-P could discriminate between stages of disease, performance status, and PSA levels and is sensitive to changes

in performance status and PSA. The Total FACT-P uses a Likert-like scale measuring from 0 to 4, with higher scores representing better quality of life.

### *Health Care Costs*

The Health Service Utilization Inventory (HSUI) is a self-report questionnaire designed to assess the direct and indirect costs of health care (Browne, Gafni, Roberts, Goldsmith, & Jamieson, 1995). The HSUI can be utilized to evaluate costs from a societal, employer, government, and/or health care consumer perspective. In this study, costs were evaluated from the perspective of the Ministry of Health, organizations, and health professionals involved in funding, planning, and/or providing health care services for patients with prostate cancer (Appendix O). As such, only direct costs associated with health care services were evaluated. Since most subjects would be of retirement age, indirect costs associated with time off work were not considered. Respondents reported their use of different types of health and social services such as: health and social service providers; paid and unpaid community services; emergency services; days of hospitalization; outpatient medical procedures, diagnostic tests, blood tests; equipment and supplies; and prescription and non-prescription medications. Inquiries were restricted to the following durations of recall: 2 days for medication use, 6 months for hospitalizations, and 12 months for supplies and health services. High levels of observer agreement (0.72 - 0.99) between the patient's report and medical record are reported (Browne, Arpin, Corey, Fitch, & Gafni, 1990; Browne et al., 1995). Annual utilization rates per person were calculated by multiplying the observed utilization rates for each item by the appropriate number (e.g. 6 months x 2). Annual costs were calculated by

multiplying annual utilization rates by the estimated dollar amount for that item (Browne et al., 1995). Unit costs are based on year 2001 costs in Canadian dollars established from a recent Ontario survey of government, agency, and professional fee schedules (Browne et al., 2001).

### *Data Analysis*

Descriptive statistics in the form of frequency counts, percentages, and mean or median scores were utilized to describe the patient population. Chi squared and Fisher's Exact Test were utilized to test for demographic differences between groups with and without a mental health disorder, as determined by the CIDI-SF, for categorical data related to age, living situation, marital status, education, employment type and situation, income, disease status, stage at diagnosis, current treatment, and co-morbid conditions. For demographic comparisons involving continuous data such as mean years since diagnosis, the unpaired Student's t test was used. For tests of differences regarding demographic characteristics, the alpha level was pre-set at 0.01 to reduce the risk of type one error associated with multiple testing.

For the primary outcome of interest, the unpaired Student's t test was used to examine mean differences in multiple domains of general and prostate cancer HRQL between patients with and without a mental health disorder. Confidence intervals around the mean differences in HRQL between groups were also calculated. In order to reduce

the risk of type one error associated with multiple tests of differences, statistical significance was determined using the Holm method of Bonferroni correction.<sup>1</sup>

Prior to data analysis, the scores for negatively worded questions on the Total FACT-P are reversed so that high scores always represent better quality of life. For subscales with missing items, prorated subscale scores were calculated ( [sum of scores for each item] x [number of items in subscale] / [number of items answered] ). Separate scores are calculated for each subscale and a total score is calculated by summing the subscale scores.

Clinically important differences in HRQL were established using the following pre-determined endpoints of 2, 7, and 10-point differences on FACT subscales, FACT-G, and Total FACT-P scores respectively. Previous studies have indicated that a difference of 2 to 3 points on FACT subscales and 7 to 10 points on total scale scores is indicative of clinically important differences in HRQL and performance status (Cella et al., 1995; Lee, McQuellon, Harris-Henderson, Case, & McCullough, 2000; McQuellon et al., 1997). Other studies have also found that clinically important differences occurred with similar changes (0.5 points per item on a 7 point scale) in likert scale scores (Jaeschke, Singer & Guyatt, 1989; Neymark et al., 1998).

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<sup>1</sup> The Holm method of Bonferroni correction is a less conservative method for dealing with multiple comparisons (Norman & Streiner, 2000). The Bonferroni procedure is too conservative when there are multiple endpoints and/or when the endpoints (such as different domains of HRQL) are likely to be highly correlated. The Holm method is a step-wise procedure that improves the Bonferroni method by minimizing reduction of power while maintaining the experiment wise error rate (Sankoh, Huque, & Dubey, 1997). For this method, significant p values less than 0.05 are ordered from smallest to largest or in this case p values for 7(k) comparisons of Total FACT-P subscale and total scale scores. P1 is compared to  $\alpha/k$ . If P1 is less than the adjusted alpha the result is significant and you move on to test P2. P2 is compared to  $\alpha/k-1$ , P3 is compared to  $\alpha/k-2$  etc. Testing for each subsequent p value occurs only if p values remain less than the newly adjusted p.



Secondary outcomes of interest involved comparisons of health care costs related to mental health and disease status. For health care costs, two and three group comparisons were made using Mann-Whitney U test and Kruskal-Wallis test respectively. These non-parametric tests were utilized due to the wide standard deviation and violation of assumptions regarding normal distribution of data for health care costs.

## Results

### *The Sample*

One hundred and ninety-nine potential study patients were identified from clinic appointment schedules (Figure 1). Forty-nine patients were ineligible because they could not be contacted by phone (7), had died prior to telephone contact (24), or had recurrent but not documented advanced stage disease (18). Of 150 eligible patients, 99 or 66% participated in the study. Reasons for non-participation included refused (35), too sick (13) or language barrier (3). This response rate is lower (66% versus 88%) than an earlier HRQL study involving similar subjects (Bryant-Lukosius et al., unpublished manuscript). Over recruitment to other prostate cancer studies, recruitment via letter rather than face-to-face contact, and reluctance to discuss mental health issues may have been barriers to study participation. The non-study participants included those with hormone sensitive (13/51), hormone refractory (33/51), palliative (5/51) stage disease. Non-study participants were slightly older than study participants with a median age of 75 years. There were no other differences between study and non-participants related to living arrangements, marital status, employment status, or current treatment.

*Figure 1. Flow Diagram of Study Population and Sample*

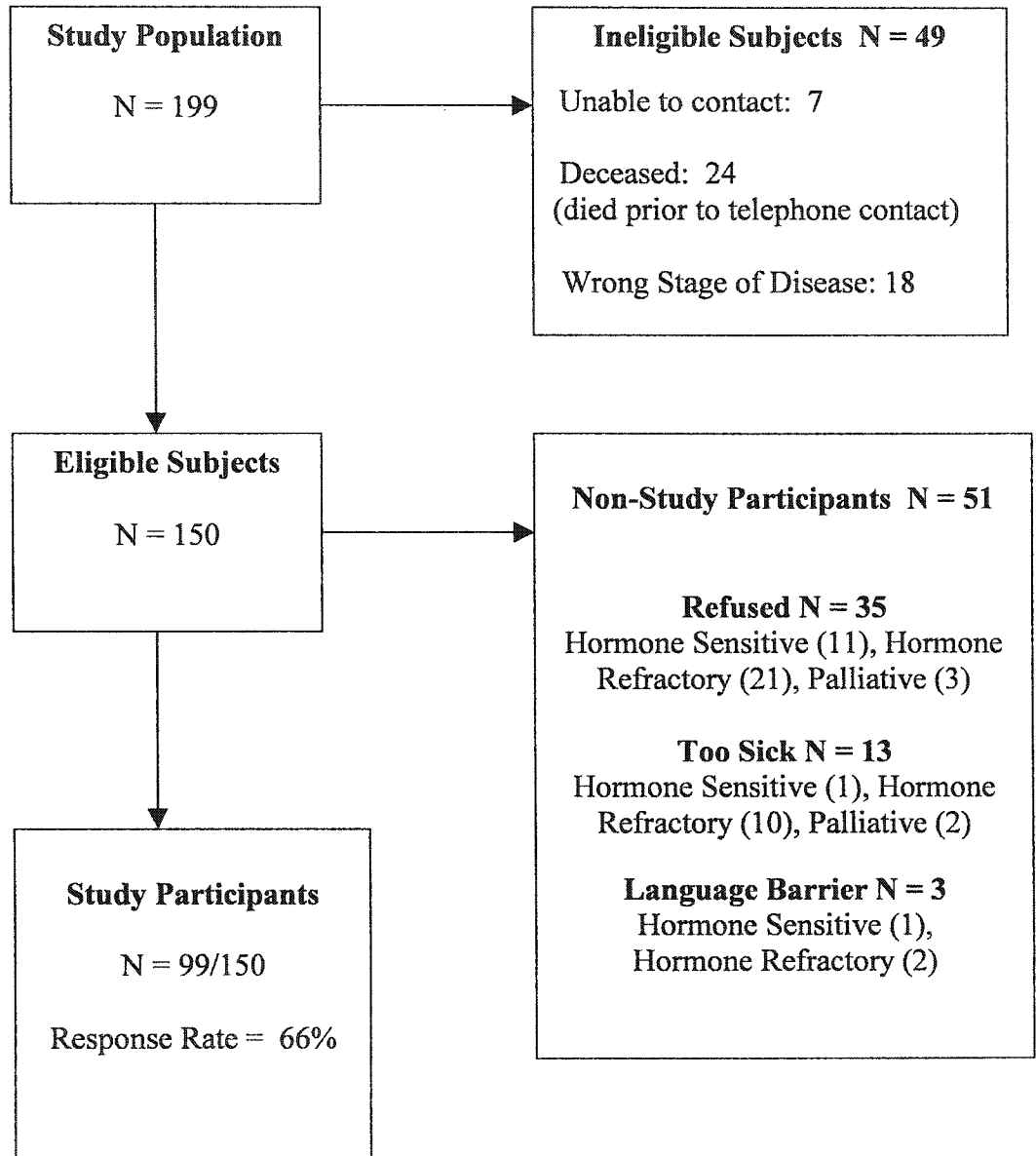


Table 1 provides a summary of demographic data. The median age of the study sample participants was 72 years. Most men were married and were living with family. They were a well-educated group and a high proportion of subjects were currently or previously employed in professional and management positions. The majority were retired and living on pension based incomes. There was a high prevalence of co-morbid conditions consistent with those affecting elderly populations. Almost half of the participants (47/99), reported two or more other chronic conditions. Cardiac disease (31%), hypertension (27%), and arthritis (25%) were the most common health problems. A sizeable proportion (17%) also had a second diagnosis of cancer. Only 1 subject reported a previous history of mental health problems.

The chronic nature of prostate cancer was evident in the time since diagnosis and the number of subjects who had experienced recurrent disease. Participants were on average 5.6 years post diagnosis. Most participants had early (stage A or B) or locally advanced disease (stage C) at initial diagnosis, and subsequently developed metastatic disease. In terms of their advanced stage status, 9 participants had hormone sensitive disease with a stable PSA <1.0 on hormone suppression therapy. Most participants (77/99) had hormone refractory disease characterized by a progressive rise in PSA following a response to androgen suppression. A smaller group of hormone refractory patients (13/99) were identified as being in the later stages of palliative treatment. These patients were experiencing new or increasing symptoms of progressive disease following previous response to palliative therapies including mitoxantrone chemotherapy, and/or radiation therapy. Despite their advanced stage of disease, a large proportion of the study

**Table 1*****Demographic Characteristics of Study Sample and Mental Health Disorder Groups***

Characteristic	Mental Health Disorder						P value
	Total (N = 99)		Present (N = 19)		Absent (N = 90)		
Median Age (years ± SD)	72.36	(8.25)	68.62	(9.39)	72.35	(7.90)	0.34 <sup>a</sup>
Age Range in Years (%)							
51-60	10		3	(16)	7	(9)	0.515
61-70	32		7	(37)	25	(31)	
> 70	57		9	(47)	48	(60)	
Living Situation (%)							
Alone	12		4	(21)	8	(10)	0.240 <sup>b</sup>
With Family	87		15	(79)	72	(90)	
Marital Status (%)							
Never married	4		2	(11)	2	(3)	0.462
Married	79		14	(74)	65	(82)	
Separated/Divorced	5		1	(5)	4	(4)	
Widowed	11		2	(10)	9	(11)	
Education (%)							
Grade School	13		3	(16)	10	(12)	0.510
High School	43		6	(32)	37	(47)	
Post Secondary School	43		10	(52)	33	(41)	
Employment Status (%)							
Full Time	6		1	(5)	5	(6)	0.77
Part Time	3		0	(0)	3	(4)	
Retired	87		17	(90)	70	(88)	
Disabled	3		1	(5)	2	(2)	
Employment Type (%)							
Unskilled	14		4	(21)	10	(12)	0.464
Skilled	31		4	(21)	27	(34)	
Middle Management	15		4	(21)	11	(14)	
Professional/Senior Management	39		7	(37)	32	(40)	
Source of Income (%)							
Wages	7		1	(5)	6	(7)	0.169
Social Assistance	1		1	(5)	0	(0)	
Pension	88		17	(90)	71	(89)	
Other	3		0	(0)	3	(4)	

Table 1 continued

*Demographic Characteristics of Study Sample and Mental Health Disorder Groups*

Characteristic	Total (N = 99)	Mental Health Disorder		P
		Present (N = 80)	Absent (N = 19)	
<b>Disease Status (%)</b>				
Hormone Sensitive	9	1 (5)	8 (10)	0.003 <sup>c</sup>
Hormone Refractory	77	11 (58)	66 (83)	
Palliative	13	7 (37)	6 (7)	
<b>Stage at Diagnosis (%)</b>				
A or B	15	3 (16)	12 (13)	0.712
C	37	5 (26)	32 (40)	
D	44	11 (58)	33 (43)	
Not Known	3	0 (0)	3 (4)	
Mean Years Since Diagnosis (SD)	5.63 (3.73)	4.72 (1.99)	5.85 (4.02)	0.237 <sup>a</sup>
<b>Current Treatment (%)</b>				
None	36	6 (32)	30 (38)	0.235
Hormones	38	6 (32)	32 (40)	
Chemotherapy	10	3 (16)	7 (9)	
Radiation	3	0 (0)	3 (4)	
Symptom Control	11	4 (20)	7 (9)	
<b>Number of Co-morbid Conditions (%)</b>				
None	21	2 (11)	19 (24)	0.508
One	31	5 (26)	26 (32)	
Two	26	6 (32)	20 (25)	
Three	12	4 (21)	8 (10)	
Four or More	9	2 (10)	7 (9)	

Note. **a** = t Test (t = 0.92, df = 1,97)

**b** = Fisher's Exact 2 tail

**c** = Chi Square 11.641, df = 2

population was not receiving treatment. Fewer subjects were receiving chemotherapy, radiation, or other symptom control measures.

### ***Prevalence of Mental Health Disorders***

According to the CIDI-SF, 19% of subjects were identified as having one or more mental health disorders (Table 2). Post hoc calculation of the estimation of error is 0.077.<sup>2</sup> Therefore the 95% confidence interval (CI) for a prevalence of 19% is 11.3% to 26.7%. Affective disorders accounted for the greatest number of mental health problems, involving 14% (95% CI = 7.3% to 20.7%) of the study population. Major depressive episodes involving sadness or lost interest were identified in 10 and 4 subjects respectively. One or more anxiety disorders were identified in 6% of subjects (95% CI = -8.7% to 20.7%). The types and distribution of anxiety disorders included: generalized anxiety disorder (N = 1), simple phobia (N = 4), and panic disorder (N = 2). No cases of social phobia, agoraphobia, or substance dependency were identified. Most (N = 14) had only one mental health disorder and only 1 patient was thought to have both an affective and anxiety disorder. There were no differences in demographic characteristics between subjects who screened negatively or positively for a mental health disorder, except related to disease status (Table 1). Hormone sensitive or hormone refractory patients were less likely to have a mental health disorder compared to palliative patients ( $\chi^2 = 11.641$ ,  $df = 2$ ,  $p = 0.003$ ).

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<sup>2</sup> Error = 1.96/ square root of (n/p/q), p=probability, q =1-p, n = sample size. Program by A. Chang (2000), Dept Obstetrics & Gynecology. CUHK. <http://department.obg.cuhk.edu.hk/ResearchSupport/Sample>.

**Table 2*****Prevalence and Distribution of Mental Health Problems Based on CIDI-SF***

<b>Mental Health Problems</b>	<b>N</b>	<b>(%)</b>	<b>95% Confidence Interval</b>
One or More Mental Health Disorders	19	(19)	11.3 to 26.7%
One Disorder	14	(14)	
Two Disorders	4	(4)	
Three or More Disorders	1	(1)	
Affective Disorder	14	(14)	7.3% to 20.7%
Major Depression (sadness)	10	(10)	
Major Depression (lost interest)	4	(4)	
One or more Anxiety Disorder	6	(6)	-8.7% to 20.7%
Generalized Anxiety Disorder	1	(1)	
Simple Phobia	4	(4)	
Agoraphobia	0	(0)	
Social Phobia	0	(0)	
Panic Attack	2	(2)	
Substance Abuse	0		
Drug Dependence	0		
Alcohol Dependence	0		
Affective + Anxiety Disorder	1	(1)	
Affective Disorder Only	13	(13)	
Anxiety Disorder Only	5	(5)	

### *Quality of Life (Total FACT-P) and Mental Health Disorders*

For this study population, internal consistency of Total FACT-P was high with Cronbach's alpha coefficients ranging from 0.68 to 0.91 for all subscales and scales. According to Cella (1997), Total FACT-P is considered to be an acceptable indicator of patient quality of life as long as the overall item response is greater than 80% for FACT-G or Total FACT-P scales (e.g. 22 of 27 FACT-G items) and 50% for each of the 5 subscales (e.g. 7 of 12 prostate subscale items). The item response rate for the two scales (FACT-G & Total FACT-P) and five subscales was over 91%. Four out of five subscales had complete data. Missing data was only attributed to 1 item in the social well-being subscale related to satisfaction with sex life. Therefore, the Total FACT-P results reported are believed to accurately reflect this measure of HRQL for this study population.

Quality of life data for Total FACT-P subscales and scales are reported in Table 3. Higher Total FACT-P scores reflect better HRQL. For the study sample, the lowest scores or poorest domains of HRQL relate to social, functional, and prostate cancer well-being. Statistically significant differences in HRQL were identified for men with and without a mental health disorder.<sup>3</sup> Men with a mental health disorder had lower FACT-G and Total FACT-P mean scores indicating poorer general cancer and prostate cancer specific HRQL. All domains of HRQL related to physical, social, emotional, functional, and prostate cancer well-being for men with mental health disorders were

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<sup>3</sup>The stepwise adjusted p values for FACT-G, FACT-P, functional, physical, emotional, social, and prostate cancer well-being are .007, .008, .01, .0125, .016, .025, and .05 respectively. The p values for FACT-P comparisons related to mental health were less than their stepwise-adjusted p and thus remained significant.



**Table 3*****Health Related Quality of Life (HRQL) and Mental Health Disorders***

HRQL	Mental Health Disorder						Mean Difference	P	95% CI Around Mean Difference
	ALL		Present (N = 19)		Absent (N = 90)				
	Mean	(SD)	Mean	(SD)	Mean	(SD)			
FACT-G (0-108)*	80.8	(14.6)	69.9	(15.38)	83.3	(13.3)	13.4	< 0.001	6.5 - 20.3
Total FACT-P (0-156)*	114.1	(20.5)	99.6	(19.6)	117.5	(19.2)	17.9	< 0.001	8.2 - 27.5
Physical (0-28)*	22.4	(4.9)	19.6	(5.6)	23.0	(4.5)	3.3	0.007	0.9 - 5.7
Social (0-28)*	20.5	(4.7)	18.1	(6.5)	21.1	(4.0)	3.0	0.011	0.7 - 5.3
Emotional (0-24)*	19.7	(3.3)	17.8	(4.3)	20.1	(2.9)	2.3	0.007	0.7 - 3.9
Functional (0-28)*	18.0	(6.4)	14.3	(7.2)	18.9	(5.9)	4.6	0.004	1.5 - 7.7
Prostate Cancer (0-48)*	33.3	(7.1)	29.7	(6.4)	34.2	(7.0)	4.4	0.013	0.9 - 7.9

Note. \*Subscale or scale score range in brackets. For all HRQL measures, higher scores reflect better quality of life. FACT-G = physical + social + emotional + functional well-being. Total FACT-P = FACT-G + prostate cancer subscale. All p values are significant based on their stepwise-adjusted p using the Holm method of Bonferroni Correction for multiple comparisons.

significantly lower representing poorer HRQL compared to men without a mental health disorder. The differences in HRQL for men with and without a mental health disorder were also clinically important. Mean group differences for all subscales and scales exceeded the pre-determined cut points for clinical significance.

### ***Health Care Costs***

Table 4 summarizes the annual health care costs for the study sample and mental health disorder groups. For the study sample, the highest costs related to direct (non-hospital) costs for health care provider services and diagnostic tests. Differences in health care costs between mental health groups were economically and administratively important but not statistically significant. Mean total direct annual expenditures for men with a mental health disorder were double the cost of those without a disorder. Direct (non-hospital) and hospital annual expenditures were respectively \$5490.27 and \$2289.54 higher for the mental health disorder group.

For specific expenditures, patients with a mental health disorder had higher mean costs compared to the non-disorder group related to: ambulance (180.53 vs. 36.75), emergency room visits (288.49 vs. 97.88), psychiatrist (20.90 vs. 0.71), occupational therapist (122.66 vs. 48.07), social worker (29.91 vs. 0), homemaker (2714.80 vs. 952.73), laboratory specimens (51.72 vs. 9.70), pulmonary tests (5.88 vs. 0.84), and endoscopic examinations (59.37 vs. 18.33).

Table 4

*Comparison of Annual Health Care Costs and Mental Health*

Expenditures	Mental Health Disorders						U	P
	Total		Present (N = 19)		Absent (N = 90)			
	Mean	SD	Mean	SD	Mean	SD		
<b>Health Services:</b>								
Family Physician	200.13	193.83	312.99	322.98	173.33	138.01	631.50	0.249
Specialist Physician	489.85	307.63	553.63	415.48	474.71	277.22	693.50	0.553
Emergency Room	134.46	230.01	288.49	388.07	97.88	155.74	569.00	<b>0.051</b>
Physiotherapist	233.15	1058.37	246.04	595.39	230.08	1143.99	658.50	0.148
Psychiatrist	4.59	28.86	20.90	63.33	0.71	6.34	688.50	<b>0.032</b>
Occupational Therapist	62.38	330.57	122.66	341.90	48.07	328.39	669.00	<b>0.051</b>
Social Worker	5.74	46.99	29.91	106.10	0	0	680.00	<b>0.004</b>
Nutritionist	7.95	43.97	16.58	52.65	5.91	41.76	707.50	0.219
Naturopath	8.64	79.57	0	0	10.69	88.49	741.00	0.488
Visiting Nurse	951.68	2602.80	1786.43	3917.44	753.42	2167.91	658.50	0.282
Chiropractor	22.28	106.22	43.16	162.01	17.32	88.80	680.00	0.110
Homemaker	1290.91	3948.09	2714.80	5618.65	952.73	3397.04	580.00	<b>0.017</b>
Meals on Wheels	3.43	34.17	0	0	4.25	38.01	750.50	0.626
911	1.41	6.51	1.23	5.35	1.46	6.78	758.50	0.972
Ambulance	64.34	211.70	180.53	354.49	36.75	151.48	575.50	0.004
Other Health Provider	0.45	4.51	0	0	0.56	5.01	750.50	0.626
All Laboratory & Diagnostic Tests	448.71	340.26	633.57	501.32	404.80	276.03	583.00	0.116
Blood Tests	185.04	203.18	285.11	294.92	161.27	168.56	557.50	0.069
Lab Specimens	17.76	50.13	51.72	105.40	9.70	15.60	480.50	<b>0.007</b>
Endo-Scopes	26.21	71.76	59.37	115.09	18.33	55.15	606.50	<b>0.029</b>
Xrays	54.13	78.80	45.79	60.33	56.12	82.78	709.50	0.640
Scans	144.15	122.51	167.45	152.30	138.62	114.78	683.00	0.475
Pulmonary Tests	1.81	6.12	5.88	10.11	0.84	4.27	588.50	<b>0.001</b>
ECG	15.27	19.04	15.30	19.99	15.26	18.93	742.00	0.862
EEG	2.83	12.33	2.95	12.86	2.80	12.29	758.00	0.963
EMG	1.51	14.99	0	0	1.86	16.67	750.50	0.626
Drugs	3470.18	4175.28	4837.25	6917.92	3145.50	3188.29	717.00	0.702
Supplies	255.57	822.78	480.89	1123.32	202.05	732.91	614.00	0.107
<b>Total Direct Non-Hospital Costs</b>	<b>6965.87</b>	<b>8921.31</b>	<b>11402.45</b>	<b>14422.38</b>	<b>5912.18</b>	<b>6743.87</b>	609.00	0.180
<b>Total Hospital Costs</b>	<b>2102.72</b>	<b>5236.41</b>	<b>3952.85</b>	<b>8593.30</b>	<b>1663.31</b>	<b>4021.25</b>	735.00	0.774
<b>Total Costs</b>	<b>9068.59</b>	<b>12607.77</b>	<b>15355.30</b>	<b>22064.96</b>	<b>7575.50</b>	<b>8630.88</b>	645.00	0.307

Note. Mean costs are based on unit costs for the year 2001, in Canadian dollars.  
 Total Costs = Direct + Direct Non-Hospital Costs. U = Mann-Whitney Test.  
 Significance at  $p = 0.05$ .

Patients with palliative disease also utilized substantively greater health care resources in all areas related to drugs, supplies, and direct costs including hospitalization (Table 5). The magnitude of total cost differences between palliative and non-palliative patients is large and borders on statistical significance. Total annual expenditures for patients with palliative disease were \$17677.61 higher than hormone refractory patients and \$18260.61 higher than costs for hormone sensitive patients. Statistically significant differences were observed between hormone sensitive, hormone refractory, and palliative patients related to direct (non-hospital) costs. Post hoc comparisons showed that patients receiving palliative care had higher mean annual costs compared to those with hormone refractory disease related to direct (17884.31 vs. 5263.00,  $U = 256.00$ ,  $p = 0.005$ ), and total (26359.29 vs. 6800.29,  $U = 294.00$ ,  $p = 0.018$ ) costs. There were no differences in mean annual direct, hospital, or total health care costs between hormone sensitive and hormone refractory patients.

Costs for specific expenditures differed among patient groups. Patients with hormone refractory disease had higher mean costs for all laboratory and diagnostic tests compared to those with hormone sensitive disease ( $U = 140.50$ ,  $p = 0.004$ ). Patients receiving palliative care had higher mean costs for home nursing ( $U = 23.00$ ,  $p = 0.017$ ), supplies ( $U = 290.00$ ,  $p = 0.051$ ), and blood tests ( $U = 19.50$ ,  $p = 0.007$ ) compared to those with hormone sensitive disease. Patients with palliative disease also had higher mean costs related to home nursing ( $U = 244.00$ ,  $p = 0.001$ ), occupational therapy ( $U = 357.50$ ,  $p < 0.001$ ), social work ( $U = 423.50$ ,  $p = 0.001$ ), homemaking ( $U = 238.50$ ,  $p < 0.001$ ), supplies ( $U = 290.00$ ,  $p = 0.003$ ), and ambulance services ( $U = 352.00$ ,  $p = 0.004$ ).

**Table 5*****Comparison of Annual Health Care Costs and Disease Status***

Expenditures	Hormone Sensitive		Hormone Refractory		Palliative		H	P
	(N = 9)		(N = 77)		(N = 13)			
	Mean	SD	Mean	SD	Mean	SD		
<b>Health Services:</b>								
Family Physician	91.59	37.37	192.70	172.30	319.31	305.44	4.07	0.131
Specialist Physician	350.40	173.68	476.17	271.86	667.44	484.47	3.65	0.161
Emergency Room	65.25	97.88	122.03	205.90	255.99	369.57	1.41	0.495
Physiotherapist	1201.14	3188.69	102.45	406.77	337.12	705.23	3.88	0.144
Psychiatrist	0	0	3.68	26.58	13.09	47.21	1.28	0.528
Occupational Therapist	0	0	+ 13.62	106.89	+ 394.41	826.10	16.36	<b>0.000</b>
Social Worker	0	0	+ 0	0	+ 43.72	127.40	13.37	<b>0.001</b>
Nutritionist	0	0	6.14	42.56	24.23	62.91	3.65	0.162
Naturopath	0	0	11.11	90.20	0	0	0.58	0.749
Visiting Nurse	# 77.76	202.55	+498.18	1258.24	#+4242.78	5625.40	13.35	<b>0.001</b>
Chiropractor	0	0	27.55	119.72	6.53	23.53	0.75	0.688
Homemaker	1956.25	4868.94	+647.24	2600.54	+ 4642.79	7314.36	20.01	0.000
Meals on Wheels	0	0	4.42	38.75	0	0	0.29	0.867
911	0	0	1.21	5.21	3.59	12.94	0.71	0.702
Ambulance	0	0	+ 47.73	182.30	+ 207.31	358.49	10.38	<b>0.006</b>
Other Health Provider	4.98	14.95	0	0	0	0	10.00	<b>0.007</b>
All Laboratory & Diagnostic Tests	+199.22	121.72	+484.88	348.17	407.19	333.10	8.87	<b>0.012</b>
Blood Tests	# 76.57	46.57	191.91	211.65	# 219.45	203.93	8.17	<b>0.017</b>
Lab Specimens	1.44	4.31	20.82	56.01	10.94	18.17	5.67	0.059
Scopes	0	0	27.83	75.79	3 4.71	71.11	2.17	0.338
Xrays	15.74	30.69	61.92	84.98	34.80	49.21	6.31	<b>0.043</b>
Scans	80.80	84.35	159.37	127.84	97.89	86.73	6.02	<b>0.049</b>
Breathing Tests	0	0	1.74	6.03	3.44	8.39	1.72	0.424
ECG	2.15	6.46	18.37	19.86	5.96	12.22	12.73	<b>0.002</b>
EEG	6.23	18.68	2.91	12.52	0	0	1.37	0.504
EMG	16.57	49.70	0	0	0	0	10.00	0.007
Drugs	2194.49	2082.97	3099.63	3212.99	6548.11	7856.92	2.74	0.254
Supplies	# 64.67	194.00	+193.14	742.78	# + 757.46	1297.67	10.18	<b>0.006</b>
<b>Total Direct Non-Hospital Costs</b>	<b>5763.77</b>	<b>5586.17</b>	<b>+5263.00</b>	<b>5564.50</b>	<b>+17884.31</b>	<b>16859.40</b>	<b>8.04</b>	<b>0.018</b>
<b>Total Hospital Costs</b>	<b>453.53</b>	<b>1360.36</b>	<b>1537.28</b>	<b>3698.49</b>	<b>6593.60</b>	<b>10493.94</b>	<b>1.84</b>	<b>0.398</b>
<b>Total Costs</b>	<b>6217.29</b>	<b>5737.36</b>	<b>+6800.29</b>	<b>6708.62</b>	<b>+24477.90</b>	<b>26359.29</b>	<b>5.88</b>	<b>0.053</b>

Note. Costs are based on unit costs for the year 2001, in Canadian Dollars.

Total Costs = Direct & Direct Non-Hospital Costs.

H = Kruskal-Wallis Test. Significance at  $p = 0.05$ .

Mann-Whitney U Test was used for post hoc paired group comparisons. Pairs of groups with cost differences share the same symbol (+) or (#) on the same line of the table.

compared to those with hormone refractory disease. For specific expenditures, the largest differences between palliative and non-palliative groups were for home nursing and homemaking support. For patients with palliative stage disease, home nursing costs were \$4242.78 compared to \$498.00 and \$78.00 for hormone refractory and hormone sensitive patients respectively. Homemaking costs for palliative patients (\$4642.79) were more than double that of hormone sensitive (\$1956.00) and hormone refractory (\$647.00) patients.

## **Discussion**

### ***Prevalence of Mental Health Disorders in Advanced Prostate Cancer***

The prevalence of depression (14%) in this study is in keeping with reports of depression (8% to 17%) in other studies involving mixed cancer populations evaluated using structured diagnostic interviews like the CIDI-SF (Berard, Boermeester, Viljoen, 1998; Chochinov, Wilson, Enns, & Landers, 1994; Harter et al., 2001; Razavi, Delvaus, Farvacques, & Robaye, 1990). The prevalence of depression in our study was also comparable to the 10 to 15% prevalence of depression in elderly patients in primary care or acute care medical settings (Schulberg et al., 1992; Koenig et al., 1993). The 12 month prevalence of depression (14%) in advanced prostate cancer reported in our study is higher than estimates of depression for Canadian (3.5% to 5.2%) and American (7.7%) men in general population based surveys using the UM-CIDI or CIDI-SF (Kessler et al, 1994; Patten, 2000). Other studies have also found higher rates of depression in cancer populations compared to the general population (Sellick & Crook, 1999; McDaniel et al.,

1995). These data suggest that the prevalence of depression in advanced prostate cancer may be similar to that of other cancer and medically ill elderly populations.

Only one identified study evaluated psychiatric disorders using diagnostic criteria for patients with predominantly advanced prostate cancer (Roth et al., 1998). This study reports a lower prevalence of psychiatric disorders in which 9% of subjects initially screened for psychological distress, were subsequently found to have depression or adjustment disorder based on a clinical diagnostic interview. The inclusion of some early stage patients, selection bias, high refusal rate, and failure to refer patients for the clinical diagnostic interview may account for the differences in these study results.

An important difference in our study is the low prevalence of anxiety and the higher prevalence of depression compared to all anxiety disorders. Anxiety is reported in 1% to 49% of cancer populations using a variety of screening and diagnostic tools (Van't Spijkjer et al., 1997). The prevalence of anxiety disorders (6%) is lower than 12 month estimates of anxiety disorders (9% to 11.8%) for men in the general population (Ontario Ministry of Health, 1994; Kessler et al., 1994). In these studies, higher rates of anxiety disorders also occur in younger age groups. The absence of men over the age of 65 years in these community studies may contribute to differences in prevalence rates. However, multiple studies involving prostate cancer patients, medically ill men, and men in the general population report an overall higher prevalence of anxiety (7 to 33%) rather than affective (4 to 15%) disorders (Booth, Blow, & Loveland Cook, 1998b; Cliff & MacDonaugh, 2000; Kessler et al., 1994; Roth et al., 1998). High co-morbidity or co-occurring anxiety and affective disorders are also reported but this occurred in only one

patient in our study (Derogatis et al., 1983; Kessler et al., 1993; Lewis & Araya, 2001). In an early study we also found that men reported more severe symptoms of anxiety compared to depression (Bryant-Lukosius et al., unpublished manuscript). Thus while the prevalence of anxiety disorders for this population of men with prostate cancer may reflect true low levels of psychiatric morbidity compared to other study results, the underreporting or under-diagnosis of anxiety using the CIDI-SF cannot be ruled out.

Similar issues related to underreporting and false negative results may also account for the notable absence of substance abuse problems in the study sample. This contrasts with existing data documenting a higher prevalence rate of substance abuse disorders for men compared to women in the general population (Harris, 2001; Kessler et al., 1994; Ustan, 2000). Once again this comparison is limited by the lack of older men in these community-based studies.

The greater proportion of palliative patients with a mental health disorder is consistent with results from several studies in which patients with more severe symptoms or physical disability are more likely to become depressed or anxious (Bukberg, Penman & Holland, 1984; Ciaramella & Poli, 2001; Cliff & MacDonaugh, 2000; Derogatis et al., 1983; Harter et al., 2001). However, because this is a study of advanced stage patients, the number of patients who met the DSM-III-R criteria may be an overestimation of true cases of depression. Confounding symptoms of depression such as fatigue, decreased appetite, and weight loss are common among men with advanced prostate cancer (Bryant-Lukosius, unpublished manuscript; Fossa et al., 1990). However, Chochinov et al., (1994) found that there were no differences in the prevalence of depression between



measures that include or exclude somatic symptoms, when high thresholds for symptom severity were utilized. The high threshold criteria used in the Chochinov et al. (1994) study are similar to the DSM-III-R criteria on which the CIDI-SF is based.

A final and post-study observation is that when the charts of the 19 patients identified as having a mental health disorder were retrospectively reviewed, only seven documented a referral for psychiatric evaluation. The under-diagnosis and treatment of mental health disorders in cancer patients is well established (Cull, Stewart, & Altman, 1995; Lynch, 1995; Stiefel et al, 2001). As Roth et al. (1998) point out many patients are only referred for psychiatric assessment when their symptoms or level of impairment are severe enough to hit the radar screens of health professionals. For patients with advanced prostate cancer, the assessment of mental health disorders may be compromised when symptoms are confused or attributed only to disease and cancer treatment and not psychological morbidity.

### ***Quality of Life and Mental Health***

Mean scores for physical, emotional, social, functional and prostate cancer well-being are consistent with FACT-P results reported in other studies involving patients with advanced prostate cancer (Bryant-Lukosius et al., unpublished manuscript; Esper et al., 1997). In this first study examining the relationship between mental health and HRQL in prostate cancer, our findings suggest that men with mental health disorders have poorer quality of life in all domains compared to men without mental health disorders. Of particular importance is the observation that the mean scores for all FACT-P domains of HRQL were substantially lower for men with a mental health disorder. The magnitude of

differences in Total FACT-P scores suggests that the cumulative effect of poor quality of life in all domains for men with mental health disorders is profound. Previous research indicates that the negative effect of mental illness is additive in which the heightened levels of impaired function and poor HRQL are over and above that related to medical illness alone (Booth et al., 1998b). In primary care populations, depression alone is associated with greater symptom distress, impairment, and disability related to physical, social, and functional well-being compared to impairment due to other common medical illnesses such as arthritis, diabetes, or congestive heart failure (Hays, Wells, Sherbourne, Roger, & Spritzer, 1995; Wells et al., 1989; Wells & Sherbourne, 1999).

#### ***Annual Per Person Health Care Expenditures***

The observed differences in annual per person expenditures for health and social services between groups with and without a mental health disorder are economically and administratively important, but these results were not statistically significant. According to O'Brien and Drummond (1994), the size of cost differences that are economically important may be a valid consideration in studies where cost analyses are secondary and the sample size may not be adequate to detect statistically significant differences. The pattern of higher health care costs in all expenditure categories coupled with the magnitude or greater than two fold increase in total health care costs for men with a mental health disorder suggest that important differences in health care costs may exist. This trend, suggestive of higher health care utilization by patients with mental illness, is consistent with similar results in several studies evaluating primary care and medically ill populations (Browne et al., 1993; Luber et al., 2000; Hall, 1995). While

these data are not sufficient to direct practice or policy, it may inform future economic evaluations in prostate cancer.

It is not surprising that palliative patients with prostate cancer had total health care costs that were more than three times higher than patients with less progressive or end stage disease. Other studies have also identified the high costs of palliative care, particularly related to hospitalization and terminal care in the last few weeks of life (Chochinov & Kristjanson, 1998; Goodwin & Shepherd, 1998; Maltoni et al., 1997). In Canada, it is estimated that for men aged 40 to 80 years in 1997, life time health care costs for prostate cancer will exceed \$9.7 billion dollars and that at least 25% of these costs will be for palliative care (Grover et al., 2000).

There are few studies that have evaluated costs associated with prostate cancer care. A retrospective evaluation of Canadian palliative prostate cancer patients treated with strontium-89 for bone metastasis, estimated the 1989 costs of medical care only (excluding the cost of strontium) to be \$1,400 per month or over \$16,000 per year (McEwan et al., 1994). The higher costs of non-medical care such as community and home care services documented for palliative patients in our study, demonstrate the importance of also including these expenditures in economic evaluations of cancer care.

The types of health care services utilized more frequently by palliative patients were consistent with community-based care and health problems related to declining physical and functional well-being. Palliative patients tended to use more services to maintain independent living in their own homes, such as occupational therapy,

homemaking, other health care providers, and home nursing. Palliative patients also had more supply costs related to mobility aids and home equipment.

In contrast, higher health care service costs associated with mental health disorders resulted from more emergency room visits, blood work, laboratory specimens, breathing tests, and other investigations. Patients with mental health disorders were also more likely to have been seen by a psychiatrist but the average annual cost per person for this service was miniscule (\$20.90). The low cost of psychiatric care may reflect limited access to this type of service. Hospital costs were more than double for patients with a mental health disorder. Other studies have also found that cancer and/or medical patients with major depression had significantly longer hospital lengths of stay compared to similar patients with no depression (Booth et al., 1998b; Hosaka et al., 1999).

### ***Study Strengths & Limitations***

The strengths of this study with respect to determining the prevalence of mental health disorders include the sampling of the whole clinic population over a one year period and the fairly good response rate (Loney, Chambers, Bennet, Roberts, & Strafford, 2001). However, non-random sampling, the small sample size, and narrow focus of the sample limit the generalizability of study results beyond the study population. The small sample size has also contributed to wide confidence intervals and less accuracy regarding estimates of prevalence (Table 2). The overall prevalence of mental health disorders may be as low as 11.3% or as high as 26.7%. The lower boundary of the confidence interval for depression (7.3%) is comparable to estimates of depression for the general population, while the upper limit (26.7%) is almost 3 times higher. More precise and comprehensive

evaluations of the prevalence of mental health disorders in advanced stage prostate cancer would require a multi-centre study involving a minimum of 322 subjects (CI = 95%, error rate of 5%). Stratified sampling according to disease severity (hormone sensitive, hormone refractory, palliative) would also be an asset but would require 300 subjects per group (Loney et al., 2001).

The CIDI-SF and other structured diagnostic interviews used in research identify subjects with a high probability of having a psychiatric diagnosis but in the clinical setting are not a replacement for the criterion standard diagnosis or the physician administered Structured Clinical Interview for DSM-III-R (SCID). Clinical confirmation of diagnoses based on the SCID for those subjects identified as having a mental health disorder would have been helpful to determine which subjects may have benefited the most from treatment. Further validation studies to evaluate the sensitivity, specificity, and positive/negative predictive value of the CIDI-SF compared to the SCID for patients with advanced prostate cancer are warranted.

Underestimation of the prevalence of mental health problems may have occurred due to the 34% of patients who refused study participation, many of whom may have had high levels of functional impairment, and consequently higher risk for mental health problems. Reporting bias may have also played a role in underestimating the true prevalence of mental health disorders especially related to anxiety disorders.

Underreporting or non-disclosure of psychiatric symptoms is a common source of bias in studies where subjects have not sought mental health services (Kessler, 2000). For men, lack of disclosure or non-study participation may not necessarily reflect the desire to be

less than forthcoming, but gender specific coping strategies. The cancer literature suggests that men and women use different emotion-focused coping strategies. Men have the tendency to deny, minimize, and avoid discussing the negative aspects and psychological impact of their cancer situation (Fife, Kennedy, & Robinson, 1994; Znajda, Wunder, Bell, & Davis, 1999; Pettingale, Burgess, & Greer, 1988).

There are convincing data that patients with advanced prostate cancer and mental health disorders have significantly poorer quality of life compared to those with no mental health disorders. However, the lower boundaries of the confidence intervals for mean differences in FACT-P scale and subscale scores are less than the 2 or 10 point difference respectively, suggestive of clinically important differences in HRQL (Table 3). This indicates that the sample size may be too small and that subsequent studies with a larger sample size are required to confirm these results (Guyatt et al., 1995). The cross-sectional study design does also not permit evaluation of the temporal or causal nature of relationship between mental health disorders and quality of life.

The small sample size and wide variation in individual responses related to health care costs may have also resulted in the inability to detect a statistically significant difference in health care costs between mental health groups. Cost data are often more variable than outcome data and may require very large sample sizes to detect a difference (Drummond, O'Brien, Stoddart, & Torrance, 1998).

A major limitation of this and other economic evaluations of cancer care is that the costs that patients and families incur due to out of pocket expenses or time lost from work have not been evaluated. This is a particularly important consideration in Canada

where government funding for community-based care has not kept pace with the increasing demand for service. Lack of funding combined with a shortage of home health care providers means that patients and families are not only paying for more services but families are also responsible for providing more patient care. The out of pocket expenses incurred by patients and families for palliative care can be equivalent to that of long term nursing care (Chochinov & Kristjanson, 1998).

### *Implications for Practice*

The results suggest that the supportive care of patients with advanced prostate cancer should include assessment and management of mental health problems. A small but not insignificant proportion (19%) of men in our study had a high probability for having an affective or anxiety disorder warranting further clinical evaluation. These men also experienced significantly higher levels of functional impairment, poorer quality of life, and higher expenditures for the use of health care services in the same year compared to those with no mental health problems. Our study did not identify patients experiencing symptoms of depression or psychological distress who did not meet the diagnostic criteria for a psychiatric disorder. These individuals may also have substantial reductions in HRQL and benefit from additional psychological support (Wells et al., 1989; Wilson et al., 2000).

The assessment and management of mental health problems in advanced prostate cancer is complex due to factors such as increasing age, gender, co-morbid conditions, and confounding symptoms of advanced disease. Lack of knowledge and clinical skills and time restraints can be barriers to recognizing and treating mental health disorders in

patients with advanced cancer (Block et al., 2000). Health care providers require a high level of knowledge and skill regarding mental health and prostate cancer related health issues. The feasibility of screening for mental health problems in clinical settings has been demonstrated in several studies using a variety of instruments such as the Hospital Anxiety and Depression Scale, the Beck Depression Inventory, and the Primary Care Evaluation of Mental Health Disorders (Carroll et al., 1993; Heim & Oei, 1993; Leopold et al., 1998; Roth et al., 1998). Practical issues related to resources and staff training and other factors such as disease and treatment status should be considered in the selection of screening instruments (Ibbotson, Maguire, Selby, Priestman, & Wallace, 1994).

Strategies to identify patients at high risk for mental health problems would also be an important component of a screening program. We found that palliative patients with progressive symptoms of advanced disease are at risk for mental health problems. Other individuals at risk may be those with multiple psychosocial problems and those with a prior history of mental illness (Cull et al., 1995; Grassi & Rosti, 1996; Nordin, Berglund, Glimelius, & Sjoden, 2001). These high-risk groups may benefit the most from psychiatric intervention and are obvious priorities for screening and assessment of mental health problems.

Drug therapy and a variety of counselling techniques for treating anxiety and depression in advanced cancer have been found to improve emotional well-being, functional ability, disease and treatment related symptoms, and HRQL (Meyer & Mark, 1995; Payne & Massie, 2000; Sellick & Crooks, 1999; Sivesind & Baille, 2001; Stiefel et al., 2001; Wilson et al., 2000). Patients are most likely to benefit from combined therapy



involving medication and psychotherapeutic support (Wilson et al., 2000). There are many factors to consider in the selection of appropriate medications including: patient prognosis, onset of drug action, co-morbidity, drug interactions, and potential side effects. In elderly patients with prostate cancer, selective serotonin reuptake inhibitors (SSRIs) may be more beneficial than tricyclic medications because they have fewer side effects related to urinary retention, orthostatic hypotension, sedation, and cardiac conduction (Block et al., 2000). Some palliative care experts recommend that clinicians have a low threshold for treating depression, particularly for terminally ill patients, given the complexity of and morbidity associated with this disorder in advanced cancer (Block et al., 2000).

Aggressive assessment and management of prostate cancer related health problems are also important for promoting mental health. Pain, fatigue, and decreased physical activity are common problems among men with advanced prostate cancer (Bryant-Lukosius et al., unpublished manuscript). Uncontrolled pain is associated with symptoms of depression and anxiety in patients with prostate cancer (Cliff & Macdonagh, 2000; Heim & Oei, 1993). In palliative populations, pain and depression often occur in tandem and other symptoms of depression such as insomnia, anorexia, and fatigue are aggravated by uncontrolled pain and vice versa (Heim & Oei, 1993; Stiefel et al., 2001). Pain and depression are also risk factors for suicide in advanced cancer (Breitbart & Rosenfeld, 1999). Although the mechanisms of interaction are not entirely known, the literature describes a dual relationship between pain and depression. Temporally, depression often follows episodes of persistent and uncontrolled pain and

depression has also been found to heighten perceptions of pain and other physical symptoms (Ciaramella & Poli, 2001; Spiegel, 1996; Stiefel, et al, 2001; Wilson et al, 2000). Regardless of the mechanisms involved, pain control is identified as a priority and the first step in assessing and managing depression (Block et al, 2000). Symptoms of anxiety and depression will often improve with effective pain control (Breitbart et al, 1995; Payne & Massie, 2001).

The chronic nature of prostate cancer and mental illness has important implications for screening and the ongoing assessment of mental health disorders. In this study men, were on average, almost 6 years post diagnosis. Common health problems in advanced prostate cancer, such as urinary symptoms, erectile dysfunction, and fatigue may represent long-term consequences of both disease and treatment. Over time, the culmination of multiple health problems may not only affect quality of life but mental health. This study provides only a snap shot of the 12 month prevalence of mental health disorders at one end of a long continuum for men living with prostate cancer. Patients with chronic conditions such as prostate cancer are at risk for recurrent episodes of mental illness and long-term reductions in function and well-being (Burg & Abrams, 2001; Hays et al, 1995; Unutzer et al, 2000). High levels of anxiety and depression at the time of diagnosis may be predictive of future symptoms of psychological distress (Nordin et al, 2001). Thus our ability to make substantial improvements in the health and quality of life for men in the latter stages of advanced prostate cancer may also depend on efforts to assess and manage physical and mental health problems earlier on in the illness experience.

### *Implications for Research*

Women with breast cancer have been the focus of psychosocial intervention studies and few studies have included economic evaluations. The cost effectiveness of psychosocial interventions in cancer and other chronic illnesses has been demonstrated in a small number of studies (Groessler & Cronan, 2000; Lorig et al, 2001; Simpson, Carlson, & Trew, 2001). Future studies should evaluate the long-term impact of mental health screening and intervention programs in both early stage and advanced prostate cancer. Relevant outcomes include recurrent episodes of mental illness, HRQL, functional capacity, and health care costs. Cost savings from subsequent reductions in health care utilization may offset screening and interventions costs. Health care resources used more predominantly by patients with mental health disorders in this study could be considered as targeted outcome measures for intervention studies. These resources include emergency room visits, diagnostic tests, and days in hospital. More importantly, patient preferences for specific health states related to the assessment and management of mental health issues in prostate cancer should also be evaluated. Treatment for psychiatric disorders can have negative side effects and the stigma associated with mental illness may be a barrier for some individuals.

To date there has been very little research regarding the effectiveness of supportive care interventions in prostate cancer. Existing data suggest that information seeking rather than emotional support is the primary reason that men with prostate and other types of cancer access supportive care services (Gray et al, 1997; Klemm et al, 1999). Supportive care interventions that focus on information sharing, maintaining

health, and improving quality of life while providing opportunities for psychosocial support may be more attractive to patients with prostate cancer than those focused on mental health alone. Further research regarding prostate cancer patients' priorities for supportive care and the modes of delivery that are acceptable to them is required.

### **Conclusions**

Mental health disorders are associated with inordinate and unnecessary suffering for men with advanced prostate cancer. Mental illness robs these men of their independence, ability to enjoy their families, and participate in meaningful activities in the last few years or months of life. Potential opportunities to improve the quality of life for men with advanced prostate cancer may require a shift from a singular focus on disease or cancer treatment to one that includes an emphasis on health promotion, addresses health issues relevant to older men, and involves routine assessment and aggressive management of mental health problems. A pro-active approach to maintaining the health and functional capacity of this older population of patients with cancer may also be a prudent strategy for health planners and policy makers who are interested in minimizing the high costs associated with prostate cancer care.

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## **CHAPTER 6: CONCLUSIONS**

### **Recommendations for Defining and Developing The Advanced Practice Nursing**

#### **Role for Patients with Advanced Prostate Cancer**

##### *Overview of Thesis Objectives and Results*

Chapter 2 affirmed that the central core or mandate of APN roles is to achieve optimal patient health and well-being. Five role domains related to clinical practice, education, research, organizational leadership, and professional development work synergistically to achieve patient health goals (Calkin, 1984; Canadian Association of Nurses in Oncology, Davies & Hughes, 1995; Hamric, 2000). In applying Step 3 of the PEPPA Framework to define the APN role for patients with advanced prostate cancer, this thesis has involved two studies focused on identifying patient health needs within the existing model of care at a regional cancer centre.

One assumption of the thesis is that the APN role should be framed within the Cancer Care Ontario Model of Supportive Care that is consistent with a focus on health (Fitch, 1994). This model considers the multidimensional health needs of patients affected by cancer and recognizes that health needs change across the continuum of cancer care from the time of diagnosis to palliation. It was hypothesized that the supportive care role of the APN for patients with advanced prostate cancer would require a strong mental health focus.



### *Quality of Life in Prostate Cancer (Chapter 4)*

In this study, the health needs of patients with advanced prostate cancer were examined within the context of the continuum of prostate cancer care represented by five patient groups that differ by stage of disease and treatment status: early stage newly diagnosed, early stage receiving treatment, early stage receiving follow-up care, advanced hormone sensitive, and advanced hormone refractory. Patients with advanced hormone refractory disease were found to have significantly poorer HRQL, more severe health problems, and different perceptions regarding the importance of health problems compared to the other patient groups. Previous studies have found that men with early stage prostate cancer experience good quality of life that is similar to age matched controls with no history of prostate cancer (Litwin et al., 1995; Wei et al., 2002). This study found that patients with advanced hormone sensitive disease also experience good HRQL that is similar to those with early stage disease.

Study results also reinforce previous research indicating that problems related to sexual health and urinary function are common among men with prostate cancer and provide new insight into the perceived importance of these and other health problems across the continuum of care (Henke Yarbro, Estwing Ferrans, 1998; Kornblith et al, 1994; Litwin et al., 1995). Erectile dysfunction and dissatisfaction with their sex life were the most frequently reported health problems across the five groups. Improving their sexual function was the top priority for early stage and advanced hormone sensitive groups. A greater proportion of patients with advanced hormone refractory disease reported severe problems related to sexual health, but alleviating pain and symptoms of

fatigue was more important for this group. Urinary incontinence was more likely to be reported as a priority concern by patients with early stage disease, while patients with advanced stage disease were more likely to identify urinary frequency and sleep difficulties as priority concerns. Other common problems across the groups were dissatisfaction with comfort level, dissatisfaction with how they were coping, decreased physical ability, and fatigue. Patients with newly diagnosed early stage disease were the only group to identify mental health issues and the need for more information about their disease and treatment as priorities.

Decreased levels of physical function have been reported in studies of patients with advanced but not early stage prostate cancer (Curran et al, 1997; Fossa et al., 1990). A notable finding was the importance of physical function for early stage newly diagnosed and follow-up patients and those with advanced disease. For these patient groups, increasing their level of physical activity was identified as a priority for improving their health just as often or more frequently than other problems commonly associated with prostate cancer, such as urinary incontinence. A variety of patient and prostate cancer related variables were evaluated as potential predictors of HRQL. Higher levels of PSA, advanced hormone refractory disease, and a history of mental health problems were modest predictors of poor HRQL.

### ***Mental Health in Advanced Prostate Cancer (Chapter 5)***

This study focuses on an in-depth examination of the prevalence of mental health problems in advanced stage prostate cancer and their impact on HRQL and health care costs. Differences in HRQL and health care costs related to the severity of advanced

stage disease were also examined. A small but substantial proportion of patients (19%) were found to have a high probability for having an anxiety or affective disorder. Patients with a mental health disorder had statistically significant poorer levels of well-being in all domains of HRQL compared to those with no mental health problems. Total annual health care costs for patients with a mental health disorder were double those with no mental health problems.

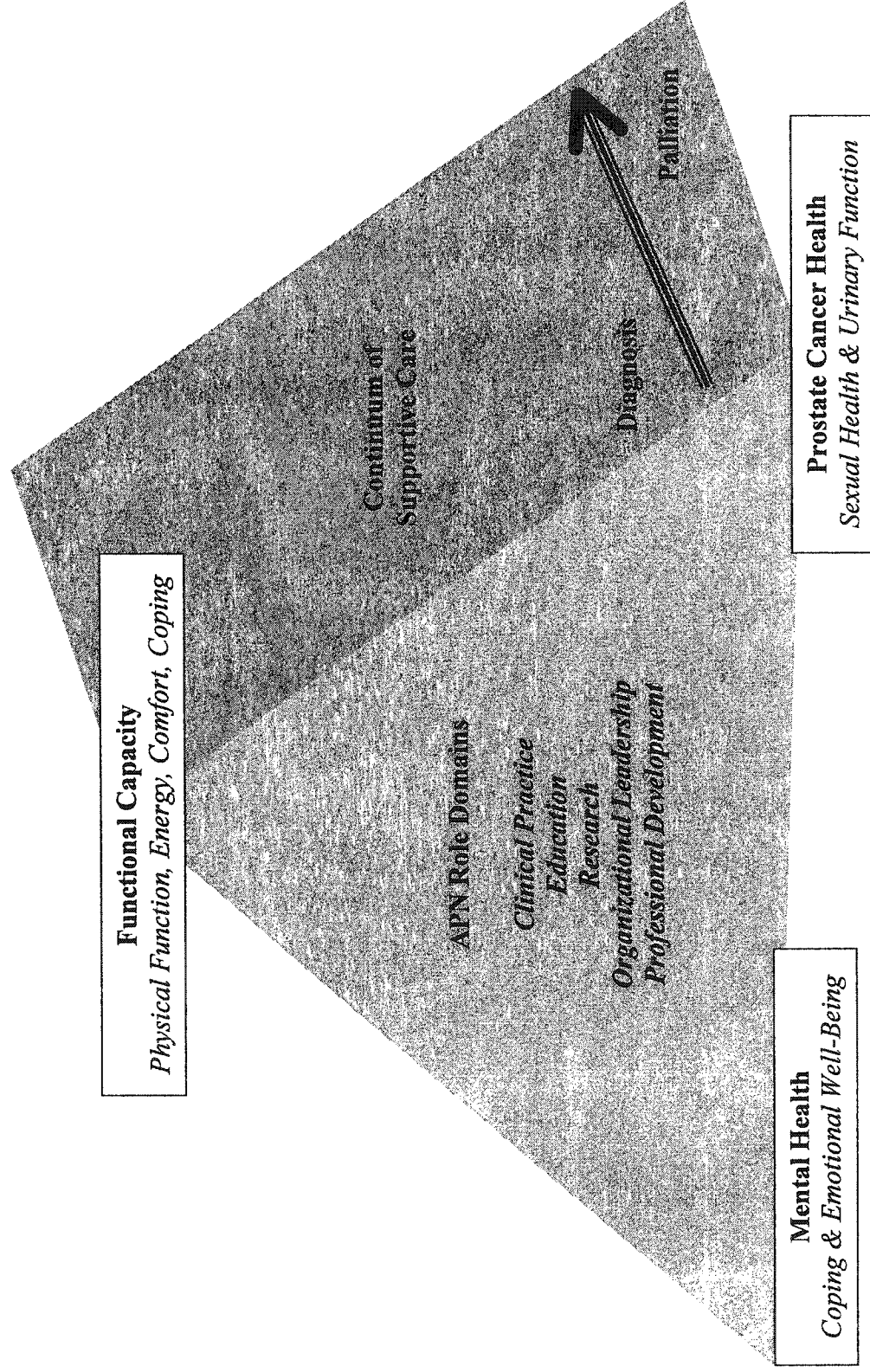
As found in other cancer studies, a greater proportion of patients receiving palliative care for progressive end stage prostate cancer had mental health problems. These patients also had significantly higher total annual health care costs compared to those with less symptomatic hormone sensitive or hormone refractory disease. Patients receiving palliative care tended to use more services to maintain independent living in their own homes compared to patients with less severe disease. In contrast, patients with mental health problems tended to use more emergency, diagnostic, and hospital services compared to patients with no mental health problems.

### *Implications for Defining the APN Role*

A main objective of this thesis was to define, from a patient perspective, targeted priorities for the APN role related to advanced prostate cancer. Figure 1 provides a potential model for articulating the supportive care role of the advanced practice nurse designed to improve the health and quality of life for patients with advanced prostate cancer. The combined study results suggest that there are three priorities or primary areas of focus for the APN role related to prostate cancer health, mental health, and functional capacity.

**Figure 1**

***Improving Health and Quality of Life in Advanced Prostate Cancer: The Focus for Advanced Practice Nursing Roles***



### *Prostate Cancer Health*

Prostate cancer health involves the promotion of sexual health and urinary function. Loss of erectile function was almost universal for patients with advanced disease. However, maintaining erectile function following treatment for prostate cancer does not necessarily guarantee sexual satisfaction (Lerner et al., 1996). The World Health Organization (2002) views sexual health as being more than the absence of dysfunction but involves physical, emotional, mental, and social well-being related to sexuality. The impact of prostate cancer on sexual health is evident in results of the study that examined quality of life. Reducing hot flashes as a distressing side effect of androgen suppression was a priority for patients with advanced hormone sensitive disease. Social well-being related to dissatisfaction with their sex life was severely and adversely affected in 75% or more of men with advanced hormone sensitive or hormone refractory disease. A significant number of men with advanced stage disease also had a decreased sense of masculinity or negative perception of male self-image. Other studies also describe the negative impact of erectile dysfunction related to body image, perceptions of virility, and social relationships (Bokhour et al, 2001; Cassileth et al, 1992; Gray, Fitch, Fergus, Mykhalovsky, & Church, 2002; Heyman & Rosner, 1996; Stone et al, 2000).

Based on published studies and my own findings, I propose that evaluating the impact of advanced prostate cancer on sexual health is an important clinical component of the APN role. One descriptive report of the APN role for patients following radical prostatectomy, noted that few patients volunteered information regarding their sexual

concerns (Monturo, Rogers, Coleman, Robinson, & Pickett, 2001). Establishing a trusting relationship with the patient and his partner and using a structured interview guide are helpful strategies for evaluating sexual health concerns (Monturo et al., 2001). It is also important to determine the patient's goals in relation to sexual health. Although 75% of men in the advanced hormone sensitive group were dissatisfied with their sex life, only 34% identified sexual function as a priority for improving their health. Increasing age may play a role in the importance sexual function has for some men. Men over 74 years of age with prostate cancer were found to be less concerned about the loss of sexual function compared to younger men (Fransson & Widmark, 1996). Some men may also be reluctant to utilize sexual health resources or services due to discomfort in addressing sexual health issues (Butler et al., 2001).

Nursing interventions for improving sexual health include providing information and counselling to promote patient and partner communication and opportunities for intimacy, and to expand the patient's full range of sexual expression (Monturo et al., 2001). For patients with advanced hormone refractory prostate cancer, other health problems related to fatigue, pain, or mood may need to be alleviated before the patient is interested in or able to address issues related to sexual health.

Urinary frequency and incontinence are important concerns among men with prostate cancer, although urinary frequency appears to be more problematic for patients with advanced disease. The treatment of urinary problems in advanced stage prostate cancer is a challenging clinical issue as there are few effective medical or nursing interventions. In addition to urinary obstructive symptoms due to localized pelvic

disease, these patients may also have long standing urinary problems related to prior surgery and radiation therapy. Previous research indicates that the patient's appraisal of urinary problems regarding the extent to which they disrupt activities of daily living is an important predictor of HRQL ((Fowler et al., 1995; Rondort-Klym & Colling, 2003). A key aspect of the APN role is to assist patients in coping with and managing urinary symptoms and minimizing their impact on day-to-day activities.

### ***Mental Health***

Both studies support the hypothesis that the APN role in advanced prostate cancer should include a prominent mental health focus. Patients with advanced prostate cancer were found to have a higher rate of depression compared to the general population (14% versus 3 to 5%) (Kessler et al., 1994; Patten, 2000). Patients with advanced stage disease were also more likely to have a documented history of mental health problems. Patients receiving palliative care for end stage disease appear to be at greater risk for mental health problems. However, 17% or more of patients in all groups across the continuum were highly dissatisfied with how they were coping and early stage newly diagnosed patients identified problems associated with mood as a priority for improvement. These findings suggest that assessment of mental health problems should occur at the time of initial diagnosis of prostate cancer and with changes in stage of disease or treatment status.

Identification of patients experiencing severe symptoms of psychological distress depression and those at high risk for developing mental health problems is an important aspect of the clinical role of the APN. Mental health should be included as an integral

component of the APN's initial patient health assessment and as part of ongoing clinical care. The feasibility of screening for mental health problems in clinical settings has been demonstrated in several studies using a variety of instruments such as the Hospital Anxiety and Depression Scale, the Beck Depression Inventory, and the Primary Care Evaluation of Mental Health Disorders (Carroll et al., 1993; Heim & Oei, 1993; Leopold et al., 1998; Roth et al., 1998). Implementing a mental health screening program at strategic time points such as at the time of diagnosis and for patients with progressive or palliative stages of disease should be considered.

Although it has been recommended, mental health screening is not a routine component of clinical care in most Ontario cancer settings (Cancer Care Ontario, 2002). Specialized oncology nurses with additional training to assess mental health problems have been found to significantly increase the rate of psychiatric referrals and treatment (Maguire, 1995). A potential challenge in expanding the clinical care of patients with prostate cancer to include a mental health focus, may be limited access to psychiatrists, clinical psychologists, and other resources necessary to support an increased number of patients. Therefore, a key aspect of the leadership role of the APN will be to work with other health care team members, mental health care providers, and administrators to ensure that adequate resources and structures are in place to support this change in clinical practice.

The APN role should also focus on interventions to prevent development of mental health problems. Declining levels of physical function and uncontrolled pain are associated with increased symptoms of anxiety and depression in prostate cancer (Cliff



and MacDonagh, 2000; Heim & Oei, 1993). Aggressive pain and symptom management and interventions that enhance physical function may promote optimal mental health. Information seeking has been identified as a frequently used coping strategy for men with prostate and other types of cancer (Gray et al., 2002; Gray, Fitch, Davis, & Phillips, 1997; Heyman & Rosner, 1996; Klemm et al., 1999). Nursing interventions focused on providing patients with information about their disease and treatment have been found to reduce levels of anxiety and depression, and increase patient involvement in their own care (Davison & Degner, 1997; Davison, Goldenberg, Gleave, & Degner, 2003). As such, patient education and supporting patient coping strategies in seeking information should also be an important focus of the APN role in promoting mental health.

### ***Functional Capacity***

Functional capacity related to physical and functional well-being is an important issue for men with prostate cancer. Improving levels of physical activity was a priority for men with prostate cancer, especially those with advanced hormone refractory disease. Patients with progressive and symptomatic prostate cancer use a variety of community services, supports, and equipment to maintain functional independence at home. The importance of sustaining a normal life style and maintaining usual activities of daily living and social roles has been described in several qualitative studies involving men with prostate cancer (Gray, Fitch, Phillips, Labrecque & Fergus, 2000; Gray, Fitch, Fergus, Myhalovsky, & Church, 2002; Heyman & Rosner 1996). Cliff and MacDonagh (2000) found that physical limitations associated with prostate cancer were also a source of worry for patients and their partners.

Common prostate cancer related problems related to pain, lack of energy, and urinary function may impede activities of daily living and functional capacity. Androgen suppression therapy is associated with significant increases in fatigue, loss of voluntary muscle function, and decreased muscle mass that may impair functional capacity (Lubeck, Grossfeld, & Carroll, 2001; Stone, Hardy, Huddart, A'Hern, & Richards, 2000). However, functional capacity involves more than physical ability or effective management of prostate cancer related health problems. We found that patients with mental health problems had poorer levels of physical and functional well-being. Stone et al. (2000) found that symptoms of anxiety and depression accounted for almost one third of the variance of fatigue severity prior to the onset of hormone therapy for a mixed stage population of patients with prostate cancer.

Therefore, to achieve optimal functional capacity, the APN role must consider the overall impact of prostate cancer on physical, psychological, and social well-being that extends beyond a focus on urinary and sexual function. Priorities for the APN role are to promote maximal levels of physical function, energy, comfort, and coping. Effective use of community services and supports may enhance patient levels of physical function in their own homes.

### ***The Continuum of Supportive Care***

The results of both studies indicate that it is beneficial for the advanced practice nurse to view the supportive care needs of patients with prostate cancer as occurring across a continuum. Problems related to sexual health, urinary function, energy, comfort, coping, and physical function are a common thread across the continuum of care.

However, the extent and importance of these and other health problems vary in relation to stage of disease and treatment status. In advanced prostate cancer, differences in patient health needs were observed for those with hormone sensitive, hormone refractory, and palliative stages of disease.

In Chapter 4, we found that the majority of patients with advanced prostate cancer were originally diagnosed with early stage disease and were 5 to 6 years post diagnosis. Thus conceptualizing prostate cancer care as occurring along a continuum highlights the chronicity of the illness experience for many patients. The management of health problems at early time points along the continuum of care may have important implications for improving the health and quality of life for patients who subsequently develop advanced disease. Incorporating the continuum of care in developing the APN role in advanced prostate cancer provides increased opportunity for health promotion and earlier intervention. For example, the development and evaluation of nursing interventions focused at the time of diagnosis may be found to enhance functional capacity in later stages of advanced disease and should be a focus of future study. Early detection and intervention for those at risk for mental health problems at the time of diagnosis may lead to long term improvements in HRQL and reduction of health care costs by preventing the development or recurrence of psychiatric disorders.

#### ***Implications for Further Development of the APN Role***

##### ***Supportive Care Health Needs and the Status of Nursing Knowledge***

There are two randomized controlled trials evaluating the effectiveness of APN roles in prostate cancer that include patients with predominately early stage disease

(Faithfull et al., 2001; Helgesen et al, 2000). In these studies the nurse-patient interaction was limited by the treatment time period (e.g. 12 weeks following the start of radiation therapy) or was very intermittent (on-demand patient telephone call or followup call once every 6 months). In both studies, patient outcomes in the APN treatment group were similar to those randomized to medical care alone, but health care costs in the APN group were reduced by up to 37%. Patients in the APN treatment group also felt that they benefited from continuity of care and were significantly more satisfied with their care (Faithfull et al., 2001). These findings suggest that patients with early stage or stable advanced hormone sensitive prostate cancer may benefit from APN roles that provide episodic care during specific time periods along the continuum of care. However patients with hormone refractory disease with multiple, progressive, and distressing health problems will likely require more frequent and continuous nursing interactions. Thus the nature of patient health needs and the required intensity of nursing interactions will influence the structure and function of the clinical aspect of the APN role.

A review of seven randomized controlled trials of APN transitional care involving a variety of high risk and/or medically complex patient populations also indicated that the intensity of nursing interactions or the “nurse dose” varied according to patient health needs (Brooten et al., 2002). Improved patient outcomes and lower health care costs in the APN groups of all seven studies were attributed to continuity of care and the ability of the APN to intervene across health care settings and systems in order to meet patient health needs. This suggests that promoting continuity of care for patients with advanced prostate cancer should be considered in developing the clinical domain of the APN role.

Also, effective management of complex health needs for patients with symptomatic hormone refractory prostate cancer may require APN interaction across settings such as the cancer clinic, home, hospital, or hospice.

Patients with early stage prostate cancer have been the subject of nursing research (Butler et al., 2001; Davison et al., 2003; Faithfull et al., 2001; Moore & Estey, 1999; Robinson et al., 1999; Rondorf-Klym & Colling, 2003). In addition, there is limited research and evidence documenting the effectiveness of nursing interventions for common health problems in prostate cancer such as urinary and sexual function (Moore & Glazener, 2003; Shell, 2002). There is an absence of research focused on nursing interventions in advanced prostate cancer particularly with respect to patient priority health needs related to physical function, energy, comfort, or coping. Further research to generate new nursing knowledge and skills will be necessary to significantly improve the health and quality of life in patients with advanced prostate cancer. This suggests the importance and potential benefit of the research component in developing new APN roles in advanced prostate cancer. Sufficient time allocation to participate in research, provision of resources, and access to research expertise are necessary to support the development of the research role. Clear goals and expectations for developing and evaluating nursing interventions in relation to supportive care health needs for individual APN roles should also be identified.

#### ***Application of the PEPPA Framework***

In relation to the PEPPA Framework, this thesis has only partially addressed Step 3 by identifying patient perceptions of their health needs to define the APN role. Some

consequences of these health needs in relation to quality of life and health care costs have been identified and the context of patient health needs in relation to the continuum of prostate cancer has also been considered. Further refinement of the APN role requires a more comprehensive assessment of patient health needs to determine the strengths and limitations of the existing model of care. This assessment includes broader stakeholder input to determine perceptions of patient health needs and to identify health care provider, organizational, and health care systems needs and expectations. Additional research should examine factors that may contribute to unmet patient health needs such as awareness of, timely access to, acceptability of, and satisfaction with existing health care services.

In moving to Step 4, this information can be used to establish stakeholder consensus regarding priorities and goal related outcomes for improving the model of care. In Step 5, goals for improving the model of care ultimately shape the specific structure and functions of each domain of the APN role related to clinical practice, education, research, organizational leadership, and professional development. Other factors that will influence the specific characteristics of APN role dimensions include the complement, skill mix, roles, and responsibilities of health care providers within the model of care.

For example, the nature of the APN's clinical role in mental health screening will be dependent upon the number and type of other mental health care providers within the model of care. In a setting that is rich in mental health resources, the APN may have a consultative role or be involved in referring high risk patients for screening. In a setting

with few mental health resources, the APN may be involved in the actual screening and have a strong case management role in providing follow-up care for patients diagnosed with a psychiatric disorder. Shortages of mental health care providers may require that the APN have a strong educational role in providing learning opportunities to increase the number of other health care team members with knowledge and skills related to prevention, identification, and management of mental health problems.

### *Thesis Strengths, Limitations, and Challenges*

Strengths of this thesis include the use of a series of planned, systematic steps to provide recommendations regarding the focus and development of APN roles in advanced prostate cancer. These steps involved clarifying and confirming the mandate and characteristics of APN roles, identifying factors that affect implementation of APN roles, utilizing a patient-focused, holistic, and health oriented approach to identifying APN role priorities, and generating empiric data to support role delineation.

The PEPPA Framework draws on previous research regarding the implementation of APN roles to outline a process and key strategies to promote successful APN role development. A major limitation of the framework is that it has not been empirically developed or evaluated. Thus the extent to which the framework is effective in improving the implementation of APN roles and achieving expected role outcomes remains to be determined. At a practical level, the framework is valuable in promoting an increased understanding of APN roles and factors that influence successful role implementation. Key features that can assist health care funders, administrators, and advanced practice nurses in developing new APN roles include: a well defined patient

population and identification of patient health needs, clearly defined goals and expectations for each domain of the APN, a systems view of APN roles and APN environments, and the need for strategies to promote social change. The framework demonstrates that introduction and full development of new APN roles is a complex and lengthy process requiring a high level of commitment and support at various levels within APN environments.

The study on HRQL in prostate cancer is one of few evaluations to include men with advanced hormone refractory disease and is the first cross sectional study to examine HRQL across the continuum of care from the time of diagnosis to palliation. Despite this comprehensive approach, identification of supportive care needs is likely incomplete as health problems specific to community based patients and patients with newly diagnosed advanced or recurrent disease were not evaluated. While this study examined patient perceptions of the importance and frequency of severely distressing health problems, how these health problems impacted their day-to-day life and overall quality of life was not explored. Except in relation to co-morbid conditions and mental health disorders, the extent to which specific prostate cancer related health problems were predictive of poor HRQL was not evaluated. Both studies described in this thesis involved non-random sampling of prostate cancer patients from a single setting. Therefore, the generalizability of results to other cancer settings may be limited by demographic, geographic, and treatment practice differences.

In the study evaluating mental health in advanced prostate cancer, the small sample size and use of a psychiatric instrument that included somatic symptoms may



have contributed to an over or underestimation of psychiatric disorders and therefore limit the accuracy of estimates regarding the prevalence of mental health disorders. As such, the study results alone are insufficient for making significant changes in clinical practice. However, the prevalence of mental health problems found in this study and their negative impact on HRQL and health care costs are consistent with numerous studies regarding mental health disorders in cancer, prostate cancer, and chronic illness (Berard, Boormeester, & Viljoen, 1998; Booth et al., 1998; Chochinov, Wilson, Enns, & Landers, 1994; Cliff & MacDonaugh, 2000; Hall, 1995; Harter et al., 2001; Hosaka et al., 1999; Luber et al., 2000; Shag, Ganz, Wing, Sim, & Lee, 1994). In this context, the study results and previous research support recommendations that a central focus of the APN role involve the prevention, detection, and management of mental health problems in advanced prostate cancer.

### *Implications for Research*

In relation to the implementation of new APN roles, an important focus for future research will be to test the validity and comprehensiveness of assumptions, principles, steps, and strategies outlined in the PEPPA Framework and secondly to evaluate the impact of this process on APN role development.

In relation to the APN role in advanced prostate cancer, priorities for future research include clarifying, refining, and validating the concepts of prostate cancer health, mental health, and functional capacity. The concept of functional capacity is particularly intriguing. Further exploration of this concept and identification of factors

affecting functional capacity may provide new insight for improving health and quality of life in advanced prostate cancer.

Increased stakeholder involvement from patients, families, health care providers, administrators, and funders to confirm priority patient health needs and establish goals for improving the delivery of cancer care services will be necessary to further define the APN role. Focus groups, in-depth interviews, surveys, and consensus methods are some examples of systematic approaches that can be used to obtain stakeholder input.

Further development of the APN role and nursing interventions will require a more comprehensive understanding of patient health needs. Research, using both qualitative and quantitative methods, must examine the daily impact of living with advanced prostate cancer, the nature of met and unmet patient health needs, and how patients and their partners cope with advanced prostate cancer at different time points along the continuum of care. Other important research considerations for developing targeted nursing interventions include: examination of interaction among health problems such as pain, depression, and decreased physical function; evaluation of the impact of specific health problems on HRQL; and identification of key predictors and potential mediators of HRQL.

There is also a need to increase our understanding about the prevalence, predictors, and consequences of mental health problems in both early and advanced stage prostate cancer. Longitudinal and large multi-centre studies would be beneficial in future assessments of mental health problems in prostate cancer. The evaluation of new nursing

interventions related to priority patient health needs should include mental health outcomes.

### *Conclusions*

Health problems related to sexual health, urinary function, energy, comfort, and coping have significant impact on the quality of life for men with advanced prostate cancer. Issues related to sexual and urinary function have been a primary focus for research and nursing interventions. The findings of this thesis identify the need for a greater emphasis on health promotion and a more comprehensive approach to providing supportive care in prostate cancer.

Incorporating the continuum of prostate cancer care in developing APN roles creates new opportunities to improve HRQL in advanced disease through prevention and early intervention. Three areas of focus related to prostate cancer health, mental health, and functional capacity have been proposed as a beginning effort to define and conceptualize a patient-focused APN role for improving health and quality of life in advanced prostate cancer. These foci establish a foundation for directing future research to develop and evaluate APN roles and nursing interventions and for improving models of health care delivery for patients with advanced prostate cancer.

A major challenge in implementing new APN roles and applying the PEPPA Framework is the extent to which the models of health care delivery must move from a singular focus on disease and illness to one that also values patient-centred and health oriented care. To a large extent this transition in health care will be dependent on continued research and efforts to increase understanding about the benefits of APN roles

and nursing interventions in achieving patient and health care systems outcomes. In advanced prostate cancer in particular, there is need for research to develop nursing interventions relevant to prostate cancer health, mental health, and functional capacity. Clinical practice as the primary domain of APN roles is often the main focal point of APN role development. However, given the developmental nature of nursing practice in prostate cancer, it will also be important to strengthen the non-clinical aspects of the APN role. Supporting the development of all role domains related to clinical practice, education, research, organizational leadership, and professional development will enable advanced practice nurses to move forward the nursing care provided to men with advanced prostate cancer.

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**Appendix A**

***Health Related Quality of Life in Prostate Cancer : Study Funding***



JANSSEN-ORTHO Inc.

September 13, 1999

McMaster University c/o SystemLink Research Unit  
For Health & Social Services  
1200 Main St. W.  
Hamilton, ON

Cc: Denise Bryant-Lukosius, BScN, MScN, CON (C)

Re: Prostate Cancer Study

To Whom It May Concern:

This letter is a follow-up as means of explanation for the cheque which was sent to you by Janssen Ortho Inc. in the amount of \$9763.15.

The purpose of the cheque was for the financial support of the study entitled "The First Steps in Planning a Programme of Care for Patients with Prostate Cancer: A Survey of Patient Health Problems and Needs." The amount of the cheque corresponds with the budget which had been submitted to Janssen Ortho Inc. The study is being conducted to identify and understand the needs of patients and families affected by prostate cancer, and is headed by Denise Bryant-Lukosius.

There are no restrictions/conditions on the use of these funds, other than to acknowledge that use of these funds are to be directed to the above named study. If you have any questions regarding this information, please don't hesitate to contact me at the number listed below.

Thanks,

A handwritten signature in black ink, appearing to read 'MFBaird'.

Michele Frost-Baird  
Janssen Ortho Inc.  
1-800-387-8781, ext.2698

19 Green Bell Drive, Toronto, Ontario, Canada M3C 1L9  
Tel: (416) 449-9444, Fax: (416) 449-2658

**QUALITY**  
EXCELLENCE

**Appendix B**

***Health Related Quality of Life In Prostate Cancer: Ethics Approval***



*Hamilton Regional Cancer Centre*  
*Centre Régional de Cancérologie de Hamilton*  
 699 Concession Street  
 Hamilton, Ontario L8V 5C2  
 Tel: (905) 387-9495

July 7, 2000

Ms. Denise Bryant-Lukosius  
 Nursing Fellow, Malignant Urology  
 HRCC

Dear Ms. Bryant-Lukosius:

Thank you for forwarding the study "The First Steps in Planning a Program of Care for Patients with Prostate Cancer: A Survey of Patient Needs".

This study involves two self-report questionnaires which include a revised prostate quality of life tool and fatigue assessment tool as well as documenting hemoglobin levels which would be done as part of routine care. The data is to be collected on the day of the regularly scheduled clinic visit. The study has been funded by Janssen-Ortho for the cost of developing the database and collecting and analyzing the data. There are no other resources that are required from any other clinic departments and it has the approval of the GU site.

As this is an information gathering study, there is no need to submit this to the HHSC REB. I have discussed this with the REB Chair, Dr. P. McCulloch. You have the approval of the Protocol Review Committee to proceed with this study.

Sincerely,

H. W. Hirte, MD, FRCPC  
 Chair, HRCC Protocol Review Committee  
 HWH/ll

**Appendix C**

***Health Related Quality of Life in Prostate Cancer: Consent Form***

**Appendix D**

***Health Related Quality of Life in Prostate Cancer: Demographic Data Sheet***



<b>Prostate Cancer: Needs and Health Problems Study</b>	<b>Form .</b>
Patient's Initials: _____	
Study ID #: _____	Date: ___/___/___ dd mm yyyy

### DEMOGRAPHIC DATA SHEET

Name: \_\_\_\_\_  
First
Last

Address: \_\_\_\_\_  
Street Address

\_\_\_\_\_

City	Province	Postal Code
------	----------	-------------

Birthdate: \_\_\_/\_\_\_/\_\_\_      OCTRF No.: \_\_\_\_-\_\_\_\_  
dd    mm    yyyy

Date of diagnosis of prostate cancer: \_\_\_/\_\_\_/\_\_\_  
dd    mm    yyyy

Time since diagnosis of prostate cancer ( check one):

- 1     < 3 months
- 2     3 months but < 1 year
- 3     1 year but < 2 years
- 4     2 years but < 5 years
- 5     5 years but < 6 years
- 6     6 years but < 10 years
- 7     10 or more years

Stage: \_\_\_\_\_      \_\_\_/\_\_\_/\_\_\_  
TMN      AUS

- 1     0
- 2     I
- 3     II
- 4     III
- 5     IV

Stage as recorded in patient file:

Hemoglobin level: \_\_\_\_\_ g/L      Date: \_\_\_/\_\_\_/\_\_\_ (+/- 2 weeks of appt.)  
dd mm yyyy

PSA level: \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_ ug/mL      Date: \_\_\_/\_\_\_/\_\_\_  
dd mm yyyy

Patient's point along disease continuum (check  only one):

Early Stage= all Stage 0 – III disease (e.g., Stage A, B, C or T <sub>1</sub> – T <sub>3</sub> )
Advanced Stage = all Stage D or T <sub>4</sub>

- 1 Early Stage - new diagnosis (prior to treatment)
- 2 Early Stage - on treatment or up to 2 months post treatment
- 3 Early Stage - >2 months post treatment (i.e., after 2<sup>nd</sup> visit post RT) and on follow-up
- 4 Advanced Stage: 1) New diagnosis (prior to treatment)  
2) On hormone therapy  
3) Recurrence
- 5 Advanced Stage: 1) On follow-up  
2) On Chemotherapy  
3) Palliative care

**Current treatment for prostate cancer:**

Check  only ONE answer below that best describes the patient's CURRENT TREATMENT or purpose of his appointment today.

- 1 Assessment, tests results, and/or treatment information for a NEW diagnosis of prostate cancer.
- 2 Observation or followup of treatment
- 3 Radical prostatectomy
- 4 Curative radiation therapy only to prostate gland (30-35 Tx @ 6,000 rads)
- 5 Iridium implant
- 6 Hormone therapy only
- 7 Curative radiation therapy and hormone therapy combined
- 8 Orchidectomy (removal of testicles)
- 9 Chemotherapy
- 10 Radiation for relief of symptoms (<10 Tx @ < 6,000 rads)
- 11 Pain and symptom management
- 12 Other (please describe) \_\_\_\_\_

**Previous treatment for prostate cancer:**

Check  ALL of the PREVIOUS TREATMENTS the patient has had for his prostate cancer. Do not include the current treatment checked above.

- 1 Assessment, tests results, and/or treatment information for a NEW diagnosis of prostate cancer.
- 2 Observation or followup of treatment
- 3 Radical prostatectomy
- 4 Curative radiation therapy only to prostate gland (30-35 Tx @ 6,000 rads)
- 5 Iridium implant
- 6 Hormone therapy only
- 7 Curative radiation therapy and hormone therapy combined
- 8 Orchiectomy (removal of testicles)
- 9 Chemotherapy
- 10 Radiation for relief of symptoms (<10 Tx @ < 6,000 rads)
- 11 Pain and symptom management
- 12 Other (please describe) \_\_\_\_\_
- 13 None

**Comorbidity:**

In addition to prostate cancer, what other health problems does the patient have that requires regular medical followup and/or treatment? Check  ALL of the problems below that apply to the patient:

- 1 Heart (heart attack, congestive heart failure, angina)
- 2 Circulation (peripheral vascular disease, stroke, blood clot)
- 3 High blood pressure
- 4 Lung (asthma, chronic lung disease)
- 5 Diabetes
- 6 Arthritis
- 7 Another cancer (please specify) \_\_\_\_\_
- 8 Hearing
- 9 Vision
- 10 Mental illness (depression, anxiety)
- 11 Other (please describe) \_\_\_\_\_
- 12 None
- 13 Not stated in dictation

**Reason for ineligibility (check  only one):**

- 1 Patient too ill
- 2 Not able to enroll patient in study
- 3 Language barrier
- 4 Patient mentally incapable
- 5 Other, please specify: \_\_\_\_\_
- 6 Patient refused

**Marital Status (check  only one):**

- 1 Married/Cohabiting
- 2 Single
- 3 Divorced
- 4 Widowed
- 5 Data Unavailable

**Postal Code:** \_\_\_\_\_**Living Arrangement:**

- 1 Living with Spouse/Significant Other/Family
- 2 Living Alone
- 3 Data Unavailable

**Appendix E**

***Total FACT-P Instrument***

## TOTAL FACT - P

Below is a list of statements that other people with your illness have said are important. By circling one number per line, please indicate how true each statement has been for you during the past 7 days.

PHYSICAL WELL-BEING		Not at all	A little bit	Some what	Quite a bit	Very much
1	I have a lack of energy .....	0	1	2	3	4
2	I have nausea.....	0	1	2	3	4
3	Because of my physical condition, I have trouble meeting the needs of my family .....	0	1	2	3	4
4	I have pain.....	0	1	2	3	4
5	I am bothered by side effects of treatment .....	0	1	2	3	4
6	I feel sick.....	0	1	2	3	4
7	I am forced to spend time in bed.....	0	1	2	3	4
SOCIAL/FAMILY WELL-BEING		Not at all	A little bit	Some what	Quite a bit	Very much
<i>During the past 7 days:</i>						
8	I feel close to my friends .....	0	1	234		
9	I get emotional support from my family.....	0	1	2	3	4
10	I get support from my friends .....	0	1	2	3	4
11	My family has accepted my illness.....	0	1	2	3	4
12	I am satisfied with family communication about my illness.....	0	1	2	3	4
13	I feel close to my partner (or the person who is my main support).....	0	1	2	3	4
14	<i>Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box <input type="checkbox"/> and go to the next section.</i>	0	1	2	3	4
	I am satisfied with my sex life.....					
EMOTIONAL WELL-BEING		Not at all	A little bit	Some what	Quite a bit	Very much
<i>During the past 7 days:</i>						
15	I feel sad.....	0	1	2	3	4
16	I am satisfied with how I'm coping with my illness .....	0	1	2	3	4
17	I am losing hope in the fight against my illness.....	0	1	2	3	4
18	I feel nervous .....	0	1	2	3	4
19	I worry about dying.....	0	1	2	3	4
20	I worry that my condition will get worse.....	0	1	2	3	4

## TOTAL FACT-P

FUNCTIONAL WELL-BEING		Not at all	A little bit	Some what	Quite a bit	Very much
<i>During the past 7 days:</i>						
21	I am able to work (include work in home).....	0	1	2	3	4
22	My work (include work in home) is fulfilling .....	0	1	2	3	4
23	I am able to enjoy life .....	0	1	2	3	4
24	I have accepted my illness .....	0	1	2	3	4
25	I am sleeping well.....	0	1	2	3	4
26	I am enjoying the things I usually do for fun.....	0	1	2	3	4
27	I am content with the quality of my life right now .....	0	1	2	3	4
ADDITIONAL CONCERNS		Not at all	A little bit	Some what	Quite a bit	Very much
<i>During the past 7 days:</i>						
28	I am losing weight .....	0	1	2	3	4
29	I have a good appetite .....	0	1	2	3	4
30	I have aches and pains that bother me .....	0	1	2	3	4
31	I have certain areas of my body where I experience significant pain .....	0	1	2	3	4
32	My pain keeps me from doing things I want to do .....	0	1	2	3	4
33	I am satisfied with my present comfort level.....	0	1	2	3	4
34	I am able to feel like a man.....	0	1	2	3	4
35	I have trouble moving my bowels.....	0	1	2	3	4
36	I have difficulty urinating .....	0	1	2	3	4
37	I urinate more frequently than usual .....	0	1	2	3	4
38	My problems with urinating limit my activities.....	0	1	2	3	4
39	I am able to have and maintain an erection.....	0	1	2	3	4

**Appendix F**

***Health Related Quality of Life in Prostate Cancer: Priority Problem Question***



<b>Prostate Cancer: Needs and Health Problems Study</b>		Form
Patient's Initials: _____		
Study ID #: _____	Date: ___ / ___ / ___ dd mm yyyy	

### PRIORITY PROBLEMS

If only three of ALL the problems related to your health that you have identified above could be made better, which health problems would be a priority or the most important for you?

Check  only 3 of your priority problems below?

- |    |  |    |                            |
|----|--|----|----------------------------|
| 1  | Pain                                   | 20 | Physical activity          |
| 2  | Fatigue                                | 21 | Appetite                   |
| 3  | Constipation                           | 22 | Urinary problems           |
| 4  | Diarrhea                               | 23 | Control of urination       |
| 5  | Rectal discomfort                      | 24 | Overall well being         |
| 6  | Control of bowel movements             | 25 | Sleeping                   |
| 7  | Mood                                   | 26 | Sexual desire              |
| 8  | Breathing                              | 27 | Sexual function            |
| 9  | Nausea                                 | 28 | Emotional coping           |
| 10 | Vomiting                               | 29 | Emotional support          |
| 11 | Enjoying time with family and friends  | 30 | Work responsibilities      |
| 12 | Thinking or concentration              | 31 | Household responsibilities |
| 13 | Information about disease or treatment | 32 | Family responsibilities    |
| 14 | Treatment side effects                 | 33 | Finances                   |
| 15 | Family communication                   | 34 | Weight                     |
| 16 | Family coping                          | 35 | Headaches                  |
| 17 | Hot flashes                            | 36 | Dizziness                  |
| 18 | Breast swelling                        | 37 | Practical needs            |
| 19 | Breast tenderness                      | 38 | Other (describe):<br>_____ |

Thank you for taking the time to complete this questionnaire.

**Appendix G**

***Mental Health Disorders in Advanced Prostate Cancer: Study Funding***

**Appendix H**

***Mental Health Disorders in Advanced Prostate Cancer: Ethics Approval***

**Appendix I**

***Mental Health Disorders in Advanced Prostate Cancer: Patient Information Letter***

**Appendix J**

***Mental Health Disorders in Advanced Prostate Cancer:***

***Demographic Data Questionnaire***

# Prostate Cancer Questionnaire

Identification Number: \_\_\_\_\_

Date of Interview:                          
                                 yy    m m    d d

Interviewer Initials: \_\_\_\_\_

**Section DD - DEMOGRAPHIC DATA:**

DD1. Are you:       1       Male  
                          2       Female

DD2. What is your date of birth:   \_\_\_\_\_   \_\_\_\_\_   \_\_\_\_\_  
  y y    m m    d d

DD3. How many children do you have: \_\_\_\_\_

DD4. What is your present marital status:

- 1       Married (once)
- 2       Living together/common-law
- 3       Separated
- 4       Divorced/Annulled
- 5       Widowed
- 6       Remarried (2 or more marriages)
- 7       Never married

*[Note: This question should be answered by everybody EXCEPT never married.]*

DD4a. Since when have you had this (relationship/non-relationship):

\_\_\_\_\_   \_\_\_\_\_  
month   year

**Now I would like to ask you questions about your schooling and work.**

DD5. How many years of education have you completed (circle one)

Grade School       1 2 3 4 5 6 7 8

High School        9 10 11 12 13

Training School    14 15 16 17 18 19 20

DD6. What type of job did you work at the longest:

Specify: \_\_\_\_\_

- |                                |  |                                  |
|--------------------------------|--|----------------------------------|
| 1. Self-employed professionals | 8. Foremen and forewomen                     | 15. Unskilled manual             |
| 2. Employed professionals      | 9. Skilled clerical, sales and service       | 16. Farm labourer                |
| 3. High-level management       | 10. Skilled crafts and trades                | 00. Never Employed/<br>Homemaker |
| 4. Semi-professionals          | 11. Farmers                                  |                                  |
| 5. Technicians                 | 12. Semi-skilled clerical, sales and service |                                  |
| 6. Middle-management           | 13. Semi-skilled manual                      |                                  |
| 7. Supervisors                 | 14. Unskilled clerical, sales and service    |                                  |

DD7. What is your current employment status (in order of importance)

- |                           |              |                                    |               |
|---------------------------|--------------|------------------------------------|---------------|
| 1. Full time work for pay | 3. Homemaker | 5. Retired from work for pay       | 7. Unemployed |
| 2. Part time work for pay | 4. Student   | 6. Disabled/unable to work for pay | 8. Volunteer  |

\_\_\_\_\_ (first priority)

\_\_\_\_\_ (second priority)

\_\_\_\_\_ (third priority)

DD8. Could you tell us where you got your income in the past 12 months:

- |                            |                |                            |
|----------------------------|----------------|----------------------------|
| 1=GWA                      | 4=wages/salary | 7=alimony or child support |
| 2=FBA (Mother's Allowance) | 5=family       | 8=other income             |
| 3=Unemployment Insurance   | 6=marriage     |                            |

(a) source \_\_\_\_\_ from \_\_\_\_\_ month \_\_\_\_\_ year

to \_\_\_\_\_

(b) source \_\_\_\_\_ from \_\_\_\_\_ month \_\_\_\_\_ year

to \_\_\_\_\_

(c) source \_\_\_\_\_ from \_\_\_\_\_ month \_\_\_\_\_ year

to \_\_\_\_\_

(d) source \_\_\_\_\_ from \_\_\_\_\_ month \_\_\_\_\_ year



In addition to prostate cancer, what other health problems do you have that require regular medical follow up and/or treatment?

**CHECK ALL OF THE PROBLEMS THAT APPLY TO YOU:**

- Cardiac (heart attack, congestive heart failure, angina)
- Circulation (peripheral vascular disease, stroke, blood clot)
- High Blood Pressure
- Lung (asthma, bronchitis, emphysema)
- Diabetes
- Arthritis
- Another Cancer (Please Specify: \_\_\_\_\_)
- Hearing
- Vision
- Mental Illness (depression, anxiety)
- Other (Please Specify: \_\_\_\_\_)

**Appendix K**

***Mental Health Disorders in Advanced Prostate Cancer: Chart Audit Form***

## MENTAL HEALTH STUDY CHART AUDIT FORM

<b>Prostate Cancer: Mental Health Study Chart Audit Form</b>	
Patient's Initials: _____	
Study ID #: _____	Date: ___ / ___ / ___ dd mm yyyy

### DEMOGRAPHIC DATA SHEET

Name: \_\_\_\_\_  
First
Last

Address: \_\_\_\_\_  
Street Address

\_\_\_\_\_

City	Province	Postal Code
------	----------	-------------

Birth Date: \_\_\_ / \_\_\_ / \_\_\_      OCTRF No.: \_\_\_\_\_ - \_\_\_\_\_  
dd    mm    yyyy

Date of diagnosis of prostate cancer: \_\_\_ / \_\_\_ / \_\_\_  
dd    mm    yyyy

Time since diagnosis of prostate cancer ( check one):

- 1      < 3 months
- 2      3 months but < 1 year
- 3      1 year but < 2 years
- 4      2 years but < 5 years
- 5      5 years but < 6 years
- 6      6 years but < 10 years
- 7      10 or more years

Stage at Diagnosis:                    \_\_\_ / \_\_\_ / \_\_\_      \_\_\_ / \_\_\_ / \_\_\_  
TMN
AUS

- 1      0
- 2      I
- 3      II
- 4      III
- 5      IV

Stage as recorded in patient file:

Hemoglobin level: \_\_\_\_\_ g/L      Date: \_\_\_ / \_\_\_ / \_\_\_ (+/- 2 weeks of appt.)  
dd mm yyyy

PSA level: \_\_\_\_\_, \_\_\_\_\_ ug/mL      Date: \_\_\_ / \_\_\_ / \_\_\_

## MENTAL HEALTH STUDY CHART AUDIT FORM

**Patient's Current Stage of Advanced Disease (check  only one):**

**D1:** Pelvic lymph node metastasis or ureteral obstruction causing hydronephrosis or both \_\_\_\_\_

**D2:** Bone, soft tissue, organ, or distant lymph node metastasis \_\_\_\_\_

**Patient's Current Disease Status (check  only one):**

- 1) **Hormone Sensitive:** stable PSA < 1.0 on hormone suppression therapy \_\_\_\_\_  
(may have new diagnosis of advanced prostate cancer or recurrent disease following previous treatment for early stage disease)
- 2) **Hormone Refractory:** \_\_\_\_\_  
Meets these criteria:
  - a) 3 progressive rises in PSA following a response to androgen suppression therapy
 

Date 1: _____	PSA = _____ ug/L
Date 2: _____	PSA = _____ ug/L
Date 3: _____	PSA = _____ ug/L
  - b) Asymptomatic, stable symptoms, or symptoms responsive to treatment
  - c) Has not required mitoxantrone chemotherapy
- 3) **Hormone Refractory Receiving Palliative Care:** \_\_\_\_\_  
Meets all these criteria:
  - a) Hormone Refractory as above with continued rise in PSA
 

Date 1: _____	PSA = _____ ug/L
Date 2: _____	PSA = _____ ug/L
Date 3: _____	PSA = _____ ug/L
  - b) New symptoms and/or progressive symptoms such as pain, fatigue, weight loss, or nausea
  - c) Completed course of mitoxantrone chemo, or was not eligible to receive mitoxantrone because of cardiac status
  - d) Requiring aggressive pain and symptom management such as: escalating analgesia, steroids, palliative radiation, strontium

## MENTAL HEALTH STUDY CHART AUDIT FORM

### Current Symptoms:

Pain	_____	Urinary Incontinence	_____
Fatigue	_____	Bowel Incontinence	_____
Nausea	_____	Urinary Symptoms (dysuria, frequency hematuria)	_____
Vomiting	_____		
Appetite	_____	GI Mucosal	_____
Constipation	_____	Hot Flashes	_____
Diarrhea	_____	Impotence	_____
Mobility	_____	Respiratory	_____
Infection	_____	Coping	_____
Other	_____		

### Current treatment for prostate cancer:

Check  only ONE answer below that best describes the patient's CURRENT TREATMENT or purpose of his appointment today.

- 1      Observation
- 2      Hormone Therapy
- 3      Chemotherapy
- 4      Radiation for relief of symptoms (<10 fractions @ < 6,000 cGy)
- 5      Pain and symptom management
- 6      Other

## MENTAL HEALTH STUDY CHART AUDIT FORM

### Previous treatment for prostate cancer:

Check  ALL of the PREVIOUS TREATMENTS the patient has had for his prostate cancer. Do not include the current treatment checked above.

- 1 Assessment, tests results, and/or treatment information for a NEW diagnosis of prostate cancer.
- 2 Observation or followup of treatment
- 3 Radical prostatectomy
- 4 Curative radiation therapy only to prostate gland (30-35 Tx @  $\geq 6,000$  cGy)
- 5 Iridium implant
- 6 Hormone therapy only
- 7 Curative radiation therapy and hormone therapy combined
- 8 Orchiectomy (removal of testicles)
- 9 Chemotherapy
- 10 Radiation for relief of symptoms (<10 Tx @ < 6,000 rads)
- 11 Pain and symptom management
- 12 Other (please describe) \_\_\_\_\_
- 13 None

### Reason for ineligibility (check only one):

- 1 Patient too ill
- 2 Not able to enroll patient in study
- 3 Language barrier
- 4 Patient mentally incapable
- 5 Other, please specify: \_\_\_\_\_
- 6 Patient refused

### Marital Status (check only one):

- 1 Married/Cohabiting
- 2 Single
- 3 Divorced
- 4 Widowed
- 5 Data Unavailable

Postal Code: \_\_\_\_\_

### Living Arrangement:

- 1 Living with Spouse/Significant Other/Family
- 2 Living Alone
- 3 Data Unavailable

**Appendix L**

***The University of Michigan Composite Diagnostic Interview (UM-CIDI)***

## The University of Michigan Composite Diagnostic Interview (UM-CIDI)

### SECTION A:

- A1. During the past 12 months, was there ever a time when you felt sad, blue, or depressed for two weeks or more in a row?
1. Yes
  2. No Go to A9
- If volunteered:
3. On medication/anti-depressants Go to A9
- A1a. For the next few questions, please think of the two-week period during the past 12 months when these feelings were worst. During that time did the feelings of being sad, blue, or depressed usually last all day long, most of the day, about half the day, or less than half the day?
1. All day long
  2. Most
  3. About half Go to A9
  4. Less than half Go to A9
- A1b. During those two weeks, did you feel this way every day, almost every day, or less often?
1. Every day
  2. Almost every day
  3. Less often Go to A9
- A1c. During those two weeks did you lose interest in most things?
1. Yes
  2. No
- A1d. Did you feel tired out or low on energy all the time?  
*(Note to Interviewer: If R asks: "Are we still talking about the same two weeks?" Answer "Yes.")*
1. Yes
  2. No
- A2. Did you gain or lose weight without trying, or did you stay about the same?  
*(Note to Interviewer: If R asks: "Are we still talking about the same two weeks?" Answer "Yes.")*
1. Gain
  2. Lose
- If volunteered:
3. Gained and lost
  4. Stayed about the same Go to A3
- If volunteered:
5. Was on a diet Go to A3



### The University of Michigan Composite Diagnostic Interview (UM-CIDI)

- A2a. About how much did (you gain/you lose/your weight change)?  
*(Note to Interviewer: If R gives a fraction, probe: "Please round to the nearest pound.")*  
 Pounds: \_\_\_\_\_
- A3. Did you have more trouble falling asleep than you usually do?  
*(Note to Interviewer: If R asks: "Are we still talking about the same two weeks?" Answer "Yes.")*
1. Yes
  2. No Go to A4
- A3a. Did that happen every night, nearly every night, or less often during those two weeks?
1. Every night
  2. Nearly every night
  3. Less often
- A4. Did you have a lot more trouble concentrating than usual?  
*(Note to Interviewer: If R asks: "Are we still talking about the same two weeks?" Answer "Yes.")*
1. Yes
  2. No
- A5. People sometimes feel down on themselves, no good, or worthless. Did you feel this way?  
*(Note to Interviewer: If R asks: "Are we still talking about the same two weeks?" Answer "Yes.")*
1. Yes
  2. No
- A6. Did you think a lot about death -- either your own, someone else's, or death in general?  
*(Note to Interviewer: If R asks: "Are we still talking about the same two weeks?" Answer "Yes.")*
1. Yes
  2. No
- A7. INTERVIEWER CHECKPOINT -- (Count "Yes" responses in A1c-A6)
1. Zero "Yes" responses Go to B1
  2. One or more "Yes" responses Go to A8
- A8. Reviewing what you just told me, you had two weeks in a row during the past months when you were sad, blue, or depressed and also had some other things like losing interest, feeling tired, gaining weight, losing weight, trouble falling asleep, trouble concentrating, feeling down on yourself, thoughts about death. About how many weeks altogether did you feel this way during the past 12 months?  
 Number of weeks: \_\_\_\_\_  
*If response is less than 52 wks. Go to A8a*  
*If response is entire year (or more than 52 wks.) Go to B1*

**The University of Michigan Composite Diagnostic Interview (UM-CIDI)**

- A8a. Think about this most recent time when you had two weeks in a row when you felt this way. In what month and year was this?  
 Month: \_\_\_\_\_ Year: \_\_\_\_\_ Go to B1
- A9. During the past 12 months, was there ever a time lasting two weeks or more when you lost interest in most things like hobbies, work, or activities that usually give you pleasure?  
 1. Yes  
 2. No Go to B1  
 If volunteered:  
 3. On medication/anti-depressants Go to B1
- A9a. For the next few questions, please think of the two-week period during the past 12 months when you had the most complete loss of interest in things. During the two-week period, did the loss of interest usually last all day long, most of the day, about half the day, or less than half the day?  
 1. All day long  
 2. Most  
 3. About half Go to B1  
 4. Less than half Go to B1
- A9b. Did you feel this way:  
 1. Every day  
 2. Almost every day  
 3. Less often Go to B1
- A9c. During those two weeks, did you feel tired out or low on energy all the time?  
 1. Yes  
 2. No
- A10. Did you gain weight, lose weight, or stay about the same?  
*(Note to Interviewer: If R asks: "Are we still talking about the same two weeks?" Answer "Yes.")*  
 1. Gain  
 2. Lose  
 If volunteered:  
 3. Both gained and lost weight  
 4. Stay about the same Go to A11  
 If volunteered:  
 5. Was on a diet Go to A11
- A10a. About how much did (you gain/you lose/your weight change)?  
*(Note to Interviewer: If R gives a fraction, probe: "Please round to the nearest pound.")*  
 pounds: \_\_\_\_\_

### The University of Michigan Composite Diagnostic Interview (UM-CIDI)

- A11. Did you have more trouble falling asleep than you usually do?  
*(Note to Interviewer: If R asks: "Are we still talking about the same two weeks?" Answer "Yes.")*
1. Yes
  2. No Go to A12
- A11a. Did that happen every night, nearly every night, or less often during those two weeks?
1. Every night
  2. Nearly every night
  3. Less often
- A12. Did you have a lot more trouble concentrating than usual?  
*(Note to Interviewer: If R asks: "Are we still talking about the same two weeks?" Answer "Yes.")*
1. Yes
  2. No
- A13. People sometimes feel down on themselves, no good or worthless. Did you feel this way?  
*(Note to Interviewer: If R asks: "Are we still talking about the same two weeks?" Answer "Yes.")*
1. Yes
  2. No
- A14. Did you think a lot about death -- either your own, someone else's, or death in general?  
*(Note to Interviewer: If R asks: "Are we still talking about the same two weeks?" Answer "Yes.")*
1. Yes
  2. No
- A15. INTERVIEWER CHECKPOINT -- (Count "Yes" responses in A9c-A14)
1. Zero "Yes" responses Go to B1
  2. One or more "Yes" responses Go to A16
- A16. Reviewing what you just told me, you had two weeks in a row during the past 12 months when you lost interest in most things and also had some other things like feeling tired, gaining weight, losing weight, trouble falling asleep, trouble concentrating, feeling down on yourself, thoughts about death. About how many weeks did you feel this way during the past 12 months?
- Weeks: \_\_\_\_\_  
*If response is less than 52 wks. Go to A16a*  
*If response is entire year (or more than 52 wks.) Go to B1*
- A16a. Think about this most recent time when you had two weeks in a row when you felt this way.  
 In what month and year was this? Month: \_\_\_\_\_ Year: \_\_\_\_\_

**The University of Michigan Composite Diagnostic Interview (UM-CIDI)**

**SECTION B:**

- B1. I already asked you about two weeks in a row of feeling sad or depressed. The next question is related, but slightly different. (READ SLOWLY) During the past 12 months, did you feel sad or depressed most of the time, even if there were some days when you felt OK?
1. Yes
  2. No Go to C1
- If volunteered:
3. On medication/anti-depressants Go to C1
- B2. On the days you felt sad or depressed, did these feelings usually last:
1. All day long
  2. Most
  3. About half
  4. Less than half the day Go to C1
- B3. During the past two years, has this been a pretty constant thing that happens just about every day or something that comes and goes from day to day?
1. Pretty constant Go to B4
  2. Comes and goes Go to B3a
- If volunteered:
3. Only one time Go to B3c
- B3a. During the past two years, how many days, weeks, or months, did a typical period of being sad or depressed usually last?
- Months: \_\_\_\_\_
- B3b. And how much time usually went on between the end of one period and the beginning of the next?
- months: \_\_\_\_\_ Go to B4:
- B3c. How many months did that period last during the past two years?
- Months: \_\_\_\_\_
- B4. Think about the last time you felt sad or depressed. In what month and year was that?
- Month: \_\_\_\_\_ Year: \_\_\_\_\_
- B5. During the period(s) when you (are/were) sad or depressed, (do/did) you have any of the following experiences:
- B5a. (Do/did) you frequently feel hopeless?
1. Yes
  2. No

**The University of Michigan Composite Diagnostic Interview (UM-CIDI)**

B5b. (Do/did) you lose your appetite?

1. Yes
2. No

B5c. (Do/did) you lack energy or feel tired out all the time even when you (have/had) not been working very hard?

1. Yes
2. No

B5d. (Are/were) you unable to make up your mind about things you ordinarily have no trouble deciding about?

1. Yes
2. No

**SECTION C:**

C1. During the past 12 months, did you ever have a period lasting one month or longer when most of the time you felt worried and anxious?

1. Yes
2. No

Go to D1

C2. Has that period ended or is it still going on?

1. Ended
2. Still going on

Go to C2b

C2a. How many months did it go on before it ended?

Months: \_\_\_\_\_

Rule: If less than 6 months  
If 6 months or more

Go to C3  
Go to C3

If volunteered:

"All my life" or  
"as long as I can remember"

Go to C3

C2b. How many months or years has it been going on?

1. less than 6 months
2. greater than 6 months

If volunteered:

3. "All my life" or  
"as long as I can remember"

**The University of Michigan Composite Diagnostic Interview (UM-CIDI)**

**C3. INTERVIEWER CHECKPOINT**

1. C2 is 1 and C2a is six months or more  
or R volunteered: "all my life" or  
"as long as I can remember" Go to C4a
  2. C2 is 2 and C2b is six months or more  
or R volunteered: "all my life" or  
"as long as I can remember" Go to C4d
  3. C2a is less than 6 months or  
C2b is less than 6 months Go to D1
- C4a. During that period, did you worry about things that were not likely to happen?
1. Yes Go to C4c
  2. No
- C4b. Did you worry a great deal about things that were not really serious?
1. Yes
  2. No Go to D1
- C4c. During that period, did you have different worries on your mind at the same time?
1. Yes Go to C5
  2. No Go to D1
- C4d. Do you worry about things that are not likely to happen?
1. Yes Go to C4f
  2. No
- C4e. Do you worry a great deal about things that are not really serious?
1. Yes
  2. No
- C4f. Do you have different worries on your mind at the same time?
1. Yes
  2. No Go to D1
- C5. When you (are/were) worried or anxious, (are/were) you also...
- C5a. ...restless?
1. Yes
  2. No
- C5b. (Are/were) you keyed up or on edge?
1. Yes
  2. No

**The University of Michigan Composite Diagnostic Interview (UM-CIDI)**

- C5c. (Are/were) you particularly irritable?  
 1. Yes  
 2. No
- C5d. (Are/were) you aware of your heart pounding or racing?  
 1. Yes  
 2. No
- C5e. (Are/were) you easily tired?  
 1. Yes  
 2. No
- C5f. (Do/did) you also have trouble falling asleep or staying asleep?  
 1. Yes  
 2. No
- C5g. (Do/did) you feel faint or unreal?  
 1. Yes  
 2. No

**SECTION D:**

The next questions are about unreasonably strong fears of situations or objects. By "unreasonably strong" we mean always being very upset or badly frightened when most people would not be afraid.

Definition: "Unreasonably strong fear" means always being very upset or badly frightened when most people would not be afraid.

*(Note to Interviewer: Repeat definition as often as necessary.)*

- D1. Do you have an unreasonably strong fear of...
- D1a. ...heights, storms, thunder, lightning, or flying?  
 1. Yes  
 2. No
- D1b. ...being in a closed space or being alone or being in water like a pool or a lake?  
 1. Yes  
 2. No
- D1c. ...snakes, birds, rats, bugs or other animals?  
 1. Yes  
 2. No
- D1d. ...seeing blood, getting a shot or injection, or seeing a dentist?  
 1. Yes  
 2. No

### The University of Michigan Composite Diagnostic Interview (UM-CIDI)

- D2. INTERVIEWER CHECKPOINT -- See D1a-D1d
1. One or more "Yes" responses Go to D3
  2. All 'No's Go to E1
- D3. Thinking only of the situations that we just reviewed which cause you unreasonably strong fears, do you get very upset or badly frightened:
1. Every time you are in these situations
  2. Most of the time
  3. Only some of the time Go to E1
- If volunteered:
4. Only one or two times ever Go to E1
- D4. How long have you had these fears:
1. Less than 1 year
  2. Between 1 and 5 years Go to D5
  3. More than 5 years Go to D5
- D4a. About how many months? Months: \_\_\_\_\_
- D5. The next question is about seeing a doctor or other professional about these fears. By "doctor", we mean a medical doctor or a student in training to be a medical doctor. By "other professional", we mean a nurse, psychologist, social worker, counsellor, minister, priest, or rabbi. With these definitions in mind, did you ever tell a doctor or other professional about your fears?  
(*Note to Interviewer: Repeat definitions as often as necessary*)
1. Yes
  2. No
- D6. During the past 12 months were you ever very upset with yourself for having any of these fears?
1. Yes
  2. No
- D7. During the past 12 months, how much did these fears interfere with your life or activities:
1. A lot
  2. Some
  3. A little
  4. Not at all

#### SECTION E:

Here's another list of situations that can cause unreasonably strong fears. Remember that "unreasonably strong" means always being very upset or badly frightened when most people would not be afraid. Definition: "Unreasonably strong fear" means always being very upset or badly frightened when most people would not be afraid. (*Note to Interviewer: Repeat definition as often as necessary.*)



### The University of Michigan Composite Diagnostic Interview (UM-CIDI)

- E1. Do you have an unreasonably strong fear of...
- E1a. ...speaking in public, talking in front of a small group of people, or sounding foolish when you talk to people?
1. Yes
  2. No
- E1b. ...(how about of) eating or drinking in public, writing when someone watches, or having to use the toilet when away from home?
1. Yes
  2. No
- E2. INTERVIEWER CHECKPOINT -- See E1a-E1b
1. One or more "Yes" responses Go to E3
  2. All No's Go to F1
- E3. Thinking only of the situations that we just reviewed which cause you unreasonably strong fears, do you get very upset or badly frightened every time you are in these situations, most of the time, or only some of the time?
1. Every time
  2. Most of the time
  3. Some of the time Go to F1
- If volunteered:
4. Only one or two times ever Go to F1
- E4. Do you try to avoid these situations?
1. Yes
  2. No
- E5. How long have you had (this/these) fear(s):
1. Less than 1 year Go to E5a
  2. Between 1 and 5 years Go to E6
  3. More than 5 years Go to E6
- E5a. About how many months? Months: \_\_\_\_\_
- E6. During the past 12 months, were you ever very upset with yourself for having (this/any of these) fear(s)?
1. Yes
  2. No

## The University of Michigan Composite Diagnostic Interview (UM-CIDI)

- E7. During the past 12 months, how much did (this/these) fear(s) interfere with your life or activities:
- 3. A lot
  - 3. Some
  - 3. A little
  - 3. Not at all

### SECTION F:

Here's a final list of situations that cause some people to have unreasonably strong fears.

Definition: "Unreasonably strong fear" means always being very upset or badly frightened when most people would not be afraid. *(Note to Interviewer: Repeat definition as often as necessary.)*

- F1. Do you have an unreasonably strong fear of...
- F1a. ...being in a public place, or a crowd or a line?
- 3. Yes
  - 3. No
- F1b. ...(how about of) leaving your home or being alone away from home?
- 3. Yes
  - 3. No
- F1c. ...(how about of) crossing a bridge or riding in cars, trains, or buses?
- 3. Yes
  - 3. No
- F2. INTERVIEWER CHECKPOINT – See F1a-F1c
- 1. One or more "Yes" responses Go to F3
  - 2. All No's Go to G1
- F3. Thinking only of the situations that we just reviewed which cause you unreasonably strong fears, do you get very upset or badly frightened:
- 3. Every time you are in (this/these) situations
  - 3. Most of the time
  - 3. Only some of the time Go to G1
- If volunteered:
- 4. Only one or two times ever Go to G1
- F4. How long have you had these fears:
- 1. Less than 1 year Go to F4a
  - 2. Between 1 and 5 years Go to F5
  - 3. More than 5 years Go to F5
- F4a. About how many months? Months:

### The University of Michigan Composite Diagnostic Interview (UM-CIDI)

- F5. When you are in these situations, are you afraid that you might faint, lose control, or embarrass yourself in other ways?
2. Yes  
2. No
- F6. When you are in these situations, do you worry that you might be trapped without any way to escape?
2. Yes  
2. No
- F7. When you are in these situations, do you worry that help might not be available if you needed it?
2. Yes  
2. No

#### SECTION G:

- G1. During the past 12 months, did you ever have a spell or an attack when all of a sudden you felt frightened, anxious, or very uneasy when most people would not be afraid or anxious?
1. Yes Go to G2  
2. No
- G1a. During the past 12 months, did you ever have a spell or attack when for no reason your heart suddenly began to race, you felt faint, or you couldn't catch your breath?  
*(Note to Interviewer: If R volunteers only when having heart attack, or due to physical causes, mark "No")*
2. Yes  
2. No Go to H1
- G2. About how many attacks did you have in the past 12 months?  
 Number: \_\_\_\_\_
- G3. In what month and year did you have (the most recent one/this attack)?  
 Month: \_\_\_\_\_ Year: \_\_\_\_\_
- G4. Did (this attack/these attacks ever) happen in a situation when you were not in danger or not the center of attention?
2. Yes  
2. No Go to H1
- G5. A moment ago, we discussed situations that cause unreasonably strong fears. When you have attacks of the sort you just described, do they usually occur in situations that cause you unreasonably strong fear?  
*(Note to Interviewer: If necessary, clarify: "Unreasonably strong fear" means always being very upset or badly frightened when most people would not have been afraid.)*
2. Yes  
2. No Go to G6

**The University of Michigan Composite Diagnostic Interview (UM-CIDI)**

- G5a. Did you ever have an attack in the past 12 months when you were not in a situation that usually causes you to have unreasonably strong fears?
1. Yes
  2. No Go to H1
- G6. When you have attacks, does...
- G6a. Does your heart pound?
1. Yes
  2. No
- G6b. Do you have tightness, pain, or discomfort in your chest or stomach?
1. Yes
  2. No
- G6c. Do you sweat?
1. Yes
  2. No
- G6d. Do you tremble or shake?
1. Yes
  2. No
- G6e. Do you have hot flashes or chills?
1. Yes
  2. No
- G6f. Do you, or things around you, seem unreal?
1. Yes
  2. No

**SECTION H:**

- H1. The next questions are about how frequently you drink alcoholic beverages. By a "drink" we mean either a bottle of beer, a wine cooler, a glass of wine, a shot of liquor, or a mixed drink. With these definitions in mind, what is the largest number of drinks you had in any single day during the past 12 months?:
- (Note to Interviewer: If R volunteers "I never drink", accept the answer and check "NONE" in the response options.)*
1. None Go to I1
  2. 1-3 Go to I1
  3. 4-10
  4. 11-20
  5. More than 20 in a single day

*(Note to Interviewer: The next questions are awkwardly worded. Read slowly)*

**The University of Michigan Composite Diagnostic Interview (UM-CIDI)**

- H2. In the past 12 months, have you often been under the effects of alcohol or suffering its after-effects while at work or school or while taking care of children?
1. Yes
  2. No Go to H3
- If volunteered:
3. I am a casual/social drinker Go to I1
- H2a. How often?:
1. Once or twice
  2. Between 3 and 5 times
  3. Between 6 and 10 times
  4. Between 11 and 20 times
  5. More than 20 times
- H3. During the past 12 months, were you ever under the effects of alcohol or feeling its after-effects in a situation which increased your chances of getting hurt - like when driving a car or boat, using knives or guns or machinery, crossing against traffic, climbing or swimming?
1. Yes
  2. No
- If volunteered:
3. I am a casual/social drinker Go to I1
- H4. During the past 12 months, did you have any emotional or psychological problems from using alcohol -- such as feeling uninterested in things, feeling depressed, suspicious of people, paranoid, or having strange ideas?
1. Yes
  2. No
- If volunteered:
3. I am a casual/social drinker Go to I1
- H5. During the past 12 months, did you have such a strong desire or urge to use alcohol that you could not resist it or could not think of anything else?
1. Yes
  2. No
- If volunteered:
3. I am a casual/social drinker Go to I1
- H6. During the past 12 months, did you have a period of a month or more when you spent a great deal of time using alcohol or getting over its effects?
1. Yes
  2. No
- If volunteered:
3. I am a casual/social drinker Go to I1

**The University of Michigan Composite Diagnostic Interview (UM-CIDI)**

- H7. During the past 12 months, did you often use much larger amounts of alcohol than you intended to when you began, or did you use it for a longer period of time than you intended to?
1. Yes
  2. No Go to H8
- If volunteered:
3. I am a casual/social drinker Go to I1
- H7a. How often?:
1. Once or twice
  2. Between 3 and 5 times
  3. Between 6 and 10 times
  4. Between 11 and 20 times
  5. More than 20 times
- H8. During the past 12 months, did you ever find that you had to use more alcohol than usual to get the same effect or that the same amount had less effect on you than before?
1. Yes
  2. No
- If volunteered:
3. I am a casual/social drinker

**SECTION I:**

- I1. The next questions are about your use of drugs on your own. By "on your own" we mean either without a doctor's prescription, in larger amounts than prescribed, or for a longer period than prescribed. With this definition in mind, did you ever use any of the following drugs on your own during the past 12 months?
- How about/during the past 12 months, did you use...
- I1a. ...sedatives, including either barbituates (bar-BIT-chew-its) or sleeping pills on your own? (eg. Seconal, Halcion, Methaqualone)
1. Yes
  2. No
- I1b. ...tranquilizers or "nerve pills" on your own? (eg. Librium, Valium, Ativan, Meprobamate, Xanax)
1. Yes
  2. No
- I1c. ...amphetamines (am-FET-ah-means) or other stimulants on your own? (eg. Methamphetamine, Preludin, Dexedrine, Ritalin, "Speed")
1. Yes
  2. No

### The University of Michigan Composite Diagnostic Interview (UM-CIDI)

- IId. ...analgesics (an-uhl-JEEZ-icks) or other prescription painkillers on your own? (NOTE: this does not include normal use of aspirin, tylenol without codeine, etc. but does include use of tylenol with codeine and other Rx painkillers like Demerol, Darvon, Percodan, Codeine, Morphine, and Methadone)
1. Yes
  2. No
- IIf. ...inhalants that you sniff or breathe to get high or to feel good?  
(eg. Amylnitrate, Freon, Nitrous Oxide ("Whippets"), Gasoline, Spray paint)
1. Yes
  2. No
- IIf. ...marijuana (mare-ih-WAH-nah) or hashish (HASH-eesh)?
1. Yes
  2. No
- IIf. ...cocaine (KO-kane) or crack or free base?
1. Yes
  2. No
- IIf. ...LSD or other hallucinogens (ha-LOOSE-en-oh-jens)? (eg. PCP, angel dust, peyote, ecstasy (MDMA), mescaline)
1. Yes
  2. No
- IIf. ...heroin (HAIR-oh-in)
1. Yes
  2. No
- I2. INTERVIEWER CHECKPOINT -- See I1a-I1i
1. At least one "Yes" response continue
  2. Zero "Yes" responses You're done
- (Note to Interviewer: The next questions are awkwardly worded. Read slowly)*
- I3. In the past 12 months, have you often been under the effects of (NAME OF DRUG/any of these substances) or suffering (its/their) after-effects while at work or school or while taking care of children?
1. Yes
  2. No Go to I4
- I3a. How often?:
1. Once or twice
  2. Between 3 and 5 times
  3. Between 6 and 10 times
  4. Between 11 and 20 times
  5. More than 20 times

**The University of Michigan Composite Diagnostic Interview (UM-CIDI)**

- I4. During the past 12 months, were you ever under the effects of (NAME OF DRUG/any of these substances) or feeling (its/their) after-effects in a situation which increased your chances of getting hurt -- like when driving a car or boat, using knives or guns or machinery, crossing against traffic, climbing or swimming?
1. Yes
  2. No
- I5. During the past 12 months, did you have any emotional or psychological problems from using (NAME OF DRUG/any of these substances) -- such as feeling uninterested in things, feeling depressed, suspicious of people, paranoid, or having strange ideas?
1. Yes
  2. No
- I6. During the past 12 months, did you have such a strong desire or urge to use (NAME OF DRUG/any of these substances) that you could not resist it or could not think of anything else?
1. Yes
  2. No
- I7. During the past 12 months, did you have a period of a month or more when you spent a great deal of time using (NAME OF DRUG/any of these substances) or getting over any of (its/their) effects?
1. Yes
  2. No
- I8. During the past 12 months, did you often use much larger amounts of (NAME OF DRUG/any of these substances) than you intended to when you began, or did you use (it/them) for a longer period of time than you intended to?
1. Yes
  2. No
- Go to I9
- I8a. How often?:
1. Once or twice
  2. Between 3 and 5 times
  3. Between 6 and 10 times
  4. Between 11 and 20 time
  5. More than 20 times
- I9. During the past 12 months, did you ever find that you had to use more (NAME OF DRUG/any of these substances) than usual to get the same effect or that the same amount had less effect on you than before?
1. Yes
  2. No



**Appendix M**

*The University of Michigan Diagnostic Composite Interview (UM-CIDI):*

*Stem Questions*

## Appendix M

### *Stem Questions for CIDI-SF Syndromes Based on DSM-III-R Criteria*

#### *Major Depression*

During the past 12 months, was there ever a time when you felt sad, blue, or depressed for two weeks or more in a row?

#### *Generalized Anxiety Disorder*

During the past 12 months, did you ever have a period lasting one month or longer when most of the time you felt worried and anxious?

#### *Panic Disorder*

During the past 12 months, did you ever have a spell or an attack when all of a sudden you felt frightened, anxious, or very easy when most people would not be afraid or anxious?

#### *Simple Phobia*

An unreasonably strong fear means being very upset or badly frightened when most people would not be afraid. Do you have an unreasonably strong fear of: heights, storms, thunder, lightening or flying; being in a closed space; snakes, birds, rats, bugs, or other animals; seeing blood, getting an injection or seeing a dentist?

#### *Social Phobia*

Do you have an unreasonably strong fear of: speaking in public, talking in front of a small group of people, or sounding foolish when you talk to people; eating or drinking in public, writing when someone watches, or having to use the toilet when away from home?

## Appendix M

### *Stem Questions for CIDI-SF Syndromes Based on DSM-III-R Criteria*

#### *Agoraphobia*

Do you have an unreasonably strong fear of: being in a public place, or a crowd or a line; leaving your home or being alone away from home; crossing a bridge or riding in cars, trains, or buses?

#### *Alcohol Dependence*

The next questions are about how frequently you drink alcoholic beverages. By a drink we mean a bottle of beer, a wine cooler, a glass of wine, a shot of liquor, or a mixed drink. With these definitions in mind, what is the largest number of drinks you had in any single day during the past 12 months? (1 to 3; 4 to 10; 11 to 20; > 20).

#### *Drug Dependence*

The next questions are about your use of drugs on your own. By on your own we mean either without a doctor's prescription, in larger amounts than prescribed, or for a longer period than described. With this definition in mind, did you use any of the following drugs on your own during the past 12 months?

Note. From R. Kessler and D. Mroczek (1993). *Scoring for UM-CIDI Short Forms*.

University of Michigan: Institute for Social Research/Survey Research Centre.

**Appendix N**

**UM-CIDI Cut-Point Scores and Probability for CIDI Caseness for  
Mental Health Disorders**

**Appendix N**

*UM-CIDI Cut- Point Scores and Probability for CIDI Caseness for  
Mental Health Disorders*

Mental Health Disorder	Cut-Point Score	Probability for CIDI Caseness
Major Depression (sadness or loss of interest)	4	.8125
Generalized Anxiety Disorder	3	.5000
Simple Phobia	1	.8078
Social Phobia	2	.9220
Agoraphobia	1	.9958
Panic Attack	3	.8701
Alcohol Dependence	3	.8411
Drug Dependence	3	.7561

*Note.* From “Scoring for UM-CIDI Short Forms,” by R. Kessler and D. Mroczek, 1993.

University of Michigan: Institute for Social Research/Survey Research Centre.

**Appendix O**

***The Health Service Utilization Questionnaire***

**The Health Service Utilization Questionnaire**

HS1. In the last 12 months, how many visits have you had with a:

- |                                       |   |
|---------------------------------------|---|
| 1. Family Physician or walk-in clinic | <input type="checkbox"/> <input type="checkbox"/> |
| 2. Physician specialist               | <input type="checkbox"/> <input type="checkbox"/> |
| 3. Emergency room                     | <input type="checkbox"/> <input type="checkbox"/> |
| 4. Physiotherapist                    | <input type="checkbox"/> <input type="checkbox"/> |
| 5. Psychiatrist                       | <input type="checkbox"/> <input type="checkbox"/> |
| 6. Psychologist                       | <input type="checkbox"/> <input type="checkbox"/> |
| 7. Occupational Therapist             | <input type="checkbox"/> <input type="checkbox"/> |
| 8. Social Worker                      | <input type="checkbox"/> <input type="checkbox"/> |
| 9. Family Counselor                   | <input type="checkbox"/> <input type="checkbox"/> |
| 10. Probationary Services             | <input type="checkbox"/> <input type="checkbox"/> |
| 11. Nutritionist                      | <input type="checkbox"/> <input type="checkbox"/> |
| 12. Naturopath/homeopath              | <input type="checkbox"/> <input type="checkbox"/> |
| 13. Public Health Nurse               | <input type="checkbox"/> <input type="checkbox"/> |
| 14. VON                               | <input type="checkbox"/> <input type="checkbox"/> |

### The Health Service Utilization Questionnaire

- |       |  |     |
|-------|--|-----|
| 15.   | St. Elizabeth's Visiting Nurses  | □□  |
| 16.   | Chiropractor   | □□  |
| 17.   | Homemaker  | □□  |
| 18.   | Meals on Wheels ( <i>past 12 months</i> )                                      | □□  |
| 19.   | Employment Retraining Services   | □□  |
| 20.   | Recreational Services ( <i>ie. Scouts</i> )                                    | □□  |
| 21.   | Other health care providers/services<br><i>Please specify providers:</i> _____ | □□  |
| 22.   | Other unpaid providers/helpers ( <i>i.e. priest, neighbour</i> )               | □□  |
| 23.   | 911  | □□  |
| 24.   | Ambulance  | □□  |
| HS2.  | Have you had a hospital admission in the past 6 months?                        | Y N |
| HS2a. | How many hospital admissions in the last 6 months                              | □□  |
| HS2b. | Total number of days in the hospital (6 months)                                | □□□ |
| HS3.  | Have you had any out-patient tests done in the past 12 months?                 | Y N |



### The Health Service Utilization Questionnaire

*If yes, please tell me how many times for each of the following tests:*

- |     |   |   |
|-----|---|---|
| 1.  | Blood   | <input type="checkbox"/> <input type="checkbox"/> |
| 2.  | Specimens (ie. urine, throat swab)                  | <input type="checkbox"/> <input type="checkbox"/> |
| 3.  | Scopes (ie. endoscopy, bronchoscopy, sigmoidoscopy) | <input type="checkbox"/> <input type="checkbox"/> |
| 4.  | X-rays  | <input type="checkbox"/> <input type="checkbox"/> |
| 5.  | Scans (ie. ultrasound, CT scan)                     | <input type="checkbox"/> <input type="checkbox"/> |
| 6.  | Breathing tests (ie. spirometry)                    | <input type="checkbox"/> <input type="checkbox"/> |
| 7.  | ECG (heart monitoring)                              | <input type="checkbox"/> <input type="checkbox"/> |
| 8.  | EEG (brain waves)                                   | <input type="checkbox"/> <input type="checkbox"/> |
| 9.  | EMG (muscles)                                       | <input type="checkbox"/> <input type="checkbox"/> |
| 10. | Other tests   | <input type="checkbox"/> <input type="checkbox"/> |
- Please specify test: \_\_\_\_\_

HS4. Have you taken any medications over the past 2 days? Y N

*If yes, please list any medications that you have taken in the last 2 days (including prescription medications, over-the-counter drugs, homeopathic, etc.):*

Drug name & dose \_\_\_\_\_

# of pill/doses \_\_\_\_\_

Cost coded later

Drug name & dose \_\_\_\_\_

# of pill/doses \_\_\_\_\_

Cost coded later

Drug name & dose \_\_\_\_\_

# of pill/doses \_\_\_\_\_

Cost coded later

### The Health Service Utilization Questionnaire

Drug name & dose \_\_\_\_\_

# of pill/doses

\_\_\_\_\_

Cost coded later

Drug name & dose \_\_\_\_\_

# of pill/doses

\_\_\_\_\_

Cost coded later

Drug name & dose \_\_\_\_\_

# of pill/doses

\_\_\_\_\_

Cost coded later

HS5. Have you used any supplies, aids or devices in the past 12 months Y N  
*(ie. wheelchairs, syringes, walker, crutches, dressings, pillows, tissues, etc.)*

Item description

\_\_\_\_\_

Cost to nearest \$

Item description

\_\_\_\_\_

Cost to nearest \$

Item description

\_\_\_\_\_

Cost to nearest \$

Item

description \_\_\_\_\_

Cost to nearest \$