2010

Development And Validation Of A Palliative Care Needs Assessment Instrument-English/Arabic Versions (Pcna-Eav), For Use With Patients With Advanced Cancer

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Recommended Citation

Volker, Susan Edith, "Development And Validation Of A Palliative Care Needs Assessment Instrument-English/Arabic Versions (Pcna-Eav), For Use With Patients With Advanced Cancer" (2010). *All ETDs from UAB*. 3231.
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DEVELOPMENT AND VALIDATION OF A PALLIATIVE CARE NEEDS ASSESSMENT INSTRUMENT-ENGLISH/ARABIC VERSIONS (PCNA - EAV), FOR USE WITH PATIENTS WITH ADVANCED CANCER

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A DISSERTATION PROPOSAL
Submitted to the graduate faculty of The University of Alabama at Birmingham,
in partial fulfillment of the requirements of the degree of
Doctor of Philosophy

BIRMINGHAM, ALABAMA

2010

DEVELOPMENT AND VALIDATION OF A PALLIATIVE CARE NEEDS ASSESSMENT INSTRUMENT-ENGLISH/ARABIC VERSIONS (PCNA-EAV), FOR USE WITH PATIENTS WITH ADVANCED CANCER

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ABSTRACT

The aim of this study is to develop and translate a psychometrically valid and reliable, population-based, needs assessment instrument, the PCNA-EAV, to measure the health care and support care needs of patients with advanced cancer.

The cross-sectional study design combined qualitative and quantitative methods, to test instrument reliability and validity, and to examine the association between sample characteristics and health care and support needs. The 116-item, PCNA-EAV, comprised 10 domains of need: physical/functional; social; psychological/emotional; information; communication; helpful resources; financial; religious/spiritual; priority of need; and preference for care

The target population was all cancer patients in the department of oncology at King Abdulaziz Medical City-Riyadh (KAMC-R), Saudi Arabia. The survey was conducted in three stages: pretest, pilot and retest, using a purposive sampling technique to recruit pretest and pilot subjects. Retest subjects were all participants in the pilot phase, who consented to be re-interviewed.

Results for estimates of reliability and validity were mixed. Eight of the 16 PCNA-EAV scale and subscale estimates of reliability (Cronbach's alpha) were acceptable to excellent, ranging from $\alpha = 0.70$ to $\alpha = 0.91$. Test-retest reliability showed 11 of the 16 scales reliable over time (p =>.05), ranging from $r(9) = .44$, $p = .17$, to $r(9) = .12$, $p = .72$. Face and content validity were demonstrated, through expert panel review. *P*-values for the test for convergent validity are not significant (p.05); however, the trend indicates a positive association between variables, overall.

This study extends existing work on cross-cultural instrument translation, adaptation, and validation. Further research is required, using multiple sites, and a larger sample size, to psychometrically validate the instrument, which has the potential to be a useful measure for use in Arabic-speaking, Islamic cultures.

Key words: needs assessment, palliative care, instrument, validation, reliability, cancer

DEDICATION

To my sister, Mary and to my brothers Chris and Rees, and their families, for their love and support as I took the road less travelled.

ACKNOWLEDGEMENTS

As I have travelled this journey there have been so many friends and colleagues cheering me on my way and providing encouragement when the road seemed impassable.

Firstly I would like to acknowledge and thank my committee for their guidance and support through this dissertation process. Dr. Donna Slovensky, my committee chair, and Dr. Howard Houser, co-chair, believed in my ability from the start, and encouraged and guided me along the way. Their long-distance mentorship, and that of my other committee members, Dr. Gerald Glandon, Dr. Russell Foushee and Dr. Frank Ferris, provided me with the necessary insight, and knowledge to achieve this goal. I thank each one of them. My thanks also to Dr. Robert Hernandez, Director, PhD program, for his kind assistance in helping me negotiate any obstacles blocking the path.

I owe a great deal also, to my classmates in the doctoral program – Greg Ellis, Tony Goudie, Joe Gerald and Charlie Saunders. It was a privilege to know them, and to work with them. Their kindness and support, and sense of fun enriched my student days. Their wisdom and friendship was an unexpected and much appreciated blessing. My thanks also to dear colleagues, Shamly Austen, Tony Panjamapirom, and Haiyan Qu, for their friendship and support.

There are many other colleagues, both here and abroad, who have encouraged my interest in palliative care. Derek Doyle, OBE, of Edinburgh, Scotland, was my guiding light as I ventured forth into the world of the unknown at King Faisal Hospital and Research Center (KFSH&RC) in Saudi Arabia in the late eighties. He, together with His Excellency Dr. Fahad Al Abdul Jabbar, then CEO of KFSH&RC, made this journey possible. Without their vision and guidance, the first palliative care/home care program in the Kingdom would not have been established. I will be forever grateful for their continuing interest and countenance over the years.

I also wish to thank Dr. Abdulrahman Jazieh, Chairman of the Department of Oncology, at KAMC-Riyadh, and all colleagues in the department, for support. Without them this study would not have come to fruition. I also thank Dr. Abdulwahab Andejani, Section Head in the Department of Oncology, at KAMC in Jeddah, KSA, for his friendship, sense of humor, and continuing support of my work.

I wish to recognize the love and encouragement of my late husband, Dr. Jim Volker, and his brother, the late Dr. Joe Volker, first president of the University of Alabama at Birmingham, for their vision. Together these two dear souls encouraged me to pursue my dream and "get my tickets". Today this support continues, through the friendship and kindness of Dr. Charles "Scotty" McCallum, who, six years ago, gave me the courage to apply to the Doctoral Program at the School of Health Professions. He has followed my progress with much interest, and now has the pleasure of seeing his advice was not in vain.

My thanks to Ms. Martha Hilley, coordinator of the doctoral program at SHP. Her diligence made my life so much less complicated. I sincerely appreciate her friendship and support. My sincere appreciation and thanks, also, to Ms. Lee Test, personal assistant to Dr. Slovensky. Her cheerful help and expertize with my documents was just amazing.

Lastly, but by no means least, I thank my sister, Mary Wade and my two brothers, Chris and Rees James, and all my dear family. They have stayed by my side, offering encouragement when needed, and stoically listening to my tales of woe, as well as rejoicing in my victories. Their unconditional love has been my strength.

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LIST OF ABBREVIATIONS

ABHPM	American Board of Hospice and Palliative Medicine
ABIM	American Board of Internal Medicine
CAPC	Center for the Advancement of Palliative Care
CEO	Chief Executive Officer
CHPCA	Canadian Hospice and Palliative Care Association
EBM	Evidence Based Medicine
EPEC	Education for Physicians in End-of-life Care
KAMC-R	King Abdulaziz Medical City – Riyadh
KSA	Kingdom of Saudi Arabia
KFSH & RC	King Faisal Specialist Hospital and Research Center
NCR	National Cancer Registry (Kingdom of Saudi Arabia)
NHPCO	National Hospice and Palliative Care Organization
NHS	National Health Service (United Kingdom)
PHC	Primary Health Care
RCT	Randomized Controlled Trial
SANGHA	Saudi Arabian National Guard Health Affairs
SDT	Self-Determination Theory
SF-36	The Short Form Health Survey
TSE	Theory of Self-Efficacy
US	United States
UK	United Kingdom
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

Chapter one of this dissertation provides an introduction to the process of developing and translating a new and unique instrument to measure the health care and support needs of adults with advanced cancer. The first section outlines the framework of the study, including a statement of the problem being examined, the purpose and the significance of the study and the research questions posed. The second section covers the background of the study, including a brief overview of the global problem of cancer and the history of palliative care. In the third section, the topics of cross-cultural research and psychometric validation of new measures are discussed. The fourth section gives an overview of the Kingdom of Saudi Arabia, the country where the study was conducted, including its demographics, its health care system, and widely held health care attitudes and beliefs of the population, to provide the contextual framework for the study. The final section of the chapter describes the Saudi Arabian National Guard Health Affairs (SANGHA) and its unique population and health care system, including the King Abdulaziz Medical City in Riyadh, the setting for the study.

Background

Statement of the Problem

The health care and support needs and preferences of patients with advanced cancer are, in general, poorly understood from the perspective of service planning. The lack of understanding of how patients perceive and prioritize their need for care and support has resulted in a collage of experiences; confusion for many, futile therapies for some, and sub-optimal care over time for the majority of patients with advanced cancer, serving only to compound the burden of illness. The service provision model for this patient population has historically been shaped on the whole by the normative needs expressed by medical experts, rather than those expressed by patients themselves. This study aims to examine needs from the cancer patients' perspective.

Within the field of cancer care research, many measures focus on patients' quality of life and well-being (Richardson, Wingo, Zack, Zahran, & King, 2008).One of the most well-known to researchers and clinicians is the McGill Quality of Life Questionnaire, developed in 1995, in Toronto, Canada (Cohen, Mount, Strobel, & Bui, 1995). Other measures are designed as clinical screening tools, rather than population-based measures, to elicit data for service planning, as shown in Table 1. Access to population-based empirical data, which uses appropriate methodology and data collection tools, is essential for effective program development and strategic planning, especially in developing countries.

A review of the literature revealed no culturally sensitive, psychometrically validated instrument measuring palliative care needs in a Moslem, Arabic-speaking society. A major reason for this deficit is that, until recently, there were few professionals with the research interest, expertise and background to initiate research projects in palliative care. The concept of palliative care is relatively new in the Kingdom of Saudi Arabia and, as yet, is not an integral component of the Saudi health care system. As a consequence of this deficit, the efficacy of existing services for those living with cancer in the Kingdom has not, to date, been systematically addressed through empirical research.

Purpose of the Study

The specific purpose of this study is to psychometrically validate a new and original instrument, entitled "Palliative Care Needs Assessment – English-Arabic Version (PCNA-EAV) for use with Patients with Advanced Cancer" to measure the health care and support needs of adult patients with advanced cancer in an Islamic, Arabic-speaking society. The instrument will be evaluated for its psychometric validity and reliability and assessed for cultural equivalence, upon translation from English to Arabic.

Significance of Study

The significance of this study lies in its contextual innovation and originality. No psychometrically validated instrument has been identified in the literature that incorporates the cultural and demographic variables necessary for a comprehensive needs assessment of cancer patients in an Islamic, Arabic-speaking society. This measure will be the first of its kind to be designed, developed, translated and validated specifically for this purpose.

Complete, accurate, and systematic needs assessment is known to be essential for planning effective health care and support services in any setting and is at the heart of any research-based health care service (Doyle, verbal communication, 10 March, 1992; Richardson, Medina, Brown, & Sitzia, 2007; Robinson & Elkan, 1996). Over recent decades it has been shown that patients with unmet needs have a decreased quality of life, decreased satisfaction with care, impose a greater caregiver burden, and show an increased utilization of resources and services (Mor, Allen, Siegel, & Houts, 1992; Mowen, Licata, & McPhail,1993). As noted by Swan and Martin (1994), "To develop an effective measure of any construct, the operational measure should accurately reflect the theoretical construct; it should be consistent, or congruent, with the theoretical construct it is designed to measure."

The psychometrically validated needs assessment instrument produced in this study will meet the standards recommended by Swan and Martin and contribute significantly towards informed policy decisions and strategic planning. The ultimate goal is to facilitate provision of appropriate, culturally acceptable and cost-effective palliative care services, based on scientific evidence, for those patients with incurable cancer in Saudi Arabia, and to provide a foundation for future studies.

Research Questions

The research questions for this study are as follows:

RQI: Does the PCNA-EAV demonstrate reliability as an instrument to measure the health care and support needs of patients with advanced cancer?

RQ2: Does the PCNA-EAV demonstrate validity as an instrument to measure the health care and support needs of patients with advanced cancer?

RQ.3: What is the association between health care and support needs and patient characteristics?

Study Limitations

The following are limitations of this study, due to the study design, limited resources and other factors:

- The PCNA-EAV measure is validated only among adult patients with advanced cancer at KAMC-Riyadh, and may not be generalizable to cancer patients with similar characteristics at other health care institutions.
- The results are obtained from a sample of adult oncology patients with advanced disease and may not be generalizable to all oncology patients.

- Study participation was voluntary, and data collected may not accurately represent those who did not participate.
- The sample size for the pilot study is small (N = 50).

Assumptions of Study

The following assumptions were made in this study:

- Interval data are assumed for Likert scale response options for the non-clinical, non-demographic variables.
- Ordinal categories are assigned to the demographic and clinical predictor variables and do not distort the underlying metric scaling.

Overview

The journey taken by those living with advanced cancer is fraught with challenges and obstacles as they attempt to go about their daily lives. The diagnosis of cancer reveals a unique, complex Pandora's box of health care and support needs, some quiet and unobtrusive, others aggressive and all-demanding, crowding out any sense of well-being or normalcy. When it comes to service planning to meet the needs of this patient population, one size does not fit all. Recognition of the cultural, societal and environmental factors influencing frequency, types and levels of needs reported by patients is paramount to the success and sustainability of services provided. It is essential to measure needs in the context of these differences and from the perspective of patients themselves, to reliably assist providers and policy-makers in their decision-making.

The Global Problem

The care and treatment of terminally ill cancer patients poses a significant global public health problem (World Health Organization, 1993). Populations are growing older as health care interventions become increasingly more effective in the management of acute and chronic diseases. However, with these aging populations the incidence of cancer cases is increasing, and the number of patients presenting in relatively late-stage disease at the time of diagnosis is also rising. It is estimated that at least 60% of the 58 million people dying annually across the world would benefit from some form of palliative care (Stjernsward & Clark, 2004).

In response to global suffering, various models of palliative care programs have been established in many culturally diverse countries. Well-planned, evidence-based services, based on the findings of a needs assessment of the population of interest, have the potential to make a significant difference in the well-being and quality of life of many thousands of patients and families.

Historical Overview of Palliative Care

Early models of care

Care of the sick and dying has evolved over the centuries, from the Middle Ages, when simple shelters were established to help pilgrims and travelers as they journeyed to religious shrines throughout Europe, to the 21st century, with purpose-built facilities providing specialist care of the dying.

In the mid-1800s hospices were established by religious orders in Lyon, France, and in Dublin, Ireland, to care for the dying. The first hospice in England, St Luke's Hospice, was opened in London in 1900, followed by St. Joseph's Hospice in London's East End, established in 1905 by the Irish Sisters of Charity (Hospice Education Institute, 2008).

20th Century Visionaries

One of the first physicians to recognize the value of specialized care for those with advanced, incurable cancer was Dame Cicely Saunders. Dame Cicely established the now world-renowned St. Christopher’s Hospice, just south of London, in 1967, laying the foundation for the present-day hospice and palliative care movements.

In the United States (U.S.) awareness of the suffering that many terminally ill patients experience was brought to the forefront by Elizabeth Kubler-Ross, a Swiss-born psychiatrist. Her groundbreaking 1969 book *On Death and Dying*, in which she proposes there are five stages of grief, gave momentum to the development of organized end-of-life care in the U.S. The first hospice established in the U.S., was the Connecticut Hospice, in New Haven, Connecticut, in 1974. This was followed in 1977, by the founding of the San Diego Hospice, in San Diego, California. These two hospices became the prototype for the more than 3,000 hospices currently established throughout the nation.

The hospice/palliative care movement also began in Canada in the early 1970s with the seed sown by Kubler-Ross during a discussion of her book at a church-sponsored seminar in Montreal. Dr. Balfour Mount, a Canadian urological surgeon, was attending the seminar after visiting St. Christopher's Hospice in the United Kingdom (U.K.). He was so affected by the stories of suffering that he was prompted to enlist the help of two medical students at Montreal’s Royal Victoria Hospital to conduct a survey of terminally ill patients at the hospital. The findings of this small study revealed that care of dying patients was impersonal, dehumanized and overly dependent on technology. Mount is quoted as saying “that to die at the Royal Vic was a catastrophe. And the Royal Vic, I would say, was one of the flagship academic hospitals in North America." (Duffy, 2005; Seely & Mount, 1999).

The term “palliative care” was first applied to end-of-life care in 1974 in Canada, in the French culture of the Province of Quebec, where the word "hospice" implied a place of last resort for the poor and the derelict. Dr. Mount coined the term "palliative care" (or soins palliatifs) to be a synonym for "hospice" that would be acceptable to both English-speaking and French-speaking Canadians. By the 1980s the concept of palliative care was widely accepted. In 2001 the Secretariat on Palliative and End-of-Life Care was created to develop a Canadian strategy for terminal care and especially access to appropriate palliative care services (Health Canada, 2007).

Other leading pioneers in the palliative care movement were Robert Twycross, a co-founder of Sir Michael Sobell Hospice in Oxford, England, and a pioneer in pain and symptom management in the international arena, and Derek Doyle, MBE, a co-founder of St. Columba’s Hospice in Edinburgh. Doyle has greatly contributed to the body of knowledge in palliative care through publications in peer-reviewed journals and textbooks and is chief editor of the first major textbook in the field, *The Oxford Textbook of Palliative Medicine* (Doyle, Hanks, & MacDonald, 1993). Doyle has also been instrumental in teaching and mentoring many hundreds of students of palliative care world-wide. In the early 1990s he visited Saudi Arabia to give guidance and direction to colleagues establishing the first Home Care/Palliative Care program in the Middle East at King Specialist Hospital and Research Center (KFSH&RC). The program was made possible by the vision of His Excellency, Dr. Fahad Al Abdul Jabbar, then CEO of the institution, who recognized the value of providing such services for KFSH&RC patients in the community, and by Adnan Ezzat, who served as medical director of the program. These two physicians understood how these service models were having a positive impact on the quality of care received by patients with advanced cancer worldwide.

Palliative care programs can now be found throughout North America, Europe, Africa, Asia, Australia and other areas of the globe. The southern state of Kerala in India has led the way in developing countries in palliative care clinical programs and in research and educational programs. Lead by Suresh Kumar, a dedicated and visionary director, the Institute of Palliative Medicine in Calicut, is recognized as a center of excellence and is setting high standards for programs in developing countries (International Association of Hospice and Palliative Care, 2010).

In the Middle East there has been some progress over the last two decades towards improving end-of-life care for cancer patients. The concept and value of organized end-of-life care is relatively new and not well-understood by the majority of physicians and health care policy-makers in the region; however, the countries of Jordan, Oman, Kuwait, Egypt, the United Arab Emirates and the Kingdom of Saudi Arabia are implementing programs to ensure that palliative care services become available to those in need.

The Concepts of Palliative Care and Hospice

Since the early 1960s, there have been great strides in the palliative care movement, with many dedicated, altruistic individuals devoting their careers to the movement. However, though both hospice and palliative care are widely practiced, there remains much discussion regarding the use of the two terms. For the purpose of this study it is of importance to distinguish between the two concepts. There is currently no national consensus regarding the definition of palliative care in the U.S. (Center for the Advancement of Palliative Care, 2008). According to Lynn (2001), the definition of palliative care is “in flux” and requires further clarification. There is no definitive boundary between palliative and curative care; in the opinion of experts they are not mutually exclusive (O'Neill, Marconi, & Surapruik, 2000). The WHO posits that the term refers to the relief of suffering, at any point along the disease trajectory, whether physical, psychological or spiritual (WHO, 1993).

According to the Center for the Advancement of Palliative Care (CAPC, 2008), "Hospice care is an organized program for delivering palliative care", and the two concepts need to be differentiated, to be better understood. It has been referred to as the "gold standard" of palliative care in the US. Hospice programs in the U.S. have focused on caring for the terminally ill in their own homes; however, a growing number of hospice organizations provide palliative care services earlier in the course of illness (von Guten, Ferris, Portenoy, & Glaichen, 2001a).

Though closely intertwined with palliative care, having a similar philosophies and core competencies, hospice care focuses on caring for the dying, usually in the last 6 months of life, whilst palliative care aims to maintain the patient's ability to go about their daily life as comfortably and effectively as possible, from the time it is clinically determined that cure is no longer a realistic option, through death and bereavement. Palliative care may also be introduced into the patient's plan of care whilst receiving curative therapy, if determined to be beneficial to the patient, although this is the exception rather than the rule

Definitions of Palliative Care

Definitions of palliative care range from a single sentence to a comprehensive definition several paragraphs in length (WHO, 1993; American Board of Hospice and Palliative Medicine, 2000; National Hospice and Palliative Care Organization, 2000). In the introduction to the *Oxford Textbook of Palliative Medicine,* Doyle et al. define palliative care as “the study and management of patients with active, progressive, far-advanced disease for whom the prognosis is limited and the focus of care is on quality of life” (Doyle, et al, 1993).

The World Health organization has a comprehensive definition of palliative care, addressing the concept from a holistic perspective:

> “Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual. Palliative care: provides relief from pain and other distressing symptoms; affirms life and regards dying as a normal process; intends neither to hasten or postpone death; integrates the psychological and spiritual aspects of patient care; offers a support system to help patients live as actively as possible until death; offers a support system to help the family cope during the patients illness and in their own bereavement; uses a team approach to address the needs of patients and their families, including bereavement counseling, if indicated; will enhance quality of life, and may also positively influence the course of illness; is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.” (WHO, 2010).

The Kansas Life Project (2007), identifies at least 15 definitions currently in use; however, common threads can be found running through these various definitions, including the relief of suffering; enhanced quality of life for patients and family members; decreased burden of care; multidisciplinary care; dignity and respect for the individual; and compassion. Notably, only two definitions specifically address the importance of research in palliative care. In the definition by Doyle et al., the phrase “*the study of patients*” is included. In the WHO definition, the need for research is addressed by stating that investigations are needed to better understand and manage distressing clinical complications.

Palliative Care Research

Recognition of the field of palliative care as a medical specialty, coupled with the trend towards evidence-based medicine (EBM) and increased funding for palliative care research in the past decade, has spurred additional interest. However, certain barriers exist that prevent the forward momentum of research in this field. Primary barriers are the reticence on the part of some researchers to conduct studies involving potentially frail or vulnerable subjects and the lack of experienced researchers in end-of-life care (Thomas & Wilson, 2005).

Studies of terminally ill cancer patients are essential if informed policy decisions are to be made. The foundation for policy-making and service planning begins with needs assessment (Doyle, 2006). This research proposes that measuring the perceived care and support needs of patients with advanced cancer is an appropriate metric to determine the efficacy of existing cancer care services. Examining patients' perceived needs will enable oncologists, palliative care practitioners and others to more readily identify gaps in service provision.

Many validated instruments frequently used in end-of-life care do not include the culturally specific demographic items or domains necessary to reflect cultural norms, or do not translate adequately to demonstrate cultural equivalence (Bowling, 1998; Aday & Cornelius, 2006). It is expected that socio-cultural, religious, and health care service-related differences influence the perceived needs of terminally ill cancer. It is therefore necessary to develop, translate and validate an original instrument to estimate the needs of the target population of cancer patients within specific cultures.

Cross-Cultural Research

In an age of growing international interest in health services research, the necessity of having culturally appropriate measurement tools on hand is becoming more pressing. When undertaking basic survey research across cultures, determining how different populations define health, health care and health care needs is of central interest. It is imperative to identify cultural differences and cultural equivalencies when undergoing the process of translating existing or developing new instruments for use across cultures. This study describes the development, translation and psychometric properties of a measure of attitudes, beliefs and self-reported behaviors related to the identification and prioritization of health care and supportive care needs of terminally ill cancer patients. This project was initiated in response to an identified gap in the body of knowledge in this field in this specific culture.

Over the last several decades, English-speaking societies have become more culturally diverse as migration across international borders has increased. As populations become more multi-cultural, it has become necessary to conduct health research within non-English-speaking populations residing in English-speaking cultures. This trend has extended to non-English-speaking countries, presenting many challenges when adaptating and translating existing instruments from the source language to the target language (Bullinger, Anderson, Cella, & Aaronson, 1993; Herdman, Fox-Rushby, & Badia, 1998; Skevington, 2002).

There has been a plethora of cross-cultural generic and disease-specific quality of life studies (Diehr, Laffery, Patrick, Downey, & Standish, 2007; Herdman, Fox-Rushby, & Badia, 1997; Richardson, et al., 2008). A number of these studies used existing instruments translated from a source language, usually English. Two of the most frequently translated instruments are the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983), and the SF-36 screening tool (Ware & Sherbourne, 1992). These have been adapted for use in different cultures and have been translated into several languages, including Chinese, Turkish, Iranian, and Spanish (Al Awadhi, et al., 2002; Guzelant, et al., 2004; Li, Wang, & Shen, 2008; Montazeri, Goshtasebi, Vahdaninia, & Gandek, 2005; Montazeri, Vahdaninia, Ebrahimi, & Jarvandi, 2003). In contrast, however, there have been few population-based studies identified which examine patient needs (Rainbird, Perkins, & Sanson-Fisher, 2005; Sanson-Fisher, et al., 2000), and none have been translated into other languages.

The setting for this study is a country in which Arabic is the mother tongue, and which has many unique qualities directly impacting the study design. The following pages provide a snapshot of the Kingdom of Saudi Arabia and its culture, to give deeper understanding of the uniqueness and complexities faced in this specific research project.

The Kingdom of Saudi Arabia

The Kingdom of Saudi Arabia, located in the Middle East, on the Arabian peninsula, is a rapidly evolving nation-state, transitioning from its early Bedouin roots to a thriving, modern society. This transition has occurred essentially over the last six decades, with the discovery of oil within its borders. Prior to this, the economy was based mainly on trading, its small towns serving as trading crossroads for caravan routes traveling between East Asia and the Mediterranean.

Saudi Arabia, comprising 14 administrative regions (see Figure 1), is bordered by the Red Sea to the west, the Arabian Gulf to the northeast; Jordan, Iraq and Kuwait to the north and Oman and Yemen to the east and south. Its borders are closed to the majority of non-Moslems, unless they have business interests in the Kingdom, or are expatriates with contractual employment. However, many millions of visitors of the Islamic faith enter the country each year from all over the world, fulfilling their obligatory pilgrimage to visit the holy cities of Mecca and Medina, the birthplace of the Prophet Mohammed in 635 A.D. Over the centuries, many of these pilgrims have settled in the Kingdom as traders, merchants and entrepreneurs, giving rise to a diverse, multi-ethnic Islamic society. In the first decade of this century, the population has grown significantly and is now is estimated at 17 million Saudi citizens with a 1:1 ratio of males to females. 95% of its citizens are under 65 years of age. There are also an additional 6.1 million expatriates living and working in the Kingdom (National Cancer Registry, 2004).

Figure 1. Administrative regions of Saudi Arabia (NCR, 2004).

The Saudi Health Care System

Many strides have been taken to modernize the Saudi health care system since the early 1950s, when the Saudi Ministry of Health (MOH) successfully collaborated with the World Health Organization (WHO) and Saudi Aramco, a leading oil company, to eradicate malaria in the Kingdom. Since that time the health care system has evolved into an integrated, three-tier system of primary, secondary and tertiary care facilities throughout the country (Al Yousef, Akerele, & Al Mazrou, 2002).

There are 19 health regions in the Kingdom, each with a number of sections and each having at least one general hospital and several health centers and primary health care clinics (PHCs). According to Al Yousef et al., (2002) there were 1,756 health centers in the Kingdom in the year 2000, complying with Ministry of Health directives.

The MOH policies are implemented throughout the Kingdom on a regional basis and according to the number and type of government organizations located in each region. In addition to health facilities operated by the MOH, the Saudi Arabian National Guard Health Affairs (SANGHA) and other branches of the military and security forces have their own independently run health care systems, funded by the Ministry of Finance. There are also numerous private hospitals, clinics, and pharmacies nationwide, although currently there are no government-funded community nursing programs in the Kingdom for follow-up care of those with chronic health care problems, including cancer.

Cancer and Cancer Care

The Kingdom has established cancer centers in three major cities, Riyadh, Jeddah and Dhahran. There are also a number of smaller government and non-government hospitals providing chemotherapy and surgical interventions for treatment of cancer patients. Current service provision is insufficient to provide the comprehensive quality care required to meet the needs of all patients with cancer in the Kingdom.

The total number of reported adult cancer cases in Saudi Arabia for 2004 was 9,381 (NCR, 2004). Of the total number of cases, 4,778 (50.9%) were males and 4,603 (49.1%) were females, giving a ratio of 104:100. The majority of cases reported in 2004 had invasive disease, 9,189, versus 191 with in-situ disease. The most common cancer cases in Saudi Arabia are colorectal cancer for males and breast cancer for females (NCR, 2004).

According to Gray et al. (Gray, Ezzat, & Volker, 1995), an estimated 70% of cancer patients kingdom-wide, present with incurable disease at the time of diagnosis. This is in marked contrast to U.S. figures. On examination of the U.S. National Cancer Database 1998-2004 patient characteristics by site, it was found that, of 12 diagnoses reviewed, the percentage of patients with advanced, stage IV disease at time of diagnosis ranged from 4.2% for female breast cancer to 62.8% for cancer of the pancreas, with an average for all 12 diagnoses of 19.8% (Halpern, et al., 2008). No recent data are available for the current percentage of patients with advanced disease at time of diagnosis in Saudi Arabia, but anecdotal information from oncology and palliative care colleagues and personal observation indicate that figures have not changed significantly from the estimated 70% in the mid-1990s.

Palliative Care

As noted earlier in this chapter, the concept and practice of palliative care was introduced into the Kingdom at King Faisal Specialist Hospital and Research Center (KFS&RC), in the early 1990s, under the direction of H.E. Dr. Fahad Al Abdul Jabbar, Chief Executive Officer, KFS&RC (Gray, yet al., 1995). The program was initiated in response to the suffering and desperation of many patients with advanced cancer seen in the hospital’s emergency department and who were being sent home, with no community follow-up or support.

Subsequent home care and palliative care programs were established at King Khalid National Guard Hospital in Jeddah and the King Abdulaziz SANGHA hospital in Riyadh. The acceptance and success of the home care/palliative care programs has demonstrated that the principles of palliative care are accepted in Islamic society. Published research on attitudes towards hospice in Saudi Arabia (Al Muzaini, Salek, Nicholls, & Al Omar, 1998) also indicates that the concept of formal end-of-life care is acceptable in the Kingdom. In their multi-site study of 170 adult cancer patients and 161 caregivers and professional providers, the Muzaini et al. found that 381 (96%) of professionals surveyed, believed that terminally ill cancer patients would benefit from formal palliative care services, both in hospitals and in the community. 92% of patients reported they would be content to spend their final days in a special facility, if it was staffed by experienced, specialist personnel. This is in sharp contrast to views expressed in Riyadh in the early 1990s, when it was considered to be neglectful of ones' Islamic duty to place ones' parents or relative in any type of non-hospital facility in the last days of life.

Although individual health care organizations in Saudi Arabia have established palliative care services for terminally ill patients in their care (Gray, Ezzat, & Volker, 1995), specialist palliative care services thus far are limited to major oncology centers in urban areas. The majority of patients with advanced cancer do not have easy access to appropriate and timely follow-up care, especially those living in rural or desert areas whose only access to health care may be a local primary health care (PHC) clinic (Al Shehri, Brown, Ezzat, & Khatib, 2004). PHC clinics are staffed mainly by physicians who are either non-Saudi, non-Arabic speaking, who have no postgraduate qualifications, or who have been trained in medical specialties other than palliative care. (Mahfouz, et al., 2007).

Palliative Care Education

Saudi Arabia has much work to do to achieve the levels of palliative care services extant in the U.S. and elsewhere. The first American Hospice and Palliative Medicine Certification examinations, developed and administered by the American Board of Internal Medicine (ABIM), and recognized by nine other American Boards, was administered in the US the fall of 2008 (ABIM, 2008). Recognition of the specialty in Saudi Arabia is an even more recent. Following the U.S. lead a number of Saudi physicians at KAMC-R developed an oncology and palliative care curriculum which is now implemented in the NGHA's own university, the King Saud University for Health Sciences in Riyadh. Similar plans are being made for palliative care to be part of the curriculum in schools of nursing, with a number of senior nurses at KAMC-R mentoring Saudi nurses who have an active interest in the field of palliative care nursing.

Availability of Essential Medications

The major tertiary care hospitals in the Kingdom, especially those providing comprehensice cancer care services, include most of the essential palliative care medications in their formularies. These medications include various forms of opioids, from immediate release morphine elixir to slow-release tablets and injectable morphine. The same provision does not apply to the majority of smaller community hospitals, either in major metropolitan areas or in rural or desert communities. This lack of availability of analgesics for the control of severe cancer-associated pain was a major complaint voiced by patients, caregivers and providers (Al Muzaini et al., 1998).

Although supplies of oral and/or injectable morphine and other opioids and essential drugs are available in their formularies, many do not have the medical or pharmacy trained staff to prescribe and dispense these medications safely and effectively (Andejani & Volker, 2002).

Public Understanding of Cancer

An early study of Muslim Arab parents' perception of and attitude towards cancer, Bahakim (1987), found that, despite the fact that 87% of parents of children with malignant disease were illiterate or did not attend secondary school, 67% gave a reasonable description of cancer (the definition of “reasonable” was not given) and the majority (60%) considered it important to know about the symptoms accompanying the disease. Findings also indicated that the majority believed the child’s prognosis lay in the hands of Allah and was beyond the control of the treating physician.

Findings by Ibrahim and colleagues (Ibrahim, Al-Muhanna, Saied, Al Jishi, et al., 1991) indicated that, although for Saudis over the age of thirty, age did increase adult awareness and understanding about cancer and its treatment, the overall knowledge about the subject among adults was disappointingly poor. It is not known if these findings can be generalized to the National Guard population, as this is a unique sub-group of Saudi society.

Beliefs and Attitudes towards Cancer

Historically many physicians have been reluctant to work in palliative care, as it was considered a somewhat unscientific branch of medicine. Training in the specialty was seen by most as "lacking in credibility." When a patient’s illness is expected to end in early death, ideally the goals of health care should shift from prolonging life (curative care), through the use of aggressive and expensive therapies, towards supportive care and relief of suffering (palliative care) (Garber, MaCurdy, & McLellan, 1998). However, many physicians continue to prescribe aggressive therapies, either due to their own beliefs and value systems, or at the request of patients and/or family members, even when cure is no longer possible.

Over the last 30 years, an increasing number of Western, or Western-trained, physicians have adopted the practice of informing their terminally ill patients about their prognoses and allow them to make their own decisions about treatment options (Novack, Plumer, & Smith, 1979). They are also offering palliative interventions and support services earlier in the disease trajectory, either by consulting with other disciplines,(e.g., social services and dieticians), or by referring patients to palliative care services for management of treatment side effects or problems associated with advancing disease.

This change in practice is based, in part, on American and other Western cultural beliefs about the importance of autonomy, on the work of Elizabeth Kubler-Ross (1969) on death and dying, and on the tenets of the first hospices. This paradigm shift from cure to comfort care is challenging to many physicians, whose education and training has emphasized cure and therefore may be reluctant to discontinue “curative” therapy, and who may be reluctant to be the deliverer of “bad news” and therefore the principles of the specialty are not always translated into practice.

As part of a coordinated effort to improve understanding and practice of palliative care, a workshop entitled *Education in Palliative and End-of-Life Care* (EPEC), was held at King Abdulaziz Medical City (KAMC) in Riyadh, in 2008. The workshop was lead by Dr. Frank Ferris, a world renowned, palliative care educator and clinician, with assistance from colleagues from San Diego Hospice and Capital Hospice in Washington D.C. In this workshop a leading and respected member of the NGHA, Dr. Abdullah Al Shimemri, Dean of Academic Affairs and Postgraduate Training at NGHA, discussed in his presentation the lengths to which some practitioners may go, in an attempt to achieve a cure. During the post-presentation discussion, many Saudi physician participants agreed it was extremely difficult for them to cease curative interventions, even knowing they were futile. It was acknowledged that faith in Allah kept hope alive, and they believed they must continue with aggressive therapies.

A significant barrier to effective pain management in Saudi Arabia, are the beliefs and attitudes of some political, professional and religious communities concerning the use of opioids. Restricitve government regulations proscribe the types and quanitities of opioid medications which may be held in hospital and community pharmacies (Al Muzaini, et.al., 1998). This study of health professionals' attitudes towards hospice care in Saudi Arabia by Al Muzaini and colleagues, is singular in examining end-of-life care in the Kingdom. Al-Shahri and colleagues (Al Shahri, Brown, & Bruera, 2004) suggest that seeking support from religious scholars would help to break down these barriers. National education programs for policy-makers and professionals involved in cancer care may also be beneficial in this society.

Information Disclosure

In a comparative study of information disclosure and decision making in the Middle East versus the Far East and the West (Mobeireek, Al Kassimi, Al Zahrani, Al Shimemeri, et al., 2008), the authors found that the majority of doctors (67%) in the Saudi arm of the study and 51% of patients thought that patients with cancer had the right to be informed of their diagnosis, as opposed to only the family being informed. An estimated 50% of both doctors and patients thought that it was inapproriate for the family to deny patients full disclosure.

Mobeireek, et al. (2008), suggest their findings indicate that, even in traditionalist countries like Saudi Arabia, many physicians and patients are advocating the Western model of disclosure and patient autonomy. How this conclusion translates into actual practice is less clear. Current experience at KAMC does not fully support these findings. Discussions with oncology and nursing staff indicate that a significant number of patients are not fully informed of their diagnosis or prognosis by their attending physician and that it is considered sufficient to inform family members only.

The Saudi Arabian National Guard

The Saudi Arabian National Guard (SANG) security force was established early last century to protect the people of this vulnerable desert Kingdom from both internal and external threats. The "Guard" is approximately 75,000 strong, headed by HRH. King Abdullah bin Abdulaziz Al Saud, and comprises personnel drawn from tribes loyal to the king and royal family. These soldiers guard the King and all members of the royal family and their residences. They also guard all SANG and NGHA facilities and are posted around the perimeter of the KAMC-Riyadh hospital complex to protect all who visit the facility, as well as its Saudi and expatriate employees.

The Saudi Arabian National Guard Health Affairs

The Saudi Arabian National Guard Health Affairs (SANGHA) hospitals and primary health care (PHC) clinics provide free health care throughout the Kingdom for all SANG soldiers, dependents and company employees, a total of 970,210 individuals in 2006, 95% of whom are under the age of 65 years. The average life expectancy at birth for individuals in the National Guard community is 73.1 years (SANGHA, 2008). SANGHA facilities also provide care to non-eligible patients by exception, with approval from the Executive Medical Director of the regional facility. A government mandate decrees that patients may receive free health care at a facility of their choosing if they have one of the following diseases: cancer; diabetes; cardio-vascular disease; end-stage renal and liver disease; congenital malformation; and metabolic/endocrine disorders. In recent years the NGHA has also established a business center, which enables fee-for-service access to specialist care for patients with specific conditions, if accepted by a consultant physician.

Riyadh, the capital of Saudi Arabia, is home to the SANGHA administration for all regions and is also the largest of the four SANGHA medical cities, King Abdulaziz Medical City, Riyadh (KAMC-R). The Guard had a total of 1,949 licensed hospital beds in 2006, approximately 2.5% of the total beds in the Kingdom (SANGHA, 2008). The KAMC-R hospital, a 600-bed tertiary care facility, treats patients from across the Kingdom. It is a modern facility with state-of-the-art technology and staffed by qualified personnel from around the globe.

KAMC- Riyadh Department of Oncology

The Department of Oncology is headed by its chairman, Dr. Abdulrahman Jazieh, a leading oncologist trained in the US. The Department is organized into six sections: adult medical oncology; adult hematology; gynecology oncology; radiation oncology; pediatric hematology oncology; and palliative care services. Each section is headed by a Saudi consultant.

The department currently has limited resources, having only two inpatient wards, one for adult and one for pediatric patients, giving a total of 30 beds. Within the next two years, however, a new cancer center is scheduled to be commissioned, as part of a larger expansion plan, including a university campus. The center will have an estimated 200 inpatient beds, outpatient facilities, pediatric and adult stem cell transplant units, surgical suites and a radiation therapy unit. In addition a new palliative care center is also planned, the first of its kind in the Middle East.

Incidence of Cancer Cases at KAMC-R

Exact statistics of all cancer cases seen at KAMC-R are not currently available. One reason for this is that patients with a diagnosis of hepatocellular cancer (an estimated 300 cases per year) and a small number of those requiring surgical interventions are admitted to departments other than oncology. Overall, an average of 58 patients aged 18 years and older was seen each month in the oncology inpatient and outpatient settings, over the past 34 months. The average age was 57 years, with a male to female ratio of 1:1 (KAMC-R Cancer Registry, 2008).

There is an active National Cancer Registry (NCR), based in King Faisal Specialist Hospital and Research Center (KFSH&RC) in Riyadh. This registry collects, analyzes and publishes cancer statistics from all facilities providing cancer care in the Saudi health care system (NCR, 2004). Cancer data have been collected at KAMC-Riyadh through the Tumor Board Registry since 1994.These data sets are incomplete, however, due to unreliable documentation in the patients' medical records, fragmented data abstraction processes, and lack of trained, certified registrars at NGHA facilities.

Reliable data for oncology inpatient deaths is available, however. It is reported by the KAMC-R cancer registry that in the 6 months from December 1, 2008 through May, 2009, there were 60 oncology inpatient deaths, with 60 palliative care team consultations, for expert management of oncology inpatients. Thirty of the patients who died, were in the care of the palliative team at time of death; however, the majority of patients are not usually referred to the team, until the patient is in the last days of life.

Summary

The SANGHA organization, based primarily on Western models of health service provision, is gradually evolving from service-based, to needs-based programs, with a subsequent paradigm shift in strategic planning. With this change comes the need for the NGHA policy-makers to have evidence-based data on hand, to guide and support their decisions. These data can only be made available, by conducting well-designed studies which measure and reflect real-world issues, and real world needs experienced by those living with cancer.

This study will contribute to the body of knowledge across several disciplines. It will add to the literature in palliative care research, particularly in cross-cultural studies. It will also extend the literature addressing the process of instrument translation and in the development and psychometric validation of original translated instruments. The study will be ultimately useful to health care practitioners and policy makers in the Kingdom of Saudi Arabia, enabling informed decisions to be made when planning new or expanded services for patients with advanced cancer.

CHAPTER 2

LITERATURE REVIEW

Introduction

The focus of this chapter is a review of the literature pertaining to human needs. It also examines the literature for psychometric processes used in developing and translating an instrument to measure these needs, specifically an instrument to measure the self-reported health care and support needs of patients with advanced cancer.

The review addresses a range of topics, including the theoretical foundation of human need, factors influencing human need and health care and support needs, and a critical review of existing study design, methodology, and findings. Also included in the chapter is a review of the theoretical background and methodology used in cross-cultural instrument translation and validation techniques, some of which have been applied and extended in the development of this new needs assessment instrument. The final issues addressed in this chapter comprise a brief overview of the evolution of palliative care research and a review of psychometrically validated instruments related to palliative care.

The theoretical framework for this research has been developed to provide a structural foundation for the study design and methodology. The framework also serves to explain the choice of variables and expected relationships between variables in the target population being assessed for their health care and support needs.

Human Need

Human need is a universal, complex, multi-layered construct, which has many facets, and is influenced by multiple internal and external factors, (Maslow, 1970a; Greer, Mor, Morris, & Sherwood, et al., 1986). Need is thought to be similar, or comparative across geographic locations for people with similar socio-demographic characteristics (Bradshaw, 1972). It is an innate physical and psychological phenomenon directly related to a sense of well-being, satisfaction, and attainment of goals (Deci and Ryan, 2000; Maslow, 1970a; Bradshaw, 1972). McKelvie proposes that needs are “The natural desires for the things that every human requires for the pursuit of happiness” and that people usually know needs when they see them, or when they are deprived of them (McKelvie, 2010).

The experience of human need is universal, and has been modeled by many theorists (see Table 1), from Aristotle and the pursuit of happiness, to Burton and social conflict resolution (1990). In the 4th century BC, Aristotle theorized that four conditions were necessary for true happiness: moral virtues related to social relations; the intellectual-spiritual virtue of contemplation; sufficient wealth that permitted need satisfaction related to food, clothing and housing; and good fortune to minimize the potential for debilitating disease (Reeve, 1995). In the 20th century, Burton examined need from a social conflict perspective and proposed that the needs most related to an understanding of social conflict were those of identity, recognition, security and personal development.

Table 1

Human Need and Related Theories

Date	Theorist/Author	Theory	Needs Categories
4th Century BC	Aristotle	Pursuit of Happiness	Moral virtues Contemplation Sufficient wealth Good fortune
1990	Burton	Social Conflict Resolution	Identity Recognition Security Personal development
1970	Maslow, A.	Motivational Theory	Physiological Safety and Security Love and Belonging Esteem Self-Actualization
1972	Bradshaw, J.	Theory of Social Need	Normative Felt Expressed Comparative
1998	Glasser, W.	Choice Theory	Survival Love-belonging Power Freedom Fun
2000	Deci, E. L., and Ryan, R.M.	Self-Determination Theory	Competence Relatedness Autonomy

Maslow's Classification of Needs

For many decades, much of psychology, sociology and behavioral research addressed the concept of human needs using the classic hierarchical model, based on the motivational theory proposed by behaviorist Abraham Maslow, one of the foremost psychologists of the 20th century (1970a). Maslow proposes that motives, or needs, do not appear randomly, but follow an ordered succession, depending upon their biological urgency. A point is made by Richard Lowry, Professor of Psychology Emeritus at Vassar College, Poughkeepsie, New

York, in the editor's introduction to the third edition of Maslow's *Toward a Psychology of Being* (1999):

> "…motivating factors, such as the need for food, are clearly primary, basic, built-in to the biological core of the species; while others, such as the desire to collect stamps or butterflies or violins, are clearly not built-in to the biological core of the species". Lowery proceeds to note that "The orthodox doctrine also held that a motive could be regarded as basic to the species only if it manifested itself universally throughout the species. Thus food-hunger is basic, because it appears in everyone, whereas the motive to collect stamps or violins cannot be seen as basic, because it appears in only a few. Personally, I would walk barefoot over hot coals to collect a fine violin, but find the prospect of collecting stamps about as appealing as watching cars rust in the parking lot." (Maslow, 1999).

Thus Lowry expresses how needs vary between individuals and differ in the level of importance or priority assigned to certain higher, i.e. non-basic, needs. The priority assigned to needs, specifically in relation to illness and the need for health care and support, may differ significantly across cultures, depending on external influences, such as social and religious factors and cultural values. However, the basic model proposed by Maslow provides a framework upon which to explore the perceived needs of patients in this study.

Maslow's original hierarchy of needs comprises five levels, providing a framework for behavioral motivation, commonly diagrammed in pyramid form, as seen in Figure 2. According to Maslow, each lower level must be satisfied before moving to the next higher level. He believed that the four lower levels in his hierarchy were similar to instincts and motivated certain behaviors. He labeled them "deficiency" needs (D-needs) arising out of deprivation and suggested they must be satisfied in order to avoid unpleasant and anxiety-provoking feelings.

Once the basic biological and physiological needs have been satisfied (Level 1), they are no longer a motivator, and the individual moves up to the next level. The need for safety, security and protection from danger is not limited to tangible, physical threats, however. It also includes intangibles, such as loss of control over health care decisions or loss of status within the family unit. The third level is that of social need; the need to be accepted, to belong, and to be loved. Social needs recognize that most people need to function as a part of a group, whether it is a family unit or social or work-related group, and need to feel a sense of belonging. This is of particular relevance when conducting studies in cultures that place emphasis on collectivistic rather than individualistic values.

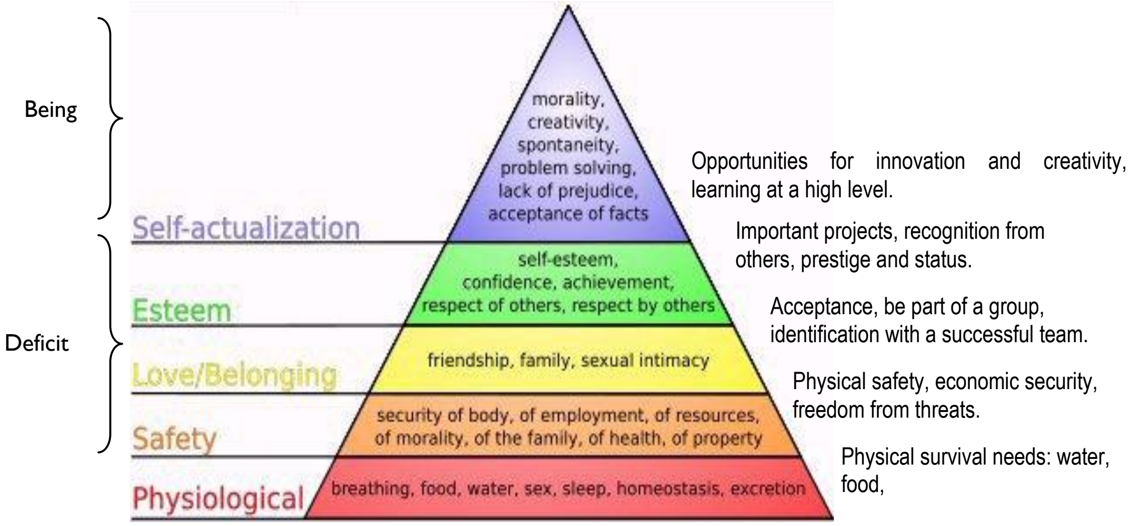

Figure 2. Adaptation of Maslow's Hierarchy of Needs (Wikepedia, 2010).

The fourth level, the penultimate level in Maslow's five-tier hierarchy, is the need for self-esteem – to feel good about oneself and ones' life accomplishments, and to be recognized for "a job well done." Maslow proposed that all humans need to feel valued and respected and to experience a sense of achievement.

The ultimate level in the five-tier hierarchy is that of self-actualization. According to Maslow this includes realizing personal potential, self-fulfillment, problem-solving, acceptance of factual reality and seeking personal growth, and classified as "being" needs (B-needs). He theorized that if at some future time a deficiency is felt at any level, the individual will act to remove the deficiency. His basic premise is that, as individuals achieve self-actualization, they will attain more wisdom and intuitively know how to respond in any particular life situation. The weakness seen in this argument is that a potentially life-threatening situation can drastically alter one's ability to cope and make decisions, which is of paramount importance to many individuals with terminal illness. Levels of the hierarchy are not mutually exclusive; one can be in physical pain, whilst at the same time have a need to be valued by one's family. It is not necessary for the individual to descend the hierarchy to focus on satisfying physical and safety needs before seeking to experience love and belonging. For example, patients suffering from acute vomiting or a foul-smelling wound, which occur indiscriminately in certain types of advanced cancer, do not necessarily relinquish the need to be loved; in fact it may result in just the opposite effect – a strong need to be loved in spite of the symptoms. It is suggested, however, that patients with advanced, life-threatening illness rarely achieve the level of self-actualization due to the inability to achieve satisfaction of lower level needs (Zalensky and Raspa, 2006).

A further criticism of Maslow's hierarchy has been that there is little empirical evidence to support his theory (Kiel, 1999). His model of human need, although innovative for its time, was not all inclusive; it did not address in depth how different cultural, social and religious values influenced the perception of need or their place in the hierarchy. For example, the attainment of self-actualization, praiseworthy in some individualistic societies, such as the U.S., or Japan, may not be viewed as a condition to aspire to in collectivistic societies, especially among older adults. In certain societies spiritual needs permeate all levels and categories of need. In searching for a system of human values, Maslow strongly advised against relying on "tradition, on consensus, on cultural habit, and unanimity of belief" (1970b). He posited that "we need a validated, usable system of human values, values we can believe in and devote ourselves to because they are true rather than because we are exhorted to ‘believe and have faith’" (1970b). This theoretical basis for assessing human need does not, however, fit the contextual values and attitudes of societies which function within the bounds of a totalitarian and unquestioning single religion.

In contrast to Maslow, Bradshaw (1972) approached human needs from a sociological perspective. He viewed needs from a stakeholder perspective, from providers to consumers, and judged that needs assessed by professionals (normative needs) would be much different from those of consumers of services (felt and expressed needs). He also considered that needs arising from consumers in one location may be similar to the needs of consumers with similar socio-demographics in another location (comparative need). Asadi-Lari and colleagues (Asadi-Lari, Packham, & Gray, 2003) consider Bradshaw’s taxonomy of need provides a practical framework to health services research. The taxonomy makes an important and necessary contribution to the extension of Maslow’s work towards the theoretical foundation for this study.

Other theories of need were reviewed for this study. An extension of Maslow’s hierarchy of needs and motivation theory is the work of William Glasser and his Choice Theory (1998). Glasser, a psychiatrist specializing in the US, proposes that human behavior is based on five innate categories of need: survival, love-belonging, power, freedom, and fun. Survival equates to the first two levels of Maslow's hierarchy: physical needs and safety and security, and love and belonging to the third level. Glasser's freedom category equates with Maslow's safety and security, but also to self-actualization, which encompasses spontaneity and creativity. The fun category may be viewed as a component of love and belonging and/or of self-actualization. Glasser's Choice Theory presents an alternate perspective on human need, as it relates to behavior and motivation, with a strong focus on relationships in management. Maslow's hierarchy of need gives a more structured theoretical framework for conducting this health care needs assessment. The model postulated by Maslow encompasses not only the need for relief of physical distress, but also enables assessment of psychological, social and spiritual needs and the need for self-efficacy and self-determination.

A definition of need currently used in the National Health Service (NHS) in the U.K. is "the capacity to benefit from health care," in terms of extending life or restoring normal function (Robinson & Elkan, 1996). The definition was clarified and extended by Andrew Stevens, professor of public health at the University of Birmingham, England, and Stephen Gillam, of the King's Fund, London (1998), in the third of their six articles on needs published in the *British Medical Journal*. They concurred that the definition was a significant advance in health care research in general, and needs assessment specifically; however, they posited that, "The purpose of needs assessment in health care is to gather the information required to bring about change beneficial to the health of the population." The authors argue that, whilst every outcome may not be beneficial, the presence of need implies the potential to benefit, which, on average, is effective. Two additional points are made in the article, which are most applicable to palliative care:

- The benefit is not just a change in clinical status, but can include reassurance, supportive care, and the relief of caregivers. The list of beneficiaries of care can extend beyond the patient to families and caregivers.
- Health care includes not just treatment but also prevention, diagnosis, continuing care, rehabilitation, and palliative care.

However, the precise definition of “capacity,” “benefit,” and “health care,” remains unclear in this context, and the phrase “capacity to benefit from health care” is open to subjective interpretation.

Upon reviewing these models and definitions of need, the theoretical framework for this study will be based on Maslow’s hierarchy of need, as viewed from the patient’s perspective; i.e., the felt needs of Bradshaw’s taxonomy. The model is extended to incorporate religious and spiritual needs and their influence on the domains of need identified for the study population in relation to the five levels of the hierarchy. As proposed by Zalensky and Raspa (2006), Maslow’s theory of need is appropriate as a framework for assessing the needs of cancer patients. Robert Zalensky, director of the palliative care unit at Sinai-Grace Hospital and professor of emergency medicine at Wayne State University, Detroit, Michigan, and his colleague Richard Raspa, professor and graduate chair of interdisciplinary studies, also at Wayne State University, describe how Maslow’s hierarchy provides a comprehensive approach to needs assessment and addresses the spectrum of issues encountered at each level of the hierarchy.

Physical Needs

Physical Symptoms

Physical comfort is a first-order need in Maslow's hierarchy (Maslow, 1970a; Zalensky & Raspa, 2006). The basic physical needs of oxygen, water, food, sleep, homeostasis, excretion and sex are seen by Maslow as fundamental necessities to life and well-being, although one could argue that it is possible to exist and function quite satisfactorily for long periods of time without having sexual needs satisfied. The degree of need experienced and the priority in which needs are ordered influence progression to the next level.

The prospect of achieving satisfaction at the second level is remote if physical needs necessary for survival are not met. The ability to focus on self-actualization is essentially non-existent, or at least severely compromised if one is acutely short of breath or in unrelenting pain. Extreme debilitating physical symptoms are all-consuming, to the exclusion of self-esteem or self-efficacy; however, unsatisfied needs at a lower level do not necessarily exclude all needs at a higher level; the need for love and belonging is likely to remain, even in the face of unbearable physical distress.

Unmet needs at lower levels, for example, prolonged distressing physical symptoms, may pose a threat to higher order needs for safety and security or to belonging and affection, or to self-esteem. Inability to access analgesics potent enough to control severe cancer pain may lead to a perceived threat to safety and security or fear of a terrible death. Lack of appropriate anti-emetic medications with subsequent, unrelenting vomiting may compromise self-esteem and result in low self-esteem, guilt, depression and social isolation.

Activities of Daily Living / Instrumental Activities of Daily Living

Activities of daily living (ADL) are categorized within the physical domain of the majority of measures, together with Instrumental Activities of Daily living (IADL). Whereas ADLs are concerned with mobility, and physical ability to perform self-care, such as personal hygiene, dressing, getting out of bed, IADLs are concerned with the ability to perform usual activities, such as cooking, cleaning, traveling within one's community, managing money, taking medications, using the telephone and shopping, without requiring assistance from others (U.S. Census Bureau, 2010; National Cancer Institute, 2010)

One of the earliest studies related to the assessment of patient functional needs is that by Fortinsky and colleagues in the Department of Medicine at Brown University (Fortinsky, Granger, & Seltzer, 1981). In this study, the authors examined the efficacy of three different instruments to measure the needs of disabled and chronically ill patients living at home. It was posited that personal care needs of patients living at home are not defined through clinical diagnosis, but rather in functional terms, and that the emphasis of care should be on achieving maximum function for as long as possible, that " the ability or inability to maintain independent living is the principal determinant of need."

The three different measures used in Fortinsky's study were the Bartel Index for functional assessment; the ESCROW measure to determine socio-economic need; and items from the Brief Psychiatric Rating scale to determine psychiatric needs. The ESCROW tool measures Environment, Social support, Cluster of family members, Resources, Outlook, and Work or school status. Although the aim of this early study was not to assess the needs of individual patients, but to determine the efficacy of the instruments, this study highlights the importance of addressing care and support needs from a holistic perspective.

A seminal study of patient needs, where all participants had a diagnosis of cancer, was conducted by Vincent Mor, Director of the Center of Gerontology and Health Services Research at Brown University (Mor, Allen, Siegel, & Houts, 1992), a decade after the study by Fortinsky et al. (1981) at the same institution. This study examines the constructs of functional ADL and IADL of adult cancer patients residing at home in three states: Pennsylvania, Rhode Island, and New York. The three areas of need examined were personal care, instrumental tasks, e.g. housework, shopping, cooking, and transportation. The study subjects had advanced disease, and all were receiving either palliative chemotherapy and/or radiation therapy on an outpatient basis. Proxy respondents were utilized in 92 (14.6%) of the interviews. In this study, the impact of physiological and social factors on the patient’s need for assistance was investigated and whether those needs were being met. Results demonstrated the association between level of physical need, i.e., ADLs and IADLs, and individual well-being. Approximately 50% of those participating reported a need for assistance with instrumental tasks and transportation and 14% for help with personal care. This positive association highlights the multi-factorial influences on patient well-being, and the importance of assessing the need for informal care, as well as assessing symptoms and functional impairment.

Physical/Psychological Needs

Maslow’s concepts of safety and security assume many guises, and may be classified under both physical needs and psychological needs. From Maslow’s perspective, they were examined from both a personal and a social perspective (Zalensky & Raspa, 2006). Humans need to exist in a safe, stable environment, with a sense of order and harmony and protected from harm. If one’s environment becomes disrupted, whether through external forces or internal imbalances such as illness, the focus of daily life may be fear and anxiety about the future. Safety and security, first- and second-order needs, may mean a home to live in; a safe neighborhood; having a loving and supportive family; a dependable income; or being in good health, so that you don’t have to rely on the good will or compassion of others to provide the care you need.

The need for safety and security experienced by patients with advanced cancer are very real, compounded by the uncertainty of progressive illness and fear of the future. One major concern of patients is the degree of willingness of family caregivers to provide a safe environment, when patients are no longer able to provide self-care (Sharpe, Butow, Smith, McConnell, & Clarke, 2005). Patients need to feel assured that there is a place where they will feel safe and secure and that their preferences for setting of care are considered. Another perceived threat to safety and security is fear of severe unrelieved pain or other distressing symptoms, a first-order need, resulting from the disease process or treatment interventions (Zalensky & Raspa, 2006). Financial security is a major concern for some patients – will they be able to pay their bills, or will they be a financial burden on their family? It is therefore essential to assess the safety and security needs of patients with advanced cancer from multiple perspectives, including support systems, physical environment, financial status, and psychological stressors.

Psychological adjustment to life’s stressors is particularly challenging, especially when those challenges revolve around life or death situations. For those diagnosed with advanced cancer, the challenges to their emotional and psychological equilibrium can be profound and include a range of feelings, such as denial, anger, bargaining, depression, and acceptance, as described by Kubler-Ross in her seminal text *On Death and Dying* (1969). Other emotions frequently experienced by patients with advanced disease include uncertainty, vulnerability, hopelessness, isolation, fear, and the search for meaning and hope (Moadel, Morgan, Fatone, Grennan, et al, 1999; McLain, Rosenfeld, & Breitbart, 2003). Fear of death, disability, and dependency may lead to anxiety and depression in patients with advanced cancer. The incidence of self-reported psychological needs was reported to be as high as 62% in a study of unmet needs in cancer patients (Piggott, Pollard, Thomson, & Aranda, 2007).

Anxiety/Depression

An individual's emotional health can be severely challenged when given a diagnosis of cancer, especially when the cancer is advanced. Anxiety and depression are a normal grief reaction with such a life-changing event. However, over time, the normal emotions of fear, and anticipation of what the future may hold, may transform into clinically significant depression and anxiety, In Tehran, Iran, a study of patients with gastrointestinal cancer using the Hospital Anxiety and Depression Scale (HADS), found that patients who knew their diagnosis demonstrated higher levels of psychological distress than those who did not know their diagnosis (Azadeh, Mohagheghi, Montazeri, Roshan, et al, 2007).The authors suggested this outcome was possibly related to cultural issues and the way in which information was communicated to patients. In a similar study of cancer patients in Turkey, it was also found that, psychiatric morbidity was found to be significantly higher (P=0.03) in the group who knew their diagnosis, 53 (45.3%), than those who did not know (Aresci, Baltalarli, Oguzhanoglu, Karadag, Ozdel, et al., 2004). It was not stated, however, how the patients learned of their diagnosis or if any of the respondents had received counseling.

Self-Efficacy

The Theory of Self-Efficacy (TSE) refers to "an individual's belief in their capacity to behave in ways which will lead to achievement of their performance goals" (Bandura, 1977).

It is a process which requires adaptation and learning new behaviors and skills to cope with changing life events and stressors. If a person has a high level of confidence in his or her own abilities, he or she can achieve certain context-specific outcomes.

According to Bandura, “Self-efficacy is the belief in one’s capabilities to organize and execute the courses of action required to manage prospective situations” (1977). In other words, how confident is an individual in their ability to do what they want, when they want, in the way they want? Self-efficacy influences the choices we make, how we feel, the effort we expend, and how long we persist in pursuing our goals, in the face of these challenges. Bandura posits that self-efficacy involves three important components:

A person’s estimate of his/her own level of capability to achieve certain goals in a particular environment; being confident in accomplishing specific tasks; and believing that they have control over their thought, feelings and actions.

The third of the three components of self-efficacy should be critically reviewed when assessing need in the context of a structured, strongly paternalistic society where, in some instances, the belief system discourages independent thoughts, feelings, or actions. For some, overriding cultural and religious expectations influence daily life and capacity to respond to disease-associated stressors. Examples of this are female patients who have never made major life-decisions for themselves – they assign, or are forced to assign, proxy control to others (Bandura, 1997) (p. 17). Societal expectations traditionally decree it is the male head of family (or his designee) who makes these decisions on behalf of the female. Another example, not exclusive to Saudi society, though more pronounced because of family dynamics, is the influence of male family members on physician communication concerning a patient's right to know – informed consent is fluid and very loosely interpreted on occasion.

There also may be a generational differences, with regards to decision-making. Younger, more educated women may actively participate in their health care decisions, whilst for older females the decision for care is still largely dominated by male family members. Until recently, male family members signed informed consent forms for their female relatives, often without the full knowledge of the patient. This practice has since been revised to allow female patients aged 18 years and older to sign their own consent forms.

For patients facing the challenges and uncertainties of terminal illness, their confidence in their abilities may diminish over time, leaving the patient with feelings of helplessness and despair, which in turn moderates the ability to cope with the burden of disease. When addressing the overall needs of terminally ill cancer patients, it is important to measure the construct of self-efficacy. Terminal illness is known to change an individual's self-perception, values and beliefs, and their ability to cope with life stresses, both physical and psychological, as the disease progresses. In her work on promoting self-efficacy of family caregivers, Teno (2002) describes how feeling alone, exhausted, and uncertain about the future can evolve into a sense of abandonment, and inadequacy, frustration and guilt.

Self-Determination

The concept of self-determination is another major contributor to an individual's ability to cope with stressors associated with illness. In their Self-Determination Theory (SDT), Deci and Ryan (2000) view human need as "innate psychological nutriments that are essential for ongoing psychological growth, integrity, and well-being." The authors posit that these three nutriments: competence; autonomy; and relatedness, must be satisfied for an individual to function at optimal level. When applied to Maslow's hierarchy, the concept of relatedness, the "sense of belonging," readily fits in the third level of the hierarchy, and that of autonomy into the fifth level.

Within SDT, feelings or perceptions of competence, with respect to an activity, are considered essential to the achievement of personal goals; a high perception of competence facilitates goal attainment, and provides the individual with a sense of need satisfaction. In the context of terminal illness, and the stressors associated with living with a life-threatening disease, perceived competence, autonomy, and relatedness play an important role in the patient's feelings of self-worth and continued value to society.

Whereas contemporary Western medical ethics focus on individual rights, autonomy, and self-determination, traditional societies place greater emphasis on a paternalistic approach by the physician, the role of the family in medical decision-making, and the non-disclosure of unfavorable medical information to critically ill patients. For example, whilst the concepts of advance directives and discussion of code status with patients are, to an increasing degree, being incorporated into medical practice in the U.S., these concepts are quite foreign to most countries outside North America (Ip, Gilligan, Koenig, & Raffin, 1998; Doyle, 2006; Gray, et al., 1995).

The concept of autonomy has not historically been an integrated part of Saudi culture, especially for females. In the context of health care and hospitalization, male family members assume the role of advocate and decision-maker for seriously ill relatives. The practice of informing terminally ill patients about their prognosis has not been widely accepted in the culture of the Kingdom. When writing "Do-Not-Resuscitate" orders, Saudi law does not require that the patient or any of their family agree to the decision, but they should be informed when the order is written. The law only requires that three "trusted" physicians, who are aware of the patient's condition, sign the order (A. Shimemri, personal communication, 17 March, 2009).

Social Needs

Love and Belonging

Feelings of connectedness within an individual’s social sphere have been shown to predict the quality of the relationships, feelings of competence, and degree of satisfaction experienced (La Guardia, Ryan, Couchman, & Deci, 2000). There are significant interactions between life stress and social support; having more people in the patient’s support system is associated with less mood disturbance (Kooperman, Hermanson, Diamond, Angell, & Spiegel, 1998). In addition, being provided with the necessary information and skills one believes one needs, promotes a sense of self-worth and value, which, in turn promotes self-efficacy. If a person has a high level of confidence in their own abilities he or she can achieve certain context-specific outcomes.

Information and Communication Needs

It has been shown that the need for information influences levels of satisfaction with care (Gustafson, Arora, Nelson, & Boberg, 2001). Typically, in satisfaction surveys, patients are less satisfied with how well their need for information and support are met than they are with how well their healthcare delivery needs are met. Gustafson et al. argue that the majority of patient satisfaction surveys do not adequately address the major areas of need considered to be important to patients and, therefore, do not lead to significant improvements in care. They suggest two strategies to increase the impact of satisfaction assessment: a) more complete identification of patient and family needs; and b) more accurate estimation of the importance of those needs.

The amount of information patients receive contributes to the individual’s perception of self and ability to cope with life stressors, as in levels three and four in Maslow's hierarchy. Information needs also relate to the level of need at the physical and psychological levels and, in fact, all levels of the hierarchy. One needs information for problem solving and acceptance of life's realities, and to achieve a degree of self-actualization in the face of a life-threatening illness. Information about symptom control, diet, rest, exercise, and functional limitations all contribute to improved satisfaction of physical needs. Patients may verbalize a need for specific information (Bradshaw's expressed needs), which can be directly addressed, or they may simply demonstrate certain behaviors which indicate a felt need for information, which has not transitioned into a demand and is thus unmet, leading to compromised self-management and inability to achieve short-term goals. Research shows that cognitive abilities and processes are related to functional ability and the need for care, and that patients often forget or are confused by the information they are given when they are stressed (Ball, Berch, Helmers, Jobe, et al., 2002). In some instances, patients report they have not been given information, though the information may have already been given. This indicates an information need.

Patient Information Needs

Tamborini and colleagues, at the Italian Institute Against Cancer, examined hospitalized cancer patients' needs, to determine primary needs arising from the disease itself and from subsequent hospitalization (Tamborini, Gangeri, Brunelli, Beltrami, et al., 2000). In interviews of 30 patients, it was found that information needs were a high priority, especially regarding diagnosis (56%), prognosis (74%), exams (52%), and treatments (51%). Another important finding was the high percentage of patients reporting the need for information on insurance and finance (43%) and a need to feel more useful within their own family unit

(46%). It is, therefore, important to include the construct of informational needs in the needs assessment survey of terminally ill cancer patients.

Professional Communication

For patients with advanced cancer, communication of information plays an important role in overall feelings of well-being. Some patients may seek full disclosure of all information concerning their diagnosis, treatment options and prognosis. Others may prefer not to have this information in detail, and some prefer to have none at all. The culture of “truth-telling” varies from country to country. In many developing countries, the amount of information shared and decisions about “truth telling” rests with physician and/or family members, not with patients.

In a study of oncology physicians’ attitudes, in Chengdu in the Peoples’ Republic of China, Jiang and colleagues found that 84% of 232 physicians reported that patients with early-stage cancer should be informed of their diagnosis, while only 40.5% believed that patients with advanced cancer should know the truth ($P<0.001$) (Jiang, Li, Liu, Huang, et al, 2006). Similarly, in a study of relatives of patients with cancer in Turkey, 66% of patients’ relatives reported they did not want the patient to be told the truth about their disease. Insufficient knowledge of the relative about cancer in general and a strong religious belief of the relative were associated with a greater likelihood of the relative having a “do not tell” attitude ($p=0.128$, $p=0.058$ respectively).

Patients’ preferences for information vary widely. Too much may result in feelings of anxiety, and a perceived threat to safety and security (corresponding to level two in Maslow’s hierarchy). Too little information may also have the same result. At KAMC-R, anecdotal reporting by physicians concerning patients’ informational needs is usually predicated by references to patient relatives and the barrier to truth-telling they represent.

Even though the importance of physician-patient communication in cancer care is recognized, it continues to be a major problem. Disclosure of a diagnosis of cancer, especially if the disease is advanced, is a difficult proposition for physicians in developing countries where, traditionally, family members represent patients in decision-making. In Saudi Arabia, physicians are faced with family members wishing to protect the patient, preferring to let the patient's believe that the illness is the will of Allah which gives them strength to face the illness and maintain hope of recovery.

Religious/Spiritual Needs

In recent years religious and spiritual factors have been recognized as playing a central role in adaptation to life stressors. It is hypothesized that psychological functioning and adjustment to illness are directly related to spiritual well-being (Moadel et al., 1999) and applies to all faiths, including Islam. Spiritual or religious care is an integral component of cancer care and plays an invaluable role in enabling both patients and their family caregivers to cope with living with cancer (Al Muzaini et al., 1998). In Saudi Arabia, a conservative Islamic country, all health care services and activities, as with all activities of daily life, are practiced within the tenets of the religious and cultural norms of the Islam. Medical knowledge and technologies imported from western societies are, to a large extent, considered acceptable in Islam, as this knowledge is bestowed by Allah.

Islam is the youngest of the three monotheistic religions. The religion follows the sayings of the Prophet Mohammed (571 – 635A.D.), as written in the Islamic holy book, the Holy Quran, and the belief that there is only one God, Allah. Islam shares its basic doctrines, including belief in the Day of Judgment, with Christianity and Judaism. There is no formally organized church, as in Christianity or Judaism, and no theological body speaks for the entire Islamic community. The predominant Islamic sect in Saudi Arabia is Sunni, whilst the other major sect, Shia, is found in Pakistan, Iran and other Middle Eastern countries.

Faith in the religion of Islam is *the* core value of Saudi society, and belief in the Holy Quran and the words of the Prophet Mohammed are central to social attitudes, behaviors and expectations and the conduct of everyday activities and social interactions. Believers in Islam are "exhorted" to believe only in Allah and obey the public call to prayer five times a day. Moslems believe in divine destiny, that all that happens in one life, both good and otherwise, is the will of Allah, and therefore should not be questioned. This belief guides many Moslems not to fear sickness or death, as expressed in the Quranic verses: “The angel of death, who is given charge of you, shall cause you to die, then to your Lord you will be returned. (Holy Quran, 32:11),” and “It is not given to any soul to die, but with the permission of Allah at the appointed time (Holy Quran, 3:145).

The Islamic religion is based on the Five Pillars of Islam: Declaration of faith in only one God, Allah, and in the sayings of the Prophet Mohammed (*shehadah*); observation of the holy month of Ramadan through worship and fasting (*saum*); giving alms to the poor and underprivileged (*zakat*); performing a pilgrimage to the holy city of Mecca at least once in a lifetime; and answering the call to prayer five times a day (*salat*). Along with belief in divine destiny, many Moslems also believe that they should consider scientific knowledge and technologies resulting from human endeavor, that this knowledge is also a gift from Allah. This encompasses the field of health care, the treatment of disease and the relief of suffering; however, this may be seen as ambiguous by some, leading to feelings of confusion or guilt about receiving certain interventions. If pain and suffering is a form of test or trial to confirm a believer’s faith (Holy Quran, 2: 153-157), is it acceptable to receive medications, or other treatment to block that suffering?

The availability of modern medicine and technologies has led some to question whether these “western” influences are acceptable in a strongly Islamic society. Experience shows that this knowledge is embraced, to a great extent and accepted by Saudi society, within the moral and legal parameters imposed by Islamic scriptures.

Few survey instruments have been identified that include an existential domain designed specifically to measure the concept of religious or spiritual need from an Islamic perspective (Asadi-Lari, Madjd, & Gousshegir, 2008). Most quality of life (QOL) instruments are designed to measure functional quality of life, and include few items on religiousness or spirituality (Byock, 1995; Cohen, Mount, Strobel, & Bui, 1995; Ferrans & Powers, 1985). Those instruments designed to measure religiousness/spirituality, focus mainly on Christian, or multiple faith respondents, but not exclusively Islam (Reed, 1987).

A study conducted in Jordan in 2006, by Jehad Halaby (2006), was one of the first studies of its kind in the Middle East, translating into Arabic an existing quality of life measure, the Quality of Life Index (QOLI) (Ferrans & Powers, 1985), and assessing its psychometric properties. It is not reported in the study how the religious/spiritual item in QOLI was used. Possibly it modified, or perhaps skipped, for Moslem respondents. For the purpose of this study, it would not be acceptable to ask a Saudi patient how important their faith in God was to him or her, as asked in item 28 of the QOLI.

Some studies show that spiritual resources are negatively associated with distress (Acklin, Brown, & Mauger, 1983; Baider, Russak, Perry, Kash, et al., 1999), whilst other studies show no relationship (Smith, Nehemkis, & Charter, 1983). Whether spiritual resources are helpful and whether spiritual beliefs increase as a patient’s death approaches are topics of continuing debate; however, the assumption is made for this study that there is a relationship between subjects' faith in Islam and their level and type of need.

Experience gained whilst working as a palliative care clinician in both hospital and community settings in the Kingdom raised my awareness of the existence of perceived negative influences of spiritual (satanic) entities, or “jinn” (*shaitan*), on the health or “bad luck” of individuals. Some in ill health freely stated they believed someone had cast a spell on them because of jealousy or of family feuding. It is acknowledged by professional colleagues that these beliefs continue across a wide spectrum of the population at all levels of society. Items measuring the perceived influence of jinns on health status were deemed culturally acceptable for inclusion in the survey instrument, after discussion with Saudi colleagues and friends.

Clinical Factors

Co-morbidity

The presence of co-morbidities influence health care needs and are associated with less desirable outcomes and more complex clinical management and increased health care costs (Valderas, Starfield, Sibbald, Salisbury, & Roland, 2009**)**. Cancer patients frequently have other diseases or conditions which influence their response to therapy and their level of care and support needs (Satariano & Muss, 2008), and the influence of concurrent and previous illnesses on the course of cancer treatment, especially in the elderly, should be assessed routinely. The presence of co-morbidities has been shown to influence patients’ ability to cope with living with their cancer (Satariano & Muss, 2008). In a presentation by a working group in 2008, on the “Effects of Co-morbidity on Cancer” (2008), William Satariano, at the University of California School of Public Health at Berkley, California, whose focus of interest is the economics of aging, proposed that “co-morbidity elevates the risk of disability and death among cancer patients." He also proposed that "co-morbidity is associated with the receipt of less definitive cancer therapy, and that less definitive therapy is associated with poorer outcomes after adjustment for co morbidity."

Assessment of the impact of pre-existing health problems, co-morbidity, is crucial in determining the complexity and level of need. The Public Health Agency of Canada defines co-morbidity as the "presence of more than one disease or health condition in an individual at a given time" (2007). To determine the degree of concurrent disease, co-morbidity scores, such as the Charlson Index and the Kaplan-Feinstein Index (Kaplan & Feinstein, 1974), are used to reduce potential confounding in epidemiological research and to predict mortality and health service use (Schneeweiss & Maclure, 2000). The Kaplan Feinstein

Index (KFI) classifies each disease and quantifies the severity of each condition into one of four groups, according to degree of severity:

- None – no co-morbidity.
- Mild – not hospitalized (for this co-morbidity).
- Moderate – hospitalized over 6 months ago.
- Severe – hospitalized less than six months ago.

The highest ranked (severest) co-morbidity score will be the overall co-morbidity score; however, where two or more moderate co-morbidities occur in different organ systems, the overall category is classified as severe (Kaplan & Feinstein, 1974; Picarrillo, 1999). For the purpose of this study, classification will be modified to address simple co-morbidity: frequencies and timing of recent hospitalizations will be used to estimate level of co-morbidity.

Time since Diagnosis

For patients with advanced cancer, the difficulties associated with their disease are compounded by a demonstrated decline in physical and functional changes due to the death process, a phenomenon termed by gerontologists as “terminal drop” (Diehr, Lafferty, Patrick, & Downey, 2007). These multiple influences can have a profound effect on the "real-world" of the cancer experience. The physical, emotional, psychological, social and spiritual facets of an individual's life can change dramatically, altering their perceptions of self and the world around them (Pigott, Pollard, Thomson, & Aranda, 2008). With changes in the internal and external environmental factors come fluctuating changes in their need for care and support. These needs evolve from a progressively complex web of problems faced by cancer patients, as they transition the disease trajectory and are not always recognized or well understood by health care providers (Clark, Malson, Small, Daniel, & Mallett, 1997).

Demographic Factors

Gender

Patients with advanced cancer experience different levels of health care and support needs as their disease progresses. The frequency, type, and level of these needs are influenced by gender in some cultures, as shown in prior studies of health care needs in the U.S. and U.K. (Mor et al., 1992). Mor and colleagues found that women are four times as likely as men to report needing assistance with instrumental tasks and twice as likely as men to report needing help with transportation. and older patients, $\geq$65 years, are twice as likely to report a need for help with personal care, but less likely to need help with instrumental tasks than younger patients. 15 to 33% of all patients in the study were found to have insufficient help to meet their needs, across all task areas. Female patients have also been shown to report higher levels of psychological needs than men (Cossich, Schofield, & McLachan, 2004).

Studies indicate that there is disparity in perceptions in reporting between self-reporting and proxy reporting, where proxy respondents tend to over-report patients' functional impairment (Hinton, 1996; Magaziner, Simonsick, Kashner, & Hebel, 1998; Newell, Sanson-Fisher, Girgis, & Bonaventure, 1998). As Mor et al. (1992) noted, a dummy variable (0, 1) was used to determine if effects were unduly inflated by proxy report. The proxy respondents did report more bed-days and more reduced activity days than patient respondents. Findings showed that patients with proxy respondents were 3.6 times as likely to report need for help with personal care (CI:1.90, 7.08); 1.5 times more likely to report needing help with instrumental tasks (CI: 0.83, 2.83); and 1.8 times more likely to report needing help with transportation (CI: 0.99, 3.38), controlling for all other factors. They found, however, that inclusion of a dummy variable for proxy status did not alter the magnitude or the level of statistical significance of the regression coefficients.

It was expected by the authors that duration of disease and co-morbidities would result in a greater need for assistance and that the social support: i.e., marital status, living alone, helping networks, and adult children living nearby would reduce their level of need. Demographic variables including age, sex and socio-economic status were thought likely to influence level of need. Findings demonstrated that even basic tasks of everyday living, such as shopping for groceries, or bathing and dressing, may be difficult or impossible to accomplish without assistance. The study showed that physiological factors, such as metastases, disease stage, and functional status were associated with need for assistance in all three areas.

The results of this study (Mor et al., 1992) contributed to a better understanding of the non-medical needs and unmet needs of cancer patients in the community and laid the foundation for future empirical studies of patient needs. There remained many unanswered questions as to patients’ perceptions of what *they* believe they really need to cope with living and dying with incurable cancer. This study emphasized the need to examine non-medical factors when assessing cancer patients needs for care. However, the psychological and spiritual dimensions of need were not measured in the study, nor the distressing side-effects and complications of chemotherapy and radiotherapy.

Age

The influence of age on patients with cancer has been examined from many perspectives, from clinical outcomes to satisfaction with care and need for assistance. Sanson-Fisher and colleagues (Sanson-Fisher, et al., 2000) found in their study of unmet supportive care needs in cancer patients, that participants 31-50 years of age were more likely than those in older or younger age groups to report a need for help. Younger patients (<65 years) have been found to be more likely than those 65 years and over to report social isolation (Asadi-Lari, et al., 2003) and those over 65 years of age predicted a higher level of need for help with personal care (Mor et al., 1992), whilst they were less likely to report need for help with IADLS than younger patients.

Financial Factors

Financial problems impact many levels of human need. As financial resources become scarcer the threat to physical and psychological well-being increases. If household income does not cover the costs of medical care or of living expenses, anxiety increases, feelings of self-worth decrease, and the potential for increased anxiety and/or depression increase. For patients who can no longer work and provide for their families, this role-change – especially for male patients in some societies – is also a threat to self-esteem and self-efficacy, which is Maslow’s third level of need, and curtails coping skills. Mor and colleagues (1992) found that low income patients were twice as likely to report need for assistance in all domains.

The concern about having adequate funds to pay for medical expenses or pharmaceuticals is not relevant to this study, as all medical care is free to the NGHA community in general. However, there is wide variation in income within the Guard population. Those who are less well educated, especially the older generation, may experience severe financial hardship through deceased household income and a subsequent increase in need across the spectrum.

Level of Education

Level of education and literacy skills has been shown to influence patients’ health care and support needs and coping skills, as well as the level of importance they attached to those needs (Jacobs-Lawson, Schumacher, Hughes, & Arnold, 2009). An individual’s level of education influences health literacy; i.e., "The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions". (U.S. Department of Health and Human Services, 2000).

Setting of Care Preferences

It is frequently proposed that the majority of patients prefer to be cared for and to die at home (Mor et al., 1992; Luptak, 2006). However, care preferences are often not known by physicians and other health care providers (Coppola, Ditto, Danks, & Smucker, 2003; Heffner & Barbieri, 2000).

Instrument Development

When developing needs assessment instruments, it is essential to understand how needs relate to one another and how these relationships influence satisfaction with care and quality of life (Wen, & Gustafson, 2004; Asada-Lari, Tamburini, & Gray, 2004). In their paper, Wen and Gustafson model some of these relationships and make the case for reassessing the concept of needs assessment.. There is a strong need for better understanding of how terminally ill individuals perceive, define, interpret, and prioritize the concept of need across cultural, national and geographical contexts (Streiner & Norman, 2007; Clark, Malson, Small, Daniel, & Mallett, 1997). Cultural values, which are held on an unconscious level, give an individual a sense of direction.

Those living in more collectivist, or pluralistic countries, such as Saudi Arabia, tend to value family and social needs over the more individualistic ego and self-actualization needs. Religious (Islamic) beliefs and practices, and family dominate most aspects of daily life in Saudi Arabia, and these cultural influences and sensitivities are incorporated in the design and content of the measure.

The PCNA-EAV Instrument

The PCNA-EAV is an original population-based measure, developed specifically for this doctoral research. Items generated for the PCNA-EAV were developed by the principal investigator, based on a) clinical experience and personal observations in the field of palliative care and home health care in the U.S., U.K., and Kingdom of Saudi Arabia; b) existing needs assessment instruments, primarily the population-based Needs Assessment for Advanced Cancer Patients (NA-ACP), (Rainbird, Perkins, & Sanson- Fisher, 2005); the Patient Needs Assessment Tool (PNAT) (Coyle et al., 1996); and others (Mor, Guadagnoli, &

Wool, 1987; Mor, Allen, Siegel, & Houts, 1992; Emanuel, Alpert, & Emanuel, 2001); c) a review of pertinent literature; d) and discussion with experts in oncology and palliative care**.**

The initial idea for this research project stemmed from personal observations of the pain and suffering of cancer patients seen in emergency rooms in the Saudi Arabia and the despair and guilt experienced by their family members. It also evolved from recognition of the urgent need for culturally appropriate tools to measure the outcomes and effectiveness of existing services for patients with advanced cancer.

The development of the research questions evolved from professional experience, from a review of the literature and an examination of the methodology for developing and translating new instruments for use in cross-cultural health services research. The domains of need to be included in this measure were identified through previous experience in the fields of cancer care, home health care, and palliative care in the Kingdom of Saudi Arabia; discussions with professional colleagues; and a review of published literature relating to patient needs, quality of life of patients with cancer, satisfaction with care, and related palliative care literature (Moadel, et al.,1999; Ferris, Balfour, Bowen, Farley, et al., 2002; Rainbird, 2005; Emanuel, 2001; Newell, Sanson-Fisher, Girgis, & Ackland, 1999). The domains include physical, psychological, social, information/communication, religious/spiritual, financial, and setting of care. Items were also included for needs prioritization, i.e., level of importance to respondent. Clinical, demographic, and cultural influences were also examined as moderating factors in the level of patient's reported health care and support needs (outcome variables).

The work by Ferris and colleagues (2002) with the Canadian Hospice Palliative Care Association in Ottawa also influenced the development of the PCNA-EAV instrument. In their “Square of Care” model, common issues which affect patients with advanced disease, are identified and categorized under the domains of disease management; physical, psychological, social, spiritual, practical, end-of-life/death management, and loss/grief. The first six domains in the Square of Care are included in the PCNA-EAV instrument. The end-of-life/death management and loss/grief are not included in this study, as the concepts are sensitive and complex and require additional time and resources. These topics have not been explored in depth in the Kingdom, and future research in this area would be expected to greatly benefit patients, clinicians and policy makers.

The only population-based patient needs assessment tool identified in the literature designed specifically to measure the needs of patients with advanced cancer is the Needs Assessment Advanced Cancer Patients (NA-ACP) instrument, developed in Australia by Rainbird and colleagues (2005). This research has served as one of the primary studies for this research project (see Table 2).

As previously noted, the aim of this research is to develop a psychometrically valid and reliable needs assessment which demonstrates cultural equivalence during translation. The cultural and social practices and belief systems of the target population have been shown to influence the perception of needs experienced by terminally ill patients. Moreover, such moderators as meaning, context, and personal history, which evolve from the individual’s interpretation of their personal experiences, may also influence perception of need (Baron & Kenny, 1986). It is therefore important to be sensitive to these influences when constructing and selecting items for a needs assessment survey instrument.

Table 2

Key Needs Assessment Instruments and Models

First Author (Year)	Instrument
Rainbird, et al. (2005)	Needs Assessment for Advanced Cancer Patients (NA-ACP) (Population-based Tool)
Sanson-Fisher, et al. (2000)	Supportive Care Needs Survey (SCNS) (Clinical Screening Tool)
Tambourini, et al. (2000)	Needs Evaluation Questionnaire (NEQ) (Clinical Screening Tool)
Emanuel, et al. (2001)	Needs near the End-of-life care Screening Tool (NEST) (Clinical Screening Tool)
Coyle, et al. (1996)	Patient Needs Assessment Tool (PNAT) (Clinical Screening Tool)
Piggott, et al. (2008)	Supportive Needs Screening Tool (SNST) (Clinical Screening Tool)
Cossich, et al. (2004)	Validation of the Cancer Needs Questionnaire (CNQ) short-form version in an ambulatory cancer setting (Screening Tool)
Ferris,et al. (2002)	A model to guide hospice palliative care

In their review of needs assessment instruments, Wen and Gustafson (2004) found that each of the 17 selected instruments met some, but not all, of their criteria for validity, reliability, responsiveness, and burden. This study attempts to address these issues in the instrument design and study methodology to fill the gap in the literature in cross-cultural instrument development and psychometric validation, specifically for use in Arabic-speaking, Islamic societies.

Building on existing studies, particularly those of Mor et al. (1987, 1992) and of Sanson-Fisher et al. (2000), Rainbird developed and validated a needs assessment instrument designed specifically for use with patients with advanced cancer, the NA-ACP (Rainbird, Perkins, & Sanson-Fisher, 2005). In their review of the literature of perceived need, quality of life of patients with cancer, and caring for patients with advanced, incurable cancer, the authors determined that, in addition to physical and daily living needs, patients' psychological, medical communication/information, financial, social and spiritual domains should be addressed. These domains are included in the current study.

In addition to receiving input on the pool of items generated from the literature review, the study design included input from a patient focus group (Rainbird et al., 2005) that identified any additional issues they believed should be included in the questionnaire. A total of 132 items were generated for the NA-ACP study.

Conceptual Framework

Based on these reviews and discussions with colleagues, a conceptual model for the study (see Figure 3) was developed. It is posited that the following predictor variables influence the level of perceived need: age, sex, and location of residence.

Study Design

Clinical versus Population-based Design

Patient needs assessment measures essentially take two forms; the first is clinically oriented, identifying individual patient needs through application of the instrument as a screening tool and tailoring the plan of care to address those needs, as with the Patient Needs Assessment Tool (PNAT) developed by Coyle and colleagues (Coyle, Goldstein, Passik, Fishman, & Portenoy, 1996). The instrument is a clinically oriented, interviewer-rated scale, screening cancer patients for potential problems with physical and psychological functioning. The second approach, used by Mor et al., (1992), is community based, designed to determine the level of care needs and support needs within the population, providing data for policy-making and service planning.

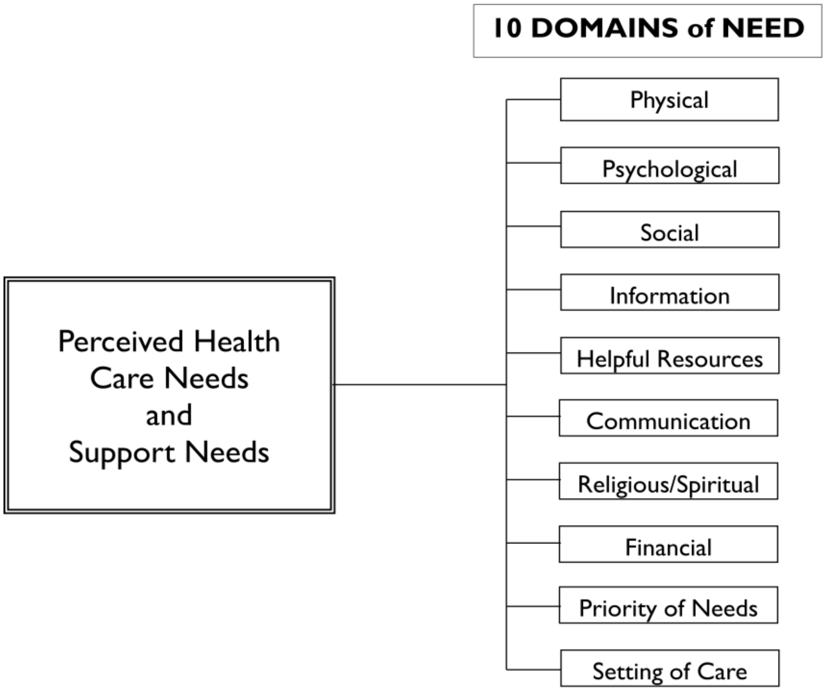

Figure 3. Conceptual model of health care and support needs

According to Bowling (1998) “A basic assumption of the use of structured questionnaires is that researchers and respondents share the same theoretical frame of reference and interpret the words, phrases and concepts in the same way.” This assumption must be psychometrically validated in order to accurately reflect the construct being measured. A literature review of relevant studies of patient needs assessment instruments indicates a consensus among experts (Emanuel et al. 2001; Wen & Gustafson, 2004): For an instrument to be useful, it must be derived from a validated, comprehensive framework to ensure that a full range of domains is included.

Although the majority of the literature of equivalence in cultural adaptations (translations) of instruments has focused on the measuring the concept of health-related quality of life (HRQoL), the approach to the process of cross-cultural research and adaptation of instruments is considered to be the same for the measurement of health-related care and support needs (Bowden & Fox-Rushby, 2003).

Instrument Adaptation and Translation

The experiences and subsequent needs of terminally ill cancer patients are influenced in varying degrees by the environment in which the patients live and by the social and cultural practices and belief systems of that environment. It is, therefore, necessary to be sensitive to these influences when constructing and selecting items for inclusion in a measure of need.

This new, Arabic language measure must address the socio-cultural influences of an Islamic society that potentially influence the perception of need. The importance respondents in an Islamic, Arabic-speaking society attach to their perceived needs is expected to differ significantly from a non-Islamic society, dependent upon their clinical status, coping skills, support systems and beliefs and values present in their everyday lives (Tamburini, et al., 2000). New adapted measures must meet widely accepted criteria for validity, reliability, responsiveness, and burden (Richardson, et al., 2007), and also must be adapted in a culturally sensitive manner, demonstrating cultural equivalence in translation.

The lack of translated needs assessment tools is seen as a major gap in the field of health services research. In an international research context, the concept of need is mediated by a host of socio-cultural influences, beliefs, values, and attitudes foreign to many researchers, and poorly understood or overlooked entirely. To be confident the findings of a study accurately reflect the contextual perception of need, it is necessary to translate the instrument into the language of the population under investigation (target population) and be able to demonstrate its cultural equivalence and adaptation.

Translation Models

The development of standardized methods for the translation of survey instruments began in the late 1960s and early 1970s with the seminal work in cross-cultural research of Richard Brislin, of Pennsylvania State University. Researchers have since developed best practices for the translation and assessment of translations of survey instruments.

The approach to standardized translation methods takes many forms. Brislin (1970) developed a model for translating and back-translating instruments (see Figure 4), which is frequently used for producing valid and reliable tools for cross-cultural research (Jones, Lee, Phillips, Zhang, & Jaceldo, 2001). Essentially there are two steps in Brislin's model, forward translation and back-translation. An iterative process of the two steps is used until a consensus is reached on its cultural content, and face validity. One bilingual expert translates the instrument from the source language into the target language, and a second bilingual expert blindly (without access to the source language version) back-translates it into the source language.

If errors in meaning or cultural equivalence occur, a second bilingual expert performs an independent back-translation and the two translations compared. Further translation and back-translations are performed to eliminate errors. This iterative process is continued until a satisfactory translation, with congruence of meaning between the two versions, is agreed upon (Jones et al., 2001).

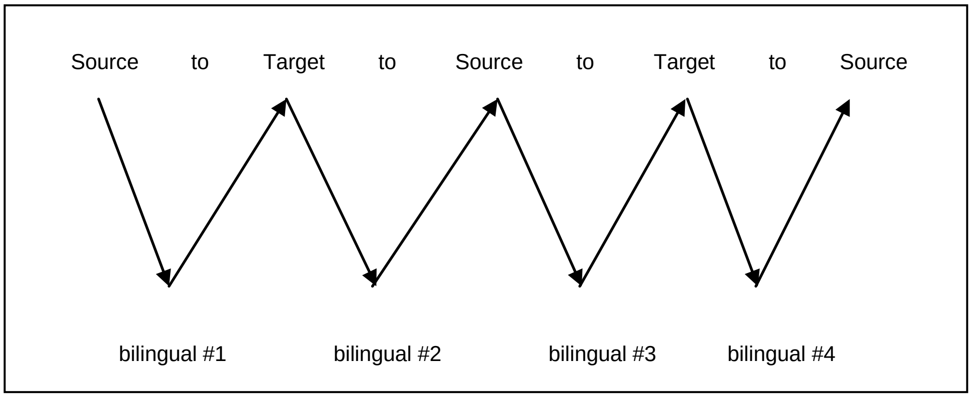

Figure 4. Translation Model (Brislin, 1970).
Note: From "An adaptation of Brislin's translational model for cross-cultural research" by P.S. Jones, J.W. Lee, L.R. Phillips, X.E. Zhang, & K.B Jaceldo, 2001, *Nursing Research*, 5, p. 303. Copyright 1970 by Richard W. Brislin. Reprinted with permission (see Appendix A).

According to Bullinger (1993), there was a considerable lack of defined procedures for developing international measures and evaluating their cross-cultural equivalence, and most studies focused on quality of life. Herdman and colleagues (Herdman et al., 1998) authored a seminal work on cross-cultural equivalence in health-related quality of life (HRQoL), which contributed significantly to the standardization of the translation process. In this work, the authors propose an approach to cross-cultural equivalence from an "absolutist" perspective versus a "universalist" perspective. They suggest that taking an absolutist approach makes the initial assumption that "there will be nil or negligible change in the content and organization of concepts such as HRQoL across cultures and that careful attention to linguistic elements will make a questionnaire developed for use in one culture acceptable for use in another culture." The authors argued that, for this to be accepted, a strong theoretical and empirical foundation is required, and that this was not available at the time of the study

An alternative perspective to cross-cultural research is presented, in the form of the "universalist" approach (Herdman et al., 1998). This approach does not make prior assumptions of equivalence, but implies the need to establish that a particular construct exists in the two cultures and the degree to which similarities in translation can be identified.

In 2001, Jones and colleagues adapted and extended Brislin's translation model, (see Figure 5), in part because the authors believed that, while efficient, the process was not always effective, particularly in languages with multiple dialects. In this adapted model, the authors recommend that two or more translators be used from the different regions that independently but simultaneously develop target versions for back-translations. Group discussions between all translators then follow until a consensus is reached regarding the most accurate and easily understood terms. This approach certainly deserves consideration when conducting surveys in different countries or ethnic regions; however, it may be problematic in resource-poor countries, in that it will add cost and require additional resources. It may also be difficult to identify translators with the required level of linguistic skills.

There are many variations of the translation process. Beaton et al. (2000) suggest a six-stage process of translation: Synthesis, back-translation, expert committee review, pretesting, submission, and appraisal. The translation model proposed by Doward and colleagues (Doward, McKenna, Meads, Twiss, et al., 2007) incorporates a dual-panel approach in their translation and validation of non-English versions of the Ankylosing Spondylitis Quality of Life (ASQOL) questionnaire. This model involves having two panels, a bilingual and a lay panel, in each target country. The bilingual panels produced an initial translation for consideration by the lay panel. The lay panel comprises individuals of average or lower educational levels who critique the draft translation to ensure that the content is expressed in clear everyday language. The model focuses on the readability of the ASQOL questionnaire, and may be useful when extending cross-cultural research in future studies in palliative care.

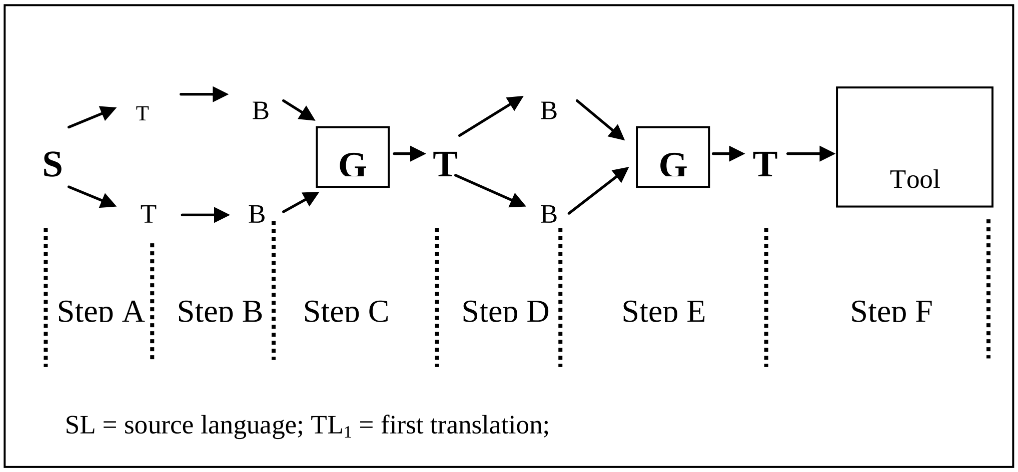

Figure 5. Adaptation of Brislin's Translation Model (Jones et al., 2001).
Note: From "An adaptation of Brislin's translational model for cross-cultural research" by P.S. Jones, J.W. Lee, L.R. Phillips, X.E. Zhang, & K.B Jaceldo, 2001, Nursing Research, 5, p. 303. Copyright 2001 by Wolters Kluwer Health. Reprinted with permission (see Appendix B).

In Jones' translation model, there are two forward translations by independent translators whose primary language is the one into which the questionnaire is being translated (target language). There is then a reconciliation of the two forward translations followed by two backward translations, ideally by people whose primary language is English. According to Jones, potentially the most important part of the whole process is the testing of the instrument on patients (cognitive debriefing).

The purpose of this debriefing, or pretesting, is to ensure that the words and phrases selected in the translation process will be easily and accurately understood by participants and that cultural equivalence has been established. It is essential to use the words that participants themselves use to describe their symptoms and needs, not the more scientific terms used by clinicians or in other cultures. An example of this problem can be illustrated by the inclusion of the term "family doctor" in one of the items in the new PCNA-EAV instrument. According to a clinical psychologist colleague at KAMC-Riyadh, there is no direct translation of the term in Arabic. Family doctors are not an integral part of the NGHA system. Instead, it was suggested that the Arabic term of "Family Practice Doctor" was used in the translation. This would be understood by respondents and would be the cultural equivalent.

Ideally, every new cultural adaptation should undergo a complete measurement property validation, if time and resources permit. If insufficient resources and expertise are dedicated to correctly translate and adapt survey instruments, the cultural and conceptual equivalence often is inadequate and study findings are unreliable. However, there is now good evidence that if the cultural adaptation is done to a high standard, the resulting questionnaire will have measurement properties very similar to those of the original.

In their language translation guidelines, the U.S. Census Bureau summarizes the objectives of their process: “Census Bureau data collection instruments that are translated form a source language into a target language should be reliable, complete, accurate and culturally competent,” (U.S. Census Bureau, 2010).

The participation of bi-lingual, non-health care professionals in the back-translation and verification process will ensure that the questionnaire can be easily understood by patients. The McGill Quality of Life (MQOL) questionnaire has been translated into several languages. As it was being developed and translated into Chinese for use in Hong Kong, several items were modified to ensure cultural appropriateness and easy comprehension by the participants (Lo, Woo, Zhoc, Li, Yeo, Johnson, & Mak, Y., 2001).

Assumptions

The foundation of this study is based on the assumption that the perceived health care and support needs of patients with advanced cancer are mediated by a number of predictor or moderating factors.

The following assumptions were made in the design of this study:

1. The study participants did not misrepresent their true level of need when self-reporting on the

rating scales.

2. The study participants accurately represented the population of patients with cancer at KAMC-Riyadh.

Limitations

The limitations inherent in this study, due to study design are:

1. This study of the needs of cancer patients was conducted using a cross-sectional design. The research therefore demonstrates only if an association between variables is present. No causal relationships can be assumed from the results.
2. Respondents voluntarily consented to participate in this study, and results may not be truly representatives of those who did not participate.
3. Patients who were too physically or mentally fragile were excluded from the study, which may result in an underestimation of problems experienced by patients with advanced cancer.
4. The study relies on respondents’ self-report of their perceptions of need, potentially introducing social desirability bias.
5. The PCNA-EAV was validated only for patients with advanced cancer in the department of oncology at KAMC-Riyadh and may not be generalizable to other cancer patients.

Research Questions

The research questions for this study are as follows:

RQI: Does the PCNA-EAV demonstrate reliability as an instrument to measure the health care and support needs of patients with advanced cancer?

RQ2: Does the PCNA-EAV demonstrate validity as an instrument to measure the health care and support needs of patients with advanced cancer?

RQ.3: What is the association between health care and support needs and patient characteristics?

Specific Aims and Hypotheses

The following specific aims and primary hypotheses have been formulated for this study:

Specific Aim I

To demonstrate the reliability of the PCNA-EAV instrument, in assessing the health care and support needs of patients with advanced cancer.

H_1: The PCNA-EAV instrument demonstrates reliability, as a measure for assessing the health care and support needs of adult patients with advanced cancer.

Specific Aim II

To demonstrate the extent to which the PCNA-EAV instrument measures the health care and support needs of patients with advanced cancer by assessing its psychometric validity.

H_2: The PCNA-EAV measure demonstrates validity, as measure for assessment of the health care and support needs of adult patients with advanced cancer.

Specific Aim III

To identify associations between the demographic characteristics and reported levels of health care and support needs in patients with advanced cancer.

H_{3a}: Males will report proportionately lower levels of psychological needs than females.

H_{3b}: Older patients (=> 50 years) will report proportionately higher levels of physical needs than younger patients (18 – 49 years).

H_{3c}: Patients who live in the city of Riyadh will report proportionately lower levels of physical needs than those who do not live in Riyadh.

H_{3d}: Patients with an ECOG score =<1 will report proportionately more physical needs than those patients with and ECOG score>1.

Summary

A review of the literature supports the premise that relationships exist between demographic and clinical characteristics, and the health care and support needs experienced by patients with advanced disease. patients' perceived levels of need influence feelings of well-being and quality of life. It has also been demonstrated that social and cultural factors influence the experiences, perceptions, and coping abilities of patients with advanced disease.

While assessment tools have been developed and validated to measure the health care and support needs of patients with advanced cancer, no instrument has been specifically designed to measure these needs in the context of an Islamic, Arabic-speaking society. This study is unique and original, in that a new instrument has been designed, translated, and psychometrically validated specifically for use with this population. The study combines qualitative and quantitative methods, and an iterative process of translation and back-translation, to develop items and the overall content, format of the instrument.

CHAPTER 3

METHODOLOGY

Introduction

Chapter three discusses the central paradigm for the research, and design and methodology of the study. The first section comprises a description of the study design and a discussion of the design options available. The second section describes the study methodology, including the population of interest, inclusion and exclusion criteria, study setting, data collection method, and data analysis. In the third section, the four phases of instrument development and validation are described (Figure 6). These phases comprise scale development; initial scale validation; research coordinator training, IRB submission, and pretest; and data collection and analysis. The final section of the chapter is a summary of issues described and discussed.

The discussion of study design and methodology provides a framework for the development and implementation of the project data collection and analysis processes and provides justification for the methods used.

Central Paradigm

The central paradigm applied to this study is the belief that the optimal means of understanding a phenomenon is to view it in a contextual perspective (Trochim, 2001). Participants' reality is subjective, according to their experience and the meanings they attached to the phenomenon of interest, i.e., their health care and support needs (Kraus, 2005). According to Kraus, meaning lies in cognition, not in external elements. The ontological assumption guiding this research, is the view that the phenomenon being measured, i.e., the perception of need, is essentially subjective, with individuals having their own thoughts and experiences, and assigning unique meaning and interpretation to these experiences. Under this assumption, perceptions of health care and support needs are different between individual subjects, based on the individual’s life experiences and socio-cultural influences. This study will assess these perceptions of needs, using a new and unique measure.

Study Design

This survey is a cross-sectional, mixed-methods design, combining qualitative and quantitative methodology. It utilizes in-depth expert panel interviews, and expert panel discussions to provide the qualitative data, and cross-sectional data obtained from patient interview. The interviews are conducted in 3 stages, pretest, pilot and retest, using the interviewer-administered PCNA-EAV instrument to collect the data.

The strategy of combining qualitative and quantitative methods enables a more rigorous approach to instrument validation. "The design of a data collection instrument is to yield reliable, valid and sensitive, unbiased, and complete data" (Collins, 2003). The development of these two complementary research methods in the study design increases the likelihood of producing better results in terms of quality and scope. Qualitative data help to shape instrument development and achieve a more accurate measure.

Several designs were considered for this study. The one-time cross-sectional design was chosen over time-series, longitudinal, and other designs, specifically because of the characteristics of the patient population being investigated. The target population has a diagnosis of advanced cancer, and thus prognosis and survival over time is, by the very nature of the disease, known to be limited, on average, to weeks or months, rather than years. Time series or longitudinal design would thus potentially result in an increased non-response and drop-out rate. The cross-sectional survey will give a point in time measure of need; however, respondents' time since diagnosis will range from days to months, enabling comparison of needs over time.

Existing Instruments

A review of the literature was conducted to identify existing needs assessment instruments. Once identified, these were assessed for appropriateness as a measure of need for this study (Table 3). The instruments were also reviewed for specific items which could be included in the development of a new instrument. Studies in related fields, such as quality of life and satisfaction with care (Mowen, 1993), also provided useful information on possible options for study methodology.

Much work has been done to develop measures to assess the needs of patients with advanced cancer. However, the majority of these measures have been designed as clinical screening tools (Piggott et al., 2008; Emanuel, E. Alpert, & Emanuel, 2001,) or for a specific setting of care (Mor et al., 1992), (see Table 3). The primary limitation to the use of existing scales for this study is that they are tailored to measure needs in western societies and do not include the cultural or religious components required for use in Islamic societies; the wording of some items may have no cultural equivalence, and may be offensive or inappropriate in Saudi society.

Table 3

Primary Sources for Study Design

Author/Year	Title	Focus	Study Design
Rainbird (2005)	The Needs Assessment for Advanced Cancer Patients (NA-ACP): A measure of the perceived needs of patients with advanced, incurable cancer. A study of validity, reliability and acceptability.	Design and methodology of a population-based needs assessment instrument for use with cancer patients.	Patients with advanced cancer in multisite outpatient settings. (N=246). Cross-sectional self-administered structured 132-item questionnaire. Reliability assessed by internal consistency and test-retest reliability. Construct validity assessed by Principal Components Analysis.
Emanuel, et al. (2001)	Concise screening questions for clinical assessments of terminal care: The Needs near the End-of-Life Screening Tool (NEST).	Design and methodology of a clinical needs screening tool.	Generic, cross-sectional, interviewer-administered structured questionnaire. Patients at home (N=988). Reliability assessed by internal consistency and test-retest reliability. Construct validity assessed by Principal Components Analysis.
Tamborini, et al. (2000)	Assessment of hospitalized cancer patients' needs by the Needs Evaluation Questionnaire (NEQ).	Design and methodology used in development of a 17-item, semi-structured, clinical screening tool.	Hospitalized patients (N=392). Interviewer-administered, cross-sectional survey of sub-samples to determine content analysis; reliability; construct validity.
Boneviski, et al. (2000)	Evaluation of an instrument to assess the needs of patients with cancer.	Design and methodology used in development of the Supportive Care Needs Survey, a 52-item, semi-structured, interviewer-administered instrument.	Outpatients (N=1354) Self-reported cross-sectional survey.
Mor, et al. (1992)	The changing needs of patients with cancer at home.	Administration of two modified scales: the Index of Activities of Daily Living and the Scale for Instrumental Activities of Daily Living.	Outpatients (N=629). Interviewer-administered longitudinal survey; baseline, three and six months post-baseline.

(continued)

Table 3 (Continued)

Primary Sources for Study Design

Author/Year	Title	Focus	Study Design
Coyle, et al. (1996)	Development and validation of a patient needs assessment tool (PNAT) for oncology clinicians.	Design, methodology and validation of a scale for clinical screening of cancer patients.	Inpatients and outpatients (N=36). A cross-sectional, interviewer-rated measure for adult patients with varied cancer diagnoses. Domains: physical and psychological and social functioning. Reliability assessed by inter-rater reliability and intra-class correlations. Validity was assessed by Spearman rank order correlations.
Sanson-Fisher, et al. (2000)	The unmet supportive care needs of patients with cancer.	Administration of a modified version of an existing instrument, the Supportive Care Needs Survey, to identify prevalence of unmet needs in the population.	A multisite cross-sectional survey of inpatients and outpatients (N=1354) undergoing treatment for various cancer diagnoses. Domains comprised: physical and daily living; psychological; health system and information; patient care and support; and sexuality.
Cossich, et al. (2004)	Validation of the Cancer Needs Questionnaire (CNQ) short-form version in an ambulatory cancer setting	Validation of an existing population-based assessment tool use with cancer patients.	Cross-sectional survey of ambulatory cancer patients (N = 450) Domains: Psychological, health information, physical and daily living, patient care and support, and interpersonal communication needs. Reliability assessed by Cronbach’s alpha. Validity assessed by convergent and contrasting groups construct validity.
Ferris, et al. (2002)	A model to guide hospice palliative care.	Includes a conceptual framework, “The Square of Care” for steps to use in the process of providing palliative care. Developed for the Canadian Hospice Palliative Care Association	Includes: domains of care, definitions of terms, foundational concepts, values, guiding principles, and development and function of hospice palliative care organizations.

Institutional Review Board (IRB) Approval

Approval to conduct this study was obtained from the institutional review board (IRB) at the University of Alabama at Birmingham (see Appendix C), and from the Saudi Arabian National Guard Health Affairs IRB (see Appendix D), prior to implementation. In addition, written permission was also obtained from the Executive Director, Medical Services, NGHA Central Region, as per NGHA policy.

Population of Interest

Target Population

The study population is a critical component of any cross-cultural empirical research and is specified early in the study in order to generate research questions and hypotheses. A concise definition of the reference or target population and clear description of the population sampling method used is essential to produce the population estimates required. The use of a single homogenous target population in this study controlled for any extraneous variation.

The target population for this study comprises patients with a diagnosis of advanced cancer, in the care of a consultant physician (Most Responsible Physician, or MRP) in the Department of Oncology at KAMC-R, during the study time frame.

Inclusion criteria

Patients must have met all of the following inclusion criteria to be eligible for participation in the study:

- Saudi citizen
- Aged 18 years and over
- Male or female

- Histologically and/or clinically confirmed diagnosis of advanced cancer (solid tumor or lymphoma)
- Aware of diagnosis and expected prognosis (informed and documented by MRP)
- Cognitively and physically able to participate in the study
- A life expectancy estimated by their physician to be less than one year

Exclusion Criteria

Patients who met any of the following exclusion criteria were ineligible to participate in the study:

- Receiving curative therapy.
- Admitted to an intensive care unit.
- Receiving treatment from another institution.
- Have diminished cognitive capacity; for example, are receiving opioid medications which have dulled their cognitive reasoning ability, or who are confused secondary to their disease process or any other extrinsic factors.
- Have diminished physical capacity, e.g. severe pain, shortness of breath, lethargy, resulting in difficulty or distress when attempting to respond to questions.

Sample Size

The sample size for the pilot study was limited to N = 50. The primary justifications for this cut-off point were the number of patients available in the target population, the limited resources available, and time constraints. An average of 1,100 new patients per year, are seen in the department of oncology at KAMC-R. Approximately 40% of these are patients with cancer diagnoses which do not meet the inclusion criteria of the study, i.e. do not have a diagnosis of solid tumor or lymphoma, Therefore, the remaining 660 patients per year may be eligible for the study (averaging 55 patients a month), if they are Saudi, aged 18 years and or above, and have advanced disease. The percentage of patients with advanced disease at time of presentation is estimated to be 60-70% (exact figures are not available); thus of the 55, only an estimated 33 patients may be eligible. Of these, some may not know their diagnoses; some may refuse to participate, or be screened out as physically or psychologically compromised. It was estimated, therefore, that enrollment of 50 patients into the pilot study, may take from two to three months, the maximum time available, if study deadlines were to be met.

Study Setting

The setting for the study was a single site, tertiary care facility in Riyadh, the capital city of Saudi Arabia. Interviews were conducted in the patient's room in the inpatient setting, or in an examination room or nursing office in the clinic setting. Most of the inpatient rooms were single occupancy and every effort was taken to ensure privacy and patient comfort.

George (2001) recommends that end-of-life studies include patients from multiple sites and use carefully developed inclusion and exclusion criteria. For this study, however, the survey was limited to a single site, the King Abdulaziz Medical City - Riyadh hospital, due to limited time and resources.

Risks

The potential risks to the participants were minimal; some patients may have become fatigued, due to the length of the questionnaire, or emotionally distressed because of the questionnaire content. Potential risks were eliminated, or significantly reduced, by screening all referrals. Risks were minimized by advising the patient they may withdraw at any time, and also by allowing for short breaks during the interview. If the participant verbalized discomfort, or showed physical signs of distress, the interview would be sensitively halted to avoid causing any unnecessary anxiety. The participants were offered the choice of taking a short break, re-scheduling the interview, or withdrawing from the study. Criteria used for withdrawal from the study were: verbalization distress or requesting to stop the interview, crying, inability or refusal to answer multiple (>5 questions) in < 15 minutes or repeatedly asking for questions to be explained (>5 questions in 15 minutes). Interviewers were instructed to take note of any individual questions, or series of questions, which the participants found particularly distressing or difficult.

Benefits

There was no direct benefit to those patients participating in the study. However, in the Islamic faith, those who contribute to the health and welfare of others receive rewards in heaven. This belief was voiced by many who participated, when the risks and benefits of participation were explained at time of consenting.

Confidentiality

Each participant was assigned a study identification number (ID). The ID was linked to the patient’s medical record number (MRN) in the screening and enrollment logs. The logs, containing patient identifiers, are saved on a computer disc, which, together with any hardcopies of the logs, were stored in a secure, locked storage space in the department of oncology. Data from the study were stored on a secure, password restricted computer and backed up on a computer disc, which was stored in a separate secure storage area from the screening/enrollment logs. Only the research team had access to this information.

Prior to enrolling, the participants were informed by the Research Coordinators that they would be interviewed in private, to ensure confidentiality. The aim was to provide an environment where they were not influenced by the presence of family members when formulating their responses.

Data Collection Methods

The purpose of collecting data from this population is to systematically identify the needs of patients, as reported by patients themselves. Data collected through administration of the newly developed instrument, the PCNA-EAV, is then analyzed to determine the reliability and validity of the measure and to determine the frequency and level of self-reported needs in the various domains included.

Several alternate methods were considered for data collection (Table 4), when the PCNA-EAV instrument was being developed (Streiner and Norman, 2008; Colorado State University, 2009). Once the decision had been taken that a structured questionnaire would be the appropriate data collection method, the choice of an interviewer-administered over a self-administered instrument was relatively simple. A self-administered questionnaire was discounted as an appropriate measure, due to the relatively high illiteracy rate of this population and the potential to introduce response bias if family members completed the questionnaire.

Table 4

Data Collection Methodology: Advantages and Disadvantages

Method	Advantage	Disadvantage
Interviewer-administered questionnaire	Interviewer has greatest control; provides opportunity for observation, establishing rapport, and additional probing; interviewer control over interview environment	More expensive; requires competent, trained personnel acceptable to both male and female respondents; required pre-arranged interview time; greatest likelihood of interviewer bias
Cross-sectional time series	Captures changes over time; enrolls different subjects each time, i.e. T, T1, T2, T3. Gives larger sample size, thus increasing chance of detecting differences where differences exist	Target population has a diagnosis of advanced cancer and thus their prognosis and survival over time is considered to be < 6 months; repeated interviews may impose an unacceptable burden on fragile participants; potential for high drop-out and non-response rate; participants geographically dispersed, therefore not easy to administer on scheduled basis; expensive
Longitudinal	Captures changes over time: tests same subjects at T1, T2, T3, T4	Has lower response rate, drop-out and withdrawal rates through death and increased fragility
Focus groups	Provides unique insight into the thought processes of participants and social and cultural aspects of health care and support needs; expectations; attitudes; belief priorities placed upon each domain; aid in identifying culturally sensitive issues. Identifies any sensitive issues which may need to eliminated from instrument	Social practices, i.e. many patients, especially females, not accustomed to participating in group activities with persons outside their family/social circle; no trained Arabic speaker available to conduct the groups; requires competent, well-trained personnel; requires quiet, private space to conduct focus group – not available for this study.
Telephone Interviews		Telephone system not reliable throughout Kingdom. Some elderly or fragile patients may not be able to hear or speak sufficiently well to be interviewed

(continued)

Table 4 (Continued)

Data collection methodology: Advantages and disadvantages for this study

Method	Advantage	Disadvantage
Mail/Self-administered survey		Relatively low response rates NGHA relatively high population illiteracy rate; KSA relatively unreliable postal service; questionnaire may be completed by someone other than patient, introducing response bias, as there are significant differences in perceived levels of need between those reported by patients themselves and those reported by family members; not possible to give assistance, e.g. prompts or explanations, if required
Internet survey	Easy to administer; relatively inexpensive; can be completed at respondents' convenience; reliable data entry	Relatively high population illiteracy rate; potential for someone other than respondent to complete survey; inequitable geographical access to Internet; unreliable Internet service

It has been shown that there are differences between patient self-reporting and that reported by family members and providers. A review of proxy measures used in studies of older adults, indicated there was evidence to support the use of proxy respondents in some domains, e.g., physical functioning, cognitive status, while more modest, or negative ratings, in others (Neumann, Akeri, & Guttermann, 2000).

The decision was taken to limit the scope of data collection to face-to-face interviews of the respondents, as the focus of the study is to elicit information from the patients' perspective, i.e., to measure "felt" needs, as described by Bradshaw (1972), rather than normative needs, as perceived by experts. In addition, some clinical and demographic data were obtained from the department of oncology database, CanReg 4 (International Association of Cancer Registries, 2010), especially data for non-respondents, to compare differences between the two groups.

Instrument Development Phases

The instrument was developed in four phases, as shown in Figure 6.

Phase I: Scale Development

This phase involved identifying domains of interest, selecting dependent and independent variables, and generation of items necessary to measure the health care needs and support care needs constructs, and operationalization of measures (Streiner & Norman, 2008: Aday & Cornelius, 2006).

Phase II: Instrument Translation

In Phase II the instrument was translated, back-translated and modified, as necessary. The proposal was then submitted to the Institutional Review Boards (IRBs) at the University of Alabama at Birmingham and at King Abdullah International Medical Research Center (KAIMRC) for expedited approval. Approval was granted in October 2009, by UAB IRB, and in November 2009, by KAMC-Riyadh IRB.

Phase III: Scale Validation

This phase included research coordinator education about the study, and training in instrument administration. This phase also included assessment of the reliability and validity of the instrument through expert panel review and administration of the pretest. Data analysis included descriptive statistics, reliability and validity estimates, as described in the study methodology. The instrument was then modified to reflect the findings of the pretest. The modified instrument was then submitted to the UAB and SANGHA IRBs for approval.

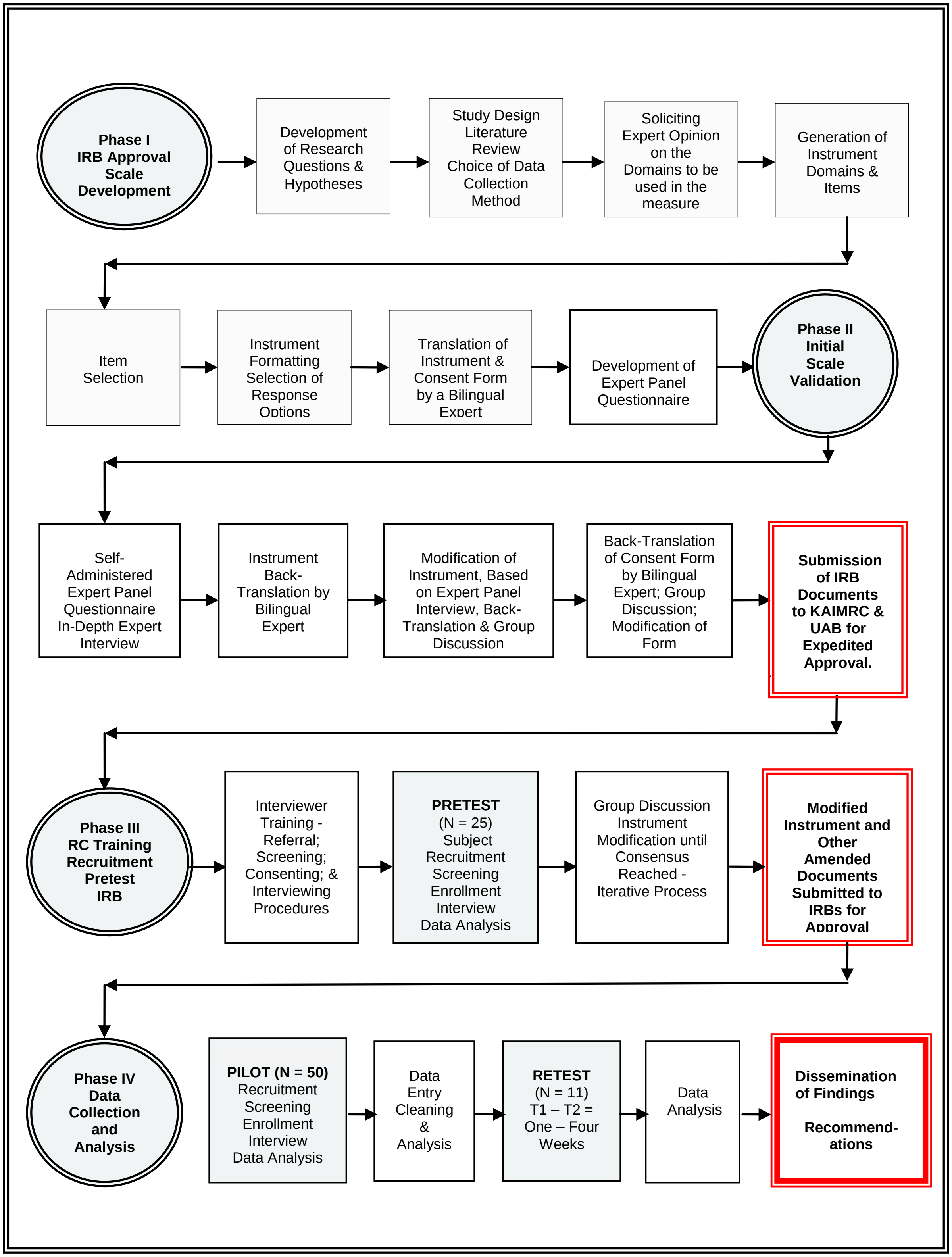

Figure 6. Phases of PCNA-EAV instrument development.

Phase IV: Pilot Implementation and Data Analysis

The pilot instrument was administered in phase IV, and the resulting data analyzed. The retest was then administered and data analysis completed and results interpreted.

Instrument Design

Domains

Domains for inclusion in the measure were identified through a review of existing needs assessment tools (English language only) and a review of the literature pertaining to patient needs, quality of life, and patient satisfaction. The eight domains identified for inclusion in this measure comprise: physical, psychological, social, financial, information/communication, religious/spiritual, and preference for setting of care. Additional items are included to measure the value, or importance attached to the reported needs; co-morbidities; the burden of participating in the interview; and demographic items.

Item Generation

The development of items for the pretest PCNA-EAV instrument (see Appendix G) was centered on the understanding that a survey item must be shown to be statistically reliable and valid and should demonstrate both content-level and item-level validity. It was also imperative that the final version of the instrument (see Appendix J) demonstrate cultural equivalency for word content and phrasing, between the English and Arabic versions.

Items were generated for this instrument by a variety of methods, including: a) previous knowledge and experience of the investigator, gained during 14 years as a home health and palliative care clinician and administrator in Saudi Arabia; b) literature searches

(English language only), using primarily PubMed, MEDLINE, JSTOR, and PsychINFO databases and the Google search engine; c) review of a range of existing instruments, including generic clinical and population-based instruments measuring patient needs and quality of life, palliative care survey instruments, and disease-specific instruments addressing outcomes and effectiveness of cancer care; and d) opinions of experts in palliative care, oncology and psycho-oncology in Saudi Arabia, and the U.K. and U.S.

Operationalization of Measures

The variables which make up the population characteristics are categorized according to the conceptual model of need: independent variables; moderating variables, comprising demographic and clinical variables; and two outcome variables: health care needs and support needs (see Table 6).The age categories used in this analysis are based upon those defined in the CanReg data registry software used by in the Department of Oncology, as are educational level, and household income.

For the gender variable, males are categorized as “1” and females “2”. Age and gender were obtained from the referral form, as was diagnosis. Clinical variables were operationalized with five measures: diagnosis, time since diagnosis, treatments received, number of co- morbidities, and number of hospitalizations in last 6 months. The need for ethnic origin, race, or religious preference was obviated by the fact that there is no racial distinction per se within Saudi society, although there is a large proportion of Saudis of African and of central Asian descent. All Saudis are of the Moslem faith.

Table 5

Operationalization of Measures

Construct	Variable	Operational Definition
Health Care and Support Needs	Physical – Symptoms	Deficit in effective management of physical disease or treatment-related symptoms (11 items)
	Physical – Activities of Daily Living	Functional/mobility deficit related to everyday activities, e.g. bathing, dressing, praying (7 items)
	Physical – Instrumental Activities of Daily Living	Functional deficit related to managing daily life activities, e.g. shopping, transportation, taking medications, childcare (5 items)
	Psychological – Self-Efficacy	Compromised self-belief (confidence) in own capabilities, interfering with coping skills (5 items)
	Psychological – Anxiety/Depression	Mental/emotional issues preventing acceptable quality of life (5 items)
	Psychological - Cognitive	Difficulties understanding, remembering, concentrating, problem-solving(5 items)
	Social – Relationships	Problems with relationships with spouse, family, friends (7 items)
	Information – Health Care	Deficits in levels of disease- and treatment-related information required from health care staff (7 items)
	Information – Sources	Degree of helpfulness of various sources of information, e.g. physicians, nurses, media (6 items)
	Communication	Style, clarity, personalization and language of communication of information (8 items)
	Religious/Spiritual	Religious beliefs, attitudes, experiences, related to illness (10 items)
	Needs priority (Importance assigned)	Importance assigned to need for assistance to resolve unmet need (8 items)
	Finance	Impact illness has had on financial status (3 items)
	Preference for setting of care	Place where respondent prefers to be when can no longer take care of self (4 items)

(continued)

Table 5 (continued)

Operationalization of measures

Construct	Variable	Operational Definition
Demographic Characteristics		
	Location of Residence	Name of town
	Location when receiving treatment	Name of town
	Current marital status	Married, widowed, divorced, separated, never married
	Number of wives	1-4
	Number of other wives husband has	1-3
	Number of children	None, 1-3, 4-6, 7-9, 10-12, >12
	Number of children living with respondent	None, 1-3, 4-6, 7-9, 10-12, >12
	Number of these teenagers or older	None, 1-3, 4-6, 7-9, 10-12, >12
	Number of female relatives who can help respondent while ill	None. 1, 2, >2
	Number of maids at home	None. 1, 2, >2
	Number of drivers	None. 1, 2, >2
	Highest level of education	No formal schooling, primary school, elementary school, high school, college graduate, post-graduate
	Current employment status	Self-employed, government employee, private sector, retired, never worked
	Average monthly household income	<2000 riyals, 2,000 – 4,999, 5,000-10,000, >10,000, unsure, prefer not to answer
Clinical Characteristics	Number of other illnesses ever received treatment (comorbidities)	High blood pressure, heart disease, diabetes, kidney disease, lung disease, other
	If other, name illness	Open-ended question
	Number of times hospitalized for illness other than cancer	None, 1, 2, 3, >3
	Number of these hospitalizations <6 months ago	None, 1, 2, 3, >3
	Types of treatment received for cancer (not mutually exclusive)	Chemotherapy, radiation therapy, surgery, hormone therapy, don't know
	Ever received tribal or traditional remedies	Yes/No
	Which remedies	Open-ended question
Burden	Level of difficulty answering questions	Extremely difficult, somewhat difficult, neither difficult nor easy, fairly easy, extremely easy
	Were the instructions easy to understand?	Yes/No
	Any other issues which should be included in the questionnaire	Yes/No
	If yes, which issues	Open-ended question
	Willing to take the same survey again in two weeks time?	Yes/No

Instrument Format

Introductory Statement

When designing the form and content of the introductory statement of the instrument, careful consideration was given to potential respondents' previous experience with face-to-face interviews. A recently completed survey of complementary and alternative medicine (CAM) used by cancer patients at KAMC-R, used face-to-face interviewing techniques. Enrollment was closed early in 2010, and data analysis was being conducted, at the time the PCNA-EAV study was initiated. The expert panel for the PCNA-EAV study was of the opinion that none of the target population for this study would have been enrolled in the CAM study, and, therefore, would have been unlikely to be familiar with participating in face-to-face interviews. The PCNA-EAV introductory statement was, therefore, longer than recommended by some researchers (16 to 64 words) (Aday & Cornelius, 2006). This was justified in order to reinforce the information contained in the consent form, to elicit the best response, and to put respondents at ease.

The introduction included the name of the facility, the name of the research coordinator conducting the interview, the purpose of the interview, and the expected length of time it would take to complete the interview. It also contained a reminder that the respondent could stop the interview at any time, could ask to take a break, and could withdraw from the study at any time without affecting the quality of care they would receive in the future.

Item Sequence

When formatting the sequence of items to be used in the pretest version of the instrument, the items measuring demographic and clinical variables were placed at the end (Aday & Cornelius, 2006) to ensure as many as possible of the survey items were administered. In the event that some participants were unable to complete the interview, due to fatigue or other discomfort, or in the event of patient withdrawal, it would have been possible to elicit most of this information at a later time from medical records or other primary sources, including family members, and would not be restricted, or adversely affect data analysis.

Response Development

Cognitive Requirements

Early in instrument design, it is important to establish not only the research questions to be asked, but also the population best able to supply the information being sought. It must also be considered how this population would be best able to supply the information required. Assessing the cognitive and reading skills of the target audience and tailoring the instrument to the level at which they would feel least threatened or anxious are key first steps.

When designing an instrument to evaluate past experiences, the respondent's ability to make a rational choice using behavioral and cognitive processes must be assessed. This is particularly so if there is perceived to be limited time to respond, limited information, or personal or social constraints on the individual (Simon, 1960; Quintana, J. personal communication, 15 March, 2006). Herbert Simon, a Nobel prizewinner and professor of computer science at Carnegie Mellon University, theorized that there are cognitive limits to knowledge and the capacity to act rationally, i.e., to make rational decisions, especially if there is imperfect information, or they are unable to compute viable alternatives. He suggested that, in general, memories are weak and often unreliable, and therefore the process of bounded rationality is used when formulating responses. The term "satisficing" was coined by Simon to describe the type of response where, rather than searching for the "best" answer, the respondent gives the first alternative response that seems reasonable at the time or seems "good enough."

To minimize satisficing in this survey, every effort was made to ensure that item wording was not ambiguous or double-barreled, and did not include jargon or medical terms that might not be easily understood.

Recall Time Frame

The time frame for retest varies between studies. When testing the new 36- item short form (SF-36), in the original Medical Outcomes Study, (Stewart & Ware, 1992) the test retest were conducted 4 months apart. This extended period could have resulted in a real change in the measures provided by the instrument, influencing the correlation between responses, as the respondents' health status could have potentially altered significantly during this time. In the evaluation of the 12-item version of the SF-36 (the SF-12) a 2-week period was used for T1 to T2 to enable a more accurate estimate of reliability (Aday & Cornelius, 2006).

A time frame of 4 weeks was utilized as a cognitively appropriate recall period for this instrument, to minimize respondent cognitive burden and minimize recall bias (Bowling, 1998; Tourangeau, et al., 2000; Streiner & Norman, 2008). A review of the pretest and discussion with the research coordinators revealed respondents were observed to have no problems with this time frame and it was retained in the pilot instrument.

Response Context

The context effects of survey questions can influence each of the stages in responding to questions; i.e., response to prior questions can influence the response to subsequent questions (Aday & Cornelius, 2006). In the field of cognitive psychology, it is theorized that respondents go through specific stages in cognitive processing when responding to questions, i.e., comprehension, retrieval, estimation or judgment, and response, and that earlier questions provide information or standards of comparison for respondents to use when making a judgment about the appropriate response to a particular item (Aday & Cornelius, 2006; Streiner & Norman, 2008).

Response Options

Four response option formats were used in the 116-item instrument; rating scales, multiple choice, dichotomous (yes/no) and open-ended questions. The majority were 5-point Likert Scales, ranging from “Strongly Agree” to “Strongly Disagree,” or “None of the Time” to “All of the Time,” both with a neutral mid-point, rather than forcing the respondent into making a positive or negative choice. For sensitive items; e.g., household income, an option of “Prefer not to Answer” was added. For scales containing sensitive questions, e.g. "What is your monthly household income?" the response option of "Prefer not to answer" was included as a sixth response option. This gave the respondent the choice to avoid sharing personal information, if that was their preference.

Response Bias

A goal in instrument design and testing methodology is to reduce the potential for systematic error, or bias, and thus increase the validity of the measure. Bias may be introduced through a variety of factors, including characteristics of the instrument, characteristics of the respondent, the context of the interview, and the actual administration of the instrument (Aday & Cornelius, 2006; Harkness, Villar, & Edwards, 2010; Streiner &

Norman, 2008). The characteristics of the respondent and the cultural influences on response style are of particular interest in this study. According to Harkness et al., response styles are commonly defined as “consistent and stable tendencies in response behavior that are not explainable in terms of question content or what a given question aims to measure."

Response Styles

Extreme Response Style (ERS) is the tendency of respondents to favor or to avoid using the endpoints of a rating scale, relatively independently of specific item content (content irrelevant) and can be a threat to the validity of the research findings (Chun, Campbell, & Yoo, 1974). ERS differences can result in differences between group means and affect the level of item inter-correlations within a scale, affecting internal consistency. It can also affect discriminant validity by altering the median scores of domains and sub-domains.

Transitional Phrases

To introduce a new topic, i.e., a series of questions in a response set, a transitional phrase was provided (Aday & Cornelius, 2006). This gave the respondent time to cognitively move from the previous series to the new topic. Each transitional phase contained a general statement about the types of questions in the next section and why they were being asked.

Item Phrasing

Careful attention was paid to item phrasing to ensure relevant meaning and cultural equivalence in translation. This minimizes confusion for the respondent and subsequent response bias. Experience has shown, through clinical practice and interaction with patients and family members in the National Guard population, that a large number of patients are either illiterate or have poor reading and comprehension skills. Although the instrument is interviewer administered, wording of items was kept to that of the reading and comprehension skills not beyond those of the average (Saudi) 12-year old (Streiner & Norman, 2008).

Translation

The translation component of this study is based on work by Brislin (1970) and Jones and colleagues (Jones, Lee, Phillips, Zhang, & Jaceldo, 2001), who developed and extended translational models for use in cross-cultural research. The translation model (Figure 7) used in this study, is an adaptation and extension of Brislin's model and Jones' adaptation of Brislin's model.

Forward Translation

The study instrument was translated from English into Arabic, the target language, by Abdullah Al Qarni, a master's prepared clinical psychologist in the Department of Oncology at KAMC-Riyadh. Mr. Al Qarni, a Saudi national with excellent bilingual skills and first-hand knowledge of the cultural and linguistic nuances and equivalencies, had previous experience in translating survey documents from English to Arabic, while studying for his Master's degree in clinical psychology in Australia (A. Al Qarni, personal communication, March 10, 2009).

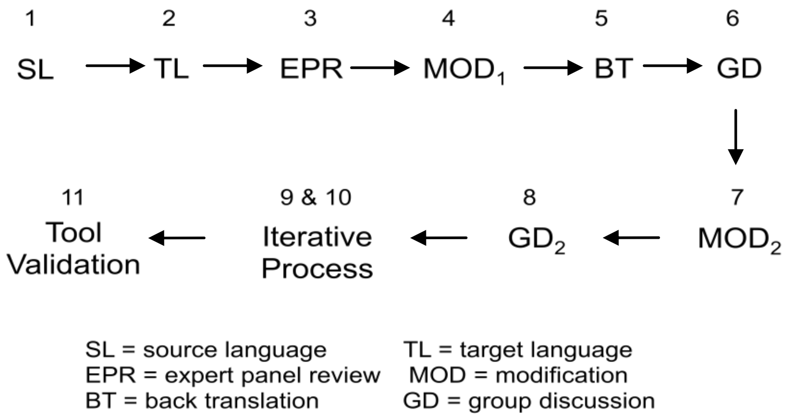

Figure 7**.** Adaptation of Jones' Translation Model

Back Translation

Once the initial translation was complete, the Arabic version of the instrument was submitted to Dr. Abdullah Al Shimemeri, Dean of Academic Affairs and Post-Graduate School, KAMC-Riyadh, who graciously agreed to conduct the back-translation. He was asked to conduct the back-translation, and also to make recommendations for any revisions, and item inclusions or deletions, based on his knowledge of Saudi culture and of the Holy Quran, (for religious sensitivities), and on his professional experience, as a physician. The back-translation (see Appendix E) was blind. i.e., the translator did not see the source version of the instrument.

It was not possible to identify a second expert with the necessary bilingual skills for the second back-translation, and who had time to devote to this endeavor, within the required time frame. Ideally a second, independent back-translation would be conducted for critical comparison (Brislin, 1970; Jones 2001; Herdman, 1998).

Group Discussion

Upon completion of the back-translation, the pretest version was then reviewed by the research team and checked for accuracy, meaning, clarity, equivalency, and cultural appropriateness for the target. Any minor edits were made at this time.

Expert Panel Review

To validate cross-cultural equivalence, and contribute to establishing face and content validity, a panel of bilingual experts was invited to review the English language version of the instrument (see Appendix F). The panel comprised six bilingual Saudi heads of division in the Department of Oncology at KAMC-R. All but one of the panel were specialist physicians, board-certified in North America. A self-administered questionnaire was designed, for completion by each panel member. Each expert was given the questionnaire (see Appendix G), and copies of the pretest instrument (see Appendix H), and asked to complete and return the questionnaire to the Principal Investigator, within seven working days. The instrument was an open-ended questionnaire, designed to elicit their views and to provide feedback on the content; format; cultural and functional equivalence of item translation; sequence of items within the scales; and the response choices for the items. The panel was asked to identify discrepancies indicative of ambiguous wording within the original survey or other problems oncologist, and a co-investigator, an experienced palliative care physician. Both versions of the instrument were revised to reflect the findings of the expert panel review recommendations.

Comments and suggestions were also informally sought from a wide variety of health care professionals regarding domains and items to be included in the instrument. These included local and international colleagues in the fields of medicine, nursing, social services, clinical psychology and members of the KAMC-R academic community.

Research Coordinators

Research Coordinators (RCs) were selected from KAMC-R Department of Oncology staff. Selection criteria included the following: fluency in English and Arabic; have worked with oncology patients for at least one year; have direct patient contact on a daily basis; and have an active interest in participating in palliative care research.

The RCs were asked to read and review the materials and make notes of any questions prior to the training session. The 3-hour session was conducted by a lecturer from the KAIMRC, who had previous experience in training survey administrators. The training included: didactic sessions and discussions regarding the purpose of the study; background and theoretical aspects of the survey instrument and the translation process; and a trial interview, using the Arabic version of the assessment instrument. All coordinators completed the IRB certification in research involving human subjects.

The training session comprised a group review of the instrument, led by the trainer, discussing the format, item content and response options and how to respond to questions from respondents. Emphasis was placed on standardization of the instrument administration and the importance of avoiding individual RC bias through subjective interaction and responses.

Each RC was given a set of folders, each containing the survey instrument, two copies of the consent form, and screening tools. A sequential ID number was assigned to each respondent by the RC, according to the sequence of the date/time of the first meeting with the respondent.

Timeline and Duration

This study was conducted in four phases, as diagrammed in Figure 6. It was originally anticipated that the study would be completed in less than 12 months and, therefore, no IRB renewal would be necessary. However, obtaining expedited approval from SANGHA IRB, including minor instrument modifications, took longer than expected. Recruiting subjects for the pretest also took considerably longer than planned. In total, recruitment of 25 subjects took 94 days, from April 12, 2009, to July 14, 2009, as opposed to the estimated 30 to 60 days. Recruitment of the 50 pilot enrollees took 6 months, from late December 2009, to June 2010. These two significant delays caused major revisions to be made in the study timeline and to submission of requests for extensions to both University of Alabama at Birmingham (UAB) and SANGHA IRBs. These renewals were both received within a two-week time frame.

Sampling and Referral

A purposive sampling technique was utilized to recruit the 25 participants for the pretest and the 50 participants for the pilot study. Department of Oncology physicians were informed of the study by: a) Informing department section heads during a monthly section head meeting; b) presenting an overview of the study at the monthly oncology departmental meeting; c) sending a letter of invitation (see Appendix I), to each oncology physician, with the exception of pediatric hematology oncology physicians. Potential candidates were identified, and a referral form completed and signed by the physician (see Appendix J), who then notified the RC by telephone. All referrals were seen the same day, or within two working days of receipt of the referral form.

The purposive sampling strategy of maximum variation is used in this study, as the target population is small. This sampling technique will provide sufficient representation of the population to capture central themes or patterns across participant variations, e.g. age, gender, residence, and to provide sufficient understanding of the health care needs experienced by these patients, in this preliminary study.

In order to avoid selection bias, and minimize sampling error, each physician was requested to refer potential participants consecutively, as they were identified in the inpatient or clinic setting, until the recruitment goal of 50 participants was achieved. For the re-test, a subgroup of the test participants who consented to the retest, were retested (T2) between 7 and 28 days after the pilot interview (T1).

Screening Process

The RCs assessed each potential participant, to determine their physical and cognitive status, for inclusion in the study. Patients were screened using the previously described inclusion and exclusion criteria, and 2 screening tools, to determine physical and psychological competencies to participate in the study. The Eastern Cooperative Oncology Group (ECOG) performance status tool (see Appendix K) is an internationally recognized instrument in the public domain, designed “to assess how a patient's disease is progressing, assess how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis” (Oken et al., 1982).

Scores from 0 – 4 were utilized in screening patients referred to the study. A score of 5 indicated the patient was deceased, and therefore it was excluded from the measure. Studies have shown that ECOG scores are accurate predictors of treatment outcomes (Christodoulou, et al., 2007). Functional status is one of several factors playing a role in cancer patient management, including comorbidity and age-related phenomena, such as altered mental status and lower levels of social support (Gebbia, Galetta, & De Marinis, 2005). The 14-item, Mini-Mental State Exam tool (MMSE) (Hartford Institute for Geriatric Nursing, 1975; Kurlowicz & Wallace, 1999) to assess five areas of cognitive function (see Appendix L, English version, and Appendix M, Arabic version).

Recruitment rates were expected to be high, given the sampling technique and the fact that motivation of individuals to participate to benefit the health of others is an integral part of the Islamic faith. Conversely response rates and drop-out rates may be higher through death or decreasing physical or mental capacity, given participants' diagnosis.

Screen Failures

Candidates were screened for inclusion into Phase I, the pretest using two instruments: the ECOG instrument, for physical capability, and the MMSE for cognitive ability. The ECOG tool proved satisfactory; the research coordinators had no difficulty accurately assessing subjects, using the tool. Conversely, there were multiple problems associated with the MMSE, which requires basic literacy and numeracy skills and experience holding a writing instrument. The underlying problem identified in item number 24 of the pretest survey instrument (highest educational level achieved), was the low literacy levels of the study population; 25% having no schooling and 25% having had primary school education only.

When examining the effects of literacy on performance on the MMSE, Weiss and colleagues found that poor reading skills were associated with lower scores on the (Weiss, Reed, Kligman, & Abyad, 1995). Subsequently, after consultation with the study expert panel, it was determined that the MMSE would not be used as a screening tool for this study. Instead, a previously validated tool, the Six-Item Screener tool (See Appendix N) was utilized for the cognitive screening of candidates for the pilot study. This tool required no literacy or numeracy skills, but focused on memory and recall.

Consenting Process

Eligible participants were given an Arabic language copy of the "Open Letter to Study Participants and Informed Consent" form (see Appendix O, for the English version, and Appendix P, for the Arabic version), and were asked to sign the form. All questions were answered and explanations about the study given by the RC, prior to the participant signing the consent form. The consenting process was administered by the RC. A family member or close friend was permitted to be present during the consenting process, and both patient and those present were given the opportunity to ask any questions, or express any concerns about the study.

Participants were informed that the purpose of the survey was to help the researchers to develop a questionnaire, to be used with other patients in the future, to better understand what their needs are and to provide better services for all patients with cancer. They were also informed that there would be no direct health benefit to them, as a result of participation, but that others may benefit in the future.

Participant Compensation

Each patient referred to the study and consented was given 100 Saudi Riyals (SAR100), approximately 25 U.S. dollars, prior to screening in compensation for time spent and travel expenses, e.g., money for gas or taxi fare. Each was advised that they were under no obligation to return the money should they not be enrolled, or did not complete the study for any reason. One participant refused the compensation, saying it was his duty to participate to help others.

The use of the figure of SAR100 was considered to be an appropriate amount to compensate for time spent or cost of travel. The compensation was paid after written consent was given and prior to screening. Payment was unconditional, the candidate being informed. The practice of paying and receiving incentives for participating in research projects is acceptable in Saudi culture.

Data Entry

Data were entered by the PI in a Microsoft Office Excel spreadsheet (Version 7), as soon as possible after the interview was completed, usually within one week. Data were cleaned and missing data identified prior to analysis. All hard and soft copies were stored according to the study protocol, to preserve confidentiality of respondent data.

Statistical Analysis

When developing scales for a new instrument, items identified as potential measures of the construct may be pooled and principal components analysis conducted, to divide the items into separate factors (or scales) (Rainbird et al., 2005; Piggott, 2009; Emanuel et al., 2001). In contrast, items for the PCNA-EAV measure were allocated to pre-determined domain scales and sub-scales identified from previous studies, personal experience and expert opinion; thus factor analysis was not required. In addition, the number of subjects to be enrolled in the study was small (N = 50), and not considered large enough to conduct a reliable factor analysis. A generally accepted ratio of observations to items is 10:1 (Aday & Cornelius, 2006).

Cooperation Rate

Cooperation rates, rather than response rates, are used in this study (H.R. Foushee, personal communication, 16 October, 2010), to ensure that the results of the sample survey are representative of the population (Streiner & Norman, 2007; Aday & Cornelius, 2006). The method used for calculating cooperation rates in this study, is described in the *Standard Definitions Final Dispositions of Case Codes and Outcome Rates for Surveys*, published online, by the American Association for Public Opinion Research (2008). The minimum cooperation rate, (COOP1), used in each of the three phases of this study, is calculated using the "number of completed interviews (numerator), divided by the number of interviews (complete plus partial), plus the number of non-interviews that involve the identification of and contact with an *eligible* respondent (refusal and break-off, plus other" (p.36).

For this study, the following criteria apply:

- Patients referred to the study, were considered *potential* candidates, by the referring physician. The physicians did not screen the patient for inclusion/exclusion, except for nationality, age, and diagnosis.
- The RCs reviewed the referral form, discussed the referral with the physician, and checked that the patient met the inclusion/exclusion criteria.
- If the RC s were not able to meet the patient, for any reason, (i.e., patient was discharged before being seen by the RC), the patient could not be classified as eligible.
- The RCs screened the patients, using the ECOG functional screening tool, and the Six-item screening tool, for psychological capability.
- The patient was enrolled in the study when the inclusion/exclusion criteria were met, and the patient had signed the consent form.

Cooperation Rate Equation

$$\text{COOP1} = \frac{I}{(I + P) + R + O}$$

Non-Response Rates

Non-response bias occurs when a) the survey fails to obtain information from a sizeable number of sample members, and b) missing item responses have influenced conclusions about the variables of interest, either because participants refuse, or lack the ability to respond, or are not available to respond (Yu & Cooper, 1983; Statistics Canada, 2003). Non-response may lead to an increase in variance of observations, as a result of a reduction in the actual sample size. It is expected that unit non-response rates will be minimized, using the purposive sampling technique (Patton, 1990) (pp. 169-186).

Questionnaire design, including the length of the questionnaire, follow-up contacts and offering incentives or compensation, is shown to increase item response rates (Streiner & Norman, 2008; Aday & Cornelius, 2006). The PCNA-EAV has been designed to include those scales measuring the major domains of need (10 domains, 116 items), for this study population, whilst aiming to keep the burden of response and item non-responses to a minimum.

Reliability

Instrument reliability may be measured in a number of ways, including internal consistency; inter-rater reliability; test-retest reliability; split-half reliability; corrected item-total correlation; and parallel-forms reliability (Aday & Cornelius, 2006; Tabachnick & Fidell, 2007; Trochim, 2001). For the purpose of this study, internal consistency and test-retest reliability were considered appropriate and sufficient for assessment of scale and instrument reliability.

Internal Consistency

Internal consistency of the domains was assessed using Cronbach's coefficient alpha (Cronbach, 1951) with a cut-off level of 0.7. The literature indicates that this cut-off value is appropriate for the social sciences and where group level differences are being examined (Aday & Cornelius, 2007).

Test - Retest

The test-retest reliability coefficient was assessed using Pearson correlation coefficient, giving an estimate of the error of measurement likely to occur due to chance (Aday & Cornelius, 2006; Tabachnick & Fidell, 2007). Correlations between item responses on the first and second administrations were analyzed for stability of responses over time. Test-retest correlations of r =.70 were determined to be reliable.

Item scores were summed within each domain (summated score), and each summated score was subjected to two analyses: correlation analysis, one of the most frequently used reliability calculations, and the signed rank test. This non-parametric test was utilized in place of a t-test, as normal distribution of scores could not be assumed. Individual item scores have the potential for more measurement error; this is minimized when individual item scores are summed. In addition, individual item scores neither can cover the broad spectrum of responses, nor discriminate among all levels of an attribute as much as summed scores (S. Musaad, personal communication, August 3, 2010).

Validity

Face and content validity

An eight-member panel, comprising seven medical oncologists, hematologists and palliative care consultants, and the data manager in the department of oncology were approached to participate in reviewing the English and Arabic language versions of pretest instrument. Of specific interest were items which the panel considered to be culturally inappropriate, or of a sensitive nature, and which might be offensive, if used in this particular measure. They were also asked to recommend additional items or deletions of items which they considered not useful in measuring the construct of interest and to recommend changes in translation of words or phrases.

Survey Implementation

The pretest, pilot, and retest were administered, according to the study protocol, following the methodology described in this chapter. Issues encountered during the three survey administrations are discussed in chapter five.

Summary

To ensure accuracy of the PCNA-EAV, as a measure of health care and support needs, attention was paid to the translation process and methodology described in previous studies. There are inconsistencies regarding optimal methods, and number of steps to be taken in the translation process, to ensure accurate translation, adaptation, and cultural equivalency of new or existing instrument. (Brislin, 1970; Harkness, et al., 2003; Jones, et al., 2001). The model developed for this study extended previous models, and followed recommended guidelines in the translation process. Some of the translation recommendations were omitted, due to time and resource limitations, and available expertise, in order to execute the necessary steps in a consistent and reliable manner.

The methodology employed in the process of developing the new instrument and implementing the survey, was grounded in the holistic approach to patient need, to include population-specific, socio-economic and religious/spiritual domains, and on prior work by colleagues in the field of palliative care and cancer care, as described in Table 3. The instruments developed in many of these studies were for use as clinical screening tools, not as a means of identifying community needs. The PCNA-EAV was developed as a population-based, culturally specific instrument, with the ultimate goal of providing evidence-based data for program development.

CHAPTER 4

RESULTS

Introduction

Chapter four presents the results of the PCNA-EAV analysis. In the first section, the 3 research questions are re-stated, and the issue of missing data is discussed. The second section presents the results of the pretest data analysis. Section three presents the principal findings of the pilot and retest data analysis, including reliability and validity testing, and the proportion of item responses in each scale, and results of the reported overall burden of participation in the survey. Section four summarizes the data analysis results.

Research Questions

The current study aims to shed light on three research questions: a) Does the PCNA-EAV demonstrate reliability as an instrument to measure the health care and support needs of patients with advanced cancer?; b) Does the PCNA-EAV demonstrate validity as an instrument to measure the health care and support needs of patients with advanced cancer?; c) What is the association between health care and support needs and respondent characteristics? Based on these three questions, eight primary hypotheses were developed and empirically tested.

Expert Panel Review

The data obtained from the expert panel, self-administered questionnaire and subsequent individual panel member interviews, were examined and summarized, (see Appendix Q) to determine face and content validity. The data manager recommended that the response categories for level of education, be increased from 3 levels, to 5 levels, and monthly household income be increased to 5 levels, to reflect the categories used in the KAMC-R cancer registry (S. Young, personal communication, April 17, 2009).

Comments were made by several of the expert panel that care should be taken to ensure the correct form (suffixes) of masculine and feminine nouns were used. In addition, one suggestion was to include separate questions for “How many children do you have?” i.e., one question for the number of boys, and a second question for the number of girls. Group consensus was that this was unnecessary. A recommendation was made to correct the translation of the word “hospitalization. A few minor corrections were necessary for spelling mistakes, which possibly occurred when some changes to the format were being made, by a secretary who did not have the necessary bilingual expertise to notice the errors.

There were no recommendations by the panel for additional domains or items to be included in the measure. There was a consensus that the instrument introduction was easily understood, as were the scale and sub-scale introductions. All were deemed culturally appropriate for the target population. Based on the small number of revisions recommended, it was determined that one round of expert interviews was sufficient and the recommended pretest instrument modifications made. Both versions of the instrument were revised to reflect the findings of the expert panel review recommendations. A consensus was reached by the research group that the instrument demonstrated face and content validity and was ready for use in the pretest phase of the study.

Pretest Results

The main purpose of the pretest was to determine, from a qualitative perspective, the ease with which respondents were able to understand each item in the PCNA-EAV; if each item intended meaning was understood and interpreted the same way, by all respondents, and that they were able, and willing, to respond to all items (Collins, 2003). Cultural relevance, and sensitivity of language, and content are essential to yield accurate data and minimize response error. Qualitative data were elicited from two sources; the findings of the pretest and the Saudi expert panel review.

Missing Data

The pretest data were examined to determine the frequency of missing data, and whether the occurrence of missing data was random or systematic. The frequency of missing data was minimal, and only for some, but not all, cases, and some, but not all, variables. The assumption is made that the data are missing completely at random (MCAR) (Allison, 2009). Those observations with missing data were excluded from the analysis, using listwise deletion of missing data. These analyses were conducted, using the SAS *proc corr* statement, with the *nomiss* option, deleting the entire observation from the analysis.

Referrals and Screening

A total of 39 patients were referred to pretest phase of the study (see Table 6). Twenty-nine of the patients referred, met the eligibility inclusion and exclusion criteria. Of these 29 candidates, 3 were screened out, due to psychological impairment, and one failed to show for the interview. 25 successfully achieved a satisfactory grade of =<4 on the ECOG, and a score of =>17, out of a total of 26, on the MMSE psychological screening tool.

Table 6

Pretest Recruitment, Screening, and Enrollment

	Freq.	% of Total Referred
Referred	39	100
Refused	1	2.6
Discharged prior to RC visit	2	5.11
Ineligible	5	12.8
Screened	31	79.5
Failed MMSE	3	7.7
Eligible	**28**	**71.8**
No show	1	2.6
Enrolled	27	69.2
Self-withdrew	2	5.1
Completed Interview	25	64.1

Non-Response Rates

Of the 28 patients eligible for the pretest, 25 (64.1%) completed the interview (see Table 7). Two (5.1%) self-withdrew, one because of fatigue, having answered four questions (partial completion), and one decided not to participate, with no specific reason given. A third patient (2.5%) did not keep the appointment for the interview, and could not be contacted by telephone.

There was no major difference in demographic and clinical characteristics, between those who completed the pretest, and those who did not. The average age of the 14 non-respondents was 43.9 years; 9 (64 %) were female; and 8 (57 %) had a diagnosis of breast cancer.

Duration of Interviews

The time taken to complete the pretest interview, was not documented for five (19%) of the respondents. For those whose time was documented, the average time taken to complete the interview was 40 minutes. The minimum time taken was 20 minutes, and the maximum time was 130 minutes.

Cooperation Rate

$$\text{COOP1} = \frac{I}{(I + P) + R + O}$$

$$\text{Pretest COOP1} = \frac{\text{25 completed the interview}}{\text{(25 complete +1 partial) + (1 no-show, post consent)} \\ \text{+ (1 self-withdrawal)}}$$

$$\text{Pretest COOP1} = \frac{25}{28} = 0.892 = 89\%$$

Pretest Data Analysis

Participant Characteristics

Demographic and clinical characteristics of the pretest respondents were assessed, using frequencies and percentages for categorical variables (see Table 8 and Table 9), and means, standard deviations, and medians for continuous variables (see Table 10). A total of 25 individuals were enrolled in the pretest. The mean age of pretest participants was 46 years, ranging from 19 to 79 years. A gender bias was shown in the number of pretest participants recruited. Eighteen (72%) of pretest participants were female. At KAMC-R, the gender of all new cases is approximately equal. In addition, of those enrolled in the pretest, 12 (48%) had a diagnosis of breast cancer, which was overly representative of the target population. At KAMC-R, approximately 25% of all new cancer cases, during years 2006 through 2008, had a diagnosis of breast cancer (ICD-9, Code 174.9) (Cancer Registry, KAMC-R, 2009).

Table 7

Demographic Characteristics of Pretest Sample

Categorical Variable	Freq	%
Gender		
Male	6	28
Female	19	72
Location of residence		
Riyadh	16	64
Outside Riyadh	9	36
Location of residence while receiving treatment		
Riyadh	16	64
Outside Riyadh	2	8
Missing	7	28
Age		
18-29 years	2	8
30-39	6	24
40-49	8	32
50-59	6	24
60-69	2	8
70+	1	4
Marital status		
Married	18	72
Widowed	2	8
Divorced	2	8
Separated	0	0
Never Married	3	12

Note. *N* = 25.

(continued)

Table 7 (continued)

Demographic Characteristics of Pretest Sample

Categorical Variable	Freq	%
Number of children		
None	2	8
One to three	2	8
Four to six	2	8
Seven to nine	2	8
Ten to twelve	14	56
More than twelve	0	0
Not applicable (Never married)	3	12
Number of children living with respondent		
None	1	4
One to Three	2	8
Four to Six	4	16
Seven to Nine	2	8
Ten to Twelve	12	48
More than Twelve	0	0
Not applicable	4	16
Educational level		
No formal schooling	7	28
Primary school	7	28
Elementary school	6	24
High school	4	16
College graduate	1	4
Post-graduate	0	0
Average monthly household income		
Less than 2,000 Riyals	1	4
2,000 – 4,999 Riyals	5	20
5,000 to 10,000 Riyals	4	16
More than 10,000 Riyals	5	20
Not sure/Unknown	9	36
Prefer not to answer	1	4
Missing	0	0

Note. *N* = 25.

Table 8

Clinical Characteristics of Pretest Sample

Categorical Variable	Frequency	%
Interview Setting		
Inpatient	6	24
Clinic	18	72
Other	1	4
Referring Division		
Adult Medical Oncology	23	92
Adult Hematology	1	4
Palliative Care	1	4
ECOG Score		
0	10	40
1	3	12
2	4	16
3	6	24
4	2	8
Diagnosis		
Breast	12	48
Lung	2	8
Liver	4	16
Other	7	28
Co morbidity (Not mutually exclusive)		
High Blood Pressure	11	22
Heart disease	2	4
Diabetes	13	26
Kidney disease	2	4
Lung disease	1	2
Other	12	24
Type(s) of cancer treatment received		
Chemotherapy only	27	54
Chemotherapy +Other	18	36
Don’t Know	4	8
Missing	1	2
Taken tribal/traditional remedies for treatment of cancer	23	92

Note. *N* = 25.

Table 9

Continuous Measures of Pretest Sample

Measure	N	Mean	SD	Min	Max
Age	27	45.6	12.05	20	79
Duration between referral & screening dates (Days)	27	1.2	9.43	1	5
Duration of interview (Minutes)	20	39.8	24.09	20	130
MMSE score (Out of 30)	27	20.8	3.05	15	25

Note. *N* = 25.

Pretest Reliability

Internal Consistency

Internal consistency of the scales and subscales (see Table 10) was assessed, using Cronbach's coefficient alpha (Cronbach, 1951), with a cut-off value of =>0.7 as being significant (Aday, & Cornelius, 2007).

Results of the test for internal consistency of the pretest scales were mixed. Eight of the 16 PCNA-EAV scales and subscale estimates of reliability (Cronbach's alpha) were acceptable to excellent, ranging from (α=0.74) (Physical symptoms), to (α=0.91) (All physical scale). Three of the reliability estimates were borderline acceptable, ranging from (α=0.65) (Priority of needs) to (α=0.69) (Communication). The remaining 5 estimates ranged from (α=0.07) (Preference for setting of Care) to (α= 0.59) (Information), which were unacceptable to questionable.

Table 10

Internal Consistency: Pretest Cronbach's Coefficient Alpha

Scale	No. Items	α
Physical	24	.91**
Symptoms	11	.74**
ADL	7	.96**
IADL	6	.85**
Psychological	14	.68*
Self-efficacy	5	.47
Anxiety/depression	5	.47
Cognition	4	.82**
Social	4	.90**
Information	6	.59
Helpful resources	7	.39
Communication	4	.69*
Religious	5	.23
Financial	3	.88**
Needs priority	9	.65*
Preference for setting of care	3	.07
Total items	117	

Note. a = Cronbach's alpha coefficient: **α = >.7-.9 Good to excellent; *α =>.6-<.7 Borderline; α =.5<.6 Questionable: α<.5 Unacceptable (Gliem & Gliem, 2003).

Pilot Phase

Subsequent to the pretest, a number of modifications were required to the study protocol (see Appendix R), and to the PCNA-EAV pretest instrument, (see Appendix S), in preparation for implementing the pilot phase of the study, using the revised version of the measure (see Appendix T). These modifications were submitted for IRB approval.

Pilot Modifications: IRB Approval

The pilot was implemented in December, 2009, once IRB approval for modifications to the protocol documents was received, from the University of Alabama at Birmingham (UAB) on 27 October, 2009, and from the Saudi Arabian National Guard Health Affairs

(SANGHA), on 17 November, 2009. The pilot survey was conducted over a 5-month period, from the end of December, 2009, to the middle of May, 2010.

Recruitment, Screening, and Enrollment

A total of 105 patients were referred to pilot phase of the study (see Table 11). The same referral process, as for the pretest, was used to recruit patients. Fourteen (13.3%) patients, or their family members, refused permission for the patient to participate in the survey. At least 5 of the refusals were known to be by family members, stating the patient did not know his/her diagnosis. Two patients (1.9%) were discharged the same day the referral was written, not giving the RC time to meet with them. Eleven (10.5%) of patients did not meet eligibility criteria, as they had not been told their diagnosis. One of these was also ineligible, because he was non-Saudi. Five of the 60 patients screened for physical capability failed, due to sub-optimal physical status, and 5 were ineligible, due to confusion of decreased mental status.

Table 11

Proportion (%) Pilot Recruitment, Screening, and Enrollment

	Freq	% of Total Referred
Referred	105	100.0
Refused	14	13.3
Discharged prior to RC visit	2	1.9
Ineligible	11	10.5
Screened	60	57.1
Failed Six-item screening	5	4.8
Failed ECOG	5	4.8
Eligible	50	48
Enrolled	50	48
Completed Interview	50	48

Note. N = 50.

Fifty candidates successfully achieved a satisfactory grade of =<4 on the ECOG physical screening tool, and a score of =>4, out of a total of 7, on the Six-item psychological screening tool. All 50 candidates were enrolled in the study. No respondents self-withdrew, or were withdrawn by the RCs.

Cooperation Rate

A total of 50 subjects were enrolled in the pilot study, out of the 50 eligible candidates, giving a cooperation rate, as follows:

$$\text{Pilot COOP1} = \frac{\text{50 completed the interview}}{\text{50 eligible}}$$

$$\text{Pilot COOP1} = \frac{50}{50} = 100\%$$

This cooperation rate was highly satisfactory, given the target population was patients with advanced cancer, who potentially could have dropped out, due to deterioration in physical or psychological status. All 50 respondents completed the interview.

Pilot non-respondent characteristics

Fifty-five (52.4%) of the 105 patients referred to the pilot study, were classified as non-respondents. Their average age was 53 years, with a minimum age of 15 years, and maximum of 80 years. Thirty-three (60%) of the non-respondents were male. The major non-respondent diagnoses were breast (16.4%), colon (18.8%), GU (14.6%) and lung (12.7%). Other diagnoses accounted for the remaining 38.3%. Lymphoma patients, referred by the division of hematology, accounted for 5.5% of total referrals to the pilot study. All other referrals came from the division of adult medical oncology. Respondents and non-respondents were similar in age, gender, location of residence, and diagnoses.

Pilot Data Analysis

Descriptive Statistics

Descriptive statistics were analyzed to determine frequencies, and normality of distribution of the demographic characteristics of the respondents (Table13 and Table 14).

Duration of Interview

The time taken to complete the pilot interview was not documented for 2 of the respondents. For the 48 whose time was documented, the average time taken to complete the interview was 41 minutes, similar to the pretest time. The minimum time taken was 19 minutes, and maximum time 90 minutes.

Pilot Participant Characteristics

A total of 50 individuals were enrolled in the pilot study. The mean age of participants was 46 years, ranging from 19 to 79 years. Thirty (60%) of pilot participants were female. Eleven (22%) of the respondents had received no formal schooling, and a further 13 (26%) had primary school education only.

Table 12

Demographic Characteristics of Pilot Sample (T1)

Characteristics	Freq	%
Gender		
Male	20	40
Female	30	60
Location of residence		
Riyadh	27	54
Outside Riyadh	23	46
Location of residence while receiving treatment		
Riyadh	41	82
Outside Riyadh	9	18
Missing	0	0
Age		
18-29 years	3	6
30-39	9	18
40-49	15	30
50-59	10	20
60-69	9	18
70+	4	8
Marital status		
Married	42	84
Widowed	4	8
Divorced	2	4
Separated	0	0
Never Married	2	4
Number of wives		
One	11	22
Two	4	8
Three	1	2
Four	1	2
Not applicable (Female, or not married)	33	66
Number of other wives husband has		
None	17	34
One	5	10
Two	1	2
Three	1	2
Not applicable	26	52

Note. *N*= 50.

(continued)

Table 12 (continued)

Demographic Characteristics of Pilot Sample (T 1)

Characteristics	Freq	%
Number of children		
None	1	2
One to Three	11	22
Four to Six	17	34
Seven to Nine	12	24
Ten to Twelve	5	10
More than Twelve	2	4
Not applicable	2	4
Number of children living with respondent		
None	2	4
One to Three	15	30
Four to Six	22	44
Seven to Nine	7	14
Ten to Twelve	1	2
More than Twelve	0	0
Not applicable	3	6
Educational level		
No formal schooling	11	22
Primary school	13	26
Elementary school	5	10
High school	7	14
College graduate	9	18
Post-graduate	5	10
Current employment status		
Currently self-employed	4	8
Currently government employee	5	10
Unable to work due to illness	9	18
Retired	7	14
Never worked	19	38
Missing	5	10
Average monthly household income		
Less than 2,000 Riyals	2	4
2,000 – 4,999 Riyals	11	22
5,000 to 10,000 Riyals	6	12
More than 10,000 Riyals	9	18
Not sure/Unknown	12	24
Prefer not to answer	4	8
Missing	6	12

Note. *N*= 50.

Table 13

Clinical Characteristics of Pilot Sample (T 1)

Characteristics	Frequency	%
Interview Setting		
Inpatient	13	26
Clinic	28	56
Other	9	18
Referring Division		
Adult Medical Oncology	41	82
Adult Hematology	9	18
Palliative Care	0	0
ECOG Score		
0	28	56
1	10	20
2	4	8
3	5	10
4	3	6
Diagnosis		
Breast	14	28
Lung	4	8
Liver	5	10
GI	3	6
GU	1	2
Lymphoma	9	18
Colon	9	18
Other	5	10
Comorbidity		
High Blood Pressure	1	2
Heart disease	15	30
Diabetes	13	26
Kidney disease	2	4
Lung disease	0	0
Other	8	16
Type(s) of cancer treatment received		
Chemotherapy	43	64
Radiation Therapy	3	6
Surgery	4	8
Hormonal Therapy	2	4
Don’t Know	4	8
Taken tribal/traditional remedies for treatment of cancer	34	64

Note. N = 50.

Table 14

Continuous Measures of Pilot Sample

Continuous Variable	N	Mean	SD	Min	Max
Age	50	49.1	13.34	20	74
Duration between referral & screening dates (Days)	50	1.0	0.51	0	4
Duration of interview (Minutes)	50	39.8	15.45	17	90
Six-item cognitive screening tool (Score out of 7 total)	50	5.9	1.05	4	7

Note. N= 50.

Results of the clinical characteristics showed, of those enrolled in the pilot study, 14 (28%) had a diagnosis of breast cancer, which was representative of the target population. At KAMC-R, approximately 25% of all new cancer cases, during years 2006 through 2008, had a diagnosis of breast cancer (ICD-9, Code 174.9) (Cancer Registry, KAMC-R, 2009).

Item Responses

Item responses were examined to identify differences in levels of reported need in the 10 domains, as shown in table 15.

Missing Responses

The scales with the highest proportion of missing item responses were the physical symptoms scale, the ADL scale, and the helpful resources scale. Within the physical symptoms scale, each of the 2 items addressing sexual dysfunction (9j), and decreased sexual desires (9k), were missing 8 (16%) responses. The ADL scale showed there were at least 2 (4%) missing responses for each of the 8 items, and at least 2 missing responses for the 6 items on the helpful resources scale.

Table 15

Percentage of Pilot Item Responses

Item	Percentage Response Options					
Over last four weeks, I have needed help with:						
Physical – Symptoms	*SA	A	N	D	SD	M/U
9a Severe pain	**48**	**24**	2	12	14	-
9b Difficulty breathing	8	14	2	40	36	-
9c Fatigue	**36**	**32**	8	16	8	-
9d Lack of sleep	**18**	**30**	4	32	16	-
9e Nausea/vomiting	14	34	6	24	20	2
9f Poor appetite	**24**	**38**	-	16	22	-
9g Eating/swallowing	6	16	-	50	26	2
9h Constipation/diarrhea	**20**	**34**	-	26	20	-
9i Bladder problems	4	18	2	42	34	-
9j Sexual dysfunction	**10**	**18**	14	26	16	**16**
9k Decreased sexual desires	**10**	**20**	14	26	14	**16**
Physical - ADL	**A	Mo	Mu	S	N	M/U
10a Getting out of bed	**12**	**2**	**4**	14	62	6
10b Bathing/showering	**10**	**6**	**2**	8	70	4
10c Getting out of bed	8	2	4	10	72	4
10d Getting dressed	8	8	2	18	60	4
10e Walking more than 10 steps	**14**	**4**	**8**	18	52	4
10f Going up stairs	14	-	2	6	74	4
10g Performing wudu	12	2	2	10	68	6
10h Performing salah	-	-	-	-	-	-
Physical - IADL	A	Mo	Mu	S	N	M/U
11a Household chores/maintenance	**40**	**4**	**6**	12	38	-
11b Shopping	**34**	**6**	**10**	14	34	2
11c Transportation	**30**	**10**	**8**	24	26	2
11d Taking medications	**22**	**4**	**8**	8	58	-
11 e Childcare	16	8	-	8	42	26

Note. *N*= 50.
*SA = strongly agree; A = agree; N = neither agree nor disagree; D = disagree; SD =strongly disagree; MU = missing/unknown.
** A=all of the time; Mo=most of the time; Mu=much of the time; S= some of the time; N = never.

(continued)

Table 15 (continued)

Percentage of Pilot Item Responses

Item	Percentage Response Options						
Over the last four weeks, I have:							
Psychological – Self-efficacy	**A**	**Mo**	**Mu**	**S**	**N**	**M/U**	**-**
12a Felt confident I can cope with illness	68	6	8	14	4	-	-
12b Felt I can make own decisions about healthcare	62	6	16	14	2	-	-
12c Felt cannot manage my life	**30**	**8**	16	18	26	2	-
12d Felt confident I can continue my usual work	38	10	14	**20**	**18**	-	-
12e Felt confident I can continue to take care of dependents	50	12	6	20	10	2	-
Psychological – Anxiety/depression							
Over last four weeks:	****N**	**S**	**Mu**	**Mo**	**A**	**M/U**	**PTNA**
13a I looked forward to beginning each new day	2	20	10	6	62	-	-
32b I felt guilty that I may be a burden on my family	48	18	**6**	**8**	**18**	2	-
13c I felt I am valued by those close to me	2	-	18	6	72	2	-
13d I feel I have no purpose in life because of my cancer	70	12	-	6	10	2	-
13e I felt fearful about my future	62	22	4	2	10	-	-
Psychological – Cognition						-	-
14a I have had trouble understanding new information	60	16	**6**	**8**	**8**	2	-
14b I have had difficulty concentrating on simple tasks	72	14	6	4	4	-	-
14c I have had difficulty taking decisions	64	24	4	2	6	-	-
14d I have been easily confused	54	30	6	6	4	-	-
14e I have had difficulty remembering what my doctor has told me about my illness	58	30	4	6	2	-	-
Social Relationships							
Over the last four weeks	****SD**	**D**	**N**	**A**	**SA**	**M/U**	**PNTA**
15a My illness has strengthened my relationship with my spouse	**4**	**4**	16	18	42	-	**16**
15b My spouse is very supportive of me	**4**	**4**	12	24	40	-	**16**
15c My relatives are very supportive of me	-	-	10	12	76	-	2
15d My friends are very supportive of me	-	2	12	16	68	-	2
15e I find friends and family are not comfortable talking with me about my illness	10	26	12	**20**	**30**	-	2
15f I find it difficult to talk about my illness, because of not wanting to burden others	16	24	8	**30**	**20**	-	2
15g I found hospital staff sensitive to my feelings and emotional needs	-	-	8	**50**	**42**	-	-

Note. *N = never; S = some of the time; Mu = much of the time; Mo = most of the time; A = all of the time; MU = missing/unknown; PTNA = prefer not to answer.
** SD = strongly disagree; D=disagree; N=neutral; A=agree; SA=strongly agree.

(continued)

Table 15 (continued)

Percentage of Pilot Item Responses

Item	Percentage Response Options					
Information	**SD**	**D**	**N**	**A**	**SA**	**M/U**
16a I need more information about my cancer	22	10	2	**34**	**32**	-
16b I have been told all I want to know about my cancer	4	16	12	**48**	**20**	-
16c My oncologist makes sure my family has up-to-date information about my care and the choices available to me	4	18	14	48	16	-
16d My oncologist has given me clear information about what to expect regarding my illness and outlook for the future	6	20	12	**34**	**28**	-
16e I need more information about therapeutic options available to keep me pain-free and comfortable	12	16	8	**34**	**30**	-
16f I have been given all the information I need to take care of myself	6	12	6	54	22	-
16g My family members have been given all the information they need to take care of me	6	10	14	50	20	-
Helpful Resources	***N**	**S**	**Mu**	**Mo**	**A**	**M/U**
17a Medical staff	6	14	12	**12**	**54**	2
17b Nursing staff	32	18	8	**14**	**22**	6
17c Other hospital staff	30	20	10	**10**	**24**	6
17d The media (television, newspapers)	**48**	**28**	8	6	6	4
17e Printed information (Brochures, pamphlets)	**48**	**28**	6	12	4	2
17f Internet websites	**60**	**12**	8	6	12	2
Professional Communication	****SD**	**D**	**N**	**A**	**SA**	**M/U**
18a My doctor takes time to answer all my questions	6	14	8	**24**	**48**	-
18b My doctor shows interest in me as a person	4	6	6	**28**	**56**	-
18c I prefer my doctor makes all my medical decisions for me	8	28	8	**20**	**36**	-
18d My doctor has explained clearly to me about the physical problems I may face	2	16	2	**38**	**40**	2
18e I prefer my doctor discusses the details of my illness only with me	20	28	2	28	20	2
18f My nurses understand me when I talk to them	6	8	8	62	14	2
18g There is always an interpreter present to translate, if needed	**10**	**16**	24	32	10	8
18h I have felt the need to have one member of hospital staff with whom I could talk about all aspects of my illness	24	26	4	**24**	**22**	-

Note. *N = never; = some of the time; M = much of the time; Mo = most of the time; A = all of the time; M/U=missing or unknown.
** SD = strongly disagree; D=disagree; N=neutral; A=agree; SA=strongly agree.

(continued)

Table 15 (continued)

Percentage of Pilot Item Responses

Item	Percentage Response Options					
Religious/spiritual	**SD**	**D**	**N**	**A**	**SA**	**M/U**
19a I believe that my suffering is a test of my faith	2		4	**24**	**70**	-
19b I question what I have done to deserve this disease	44	26	10	8	12	-
19c I believe an evil eye affected me	8	12	30	**28**	**22**	-
19d I need the guidance of a religious counselor	8	20	4	**48**	**20**	-
19e I believe my illness is a punishment from Allah	32	32	10	**22**	**4**	-
19f My religious needs are being supported by the hospital staff	**18**	**22**	20	32	4	4
19g I am afraid of the day of judgment	22	8	4	34	32	-
19h I need a religious counselor to read the Holy Quran to me	8	24	2	44	22	-
19i Allah will wash away my sins because of this illness	-	-	2	50	48	-
19j I am losing hope that my cancer will be cured	**42**	**30**	10	4	14	-
Priority of Needs	***E**	**I**	**N**	**NV**	**NA**	**M/U**
20a To see a specialist to manage my pain	**46**	**16**	2	2	34	-
20b To have assistance with bathing/dressing	**18**	**16**	-	12	54	-
20c To have help to move about more easily	**28**	**14**	-	12	46	-
20d To have help with my emotional problems	**26**	**20**	-	14	40	-
20e To receive more information about my cancer treatment	**38**	**24**	4	8	26	-
20f To receive religious counseling	**38**	**24**	6	4	26	2
20g To get help with transportation	**44**	**20**	2	6	28	-
20h To have help with childcare	**28**	**12**	-	2	36	22 N/A
Financial	***A**	**Mo**	**Mu**	**S**	**N**	**M/U**
21a I have had difficulty paying my household bills	2	4	4	14	74	2
21b My illness has been a financial hardship on my family	6	6	6	10	72	-
21c My household income has significantly decreased because of my illness	6	6	-	10	76	2
Setting of Care	****SD**	**D**	**N**	**A**	**SA**	**M/U**
22a I prefer that my family take care of me at home, if I can no longer take care of myself	10	14	10	**28**	**36**	2
22b I prefer to be in the hospital, if I can no longer take care of myself	16	22	8	**30**	**22**	2
22c I have concerns about my family's ability to take care of me	16	38	12	**24**	**8**	2
22d I prefer my family decide where I will be cared for, if I can no longer take care of myself	**16**	**38**	10	28	6	2

Note. *E = extremely important; I = important: N = neutral; NV = not very important; NA = not at all. important; M/U=missing or unknown.
** A = all of the time; Mo = most of the time; Mu = much of the time; S = some of the time; N = never.
*** SD = strongly disagree; D = disagree; N = neutral; A = agree; SA = strongly agree.

Hypothesis Testing

RQI: Does the PCNA-EAV demonstrate reliability as an instrument to measure the health care and support needs of patients with advanced cancer?

H1: *The PCNA-EAV instrument demonstrates reliability as a measure for assessing the health care and support needs of adult patients with advanced cancer.*

The pilot data were tested for internal consistency, using Cronbach’s alpha, with an estimate value of =>0.7, to demonstrate internal consistency, i.e., that the items in the scale were measuring the same construct.

Internal Consistency

Results of the test for internal consistency were mixed (see Table 16). Eight of the 16 PCNA-EAV scales and subscale estimates of reliability (Cronbach's alpha) were acceptable to excellent, ranging from (α=0.70) (Self-efficacy) to (α=0.91) (Priority of Needs). Four of the reliability estimates were borderline acceptable, ranging from (α=0.60) (Communication) to (α=0.68) (All Psychological scale). The remaining 4 estimates ranged from (α=0.01) (Anxiety/depression and Preference for Setting of Care) to (α= 0.58) (Information), which indicated unacceptable to questionable levels of reliability.

Table 16

Reliability: Pilot Internal Consistency

Scale	No. Items	α
Physical	23	.90**
Symptoms	11	.75**
ADL	7	.87**
IADL	5	.85**
Psychological	15	.68*
Self-efficacy	5	.70**
Anxiety/depression	5	.01
Cognition	5	.87**
Social	7	.63*
Information	7	.58
Helpful resources	6	.65*
Communication	8	.60*
Religious	10	.40
Financial	3	.83**
Priority of Needs	8	.91**
Preference for setting of care	4	.01

Note. α=Cronbach's alpha coefficient: **α= >.7-.9 Good to excellent; *α=>.6-<.7 Borderline; α=.5<.6 Questionable: α<.5 Unacceptable (Gliem & Gliem, 2003).

Test-Retest Reliability

The (T1) and retest (T2) data were tested for temporal stability, as shown in Table 17. Eleven of the 16 scales indicate instrument reliability over time (*p*=>.05), ranging from *r*(9)=.44, *p*=.17 (Information), to *r*(9)=.12, *p*=.72 (Anxiety/depression). The ADL scale indicated borderline reliability, *r*(9)=.62, *p*=.05. The remaining 4 scales, communication, *r*(9)=.77, *p*=.01; finance, *r*(9)=.70, *p*=.0 *r*(9)=.62, *p*=.052; priority of needs, *r*(9)=.67, *p*=.02; and preference for setting of care, *r*(9)=.94, *p*=.001, indicated there were significant differences between T1 and T2 for these scales.

Table 17

Test-Retest Reliability

			Pearson Correlation Coefficient (N = 11)			
Scale/Subscale	N	*df*	Mean (SD) T1	Mean (SD) T2	*r*	*P Value*
All Physical	11	9	55.56(17.38)	9.2(15.28	.30	.32
Symptoms	11	9	31.04(8.01)	13.45(180.82)	.33	.32
ADL	10	8	12.38(7.90)	26.27(6.05)	.62	.05
IADL	10	8	12.64(6.36)	10.80(6.21)	.36	.30
All Psychological	11	9	41.00(32.99)	3.56(12.69)	.28	.40
Self-efficacy	11	9	18.38(4.81)	18.72(3.04	.25	.46
Anxiety/depression	11	9	14.24(3.24)	13.72(2.57)	.12	.72
Cognitive	11	9	8.38(4.46)	7.64(3.32)	.23	.48
Social relationships	11	9	30.18(5.83)	28.00(5.35)	.28	.40
Information	11	9	21.16(4.37)	24.90(3.62)	.44	.17
Helpful resources	10	8	14.92(4.89)	12.72(3.93)	.18	.60
Communication	11	9	28.28(4.76)	26.90(4.04)	.77	.01
Religious	11	9	32.36(5.17)	32.37(5.71)	.37	.26
Finance	11	9	4.86(3.45)	5.45(3.53)	.70	.02
Priority of needs	11	9	23.66(10.45)	24.18(8.12)	.67	.02
Preference for setting of care	11	9	12.27(2.59)	12.90(2.74)	.94	.0001

Note. p<.05 (<.05 indicates the 2 groups are different).
r=>.6 considered appropriate cut-off point for this preliminary study.

Validity

RQ2: Does the PCNA-EAV demonstrate validity as an instrument to measure the health care and support needs of patients with advanced cancer?

H2: *The PCNA-EAV measure demonstrates validity as measure for assessment of the health care and support needs of adult patients with advanced cancer.*

Content Validity

Content validity, of both the English and translated Arabic version of the PCNA-EAV, was assessed by an expert panel of bilingual, Saudi oncology consultant physicians. It was also assessed by group discussion, before and after, any modification was made to the instrument. A consensus was reached, that the modified instrument was culturally appropriate and easily comprehensible for the target population.

Convergent Validity

Convergent validity was tested using 2 ordinal variables, *ECOG (ranked, interval, 0-4 scale), as a proxy for severity of disease, and reported physical symptoms, ADL, and IADL needs. Response options for the 23 items were presented using a 5-point, Likert scale, with response options strongly agree, to strongly disagree.

Results of the test for convergent validity were mixed. *P*-values indicate results are not significant (*p*.05). However, the trend indicates a positive association overall; as ECOG increases, (0-4), so reported physical need increases. A larger sample size may demonstrate significant convergent validity.

Predictive Validity

The PCNA-EAV was tested for predictive validity using the non-parametric Wilcoxon Scores (Rank Sums) and Kruskall-Wallis tests of association.

Table 18

Test for Convergent Validity

Wilcoxon Scores (Rank Sums) for Physical Variables Classified by Variable ECOG

Variable	ECOG	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score		P Value
Physical Symptoms	0	28	708.50	714.00	51.08	25.3	↓	.37
	1	10	265.50	255.00	41.16	26.55		
	2	4	54.00	102.00	27.92	13.50		
	3	5	142.00	127.50	30.87	28.40		
	4	3	105.00	76.50	24.44	35.00		
ADL	0	28	601.50	714.00	51.02	21.48	↓	.21
	1	10	281.00	255.00	41.12	28.10		
	2	4	116.50	102.00	27.89	29.12		
	3	5	165.50	127.50	30.84	33.10		
	4	3	110.50	76.50	24.41	36.83		
IADL	0	28	601.50	714.00	51.02	21.48	↓	.20
	1	10	281.00	255.00	41.12	28.10		
	2	4	116.50	102.00	27.89	29.13		
	3	5	165.50	127.50	30.84	33.10		
	4	0	-	-	-	-		

Note. $p<.05$

H3a: Males will report proportionately lower levels of psychological needs than females.

The predictor variable, gender, was tested for relationship with psychological subscales self-efficacy, anxiety/depression, and cognition, and the overall psychological scale, to determine differences between males and females in their reported levels of psychological needs (see Table 19).

Table 19

Test of Association between Gender and Psychological Needs

Wilcoxon Scores (Rank Sums) and Kruskall-Wallis Test Age (N = 50) Variable	Mean	Male	Female	*Sig.*
Psychological Total Summed Score	41.00	26.88	24.58	0.59
Self-efficacy	18.38	26.20	25.03	0.78
Anxiety/Depression	14.24	23.80	26.63	0.49
Cognition	8.38	27.88	23.92	0.34

Note. p<.05

The *p*-values for the psychological needs subscales, and for the summated scale, are not significant for differences between the two groups. We therefore conclude that there is no evidence that males and females differ in their level of psychological needs, in this sample.

H3b: Older patients (=> 50 years) will report proportionately higher levels of physical needs than younger patients (18 – 49 years).

Table 20

Test of Association between Age and Physical Needs for Hypothesis 3b

Wilcoxon Scores (Rank Sums) and Kruskall-Wallis Test Age (N = 50) Variable	Mean	18-49 Years	=>50 Years	*Sig*
Physical – Total Summed Score	55.56	26.02	24.94	0.79
Symptoms	31.04	26.00	24.96	0.80
ADL	12.38	26.28	22.57	0.34
IADL	12.64	26.21	24.73	0.72

Note. p<.05

Results indicate there is no difference between those ages =>50 years and those aged 18 to 49 years, in their level of reported physical needs, in this sample.

H3c: Patients who live in the city of Riyadh will report proportionately lower levels of physical needs than those who do not live in Riyadh.

Table 21

Test of Association between Location of Residence and Physical Needs

	Wilcoxen Scores (Rank Sums) and Kruskall-Wallis Test Location of Residence (N = 50)			
Variable	Mean	Riyadh	Not in Riyadh	**P* Value
Physical -Total Summed Scores	55.56	26.14	22.56	0.50
Symptoms	31.04	26.02	23.11	0.59
ADL	12.38	25.81	18.83	0.15
IADL	12.64	25.11	27.28	0.69

Note. $N = 50$

$p<.05$

Results show there is no evidence of difference in levels of physical need between those who live in Riyadh, and those who live outside Riyadh, in this sample.

Discriminant Validity

H3d: Patients with an ECOG score =<1 will report proportionately more physical needs than those patients with and ECOG score>1.

The non-parametric Kuskall-Wallis test was conducted, to determine differences between the ECOG classification groups (0 – 4) in reported levels of physical needs (see Table 23). The Kruskal-Wallis test is a non-parametric method frequently used for testing equality of population medians among groups, using rankings (ordinal data).

The discriminant validity of the PCNA-EAV was assessed using the Kruskal Wallis Chi square test to test for differences between the 5 ECOG group scores. It was hypothesized that reported levels of physical needs would differ significantly between the 5 groups.

Table 22

Test for Discriminant Validity between ECOG Groups

Scale/Subscale	Chi Square	df	*p*
All Physical Scale	9.37	4	**0.05**
Physical Symptoms	4.25	4	0.37
Physical ADL	12.06	4	**0.02**
Physical IADL	5.90	4	0.21

Note. p =<.05

These results indicate that the levels of physical ADL needs differed significantly between the 5 ECOG groups in the sample. The level of summed physical needs was borderline significant, at *p* = 0.05, differing marginally across the ECOG groups.

Retest Analysis

Cooperation Rate

Only 11 of respondents eligible to retake the interview actually consented to return for the second interview. All 11 completed the retest.

$$\text{Retest COOP1} = \frac{\text{11 completed the interview}}{\text{50 eligible}} =$$

$$\text{Retest COOP1} = \frac{11}{50} = 0.22 = 22\%$$

The majority of pilot participants had previously consented to take the retest, at the time of consenting to participate in the pilot study. However, when re-contacted to take the retest, most (88%) refused, on the grounds that they were "*taaban*" (a generic Arabic phrase that can mean feeling ill or tired). In addition, six respondents lived outside Riyadh, and stated it was too far to travel for the second interview.

Descriptive Statistics

Descriptive statistics were obtained on the retest demographic and clinical characteristics (see Table 23 and Table 24).

Table 23

Demographic Characteristics of Retest Sample(T2)

Characteristics	Freq	%
Gender		
Male	5	45
Female	6	55
Location of residence		
Riyadh	4	76
Outside Riyadh	7	24
Location of residence while receiving treatment		
Riyadh	7	64
Outside Riyadh	4	36
Missing	0	0
Age		
18-29 years	1	9
30-39	1	9
40-49	4	37
50-59	2	18
60-69	1	9
70+	2	18
Marital status		
Married	10	91
Widowed	0	0
Divorced	0	0
Separated	0	0
Never Married	1	9
Number of wives		
One	4	36
Two	0	0
Three	0	0
Four	0	0
Not applicable	7	64
Number of other wives husband has		
None	4	36
One	1	9
Two	1	9
Three	0	0
Not applicable	5	46

Note. *N*=1

(continued)

Table 23 (continued)

Demographic Characteristics of Retest Sample (T2)

Characteristics	Freq	%
Number of children		
None	0	0
One to Three	2	18
Four to Six	4	37
Seven to Nine	3	27
Ten to Twelve	1	9
More than Twelve	0	0
Not applicable	1	9
Number of children living with respondent		
None	0	0
One to Three	3	27
Four to Six	5	46
Seven to Nine	2	18
Ten to Twelve	0	0
More than Twelve	0	0
Not applicable	1	9
Educational level		
No formal schooling	3	27
Primary school	0	0
Elementary school	1	9
High school	4	37
College graduate	2	18
Post-graduate	1	9
Current employment status		
Self-employed	0	0
Government employee	2	18
Employed by private sector	1	9
Unable to work due to illness	4	37
Retired	2	18
Never worked	2	18
Missing	0	0

Note. N=11

(continued)

Table 23 (continued)

Demographic Characteristics Retest Sample (T2)

Characteristics	Freq	%
Average monthly household income		
Less than 2,000 Riyals	0	0
2,000 – 4,999 Riyals	2	18
5,000 to 10,000 Riyals	3	27.5
More than 10,000 Riyals	3	27.5
Not sure/Unknown	2	18
Prefer not to answer	1	9
Missing	0	0

Note. *N*=11

Table 24

Clinical Characteristics of Retest Sample (T2)

Characteristics	Frequency	%
Interview Setting		
Inpatient	1	9
Clinic	10	91
Other	0	0
Referring Division		
Adult Medical Oncology	8	73
Adult Hematology	3	27
Palliative Care	0	0
ECOG Score		
0	6	55
1	3	27
2	1	9
3	0	0
4	1	9
Diagnosis		
Breast	3	28
Lymphoma	3	28
Other	7	44
Comorbidity		
High Blood Pressure	2	18
Heart disease	2	18
Other	2	18
Type(s) of cancer treatment received		
Chemotherapy	11	100
Surgery	2	18
Taken tribal/traditional remedies for treatment of cancer	9	82

Note. *N*=1

Table 25

Continuous Measures of Retest Sample

Characteristic	Mean	SD	Min	Max
Age	49.9	-	20	74
Duration of interview (Minutes)	34,9	-	22	55
Six-item screening tool score (Out of 7)	6.8	-	6	7

Note. N=11

Inter-rater Reliability

Inter-rater reliability was not tested, as the retest number was small (*N*=11), and the same RC conducted 9 of the 11 retests.

Test-Retest Analysis

The time between instrument administrations, T1 and T2, ranged from 7 to 28 days, with a mean time of 9.6 days. Eleven participants (22% of the total pilot sample) completed the test-retest portion of the study.

An evaluation was made of the linear relationship between pilot (T1) and retest (T2) administrations of the PVNA-EAV measure, using Pearson's correlation coefficient with a *p* value of 0.05. In this preliminary analysis, a cut-off of *r*=0.6 for the correlation can be considered meaningful. The difference in means between T1 and T2 is also reported. Scatter plots were produced for each of the scales (see Appendix) to observe the distribution of observations, and the degree of linearity amongst observations.

Table 26

Test-retest Correlation (T1 and T2)

			Pearson Correlation Coefficient (N = 11)			
Scale/Subscales	N	*df*	Mean (SD) T1	Mean (SD) T2	*r*	*Sig.*
All Physical	11	9	55.56(17.38)	9.2(15.28	.30	.32
Symptoms	11	9	31.04(8.01)	13.45(180.82)	.33	.32
ADL	10	8	12.38(7.90)	26.27(6.05)	.62	.05*
IADL	10	8	12.64(6.36)	10.80(6.21)	.36	.30
All Psychological	11	9	41.00(32.99)	3.56(12.69)	.28	.40
Self-efficacy	11	9	18.38(4.81)	18.72(3.04)	.25	.46
Anxiety/depression	11	9	14.24(3.24)	13.72(2.57)	.12	.72
Cognitive	11	9	8.38(4.46)	7.64(3.32)	.23	.48
Social relationships	11	9	30.18(5.83)	28.00(5.35)	.28	.40
Information	11	9	21.16(4.37)	24.90(3.62)	.44	.17
Helpful resources	10	8	14.92(4.89)	12.72(3.93)	.18	.60
Communication	11	9	28.28(4.76)	26.90(4.04)	.77	.01*
Religious	11	9	32.36(5.17)	32.37(5.71)	.37	.26
Finance	11	9	4.86(3.45)	5.45(3.53)	.70	.02*
Priority of needs	11	9	23.66(10.45)	24.18(8.12)	.67	.02*
Preference for setting of care	11	9	12.27(2.59)	12.90(2.74)	.94	.0001*

Note. p=<.05
*Indicates no relationship

Results of the correlation analysis indicate statistically significant differences between T1 and T2, in five of the scales: ADL $r(8)=.62$, $p=.05$, communication $r(9)=.77$, $p<.05$) , finance $r(9)=.70$, $p<.05$), priority of needs $r(9)=.67$, $p<.05$, and preference for setting of care $r(9)=.94$, $p=.0001$. For the remaining scales, results indicate there is no significant relationship between the two administrations, therefore conclude that, overall the PCNA-EAV instrument does not demonstrate reliability over time. However, five of the scales, ADL, finance, communication priority of needs, and preference for setting of care indicate acceptable levels of reliability between the two administrations.

Validity

Construct Validity

There is no acknowledged “Gold Standard” for measuring the perceived, self-reported health care and support needs of patients with advanced, cancer. Construct validity was therefore, primarily assessed through needs theory, and the consistency of the results of the PCNA-EAV measure with those theories, i.e. comparing congruency of domain scores with specific needs theory. In addition, item scores were compared with those of the “Needs Assessment for Advanced Cancer patients” (NA-ACP) instrument (Rainbird, et al., 2005); the “Needs Near the End-of-Life” (NEST) screening tool (Emanuel et al., 2001); and the “Patient Needs Assessment Tool” (PNAT) (Coyle, et al., 1996).

Burden of Response

Item difficulty and instruction comprehension were demonstrated using summary statistics (see Table 27 and Table 28).

Table 27

Summary Statistics of Burden of Response

	Pretest (n = 25)		Pilot (n = 50)		Retest (n = 11)	
Response Option	Frequency	Percent	Frequency	Percent	Frequency	Percent
Extremely easy	19	76.00	45	90	11	100.00
Somewhat easy	5	20.00	2	4	-	-
Unknown	1	4.00	3	6	-	-

Results show that 19 (76%) of the pretest respondents, 45 (90%) of pilot respondents, and 11 (100%) of retest respondents, found answering the interview questions (Item 34), extremely easy, indicating an acceptable level of difficulty.

Table 28

Summary Statistics of Burden of Instruction Comprehension

	Pretest (n = 25)		Pilot (n = 50)		Retest (n = 11)	
Response Option	Frequency	Percent	Frequency	Percent	Frequency	Percent
Extremely easy	19	76.00	**44**	**88**	**11**	**100.00**
Somewhat easy	4	16.00	3	6	-	-
Unknown	2	8.00	3	6	-	-

The analysis of respondents' level of difficulty following instructions (Item 35) also shows the majority (76%) of pretest respondents, and 44 (88%) of pilot respondents found the instructions easy to follow, while 100% found of retest participants found the instructions easy to follow.

Summary

Findings of the PCNA-EAV reliability and validity tests were mixed. However, the internal consistency and test-retest estimates indicate that, with further testing, potentially using multiple sites, and with larger sample sizes, the psychometric reliability and validity of the instrument will be demonstrated. Examination of item responses indicated the majority of domains demonstrated areas of high levels of reported needs, specifically the physical symptoms scale, the information scale, and the religious/spiritual scale. Priorities for care were also clearly demonstrated, headed by need for transportation (64%), followed by need to see a pain management specialist; need for more information about cancer treatment; and need for religious counseling, each at 62%.

The burden of participation in this survey was shown to be minimal. The level of comprehension of questions and instructions was considered extremely easy, by the majority of respondents, and no items were found to be culturally unacceptable.

CHAPTER 5

DISCUSSION

Introduction

The purpose of this study was to develop an instrument to measure the health care and support needs of patients with advanced cancer. In chapter five, the findings of this study are discussed, and conclusions drawn about the utility of the PCNA-EAV as a measure of need. In the first section, the principal findings generated from the sample characteristics are discussed, particularly in context of cultural influences on study findings. In the second section, results generated from testing the three hypotheses are discussed, and the extent to which results met the aims of the study. In third section survey development and implementation is critically reviewed, together a discussion of the barriers and enabling factors encountered in the implementation process. Section four focuses on study limitations; lessons learned; implications for future research; and conclusions drawn.

Principal Findings

Item Responses and Sample Characteristics

Item responses revealed that the majority of participants demonstrated health care and support needs in one or more domains. This finding is corroborated by previous studies of needs of patients with advanced cancer. Sanson-Fisher and colleagues (2000) found that patients' reported needs were highest in the psychological, health system and information, and physical and daily living domains.

Contrary to the Sanson-Fisher findings, psychological needs were not the highest priority of need for this sample of cancer patients. Of particular interest for this population, was the proportion of respondents (32%) feeling guilty that they may be a burden on their family. In Saudi culture it has traditionally been the duty of family members to care for their sick relatives. This aspect of the psychological component of needs of patients could be explored from a religious, social, of psychological aspect, to understand this phenomenon. On the self-efficacy scale, 38% reported they felt they could no longer manage their life, and 38% did not feel confident they could continue working at their usual job.

When PCNA-EAV respondents were asked if they had needed help over the last four weeks with managing specific symptoms, 72% reported needing assistance to manage severe pain; 68% with managing extreme fatigue; 62% needing assistance dealing with poor appetite; and 54% dealing with diarrhea or constipation.

In the ADL and IADL scales, less than 18% of PCNA-EAV respondents reported needing assistance with ADLs over the past 4 weeks. In contrast, the reported need for assistance with IADLs was considerably higher. Forty percent reported needing help with transportation; 40% also needed help with household chores, and 40% needed help with shopping.

Examination of the percentage of item responses in the pilot survey, indicated many of the results were as expected. The domains indicating the highest levels of reported needs in the previous 4 weeks were: physical symptoms (48% severe pain; 36% fatigue; 24% poor appetite; and 20% constipation or diarrhea). When combining the two positive response options, strongly agree, and agree, (H.R. Foushee, verbal communication, 22 October, 2010), the proportion needing help with managing physical symptoms over the past four weeks was, as follows: severe pain, 72%; fatigue, 68%; poor appetite, 62%; and constipation or diarrhea, 54%. In the Sanson-Fisher study (Sanson-Fisher, et al., 2000), 33% of respondents reported a lack of energy and tiredness, and 33% reported not being able to do the things they used to do

The highest levels of reported ADL needs were walking more than 10 steps, and going up stairs, both at 14%.

Levels of reported need were higher for IADLs, however. 44% reported needing help with household chores and maintenance, all, or most, of the time; and 40% reported needing help with shopping and transportation, all, or most of the time.

The pilot sample characteristics revealed that over half (56%) of the respondents had poor literacy skills, which has serious implications for comprehension of information, and future study design. Twenty-eight percent of the respondents reported they had no formal schooling, and 28% reported attending primary school only. It also has implications for choice of methods used to educate and inform patients about their illness, the options for management of their disease, and comprehensions of benefits and risks involved in care options available.

A major issue related to educational levels, and health care outcomes, is compliance with prescribed care, including medication compliance. If much of the population does not have the education or literacy skills, to easily comprehend instructions given, outcomes of care and satisfaction with care received, is compromised (Williams, Baker, Parker, & Nurss, 1998). Twenty-six percent of respondents reported needing additional help with taking medications. This has major implications for medication compliance, and the overall outcomes of prescribed treatment.

The assessment of communication needs showed conflicting results – 66% of subjects reported they strongly agree, or agree, that they need more information about their cancer (Item 16a); however, in item 16b, 68% report they have been told all they need to know about their cancer. In item 16d, participants report their oncologist has given them full information about what to expect regarding this diagnosis and prognosis (62%). It appears this information does not include information about symptom management. In response to item 16e, 64% of subjects report needing more information about therapeutic options to keep them pain-free and comfortable.

The majority of respondents reported they found their doctors helpful resources of information (66%), and to a lesser degree, nurses 36%). The majority of physicians in the department of oncology are Arabic-speakers, whereas the majority of nursing staff are expatriate, non-Arabic-speaking staff. This may account for some of the discrepancy in reported degree of helpfulness as a resource for information, between physicians and nurses. For other information resources, over 70% of respondents did not find information provided by the media (television, newspapers), or printed pamphlets, or information on the Internet, at all helpful.

A sample characteristic expected to influence level of need, was location of residence. Findings showed, however, that location of residence did not influence the levels of physical need in this sample. In the pilot study 27 (54%) of respondents lived in Riyadh, the city where the KAMC hospital is located. It was very apparent, during years of experience working with cancer patients in Saudi Arabia, that those patients who lived long distances from the treating hospital, had greater levels of physical need, especially adequate pain and symptom management. Some family members would fly to Riyadh, from the southern or northern regions of the country, to pick up prescriptions for opioid medications for the bedridden patient at home – a practice now discontinued.

Living in a city with a cancer center also enables easy access to scheduled, and to urgent/emergent care. For the 23 respondents, (46%), living outside Riyadh, travelling long distances for their cancer care, meant major discomfort for them, and major disruption of work routine, and perhaps household income, for male family members accompanying the patient.

In this study, at least 6 patients lived in towns over 500 kilometers from the hospital. Many patients, who have scheduled appointments for chemotherapy, or other follow-up care, have no difficulty with accommodation – they stay with relatives who live in Riyadh. It is a long-standing tribal custom to show hospitality to travelers, and an expectation that those who are sick will be shown every courtesy when away from home.

For those who have no relatives to stay with locally, when coming to KAMC-R for treatment, the hospital social services department is required to find accommodation and funding for those who cannot afford to pay themselves. In addition, the government will provide airline tickets, through social services, for those patients with low household income.

The socio-economic status of SANG employees, and their dependents, varies widely, according to the rank and position of the employee, and whether they have any income other than their salary, or pension from NGHA. The household income of the respondents in this study also varied widely, from less than 2,000 Saudi Riyals (SR) per month, to over 10,000SR per month. In U.S. dollars ($), this is the equivalent of less than $533 per month, to over $2,600 per month. Two respondents (4%) reported household incomes <2,000 per month, whilst the majority of those responding (22%) reported monthly household incomes of 2,000SR to 4,900SR. Nine (18%) reported monthly household incomes over SR10,000. Thirteen (26%) responded they were not sure of their monthly household income; nine of these 13 respondents, were female. Three (6%) preferred not to answer the question, which indicated this is a sensitive issue for a minority of respondents. There were six missing observations for monthly income. All of these missing observations were from female respondents. The explanation for these missing values is that one RC had difficulty understanding the concept of “Household income”; that it included income from any source, from any household occupant. In each of the six questionnaires with missing income observations, “Does not work” was noted beside the item. This highlights the need for the PI, or designee, to have sufficient time allocated, for monitoring and oversight of the project on a daily basis. This large percentage of missing values influences the overall results for household income, given the small sample size.

Although medical care is free of charge to all NGHA employees, and their dependents, if illness prevents the main wage-earner from contributing to the household income, either because they are the patient, or because they have to take time off work to be the primary caregiver, an additional burden is placed on the family unit.

In the psychological domain, 74% of respondents felt confident they could cope with their illness all or most of the time; 68% felt they could make their own decisions about their health care options; however 38% reported they felt they could not manage their life, all the time or most of the time. 26% reported they feel guilty they be a burden on their family all of the time, or most of the time. Result of difficulties with cognition – understanding, remembering, and concentrating, revealed 22% reported having difficulty understanding new information, much, most or all of the time. This may be related to educational levels, as previously discussed, or possibly, that the time spent, and mode of communication is not effective. Results of the Sanson-Fisher study of unmet supportive care needs (Sanson-Fisher et al, 2000), showed that 38% of the 888 respondents who completed the survey, reported concerns about the worries their illness was causing those close to them. In this PCNA-EAV preliminary study, 32% of the 50 respondents reported they were feeling guilty much, most, or all of the time, about the burden they were placing on their family.

When examining the results of item responses for social relationships, 76% of respondents reported relatives were supportive, and 68% reported friends were supportive. It was also found, however, that 50% of respondents reported their family members were not comfortable with talking about their illness, and also 50% of respondents were not comfortable talking about their illness with family and friends, because they did not want to burden them. This reveals an apparent disconnect in communication of feelings and knowledge about the illness, and a need for psychological interventions for both patients and family members. Emmanuel and colleagues (Emanuel, Hillel, & Emanuel, 2001), in their study of needs at the end of life, describe their development of an item to measure “closeness”, for inclusion in their clinical screening tool, NEST. This item asked “How often is there someone to confide in?” This item was initially considered for inclusion in the PCNA-EAV; however, the item did not discern which, if any, group the respondent felt comfortable confiding in.

When examining results of the religious/spiritual scale, it was noted that the majority (94%) of those participating in the pilot survey reported that they believe their suffering is a test of their faith, and believed Allah will wash away their sins because of this illness (98%). These results were as expected; given that this is a strong Islamic belief. Addressing the spiritual component of the survey, when asked if they believed an evil eye had affected them, 50% responded they agree, or strongly agree. From a supportive standpoint, 40% disagreed, or strongly disagreed, that the hospital staff were supporting their religious needs and 68% needed the guidance of a religious counselor. The issue of religious and spiritual needs requires further research, conducted by Islamic scholars, to determine the depth and breadth of the religious and spiritual needs of patients with advanced cancer.

In a recent cross-sectional study of patient and caregiver priorities for end-of-life care in Canada, results indicated that assessment and treatment, physician availability and personal interest in them, and clear and consistent communication, rated high on patients' lists of priorities (Heyland, Cook, Rocker, Dodek, Kutsogiannis, Skrobik, et al., 2010). In the PCNA-EAV study the reported highest priority of need was the need for assistance with transportation (64%), closely followed by needing to see a specialist for pain management (62%); needing more information about their cancer (62%); and needing religious counseling (62%). A minority of respondents (10%) reported having a need for financial assistance because of their illness. This low proportion was expected, as health care is free to National Guard employees and their dependents.

Item Non-Responses

A review of the results of item responses showed that the 2 items addressing sexual dysfunction (9j), and decreased sexual desires (9k), were each missing 8 (16%) responses. The high item non-response rate for these 2 items indicates a reticence on the part of some respondents, especially in a conservative culture, to discuss sexual matters with anyone, and in particular a stranger. Optimally, a "Prefer not to answer" option should be included for any item of a sensitive nature, to reduce the non-response rate. The ADL scale showed there were at least 2 (4%) missing responses for each of the 8 items in the scale, and at least 2 missing responses for each of the 6 items on the helpful resources scale.

Instrument Reliability

The PCNA-EAV measure was tested for reliability using Cronbach's correlation coefficient alpha to measure internal consistency. The reliability estimates obtained for internal consistency of the instrument ranged from α 0.01 for the religious/spiritual domain, to α 0.90 for the physical domain. Only four of the domains were acceptable to excellent, the remaining six were questionable to unacceptable.

This result contrasts significantly with the findings from the Supportive Care Needs Survey (SCNS) (Sanson-Fisher et al, 2000), and the Needs Assessment of Patients with Advanced Cancer instrument (NA-ACP) (Rainbird, et al, 2005). Both of these instruments were shown to be reliable across domains, with Cronbach's alpha values ranging from α .87 to .97, and α .79 to α .98. However, the alpha correlation coefficients of the four PCNA-EAV scales demonstrating internal consistency, compared favorably with similar scales in the SCNS and NA-ACP.

Test-retest Reliability

The time between instrument administrations, T1 and T2, ranged from 7 to 28 days, with a mean time of 9.6 days. Eleven participants (22% of the total pilot sample) completed the test-retest portion of the study. This number was disappointingly low, as the small sample size was considered insufficient to obtain accurate results from the test-retest analysis. None of the 11 participants consenting to take the retest, were identified to have had a life change, or deterioration in condition during the time between interviews   The retest was not administered to the remaining 39 eligible respondents, as: One respondent was known to have died at home; 9 refused when approached by the RC, stating they were too unwell; and 4 stated they lived too far away to make a return journey for the retest. An additional 5 were considered by the RC to be too debilitated physically to participate. The remaining 20 were lost to follow-up, as there was no RC available to administer the retest on a regular basis, within the 28-day window of time. Follow-up telephone calls were made to at least five of these to set up a meeting time for the retest, with no positive results.

The test-retest correlation for the all physical needs scale (*r* = .30, *p*=.32), and the all psychological needs scale (*r*=.28, *p*=.40) were lower than expected, indicating that the responses to the items in this scale had changed significantly over time. The retest time in the original proposal was 7 to 14 days, as the shorter the time between T1 and T2, the higher the expected correlation and the lower the factors that may contribute to measurement error. The time had to be extended to 28 days, with number of days between T1 and T2 ranging from 7 to 29 days, in an attempt to capture as many of the respondents returning for palliative chemotherapy, as possible

Instrument Validity

Predictive Validity

The impact of the predictor variables age, gender and location of residence, on patients' reported health care and support needs, was empirically tested on two different measures of need, physical need, and psychological need. Based on results, levels of reported need, overall, were not associated with demographic predictor variables. Contrary to the hypothesized relationship between gender and levels of reported needs, there was no significant difference in levels of psychological needs between males and females. This finding was not consistent with that of other studies. In a study of unmet supportive needs in cancer patients, it was found that females were more likely than males to report psychological needs, and, overall, the psychological needs domain indicated a higher level of need than all other domains (Sanson-Fisher et al, 2000).

The results of the test of the relationship between age and levels of reported physical need also demonstrated no significant relationship. This finding is also contrary to earlier studies.

Overall, results of the tests of relationships between sample characteristics, and physical and psychological needs across the 5 ECOG groups, indicate that the PCNA-EAV fails to demonstrate discriminant validity, on the sample being examined. These results were unexpected, given the evidence from previous studies, the increase in frequency of physical symptoms, as the functionality and mobility decrease, and the demographic and clinical characteristics of the population. Further studies are required to explore differences. Larger sample sizes may show differences, if differences exist.

Issues Encountered

A number of issues proved to be problematic for this research project. The major barriers are discussed, with possible resolutions, and are itemized in Table 28.

IRB Approvals

One of the major barriers to completing the research project within the planned time frame was an unanticipated length of time to receive IRB approval. The delay caused major revisions to be made in the study timeline, and necessitated submission of requests for extensions to both UAB and SANGHA IRBs. However, both these renewals were both received within a two-week time frame.

Screening Tools

The MMSE cognitive screening tool, used for screening pretest candidates proved to be cumbersome to administer, and confusing and anxiety-provoking for some respondents. This was especially so for those who had poor literacy skills, i.e., those with no formal education, (28%) of all respondents, or only primary school education, (28%) of all respondents. The RCs reported that they had some difficulty explaining the questions to some candidates. Of particular concern was the burden imposed by the items requiring the candidate to write or draw objects. It was observed that at least two of the patients had no prior experience holding a pen – one female patient did not feel comfortable holding a writing instrument, and appeared distressed by the experience.

A search was conducted to identify a cognitive screening tool which did not require any handwriting or other literacy skills, and whose questions were easily comprehensible for the target population. The Six-Item screening tool was identified as a possible replacement for the MMSE. It is an English language, validated modified version of the MMSE. The measure was translated into Arabic by one of the RCs. A group discussion followed the translation of the instrument, and a consensus reached that the instrument translation, and the content was appropriate for use for the pilot study screening.

Pretest Issues

The pretest was completed by 25 respondents. As each survey was completed, it was reviewed for completion and for notes/comments from the RC. A number of problems with specific items were identified (see Table 28). These issues were addressed in a group discussion and modification made to the instrument. A complete list of all protocol and instrument modifications made for the pilot phase is found in Appendix S.

Duration of Pretest Interview

The time taken to complete the pretest interview was not documented for 5 (19 %) of the respondents. For those whose time was documented, the average time taken to complete the interview was 40 minutes. The minimum time taken was 20 minutes, and maximum time 130 minutes. The high maximum time was cause for concern; either the RC was rushing the respondent, or there was incorrect documentation of the time finished, or possibly, there was an interruption during the interview. No plausible explanations could be given by the RC administering both interviews. This issue highlighted the need for repeated RC training and monitoring, to standardize the administration of the instrument.

Translation

The English language translation and adaptation of the PCNA-EAV, was modeled on previous work by Brislin (1993), Guellemin et al. (1993) developed a set of guidelines for translation and back-translation, and to demonstrate cultural equivalency of the instrument. The model proposed by Brislin in the early 1970s, served as the foundation for later work by Jones et al. (2001), Harkness (2003), and Bowden and Fox-Rushby (2003), who each extended the Brislin model. These extensions included additional steps, to aid in the translation-back translation process, and to ensure cultural equivalency. Harkness proposed that 3 sets of translators are necessary to translate a survey instrument: translators, translation reviewers and translation adjudicators. She suggests each group should have varying degrees of training with the target language, translation skills, knowledge of the principles of research, and the design of the study in question. Ideally, this would certainly contribute to the accuracy of translation and adaptation. However, being able to identify individuals who have these skills and knowledge, and who are available to perform these tasks, when needed, is unrealistic for the majority of researchers in developing countries.

Instrument Modifications

In this study of patient needs, cultural equivalency of the instrument was imperative, to ensure sensitivity to respondents' beliefs and core values were respected. There was a need for several minor revisions in the formatting, sequencing and wording of items, and subsequently, in the translation of these revisions, as shown in table 29. These changes were discussed by the research team, acting as translation reviewers. No expert adjudicators were available for this study. On reviewing the responses in each completed questionnaire, and the comments and notes made by each Research Coordinator, several inconsistencies and inaccuracies were found. These were partly due to the wording and formatting of the questionnaire itself, and partly due to inconsistencies in administration of the interviews.

The 25 pretest questionnaires were reviewed by Abdullah Al Garni, clinical psychologist, who also administered some of the interviews. A small number of inaccuracies in Arabic instructions and item translations were found. These inaccuracies were corrected with a second back-translation.

Table 29

Overview of Pretest Items Requiring Modification

Item No.	Item	Recommended Modification
8	Need to replace word “oncologist”.	Use generic term “doctor”, as other physicians, such as hematologists and palliative care physicians are seeing these patients
13	How many drivers do you have? Respondent answered, “None”; uses family members to drive him about.	Need to clarify between employed drivers and male family members
17	Co-morbidity response options are not mutually exclusive.	List each option individually - dichotomous responses Y/N
25	What is your average monthly household income? Response "None".	RC needs more training – does not understand the concept of household income. Continues to note respondent “Does not work”, instead of probing deeper, and explaining concept to respondent
26	How many children do you have?	Need to expand response options, to include >12. Need to bring to front of measure with other demographic items, to avoid asking this question of a respondent who has never married
28	How many wives do you have?	Patient is single. Need to bring demographic items to front of measure, to avoid embarrassing moments for respondents.
28-29	Failed to insert a “Skip to” in instruction	Need to insert an “If male, or widowed, skip to” instruction, to avoid asking unmarried male how many wives he has.

Physician Referrals

A major barrier to completing the study within the planned time frame was the slow rate of patient referrals. It was acknowledged when designing the study, that the level of interest in this particular study, and in research activities in general, may not be optimal (A.R. Jazieh, personal communication, March 12, 2008). Physician understanding of the purpose of the study and the process of referral was key to the success of the project.

Several activities were undertaken to promote physician referrals, as noted in chapter 3. These included a presentation of the research project to department of oncology staff; members of the research team attending grand rounds and oncology clinics and education of oncology nursing staff. These activities were only moderately successful, overall. The maximum number of referrals in the 5-month enrollment period, was seen in the first month, when 13 referrals were made; thereafter monthly referrals ranged from 4 to 10. This number was disappointingly low, given that an estimated 33 to 35 patients a month would be eligible for the study.

There were several reasons for patients not being referred to the study; the major one being that many patients did not know their diagnosis. The exact number of non-referrals is not known, as it was difficult to obtain this information from the physicians. It is believed that the majority of patients with cancer at KAMC-R do not know their diagnosis, i.e., have not been told their diagnosis (R. Al Shehri, personal communication, March 7, 2010; A. Osama, personal communication, April 18, 2010). The issue of patients not knowing, or not being told, their diagnosis varies between cultures (Hebert, Hoffmaster, Glass, & Singer, 1997) and is not unique to Saudi Arabia. The attitudes, values, beliefs, and previous education and experience of the oncology physicians at KAMC-R, are also believed to have influenced the referral rate.

Regarding inaccurate completion of referral forms, the main reason stated for this problem, was that the clinics were too busy and physicians did not have time to focus on the forms (A. Al Qarni, personal communication, January 19, 2010). The purpose of having the referring physician, and not another staff member, i.e., a nurse, or social worker, completing the form, was a) the physician must be aware that the patient was referred to the study, and b) no inappropriate referrals were made, e.g. patients who had not been informed by the physician that they were being referred to the study. The protocol required that the physician complete the referral form, throughout the study recruitment period.

Research Coordinator Training

When the pretest results were reviewed, it was evident that further preparation, training, and monitoring of RCs, needed to be provided, to standardize the administration of the survey. Some items did not have any response option documented. An example of this was item number 33, asking about monthly household income. One of the RCs documented that the respondent "did not work" beside the item, instead of probing to determine how much, if any, household income from sources other than employment, there may have been.

Weekly meetings were held with the RCs, prior to, and during the pilot survey, to review the instrument administration process, and to address any problems arising. Limited resources, in terms of time and staff available to monitor RC administration of the instrument, and lack of full-time RCs for the project, were seen as a major drawback to standardization.

Recruitment, Screening and Enrollment Process

A problem encountered during the screening process was administration of the MMSE cognitive screening measure. The four RCs all reported the MMSE cumbersome to administer, and that many respondents found it confusing. Approximately four of the respondents, who were illiterate, found trying to copy the simple diagrams difficult, and were reported to appear anxious and embarrassed when attempting the task. A review of the literature identified a validated modified version of the MMSE, the Six-item Screening tool (Callahan, Unverzag, Hui, Perkins, et al., 2002). Expert group discussion reached a consensus that this tool would be effective in screening out those referrals that were not cognitively capable of participating in the survey. This tool was utilized for the pilot study.

The high maximum time taken was again, cause for concern. The RCs had been counseled, regarding how to document time taken, and to note on the survey instrument if there were any difficulties encountered during the interview. Three delays were recorded and taken into account when calculating time taken. No feasible explanation was given by the RC – just that the respondent took longer to respond to items. No difficulties with any specific items or the instructions given to the respondent, or physical problems experienced by the respondent were noted by the RC. This issue highlighted the need for repeated RC training and monitoring, to standardize instrument administration.

Table 30

Summary of Problematic Issues with Referral and Screening Process

Issue	Frequency	Action
Female patient not wanting to be interviewed by a male.	1	The patient was interviewed by the female RC 3 days later.
Patients who did not know their diagnosis or prognosis, or whose family members would not give permission or said patient did not know diagnosis, despite assurance from the referring physician that the patient had been informed.	3	Patients not recruited. The co-PI counseled physicians regarding the rights of patients to be informed of their diagnosis and prognosis, if it is considered in the patient's best interest; i.e., will do no harm by giving them this information. From an Islamic perspective a patient may be told of their condition to allow them to prepare for their death (The Holy Quran).
Lack of diligence/interest on the part of physicians to refer patients to the study.		PI and RCs frequently met physicians one-on-one and attending grand rounds and departmental meetings to remind physicians of the need for referrals.
A daily review of oncology inpatients lists, and outpatient clinic and chemotherapy infusion suite patient lists, to identify new admissions and potential subjects in the ambulatory care setting.		Will be discussed in limitations of study and will recommend inclusion in future studies.
Lack of private setting to screen/interview patients in the KAMC-R Emergency Room. Hospital-wide shortage of beds lead to terminally ill patients being held in the ER for periods up to 4 weeks, with some patients dying there. 9 potential candidates were not referred, due to this problem.	9	Patients not recruited
Breakdown in referral process: clinic staff not notifying RC that potential recruits were in the clinic setting,	2	Meetings with nurse manager and nursing staff to enlist their support in this process.

Cultural Issues

This survey was conducted in Saudi Arabia, where several cultural issues, affecting administration of the PCNA-EAV, were encountered. Firstly, one of the female respondents requested not to be interviewed by a male RC. In Orthodox Islam, it is forbidden for a female to be in a room alone with a male *(mahram*) who is not a close relative, e.g., her husband, father, brother, or son. As a consequence there should always be at least one female RC available to interview female respondents. No requests were made by male respondents to be interviewed by a male, even though the same rule applies. When discussing this issue, it was noted (A. Al Qarni, verbal communication, March 16, 2009) that all female RCs involved in future studies, must also be comfortable interviewing males.

A second issue concerning cultural differences, raised by Abdullah Al Qarni, was the difficulty assessing the non-verbal responses of females, in relation to the burden of response. He noted that it was sometimes difficult to judge facial expressions, when only the eyes were visible. The majority of Saudi females wear the head covering (*hejab*), and a veil covering the face *(niqab*), in addition to the black robe *(abaya*), and sometimes, black gloves. This is an issue that has no resolution, except to sensitively question the female respondent about any difficulty they may be having in formulating a response, or experiencing discomfort with a particular question.

Instrument Content and Formatting

Upon review of the findings by the expert panel, a consensus was reached to delete part of the introductory statement for the pilot version of the PCNA-EAV, as this was seen to be redundant. None of the respondents requested to take a rest break during the interview. Even when a rest period was offered it was declined by all respondents.

A scale (I = No difficulty, to V= Extreme difficulty), was included below each item on the pretest version of the instrument, to assess the degree of difficulty, verbal or non-verbal, that the respondent was having with each item. This scale was deleted from the pilot version of the measure; however, as the RCs reported it was particularly difficult to objectively assess some female respondents' non-verbal response, as their faces were covered by the traditional veil.

A key issue negatively affecting the flow of questions was the sequencing of demographic items, as reported by the RCs. Although the sequence was not seen to bias the responses in any way, it did cause instrument administration to be more complex than necessary, requiring additional "SKIPS", when certain respondent demographics were unknown to the RC.

It was determined that it would be prudent to modify the item sequence, placing demographic and clinical items at the beginning of the interview to filter out respondents to whom subsequent items did not apply (Bowling, 1998). These initial items were structured, non-threatening, and easy for the respondent to answer, e.g., item number one "Where do you live?" These changes reduced the number of "SKIPS" and potentially avoided inadvertently asking inappropriate questions, e.g., asking a "Never Married" respondent the number of children he or she had. On completion of the pretest, it was found that all respondents were able to complete the interview without needing to take a break. Findings indicate that, overall, the PCNA-EAV instrument is not a burden on respondents. It also shows that the translation of the instrument demonstrates cultural equivalence, and is an acceptable measure of needs for use in the target population.

Respondent Comments

The one question at the end of the survey, asking respondents if there are any other questions they would like to see included in the questionnaire, produced unexpected responses. Instead of proposing additional items, the respondents were reported to have understood the question to be asking what improvements or additional patient services they would like to see at KAMC-R. The item wording therefore needs revision, to be clearly understood and to elicit the information requested. The RCs need to restate and clarify the question, if inappropriate responses are given.

The responses to question 33, about any additional questions to be added to the instrument revealed a selection of interesting opinions regarding existing services are listed in table 31.

Table 31

Comments from Respondents

Comment	Frequency
Need more educators, and focus on education about disease	4
Need more psychologists and counseling	2
Need more community support for Saudi cancer patients	1
Need more social services to arrange for transportation; for airline tickets, and for tickets to Mecca	4
Need more beds and more doctors	2
Need better management of clinics and clinic time	2
Need Moslem scholars for counseling	2

These unsolicited opinions reinforce the need to include patient (consumer) focus groups in future study design.

Limitations

A number of limitations, which potentially influenced results of the study, have been identified. These limitations are discussed in this section of the chapter.

- The study employs a cross-sectional design, thus, no casual relationship can be drawn from the results. In addition, the differences in results between this study and other studies could be caused by the difference in the study design and the sample size.
- The study utilizes a non-experimental design that is limited by the inability to control for unobserved factors that could confound the results of the study.
- The sample size is small, and therefore study findings may not be generealizable to the study population.
- This is a correlational study, and therefore a cause and effect relationship cannot be inferred. Other study designs considered, were a time-series cross-sectional design, or a longitudinal study, to examine how patients' needs change over time. However, for this population, with advanced cancer, the drop-out rates due to death or deterioration in physical or mental status precluded these two options.
- The exclusion of patients considered too physically or cognitively fragile to participate and those who did not know their diagnosis or whose family members refused to consent to the patient's participation. This may have resulted in an under-estimation of the needs experienced by this patient population.
- The use of only one survey site. The small sample size (n = 50) potentially affected the power of the study. It is recommended that future studies validating new instruments for use in Saudi Arabia conduct the survey in multi-site settings. This will increase the power of the study by providing a larger sample size for data analysis.

- The dependence on participants' self-reporting their needs (Newell, Sanson-Fisher, Girgis, & Auckland, 1999). Previous research suggests that self-report may be unreliable to its dependence on patients' memories and individual response processes and the possibility of social desirability bias (Sudman, & Bradburn, 1974). However, research has also indicated that patients' self-report of symptoms is more reliable than those of physicians or family members (Morrow, 1984). To account for this possible limitation to self-reporting the period for recall was limited to four weeks.
- Restricted availability of interview setting. The availability of the outpatient clinic rooms for interviews proved to be a challenge. A chronic shortage of clinic space resulted in the designated interview room not always being available. It was taken by clinic physicians to examine patients to reduce waiting time, which was laudable, but caused short delays for some interviews. On several occasions the interview was interrupted by clinic staff needing the room. Disruptions were minimal overall, but this highlighted the importance of having a designated interview room.
- The inaccurate self-report of comorbidities. Research has shown that the number of comorbidities experienced by individual patients influences their level of need (Valderas, et al., 2009; Satariano, & Muss, 2008**)**. Due to time and resource constraints it was not possible to collect the co-morbidities data from the Medical Record of each participant. This information would be beneficial in predicting the level of need.

Recommendations

A number of recommendations are made, subsequent to issues encountered, during implementation, and examination of the findings of this research project.

Resources

This study highlighted several deficits in the resources available to effectively implement a research project of this nature: a)There must be a dedicated team, assigned full-time to the study, to recruit participants, to administer the survey instrument, and to follow-up patients who would otherwise be lost to the study; b) There must be an experienced biostatistician available to actively contribute to the study design and data analysis, in order to optimize the reliability and validity of an instrument; c) The PI must have sufficient time to devote to overseeing the project and available to resolve any issues which may negatively impact the efficiency and effectiveness of the study; d) RCs must be bi-lingual, and fluent in the language in which the interviews are conducted; d) An experienced researcher/trainer must be available facilitate RC training and understanding of their role in the study. The trainer will conduct repeated RC training sessions, prior to implementing the study; monitor respondent interviews; and, as necessary, repeat training sessions through the course of the study, to ensure standardization of administration and minimize response and administrator bias.

Staff Education

It is strongly recommended that the research team provides ongoing education and information about the study, for all staff involved in the referral and recruitment process. In order to maintain the active interest and participation of physicians and other staff, in a research project in a busy health care environment, verbal praise alone will not suffice. Further review of the literature, and discussion with colleagues, must be undertaken, to determine how best to maintain staff interest, and thereby increase referral rates.

Comorbidity Data

It is recommended that comorbidity data extraction from participant medical records be included in the design of future studies, to ensure accurate documentation of respondent comorbidity history.

Interview Setting

To ensure an appropriate private setting is always available for uninterrupted participant interviews, a written agreement should be signed by the nurse/person in charge of the area where the interviews are held. This form should include the name/number of the room designated for conducting the interviews and an agreement permitting posing an “Interview in Progress” notice on the interview room door. This agreement form should be included in the study protocol.

Pretest

The pre-test was used to fine-tune the survey, and refine the questions in a qualitative manner. Feedback received from the expert panel, interviewers, and other professional colleagues, elicited some comments and recommendations. Of specific interest were instrument acceptability, and the need for additional items, deletion of items, translation accuracy, and content and format. The process provided some helpful suggestions for revision of portions of the PCNA-EAV, and provided a more contextually accurate, and appropriate measure of KAMC-R patient needs.

Burden of Response

To more clearly establish the degree of burden of response, it is recommended that more feedback is solicited from the patients for whom this instrument is designed. This may be done by including items about the quality of the questions and response options in the survey, in addition to the 2 questions about the level of difficulty at the end of the survey. There could also be open-ended questions, asking about the acceptability of existing questions, and seeking respondent opinions about how the instrument could be improved.

Future Research

As a result of this preliminary study, it is recognized that further evaluation of the subscale structure of the PCNA-EAV is required to demonstrate psychometric validity of the instrument. One approach is to replicate the study, using a larger sample size, in a multi-site study, and to analyze the data using factor analysis, to confirm the validity of the subscale scores. A recommended minimum subject to item ratio for factor analysis is 10:1 (Tabachnick & Fidell, 2007; Nunally, 1978).

The low Cronbach's alpha values for some subscales were disappointing, e.g. the religious/spiritual scale. However, even those scales with a good or excellent alpha level (>0.7 acceptable, >=0.8 excellent), may not indicate one dimension (one subscale or domain). Conducting factor analysis (FA) to determine dimensionality of the scales of this instrument, as demonstrated in the SCNS and NA-ACP methodology used to validate new instruments (Sanson-Fisher, et al., 200; Rainbird, et al., 2005). Each measure was developed from a pool of items, using principal components factor analysis, to confirm the factor structure and reduce the number of items in each scale. The SCNS comprised 5 domains, physical, health system and information, physical and daily living, patient care and support, and sexuality needs. The NA-ACP measured the needs construct, using 7 domains, medical daily living, communication/information, psychological/emotional, financial, symptom, spiritual, and social.

Factor analysis plays an important role in instrument development and validation. It maximizes the likelihood of the scales to demonstrate internal consistency. However, the sample size must be sufficient for this type of analysis. In the Rainbird study, (2005) 246 (59%) of the 418 eligible patients completed the survey, and in the Sanson-Fisher study, 888 (65%) of the 1354 eligible patients completing the survey. These sample sizes were considered sufficient to conduct factor analysis in both studies. In the PCNA-EAV study, the sample size was limited to N=50, due to limited time and resources available. Future research using FA, to further develop the PCNA-EAV will help to establish the construct validity of the scale. In addition, further studies are also needed with larger test-retest samples to establish the test-retest stability of the instrument, and to confirm the PCNA-EAV stability over time.

Future studies may also include examination of the religious/spiritual needs of this population, or expanded across diagnoses, and across health care facilities in the Kingdom. A better understanding of the religious and spiritual needs of Saudi patients would contribute to improved quality of care and improved quality of life for all patients.

Based on the findings of this preliminary study, it is also recommended that studies are conducted to examine the education and information needs of SANGHA patients, to determine how best to meet their varying needs.

Conclusion

Findings of this preliminary study indicates, the PCNA-EAV has the potential to be a reliable tool to measure the health care and support needs of patients with advanced cancer. The utility of the PCNA-EAV depends on its predictive validity. If reliability, validity and responsiveness of the instrument can be confirmed, through larger, multisite studies, it has the potential to be a useful tool in service planning, for palliative care programs throughout the corporate NGHA organization, and in other Islamic, Arabic-speaking cultures. Once fully developed and validated, the PCNA-EAV could potentially be a reliable measure to identify the needs of specific groups of patients with advanced cancer, in specific geographic areas.

This study is significant, in that it is the first Arabic language instrument designed to measure the perceived needs of patients with advanced cancer. It is unique in that this interviewer-administered instrument is culturally-specific, for use in Islamic, Arabic speaking societies.Identification of needs, as viewed from the “consumer” perspective, enables providers to plan and deliver appropriate and effective health care services. The information elicited from this survey will also contribute to healthcare policy-makers’ understanding of specific problems encountered by those suffering with incurable cancer and to formulate strategic plans to remedy gaps in services to better meet patients’ health care needs efficiently and effectively. When patients’ therapeutic needs are understood by those professionals providing direct care, patients are more likely to be satisfied with care, better able to cope with their illness, and feel more strongly that their needs for clinical services had been met **(**Yamamoto, Acosta, Evans, & Skilbeck, 1984). The findings of this survey will contribute to the existing body of knowledge of patient needs. The design, methodology, issues encountered, findings, and lessons learned, will provide a foundation for future survey research in the Kingdom of Saudi Arabia, and elsewhere in the Arabic-speaking world.

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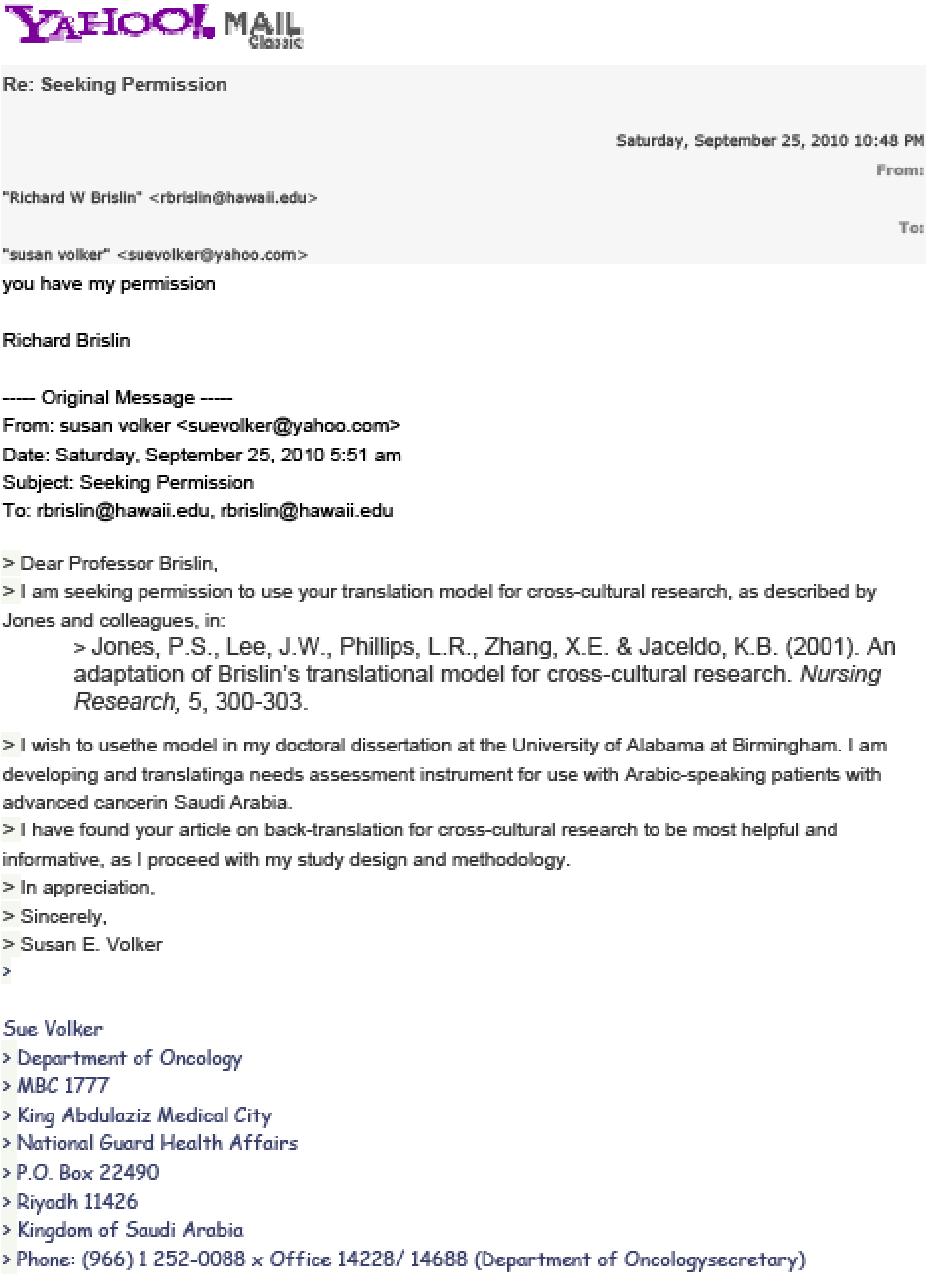
APPENDIX A

Translation Model Permission – Professor Richard Brislin



Re: Seeking Permission

Saturday, September 25, 2010 10:48 PM

From:

"Richard W Brislin" <rbrislin@hawaii.edu>

To:

"susan volker" <suevolker@yahoo.com>

you have my permission

Richard Brislin

----- Original Message -----
From: susan volker <suevolker@yahoo.com>
Date: Saturday, September 25, 2010 5:51 am
Subject: Seeking Permission
To: rbrislin@hawaii.edu, rbrislin@hawaii.edu

> Dear Professor Brislin,

> I am seeking permission to use your translation model for cross-cultural research, as described by Jones and colleagues, in:

> Jones, P.S., Lee, J.W., Phillips, L.R., Zhang, X.E. & Jaceldo, K.B. (2001). An adaptation of Brislin's translational model for cross-cultural research. *Nursing Research,* 5, 300-303.

> I wish to usethe model in my doctoral dissertation at the University of Alabama at Birmingham. I am developing and translatinga needs assessment instrument for use with Arabic-speaking patients with advanced cancerin Saudi Arabia.

> I have found your article on back-translation for cross-cultural research to be most helpful and informative, as I proceed with my study design and methodology.

> In appreciation,

> Sincerely,

> Susan E. Volker

>

Sue Volker
> Department of Oncology
> MBC 1777
> King Abdulaziz Medical City
> National Guard Health Affairs
> P.O. Box 22490
> Riyadh 11426
> Kingdom of Saudi Arabia
> Phone: (966) 1 252-0088 x Office 14228/ 14688 (Department of Oncologysecretary)

APPENDIX B

Translation Model Permission – Wolters Kluwer Health License

WOLTERS KLUWER HEALTH LICENSE TERMS AND CONDITIONS

Sep 27, 2010

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Licensed content author	Patricia Jones, Jerry Lee, Linda Phillips, et al
Licensed content date	Jan 1, 2001
Volume Number	50
Issue Number	5
Type of Use	Dissertation/Thesis
Requestor type	Individual
Order reference number	SEV/SEPT 2010
Title of your thesis / dissertation	DEVELOPMENT AND VALIDATION OF A PALLIATIVE CARE NEEDS ASSESSMENT INSTRUMENT , ENGLISH/ARABIC VERSIONS, FOR USE WITH PATIENTS WITH ADVANCED CANCER
Expected completion date	Oct 2010
Estimated size(pages)	150
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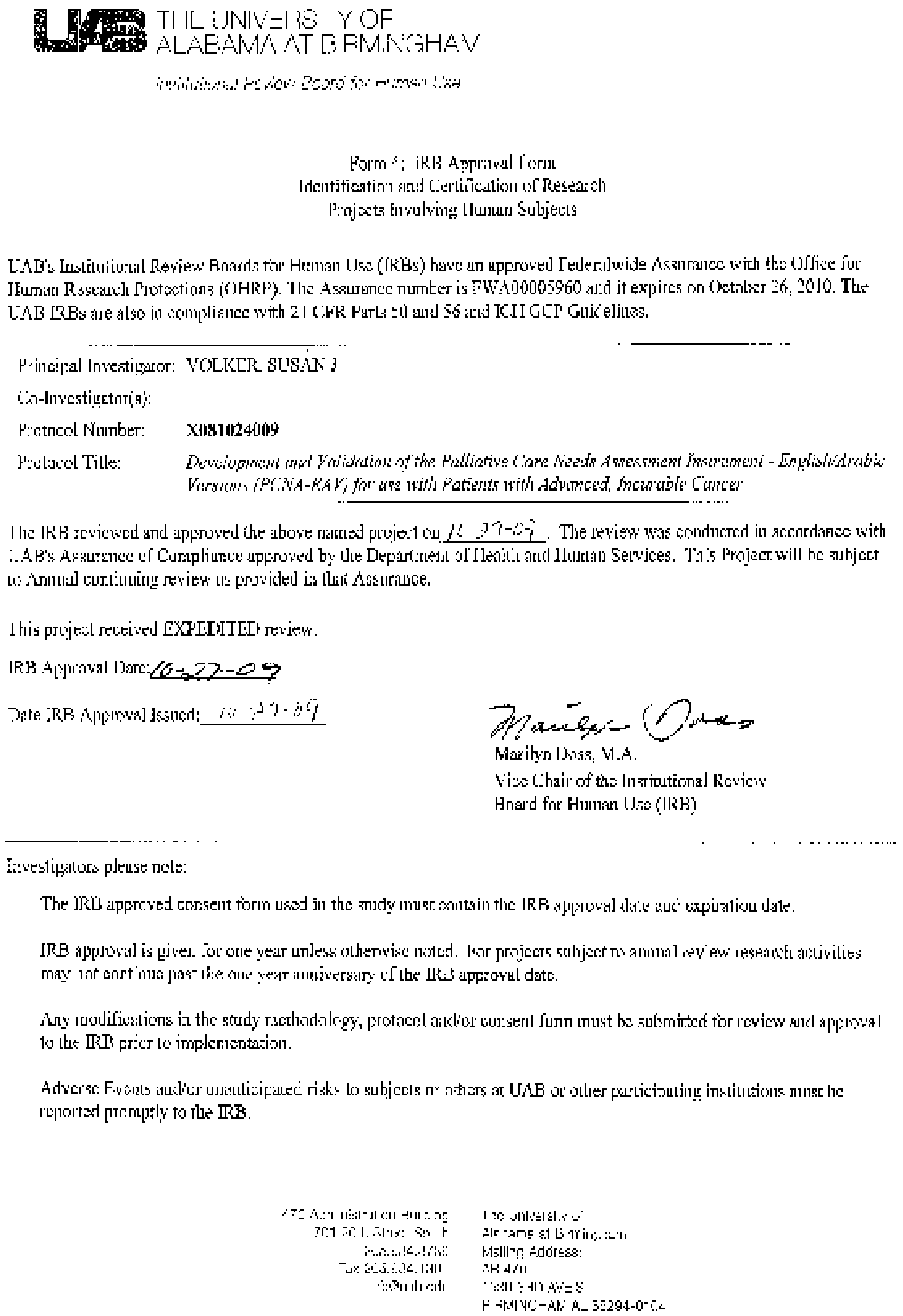
APPENDIX C
University of Alabama IRB Approval



UAB THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on October 26, 2010. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56 and ICH GCP Guidelines.

Principal Investigator: VOLKER, SUSAN J

Co-Investigator(s):

Protocol Number: **X081024009**

Protocol Title: *Development and Validation of the Palliative Care Needs Assessment Instrument - English/Arabic Versions (PCNA-EAV) for use with Patients with Advanced, Incurable Cancer*

The IRB reviewed and approved the above named project on 10-27-09. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review.

IRB Approval Date: 10-27-09

Date IRB Approval Issued: 10-27-09

Marilyn Doss

Marilyn Doss, M.A.
Vice Chair of the Institutional Review
Board for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

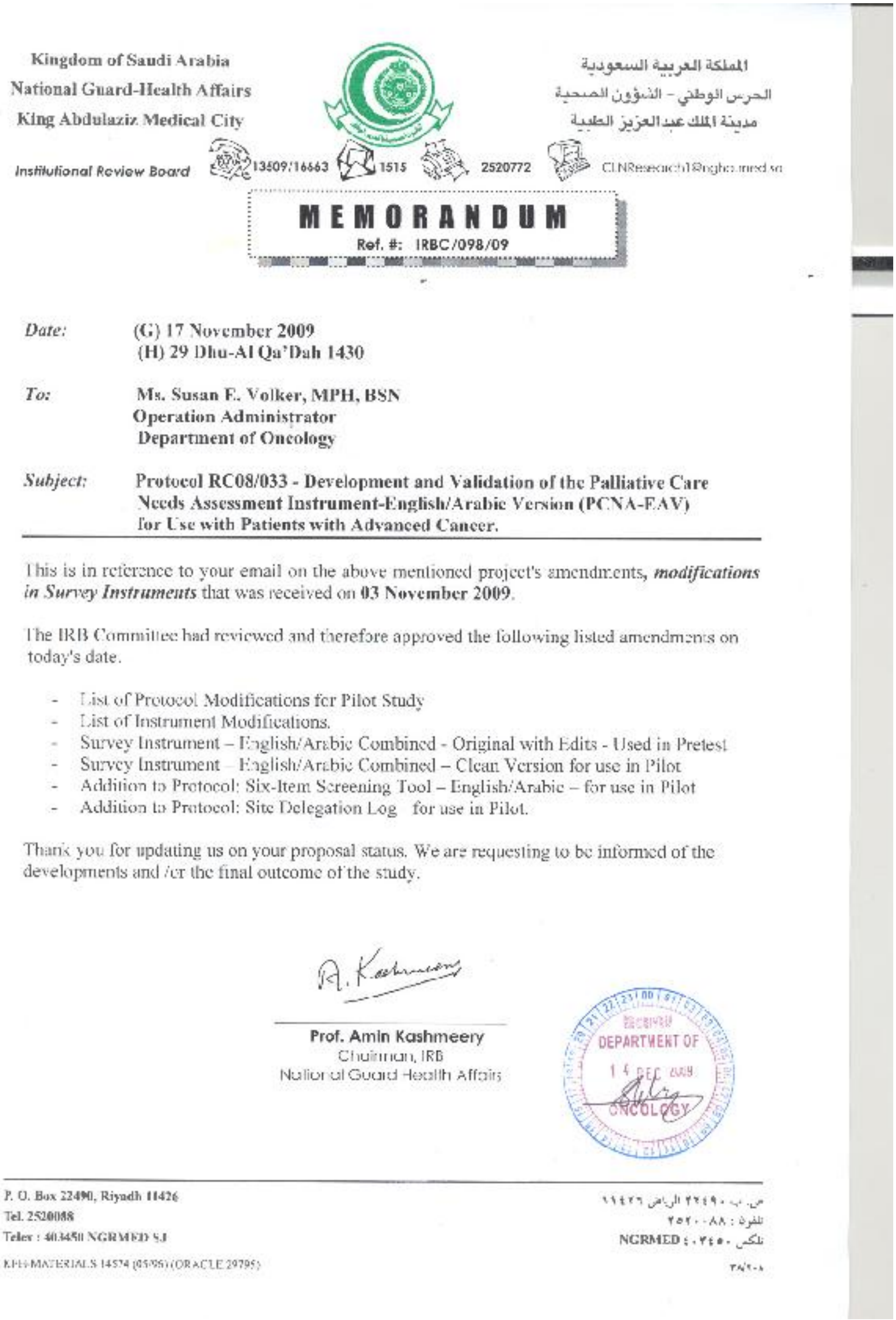
470 Administration Building
701 20th Street South
205.934.3789
Fax 205.934.1301
irb@uab.edu

The University of
Alabama at Birmingham
Mailing Address:
AB 470
1530 3RD AVE S
BIRMINGHAM AL 35294-0104

APPENDIX D

Saudi Arabian National Guard Health Affairs, Riyadh

IRB Approval



Kingdom of Saudi Arabia
National Guard-Health Affairs
King Abdulaziz Medical City

المملكة العربية السعودية
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Institutional Review Board ☎ 13509/16663 1515 2520772 CLNResearch1@ngha.med.sa

MEMORANDUM

Ref. #: IRBC/098/09

Date: (G) 17 November 2009
(H) 29 Dhu-Al Qa'Dah 1430

To: **Ms. Susan E. Volker, MPH, BSN**
Operation Administrator
Department of Oncology

Subject: **Protocol RC08/033 - Development and Validation of the Palliative Care Needs Assessment Instrument-English/Arabic Version (PCNA-EAV) for Use with Patients with Advanced Cancer.**

This is in reference to your email on the above mentioned project's amendments, ***modifications in Survey Instruments*** that was received on **03 November 2009**.

The IRB Committee had reviewed and therefore approved the following listed amendments on today's date.

- List of Protocol Modifications for Pilot Study
- List of Instrument Modifications.
- Survey Instrument – English/Arabic Combined - Original with Edits - Used in Pretest
- Survey Instrument – English/Arabic Combined – Clean Version for use in Pilot
- Addition to Protocol: Six-Item Screening Tool – English/Arabic – for use in Pilot
- Addition to Protocol: Site Delegation Log – for use in Pilot.

Thank you for updating us on your proposal status. We are requesting to be informed of the developments and /or the final outcome of the study.

A. Kashmeery

Prof. Amin Kashmeery
Chairman, IRB
National Guard Health Affairs

RECEIVED
DEPARTMENT OF
14 DEC 2009
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APPENDIX E

Table: Back Translation of Survey Instrument

#	Question	English Back Translation
CONSTRUCT: Physical - Symptoms		
1	كم كان مقدار احتياجك للمساعدة في الأسابيع الأربعة الماضية؟	How often did you need a help within the last four weeks?
1a	التعامل مع الألم	Coping (dealing) with pain
1b	التعامل مع صعوبة التنفّس	Coping (dealing) with difficulty in breathing
1c	التعامل مع الإجهاد	Coping with exhaustion
1d	التعامل مع إنعدام النوم	Coping with insomnia
1e	التعامل مع الغثيان / أو الإستفراغ	Coping with nausea or vomiting
1f	التعامل مع نقص الشهية	Coping with loss of appetite
1g	التعامل مع صعوبة الأكل / أو البلع	Coping with dysphagia or difficulty in swallowing
1h	التعامل مع الإمساك	Coping with constipation
1i	التعامل مع عدم السيطرة على المثانة و/ أو الأمعاء	Coping with urine and stool incontinence
1j	التعامل مع الضعف الجنسي	Coping with impotence
CONSTRUCT: Physical - Activities of Daily Living		
2	كيف كان معدل احتياجك للمساعدة في الأسابيع الأربعة الماضية بخصوص	How much in average you did need help for the following, the last four weeks with:
2a	الاغتسال أو الاستحمام؟	Washing or bathing
2b	إرتداء ملابسك؟	Dressing
2c	النهوض من السرير(فراشك)؟	Getting out of your bed
2d	المشي لأكثر من عشر خطوات؟ **الحث:** مثلاً المشي في الغرفة؟	Walking for more than 10 steps? (for example, walking in the room)
2e	صعود الدرج؟ **الحث:** مثلاً صعود خمس درجات من السلم؟	Going upstairs? (for example, going upstairs for 5 steps?)
2f	القيام بالوضوء؟ أي الغسل قبل الصلاة؟	Performing Wadhu, washing before prayer
2g	أداء الصلاة؟ أي طقوس الصلاة؟	Performing prayer? (for example, prayer ritual)
CONSTRUCT: Physical - Instrumental Activities of Daily Living		
2h	التسوق؟ **الحث:** مثلاً شراء المستلزمات والأشياء الشخصية الضرورية؟	Shopping, buying necessary things and personal effects
2i	الأعمال المنزلية؟ **الحث:** أي إعداد وجبات الطعام أو التنظيف؟	Domestic work such as preparing meals or cleaning
2j	أداء واجباتك الإعتيادية في العمل؟	Performing regular duties at work
2k	التنقل الشخصي؟ **الحث:** مثلاً العثور على شخص لاصطحابك بالسيارة إلى مواعيد العيادة أو زيارة الأصدقاء؟	Personal mobility such as finding someone to drive you by car to your clinic appointment or visiting friends
CONSTRUCT: Physical - Childcare		
2l	تحضير أبناءك للذهاب للمدرسة كل يوم ؟	Preparing your kids for school daily
2m	الإعتناء بأبنائك في البيت ؟	Caring for your children at home
2n	توفير وسيلة نقل لأبنائك لكي ييتمكنوا من ممارسة نشاطاتهم خارج البيت ؟ **الحث:** تمكينهم من الذاهاب للمدرسة أو المواعيد الطبية	Finding transportation for your kids to perform their activities outside your home, such as going to school or medical appointment
CONSTRUCT: Psychological - Self-Efficacy		
3	خلال الأسابيع الأربعة الماضية؟	During the last four weeks
3a	شعرت بالثقة أن في إستطاعتي التأقلم مع مرضي	I felt confident to cope with my sickness
3b	شعرت بالحرية في إتخاذ القرارات المتعلقة بالرعاية الصحية التي أتلقاها والمتعلقة بمرض السرطان؟	I felt freedom in making decisions related to my health care that I am receiving related to cancer
3c	شعرت بعدم القدرة على إدارة أمور حياتي بسبب مرضي	I felt I am unable to manage my life issues due to my sickness
3d	شعرت بالثقة أن في إستطاعتي الإستمرار في القيام بأعباء عملي الإعتيادية؟ **الحث:** مثلا: العمل في البي أو في مكان العمل	I felt confident that I could continue doing my regular work such as working at home or at work
3e	بالرغم من مرضي فلقد شعرت بالثقة في قدرتي على الإهتمام بالأشخاص الذين تحت رعايتي	Inspite of my sickness, I felt confidence in my ability to care of other person under my custody
3f	أصبحت أقل اهتماماً بأداء نشاطاتي الاعتيادية ؟ **الحث:** مثلا، التحدث في التليفون، أو زيارة الأصدقاء	I became less interested in doing my regular activities such as talking on the phone or visiting friends
3g	جعلني مرضي أكثر وعياً بمواطن قوتي الإنفعالية	My sickness makes me more aware about my emotional power
3h	شعرت بأن دوري داخل أسرتي ما زال على حاله	I felt that my role within my family is the same
CONSTRUCT: Psychological - Depression		
4a	أتطلع لبشوق لبداية كل يوم جديد	Looking eagerly for every new day
4b	أشعر بأن لا هدف لي في الحياة بسبب مرض السرطان	I feel that I have no goal in life because of cancer
4c	أشعر بالذنب لأنني ربما أمثل عائقا (حملا) لأسرتي	I feel guilty because I am considered a burden on my family
4d	معدل نومي جيد كل ليلة	Average sleeping hours are good every night
4e	أشعر بالتقدير من أولئك المقربين مني	I feel appreciation from my close persons
4f	لا يوجد أحد حولي لأكلمه عما أشعر به	I have no one around to talk to about my feelings
4g	أشعر بالحزن	I feel sad
4h	اشعر بالخوف على مستقبلي	I feel scared of my future

CONSTRUCT: Psychological - Cognition		
5a	أجد صعوبة في فهم المعلومات الجديدة	I have difficulties in understanding new information
5b	أجد صعوبة في تذكر الأشياء التي حدثت منذ أسبوع	I have difficulties in remembering events that happened a week ago
5c	أجد صعوبة في التركيز لأكثر من بضع دقائق على مهمات صغيرة كنت معتادا على أدائها بسهولة	I have difficulties in concentrating for more than few minutes on tasks that I used to easily do
5d	أجد صعوبة في إتخاذ قرارات متعلقة بنشاطاتي اليومية الروتينية	I have difficulties in making small decisions related to my daily routine activities
5e	أصاب بالحيرة بسهولة	I get confused easily
CONSTRUCT: Social - Relationships		
6a	حسَّن مرضي علاقتي بزوجتي (زوجتي)	My sickness improves my relationship with my wife
6b	زوجتي داعمة لي جداً (زوجي داعم لي جدا)	My wife / husband is very supportive
6c	أشعر بأنني أستطيع التحدث بحرية إلى زوجتي (زوجي)عما أعانيه من مشاكل	I feel I could comfortably talk to my wife / husband about my problem
6d	(يواجه زوجي صعوبة في التعامل مع مرضي)تواجه زوجتي صعوبة في التعامل مع مرضي،.	My wife / husband have difficulties in dealing with my sickness
6e	منذ أن مرضت يشعر أقاربي بعد الراحة في قضاء الوقت معي.	Since I got sick, my family feel uncomfortable to spend sometime with me
6f	يجعلني أقاربي أشعر بأنني أقل قلقا بخصوص مرضي عندما يقضون بعض الوقت برفقتي .	My relatives make me less anxious about my sickness
6g	يجعلني أصدقائي (صديقاتي) أشعر بأنني أقل قلقا بخصوص مرضي عندما يقضون بعض الوقت	My friends make me less anxious about my sickness when they stay with
CONSTRUCT: Information Needs		
7a	أحتاج لمعلومات أكثر بخصوص مرض السرطان الذي أعاني منه.	I need more information about the cancer that I suffer from
7b	أنا محتار (محتارة) بخصوص المعلومات المقدمة لي والمتعلّقة بعلاجي	I am confused about the information presented to me about my therapy
7c	لقد تمّ إخباري بكل ما أريد معرفته عن مرض السرطان الذي أعاني منه.	I have been told all what I want to know about my Cancer
7d	أفضّل أن يقوم طبيب الأورام الذي يتابع حالتي باتخاذ جميع القرارات الطبية نيابة عني..	I prefer that the oncologist looking after my case makes all the medical decision on my behalf
7e	أفضل أن يقوم طبيب الأورام الذي يتابع حالتي بمناقشة تفاصيل مرضي معي أثناء وجود أفراد أسرتي	I prefer that the oncologist following my case to discuss my sickness with me in the presence of my family members
7f	أفضل أن يقوم طبيب الأورام بالذي يتابع حالتي بمناقشة جميع تفاصيل مرضي معي فقط.	I prefer that my oncologist to discuss my sickness with me only
7g	لقد تمّ إعطائي جميع المعلومات التي أحتاج من أجل العناية بنفسي.	I have been given all the information I need to look after myself
7h	أحتاج إلى معلومات أكثر بخصوص أدويتي.	I need more information about my medicines
7i	لقد حصل أعضاء أسرتي على جميع المعلومات التي يحتاجون من أجل العناية بي	My family members receives all the information they need to take care of me
CONSTRUCT: Information Needs -Source		
8	المعلومات المقدمة لي بواسطة ــــــــــــــــ كانت مفيدة:	Information offered to me by ______________________ was useful
8a	طبيب الأسرة	Family doctor
8b	طبيب الأورام	Oncologist
8c	طاقم التمريض	Nursing staff
8d	الأخصائيين الاجتماعيين	Social specialist
8e	مثقفي المرضى	Patient educators
8f	المرضى الآخرون	Other patients
8g	الأسرة	Family
8h	الأصدقاء	Friends
8i	الوسائل الإعلامية (مثل : التلفزيون, الجرائد)	Media Services such as TV or newspaper
8j	المعلومات المطبوعة (مثل : االكتيبات, المطويات)	Printed materials such as booklets and brochures
8k	صفحات الإنترنت	Internet web page
9	على مقياس من 1 إلى 5 , ما مدى صعوبة الحصول على المعلومات التي أحتجتها ؟ (حيث (1) يعني سهل جدا, و (5) يعني بالغ الصعوبة)	On scale from 1 to 5, how difficult is it to get information that you need? For instance, scale (1) means very easy and (5) very difficult
CONSTRUCT: Communication		
10a	ناقش طبيبي كل خيارات الرعاية المتاحة لي	My physician discussed all available care options to me
10b	أمدني طبيبي بإجابات واضحة على جميع تسأؤلاتي	My physician provided me with clear answers to all my inquiries
10c	شرح لي طبيبي وبكل وضوح جميع المشاكل الجسدية التي ربما أواجهها	My physician explained clearly to me all physical problems that I may suffer from
10d	يفهمني الممرضون والممرضات عندما أتحدّث إليهم	Nurses understand me when I talk to them.
10e	يقضي الممرضون والممرضات الوقت اللازم لسماع ما أريد قوله	Nurses spend ample time listening to what I want to say.
10f	عندما يحدثني الممرضون (أو الممرضات) فإنني أفهم ما يقولون	When nurses talk about home, I understand what they say.
10g	يتواجد المترجم بشكل دائم عندما يكون هناك ضرورة لترجمة التعليمات المقدمة لي	The interpreter is always available when needed to translate the instruction that is given to me.

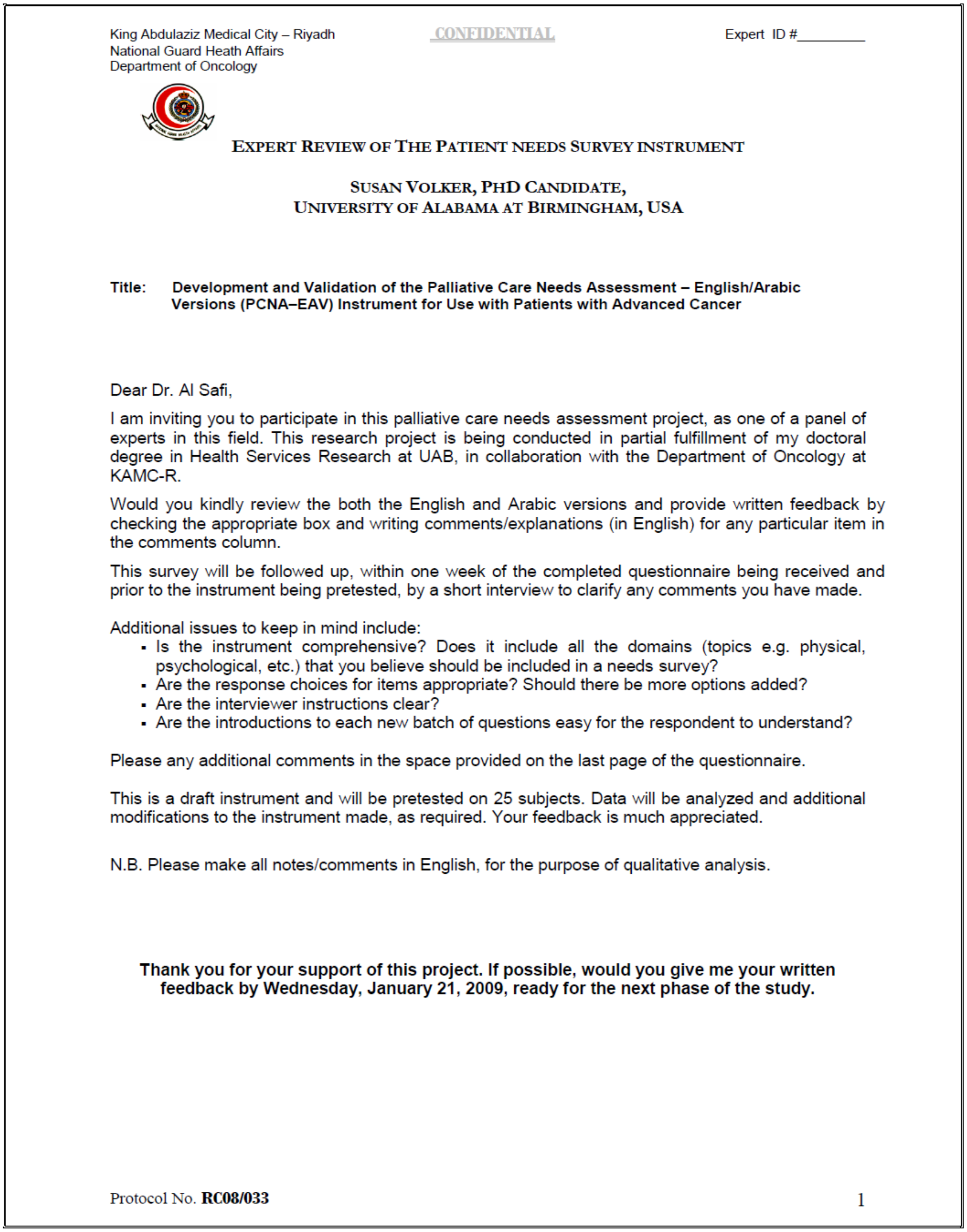
CONSTRUCT: Social Support - Numerical		
11	م عدد قريباتك البالغات اللاتي يعشن معك؟	How many female adults are living with you?
	كم عدد قريباتك البالغات اللاتي يعشن معك؟ الحثّ: البالغات 18 سنة فما فوق؟	How many female adults, above 18 years of age, are living with you?
12	كم عدد الخادمات اللاتي يعملن في بيتك؟	How many house maids are working at your house?
13	كم سائقا لديك؟	How many drivers do you have?
14	كم عدد أفراد عائلتك الذين يعيشون على بعد ساعة قيادة من بيتك وتشعر أن بإمكانك الاعتماد عليهم في المساعدة ؟	How many family members are living at an hour drive from your house that you feel you could depend on for help?
CONSTRUCT: Social Support		
15a	لدي أسرة وأصدقاء بإمكاني الاعتماد عليهم فيما لو احتجت إلى أي مساعدة.	I have a family and friends whom I can depend on when I need any help.
15b	قلت زيارات أفراد أسرتي الممتدّة عما كانت عليه قبل مرضي	My family members visits have decreased compared to visits before my sickness.
15c	أظهر أصدقائي مدى حرصهم عليّ على الرغم من مرضي	My friends show their concerns about me inspite of my sickness.
15d	ترغب أسرتي أن يتمّ تنويمي في المستشفى عندما أكون مريضاً	My family wants me to be admitted when I am sick.
15e	اشعر بأنني معزول عن الآخرين بسبب مرضي	I feel being isolated from people because of my sickness.
CONSTRUCT: Religious/Spiritual		
16a	اعتقد بأن شخصا ما قد عمل لي سحراً.	I believe that someone has made magic to me.
16b	اعتقد بأنني أصبت بعين.	I believe that I have been hurt by an enemy.
16c	أعتقد بأن شخصاً ما قد دعا علي.	I believe that somebody pray badly for me.
16d	أعتقد بأن ما أصابني إنما هو امتحاناً لإيماني.	I believe that my sickness is a test of my faith.
16e	معتقداتي الروحانية (الدينية) قوية جداً.	My religious beliefs are strong.
16f	إنني أخشى يوم الحساب	I am afraid from the judgment day.
16g	أعتقد بأن مرضي هو عقاب من الله.	I believe that my sickness is a punishment from God.
16h	سوف يغفر الله لي خطاياي بسبب مرضي هذا	God will forgive my sins for this sickness.
CONSTRUCT: Needs Priorities		
17	**ما مدى أهميتها بالنسبة لك؟**	How important to you………………. ?
17a	أن تحظى بمساعدة مهنية تساعدك على القيام بنشاطاتك اليومية؟	to get a professional assistant to help you perform your daily activities
17b	أن تحظى بمساعدة مهنية لأي مشاكل انفعالية؟	to get a professional assistant for any emotional problems
17c	أن تحصل على معلومات أكثر بخصوص مرض السرطان؟	to get more information about cancer
17d	أن تحصل على معلومات أكثر بخصوص موضوعات ذات علاقة بعلاج مرض السرطان	to get more information about treatment of cancer
17e	أن تحظى بإرشاد نفسي يساعدك في علاقاتك ؟	to get psychological guidance to help your relationship
17f	أن تحظى بإرشاد روحاني (ديني)؟	to get religious guidance or spiritual guidance
17g	أن تحظى بمساعدة تعينك على التنقل؟	to get assistance in transportation
17h	أن تحظ بمساعدة تعينك على المشي؟	to get assistance in walking
17i	أن تحظى بمساعدة تعينك على الاستحمام ؟	to get assistance in bathing
17j	أن تحصل على مساعدة مالية؟	to get financial assistance
17k	أن تحظى بنصيحة غذائية؟	to get dietary advise
17l	أن تحظى بمساعدة تعينك على رعاية أبنائك؟	to get assistance in caring of your children
CONSTRUCT: Financial Support		
18	خلال الأسابيع الأربعة الماضية	During the last four weeks,
18a	عانيت من صعوبات في دفع الفواتير المنزلية	I have difficulties in paying my domestic bills
18b	عانيت صعوبات تحمل أعباء مصاريفي الطبية. الحث: مثلاً, الأدوية, الأجهزة الطبية	I have difficulties paying the cost of my medical care (i.e., medicine, medical equipment)
18c	يعتبر مرضي عبئا ماديا على أسرتي.	My sickness is considered a financial burden on my family
Medical History		
19i	ارتفاع في ضغط الدم	Hypertension
19ii	أمراض القلب	Heart diseases
19iii	أمراض السكر	Diabetic diseases
19iv	أمراض الكلى	Kidney diseases
19v	أمراض الرئة	Lung diseases
19vi	ولا واحد مما سبق	None of the above
19vii	أمراض أخر	Other diseases
19a	ما هي الأمراض الأخرى التي أصبت بها؟	What other diseases are you suffering from?
20	كم مرة تكررخلت خلالها للعلاج من أمراض أخرى غير السرطان ؟	How many times have you been admitted to be treated from diseases other than cancer?
21	كم مرة تكرر دخولك للمستشفى خلال الأشهر الستة الماضية؟	How frequent have you been admitted to the hospital in the last 6 months?

22	ما نوع التداوي الذي تلقيته لمرض السرطان؟ **الحث:** إذا تلقيت أكثر من نوع من التداوي, فالرجاء أن تخبرني ما هي تلك الأنواع.	What kind of therapy have you received for cancer (if you received more than one type of therapy, please mention them)
22i	العلاج الكيماوي	Chemotherapy
22ii	العلاج الإشعاعي	Radiotherapy
22iii	الجراحة	Surgery
22iv	العلاج الهرموني	Hormonal therapy
22v	غير متأكد	Not sure
23	هل سبق لك أن إستعملت أي وصفات شعبية أو تقليدية لعلاج السرطان؟ الحث: مثلاً, أعشاب, أو كي	Have you ever used traditional therapy for cancer? (Herbal therapy or cautery)
23a	قل (قولي) لي ما هي أنواع الوصفات الأخرى التي سبق لك تجربتها؟	Tell me what type of prescriptions have you ever tried?
Demographics		
24	أين تسكن؟ **الحث**: مثلا , أين مسكنك الدائم إن كنت تسكن بالرياض بشكل مؤقت	Where do you live? Where is your permanent resident, if you are temporarily living in Riyadh?
24i	في الرياض	in another city
24ii	في مدينة أخرى	in a small town
24iii	في مدينة صغيرة	in a rural area
24iv	في منطقة ريفية	
25	ما هو أعلى مستوى تعليمي حصلت عليه؟	What is your highest educational attainment?
25i	ليس هناك تعليم نظامي	No regular education
25ii	ثانوية أو أقل	Secondary school or less
25iii	كلية	College education
26	ما هو متوسط دخلك الشهري؟ **الحث:** مثلاً, إذا كنت لا تعلم أو تفضل عدم الإجابة فلا بأس في ذلك ؟	What is your average monthly income? For example, if you do not know or you prefer not to answer, it is okay.
26i	أقل من 2000 ريال	Less than 2000 SAR
26ii	2,000 - 4,999	2,000 - 4,999
26iii	5,000 - 10,000	5,000 - 10,000
26iv	أكثر من 10,000	more than 10,000
26v	لست متأكداً	Not sure
26vi	أفضل عدم الإجابة	I prefer not to respond
27	كم عدد الأشخاص الذين يعيشون معك في نفس البيت؟	How many persons are living with you at the same house?
28	هل ما زال والدك على قيد الحياة؟	Is your father still alive?
29	هل مازالت والدتك على قيد الحياة؟	Is your mother still alive?
30	كم عدد أشقائك وشقيقاتك البالغين ؟	How many adult siblings do you have?
31	كم عدد إخوانك البالغين ؟ [illegible] 18 [illegible]	How many adult brothers (48 years old and above) do you have?
32	كم عدد أخواتك البالغات ؟	How many adult sisters you have?
33	ما هي حالتك الزوجية؟	What is your marital status?
33i	متزوج\ متزوجة	Married
33ii	أرمل\ أرملة	Widow
33iii	مطلق/ مطلقة	Divorced
33iv	منفصل / منفصلة	Separated
33v	لم أتزوج مسبقاً	Never married
34	كم زوجة لديك ؟	How many wives do you have?
35	كم لديك من الأبناء؟	How many children do you have?
36	كم عدد أبناءك الذين يعيشون معك في البيت؟	How many children are living with you at home?
37	ما هو أفضل وصف للمنزل الذي تعيش فيه؟	What is the right description of the house you live in?
37i	منزل \ فيلا	Villa / house
37ii	شقة	apartment
37iii	خيمة	tent
37iv	سكن آخر	other housing
38	ما هو مصدر المياه الذي يغذي منزلك؟	What is the source of water to your house?
38i	التغذية الرئيسية (التحلية)	main source (desalination)
38ii	بئر ماء	well
38iii	وايت ماء	tanker
38iv	أنابيب ضخ إضافية	extra additional pipes
39	ما هو مصدر الطاقة الكهربائية التي تصل لمنزلك؟	What is the source of electricity to your house?
39i	لا يوجد	None of the above
39ii	المصدر الرئيسي(شركة كهرباء)	Main source (electric company)
39iii	مولد	Generator

CONSTRUCT: Setting of Care		
40a	أفضل أن تقوم أسرتي برعايتي في المنزل	I prefer that my family take care of me at home.
40b	أشعر بالعزلة والوحدة عندما أكون بالمستشفى	I feel isolated and lonely when I am admitted at the hospital.
40c	أفضل أن أكون في المستشفى عندما لا أستطيع الاعتناء بنفسي	I prefer to be in the hospital when I can not take care of me.
40d	أترك لأسرتي أن تقرر أين سيتم الاعتناء بي	I leave it to my family to decide where I will be taken cared of.
40e	إذا كانت أسرتي غير قادرة على الاعتناء بي فإنني ارغب ان اقيم في مؤسسة صحية خاصة برعاية مرضى السرطان الغير قابل للشفاء. الحث: مكان يكون الأطباء والممرضين قد تلقوا تدريبا خاصا للإهتمام بمرضى السرطان	If my family is unable to take care of me, I would like to live in a special medical institute for the care of terminal cancer patients, (a place where doctors and nurses receive special training to care for cancer patients).
Burden of Participation		
41	بشكل عام , ماذا تعتقد (تعتقدين) عن الأسئلة في هذه الدراسة ؟ هل كانت:	In general, what do you think about the questions in this survey?
41i	صعبة للغاية	very difficult
41ii	صعبة إلى حد ما	difficult to some extent
41iii	معقولة	reasonable
41iv	سهلة إلى حدا ما	easy to some extent
41v	سهلة للغاية	very easy
42	بشكل عام, هل كانت تعليماتي:	In general, were my instructions ....?
42i	صعبة للغاية	very difficult
42ii	صعبة إلى حد ما	difficult to some extent
42iii	معقولة	reasonable
42iv	سهلة إلى حدا ما	easy to some extent
42v	سهلة للغاية	very easy
43	شكل عام , ما رأيك في طول الوقت المستهلك لإكمال هذه الدراسة؟	In general, what do you think about the time spent to complete this
43i	طويل للغاية	too long
43ii	طويل إلى حد ما	long to some extent
43iii	معقول	reasonable
43iv	قصير إلى حد ما	short to some extent
43v	قصير جدا	very short
44	بشكل عام: كيف كانت تجربتك في أن تأخذ هذه الدراسة .	In general, how was your experience in taking this survey?
44i	تجربة سيئة للغاية	very hard experience
44ii	تجربة سيئة إلى حد ما	bad experience, no sure extent
44iii	لا يوجد تأثير	no effect
44iv	تجربة إيجابية إلى حد ما	positive experience to some extent
44v	تجربة إيجابية للغاية	very positive experience
45	هل لديك الرغبة في الإستجابة لهذه الدراسة المسحية مرة أخرى خلال فترة لا تتجاوز إسبوع من الآن؟ الحثّ: لمساعدتنا في التأكد إذا كنا نطرح الأسئلة بالطريقة الصحيحة، أنت حر أن تختار اجراء مسح	Are you willing to take this survey again within one week from now? (to help us make sure if we were asking the questions on the right way /

Thank you for giving your time to participate in this research activity.

APPENDIX F
Expert Panel Invitation Letter



King Abdulaziz Medical City – Riyadh
National Guard Heath Affairs
Department of Oncology

CONFIDENTIAL

Expert ID #________

EXPERT REVIEW OF THE PATIENT NEEDS SURVEY INSTRUMENT

SUSAN VOLKER, PHD CANDIDATE,
UNIVERSITY OF ALABAMA AT BIRMINGHAM, USA

Title: **Development and Validation of the Palliative Care Needs Assessment – English/Arabic Versions (PCNA–EAV) Instrument for Use with Patients with Advanced Cancer**

Dear Dr. Al Safi,

I am inviting you to participate in this palliative care needs assessment project, as one of a panel of experts in this field. This research project is being conducted in partial fulfillment of my doctoral degree in Health Services Research at UAB, in collaboration with the Department of Oncology at KAMC-R.

Would you kindly review the both the English and Arabic versions and provide written feedback by checking the appropriate box and writing comments/explanations (in English) for any particular item in the comments column.

This survey will be followed up, within one week of the completed questionnaire being received and prior to the instrument being pretested, by a short interview to clarify any comments you have made.

Additional issues to keep in mind include:
- Is the instrument comprehensive? Does it include all the domains (topics e.g. physical, psychological, etc.) that you believe should be included in a needs survey?
- Are the response choices for items appropriate? Should there be more options added?
- Are the interviewer instructions clear?
- Are the introductions to each new batch of questions easy for the respondent to understand?

Please any additional comments in the space provided on the last page of the questionnaire.

This is a draft instrument and will be pretested on 25 subjects. Data will be analyzed and additional modifications to the instrument made, as required. Your feedback is much appreciated.

N.B. Please make all notes/comments in English, for the purpose of qualitative analysis.

Thank you for your support of this project. If possible, would you give me your written feedback by Wednesday, January 21, 2009, ready for the next phase of the study.

APPENDIX G

Expert Panel Questionnaire

National Guard Health Affairs
KAMC-R

Department of Oncology
Patient Needs Assessment Survey
Expert Review of Survey Instrument - English/Arabic Versions

Protocol #: RC08?033
Expert ID: __________

#	Question	Translation Accurate		Culturally Equivalent		Represents Construct		Question Clear		Include in Questionnaire		Include in Q"aire . with Changes		Comments
		Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
CONSTRUCT: Physical - Symptoms														
1	In the last four weeks, how much need for help did you have: كم كان مقدار احتياجك للمساعدة في الأسابيع الأربعة الماضية؟													
1a	Dealing with pain التعامل مع الألم													
1b	Dealing with difficulty breathing التعامل مع صعوبة التنفّس													
1c	Dealing with fatigue التعامل مع الإجهاد													
1d	Dealing with lack of sleep التعامل مع إنعدام النوم													
1e	Dealing with nausea and/or vomiting التعامل مع الغثيان / أو الإستفراغ													
1f	Dealing with poor appetite التعامل مع نقص الشهية													
1g	Dealing with difficulty eating and/or swallowing التعامل مع صعوبة الأكل / أو البلع													
1h	Dealing with constipation التعامل مع الإمساك													
1i	Dealing with bladder and/or bowel incontinence التعامل مع عدم كفاءة المثانة و/ أو الأمعاء													
1j	Dealing with sexual dysfunction التعامل مع القصور الجنسي													
CONSTRUCT: Physical - Activities of Daily Living														
2	On average, over the past four weeks how often did you need help with: كيف كان احتياجك للمساعدة في الأسابيع الأربعة الماضية بخصوص													
2a	Bathing or showering الاغتسال أو الاستحمام؟													
2b	Dressing yourself إلباسك لنفسك؟													
2c	Getting out of bed? النهوض من السرير(فراشك)؟													
2d	Walking more than 10 steps **Prompt:** For example, walking across a room المشي لأكثر من عشر خطوات؟ مثلاً المشي في الغرفة؟													
2e	Going up stairs **Prompt:** For example climbing up 5 stairs صعود الدرج؟ مثلاً صعود خمس درجات من السلم؟													
2f	Performing Wudu (Ablutions before praying) القيام بالوضوء؟ أي الغسل قبل الصلاة؟													
2g	Performing Salah (Prayer Ritual) أداء الصلاة؟ أي طقوس الصلاة؟													
CONSTRUCT: Physical - Instrumental Activities of Daily Living														
2h	Shopping **Prompt:** For example buying groceries or essential personal items التسوق؟مثلاً شراء المستلزمات اليومية والأشياء الشخصية؟													
2i	Household chores **Prompt:** preparing meals, cleaning الأعمال المنزلية؟ أي إعداد وجبات الطعام أو التنظيف؟													
2j	Performing your usual duties at work **Prompt:** Inside your home or at place of employment أداء واجباتي اليومية في العمل؟													
2k	Personal transportation. **Prompt:** For example, having to find someone to drive you to keep a clinic appointment, or visiting friends الشغل الشخصي؟ مثلاً العثور على شخص لاصطحابك بالسيارة إلى مواعيد العيادة أو زيارة الأصدقاء؟													
	On average, over the past four weeks how often did you need help with: انتقل للسؤال الثالث إذا لم يكن لدى المريض أطفال {													
2l	Getting your children to school each day? إيصال أبناءك إلى المدرسة يومياً ؟													
2m	Caring for your children at home? الإعتناء بأبناءك في البيت ؟													
2n	Getting transportation for your child's (childrens') activities outside the home Prompt: Getting them to school or to a doctor's appointment إيصال أبناءك لأحد المستشفيات للعناية الصحية بهم ؟													

#	Question	Translation Accurate		Culturally Equivalent		Represents Construct		Question Clear		Include in Questionnaire		Include in Q"aire . with Changes		Comments
		Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
CONSTRUCT: Psychological - Self-Efficacy														
3	**Over the past four weeks :** خلال الأسابيع الأربعة الماضية؟													
3a	I have felt confident I can cope with my illness شعرت بالثقة لمقدرتي على التأقلم مع مرضي													
3b	I have felt free to make my own decisions about the health care I receive related to my cancer? أنا واثق/ واثقة من القدرة على الاعتناء بعائلتي													
3c	I have felt I cannot manage my life because of my illness أشعر بحرية التصريح لطبيبي عما أفضله بخصوص رعايتي													
3d	I have felt confident I can continue my usual work activities **Prompt:** For example work at home or in place of employment أشعر بفقدي للسيطرة على حياتي													
3e	I have felt confident in my ability to take care of those I am responsible for, despite my illness لم يتغير دوري داخل أسرتي منذ أن أصبت بالمرض													
3f	I have little interest in doing everyday activities **Prompt**: talking on the phone; visiting with friends أصبحت أقل اهتماماً بأداء نشاطاتي الاعتيادية													
3g	My illness has made me more aware of my emotional strength أنا قادر على إنهاء الأشياء التي أرغب بالقيام بها													
3h	I have felt that my role within my family has stayed the same. جعلني مرضي أكثر وعياً بمواطن القوة لدي													
CONSTRUCT: Psychological - Depression														
4a	I look forward to beginning each new day أتطلع لكل يوم جديد													
4b	I feel I have no purpose in life because of my cancer أشعر بأن لا هدف لي في الحياة													
4c	I feel guilty that I may be a burden on my family أشعر بالقلق بخصوص مستقبلي													
4d	On average, I sleep well every night أنام بشكل جيد كل ليلة													
4e	I feel I am valued by those close to me أشعر بالتقدير من أولئك المقربين مني													

#	Question	Translation Accurate		Culturally Equivalent		Represents Construct		Question Clear		Include in Questionnaire		Include in Q"aire . with Changes		Comments
		Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
4f	I I have no-one to talk to about the way I am feeling أشعر بأن لا أحد حولي لأكلمه عن أفكاري ومشاعري													
4g	I feel sad أشعر بأنني مكتئب													
4h	I feel fearful about my future اشعر بالخوف بخصوص ما يحدث لي													
CONSTRUCT: Psychological - Cognition														
5a	I have trouble understanding new information أجد صعوبة في فهم المعلومات الجديدة													
5b	I have difficulty remembering things that happened a week ago أجد صعوبة في تذكر الأشياء													
5c	I have difficulty concentrating for more than a few minutes on small tasks I used to do easily أجد صعوبة في التركيز													
5d	I have difficulty taking decisions about routine daily activities يتشتت انتباهي بسهولة													
5e	I am easily confused أجد صعوبة في اتخاذ القرارات													
CONSTRUCT: Social - Relationships														
6a	My illness improved my relationship with my spouse كان لمرضي تأثير في تحسين علاقتي بزوجي/زوجتي.													
6b	My spouse is very supportive زوجتي داعمة لي جداً/ زوجي داعم لي جدا.													
6c	I feel I can talk freely to my spouse about any problems I am facing تظهر زوجتي/زوجي بأنه مهتم لما أشعر به.													
6d	My spouse is having difficulty dealing with my illness أشعر بأنني أستطيع التحدث بحرية إلى زوجتي/زوجي عما أعانيه من مشاكل.													
6e	My relatives feel uncomfortable spending time with me since my illness تواجه زوجتي/زوجي وقتاً عصيبا في التعامل مع مرضي.													
6f	My relatives make me feel less worried about my illness when they spend time with me يزورني أقاربي في البيت اكثر مما كانوا قبل مرضي.													
6g	My friends make me feel less worried about my illness when they spend time with me													

#	Question	Translation Accurate		Culturally Equivalent		Represents Construct		Question Clear		Include in Questionnaire		Include in Q"aire . with Changes		Comments
		Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
	يشعرني أصدقائي (صديقاتي) بأنني أقل قلقا بخصوص مرضي عندما يقضون معي بعض الوقت													
CONSTRUCT: Information Needs														
7a	I need more information about my cancer أحتاج لمعلومات أكثر بخصوص مرض السرطان الذي أعاني منه.													
7b	I am confused by the information I have been given about my treatment أنا محتار (محتارة) بخصوص المعلومات المقدمة لي والمتعلّقة بعلاجي													
7c	I have been told all I want to know about my cancer لقد تمّ إخباري بكل ما أريد معرفته عن مرض السرطان الذي أعاني منه.													
7d	I prefer my oncologist makes all my medical decisions for me أفضّل أن يقوم طبيب الأورام باتخاذ جميع القرارات الطبية نيابة عني..													
7e	I prefer my oncologist discusses the details of my illness with me when my family are present أفضل أن يقوم طبيب الأورام بمناقشة تفاصيل مرضي معي أثناء وجود أفراد أسرتي													
7f	I prefer my oncologist discusses all the details of my illness with me only أفضل أن يقوم طبيب الأورام بمناقشة جميع تفاصيل مرضي معي فقط.													
7g	I have been given all the information I need to take care of myself لقد تمّ إعطائي جميع المعلومات التي أحتاج من أجل العناية بنفسي.													
7h	I need more information about my medications أحتاج إلى معلومات أكثر بخصوص أدويتي.													
7i	My family members have been given all the information they need to take care of me لقد حصل أعضاء أسرتي على جميع المعلومات التي يحتاجون من أجل العناية بي													
CONSTRUCT: Information Needs -Source														
8	The information given to me by _______________ was helpful المعلومات المقدمة لي بواسطة ____________ كانت مفيدة:													
8a	My family doctor طبيب الأسرة والمجتمع													
8b	My oncologist طبيب الأورام													
8c	Nursing staff طاقم التمريض													
8d	Social workers الأخصائيين الاجتماعين													
8e	Patient educators المثقفين الصحيين													
8f	Other patients المرضى الآخرين													
8g	Family الأسرة													
8h	Friends الأصدقاء													
8i	Media, e.g. television, radio الوسائل الإعلامية (مثل : التلفزيون, الجرائد)													
8j	Printed Information from the hospital (e.g. brochures, pamphlets) المعلومات المطبوعة (مثل : االكتيبات, المطويات)													
8k	Internet Websites صفحات الإنترنت													
9	On a scale from 1 to 5, with 1 being really easy and 5 being extremely difficult, how difficult was it for you to get the information you needed? على مقياس من 1 إلى 5 , ما مدى صعوبة الحصول على المعلومات التي تحتاجها؟ (حيث (1) يعني سهل جدا, و (5) يعني بالغ الصعوبة).													
CONSTRUCT: Communication														
10a	My doctor discusses all the options for care that are available to me ناقش طبيبي كل خيارات الرعاية المتاحة لي													
10b	My doctor gives me clear answers to all my questions أجاب طبيبي على جميع أسئلتي													
10c	My doctor has explained clearly to me about the physical difficulties I may face شرح لي طبيبي وبكل وضوح جميع المشاكل الجسدية التي ربما أواجهها													
10d	My nurses understand me when I talk to them يفهمني الممرضون والممرضات عندما أتحدّث إليهم													
10e	Nurses take time to listen to what I am saying يمنحني الممرضون والممرضات الوقت اللازم لسماع ما أريد قوله													
10f	I understand what my nurses are saying when they talk to me. عندما يحدّثني الممرضون (أو الممرضات) فإنني أفهم ما يقولون													
10g	There is always an interpreter present when necessary to translate instructions I am being given يتواجد المترجم بشكل دائم عندما يكون هناك ضرورة لترجمة التعليمات المقدمة لي													
CONSTRUCT: Social Support - Numerical														

#	Question	Translation Accurate		Culturally Equivalent		Represents Construct		Question Clear		Include in Questionnaire		Include in Q"aire . with Changes		Comments
		Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
11	How many adult female relatives live with you? Prompt: Aged 14 years or over? الحثُّ: البالغات 18 سنة فما فوق؟													
12	How many maids do you have at home? كم عدد الخادمات اللاتي يعملن في بيتك؟													
13	How many drivers do you have? كم سائقا لديك؟													
14	How many family members that you feel you can rely on for help live within one hour's drive of your home? كم عدد أفراد عائلتك الذين يعيشون على بعد ساعة قيادة من بيتك وتشعر أن بإمكانك الاعتماد عليهم في المساعدة ؟													
CONSTRUCT: Social Support														
15a	I have family and friends I can count on if I need any help. لدي أسرة وأصدقاء بإمكاني الاعتماد عليهم فيما لو احتجت إلى أي مساعدة.													
15b	Since my illness members of my extended family visit me less than before قلت زيارات أفراد أسرتي الممتدّة عما كانت عليه قبل مرضي													
15c	Friends show they care about me, despite my illness أظهر أصدقائي مدى حرصهم عليّ على الرغم من مرضي													
15d	My family wants me to be admitted into hospital when I am sick. ترغب أسرتي أن يتمّ تنويمي في المستشفى عندما أكون مريضاً													
15e	I feel isolated from others because of my illness اشعر بأنني معزول عن الآخرين بسبب مرضي													
CONSTRUCT: Religious/Spiritual														
16a	I believe someone has caste a magic spell on me اعتقد بأن شخص ما قد عمل لي سحراً.													
16b	I believe an evil eye affected me اعتقد بأنني أصبت بعين.													
16c	I believe someone has prayed to Allah for me to get sick أعتقد بأن شخصاً ما قد دعا علي.													
16d	I believe that my suffering is a test of my faith أعتقد بأن ما أصابني إنما هو امتحاناً لإيماني.													
16e	My spiritual beliefs are very strong معتقداتي الروحانية (الدينية) قوية جداً.													
16f	I am afraid of the day of judgment ليس الموت ما أخافه وإنما هو يوم العقاب.													

#	Question	Translation Accurate		Culturally Equivalent		Represents Construct		Question Clear		Include in Questionnaire		Include in Q"aire . with Changes		Comments
		Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
16g	I believe my illness is a punishment from Allah أعتقد بأن مرضي هو عقاب من الله.													
16h	Allah will wash away my sins because of this illness سوف يغفر الله لي خطاياي بسبب مرضي هذا													
CONSTRUCT: Needs Priorities														
17	How important is it to you: ما مدى أهميتها بالنسبة لك؟													
17a	To receive professional assistance to help you with your daily activities? أن تحظ بمساعدة مهنية تساعدك على القيام بنشاطاتك اليومية؟													
17b	To receive professional help with any emotional problems? أن تحظ بمساعدة مهنية لأي مشاكل انفعالية؟													
17c	To receive more information about your cancer? أن تحصل على معلومات أكثر بخصوص مرض السرطان؟													
17d	To receive more information about issues about your cancer treatment? أن تحصل على معلومات أكثر بخصوص موضوعات ذات علاقة بعلاج مرض السرطان													
17e	To receive counseling to help your relationships أن تحظ بإرشاد نفسي يساعدك في علاقاتك ؟													
17f	To receive spiritual counseling? أن تحظ بإرشاد روحاني (ديني)؟													
17g	To receive assistance with transportation? أن تحظ بمساعدة تعينك على التنقل؟													
17h	To receive assistance with walking أن تحظ بمساعدة تعينك على المشي؟													
17i	To receive assistance with bathing أن تحظ بمساعدة تعينك على الاستحمام ؟													
17j	To receive financial assistance? أن تحصل على مساعدة مالية؟													
17k	To receive dietary advice أن تحظ بنصيحة غذائية؟													
17l	To receive assistance with caring for your children? أن تحظى بمساعدة تعينك على رعاية أبنائك؟													
CONSTRUCT: Financial Support														
18	Over the past four weeks:													

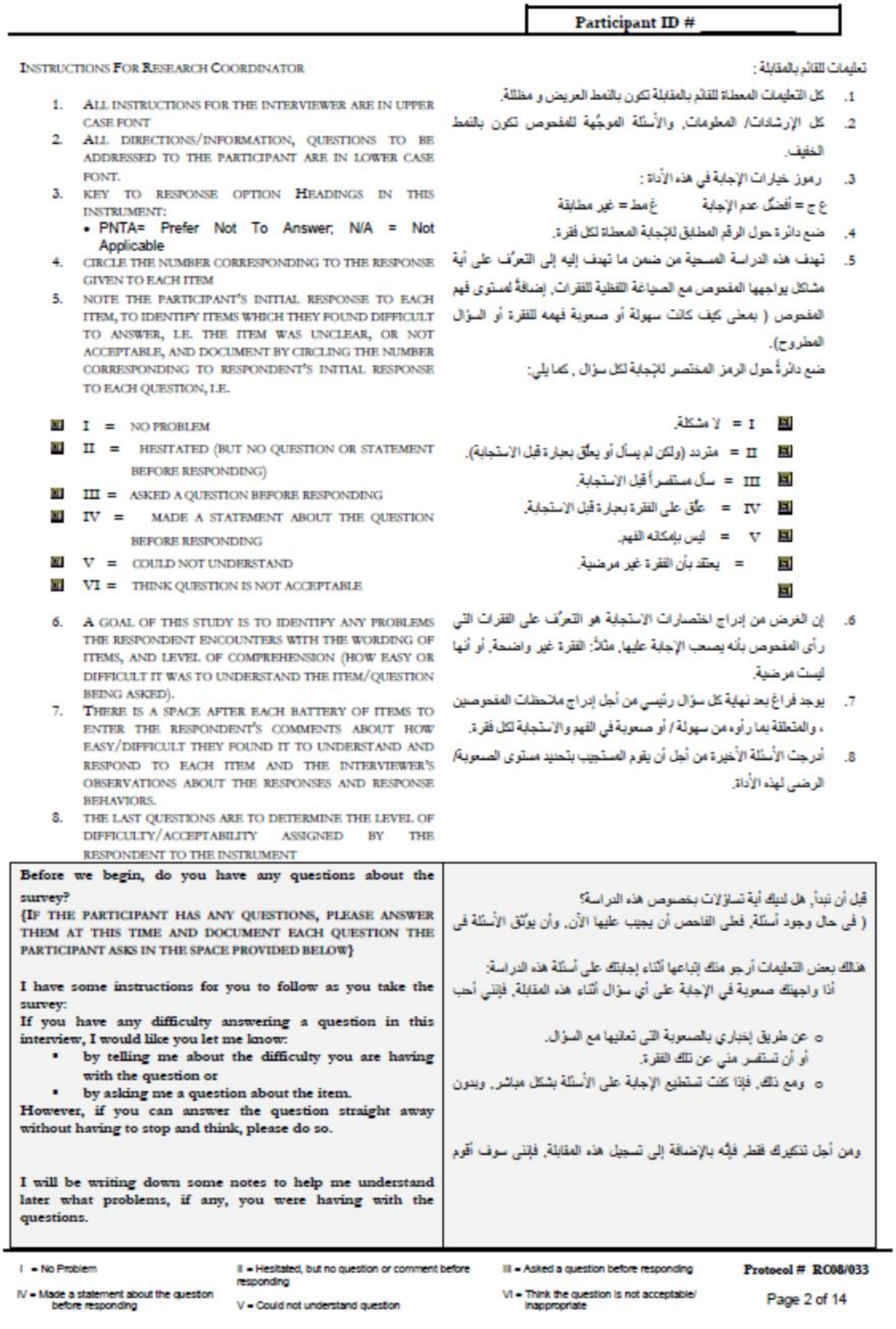
#	Question	Translation Accurate		Culturally Equivalent		Represents Construct		Question Clear		Include in Questionnaire		Include in Q"aire . with Changes		Comments
		Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
	خلال الأسابيع الأربعة الماضية													
18a	I have had difficulty paying my household bills عانيت من صعوبات في دفع الفواتير المنزلية													
18b	I have had difficulty paying for my medical expenses Prompt: for example, medications, medical equipment عانيت صعوبات تحمل أعباء مصاريفي الطبية. الحث: مثلاً, الأدوية, الأجهزة الطبية													
18c	My illness is a financial hardship on my family يعتبر مرضي عبئا ماديا على أسرتي.													
18d	My household income has significantly decreased because of my illness انخفض دخلي الأسري بشكل لافت نتيجة لمرضي.													
Medical History														
19	For which of the following illnesses have you ever received treatment? هل تلقيت علاجاً لأي من الأمراض التالية؟													
i	High blood pressure ارتفاع في ضغط الدم													
ii	Heart Disease أمراض القلب													
iii	Diabetes أمراض السكر													
iv	Kidney أمراض الكلى													
v	Lung أمراض الرئة													
vi	None of the above ولا واحد مما سبق													
vii	Any other illness أمراض أخر													
19a	Which other serious illnesses have you had? ما هي الأمراض الأخرى التي أصبت بها؟													
20	How many times have you been hospitalized for treatment of an illness other than cancer? كم عدد المرات التي أدخلت خلالها للعلاج من أمراض أخرى غير السرطان ؟													
21	How many of these hospitalizations were less than six months ago? إذا تكرر دخولك للمستشفى لأكثر من مرة فكم مرة منها كان خلال الأشهر الستة الماضية؟													
22	Which type of treatment have you received for your cancer? Prompt: If you have had more than one type of treatment, please tell me which ما نوع التداوي الذي تلقيته لمرض السرطان؟ الحث: إذا تلقيت أكثر من نوع من التداوى, فالرجاء أن تخبرنى, ما هى تلك الأنواع.													
i	Chemotherapy العلاج الكيماوي													
ii	Radiation therapy العلاج الإشعاعي													
iii	Surgery الجراحة													
iv	Hormonal therapy العلاج الهرموني													
v	Other أخرى													
vi	Unsure غير متأكد													
22a	Which other treatments have you had? قل (قولي) لي ما هي أنواع الأدوية الطبية الأخرى التي استعملت؟													
23	Have you received any tribal or traditional remedies for your cancer? Prompt: for example herbal medicines or cautery هل سبق لك أن إستعملت أي وصفات شعبية أو تقليدية لعلاج السرطان؟ الحث: مثلاً, أعشاب, أو كي													
23a	Tell me which remedies have you tried? قل (قولي) لي ما هي أنواع الوصفات الأخرى التي سبق لك تجربتها؟													
Demographics														
24	Where do you live? Prompt: Where is your permanent home, if you are only temporarily in Riyadh? أين تسكن؟ الحث :مثلا , أين مسكنك الدائم إن كنت تسكن بالرياض بشكل مؤقت													
24i	In Riyadh في الرياض													
24ii	In another city في مدينة أخرى													
24iii	In a small town في مدينة صغيرة													
24iv	In a rural area في منطقة ريفية													
25	What is your highest level of education? ما هو أعلى مستوى تعليميا حصلت عليه؟													
25i	No formal schooling ليس هناك تعليم نظامي													
25ii	High school or less ثانوية أو أقل													
25iii	College graduate كلية													
26	What is your average monthly household income? Prompt: If you don't know, or if you prefer not to answer, that is fine ما هو متوسط دخلك الشهري؟ الحث:مثلاً, إذا كنت لا تعلم أو تفضل عدم الإجابة فلا بأس في ذلك ؟													
26i	Less than 2,000 Riyals أقل من 200 ريال													
26ii	2,000 – 4,999 Riyals 2000 - 4.999													
26iii	5,000 to 10,000 Riyals 5000 - 10.000													
26iv	More than 10,000 Riyals أكثر من 10.000													
26v	Not sure لست متأكداً													
26vi	Prefer not to answer أفضل عدم الإجابة													
27	How many people live at home with you													

#	Question	Translation Accurate		Culturally Equivalent		Represents Construct		Question Clear		Include in Questionnaire		Include in Q"aire . with Changes		Comments
		Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
	كم عدد الأشخاص الذين يعيشون معك في نفس البيت؟													
28	Is your father still living? هل ما زال والدك على قيد الحياة؟													
29	Is your mother still living? هل مازالت والدتك على قيد الحياة؟													
30	How many adult siblings do you have? كم عدد أشقائك وشقيقاتك البالغين ؟													
31	How many adult brothers? Prompt: Aged 18 or over كم عدد إخوانك البالغين ؟ الحث: عمر 18 سنة فأكثر													
32	How many adult sisters? كم عدد أخواتك البالغات ؟													
33	What is your current marital status? ما هي حالتك الزواجية؟													
33i	Married متزوج\ متزوجة													
33ii	Widowed أرمل\ أرملة													
33iii	Divorced منفصل\ منفصلة													
33iv	Separated لم يسبق له \ لها الزواج													
33v	Never Married ما هي حالتك الزواجية													
34	How many wives do you have? كم زوجة لديك ؟													
35	How many children do you have? كم لديك من الأبناء؟													
36	How many of your children live with you? كم من أبنائك يعيش معك في البيت؟													
37	Which best describes the kind of home you live in? ما هو أفضل وصف للمنزل الذي تعيش فيه؟													
37i	House/Villa منزل \ فيلا													
37ii	Apartmen شقةt													
37iii	Ten خيمةt													
37iv	Other أخرى													
38	What is the source of the water supply for your home? ما هو مصدر المياه الذي يغذي منزلك؟													
38i	Mains supply (التغذية الرئيسية (التحلية)													
38ii	Well water بئر ماء													
38iii	Tanker وايت ماء													
38iv	Standpipe أنابيب ضخ إضافية													
39	What is the source of the electrical supply for your home? ما هو مصدر الطاقة الكهربائية التي تصل لمنزلك؟													
39i	None لا يوجد													
39ii	Main supply المصدر الرئيسي(شركة كهرباء)													
39iii	Generator مولد													
CONSTRUCT: Setting of Care														
40a	I prefer that my family take care of me at home أفضل أن تقوم أسرتي برعايتي في المنزل													
40b	I feel isolated and alone when I am in the hospital أشعر بالعزلة والوحدة عندما أكون بالمستشفى													
40c	I prefer to be in the hospital when I can no longer take care of myself أفضل أن أكون في المستشفى عندما لا أستطيع الاعتناء بنفسي													
40d	I leave it to my family to decide where I will be cared for أترك لأسرتي أن تقرر أين سيتم الاعتناء بي													
40e	If my family are unable to care for me, I would prefer to stay in a health care facility specially for people with incurable cancer. Prompt: a place where doctors and nurses are specially trained to look after patients with cancer إذا كانت أسرتي غير قادرة على الاعتناء بي فإنني ارغب أن أقيم في مؤسسة صحية خاصة برعاية مرضى السرطان الذين لا يرجى شفاؤهم. الحث: مكان يكون الأطباء والممرضين قد تلقوا تدريبا خاصا للإهتمام بمرضى السرطان													
Burden of Participation														
41	Overall, what did you think of the questions in this survey? Were they: بشكل عام , ماذا تعتقد (تعتقدين) عن الأسئلة في هذه الدراسة ؟ هل كانت ..													
41i	Extremely difficult صعبة للغاية													
41ii	Somewhat difficult صعبة إلى حد ما													
41iii	About right معقولة													
41iv	Somewhat easy سهلة إلى حدا ما													
	Extremely easy سهلة للغاية													
42	Overall, were my instructions to you easy to follow													

#	Question	Translation Accurate		Culturally Equivalent		Represents Construct		Question Clear		Include in Questionnaire		Include in Q"aire . with Changes		Comments
		Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
42	بشكل عام, هل كان من السهل عليك إتباع تعليماتي؟													
42i	Extremely difficult صعبة للغاية													
42ii	Somewhat difficult صعبة إلى حد ما													
42iii	About right معقولة													
42iv	Somewhat easy سهلة إلى حدا ما													
42v	Extremely easy سهلة للغاية													
43	Overall, what do you think about the length of time it took to complete this survey? Was it: شكل عام , ما رأيك في طول الوقت المستهلك لإكمال هذه الدراسة؟ هل كان......													
43i	Extremely long طويل للغاية													
43ii	Somewhat long طويل إلى حد ما													
43iii	About right معقول													
43iv	Somewhat short قصير إلى حد ما													
43v	Extremely short قصير جدا													
44	Overall, what effect did taking this survey have on you? Prompt: How was your experience taking this survey? بشكل عام , ماذا كان تأثير هذه الدراسة عليك ؟ كيف كانت تجربتك في أن تأخذ هذه الدراسة .													
44i	An extremely bad experience تجربة سيئة للغاية													
44ii	Somewhat bad experience تجربة سيئة إلى حد ما													
44iii	Had no effect لا يوجد تأثير													
44iv	Somewhat positive experience تجربة جيدة إلى حد ما													
44v	Extremely positive experience تجربة جيدة للغاية													
45	Would you be willing to take this same survey again in one week's time? Prompt: To help us be sure we are asking the questions in the right way. You are free to choose to retake it or not, as you wish. هل لديك الرغبة في الإستجابة لهذه الدراسة المسحية مرة أخرى خلال مدة لا تتجاوز إسبوع من الآن؟ الحثُ: لمساعدتنا في معرفة مدى جودة أداء هذا الاستبيان, بمرور الوقت, وللتعرُف على أي تغييرات ربما نحتاج إليها. ولك مطلق الحرية في تجربة هذا الفحص مرة أخرى كما يحق لك أن ترفض.													

APPENDIX H

Pretest Instrument



Participant ID # ______

INSTRUCTIONS FOR RESEARCH COORDINATOR

1. ALL INSTRUCTIONS FOR THE INTERVIEWER ARE IN UPPER CASE FONT
2. ALL DIRECTIONS/INFORMATION, QUESTIONS TO BE ADDRESSED TO THE PARTICIPANT ARE IN LOWER CASE FONT.
3. KEY TO RESPONSE OPTION HEADINGS IN THIS INSTRUMENT:
   - PNTA= Prefer Not To Answer; N/A = Not Applicable
4. CIRCLE THE NUMBER CORRESPONDING TO THE RESPONSE GIVEN TO EACH ITEM
5. NOTE THE PARTICIPANT'S INITIAL RESPONSE TO EACH ITEM, TO IDENTIFY ITEMS WHICH THEY FOUND DIFFICULT TO ANSWER, I.E. THE ITEM WAS UNCLEAR, OR NOT ACCEPTABLE, AND DOCUMENT BY CIRCLING THE NUMBER CORRESPONDING TO RESPONDENT'S INITIAL RESPONSE TO EACH QUESTION, I.E.

■ I = NO PROBLEM
■ II = HESITATED (BUT NO QUESTION OR STATEMENT BEFORE RESPONDING)
■ III = ASKED A QUESTION BEFORE RESPONDING
■ IV = MADE A STATEMENT ABOUT THE QUESTION BEFORE RESPONDING
■ V = COULD NOT UNDERSTAND
■ VI = THINK QUESTION IS NOT ACCEPTABLE

6. A GOAL OF THIS STUDY IS TO IDENTIFY ANY PROBLEMS THE RESPONDENT ENCOUNTERS WITH THE WORDING OF ITEMS, AND LEVEL OF COMPREHENSION (HOW EASY OR DIFFICULT IT WAS TO UNDERSTAND THE ITEM/QUESTION BEING ASKED).
7. THERE IS A SPACE AFTER EACH BATTERY OF ITEMS TO ENTER THE RESPONDENT'S COMMENTS ABOUT HOW EASY/DIFFICULT THEY FOUND IT TO UNDERSTAND AND RESPOND TO EACH ITEM AND THE INTERVIEWER'S OBSERVATIONS ABOUT THE RESPONSES AND RESPONSE BEHAVIORS.
8. THE LAST QUESTIONS ARE TO DETERMINE THE LEVEL OF DIFFICULTY/ACCEPTABILITY ASSIGNED BY THE RESPONDENT TO THE INSTRUMENT

تعليمات للقائم بالمقابلة :

1. كل التعليمات المعطاة للقائم بالمقابلة تكون بالنمط العريض و مظللة.
2. كل الإرشادات/ المعلومات, والأسئلة الموجُهة للمفحوص تكون بالنمط الخفيف.
3. رموز خيارات الإجابة في هذه الأداة :

ع ج = أفضّل عدم الإجابة   غ مط = غير مطابقة

4. ضع دائرة حول الرقم المطابق للإجابة المعطاة لكل فقرة.
5. تهدف هذه الدراسة المسحية من ضمن ما تهدف إليه إلى التعرُف على أية مشاكل يواجهها المفحوص مع الصياغة اللفظية للفقرات. إضافةً لمستوى فهم المفحوص (بمعنى كيف كانت سهولة أو صعوبة فهمه للفقرة أو السؤال المطروح).

ضع دائرةً حول الرمز المختصر للإجابة لكل سؤال , كما يلي:

■ I = لا مشكلة.
■ II = متردد (ولكن لم يسأل أو يعلّق بعبارة قبل الاستجابة).
■ III = سأل مستفسراً قبل الاستجابة.
■ IV = علّق على الفقرة بعبارة قبل الاستجابة.
■ V = ليس بإمكانه الفهم.
■ = يعتقد بأن الفقرة غير مرضية.
■

6. إن الغرض من إدراج اختصارات الاستجابة هو التعرُف على الفقرات التي رأى المفحوص بأنه يصعب الإجابة عليها, مثلاً: الفقرة غير واضحة, أو أنها ليست مرضية.
7. يوجد فراغ بعد نهاية كل سؤال رئيسي من أجل إدراج ملاحظات المفحوصين ، والمتعلقة بما رأوه من سهولة / أو صعوبة في الفهم والاستجابة لكل فقرة.
8. أدرجت الأسئلة الأخيرة من أجل أن يقوم المستجيب بتحديد مستوى الصعوبة/ الرضى لهذه الأداة.

Before we begin, do you have any questions about the survey? **{IF THE PARTICIPANT HAS ANY QUESTIONS, PLEASE ANSWER THEM AT THIS TIME AND DOCUMENT EACH QUESTION THE PARTICIPANT ASKS IN THE SPACE PROVIDED BELOW}**	قبل أن نبدأ, هل لديك أية تساؤلات بخصوص هذه الدراسة؟ (في حال وجود أسئلة, فعلى الفاحص أن يجيب عليها الآن. وأن يوثّق الأسئلة في
I have some instructions for you to follow as you take the survey: **If you have any difficulty answering a question in this interview, I would like you let me know:** **▪ by telling me about the difficulty you are having with the question or** **▪ by asking me a question about the item.** **However, if you can answer the question straight away without having to stop and think, please do so.**	هنالك بعض التعليمات أرجو منك إتباعها أثناء إجابتك على أسئلة هذه الدراسة: أذا واجهتك صعوبة في الإجابة على أي سؤال أثناء هذه المقابلة, فإنني أحب o عن طريق إخباري بالصعوبة التي تعانيها مع السؤال. أو أن تستفسر مني عن تلك الفقرة. o ومع ذلك, فإذا كنت تستطيع الإجابة على الأسئلة بشكل مباشر, وبدون
I will be writing down some notes to help me understand later what problems, if any, you were having with the questions.	ومن أجل تذكيرك فقط, فإنه بالإضافة إلى تسجيل هذه المقابلة, فإنني سوف أقوم

I = No Problem
II = Hesitated, but no question or comment before responding
III = Asked a question before responding
IV = Made a statement about the question before responding
V = Could not understand question
VI = Think the question is not acceptable/ inappropriate

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Participant ID # ____________

We will start now with a series of questions about physical problems. Many people experience different problems as their disease progresses. We would like to know about how much need for help you had with any physical problems you may have experienced over *the past four weeks*, as a result of having cancer.

Please choose one from these five possible answers:

- **High need – this problem caused you severe discomfort and you continue to need a great deal of help**
- **Moderate need – this problem caused you moderate discomfort and you continue to need a moderate amount of help**
- **Low need – this problem caused you mild discomfort and you continue to need a little help**
- **Need satisfied – was a problem, but had help and no longer a problem**
- **No need – not a problem**

سوف نبدأ الآن بطرح سلسلة من الأسئلة ذات العلاقة بالمشاكل الجسدية.
يعاني كثير من الناس من مشاكل مختلفة كلما تقدُم بهم المرض. ونرغب هنا أن

الرجاء اختيار واحدة من الإجابات الخمس المحتملة الآتية:

- لا حاجة = ليس هناك مشكلة خلال الشهر الماضي.
- حاجتى أشبعت = كان هناك مشكلة, وتلقيت المساعدة ولم يعد هناك مشكلة.
- حاجة دنيا = سببت لي عدم ارتياح بسيط وأستمر مما استدعى احتياجي
- حاجة متوسطة = سببت لي عدم ارتياح متوسط الشدة ومستمر مما استدعى
- حاجة قصوى = سببت لي عدم ارتياح شديد ومستمر مما استدعى احتياجي

{CIRCLE THE NUMBER CORRESPONDING TO THE RESPONSE}.

1	In the last four weeks, how much need for help did you have: كم كان مقدار احتياجك للمساعدة في الأسابيع الأربعة الماضية؟	Great Need حاجة قصوى	Moderate Need حاجة متوسطة	Little Need حاجة دنيا	Need Satisfied حاجتي أشبعت	No Need لا حاجة
1a	Dealing with pain التعامل مع الألم I II III IV V VI	1	2	3	4	5
1b	Dealing with difficulty breathing التعامل مع صعوبة التنفس I II III IV V VI	1	2	3	4	5
1c	Dealing with fatigue التعامل مع الخمول (الإجهاد) I II III IV V VI	1	2	3	4	5
1d	Dealing with lack of sleep التعامل مع قلة النوم (الأرق) I II III IV V VI	1	2	3	4	5
1e	Dealing with nausea and/or vomiting التعامل مع الغثيان / والتقيؤ (التطريش) I II III IV V VI	1	2	3	4	5
1f	Dealing with poor appetite التعامل مع نقص الشهية I II III IV V VI	1	2	3	4	5
1g	Dealing with difficulty eating and/or swallowing التعامل مع صعوبة الأكل / أو البلع I II III IV V VI	1	2	3	4	5
1h	Dealing with constipation التعامل مع الإمسا I II III IV V VI	1	2	3	4	5
1i	Dealing with bladder and/or bowel incontinence التعامل مع عدم التحكم في البول أو البراز I II III IV V VI	1	2	3	4	5

{IF NO SPOUSE, NOT LIVING WITH SPOUSE, OR LIVING WITH SPOUSE BUT HOSPITALISED FOR MORE THAN 1 WEEK DURING LAST FOUR WEEKS, SKIP TO Q. 2a}

1j	Dealing with sexual dysfunction التعامل مع القصور الجنسي I II III IV V VI	1	2	3	4	5
1k	Dealing with decreased sexual desires عدم الرغبة الجنسية I II III IV V VI	1	2	3	4	5

I = No Problem
II = Hesitated, but no question or comment before responding
III = Asked a question before responding
IV = Made a statement about the question before responding
V = Could not understand question
VI = Think the question is not acceptable/ inappropriate

Notes:

Sometimes patients' ability to do their usual daily activities changes over time. These next questions are about your ability to perform your usual activities over *past four weeks*.
Please choose the response which best applies to you:
All of the Time; Much of the Time; Most of the Time; Some of the Time; None of the Time

وهنا بعض الأسئلة بخصوص قدرتك على أداء نشاطاتك الاعتيادية خلال الأسابيع

الرجاء اختيار الإجابة التي تناسبك مما يلي:
لا ينطبق ، كل الوقت ، غالب الوقت ، بعضاً من الوقت ، مطلقاً (أبداً)

{BEGIN EACH QUESTION WITH THE FOLLOWING}: ابدأ كل سؤال بالتالي:

2	**On average, over the past four weeks how often did you need help with:** كيف كان احتياجك للمساعدة في الأسابيع الأربعة الماضية بخصوص	All of the Time كل الوقت	Most of the Time غالب الوقت	Much of the Time كثيراً من الوقت	Some of the Time بعضاً من الوقت	None of the Time ولا في أي وقت
2a	Bathing or showering الاغتسال أو الاستحمام؟ I II III IV V VI	1	2	3	4	5
2b	Getting dressed ارتداء ملابسك I II III IV V VI	1	2	3	4	5
2c	Getting out of bed? النهوض من السرير(فراشك)؟ I II III IV V VI	1	2	3	4	5
2d	Walking more than 10 steps **Prompt**: For example, walking across a room المشي لأكثر من عشر خطوات؟ مثلاً المشي في الغرفة؟ I II III IV V VI	1	2	3	4	5
2e	Going up stairs **Prompt**: For example climbing up 5 stairs صعود الدرج؟ مثلاً صعود خمس درجات من السلم؟ I II III IV V VI	1	2	3	4	5
2f	Performing Wudu القيام بالوضوء؟ أي الغسل قبل الصلاة؟ I II III IV V VI	1	2	3	4	5
2g	Performing Salah أداء الصلاة؟ أي بأداء أركان الصلاة؟ I II III IV V VI	1	2	3	4	5
2h	Shopping **Prompt**: For example buying groceries or personal items التسوق؟مثلاً شراء المقاضي والأشياء الشخصية؟ I II III IV V VI	1	2	3	4	5
2i	Household chores **Prompt**: preparing meals, cleaning الأعمال المنزلية؟ أي إعداد وجبات الطعام أو التنظيف، أو أعمال الصيانة؟ I II III IV V VI	1	2	3	4	5
{IF FEMALE. SKIP TO Q. 2k}						
2j	**Performing your usual work duties** أداء واجباتي اليومية في العمل؟ I II III IV V VI	1	2	3	4	5
2k	Transportation to get to an appointment at the hospital **Prompt**: For example, to see your doctor or keep a clinic appointment التنقل ؟ مثلاً العثور على شخص لاصطحابك بالسيارة إلى مواعيد العيادة أو زيارة طبيبك؟ I II III IV V VI	1	2	3	4	5

I = No Problem
II = Hesitated, but no question or comment before responding
III = Asked a question before responding
IV = Made a statement about the question before responding
V = Could not understand question
VI = Think the question is not acceptable/ inappropriate

Participant ID # ____________

Some of the following questions are about needing help with children at home. Firstly, I need to know:	**بعض الأسئلة القادمة تتعلق بطلب ا لمساعدة بخصوص الأطفال في المنزل، أولاً**

2l	How many children do you have? كم عدد أبناؤك وبناتك؟ I II III IV V VI	None One Two Three More than three	لا واحد واحد اثنان ثلثة أكثر من ثلثة	1 2 3 4 5

{IF NO CHILDREN, SKIP TO Q.3 }	**انتقل للسؤال الثالث إذا لم يكن لدى المريض أطفال**

2m	Helping your children get ready for school each day? المساعدة في تجهيز أبنائك للذهاب للمدرسة كل يوم؟ I II III IV V VI	1	2	3	4	5
2n	Caring for your children at home? الإعتناء بأبنائك في البيت ؟ I II III IV V VI	1	2	3	4	5

Notes: ____

Many people with cancer feel they cannot cope with their everyday lives as their disease progresses. These next questions are about how you have felt *over the past four weeks* about your ability to manage your life situation. Please choose the answer which best applies to you: None of the Time; Some of the Time; Much of the Time; Most of the Time; All of the Time	تهتم الفقرات التالية بالكيفية التى كنت تشعر بها خلال الأسابيع الأربعة الماضية، ولهذا نرجو منك أن تختار الإجابة التي تناسبك تماماً: ولا في أي وقت، بعضاً من الوقت، غالب الوقت، كل الوقت، أفضل عدم الإجابة.

3	Over the past four weeks : خلال الأسابيع الأربعة الماضية؟	None of the Time ولا في أي وقت	Some of the Time بعضاً من الوقت	Much of the Time غالب الوقت	Most of the Time كل الوقت	All of The Time أفضل عدم الإجابة
3a	I have felt confident I can cope with my illness شعرت بالثقة أن في استطاعتي التأقلم مع مرضي I II III IV V VI	1	2	3	4	5

3	Over the past four weeks : خلال الأسابيع الأربعة الماضية؟	None of the Time ولا في أي وقت	Some of the Time بعضاً من الوقت	Much of the Time غالب الوقت	Most of the Time كل الوقت	All of The Time أفضل عدم الإجابة
3b	I have felt free to make my own decisions about the health care I receive related to my cancer? شعرت بالحرية في اتخاذ القرارات المتعلقة بالرعاية الصحية التي أتلقاها والمتعلقة بمرض السرطان؟ I II III IV V VI	1	2	3	4	5
3c	I have felt I cannot manage my life because of my illness شعرت بعدم استطاعتي إدارة أمور حياتي بسبب مرضي I II III IV V VI	1	2	3	4	5
3d	I have felt confident I can continue my usual work activities Prompt: For example work at home or in place of employment أشعر بالثقة بأن باستطاعتي الاستمرار في القيام بالأعمال الاعتيادية I II III IV V VI	1	2	3	4	5
3e	I have felt confident in my ability to take care of those I am responsible for, despite my illness لم يتغير دوري داخل أسرتي منذ أن أصبت بالمرض I II III IV V VI	1	2	3	4	5

Notes:

____

I = No Problem
II = Hesitated, but no question or comment before responding
III = Asked a question before responding
IV = Made a statement about the question before responding
V = Could not understand question
VI = Think the question is not acceptable/ inappropriate

Different people experience different emotions when they have a serious illness. I am now going to ask you some questions about how you feel, in general.
For the next items please choose the answer which best applies to you: None of the Time; Some of the Time; Much of the Time; Most of the Time; All of the Time.

والآن إليك بعض الفقرات التي, تتعلق بما تشعر به نفسياً .

وهنا نرجو منك أن تختار الإجابة التي تنطبق عليك أكثر من غيره وهي كالآتي:
ولا في أي وقت ، بعضاً من الوقت ، غالب الوقت ، كثيراً من الوقت ، كل الوقت

4		None of the Time ولا في أي وقت	Some of the Time بعضاً من الوقت	Much of the Time كثيراً من الوقت	Most of the Time غالب الوقت	All of the Time كل الوقت
4a	I look forward to beginning each new day أتطلع بتفاؤل لبداية كل يوم جديد I II III IV V VI	1	2	3	4	5
4b	I feel guilty that I may be a burden on my family أشعر بالذنب لأنني ربما أمثل عائقاً (حملاً) على أسرتي I II III IV V VI	1	2	3	4	5
4c	I feel I am valued by those close to me أشعر بالتقدير من أولئك المقربين مني I II III IV V VI	1	2	3	4	5
4d	I feel I have no purpose in life because of my cancer أشعر بأن لا هدف لي في الحياة بسبب مرض السرطان I II III IV V VI	1	2	3	4	5
4e	I feel fearful about my future اشعر بالخوف فيما يتعلق بمستقبلي I II III IV V VI	1	2	3	4	5

Notes:

Sometimes patients with cancer find their ability to think clearly changes over time. From the following statements please choose the response that bests suits you:
All of the Time; Most of the Time; Much of the Time; Some of the Time; None of the Time

والآن هذه بعض الفقرات المتعلقة بالصعوبات التى ربما تعانى منها

ولهذا نرجو منك أن تختار من العبارات التالية الإجابة التي تناسبك وهي كالآتي:
كل الوقت، غالب الوقت، كثيرا من الوقت، بعضاً من الوقت، ولا في, أى وقت

5		All of the Time كل الوقت	Most of the Time غالب الوقت	Much of the Time ثيراً من الوقت	Some of the Time بعضاً من الوقت	None of The Time ولا في أي وقت
5a	I have trouble understanding new information أجد صعوبة في فهم المعلومات الجديدة I II III IV V VI	1	2	3	4	5
5b	I have difficulty concentrating on simple tasks أجد صعوبة في التركيز لأكثر من بضع دقائق على مهمة معينة I II III IV V VI	1	2	3	4	5
5c	I have difficulty taking decisions about routine daily activities أجد صعوبة في اتخاذ قرارات متعلقة بنشاطاتي الروتينية I II III IV V VI	1	2	3	4	5
5d	I am easily confused أشعر بالتشويش I II III IV V VI	1	2	3	4	5

<u>Notes:</u>

Sometimes people with cancer find their relationships with friends and family change over time.
From the following statements please choose the response that bests suits you:
Strongly Disagree; Disagree; Neutral; Agree; Strongly Agree; Prefer Not to Answer

والآن هذه بعض الفقرات المتعلقة بالصعوبات التى ربما تعانى منها مع الزوجة /

ولهذا نرجو منك أن تختار من العبارات التالية الإجابة التى تناسبك وهى كالآتي:
موافق بشدة, موافق, محايد, غير موافق, غير موافق بشدة, أفضل عدم الإجابة

I = No Problem
II = Hesitated, but no question or comment before responding
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V = Could not understand question
VI = Think the question is not acceptable/ inappropriate

Participant ID # ____________

IF NOT MARRIED, SKIP TO Q.6C

6		Strongly Disagree غير موافق بشدة	Disagree غير موافق	Neutral محايد	Agree موافق	Strongly Agree موافق بشدة	PNTA أفضل عدم الإجابة
6a	My illness improved my relationship with my spouse حسن مرضي علاقتي بزوجتي I II III IV V VI	1	2	3	4	5	9
6b	My spouse is very supportive of me زوجتي داعمة لي جداً/ زوجي داعم لي جدا I II III IV V VI	1	2	3	4	5	9
6c	My relatives are very supportive of me أقاربي جداً داعمين لي I II III IV V VI	1	2	3	4	5	9
6d	My friends are very supportive of me أصدقائي جداً داعمين لي I II III IV V VI	1	2	3	4	5	9

Notes:

Now I am going to ask you about information you think you need, related to your cancer and treatment. Choose one of the following responses which best describes how you feel: Strongly Disagree; Disagree; Neutral: Agree; Strongly Agree:

سوف أسألك الآن عن بعض المعلومات التى تظن أنك بحاجة إليها, والمرتبطة

موافق بشدة, موافق, محايد, غير موافق, غير موافق بشدة.

7		Strongly Agree موافق بشدة	Agree موافق	Neutral محايد	Disagree غير موافق	Strongly Disagree غير موافق بشدة
7a	I need more information about my cancer أحتاج لمعلومات أكثر بخصوص مرض السرطان لدي I II III IV V VI	1	2	3	4	5
7b	I have been told all I want to know about my cancer لقد تمَّ إخباري بكل ما أريد معرفته عن مرض السرطان لدي I II III IV V VI	1	2	3	4	5
7c	I prefer my oncologist makes all my medical decisions for me أفضّل أن يقوم طبيب الأورام باتخاذ جميع القرارات الطبية نيابة عني I II III IV V VI	1	2	3	4	5
7d	I prefer my doctor discusses the details of my illness only with me أفضل أن طبيبي بمناقشة جميع تفاصيل مرضي معي فقط I II III IV V VI	1	2	3	4	5
7e	I have been given all the information I need to take care of myself تمَّ إعطائي جميع المعلومات التي أحتاجها من أجل العناية بنفسي. I II III IV V VI	1	2	3	4	5
7f	My family members have been given all the information they need to take care of me لقد حصل أفراد أسرتي على جميع المعلومات التي يحتاجون من أجل العناية بي I II III IV V VI	1	2	3	4	5

Notes:

I = No Problem

II = Hesitated, but no question or comment before responding

III = Asked a question before responding

IV = Made a statement about the question before responding

V = Could not understand question

VI = Think the question is not acceptable/ inappropriate

Patients get information about their illness and treatment from different sources. I am now going to ask you how helpful different sources of information have been, to give you the information you need. Please answer with the response that best suits you: None of the time; some of the time, much of the time; most of the time; all of the time.

يحصل المرضى على المعلومات المتعلّقة بأمراضهم وكيفية علاجها من مصادر

وهنا نرجو منك أن تختار واحدة من الاستجابات التي تنطبق عليك أكثر من غيرها: ولا في أي وقت، في بعض الأوقات، في غالب الأوقات، كثيراً من الأوقات، كل

{FOR EACH ITEM INSERT THE SOURCE OF INFORMATION NAMED IN EACH ITEM:}

(أدخل مصدر المعلومة لكل فقرة من الفقرات أدناه)

8.	The information given to me by ______________ was helpful:	None of the Time ولا في أي وقت	Some of the Time بعضاً من الوقت	Much of the Time ثيراً من الوقت	Most of the Time غالب الوقت	All of The Time كل الوقت
8a	My doctor طبيبي I II III IV V VI	1	2	3	4	5
8b	Nursing staff طاقم التمريض I II III IV V VI	1	2	3	4	5
8c	Other hospital Staff غيره من طاقم المستشفى I II III IV V VI	1	2	3	4	5
8d	The media (e.g. television, newspapers) الوسائل الإعلامية (مثل : التلفزيون, الجرائد) I II III IV V VI	1	2	3	4	5
8e	Printed information (e.g. brochures, pamphlets) المعلومات المطبوعة (مثل : الكتيبات, المطويات) I II III IV V VI	1	2	3	4	5
8f	Internet Websites صفحات الإنترنت I II III IV V VI	1	2	3	4	5

9	On a scale from 1 to 5, with 1 being really easy and 5 being extremely difficult, how difficult was it for you to get the information you needed? على مقياس من 1 إلى 5 , ما مدى صعوبة الحصول على المعلومات التي تحتاجها؟ حيث (1) يعني سهل جدا, و (5) يعني بالغ الصعوبة I II III IV V VI	1	2	3	4	5

Notes:

Now some questions about communicating with your doctor and other hospital staff, some of whom are not fluent in Arabic. Just to remind you, this information is confidential and will not be given to your doctor or any other staff.
Please choose one of the following responses which best describes your experience in communicating with staff: Strongly Disagree; Disagree; Neutral: Agree; Strongly Agree

والآن إليك بعض الأسئلة المتعلّقة بكيفية التواصل مع طبيبك وبقية الطاقم الطبي.

وهنا نرجو منك أن تختار واحدة من الاستجابات التالية, والتي تنطبق عليك أكثر من

غير موافق بشدة, غير موافق, محايد, موافق, موافق بشدة

10		None of the Time ولا في أي وقت	Some of the Time بعضاً من الوقت	Much of the Time ثيراً من الوقت	Most of the Time غالب الوقت	All of The Time كل الوقت
10a	My doctor answers all my questions أجاب طبيبي على جميع أسئلتي I II III IV V VI	1	2	3	4	5

I = No Problem
II = Hesitated, but no question or comment before responding
III = Asked a question before responding
IV = Made a statement about the question before responding
V = Could not understand question
VI = Think the question is not acceptable/ inappropriate

10 (cont'd)		None of the Time ولا في أي وقت	Some of the Time بعضاً من الوقت	Much of the Time ثيراً من الوقت	Most of the Time غالب الوقت	All of The Time كل الوقت
10b	My doctor has explained clearly to me about the physical problems I may face شرح لي طبيبي وبكل وضوح جميع المشاكل الجسدية التي ربما أواجهها I II III IV V VI	1	2	3	4	5
10c	My nurses understand me when I talk to them يفهمني الممرضون والممرضات عندما أتحدث إليهم I II III IV V VI	1	2	3	4	5
10d	There is always an interpreter present to translate, if needed يتواجد المترجم بشكل دائم عندما الضرورة I II III IV V VI	1	2	3	4	5

People with serious illness get different types of support from various friends, family, or other sources. I now have some questions about any support you may have from different people away from the hospital.

يحصل المصابون بأمراض خطيرة على أنواع مختلفة من الدعم ومن مصادر

11 How many female relatives can you rely on to help you while you are ill?

كم عدد قريباتك اللتي بإمكانك الاعتماد عليهن لمساعدتك أثناء مرضك؟

I II III IV V VI

None 1 ولا واحد
One 2 واحد
Two 3 اثان
More than two 4 أكثر من اثان

12 How many maids do you have at home?

كم عدد الخادمات اللتي يعملن في بيتك؟

I II III IV V VI

None 1 ولا واحد
One 2 واحد
Two 3 اثان
More than two 4 أكثر من اثان

13 How many drivers do you have?
Prompt: such as male relatives or employed drivers.

كم سائقا لديك؟
حث: سواء أقربائك من الرجال أو السائقين الخاصين بك

I II III IV V VI

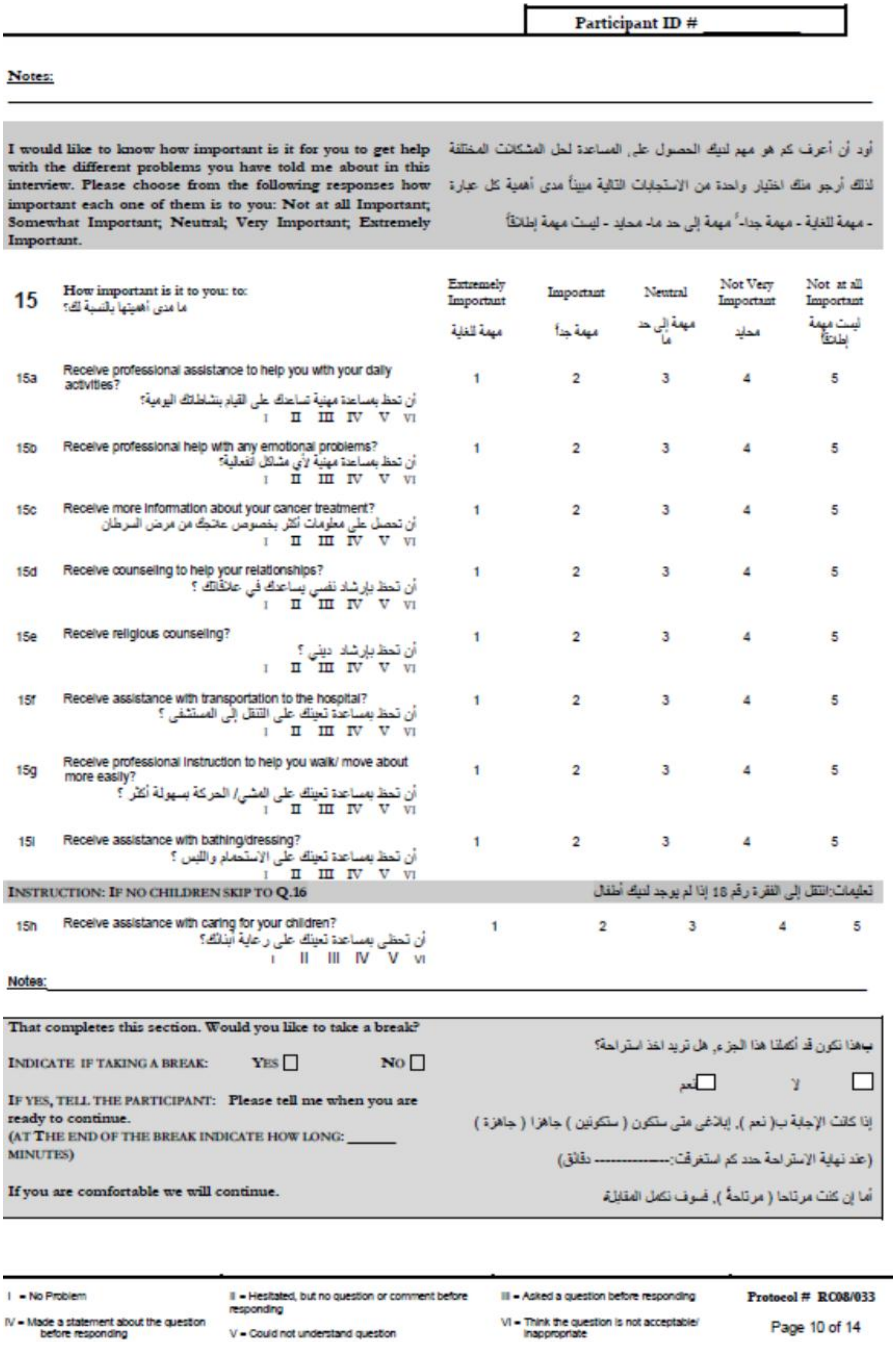
None 1 ولا واحد
One 2 واحد
Two 3 اثان
More than two 4 أكثر من اثان

Different people have different beliefs about the causes of illness. These next items are about your beliefs in relation to your illness. Please choose from the following responses: Strongly Disagree; Disagree; Neutral; Agree; Strongly Agree; Prefer Not to Answer.

يختلف الناس باختلاف ما يحملونه من معتقدات متباينة عن أسباب مرضهم. ومن

ولذلك نرجو منك أن تختار واحدة من الاستجابات التالية والتي تصف ما تعتقده على

14		Strongly Disagree غير موافق بشدة	Disagree غير موافق	Neutral محايد	Agree موافق	Strongly Agree موافق بشدة	PNTA أفضل عدم الإجابة
14a	I believe that my suffering is a test of my faith أعتقد بأن معاناتي ما هي إلا امتحاناً لإيماني I II III IV V VI	1	2	3	4	5	9
14b	I believe an evil eye affected me اعتقد بأنني أصبت بعين. I II III IV V VI	1	2	3	4	5	9
14c	I believe my illness is a punishment from Allah أعتقد بأن مرضي هو عقاب من الله. I II III IV V VI	1	2	3	4	5	9
14d	I am afraid of the day of judgment ليس الموت ما أخافه وإنما هو يوم الحساب I II III IV V VI	1	2	3	4	5	9
14e	Allah will wash away my sins because of this illness سوف يغفر الله لي خطاياي بسبب مرضي هذا. I II III IV V VI	1	2	3	4	5	9



Participant ID # ______

Notes:

I would like to know how important is it for you to get help with the different problems you have told me about in this interview. Please choose from the following responses how important each one of them is to you: Not at all Important; Somewhat Important; Neutral; Very Important; Extremely Important.

أود أن أعرف كم هو مهم لديك الحصول على, المساعدة لحل المشكلات المختلفة لذلك أرجو منك اختيار واحدة من الاستجابات التالية مبيناً مدى أهمية كل عبارة - مهمة للغاية - مهمة جدا- ً مهمة إلى حد ما- محايد - ليست مهمة إطلاقاً

15	How important is it to you: to: ما مدى أهميتها بالنسبة لك؟	Extremely Important مهمة للغاية	Important مهمة جداً	Neutral مهمة إلى حد ما	Not Very Important محايد	Not at all Important ليست مهمة إطلاقاً
15a	Receive professional assistance to help you with your daily activities? أن تحظ بمساعدة مهنية تساعدك على القيام بنشاطاتك اليومية؟ I II III IV V VI	1	2	3	4	5
15b	Receive professional help with any emotional problems? أن تحظ بمساعدة مهنية لأي مشاكل انفعالية؟ I II III IV V VI	1	2	3	4	5
15c	Receive more information about your cancer treatment? أن تحصل على معلومات أكثر بخصوص علاجك من مرض السرطان I II III IV V VI	1	2	3	4	5
15d	Receive counseling to help your relationships? أن تحظ بإرشاد نفسي يساعدك في علاقاتك ؟ I II III IV V VI	1	2	3	4	5
15e	Receive religious counseling? أن تحظ بإرشاد ديني ؟ I II III IV V VI	1	2	3	4	5
15f	Receive assistance with transportation to the hospital? أن تحظ بمساعدة تعينك على التنقل إلى المستشفى ؟ I II III IV V VI	1	2	3	4	5
15g	Receive professional instruction to help you walk/ move about more easily? أن تحظ بمساعدة تعينك على المشي/ الحركة بسهولة أكثر ؟ I II III IV V VI	1	2	3	4	5
15i	Receive assistance with bathing/dressing? أن تحظ بمساعدة تعينك على الاستحمام واللبس ؟ I II III IV V VI	1	2	3	4	5

INSTRUCTION: IF NO CHILDREN SKIP TO Q.16

تعليمات:انتقل إلى الفقرة رقم 16 إذا لم يوجد لديك أطفال

15h	Receive assistance with caring for your children? أن تحظى بمساعدة تعينك على رعاية ابنائك؟ I II III IV V VI	1	2	3	4	5

Notes:

That completes this section. Would you like to take a break?

بهذا نكون قد أكملنا هذا الجزء, هل تريد اخذ استراحة؟

INDICATE IF TAKING A BREAK: YES ☐ NO ☐

☐ لا ☐نعم

IF YES, TELL THE PARTICIPANT: Please tell me when you are ready to continue.

إذا كانت الإجابة ب(نعم), إبلاغى متى ستكون (ستكونين) جاهزا (جاهزة)

(AT THE END OF THE BREAK INDICATE HOW LONG: ______ MINUTES)

(عند نهاية الاستراحة حدد كم استغرقت:------------ دقائق)

If you are comfortable we will continue.

أما إن كنت مرتاحا (مرتاحةً), فسوف نكمل المقابلة

I = No Problem
II = Hesitated, but no question or comment before responding
III = Asked a question before responding
IV = Made a statement about the question before responding
V = Could not understand question
VI = Think the question is not acceptable/ inappropriate

The next few items are about your financial situation related to your illness, over the past four weeks.
Please choose one of the following responses:
None of the Time; Some of the Time; Much of the Time; Most of the Time; All of the Time.
If you prefer not to answer, just tell me.

لفقرات القليلة القادمة تهتم بالوضع المادي المتعلق بمرضك خلال الأسابيع الأربعة
الرجاء اختيار واحدة من الخيارات التالية والتي تصف حالتك على أكمل وجه:
ق، كل الأوقات - في، غالب الأوقات- كثيراً من الأوقات - في، بعض الأوقات - ولا
خبرني (أخبريني) في حال عدم رغبتك في الإجابة.

16	Over the past four weeks: خلال الأسابيع الأربعة الماضية	All of the Time كل الوقت	Most of the Time غالب الوقت	Much of the Time ثيراً من الوقت	Some of the Time بعضاً من الوقت	None of the Time ولا في أي وقت	PTNA أفضل عدم الإجابة
16a	I have had difficulty paying my household bills عانيت من صعوبات في دفع الفواتير المنزلية I II III IV V VI	1	2	3	4	5	9
16c	My illness has been a financial hardship on my family يعتبر مرضي عبئاً ماديا على أسرتي. I II III IV V VI	1	2	3	4	5	9
16d	My household income has significantly decreased because of my illness انخفض دخلي الأسري بشكل لافت نتيجة لمرضي. I II III IV V VI	1	2	3	4	5	9

The next questions are about any illnesses other than cancer you may have had.

الأسئلة التالية تتعلق بالأمراض الأخرى غير مرض السرطان التي يمكن أن تكون قد

17 For which of the following illnesses have you ever received treatment?

أي من الأمراض التالية قد أخذت علاجاً لها

I II III IV V VI

High blood pressure	ارتفاع في ضغط الدم	1
Heart disease	أمراض القلب	2
Diabetes	أمراض السكر	3
Kidney disease	أمراض الكلي	4
Lung disease	أمراض الرئة	5
None of the above	ولا واحد مما سبق	6
Any other illness	أمراض أخر	7

{IF RESPONE TO PREVIOUS QUESTION IS 1 THRU 6, SKIP TO Q.19} IF ANSWERING " ANY OTHER" GO TO NEXT Q. TO SPECIFY WHICH ILLNESS(S): LIST IN SPACE(S) BELOW}

إذا اخترت أي الاستجابات من 1-6 فانتقل (فانتقلي) إلى السؤال رقم 19.

17a Which other serious illnesses have you had?

ما هي الأمراض الخطيرة الأخرى التي أصبت بها؟

____
____
____

I II III IV V VI

18 How many times have you been hospitalized for an illness other than cancer?

كم مرة دخلت المستشفى للعلاج من أمراض أخرى غير السرطان ؟

I II III IV V VI

None	ولا واحد	1
One	واحد	2
Two	اثنان	3
Three	ثلاثة	4
More than three	أكثر من ثلاثة	5

{IF NONE, SKIP TO Q. 20}

19 How many of these hospitalizations were less than 6 months ago?

كم مرة من تلك التنويمات قد حصل خلال الأشهر الستة الماضية؟

I II III IV V VI

None	ولا واحد	1
One	واحد	2
Two	اثنان	3
Three	ثلاثة	4
More than three	أكثر من ثلاثة	5

20 Which type of treatment have you received for your cancer?
Prompt: If you have had more than one type of treatment, please tell me which ones.

ما نوع العلاج الذي تلقيته لمرض السرطان؟
الحث: إذا تلقيت أكثر من نوع من العلاج، فالرجاء أن تخبرني ما هي تلك الأنواع.

I II III IV V VI

Chemotherapy	العلاج الكيميائي	1
Radiation therapy	العلاج الإشعاعي	2
Surgery	لجراحة	3
Hormonal therapy	لعلاج الهرموني	4
Other	أخرى	5
Don't know	غير متأكد	8

21 Have you received any tribal or traditional remedies for your cancer?
Prompt: for example herbal medicines or cautery
هل سبق لك أن استعملت أي وصفات شعبية أو تقليدية لعلاج السرطان؟
حث:مثلاً أعشاب، أو كي
I II III IV V VI

Yes	نعم	1
No	لا	2

IF ANSWERING NO, SKIP TO Q.22
IF ANSWERING "YES" ASK PARTICIPANT TO SPECIFY WHICH REMEDIES(S). LIST IN SPACE BELOW

إذا كانت الاستجابة ب (لا), فاسأل المفحوص (المفحوص) أن يحدد ما

21a Tell me which remedies have you tried?
هي أنواع الوصفات الأخرى التي سبق وأن جربتها؟
I II III IV V VI
______
______
______

Notes:
______

The next questions are about you and about your family and home environment. I will read each statement to you and you tell me which one best applies to you. Starting with the first question:

الأسئلة التالية تهتم بك وبعائلتك وبيئة منزلك. سوف أقرا عليك كل عبارة وعليك أن

22 What is the name of your home town?
Prompt: your permanent residence
ما اسم المدينة التي تنتسب لها
I II III IV V VI
______

{IF RIYADH, SKIP TO Q. 24}

23 Where do you live while you are receiving treatment at this hospital?
أين تسكن في أثناء تلقيك العلاج في هذا المستشفى؟
I II III IV V VI
______

{ CIRCLE THE NUMBER CORRESPONDING TO THE RESPONSE GIVEN}

(تعليمات : ضع دائرة حول الرقم المطابق للاستجابة التي تنطبق عليك أكثر

24 What is your highest level of education?
ما هو أعلى مستوى تعليميا حصلت عليه؟
I II III IV V VI

No formal schooling	1
Primary school	2
High School	3
College graduate	4
Post graduate	5

25 What is your average monthly household income?
Prompt: If you don't know, or if you prefer not to answer, that is fine
ما هو متوسط دخلك الشهري
الحث: إذا كنت لا تعلم أو تفضل عدم الإجابة فلا بأس في ذلك.
I II III IV V VI

Less than 2,000 Riyals	1
2,000 – 4,999 Riyals	2
5,000 to 10,000 Riyals	3
More than 10,000 Riyals	4
Not sure	5
Prefer not to answer	9

26 How many people live at home with you?
كم عدد الأشخاص الذين يعيشون معك في المنزل؟
I II III IV V VI

None	ولا واحد	1
One	واحد	2
Two	اثنان	3
Three	ثلاثة	4
More than three	أكثر من ثلاثة	5

27 What is your current marital status?
ما هي حالتك الزواجية
I II III IV V VI

Married	متزوج\ متزوجة	1
Widowed	ملا\ أرمل	2
Divorced	مطلق\ مطلقة	3
Separated	منفصل \ منفصلة	4
Never married	لم يسبق له \ لها الزواج	5

I = No Problem
II = Hesitated, but no question or comment before responding
III = Asked a question before responding
IV = Made a statement about the question before responding
V = Could not understand question
VI = Think the question is not acceptable/ inappropriate

{IF FEMALE AND NEVER MARRIED, SKIP THE NEXT 4 QUESTIONS AND GO TO Q.33}
{IF FEMALE AND MARRIED SKIP TO Q.29}

28	How many wives do you have? كم عدد الزوجات لديك؟ I II III IV V VI	One Two Three Four	واحد اثنان ثلاثة أربعة	1 2 3 4

{IF MALE, SKIP TO Q. 31}

29	Are you the only wife of your husband? هل أنت الزوجة الوحيدة؟ I II III IV V VI	Yes No	نعم لا	1 2
30	How many other wives does your husband have? كم زوجة أخرى لدى زوجك؟ I II III IV V VI	One Two Three	واحد اثنان ثلاثة	1 2 3

IF ANSWERED "NO CHILDREN" IN Q. 21 SKIP TO Q. 33a

31	How many of your children live with you? كم عدد أبنائك وبناتك الذين يعيشون معك ؟ I II III IV V VI	None One Two Three Four More than four	ولا واحد واحد اثنان ثلاثة أربعة أكثر من أربعة	1 2 3 4 5 6

These next four questions are about where you prefer to be cared for as your illness progresses. Some people prefer to stay at home and to be cared for by their family, others prefer to be in the hospital. Please choose one of the following responses which best describes how you feel: Strongly Agree; Agree; Neutral: Disagree; Strongly Disagree:

تهتم الأسئلة الأربعة التالية بمعرفة المكان الذي تفضل أن تتلقى فيه الرعاية

الرجاء اختيار أفضل الخيارات والتي تشعر أنها مناسبة لك.
موافق بشدة۔ موافق، محايد ۔ غير موافق۔ غير موافق بشدة

32	**ما هو مقدار موافقتك على العبارات التالية:**	Strongly Disagree غير موافق بشدة	Disagree غير موافق	Neutral محايد	Agree موافق	Strongly Agree موافق بشدة
32a	I prefer that my family take care of me at home أفضل أن تقوم أسرتي برعايتي في المنزل. I II III IV V VI	1	2	3	4	5
32b	I prefer to be in the hospital when I can no longer take care of myself أفضل أن أكون في المستشفى عندما لا أستطيع الاعتناء بنفسي I II III IV V VI	1	2	3	4	5
32c	I leave it to my family to decide where I will be cared for أترك لأسرتي أن تقرر أين سيتم الاعتناء بي I II III IV V VI	1	2	3	4	5

These last two questions are about your thoughts on taking this survey. Please choose the response which best suits you.

هذه الأسئلة الأخيرة تتعلق بأفكارك خلال إجابتك على الأسئلة, فالرجاء

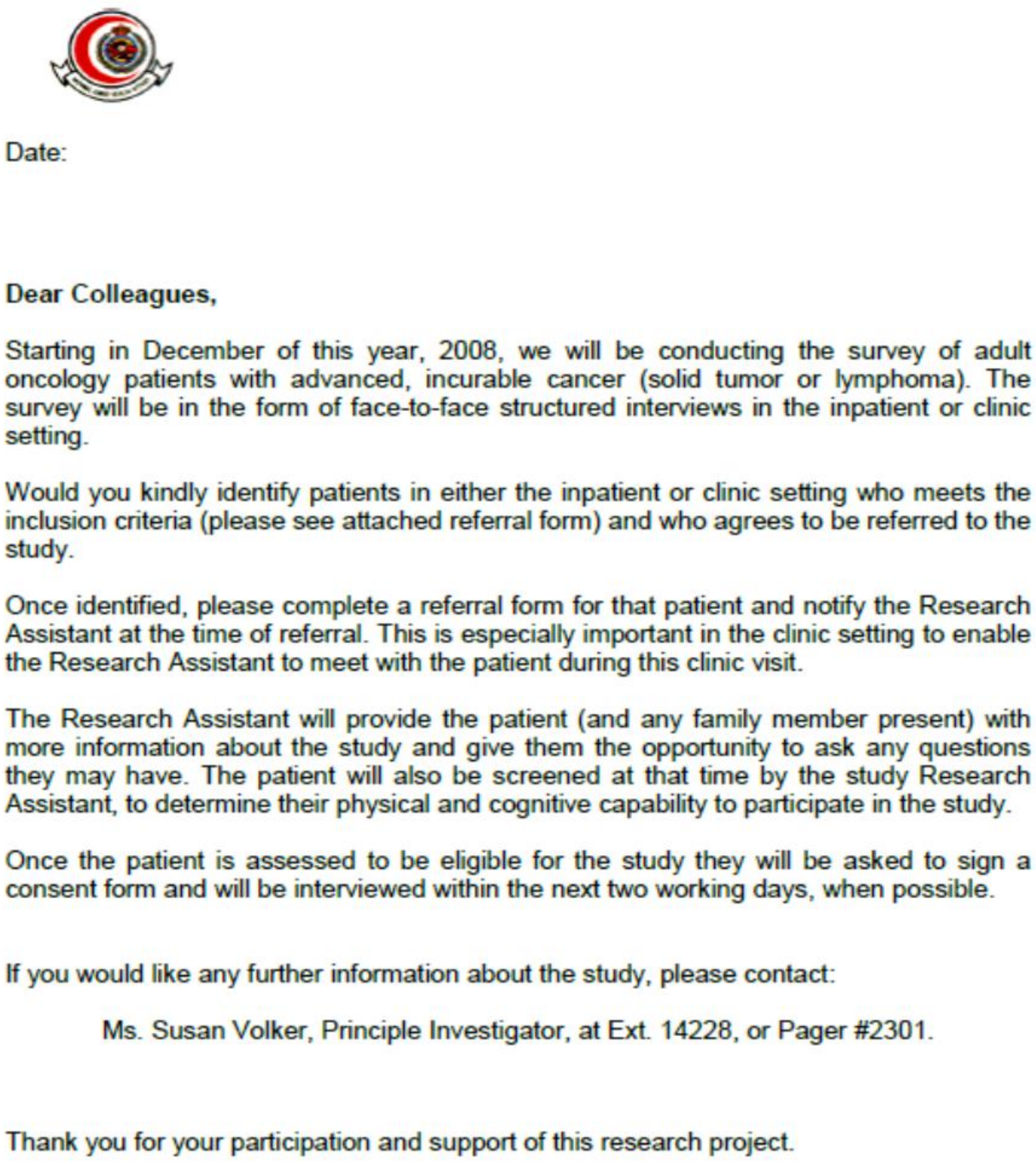
33	Overall, was answering these questions: بشكل عام , كيف كان الأسئلة في هذا المسح ؟ كانت.. I II III IV V VI	Extremely difficult Somewhat difficult Neutral Fairly easy Extremely easy	صعبة جداً صعبة إلى حد ما محايد سهلة إلى حد ما سهلة للغاية	1 2 3 4 5
34	Overall, were my instructions: بشكل عام، كيف كانت التعليمات في هذا المسح؟ كانت.. I II III IV V VI	Extremely difficult Somewhat difficult Neutral Fairly easy Extremely easy	صعبة جداً صعبة إلى حد ما محايد سهلة إلى حد ما سهلة للغاية	1 2 3 4 5

35	Would you be willing to take this same survey again? **Prompt:** In one to two weeks time, to help us develop and improve this new questionnaire هل أنت مستعد أن تملئ هذا ~~الاستبيان مرة أخرى؟~~ حث: في أسبوع إلى أسبوعين لمساعدتنا في تطوير وتحسين ~~هذا الاستبيان~~ I II III IV V VI	Yes. ~~No.~~	~~١~~ ٢	1 2
		Omit in pretest		

Those were the last questions.
On behalf of the Oncology Department at
King Abdulaziz Medical City, thank you very much for participating
❖❖❖❖❖❖❖ in this survey ❖❖❖❖❖❖❖❖

APPENDIX I

Physician Referral Invitation Letter



Date:

Dear Colleagues,

Starting in December of this year, 2008, we will be conducting the survey of adult oncology patients with advanced, incurable cancer (solid tumor or lymphoma). The survey will be in the form of face-to-face structured interviews in the inpatient or clinic setting.

Would you kindly identify patients in either the inpatient or clinic setting who meets the inclusion criteria (please see attached referral form) and who agrees to be referred to the study.

Once identified, please complete a referral form for that patient and notify the Research Assistant at the time of referral. This is especially important in the clinic setting to enable the Research Assistant to meet with the patient during this clinic visit.

The Research Assistant will provide the patient (and any family member present) with more information about the study and give them the opportunity to ask any questions they may have. The patient will also be screened at that time by the study Research Assistant, to determine their physical and cognitive capability to participate in the study.

Once the patient is assessed to be eligible for the study they will be asked to sign a consent form and will be interviewed within the next two working days, when possible.

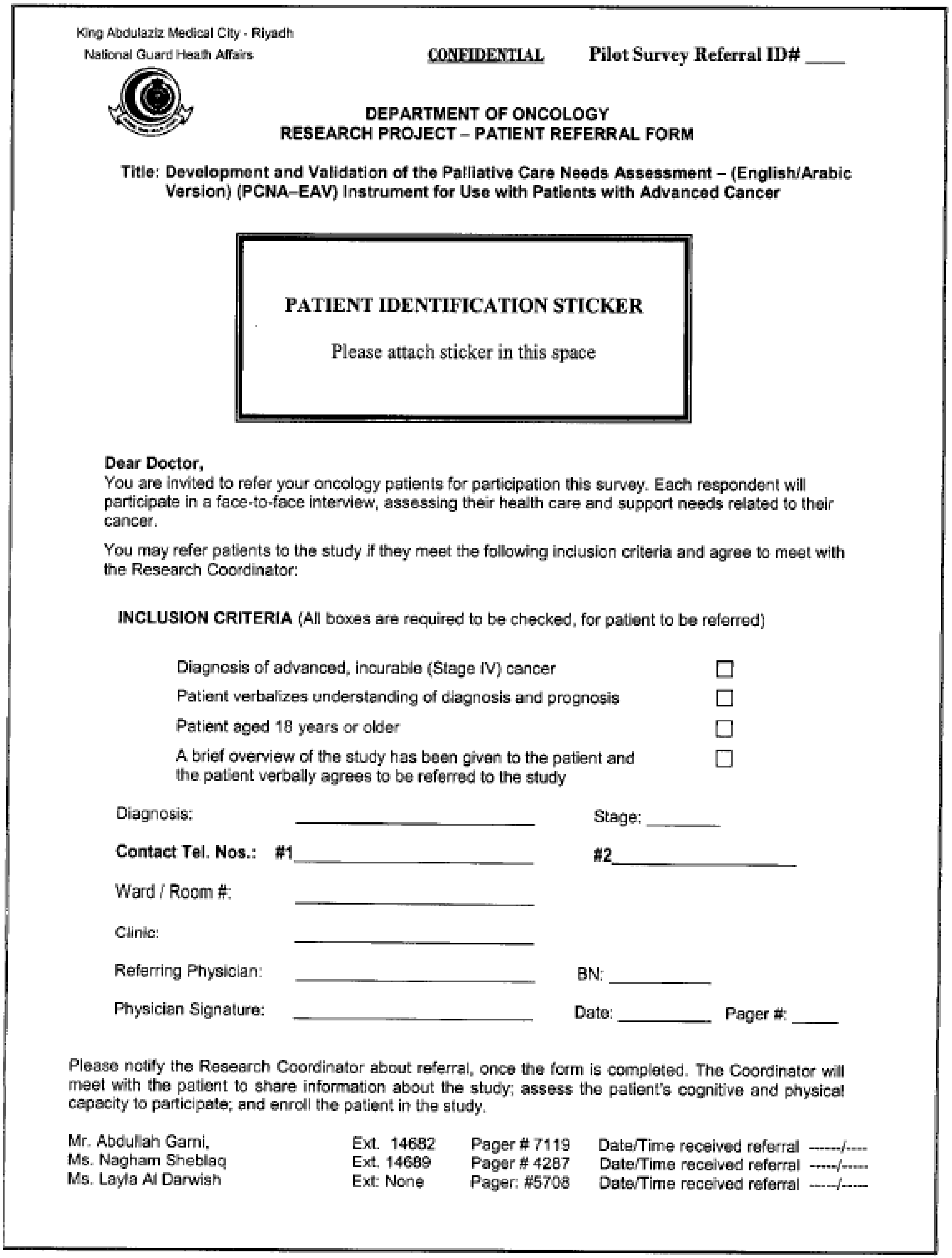
If you would like any further information about the study, please contact:

Ms. Susan Volker, Principle Investigator, at Ext. 14228, or Pager #2301.

Thank you for your participation and support of this research project.

APPENDIX J

Physician Referral Form



King Abdulaziz Medical City - Riyadh
National Guard Health Affairs

CONFIDENTIAL **Pilot Survey Referral ID# ____**

DEPARTMENT OF ONCOLOGY
RESEARCH PROJECT – PATIENT REFERRAL FORM

Title: Development and Validation of the Palliative Care Needs Assessment – (English/Arabic Version) (PCNA–EAV) Instrument for Use with Patients with Advanced Cancer

PATIENT IDENTIFICATION STICKER

Please attach sticker in this space

Dear Doctor,
You are invited to refer your oncology patients for participation this survey. Each respondent will participate in a face-to-face interview, assessing their health care and support needs related to their cancer.

You may refer patients to the study if they meet the following inclusion criteria and agree to meet with the Research Coordinator:

INCLUSION CRITERIA (All boxes are required to be checked, for patient to be referred)

- Diagnosis of advanced, incurable (Stage IV) cancer ☐
- Patient verbalizes understanding of diagnosis and prognosis ☐
- Patient aged 18 years or older ☐
- A brief overview of the study has been given to the patient and the patient verbally agrees to be referred to the study ☐

Diagnosis: ____________________ Stage: ________

Contact Tel. Nos.: #1____________________ **#2**____________________

Ward / Room #: ____________________

Clinic: ____________________

Referring Physician: ____________________ BN: __________

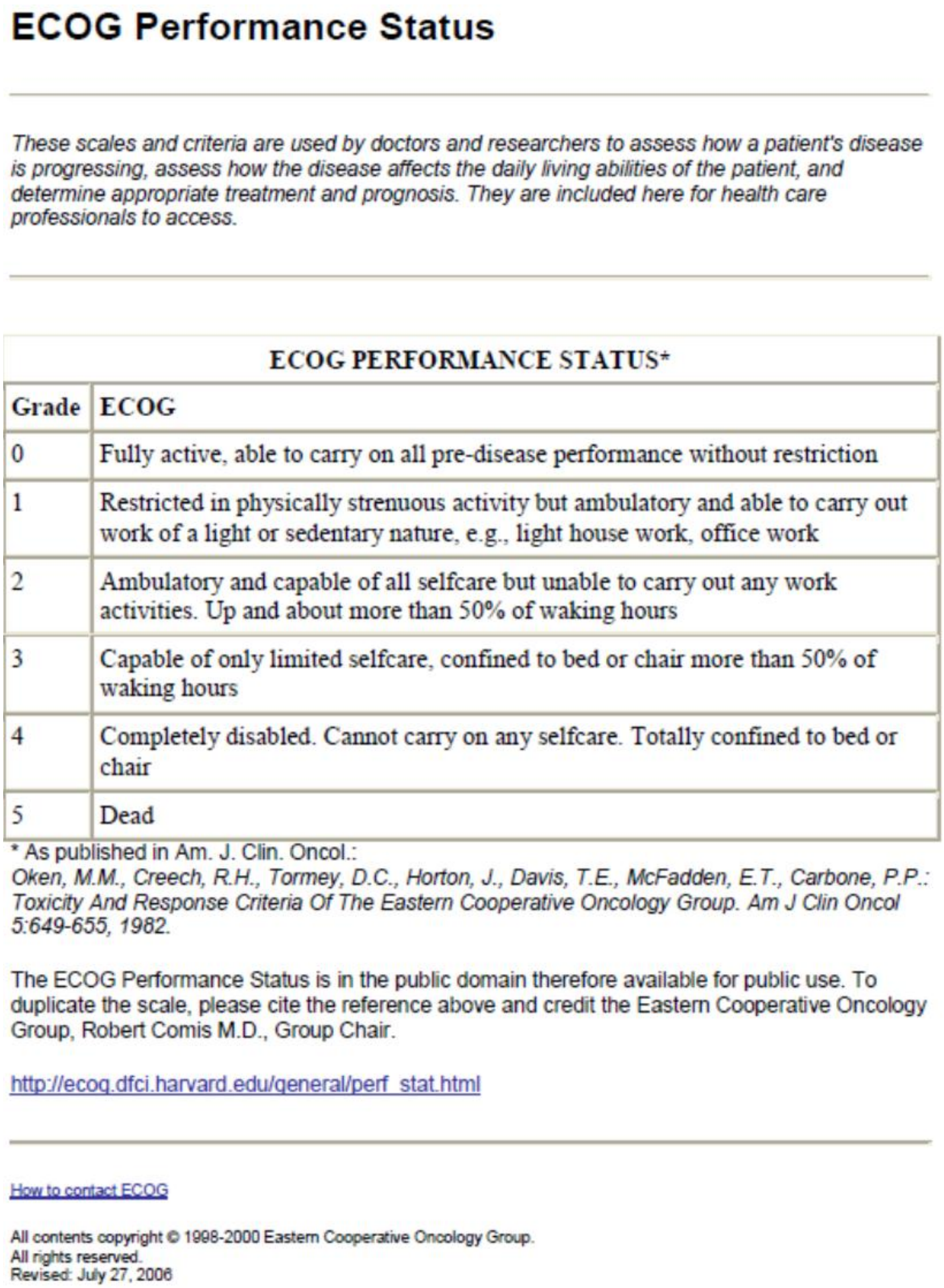
Physician Signature: ____________________ Date: __________ Pager #: _____

Please notify the Research Coordinator about referral, once the form is completed. The Coordinator will meet with the patient to share information about the study; assess the patient's cognitive and physical capacity to participate; and enroll the patient in the study.

Mr. Abdullah Garni,	Ext. 14682	Pager # 7119	Date/Time received referral ------/----
Ms. Nagham Sheblaq	Ext. 14689	Pager # 4287	Date/Time received referral -----/-----
Ms. Layla Al Darwish	Ext: None	Pager: #5708	Date/Time received referral -----/-----

APPENDIX K

Eastern Cooperative Oncology Group (ECOG)
Performance Status Tool



ECOG Performance Status

These scales and criteria are used by doctors and researchers to assess how a patient's disease is progressing, assess how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis. They are included here for health care professionals to access.

ECOG PERFORMANCE STATUS*

Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

* As published in Am. J. Clin. Oncol.:
Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982.

The ECOG Performance Status is in the public domain therefore available for public use. To duplicate the scale, please cite the reference above and credit the Eastern Cooperative Oncology Group, Robert Comis M.D., Group Chair.

http://ecog.dfci.harvard.edu/general/perf_stat.html

How to contact ECOG

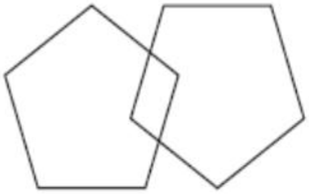
APPENDIX L

Mini-Mental State Exam Tool – English

The Mini-Mental State Exam

Patient____________________________ Examiner _________________________ Date_________

Maximum	Score	
		Orientation
5	( )	What is the (year) (season) (date) (day) (month)?
5	( )	Where are we (state) (country) (town) (hospital) (floor)?
		Registration
3	( )	Name 3 objects: 1 second to say each. Then ask the patient all 3 after you have said them. Give 1 point for each correct answer. Then repeat them until he/she learns all 3. Count trials and record. Trials _________
		Attention and Calculation
5	( )	Serial 7's. 1 point for each correct answer. Stop after 5 answers. Alternatively spell "world" backward.
		Recall
3	( )	Ask for the 3 objects repeated above. Give 1 point for each correct answer.
		Language
2	( )	Name a pencil and watch.
1	( )	Repeat the following "No ifs, ands, or buts"
3	( )	Follow a 3-stage command: "Take a paper in your hand, fold it in half, and put it on the floor."
1	( )	Read and obey the following: CLOSE YOUR EYES
1	( )	Write a sentence.
1	( )	Copy the design shown.



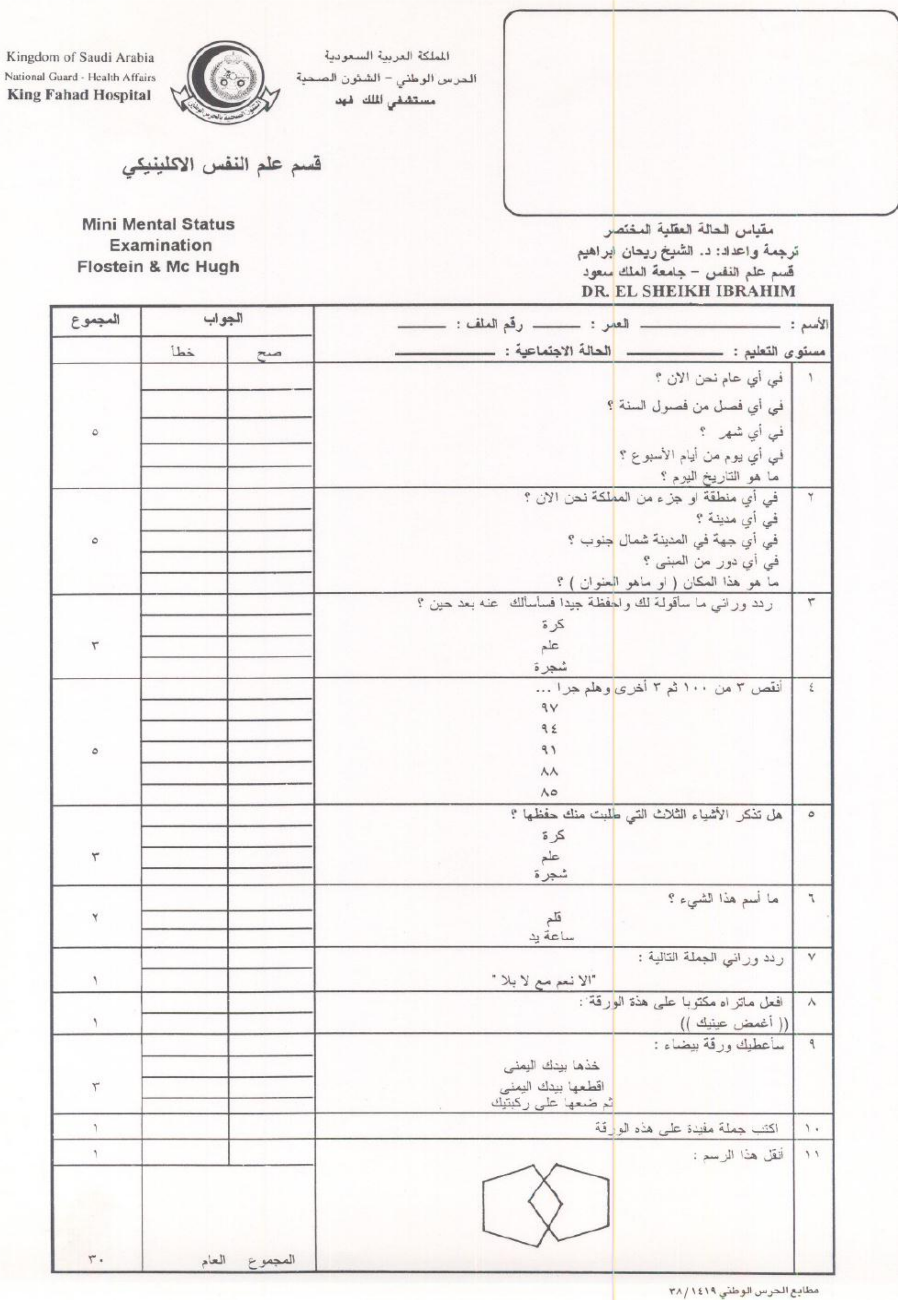
_____ Total Score

ASSESS level of consciousness along a continuum ___________

Alert Drowsy Stupor Coma

APPENDIX M

Mini-Mental State Exam Screening Tool – Arabic



Kingdom of Saudi Arabia
National Guard - Health Affairs
King Fahad Hospital

المملكة العربية السعودية
الحرس الوطني – الشئون الصحية
مستشفى الملك فهد

قسم علم النفس الاكلينيكي

Mini Mental Status
Examination
Flostein & Mc Hugh

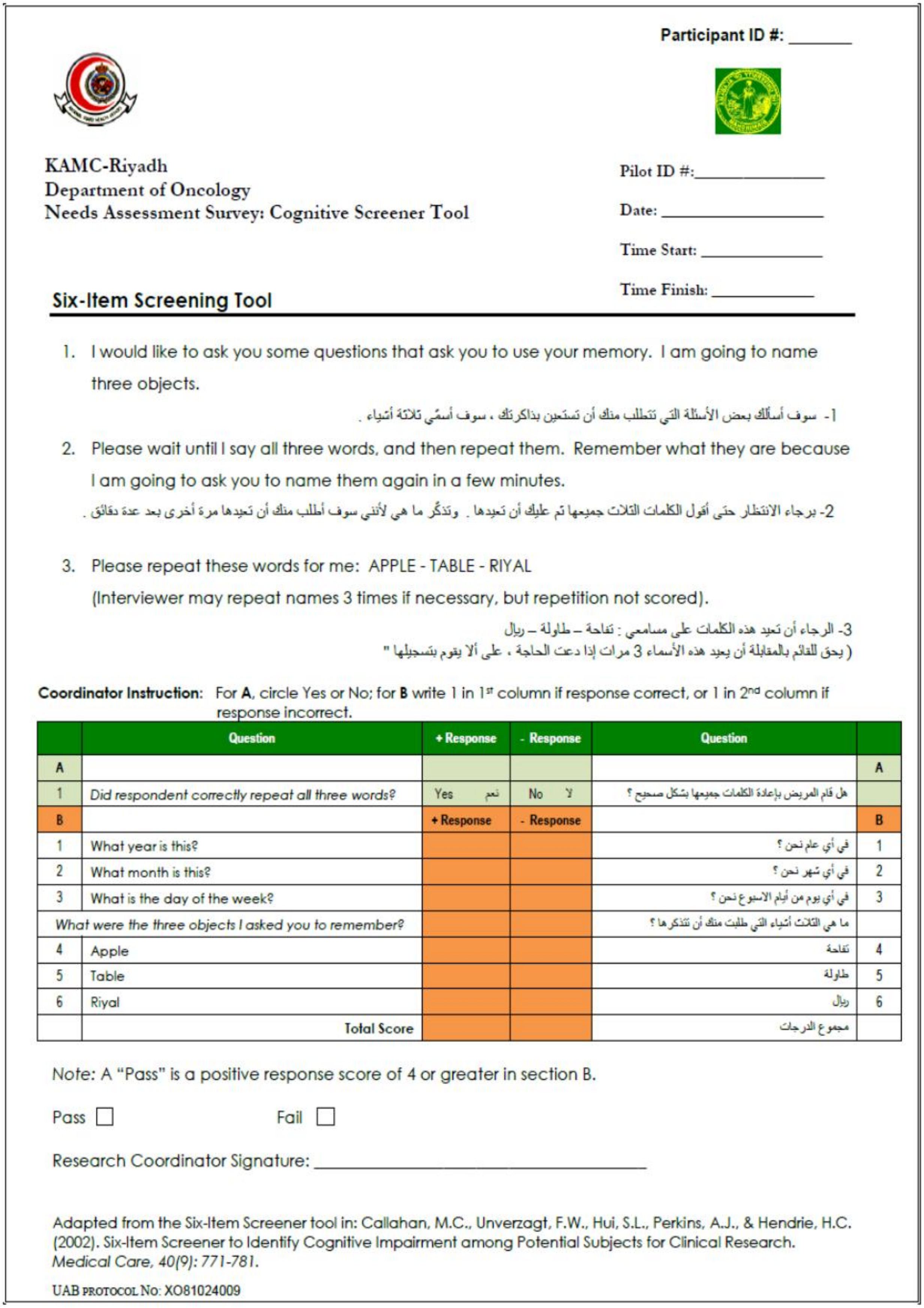
مقياس الحالة العقلية المختصر
ترجمة واعداد: د. الشيخ ريحان ابراهيم
قسم علم النفس – جامعة الملك سعود
DR. EL SHEIKH IBRAHIM

		الجواب		المجموع
	الأسم : ———— العمر : ———— رقم الملف : ————			
	مستوى التعليم : ———— الحالة الاجتماعية : ————	صح	خطأ	
١	في أي عام نحن الان ؟ في أي فصل من فصول السنة ؟ في أي شهر ؟ في أي يوم من أيام الأسبوع ؟ ما هو التاريخ اليوم ؟			٥
٢	في أي منطقة او جزء من المملكة نحن الان ؟ في أي مدينة ؟ في أي جهة في المدينة شمال جنوب ؟ في أي دور من المبنى ؟ ما هو هذا المكان (او ماهو العنوان) ؟			٥
٣	ردد وراني ما سأقولة لك واحفظة جيدا فسأسألك عنه بعد حين ؟ كرة علم شجرة			٣
٤	أنقص ٣ من ١٠٠ ثم ٣ أخرى وهلم جرا ... ٩٧ ٩٤ ٩١ ٨٨ ٨٥			٥
٥	هل تذكر الأشياء الثلاث التي طلبت منك حفظها ؟ كرة علم شجرة			٣
٦	ما أسم هذا الشيء ؟ قلم ساعة يد			٢
٧	ردد وراني الجملة التالية : "الا نعم مع لا بلا "			١
٨	افعل ماتراه مكتوبا على هذة الورقة : ((أغمض عينيك))			١
٩	سأعطيك ورقة بيضاء : خذها بيدك اليمنى اقطعها بيدك اليمنى ثم ضعها على ركبتيك			٣
١٠	اكتب جملة مفيدة على هذه الورقة			١
١١	أنقل هذا الرسم :			١
		المجموع العام		٣٠

مطابع الحرس الوطني ١٤١٩/٣٨

APPENDIX N

Six-Item Screener Tool



Participant ID #: ______

KAMC-Riyadh
Department of Oncology
Needs Assessment Survey: Cognitive Screener Tool

Pilot ID #: ______________
Date: ______________
Time Start: ______________
Time Finish: ______________

Six-Item Screening Tool

1. I would like to ask you some questions that ask you to use your memory. I am going to name three objects.

1- سوف أسألك بعض الأسئلة التي تتطلب منك أن تستعين بذاكرتك ، سوف أسمّي ثلاثة أشياء .

2. Please wait until I say all three words, and then repeat them. Remember what they are because I am going to ask you to name them again in a few minutes.

2- برجاء الانتظار حتى أقول الكلمات الثلاث جميعها ثم عليك أن تعيدها . وتذكّر ما هي لأنني سوف أطلب منك أن تعيدها مرة أخرى بعد عدة دقائق .

3. Please repeat these words for me: APPLE - TABLE - RIYAL
(Interviewer may repeat names 3 times if necessary, but repetition not scored).

3- الرجاء أن تعيد هذه الكلمات على مسامعي : تفاحة – طاولة – ريال
(يحق للقائم بالمقابلة أن يعيد هذه الأسماء 3 مرات إذا دعت الحاجة ، على ألا يقوم بتسجيلها "

Coordinator Instruction: For **A**, circle Yes or No; for **B** write 1 in 1st column if response correct, or 1 in 2nd column if response incorrect.

	Question	+ Response	- Response	Question	
A					**A**
1	*Did respondent correctly repeat all three words?*	Yes نعم	No لا	هل قام المريض بإعادة الكلمات جميعها بشكل صحيح ؟	
B		**+ Response**	**- Response**		**B**
1	What year is this?			في أي عام نحن ؟	1
2	What month is this?			في أي شهر نحن ؟	2
3	What is the day of the week?			في أي يوم من أيام الاسبوع نحن ؟	3
What were the three objects I asked you to remember?				ما هي الثلاث أشياء التي طلبت منك أن تتذكرها ؟	
4	Apple			تفاحة	4
5	Table			طاولة	5
6	Riyal			ريال	6
	Total Score			مجموع الدرجات	

Note: A "Pass" is a positive response score of 4 or greater in section B.

Pass ☐ Fail ☐

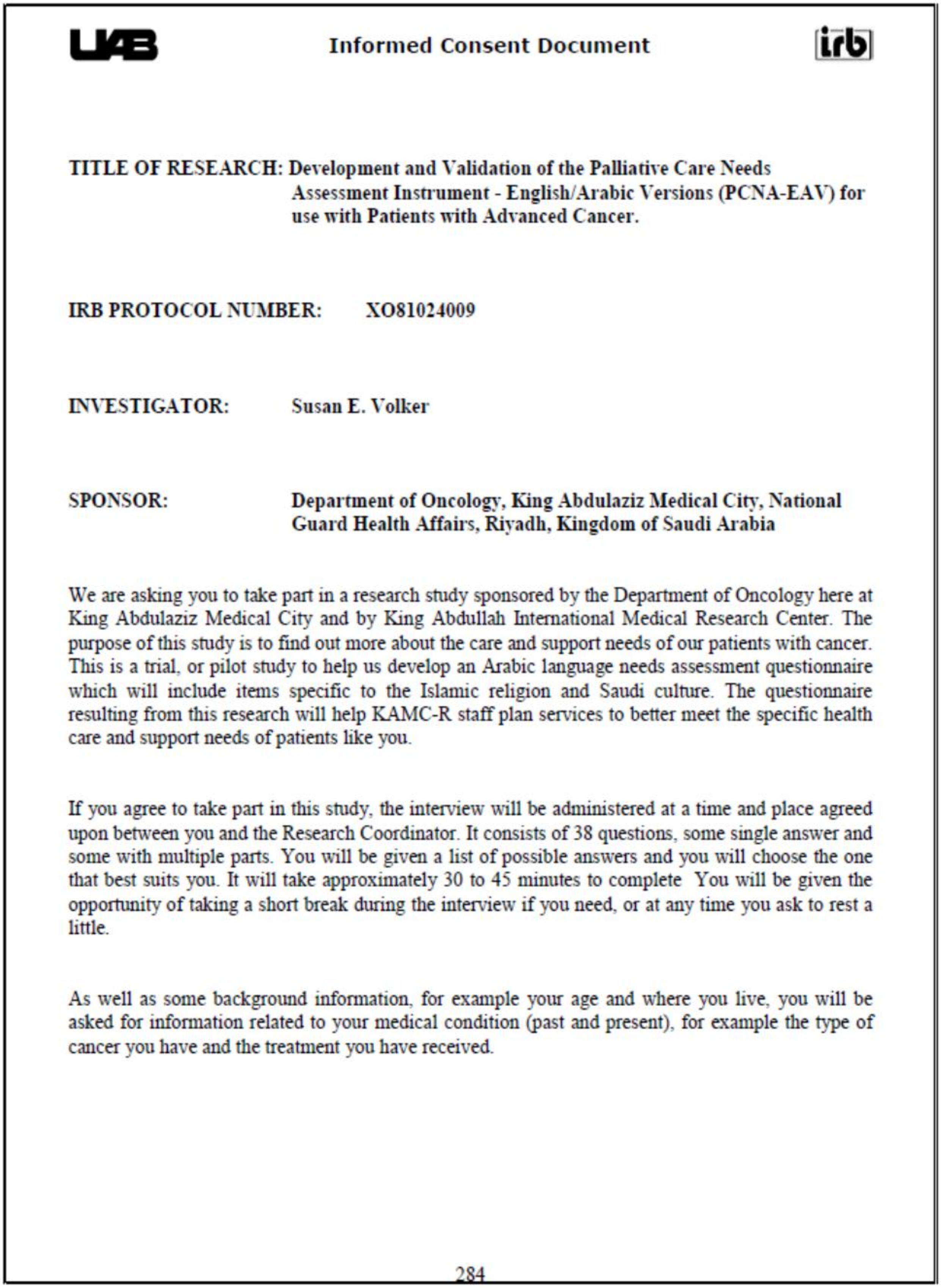
Research Coordinator Signature: ______________________________

Adapted from the Six-Item Screener tool in: Callahan, M.C., Unverzagt, F.W., Hui, S.L., Perkins, A.J., & Hendrie, H.C. (2002). Six-Item Screener to Identify Cognitive Impairment among Potential Subjects for Clinical Research. *Medical Care, 40(9): 771-781.*

UAB PROTOCOL No: XO81024009

APPENDIX O

Informed Consent Document – English



Informed Consent Document

TITLE OF RESEARCH: Development and Validation of the Palliative Care Needs Assessment Instrument - English/Arabic Versions (PCNA-EAV) for use with Patients with Advanced Cancer.

IRB PROTOCOL NUMBER: XO81024009

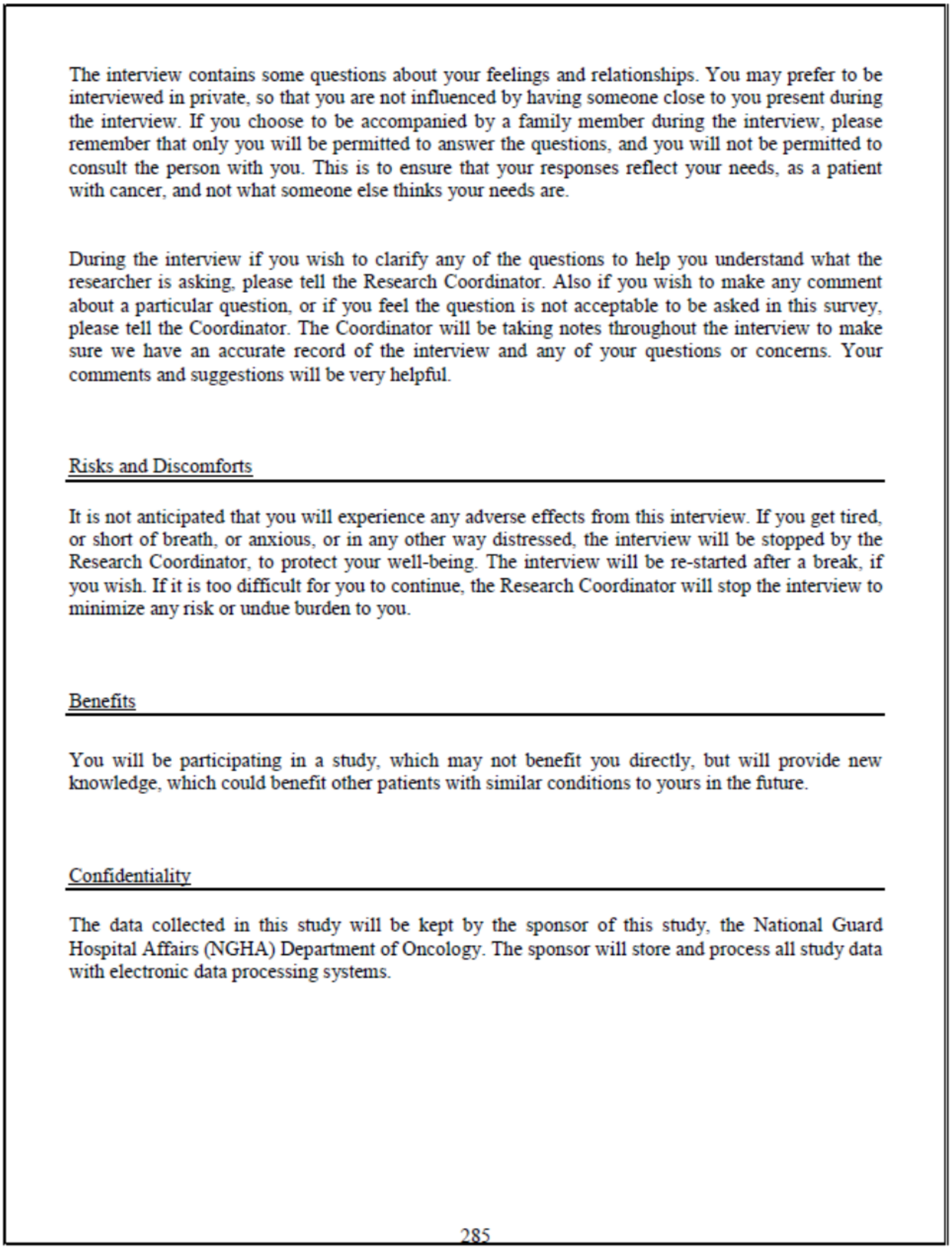
INVESTIGATOR: Susan E. Volker

SPONSOR: Department of Oncology, King Abdulaziz Medical City, National Guard Health Affairs, Riyadh, Kingdom of Saudi Arabia

We are asking you to take part in a research study sponsored by the Department of Oncology here at King Abdulaziz Medical City and by King Abdullah International Medical Research Center. The purpose of this study is to find out more about the care and support needs of our patients with cancer. This is a trial, or pilot study to help us develop an Arabic language needs assessment questionnaire which will include items specific to the Islamic religion and Saudi culture. The questionnaire resulting from this research will help KAMC-R staff plan services to better meet the specific health care and support needs of patients like you.

If you agree to take part in this study, the interview will be administered at a time and place agreed upon between you and the Research Coordinator. It consists of 38 questions, some single answer and some with multiple parts. You will be given a list of possible answers and you will choose the one that best suits you. It will take approximately 30 to 45 minutes to complete You will be given the opportunity of taking a short break during the interview if you need, or at any time you ask to rest a little.

As well as some background information, for example your age and where you live, you will be asked for information related to your medical condition (past and present), for example the type of cancer you have and the treatment you have received.



The interview contains some questions about your feelings and relationships. You may prefer to be interviewed in private, so that you are not influenced by having someone close to you present during the interview. If you choose to be accompanied by a family member during the interview, please remember that only you will be permitted to answer the questions, and you will not be permitted to consult the person with you. This is to ensure that your responses reflect your needs, as a patient with cancer, and not what someone else thinks your needs are.

During the interview if you wish to clarify any of the questions to help you understand what the researcher is asking, please tell the Research Coordinator. Also if you wish to make any comment about a particular question, or if you feel the question is not acceptable to be asked in this survey, please tell the Coordinator. The Coordinator will be taking notes throughout the interview to make sure we have an accurate record of the interview and any of your questions or concerns. Your comments and suggestions will be very helpful.

Risks and Discomforts

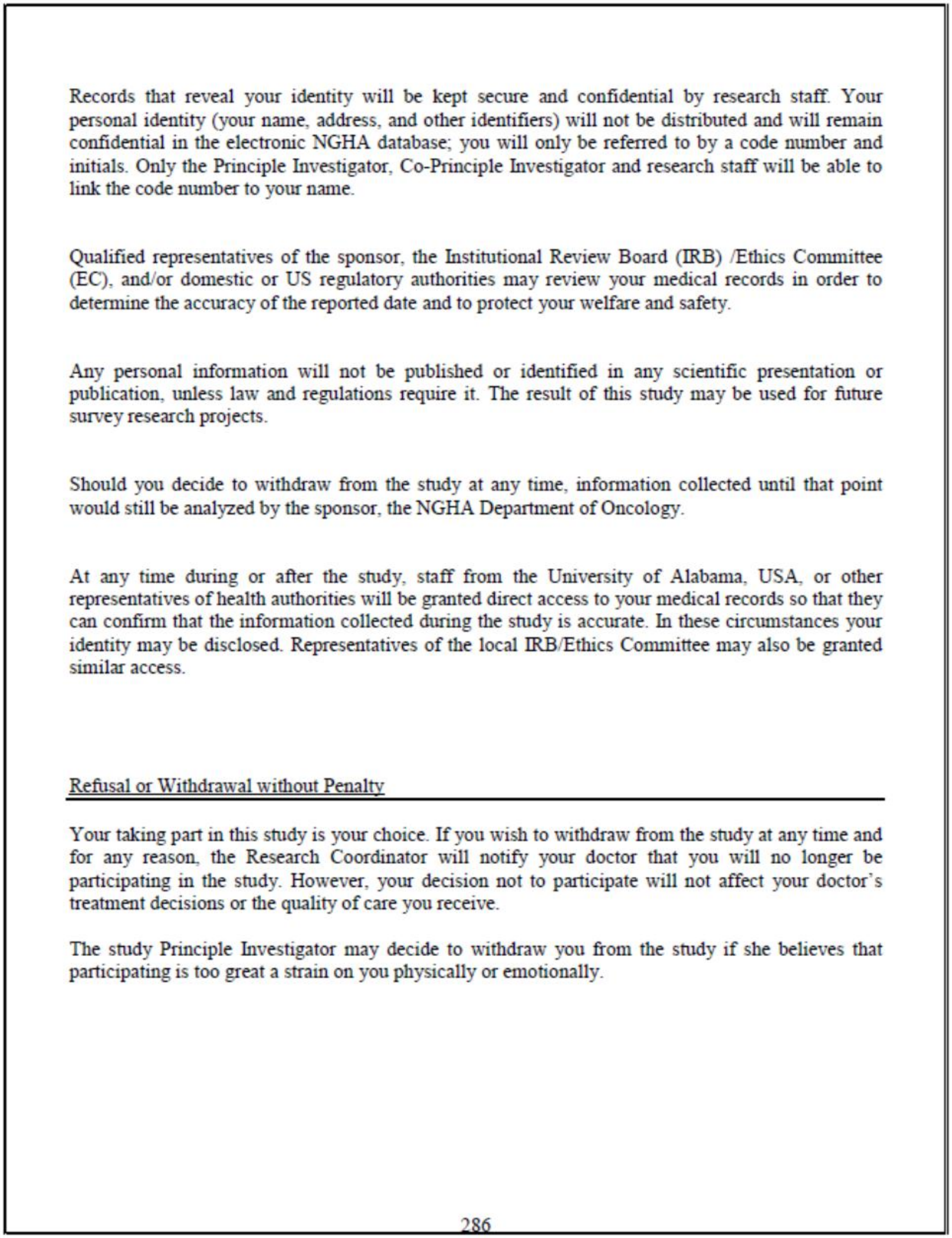
It is not anticipated that you will experience any adverse effects from this interview. If you get tired, or short of breath, or anxious, or in any other way distressed, the interview will be stopped by the Research Coordinator, to protect your well-being. The interview will be re-started after a break, if you wish. If it is too difficult for you to continue, the Research Coordinator will stop the interview to minimize any risk or undue burden to you.

Benefits

You will be participating in a study, which may not benefit you directly, but will provide new knowledge, which could benefit other patients with similar conditions to yours in the future.

Confidentiality

The data collected in this study will be kept by the sponsor of this study, the National Guard Hospital Affairs (NGHA) Department of Oncology. The sponsor will store and process all study data with electronic data processing systems.



Records that reveal your identity will be kept secure and confidential by research staff. Your personal identity (your name, address, and other identifiers) will not be distributed and will remain confidential in the electronic NGHA database; you will only be referred to by a code number and initials. Only the Principle Investigator, Co-Principle Investigator and research staff will be able to link the code number to your name.

Qualified representatives of the sponsor, the Institutional Review Board (IRB) /Ethics Committee (EC), and/or domestic or US regulatory authorities may review your medical records in order to determine the accuracy of the reported date and to protect your welfare and safety.

Any personal information will not be published or identified in any scientific presentation or publication, unless law and regulations require it. The result of this study may be used for future survey research projects.

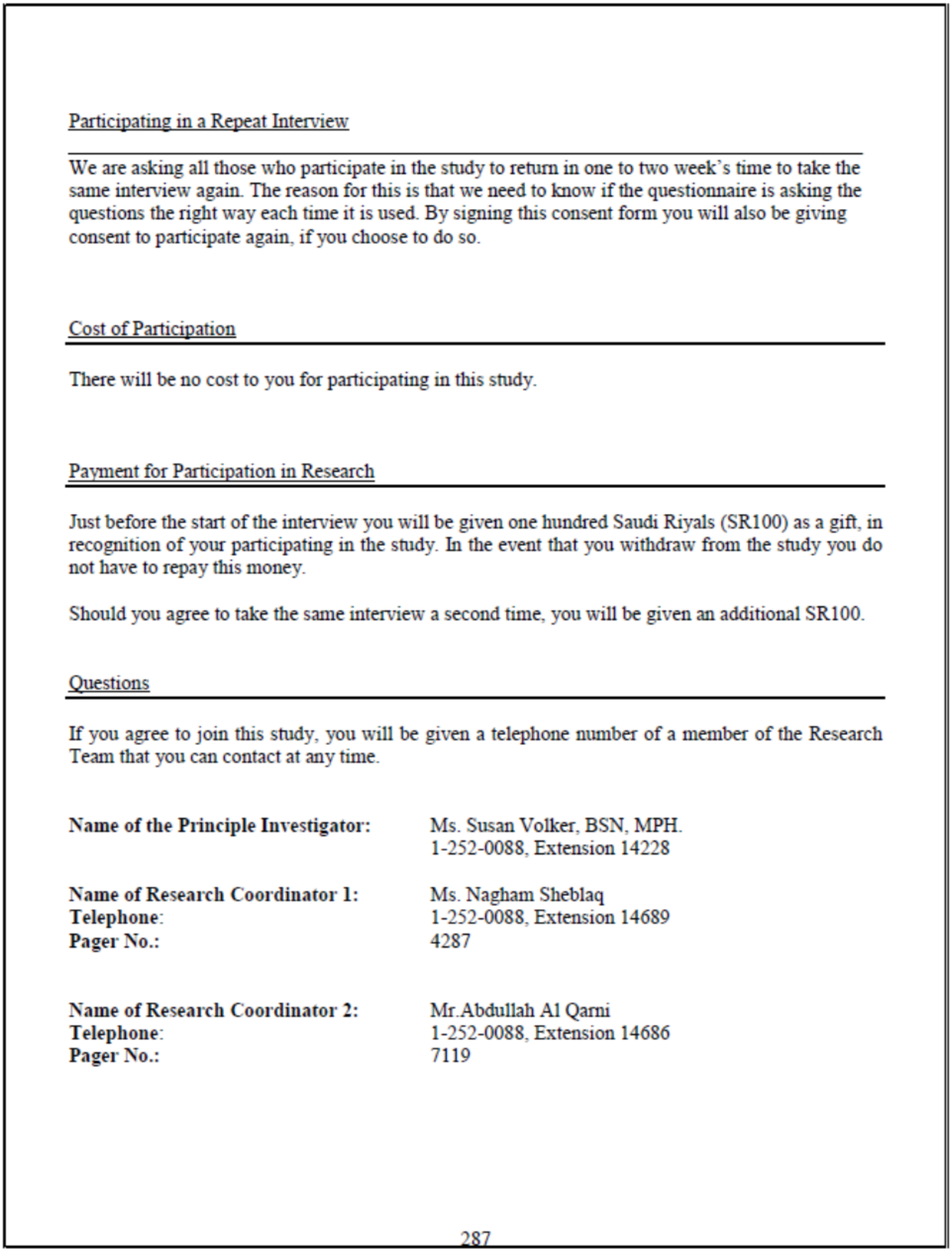
Should you decide to withdraw from the study at any time, information collected until that point would still be analyzed by the sponsor, the NGHA Department of Oncology.

At any time during or after the study, staff from the University of Alabama, USA, or other representatives of health authorities will be granted direct access to your medical records so that they can confirm that the information collected during the study is accurate. In these circumstances your identity may be disclosed. Representatives of the local IRB/Ethics Committee may also be granted similar access.

Refusal or Withdrawal without Penalty

Your taking part in this study is your choice. If you wish to withdraw from the study at any time and for any reason, the Research Coordinator will notify your doctor that you will no longer be participating in the study. However, your decision not to participate will not affect your doctor's treatment decisions or the quality of care you receive.

The study Principle Investigator may decide to withdraw you from the study if she believes that participating is too great a strain on you physically or emotionally.



Participating in a Repeat Interview

We are asking all those who participate in the study to return in one to two week's time to take the same interview again. The reason for this is that we need to know if the questionnaire is asking the questions the right way each time it is used. By signing this consent form you will also be giving consent to participate again, if you choose to do so.

Cost of Participation

There will be no cost to you for participating in this study.

Payment for Participation in Research

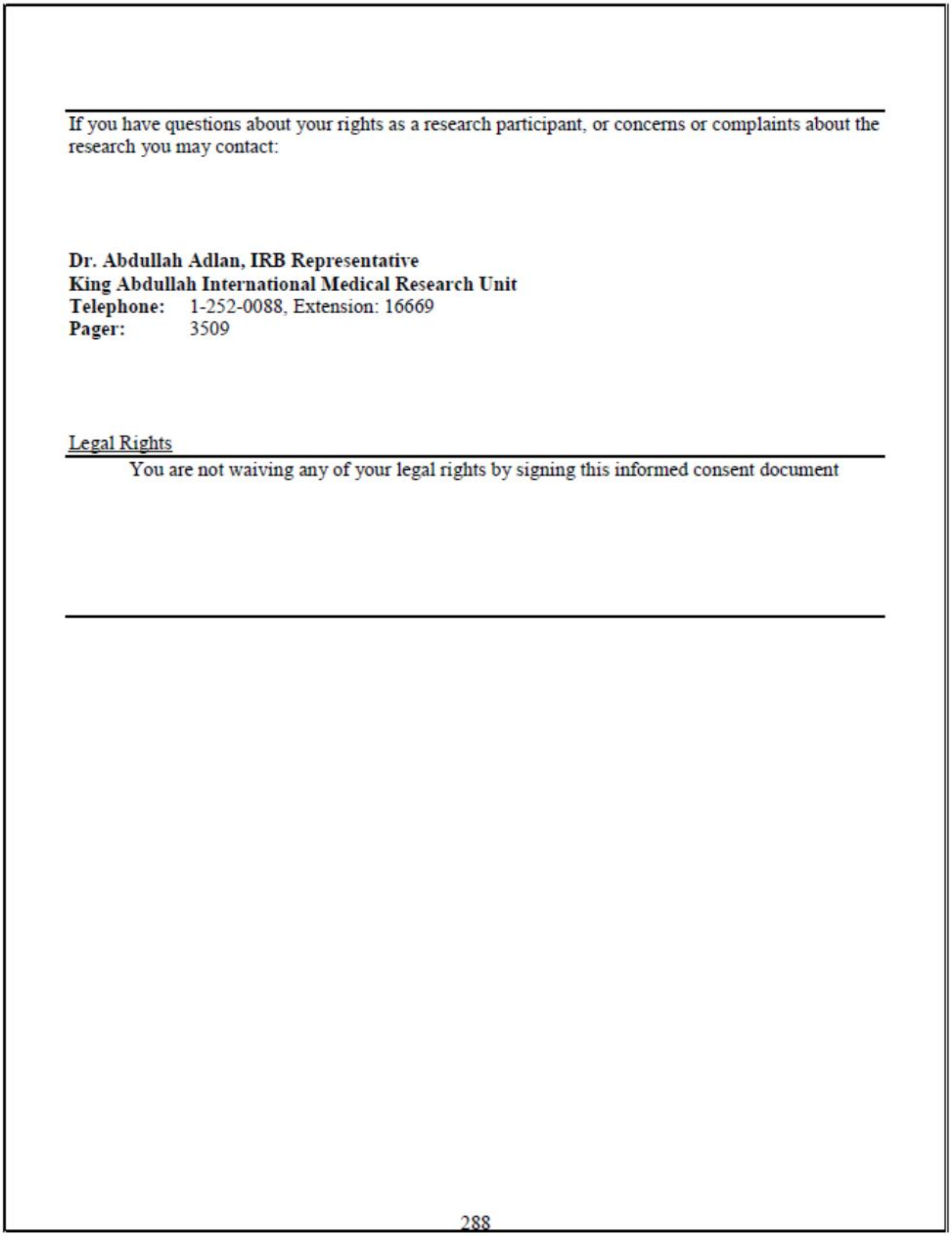
Just before the start of the interview you will be given one hundred Saudi Riyals (SR100) as a gift, in recognition of your participating in the study. In the event that you withdraw from the study you do not have to repay this money.

Should you agree to take the same interview a second time, you will be given an additional SR100.

Questions

If you agree to join this study, you will be given a telephone number of a member of the Research Team that you can contact at any time.

Name of the Principle Investigator:	Ms. Susan Volker, BSN, MPH. 1-252-0088, Extension 14228
Name of Research Coordinator 1:	Ms. Nagham Sheblaq
Telephone:	1-252-0088, Extension 14689
Pager No.:	4287
Name of Research Coordinator 2:	Mr.Abdullah Al Qarni
Telephone:	1-252-0088, Extension 14686
Pager No.:	7119

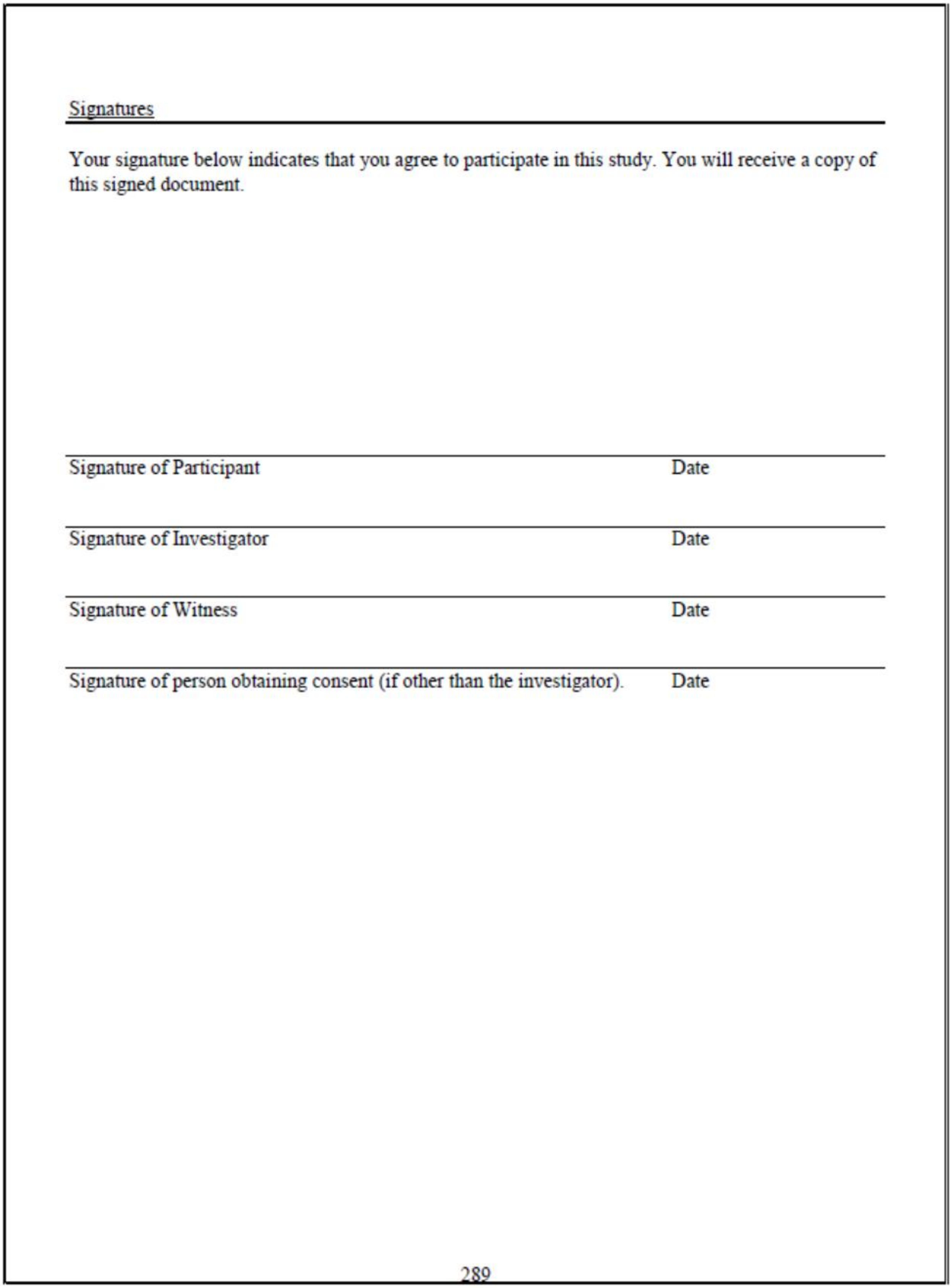


If you have questions about your rights as a research participant, or concerns or complaints about the research you may contact:

Dr. Abdullah Adlan, IRB Representative
King Abdullah International Medical Research Unit
Telephone: 1-252-0088, Extension: 16669
Pager: 3509

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document



Signatures

Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed document.

Signature of Participant Date

Signature of Investigator Date

Signature of Witness Date

Signature of person obtaining consent (if other than the investigator). Date

APPENDIX P

Informed Consent Document – Arabic

UAB **Informed Consent Document** irb

عنوان البحث: دراسة حول تطوير وتقييم احتياجات الرعاية التلطيفية باستخدام استمارة باللغتين العربية/الانجليزية (PCNA - EAV) مع مرضى السرطان في المراحل المتقدمة، المتطورة، الغير قابلة للشفاء.

رقم بروتوكول IRB : X081024009 هو رقم الدراسة في هيئة مراجعة الأنظمة واللوائح في جامعة ألاباما بيرمنغهام، الولايات المتحدة الأمريكية

اسم الباحث الرئيسي: سوزان إي فولكر

راعي البحث: قسم الأورام بمدينة الملك عبد العزيز الطبية ، الشؤون الصحية للحرس الوطني، الرياض، المملكة العربية السعودية.

نطلب منك المشاركة في دراسة بحثية تحت رعاية كل من قسم الاورام بمدينة الملك عبد العزيز الطبية والملك عبد الله المركز الدولي للبحوث الطبية. الغرض من هذه الدراسة هو معرفة المزيد عن احتياجات الرعاية والدعم لمرضانا المصابين بالسرطان . إن هذه تجربة أو دراسة تمهيدية لمساعدتنا في تطوير استبيان باللغة العربية لتقييم الاحتياجات وسيشمل بنود خاصة بالديانة الاسلامية والثقافة السعودية ، نتائج هذا الاستبيان سوف تساعد موظفي الرعاية الصحية في مستشفى الحرس الوطني/الرياض للتخطيط للقيام بخدمات على نحو افضل لتقديم احتياجات الرعاية الصحية والدعم للمرضى مثلك .

إذا وافقت على المشاركة في هذه الدراسة فستجرى تلك المقابلة في مكان ووقت متفق عليه بينك وبين منسق البحث . الاستبيان مكون من 38 سؤال ، بعض الاسئلة لها اجابات فردية والبعض الاخر متعدد الاجابات وستعطى قائمة بالإجابات المحتملة وعليك ان تختار الإجابة الاكثر مناسبة لك ، سيأخذ الاستبيان لإنهائة من 30 إلى 45 دقيقة ، ويمكنك أن تأخذ استراحة قصيرة أثناء المقابلة إذا رغبت بذلك أو في أي وقت احتجت أن تستريح قليلا .

وبجانب بعض المعلومات الأساسية مثل سنك ومكان اقامتك ، سيُطلب منك معلومات متعلقة بحالتك الصحية (في الماضي والوقت الحاضر) مثل نوع مرض السرطان لديك والعلاج الذي تلقيته.

تحتوى المقابلة على بعض الاسئلة المتعلقة بمشاعرك وعلاقاتك الإجتماعية ، وقد تفضل إجراء المقابلة على إنفراد بحيث لا تتأثر بوجود شخص مقرب إليك أثناء المقابلة . وإذا اخترت ان يصطحبك فرد من العائلة أثناء المقابلة فإنك الوحيد المسموح له بإجابة الأسئلة ولا يمكنك استشارة هذا الشخص وذلك لضمان أن اجابتك تعكس احتياجاتك كمريض سرطان وليس ما قد يعتقده الشخص الأخر مناسبا لك .

يمكنك أن تسأل منسق البحث أثناء المقابلة إذا رغبت في توضيح بعض الأسئلة لتساعدك على الإجابة ، كما يمكنك أيضا أن تخبره إذا رغبت أن تعلق على سؤال معين أو انك تشعر ان السؤال غير مقبول في هذه الدراسة ، سيقوم المنسق بأخذ الملاحظات طوال المقابلة للتأكد بأن لدينا سجلا دقيقا للمقابلة وأي من أسئلتك أو استفساراتك . ستكون تعليقاتك واستفساراتك مفيدة للغاية .

ما هي مخاطر البحث؟

لا توجد أي آثار جانبية أو أخطار جراء مشاركتك في هذه الدراسة. إن شعرت بالإرهاق أو التوتر فسوف يتم وقف المقابلة من قبل منسق البحث لمصلحتك أنت، وسوف يتم استكمال المقابلة بعد أخذ فاصل زمني إن أردت ذلك، وإذا شعرت أنه من الصعب الاستمرار فسوف يوقف منسق البحث استكمال الدراسة معك.

وكما ذكرنا آنفا، إذا شعرت بأي وقت ولأي سبب خلال المقابلة، أنك لا تريد استكمال الدراسة أو تريد وقفها أو الانسحاب كلياً من الدراسة، فضلا أخبر منسق البحث بذلك ليتم وقف المقابلة ولمنع أي تأثير سلبي عليك.

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الاحرف المختصرة من اسم المشترك: ____________

ما هي الفائدة المتوقعة من المشاركة في البحث؟

إن مشاركتك في هذا البحث يمكن أن لا تفيدك بشكل مباشر، لكن سوف تقدم لنا معلومات قد تفيد مرضى آخرون بنفس الحالة التي تعاني منها مستقبلاً.

ماذا عن سرية المعلومات؟

إن المعلومات التي يتم تجميعها ستحفظ عند راعي البحث قسم الأورام في مدينة الملك عبد العزيز الطبية للحرس الوطني، وسيقوم الراعي بتخزين ومعالجة كافة بيانات السجل بواسطة نظام معالجة بيانات إلكتروني.

أما السجلات التي تكشف عن هويتك فسيتم الاحتفاظ بها بصفة سرية بواسطة الأشخاص الذين يقومون بالإطلاع عليها. لن يتم توزيع البيانات المتعلقة بهويتك الشخصية (اسمك، عنوانك، وبيانات الهوية الأخرى) وستظل سرية في قاعدة البيانات الخاصة بمستشفيات الحرس الوطني وسيتم الإشارة لك فقط برقم شفري والأحرف الأولى من اسمك، وطبيبك مع فريق البحث فقط هو الذي سيكون قادراً على ربط الرقم الشفري باسمك.

وقد يطلع مجموعة مؤهلة من قبل الراعي أو من قبل هيئة مراجعة الأنظمة واللوائح (IRB) / لجنة الأخلاقيات الحيوية (EC) أو أي سلطات تنظيمية محلية أو أجنبية على سجلاتك الطبية لتحديد دقة البيانات المبلغ عنها من أجل حماية سلامتك ورعايتك.

أي معلومات تؤخذ من هذا البحث والتي تعرفك بصفة شخصية لن يتم نشرها طواعية أو كشفها بواسطة هذه الجهات بدون الحصول على موافقتك عدا تلك المطلوبة قانونياً بصفة محددة. لن يتم تعريفك في أي دوريات بحثية بما في ذلك المقالات الصحفية والصحف و/ أو العروض البحثية.
ومن الممكن حتى بعد انتهاء هذا البحث استخدام البيانات المجمعة لبحوث إضافية ولإعادة التحليل.

لو قررت الانسحاب من الدراسة في أي وقت فان المعلومات التي تم تجميعها عن حالتك حتى قرار انسحابك سيتم تحليلها بواسطة "راعي البحث" قسم الأورام مدينة الملك عبد العزيز الطبية للحرس الوطني من حين لآخر وفي أي وقت خلال أو بعد الدراسة وسيسمح للموظفين من جامعة ألاباما في الولايات المتحدة أو ممثليهم المعينين من طرفهم والسلطات الصحية بالاطلاع على سجلاتك الطبية وذلك للتأكد بأن المعلومات التي تم تجميعها عنك خلال الدراسة هي دقيقة .كذلك يمكن السماح لهيئة مراجعة الأنظمة واللوائح ولجنة الأخلاقيات الحيوية بالاطلاع المماثل على هذه المعلومات .

هل يجب علي أن أشارك ؟

إن المشاركة في هذا البحث اختيارية تماما، ولديك الحق كاملا في عدم المشاركة، وإن قررت ذلك أو قررت الانسحاب من تلك الدراسة فإن علاجك وموقف طبيبك أو أي من الخدمات الطبية المقدمة لك لن تتغير. كما يمكن لطبيبك أو راعي البحث أن ينهي مشاركتك في البحث إذا قرروا ذلك.

وإذا قررت المشاركة، فإن عليك التوقيع لتأكيد أنك قد أطلعت على أغراض الدراسة والتأثيرات المتوقعة وأنك قد منحتنا موافقتك في المشاركة.

المشاركة في إعادة المقابلة:

نطلب من الذين شاركوا في هذه الدراسة العودة في غضون أسبوع أو أسبوعين لإعادة إجراء الاستبيان مرة أخرى، وسبب ذلك أن هذاالاستبيان جديد ونحن بحاجة لمعرفة ما إذا كنا نقوم بطرح الأسئلة بطريقة صحيحة عند استخدامه كل مرة.

بتوقعيك على هذا النموذج فذلك بمثابة اقرار منك بالمشاركة مرة اخرى إذا رغبت في إجراء الاستبيان.

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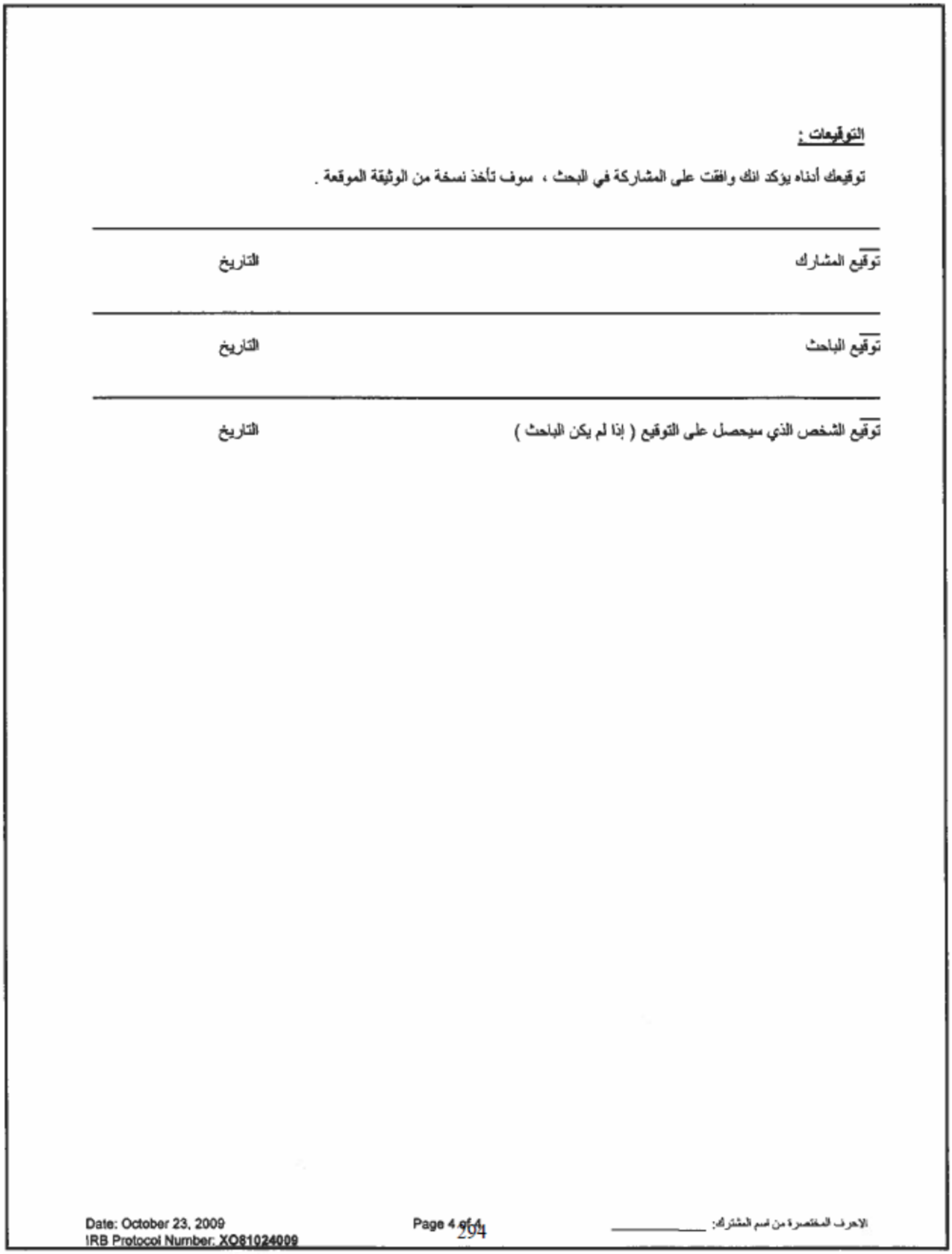
الاحرف المختصرة من اسم المشترك: ____________



التوقيعات :

توقيعك أدناه يؤكد انك وافقت على المشاركة في البحث ، سوف تأخذ نسخة من الوثيقة الموقعة .

____

توقيع المشارك التاريخ

____

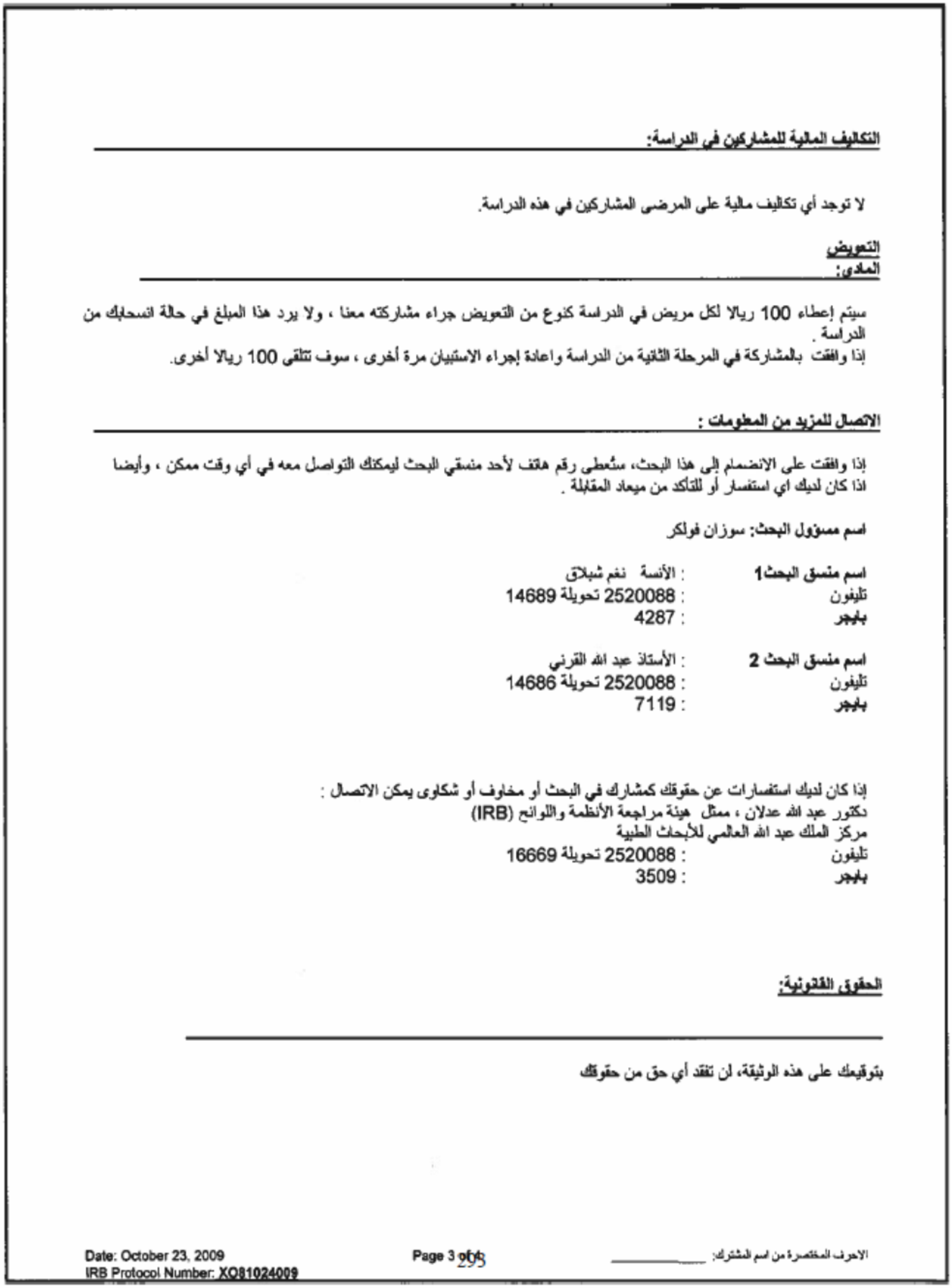
توقيع الباحث التاريخ

____

توقيع الشخص الذي سيحصل على التوقيع (إذا لم يكن الباحث) التاريخ

Date: October 23, 2009
IRB Protocol Number: XO81024009

الاحرف المختصرة من اسم المشترك: ______________



التكاليف المالية للمشاركين في الدراسة:

لا توجد أي تكاليف مالية على المرضى المشاركين في هذه الدراسة.

التعويض المادي:

سيتم إعطاء 100 ريالا لكل مريض في الدراسة كنوع من التعويض جراء مشاركته معنا ، ولا يرد هذا المبلغ في حالة انسحابك من الدراسة .
إذا وافقت بالمشاركة في المرحلة الثانية من الدراسة واعادة إجراء الاستبيان مرة أخرى ، سوف تتلقى 100 ريالا أخرى.

الاتصال للمزيد من المعلومات :

إذا وافقت على الانضمام إلى هذا البحث، ستُعطى رقم هاتف لأحد منسقي البحث ليمكنك التواصل معه في أي وقت ممكن ، وأيضا اذا كان لديك اي استفسار أو للتأكد من ميعاد المقابلة .

اسم مسؤول البحث: سوزان فولكر

اسم منسق البحث1 : الأنسة نغم شبلاق
تليفون : 2520088 تحويلة 14689
بايجر : 4287

اسم منسق البحث 2 : الأستاذ عبد الله القرني
تليفون : 2520088 تحويلة 14686
بايجر : 7119

إذا كان لديك استفسارات عن حقوقك كمشارك في البحث أو مخاوف أو شكاوى يمكن الاتصال :
دكتور عبد الله عدلان ، ممثل هيئة مراجعة الأنظمة واللوائح (IRB)
مركز الملك عبد الله العالمي للأبحاث الطبية
تليفون : 2520088 تحويلة 16669
بايجر : 3509

الحقوق القانونية:

بتوقيعك على هذه الوثيقة، لن تفقد أي حق من حقوقك

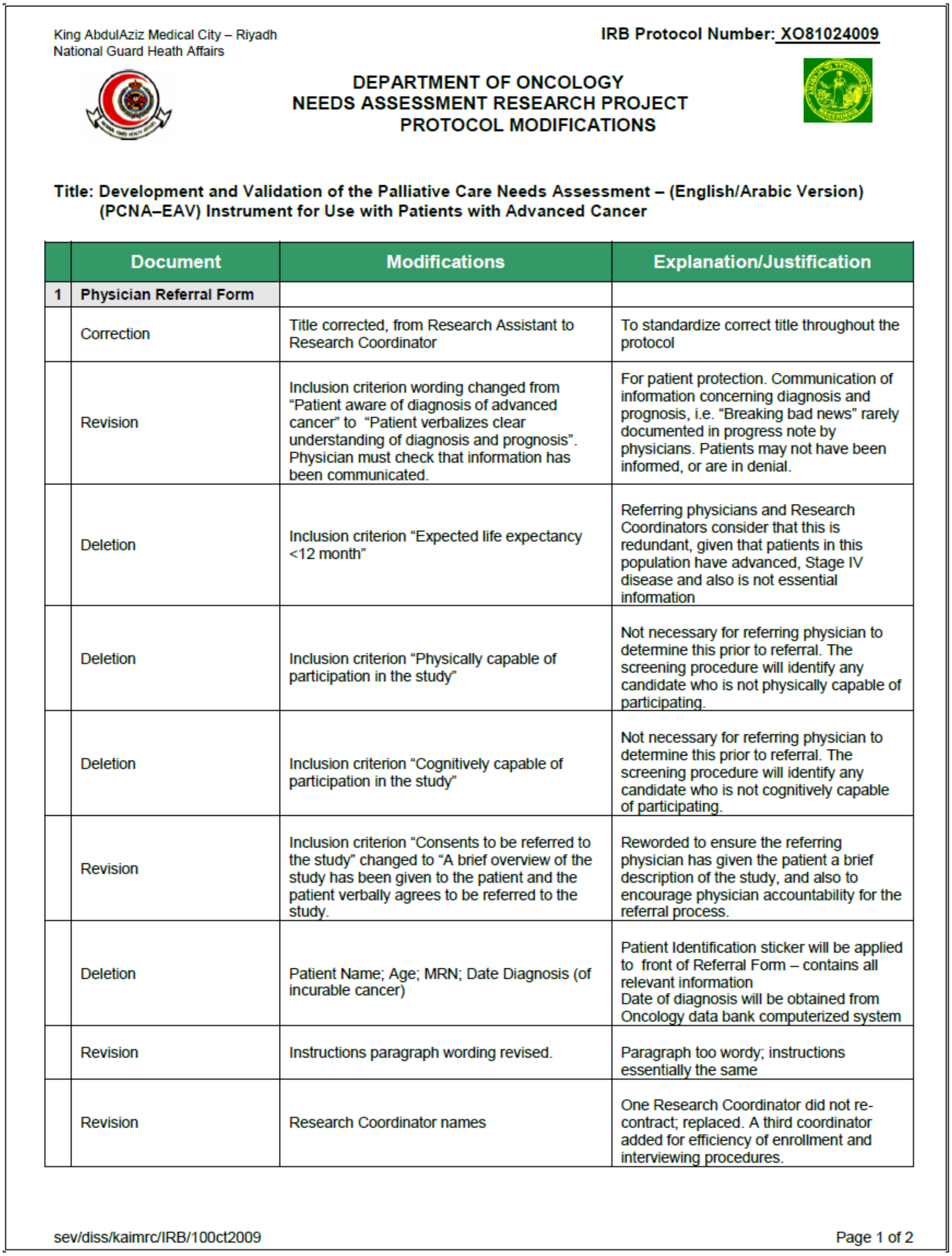
APPENDIX Q

Expert Panel Review Summary

#	Question	Expert Panel Member ID												Comments
		1	2	3	4	5	6	7	8	9	10	11	12	
Construct: Physical - Symptoms														
1c	Dealing with fatigue						🟥	🟥						Comments in Arabic
	لتعامل مع الإجهاد													
1d	Dealing with lack of sleep						🟥	🟥						Comments in Arabic
	لتعامل مع إنعدام لنوم													
1e	Dealing with nausea and/or vomiting						🟥	🟥			🟥			Correct spelling mistake in Arabic version
	لتعامل مع الغثيان / أو الإستفراغ													
1f	Dealing with poor appetite							🟥						
	لتعامل مع نقص لشهية													
1i	Dealing with bladder and/or bowel incontinence						🟥	🟥						
	لتعامل مع عدم السيطرة على لمثانة و/ أو الأمعاء													
1j	Dealing with sexual dysfunction											🟥		? Add "low libido"
	لتعامل مع لضعف الجنسي													
CONSTRUCT: Physical - Activities of Daily Living														
2	On average, over the past four weeks how often did you need help							🟥						
	كيف كان معدل احتياجك للمساعدة في الأسابيع الأربعة لماضية بخصوص													
CONSTRUCT: Physical - Instrumental Activities of Daily Living														
2i	Household chores							🟥						
	Prompt: preparing meals, cleaning													
	الأعمال المنزلية؟ **لحث:** أي إعداد وجبات الطعام أو التنظيف؟													
2j	Performing your usual duties at work							🟥						
	Prompt: Inside your home or at place of employment													
	أداء واجباتك الإعتيادية في العمل؟													Missing text in Arabic
2k	Personal transportation.				🟥									Do you mean can he/she drive a car, or do you want to know walking ability
	Prompt: For example, having to find someone to drive you to keep				🟥							🟥		or somebody at home to help get the children ready?
	التنقل الشخصي؟ **لحث:** مثلاً العثور على شخص لاصطحابك بالسيارة إلى مواعيد العيادة أو زيارة				🟥									Meaning of question not clear - is this physical?
CONSTRUCT: Physical - Childcare														? If assuming respondent has children. If view actual questionnaire can see
2n	Getting transportation for your child's (childrens') activities outside				🟥									Do you mean "taking care of your children"? It is different wording for males
	Prompt: Getting them to school or to a doctor's appointment				🟥									
	توفير وسيلة نقل لأبنائك لكي يتمكنوا من ممارسة نشاطاتهم خارج البيت ؟ **لحث:** تمكينهم من				🟥									
CONSTRUCT: Psychological - Self-Efficacy														
3	Over the past four weeks:													
	خلال الأسابيع الأربعة الماضية؟													
3d	I have felt confident I can continue my usual work activities										🟥	🟥		Add "despite my illness"
	Prompt: For example work at home or in place of employment													
	شعرت بالثقة أن في إستطاعتي الإستمرار في القيام بأعباء عملي الإعتيادية؟ **لحث:** مثلا: لعمل													Missing text in Arabic
3f	I have little interest in doing everyday activities													
	Prompt: talking on the phone; visiting with friends										🟥			Change the translation of "everyday"
	أصبحت أقل اهتماماً بأداء نشاطاتي الاعتيادية ؟ **لحث:** مثلا، التحدث في التليفون، أو زيارة													
CONSTRUCT: Psychological - Depression														
4a	I look forward to beginning each new day										🟥			Spelling mistake in Arabic
	أتطلع لبشوق لبداية كل يوم جديد													
CONSTRUCT: Psychological - Cognition														
5e	I am easily confused						🟥	🟥						Comment in Arabic
	أصاب بالحيرة بسهولة													
CONSTRUCT: Social - Relationships														
6a	My illness improved my relationship with my spouse													
	حسّن مرضي علاقتي بزوجتي (زوجتي)													
6b	My spouse is very supportive										🟥			Spelling mistake in Arabic
	زوجتي داعمة لي جداً (زوجي داعم لي جدا)													
6e	My relatives feel uncomfortable spending time with me since my							🟥			🟥			Change translation
	منذ أن مرضت يشعر أقاربي بعد لراحة في قضاء لوقت معي.													

CONSTRUCT: Information Needs														
7b	I am confused by the information I have been given about my						🟥	🟥						Comment in Arabic
	أنا محتار (محتارة)بخصوص المعلومات المقدمة لي والمتعلّقة بعلاجي													
7d	I prefer my **oncologist** makes all my medical decisions for me		🟥											My doctor, (not oncologist), since there are 3 sub-specialties
	أفضّل أن يقوم طبيب الأورام الذي يتابع حالتي باتخاذ جميع القرارات الطبية نيابة عني..													
7e	I prefer my oncologist discusses the details of my illness with me		🟥											
	أفضل أن يقوم طبيب الأورام الذي يتابع حالتي بمناقشة تفاصيل مرضي معي أثناء وجود أفراد		🟥											Arabic changes
7f	I prefer my oncologist discusses all the details of my illness with me		🟥											
	أفضل أن يقوم طبيب الأورام بالذي يتابع حالتي بمناقشة جميع تفاصيل مرضي معي فقط.		🟥											Arabic changes
CONSTRUCT: Information Needs -Source														
8b	My oncologist		🟥								🟥			My doctor
	طبيب الأورام										🟥			My is not translated accurately
8i	Media, e.g. television, radio										🟥			Radio not translated accurately
	الوسائل الإعلامية (مثل : التلفزيون, الجرائد)													
CONSTRUCT: Communication														
10f	I understand what my nurses are saying when they talk to me.											🟥		? If should add question with "doctor". As well as nurse
	عندما يحدثني المرضون (أو الممرضات) فإنني أفهم ما يقولون													
CONSTRUCT: Social Support - Numerical														
11	How many adult female relatives live with you?												🟥	? Should add male members
	كم عدد قريباتك البالغات اللاتي يعشن معك؟													
CONSTRUCT: Social Support														
15b	Since my illness members of my extended family visit me less than							🟥						
	قلت زيارات أفراد أسرتي الممتدّة عما كانت عليه قبل مرضي													
15e	I feel isolated from others because of my illness							🟥						
	أشعر بأنني معزول عن الآخرين بسبب مرضي													
Medical History														
19a	Which other serious illnesses have you had?													
	ما هي الأمراض الأخرى التي أصبت بها؟										🟥			Translation error "serious"
20	How many times have you been hospitalized for treatment of an										🟥			Translation error "hospitalised"
	كم مرة تكررخلت خلالها للعلاج من أمراض أخرى غير السرطان ؟		🟥											Arabic changes
21	How many of these hospitalizations were less than six months ago?													Would delete "of these" : Needs re-translation
	كم مرة تكرر دخولك للمستشفى خلال الأشهر الستة الماضية؟													Arabic changes
22	Which type of treatment have you received for your cancer?		🟥											Add "palliative" and "Pain management"to options Need different Arabic
	ما نوع التداوي الذي تلقيته لمرض السرطان؟											🟥		CAM study identified many patients who don't know their diagnosis.
Demographics														
24	Where do you live?												🟥	Ask for the specific town or area. Have codes for these and can then
	أين تسكن؟													What is the name of the city, town or village where you live? ___________
24i	In Riyadh في الرياض													IF IN RIYADH, SKP TO Q.25. IF OUTSIDE RIYADH, GO TO 24I
24ii	In another city في مدينة أخرى													24i What is the name of the place where your own home is?
24iii	In a small town في مدينة صغيرة													
24iv	In a rural area في منطقة ريفية													
25	What is your highest level of education?												🟥	Revise option categories
	ما هو أعلى مستوى تعليمي حصلت عليه؟													
26	What is your average monthly household income?													
	ما هو متوسط دخلك الشهري؟										🟥			Suggestion that numbers should be written in Arabic
26i	Less than 2,000 Riyals أقل من 2000 ريال													
26ii	2,000 – 4,999 Riyals 2,000 - 4,999													
26iii	5,000 to 10,000 Riyals 5,000 - 10,000													
26iv	More than 10,000 Riyals أكثر من 10,000													
26v	Not sure لست متأكداً							🟥						
26vi	Prefer not to answer أفضل عدم الإجابة													
35	How many wives does your husband have?										🟥		🟥	1 2 3 4
36	How many children do you have?										🟥			Should include Arabic for male and for female children
	كم لديك من الأبناء؟													
37	How many of your children live with you?													
	كم عدد أبناءك الذين يعيشون معك في البيت؟													
38	Which best describes the kind of home you live in?													
	ما هو أفضل وصف للمنزل الذي تعيش فيه؟													
38i	House/Villa منزل \ فيلا													
38ii	Apartment شقة													
38iii	Tent خيمة													
37iv	Others سكن آخر													
39	What is the source of the water supply for your home?												🟥	Unsure of relevance
	ما هو مصدر المياه الذي يغذي منزلك؟													

APPENDIX R
Protocol Modifications



King AbdulAziz Medical City – Riyadh
National Guard Heath Affairs

IRB Protocol Number: XO81024009

DEPARTMENT OF ONCOLOGY
NEEDS ASSESSMENT RESEARCH PROJECT
PROTOCOL MODIFICATIONS

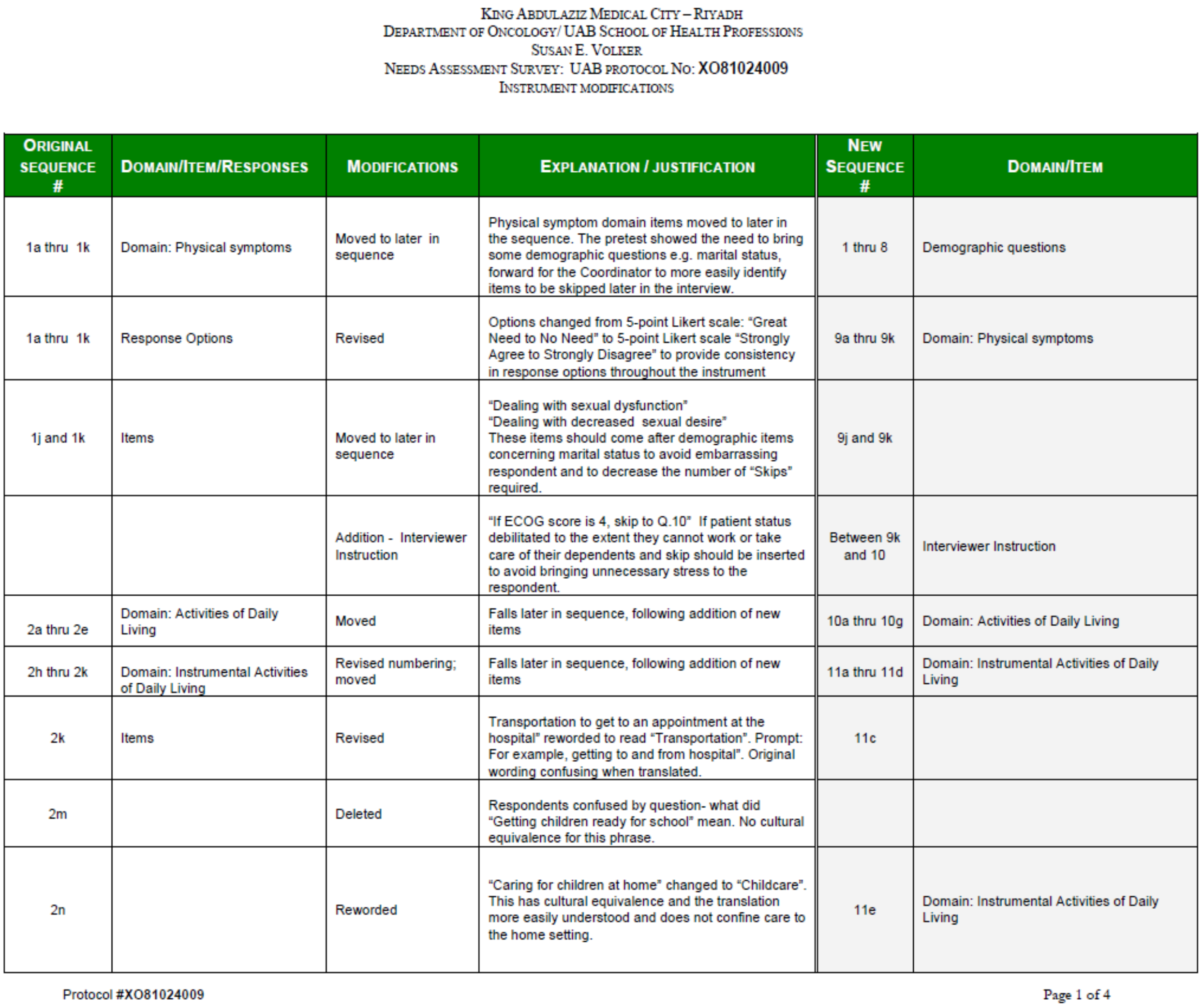
Title: Development and Validation of the Palliative Care Needs Assessment – (English/Arabic Version) (PCNA–EAV) Instrument for Use with Patients with Advanced Cancer

	Document	Modifications	Explanation/Justification
1	**Physician Referral Form**		
	Correction	Title corrected, from Research Assistant to Research Coordinator	To standardize correct title throughout the protocol
	Revision	Inclusion criterion wording changed from “Patient aware of diagnosis of advanced cancer” to “Patient verbalizes clear understanding of diagnosis and prognosis”. Physician must check that information has been communicated.	For patient protection. Communication of information concerning diagnosis and prognosis, i.e. “Breaking bad news” rarely documented in progress note by physicians. Patients may not have been informed, or are in denial.
	Deletion	Inclusion criterion “Expected life expectancy <12 month”	Referring physicians and Research Coordinators consider that this is redundant, given that patients in this population have advanced, Stage IV disease and also is not essential information
	Deletion	Inclusion criterion “Physically capable of participation in the study”	Not necessary for referring physician to determine this prior to referral. The screening procedure will identify any candidate who is not physically capable of participating.
	Deletion	Inclusion criterion “Cognitively capable of participation in the study”	Not necessary for referring physician to determine this prior to referral. The screening procedure will identify any candidate who is not cognitively capable of participating.
	Revision	Inclusion criterion “Consents to be referred to the study” changed to “A brief overview of the study has been given to the patient and the patient verbally agrees to be referred to the study.	Reworded to ensure the referring physician has given the patient a brief description of the study, and also to encourage physician accountability for the referral process.
	Deletion	Patient Name; Age; MRN; Date Diagnosis (of incurable cancer)	Patient Identification sticker will be applied to front of Referral Form – contains all relevant information Date of diagnosis will be obtained from Oncology data bank computerized system
	Revision	Instructions paragraph wording revised.	Paragraph too wordy; instructions essentially the same
	Revision	Research Coordinator names	One Research Coordinator did not re-contract; replaced. A third coordinator added for efficiency of enrollment and interviewing procedures.

DEPARTMENT OF ONCOLOGY
NEEDS ASSESSMENT RESEARCH PROJECT
PROTOCOL MODIFICATIONS

	Document	Modifications	Explanation/Justification
2	**Consent Form – All changes listed below have also been made to the Arabic language Consent Form**		
	Revision - Deletion	Title: The words “Progressive, Incurable” have been deleted from the title and from the body of the text.	To minimize any emotional impact the words may have on the subject
	Revision	The stated number of items has been revised from 48 to 37.	The change in number resulted from findings from the pretest, including Coordinator feedback; group discussion; and data analysis
	Revision	The estimated duration of the survey administration has been revised from 1-1/2 hours to 30-60 minutes.	Change based on average time taken to administer the interviews – 40 minutes
	Amendment	Compensation: an additional sentence has been inserted into the paragraph	The subject is informed he/she will receive an additional SAR100 if they choose to participate in a second interview.
	Amendment	Participating in a Repeat Interview. This section has been added to the Informed Consent	To inform the participant of the timing and purpose of the repeat interview and that this consent also covers participation in the retest, if they so choose.
	Revision and Amendment	The Researcher Coordinator list has been revised: one Coordinator name removed and one added. The total number remains the same, as originally approved.	One Research Coordinator who did not renew her contract with the institution. A replacement Coordinator name was added to maintain the efficiency of the screening, enrollment and interviewing process.
	Revision	Wording of last sentence, advising participant about consent form	Change from”You are entitled to a copy…” to “You will be given a copy…”, to clarify that the participant must take a copy home, to comply with KAIMRC and protocol guidelines.
3	**Site Delegation Log**		
	Amendment	This log is added to the Protocol to provide: a) clarity of Coordinator roles and responsibilities; b) Coordinator accountability	This is a form recently designed by Oncology research staff and is now used in all research protocols within the department.
4	**Survey Instrument**	Please see attached document: Table_ Instrument Modifications	
	Revision	This instrument was modified prior to initiating the pretest, to include in the same document both the English and Arabic versions of the items and instructions	For ease of administration and to facilitate comparison of item translation, wording, formatting, etc., during the administration process.

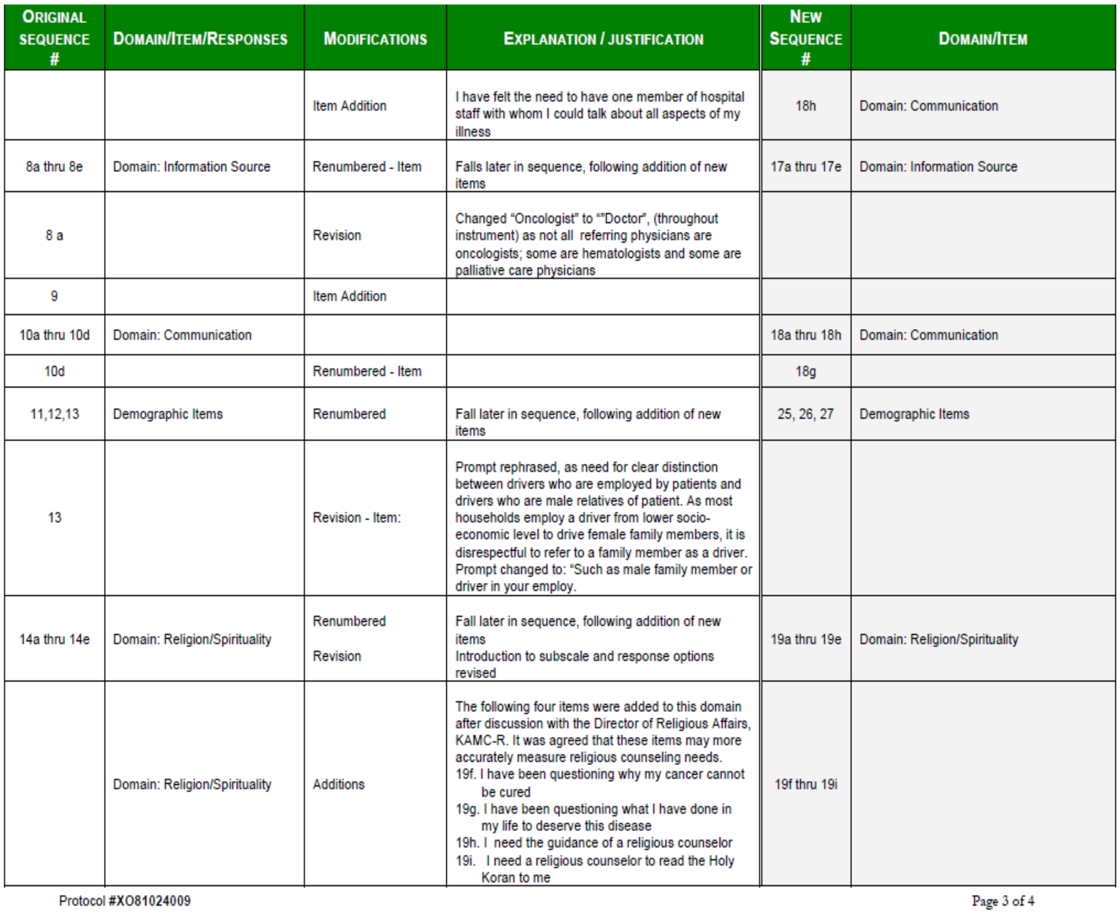
APPENDIX S
Instrument Modifications



KING ABDULAZIZ MEDICAL CITY – RIYADH
DEPARTMENT OF ONCOLOGY/ UAB SCHOOL OF HEALTH PROFESSIONS
SUSAN E. VOLKER
NEEDS ASSESSMENT SURVEY: UAB PROTOCOL NO: XO81024009
INSTRUMENT MODIFICATIONS

ORIGINAL SEQUENCE #	DOMAIN/ITEM/RESPONSES	MODIFICATIONS	EXPLANATION / JUSTIFICATION	NEW SEQUENCE #	DOMAIN/ITEM
1a thru 1k	Domain: Physical symptoms	Moved to later in sequence	Physical symptom domain items moved to later in the sequence. The pretest showed the need to bring some demographic questions e.g. marital status, forward for the Coordinator to more easily identify items to be skipped later in the interview.	1 thru 8	Demographic questions
1a thru 1k	Response Options	Revised	Options changed from 5-point Likert scale: "Great Need to No Need" to 5-point Likert scale "Strongly Agree to Strongly Disagree" to provide consistency in response options throughout the instrument	9a thru 9k	Domain: Physical symptoms
1j and 1k	Items	Moved to later in sequence	"Dealing with sexual dysfunction" "Dealing with decreased sexual desire" These items should come after demographic items concerning marital status to avoid embarrassing respondent and to decrease the number of "Skips" required.	9j and 9k	
		Addition - Interviewer Instruction	"If ECOG score is 4, skip to Q.10" If patient status debilitated to the extent they cannot work or take care of their dependents and skip should be inserted to avoid bringing unnecessary stress to the respondent.	Between 9k and 10	Interviewer Instruction
2a thru 2e	Domain: Activities of Daily Living	Moved	Falls later in sequence, following addition of new items	10a thru 10g	Domain: Activities of Daily Living
2h thru 2k	Domain: Instrumental Activities of Daily Living	Revised numbering; moved	Falls later in sequence, following addition of new items	11a thru 11d	Domain: Instrumental Activities of Daily Living
2k	Items	Revised	Transportation to get to an appointment at the hospital" reworded to read "Transportation". Prompt: For example, getting to and from hospital". Original wording confusing when translated.	11c	
2m		Deleted	Respondents confused by question- what did "Getting children ready for school" mean. No cultural equivalence for this phrase.		
2n		Reworded	"Caring for children at home" changed to "Childcare". This has cultural equivalence and the translation more easily understood and does not confine care to the home setting.	11e	Domain: Instrumental Activities of Daily Living

ORIGINAL SEQUENCE #	DOMAIN/ITEM/RESPONSES	MODIFICATIONS	EXPLANATION / JUSTIFICATION	NEW SEQUENCE #	DOMAIN/ITEM
3a thru 3e	Domain: Self -efficacy	Renumbered	Falls later in sequence, following addition of new items	12a thru 12e	Domain: Self -efficacy
4a thru 4e	Domain: Psychological/Emotional	Renumbered	Falls later in sequence, following addition of new items	13a thru 13e	Domain: Psychological/Emotional
4a thru 5d	Domain: Cognition	Renumbered	Falls later in sequence, following addition of new items	13a thru	Domain: Cognition
		Item Addition	"I have difficulty remembering what my doctor has told me about my illness". Expert panel agreed that an item measuring memory should be included.	13e	Item
6a thru 6d	Domain: Social Support	Renumbered	Falls later in sequence, following addition of new items	15a thru 15d	Domain: Social Support
		Item Addition	"I find friends and family are not comfortable talking with me about my illness".	15e	Item
		Item Addition	I find it difficult to talk about my illness because of not wanting to burden others.	15f	Item
		Item Addition	I found hospital staff sensitive to my feelings and emotional needs	15g	Item
7a thru 7c	Domain: Information	Renumbered	Falls later in sequence, following addition of new items	16a thru 16b	Domain: Information
		Item Addition	My doctor makes sure my family has up-to-date information about my care and the choices available to me	16c	
		Item Addition	My oncologist has given me clear information about what to expect regarding my illness and outlook for the future	16d	Item
		Item Addition	I need more information about therapeutic options available to keep me pain-free and comfortable	16e	Item
7d	Items	Renumbered	Falls later in sequence, following addition of new items	18e	Domain: Communication
7e, 7f	Item	Renumbered	Falls later in sequence, following addition of new items	16f	Item



ORIGINAL SEQUENCE #	DOMAIN/ITEM/RESPONSES	MODIFICATIONS	EXPLANATION / JUSTIFICATION	NEW SEQUENCE #	DOMAIN/ITEM
		Item Addition	I have felt the need to have one member of hospital staff with whom I could talk about all aspects of my illness	18h	Domain: Communication
8a thru 8e	Domain: Information Source	Renumbered - Item	Falls later in sequence, following addition of new items	17a thru 17e	Domain: Information Source
8 a		Revision	Changed “Oncologist” to “”Doctor”, (throughout instrument) as not all referring physicians are oncologists; some are hematologists and some are palliative care physicians		
9		Item Addition			
10a thru 10d	Domain: Communication			18a thru 18h	Domain: Communication
10d		Renumbered - Item		18g	
11,12,13	Demographic Items	Renumbered	Fall later in sequence, following addition of new items	25, 26, 27	Demographic Items
13		Revision - Item:	Prompt rephrased, as need for clear distinction between drivers who are employed by patients and drivers who are male relatives of patient. As most households employ a driver from lower socio-economic level to drive female family members, it is disrespectful to refer to a family member as a driver. Prompt changed to: “Such as male family member or driver in your employ.		
14a thru 14e	Domain: Religion/Spirituality	Renumbered Revision	Fall later in sequence, following addition of new items Introduction to subscale and response options revised	19a thru 19e	Domain: Religion/Spirituality
	Domain: Religion/Spirituality	Additions	The following four items were added to this domain after discussion with the Director of Religious Affairs, KAMC-R. It was agreed that these items may more accurately measure religious counseling needs. 19f. I have been questioning why my cancer cannot be cured 19g. I have been questioning what I have done in my life to deserve this disease 19h. I need the guidance of a religious counselor 19i. I need a religious counselor to read the Holy Koran to me	19f thru 19i	

ORIGINAL SEQUENCE #	DOMAIN/ITEM/RESPONSES	MODIFICATIONS	EXPLANATION / JUSTIFICATION	NEW SEQUENCE #	DOMAIN/ITEM
15a thru 15h	Level of Importance	Renumbered		23a thru 23h	Level of Importance
16a thru 16c	Domain: Financial	Renumbered		24a thru 24c	Domain: Financial
17	Clinical Items	Revision of response options format Renumbered	11 of the 25 participants surveyed verbalized confusion as to how they should answer if they had several co morbidities. Response option changed to dichotomous option yes/no	25	Clinical Items
23, 24	Demographic Items: Education and Employment Status	Renumbered	Moved to end of instrument	31, 32	Demographic Items: Education and Employment Status
25	Demographic Item - Income	Revision Renumbered	Eight of the 25 participants responded "Not Working". Response options changed to include "No regular income".	33	Demographic Item - Income
28 thru 32	Demographic Items	Renumbered	The placement of these demographic variables at the end of the questionnaire (which is usual practice in instrument development) caused confusion for respondents and for the survey administrators. One reason is the need to determine how many wives a respondent has or how many other wives the respondent's husband has. These demographics are included because they are indicators of financial responsibility and family support.	28 thru 33	Demographic Items
		Item Additions	Two questions asking respondent if they thought any other issues should be included in the survey, and to name these issues. Items added to determine if any topics had been omitted from the instrument.	36 & 37	

APPENDIX T

Pilot Instrument

CONFIDENTIAL UAB Protocol No: XO81024009 Participant ID#: ________

SAUDI ARABIAN NATIONAL GUARD HEALTH AFFAIRS
KING FAHAD NATIONAL GUARD HOSPITAL DEPARTMENT OF ONCOLOGY
PILOT STUDY ~ PATIENT NEEDS SURVEY

Start Time: ________________ **Date:** __________ **Research Coordinator:**____________________

COMMENTS

INTRODUCTION TO PARTICIPANT

My name is _________________ from King Fahad National Guard Hospital Department of Oncology.

This interview is part of a pilot study to help us develop a questionnaire that we can use in the future to help all patients with advanced cancer. By participating you will be making a valuable contribution to this work.

I am going to ask you some questions about any needs you may have related to your cancer and how you are coping in your everyday life. If at any time you wish to take a break from the interview, please let me know.

This survey is confidential. Your name will be known only to the research team and not available to anyone not involved in this study.

Also, you may stop the interview at any time and make another appointment to continue with the questions at another time, or, if you choose, you may withdraw from the study and not answer any further questions. Please let me know.

It will take approximately 30 minutes to one hour to complete the survey. Shall we continue?

Yes ☐ No ☐

مقدمة للاشتراك:

اسمي .... من إدارة الأورام، مدينة الملك عبد العزيز الطبية.

هذه المقابلة جزء من دراسة مسحية تهدف إلى مساعدتنا على تطوير" استبيان"، يمكننا في المستقبل من مساعدة جميع مرضى (السرطان المتقدم) ولذلك فإن مشاركتكم في هذه الدراسة سوف تعتبر إسهاماً قيّما لهذا العمل.

سوف أطرح عليكَ/عليكِ عدداً من الأسئلة ذات العلاقة بأيٍ من الاحتياجات التي ربما تكون قد ربطتها بمرض السرطان، وكيف تتأقلم مع مرضك في سير حياتك اليومية. والذي أرجوه منك أن تطلعني على رغبتكَ/ رغبتكِ في حال رغبتَ/رغبتِ في أخذ استراحة في أي وقت من هذه المقابلة.

ومن المهم القول بأن هذه الدراسة الفحصية سريّة, ولن يطّلع على اسمك سوى أعضاء الفريق البحثي فقط ولن يكون متوافراً لمن ليس عضواً في هذه الدراسة.

وبإمكانك كذلك, أن تطلب/تطلبي إيقاف المقابلة والحصول على موعد لاستكمالها في وقت آخر, كما باستطاعتك أن تنسحب/ تنسحبي من هذه الدراسة وألا تجيب على بقية الأسئلة في أي وقت تشاء/ تشائين. الرجاء إبلاغي متى ما رغبتم في الانسحاب.

سوف تستغرق هذه المقابلة قرابة الساعة والنصف لإنهاء هذا الاستبيان. فهل تشعر/تشعرين بالرغبة الكافية للاستمرار؟

☐ نعم ☐ لا

IF PARTICIPANT RESPONSE IS YES, PROCEED WITH THE INTERVIEW.

IF RESPONSE IS NO, DETERMINE THE REASON WHY NOT, I.E. IS IT JUST TODAY THAT THE PARTICIPANT IS EXPERIENCING DIFFICULTIES, OR HAS THERE BEEN A SERIOUS DECLINE IN THE THEIR CONDITION, WHICH WARRANTS HIS/HER WITHDRAWAL FROM THE STUDY?

IF ONLY A TEMPORARY PROBLEM, ARRANGE AN APPOINTMENT FOR ANOTHER DAY. IF THERE HAS BEEN A SERIOUS DECLINE, GIVE THE PARTICIPANT THE OPTION OF WITHDRAWING FROM THE STUDY (DOCUMENT RESPONSE)

IF DECLINING TO PARTICIPATE, OR UNABLE TO PARTICIPATE, DOCUMENT THE REASONS WHY AND ANY FOLLOW-UP ACTION TO BE TAKEN.

DECLINED: YES ☐ NO ☐
FOLLOW-UP APPOINTMENT: YES ☐ NO ☐

تعليمات القائم بالمقابلة:

إذا كانت استجابة المفحوص بنعم، فإنتقل إلى المقابلة.

أما إذا كانت الاستجابة بلا، فحدد ما هو السبب، مثلاً: أن المفحوص لم يختبر هذه الصعوبات إلا اليوم فقط. أو أن هناك تدهور جدّي في حالة المفحوص تفرض انسحابه/ انسحابها من المقابلة.

إذا كانت المشكلة وقتية, فحدد موعداً آخر لإنهاء المقابلة. أما إذا كان هناك تدهور خطيراً, فأعرض على المفحوص خيار الانسحاب من الدراسة, ووثق كل الاجابات المستنبطة.

إذا رفض المفحوص المشاركة، أو كان غير قادر عليها، فوثّق الأسباب الكامنة وراء ذلك، وأية متابعة يمكن أخذها قيد التنفيذ.

رفض: نعم ☐ لا ☐
موعد متابعة: نعم ☐ لا ☐

INSTRUCTION DETAILS FOR RESEARCH COORDINATOR

1. ALL INSTRUCTIONS FOR THE INTERVIEWER ARE IN UPPER CASE FONT
2. ALL DIRECTIONS/, NFORMATION, QUESTIONS TO BE ADDRESSED TO THE PARTICIPANT ARE IN LOWER CASE FONT.
3. KEY TO RESPONSE OPTION HEADINGS IN THIS INSTRUMENT:
   - PNTA = Prefer Not To Answer; N/A = Not Applicable
4. CIRCLE THE NUMBER CORRESPONDING TO THE RESPONSE GIVEN TO EACH ITEM

تعليمات القائم بالمقابلة :

1. كل التعليمات المعطاة للقائم بالمقابلة تكون بالنمط العريض و مظللة.
2. كل الإرشادات/ المعلومات، والأسئلة الموجّهة للمفحوص تكون بالنمط الخفيف.
3. رموز خيارات الإجابة في هذه الأداة :
   ع ج = أفضّل عدم الإجابة غ مط = غير مطابقة
4. ضع دائرة حول الرقم المطابق للإجابة المعطاة لكل فقرة.

Participant ID # ________

We are now ready to begin the interview, if that's alright with you. The first few questions will be about your home and family background, as it is always helpful to know a little about the patient before starting the questions about their illness.

نستعد الآن لبدء المقابلة إذا كان هذا مناسباً لك . ستكون مجموعة الأسئلة الأولى عن الخلفية الأسرية والمنزلية لأنه من المفيد دائماً معرفة القليل عن المريض قبل أن نبدأ الأسئلة المرتبطة بمرضهم .

1 Where do you live?
Prompt: What is the name of your home town?
أين تسكن ؟
حث : ما اسم بلدتك ؟
____

2 Where do you live while you are receiving treatment at this hospital?
أين تسكن أثناء تلقيك العلاج في هذا المستشفى؟
____

3 What is your current marital status?
ما هو وضعك الزواجي؟

Married	متزوج / متزوجة	1
Widowed	أرمل / أرملة	2
Divorced	مطلق / مطلقة	3
Separated	منفصل / منفصلة	4
Never Married	لم يسبق له / لها الزواج	5

{IF FEMALE AND MARRIED SKIP TO Q.5. IF FEMALE AND NEVER MARRIED, SKIP TO Q.8}
{ إذا كانت إمرأة ومتزوجة انتقل إلى سؤال رقم 5. إذا كانت إمرأة ولم تتزوج قط ، انتقل إلى سؤال رقم 8 }

4 How many wives do you have?
كم عدد الزوجات لديك؟

One	واحد	1
Two	اثنان	2
Three	ثلاثة	3
Four	أربعة	4

{IF MALE, SKIP TO Q. 6}
{ إذا كان رجل ، انتقل إلى سؤال 6 }

5 How many other wives does your husband have?
كم زوجة أخرى لدى زوجك؟

None	لا أحد	1
One	واحد	2
Two	اثنان	3
Three	ثلاثة	4

6 How many children do you have?
كم عدد أبناؤك وبناتك؟

None	لا يوجد	1
One – Three	واحد – ثلاثة	2
Four – Six	أربعة – ستة	3
Seven – Nine	سبعة – تسعة	4
Ten – Twelve	عشرة – اثنا عشر	5
More than Twelve	أكثر من اثنا عشر	6

{IF NONE AND MALE, SKIP TO Q. 8}
{ إذا كان لا يوجد وكان رجلا ، انتقل إلى سؤال رقم 8 }

7 How many of your children live with you?
كم عدد أبناؤك وبناتك الذين يعيشون معك ؟

None	لا يوجد	1
One – Three	واحد – ثلاثة	2
Four – Six	أربعة – ستة	3
Seven – Nine	سبعة – تسعة	4
Ten – Twelve	عشرة – اثنا عشر	5
More than Twelve	أكثر من اثنا عشر	6

8 How many people living with you are teenagers, or older?
من الذين يقيمون معك كم عدد الأشخاص في سن المراهقة أو أكبر؟

None	لا يوجد	1
One – Three	واحد – ثلاثة	2
Four – Six	أربعة – ستة	3
Seven – Nine	سبعة – تسعة	4
Ten – Twelve	عشرة – اثنا عشر	5
More than Twelve	أكثر من اثنا عشر	6

Participant ID # __________

I now have some questions about any physical problems you may have had over *the past four weeks.*
Please choose one from these five possible answers:

Strongly Agree; Agree; Neutral; Disagree; Strongly Disagree

سوف نبدأ الآن بطرح سلسلة من الأسئلة ذات العلاقة بالمشاكل الجسدية. يعاني كثير من الناس من مشاكل مختلفة كلما تقدّم بهم المرض. ونرغب هنا أن نعرف مقدار ما احتجت إليه من مساعدةٍ بسبب المشاكل الجسدية التي ربما تعرضْتَ لها خلال الأسابيع الأربعة الماضية. الرجاء اختيار واحدة من الإجابات الخمس المحتملة الآتية:-

9	**In the last four weeks, I needed help with:** في الأسابيع الأربعة الماضية ، احتجت للمساعدة في :	Strongly Agree موافق بشدة	Agree موافق	Neither Agree nor Disagree لا أستطيع التحديد	Disagree غير موافق	Strongly Disagree غير موافق بشدة
9a	Dealing with severe pain التعامل مع الألم الشديد	1	2	3	4	5
9b	Dealing with difficulty breathing التعامل مع صعوبة التنفس	1	2	3	4	5
9c	Dealing with fatigue التعامل مع الخمول (الإجهاد)	1	2	3	4	5
9d	Dealing with lack of sleep التعامل مع قلة النوم (الأرق)	1	2	3	4	5
9e	Dealing with nausea and/or vomiting التعامل مع الغثيان / والتقيؤ (التطريش)	1	2	3	4	5
9f	Dealing with poor appetite التعامل مع نقص الشهية	1	2	3	4	5
9g	Dealing with difficulty eating and/or swallowing التعامل مع صعوبة الأكل / أو البلع	1	2	3	4	5
9h	Dealing with constipation and/or diarrhea التعامل مع الإمساك / الإسهال	1	2	3	4	5
9i	Dealing with bladder problems التعامل مع عدم التحكم في البول أو البراز	1	2	3	4	5
	{IF NOT MARRIED, SKIP TO Q.10}					{ إذا لم تكن متزوجا / متزوجة ، انتقل إلى سؤال رقم 10 }
9j	Dealing with sexual dysfunction التعامل مع القصور الجنسي	1	2	3	4	5
9k	Dealing with decreased sexual desires عدم الرغبة الجنسية	1	2	3	4	5

IF ECOG SCORE 4, SKIP 10A THRU 10H AND GO TO Q 10I.

إذا كان مجموع الاختبار 4 ، تخطي مجموعة الأسئلة التالية وانتقل إلى سؤال رقم 10I .

10	On average, over the past four weeks I needed help with: كيف كان معدل احتياجك للمساعدة في الأسابيع الأربعة الماضية بخصوص:	All of the Time كل الوقت	Most of the Time أغلب الوقت	Much of the Time كثيراً من الوقت	Some of the Time بعضاً من الوقت	None of the Time ولا في أي وقت
10a	Getting out of bed النهوض من السرير(فراشك)	1	2	3	4	5
10b	Bathing or showering الاغتسال أو الاستحمام	1	2	3	4	5
10c	Getting dressed ارتداء ملابسك	1	2	3	4	5
10d	Walking more than 10 steps **Prompt:** For example, walking across a room المشي لأكثر من عشر خطوات حث : مثلاً المشي في الغرفة	1	2	3	4	5
10e	Going up stairs **Prompt:** For example climbing up 5 steps صعود الدرج حث : مثلا صعود خمس درجات من السلم؟	1	2	3	4	5
10f	Performing Wudu القيام بالوضوء؟ أي الغسل قبل الصلاة؟	1	2	3	4	5
10g	Performing Salah أداء الصلاة؟ أي بأداء أركان الصلاة؟	1	2	3	4	5

11.	On average, over the past four weeks I needed help with: كيف كان معدل احتياجك للمساعدة في الأسابيع الأربعة الماضية بخصوص:	All of the Time كل الوقت	Most of the Time أغلب الوقت	Much of the Time كثيراً من الوقت	Some of the Time بعضاً من الوقت	None of the Time ولا في أي وقت
11a	Household chores and/or <u>home</u> maintenance jobs which I usually do myself **Prompt**: preparing meals, cleaning, minor home repairs الأعمال المنزلية وأعمال الصيانة التي أقوم بأدائها في العادة حث : أي إعداد وجبات الطعام أو التنظيف ؟	1	2	3	4	5
11b	Shopping **Prompt**: For example buying groceries or personal items التسوق؟ مثلاً شراء المقاضي والأشياء الشخصية؟	1	2	3	4	5
11c	Transportation التنقل **Prompt**: For example, getting to and from hospital حث : مثلاً الذهاب إلى المستشفى والعودة منه	1	2	3	4	5
11d	Taking my medications when I am at home أخذ العلاج أثناء التواجد في المنزل	1	2	3	4	5
{IF NO CHILDREN SKIP TO Q 12a}						**{ إذا كان لا يوجد أطفال انتقل إلى سؤال رقم 12 a}**
11e	Childcare رعاية الأطفال	1	2	3	4	5

Participant ID # ___________

Many people with cancer feel they cannot cope with their everyday lives as their disease progresses. These next questions are about how you have felt *over the past four weeks* about your ability to manage your life situation. Please choose the answer which best applies to you:

None of the Time; Some of the Time; Much of the Time; Most of the Time; All of the Time.

عر كثيرا من مرضى السرطان وبسبب تقدم مرضهم بعدم قدرتهم على التكيف مع سير الحياة اليومية . تهتم الفقرات التالية بالكيفية التي كنت تشعر بها خلال الأسابيع الأربعة الماضية، وذلك
ا يتعلق بقدرتك على إدارة مواقف حياتك.
هذا نرجو منك أن تختار الإجابة التي تناسبك تماماً ولا في أي وقت، بعضاً من الوقت، غالب الوقت، كثيرا من الوقت ، كل الوقت

		None of the Time ولا في أي وقت	Some of the Time بعضاً من الوقت	Most of the Time أغلب الوقت	Much of the Time كثيراً من الوقت	All of The Time ل الوقت
12	Over the past four weeks : خلال الأسابيع الأربعة الماضية:					
12a	I have felt confident I can cope with my illness شعرت بالثقة أن في استطاعتي التعايش مع مرضي	1	2	3	4	5
12b	I have felt free to make my own decisions about the health care I receive, related to my cancer شعرت بالحرية في اتخاذ القرارات الخاصة بالرعاية الصحية التي أتلقاها والمتعلقة بمرض السرطان لدي	1	2	3	4	5
12c	I have felt I cannot manage my life because of my illness منذ مرضي شعرت بعدم استطاعتي إدارة أمور حياتي	1	2	3	4	5
12d	I have felt confident I can continue my usual work activities **Prompt:** For example work at home or in place of employment أشعر بالثقة بأن باستطاعتي الاستمرار في القيام بالأعمال الاعتيادية حث : مثلا في العمل أو في المنزل	1	2	3	4	5
12e	I have felt confident in my ability to take care of those I am responsible for, despite my illness منذ مرضي مازلت قادرا على تحمل مسئولية أسرتي	1	2	3	4	5

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UAB Protocol #: XO81024009

Participant ID # ___________

Different people experience different emotions when they have a serious illness. I am now going to ask you some questions about how you fee in general. For the next items please choose the answer which best applies to you:

None of the Time; Some of the Time; Much of the Time; Most of the Time; All of the Time.

ندما يتعرّض الناس لأمراض خطيرة ، فإنهم يختلفون باختلاف المشاعر المصاحبة للمرض ، سوف أطرح عليك بعض الأسئلة التي تتعلق بما تشعر به نفسيا ، بشكل عام .
هنا نرجو منك أن تختار الإجابة التي تنطبق عليك أكثر من غيره وها هي كالآتي: ولا في أي وقت ، بعضاً من الوقت ، غالب الوقت ، كثيراً من الوقت ، كل الوقت

13		None of the Time ولا في أي وقت	Some of the Time بعضاً من الوقت	Most of the Time أغلب الوقت	Much of the Time كثيراً من الوقت	All of the Tim ل الوقت
13a	I look forward to beginning each new day أتطلع بتفاؤل لبداية كل يوم جديد	1	2	3	4	5
32b	I feel guilty that I may be a burden on my family أشعر بالذنب لأنني ربما أمثل عبئاً (حملاً) على أسرتي	1	2	3	4	5
13c	I feel I am valued by those close to me ما زلت أشعر بالتقدير من أولئك المقربين مني	1	2	3	4	5
13d	I feel I have no purpose in life because of my cancer أشعر بأني لا هدف لي في الحياة بسبب مرض السرطان	1	2	3	4	5
13e	I feel fearful about my future أشعر بالخوف فيما يتعلق بمستقبلي	1	2	3	4	5

Sometimes patients with cancer find their ability to think clearly changes over time. From the following statements please choose the respons that bests suits you: All of the Time; Most of the Time; Much of the Time; Some of the Time; None of the Time

د مرضى السرطان في بعض الأحيان بأن قدرتهم على التفكير بوضوح تتغير مع مرور الوقت .
هذا نرجو منك أن تختار من العبارات التالية الإجابة التي تناسبك وهي كالآتي: كل الوقت، غالب الوقت، كثيراً من الوقت، بعضا من الوقت، ولا في أي وقت

14		All of the Time كل الوقت	Most of the Time أغلب الوقت	Much of the Time كثيراً من الوقت	Some of the Time بعضاً من الوقت	None of The Time ولا في أي وقت
14a	I have trouble understanding new information أجد صعوبة في فهم المعلومات الجديدة	1	2	3	4	5
14b	I have difficulty concentrating on simple tasks أجد صعوبة في التركيز على مهمات سهلة	1	2	3	4	5
14c	I have difficulty taking decisions about routine daily activities أجد صعوبة في اتخاذ قرارات متعلقة بنشاطاتي اليومية	1	2	3	4	5
14d	I am easily confused أشعر بالتشويش بسهولة	1	2	3	4	5
14e	I have difficulty remembering what my doctor has told me about my illness أجد صعوبة في تذكر ما أخبرني به طبيبي عن مرضي	1	2	3	4	5

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Sometimes people with cancer find their relationships with friends and family change over time. From the following statements please choose the response that bests suits you:

Strongly Disagree; Disagree; Neutral; Agree; Strongly Agree; Prefer Not to Answer

يجد مرضى السرطان في بعض الآحيان بأن علاقاتهم مع أعضاء الأسرة والأصدقاء تتغير مع مرور الوقت .
هذه بعض العبارات التي نرجو منك أن تختار منها الإجابة التي تناسبك وهي كالآتي: غير موافق بشدة،غير موافق، لا أستطيع التحديد ، موافق، موافق بشدة، أفضل عدم الإجابة

{IF NOT MARRIED, SKIP TO Q.15c}

{ إذا لم يكن متزوجا / متزوجة فانتقل إلى السؤال رقم c15}

15	**Over the last four weeks I have found that:** على مدار الأربعة أسابيع الماضية اكتشف الآتي :	Strongly Disagree غير موافق بشدة	Disagree غير موافق	Neither Agree nor Disagree لا أستطيع التحديد	Agree موافق	Strongly Agree موافق بشدة	PNTA أفضل عدم الإجابة
15a	My illness has strengthened my relationship with my spouse قوى مرضي علاقتي بزوجتي (زوجي)	1	2	3	4	5	9
15b	My spouse is very supportive of me زوجتي داعمة لي جداً/ زوجي داعم لي جدا	1	2	3	4	5	9
15c	My relatives are very supportive of me أقاربي داعمين لي جداً	1	2	3	4	5	9
15d	My friends are very supportive of me أصدقائي داعمين لي جداً	1	2	3	4	5	9
15e	I find friends and family are not comfortable talking with me about my illness أجد أن أصدقائي وعائلتي غير مرتاحين في التحدث معي عن مرضي	1	2	3	4	5	9
15f	I find it difficult to talk about my illness, because of not wanting to burden others أجد صعوبة في التحدث عن مرضي لأنني لا أريد أن أحمّل الآخرين العبء.	1	2	3	4	5	9
15g	I found hospital staff sensitive to my feelings and emotional needs وجدت أن العاملين بالمستشفى يراعون مشاعري واحتياجاتي العاطفية	1	2	3	4	5	9

Now I am going to ask you about information you think you need, related to your cancer and treatment. Choose one of the following respons which best describes how you feel:

Strongly Disagree; Disagree; Neutral: Agree; Strongly Agree

ف أسألك الآن عن بعض المعلومات التي تظن أنك بحاجة إليها، والمرتبطة بمرضى السرطان الذي تعاني منه وكيفية علاجه. اختر واحدة من الاجابات التالية التي تصف ما تشعر به بأفضل

موافق بشدة، غير موافق، لا أستطيع التحديد، موافق، موافق بشدة

16.		Strongly Disagree غير موافق بشدة	Disagree غير موافق	Neither Agree nor Disagree لا أستطيع التحديد	Agree موافق	Strongl Agree افق بشدة
16a	I need more information about my cancer أحتاج لمعلومات أكثر بخصوص مرض السرطان لدي	1	2	3	4	5
16b	I have been told all I want to know about my cancer لقد تمّ إخباري بكل ما أريد معرفته عن مرض السرطان لدي	1	2	3	4	5
16c	My oncologist makes sure my family has up-to-date information about my care and the choices available to me يتأكد طبيبي أن عائلتي لديها كل المعلومات عن رعايتي والاختيارات المتاحة لي	1	2	3	4	5
16d	My oncologist has given me clear information about what to expect regarding my illness and outlook for the future أعطاني طبيبي معلومات واضحة عما أتوقعه فيما يخص مرضي ونظرة شاملة للمستقبل	1	2	3	4	5
16e	I need more information about therapeutic options available to keep me pain-free and comfortable أحتاج معلومات أكثر عن مختلف خيارات العلاجات المتاحة التي تزيل الألم وتجعلني مرتاحاً	1	2	3	4	5
16f	I have been given all the information I need to take care of myself لقد حصلت على جميع المعلومات التي أحتاجها للعناية بنفسي.	1	2	3	4	5
16g	My family members have been given all the information they need to take care of me لقد حصل أفراد أسرتي على جميع المعلومات التي يحتاجونها للعناية بي	1	2	3	4	5

Participant ID # ____________

Patients get information about their illness and treatment from different sources. I am now going to ask you how helpful different sources of information have been, to give you the information you need. Please answer with the response that best suits you:

None of the time; Some of the time, Much of the time; Most of the time; All of the time.

يحصل المرضى على المعلومات المتعلّقة بأمراضهم وكيفية علاجها من مصادر مختلفة. سوف أسألك الآن كيف كانت المصادر المختلفة للمعلومات مفيدة لك من حيث توفيرها للمعلومات التي تحتاجها. وهنا نرجو منك أن تختار واحدة من الاجابات التي تنطبق عليك أكثر من غيرها: ولا في أي وقت، في بعض االوقت، في غالب الوقت، كثيراً من االوقت، كل الوقت

{INSERT THE NAME OF THE SOURCE, E.G. 17A. MEDICAL STAFF

{ أدخل مصدر المعلومة لكل فقرة من الفقرات أدناه على سبيل المثال الفريق الطبي a17 }

17.	The information given to me by ______________ was helpful: المعلومات التي حصلت عليها من خلال :	None of the Time ولا في أي وقت	Some of the Time بعضاً من الوقت	Most of the Time أغلب الوقت	Much of the Time كثيراً من الوقت	All of The Time كل الوقت
17a	Medical Staff طبيبي / طبيبتى (الأطباء)	1	2	3	4	5
17b	Nursing staff طاقم التمريض	1	2	3	4	5
17c	Other hospital Staff غيرهم من طاقم المستشفى	1	2	3	4	5
17d	The media (e.g. television, newspapers) الوسائل الإعلامية (مثل : التلفزيون, الجرائد)	1	2	3	4	5
17e	Printed Information (e.g. brochures, pamphlets) المعلومات المطبوعة (مثل : االكتيبات, المطويات)	1	2	3	4	5
17f	Internet Websites صفحات الإنترنت	1	2	3	4	5

Participant ID # ____________

Now some questions about communicating with your doctor and other hospital staff, some of whom are not fluent in Arabic. Just to remind you, this information is confidential and will not be given to your doctor or any other staff.
Please choose one of the following responses which best describes your experience in communicating with staff:

Strongly Disagree; Disagree; Neutral: Agree; Strongly Agree

والآن إليك بعض الأسئلة المتعلّقة بكيفية التواصل مع طبيبك وبقية الطاقم الطبى، علما بأن البعض منهم لا يجيد العربية بشكل جيد. وللتذكير فقط، فإن ما تدلى به من معلومات يعتبر سريا للغاية ولن تعطى لطبيبك ولا لغيره من إفراد الطاقم الطبى.وهنا نرجو منك أن تختار واحدة من الاجابات التالية، والتى تنطبق عليك أكثر من غيرها:غير موافق بشدة، ، غير موافق، لا أستطيع التحديد، موافق، موافق بشدة

18		Strongly Disagree غير موافق بشدة	Disagree غير موافق	Neither Agree nor Disagree لا أستطيع التحديد	Agree موافق	Strongly Agree موافق بشدة
18a	My doctor takes time to answer all my questions يأخذ طبيبى الوقت اللازم للإجابة على جميع أسئلتي	1	2	3	4	5
18b	My doctor shows interest in me as a person يظهر طبيبي اهتمامه بي كشخص	1	2	3	4	5
18c	I prefer my doctor makes all my medical decisions for me أفضّل أن يقوم طبيب الأورام باتخاذ جميع القرارات الطبية نيابة عني	1	2	3	4	5
18d	My doctor has explained clearly to me about the physical problems I may face شرح لي طبيبي وبكل وضوح جميع المشاكل الجسدية التي ربما أواجهها	1	2	3	4	5
18e	I prefer my doctor discusses the details of my illness only with me أفضل أن طبيبي يقوم بمناقشة جميع تفاصيل مرضي معي فقط	1	2	3	4	5
18f	My nurses understand me when I talk to them يفهمني الممرضون والممرضات عندما أتحدّث إليهم	1	2	3	4	5
18g	There is always an interpreter present to translate, if needed يتواجد المترجم بشكل دائم عند الضرورة	1	2	3	4	5
18h	I have felt the need to have one member of hospital staff with whom I could talk about all aspects of my illness شعرت أني احتاج أحد أفراد العاملين بالمستشفى لأتحدث معه عن كافة نواحي م	1	2	3	4	5

Participant ID # ___________

When dealing with a serious illness people have different beliefs about why they are sick; they also have different levels of need for religious counseling and support.
These next items are about your beliefs and religious support needs in relation to your illness. Please choose your response from the following: Strongly Disagree; Disagree; Neither Agree nor Disagree; Agree; Strongly Agree; Prefer Not to Answer.

يختلف الناس باختلاف ما يحملونه من معتقدات متباينة عن أسباب مرضهم ، كما أن لديهم مستويات مختلفة لاحتياجهم للمشورة الدينية والدعم . ومن هذا المنطلق فإن العبارات التالية تستوضح ما
تحمله (تحملين) من معتقدات وعلاقتها بمرضك.
ولذلك نرجو منك أن تختار واحدة من الاجابات التالية والتي تصف ما تعتقده على أكمل وجه. غير موافق بشدة، غير موافق، محايد، موافق، موافق بشدة ، أفضل عدم الاجابة

19		Strongly Disagree غير موافق بشدة	Disagree غير موافق	Neither Agree nor Disagree لا أستطيع التحديد	Agree موافق	Strongly Agree موافق بشدة
19a	I believe that my suffering is a test of my faith أعتقد بأن معاناتي ما هي إلا امتحاناً لإيماني	1	2	3	4	5
19b	I question what I have done in my life to deserve this disease أتساءل ماذا فعلت في حياتي لاستحق هذا المرض	1	2	3	4	5
19c	I believe an evil eye affected me اعتقد بأنني أصبت بعين.	1	2	3	4	5
19d	I need the guidance of a religious counselor أحتاج لتوجيهات مستشار دينى	1	2	3	4	5
19e	I believe my illness is a punishment from Allah أعتقد بأن مرضي هو عقاب من الله.	1	2	3	4	5
19f	My religious needs are being supported by the hospital staff يدعم احتياجتي الدينية فريق العمل بالمستشفى	1	2	3	4	5
19g	I am afraid of the day of judgment ليس الموت ما أخافه وإنما هو يوم الحساب	1	2	3	4	5
19h	I need a religious counselor to read the Holy Koran to me أحتاج مستشار دينى لقراءة القرآن لي	1	2	3	4	5
19i	Allah will wash away my sins because of this illness سوف يغفر الله لي خطاياي بسبب مرضي هذا.	1	2	3	4	5
19j	I am losing hope that my cancer will be cured بدأت افقد الأمل في شفائي من السرطان	1	2	3	4	5

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I would like to know how important is it for you to get help with the different problems you have told me about in this interview. Please choose your answer from the following responses : Extremely important; Important; Neither Important nor Important; Not Very Important; Not at all Important

أود أن أعرف كم هو مهم لديك الحصول على المساعدة لحل المشكلات المختلفة التي أخبرتني عنها في هذه المقابلة,
لذلك أرجو منك اختيار واحدة من الاستجابات التالية مبيناً مدى أهمية كل عبارة حسب الآتي:
- مهمة للغاية - مهمة جداً- ً مهمة إلى حد ما- محايد - ليست مهمة إطلاقاً

IN THE BLANK BELOW NAME EACH ONE OF THE RESPONSE OPTIONS

20	It is ______________________ for me: مهمة للغاية ________________________ أن :	Extremely Important مهمة جداً	Important مهمة إلى حد ما	Neither Important nor Unimportant	Not Very Important محايد	Not at all Important ليست مهمة إطلاقاً
20a	To see a specialist to manage my pain أرى طبيب متخصص لمساعدتي في تخفيف الألم	1	2	3	4	5
20b	To have assistance with bathing/dressing أحصل على مساعدة تعينني على الاستحمام واللبس	1	2	3	4	5
20c	To have help to move about more easily أحصل على مساعدة تعينني على الحركة (التنقل)	1	2	3	4	5
20d	To have help with my emotional problems أحصل على دعم معنوي لحل مشاكلي العاطفية	1	2	3	4	5
20e	To receive more information about my cancer treatment أحصل على معلومات أكثر بخصوص علاجي من مرض السرطان	1	2	3	4	5
20f	To receive religious counseling أحصل على إرشاد ديني	1	2	3	4	5
20g	To get help with transportation أحصل على مساعدة تعينني على التنقل إلى المستشفى	1	2	3	4	5
	{INSTRUCTION: IF NO SCHOOLAGE CHILDREN SKIP TO Q.24a}			{ تعليمات : إذا لم يوجد أطفال بالمدرسة انتقل إلى سؤال رقم 24 a }		
20h	To have help with childcare أحظى بمساعدة تعينني على رعاية أبنائي	1	2	3	4	5

THAT COMPLETES THIS SECTION. WOULD YOU LIKE TO TAKE A SHORT BREAK NOW?
INDICATE IF TAKING A BREAK: YES ☐ NO ☐

IF YES, TELL THE PARTICIPANT: Please tell me when you are ready to continue. (AT THE END OF THE BREAK INDICATE HOW LONG: ___ MINUTES). If you are comfortable we will continue.

بهذا نكون قد أكملنا هذا الجزء, هل تريد اخذ استراحة ؟
نعم ☐ لا ☐
إذا كانت الإجابة بـ(نعم)، فالرجاء إبلاغي متى ستكون (ستكونين) جاهزا (جاهزة) للاستمرار(عند نهاية الاستراحة حدد كم استغرقت:------------- دقائق)
أما إن كنت مرتاحا (مرتاحة)، فسوف نكمل

The next few items are about your financial situation related to your illness, over the past four weeks.
Please choose one of the following responses:

All of the Time; Most of the Time; Much of the Time; Some of the Time; None of the Time. If you prefer not to answer, just tell me.

لفقرات القليلة القادمة تهتم بالوضع المادي المتعلق بمرضك خلال الأسابيع الأربعة الماضية. الرجاء اختيار واحدة من الخيارات التالية والتي تصف حالتك على أكمل وجه:
في كل الوقت ، في غالب الوقت ، كثيراً من الوقت ، في بعض الوقت ، ولا في أي وقت، أفضل عدم الإجابة.أخبرني (أخبريني) في حال عدم رغبتك في الإجابة.

21 Over the past four weeks: خلال الأسابيع الأربعة الماضية		All of the Time كل الوقت	Most of the Time أغلب الوقت	Much of the Time كثيراً من الوقت	Some of the Time بعضاً من الوقت	None of the Time ولا في أي وقت	PTNA أفضل عدم الإجابة
21a	I have had difficulty paying my household bills عانيت من صعوبات في دفع الفواتير المنزلية	1	2	3	4	5	9
21b	My illness has been a financial hardship on my family يعتبر مرضي عبئا ماديا على أسرتي.	1	2	3	4	5	9
21c	My household income has significantly decreased because of my illness انخفض دخلي الأسري بشكل لافت نتيجة لمرضي.	1	2	3	4	5	9

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These next four questions are about where you prefer to be cared for as your illness progresses. People have different preferences for where they are cared for and who decides where they will be. Please choose one of the following responses which best describes how you feel:

Strongly Disagree; Disagree; Neither Disagree nor Agree; Agree; Strongly Agree

تهتم الأسئلة الأربعة التالية بمعرفة المكان الذي تفضل أن تتلقى فيه الرعاية فيما لو تقدم لديك المرض، يفضل بعض الناس المكوث في المنزل وان تتولى الأسرة العناية بهم، بينما يفضل آخرون أن يتم تنويمهم في المستشفى. الرجاء اختيار أفضل الخيارات والتي تشعر أنها مناسبة لك.
موافق بشدة، موافق،لا أستطيع التحديد ، غير موافق، غير موافق بشدة

22		Strongly Disagree غير موافق بشدة	Disagree غير موافق	Neither Agree nor Disagree لا أستطيع التحديد	Agree موافق	Strongly Agree موافق بشدة
22a	I prefer that my family take care of me at home, if I can no longer take care of myself أفضل أن تقوم أسرتي برعايتي في المنزل ، إذا لم أعد قادرا على الاعتناء بنفسي	1	2	3	4	5
22b	I prefer to be in the hospital, if I can no longer take care of myself أفضل أن أكون في المستشفى عندما لا أستطيع الاعتناء بنفسي	1	2	3	4	5
22c	I have concerns about my family's ability to take care of me لدي بعض القلق بخصوص قدرة عائلتي بالاهتمام بي	1	2	3	4	5
22d	I prefer my family decide where I will be cared for, if I can no longer take care of myself أترك لأسرتي أن تقرر أين سيتم الاعتناء بي ، إذا لم أعد قادرا على الاعتناء بنفسي	1	2	3	4	5

The next questions are about any illnesses other than cancer you may have had.

الأسئلة التالية تتعلق بالأمراض الأخرى غير مرض السرطان التي يمكن أن تكون قد أصبت بها:

23 For which of the following illnesses have you ever received treatment?
أي من الأمراض التالية قد أخذت علاجاً لها

High Blood Pressure	ارتفاع ضغط الدم	1
Heart disease	أمراض القلب	2
Diabetes	أمراض السكر	3
Kidney disease	أمراض الكلي	4
Lung disease	أمراض الرئة	5
Any other illnesses	أمراض أخرى	6

IF ANSWERING " ANY OTHER" GO TO NEXT Q. TO SPECIFY WHICH ILLNESS(S): LIST IN SPACE(S) BELOW}

إذا اخترت أي الاجابات من 1-6 فانتقل (فانتقلي) إلى السؤال رقم*19*، أما إذا لم تكن قد أصبت (أصبتي) بمرض من الامراض الماضية ، حدد (حددي) ما هي الأمراض الاخرى في مكان الفراغ ادناه :

23a Which other serious illnesses have you had?
ما هي الأمراض الخطيرة الأخرى التي أصبت بها؟ ____________________

24 How many times have you been hospitalized for an illness other than cancer?
كم مرة دخلت المستشفى للعلاج من أمراض أخرى غير السرطان ؟

None	ولا مرة	1
One	مرة واحدة	2
Two	مرتان	3
Three	ثلاث مرات	4
More than Three	أكثر من ثلاث مرات	5

{IF NONE, SKIP TO Q. 28}

{ إذا كانت الإجابة بـ (ولا مرة) ، فانتقل إلى السؤال رقم 28}

25 How many of these hospitalizations were less than 6 months ago?
كم عدد المرات التي تطلبت التنويم في المستشفى خلال السنة الماضية

None	ولا مرة	1
One	مرة واحدة	2
Two	مرتان	3
Three	ثلاث مرات	4
More than Three	أكثر من ثلاث مرات	5

26 Which type of treatment have you received for your cancer?
Prompt: If you have had more than one type of treatment, please tell me which ones.
ما نوع العلاج الذي تلقيته لمرض السرطان؟
الحث: إذا تلقيت أكثر من نوع من العلاج, فالرجاء أن تخبرني ما هي تلك الأنواع

Chemotherapy	العلاج الكيميائي	Y	N	نعم	لا
Radiation Therapy	العلاج الاشعاعي	Y	N	نعم	لا
Surgery	الجراحة	Y	N	نعم	لا
Hormonal Therapy	العلاج الهرموني	Y	N	نعم	لا
Don't Know	غير متأكد	Y	N	نعم	لا

27 Have you received any tribal or traditional remedies for your cancer?
Prompt: for example herbal medicines or cautery
هل سبق لك أن استعملت أي وصفات شعبية أو تقليدية لعلاج السرطان؟
حث:مثلاً أعشاب، أو كي

Y	نعم
N	لا

IF ANSWERING NO, SKIP TO Q.28 . IF ANSWERING "YES", ASK PARTICIPANT TO SPECIFY WHICH REMEDIES(S). LIST IN SPACE BELOW

إذا كانت الاستجابة بـ (لا) انتقل إلى السؤال رقم*28* ، أما إذا كانت الاجابة بـ (نعم) فاسأل المريض (المريضة) أن يحدد ما هي تلك الوصفات، ودونها في الفراغ أدناه

27a Tell me which remedies have you tried?
ما هي أنواع الوصفات الأخرى التي سبق وأن جربتَها؟ ____________________

People with serious illness get different types of support from various friends, family, or other sources. I now have some questions about any support you may have from different people away from the hospital.

يحصل المصابون بأمراض خطيرة على أنواع مختلفة من الدعم ومن مصادر مختلفة, كالأسرة والأصدقاء وغيرهم. سأطرح عليك الأن بعض الأسئلة بخصوص الدعم الذي ربما تتلقاه من أفراد مختلفين خارج نطاق المستشفى.

28	How many female relatives can you rely on to help you while you are ill? كم عدد قريباتك اللاتي بإمكانك الاعتماد عليهن لمساعدتك أثناء مرضك؟	None	ولا واحد	1
		One	واحد	2
		Two	اثنان / اثنتان	3
		More than Two	أكثر من اثنين / اثنتين	4
29	How many maids do you have at home? كم عدد الخادمات اللاتي يعملن في بيتك؟	None	ولا واحد	1
		One	واحد	2
		Two	اثنان	3
		More than Two	أكثر من اثنين	4
30	How many drivers do you have? Prompt: such as male relatives or employed drivers. كم سائقا لديك؟ الحث: سواء أقربائك من الرجال أو السائقين الخاصين بك	None	ولا واحد	1
		One	واحد	2
		Two	اثنان	3
		More than Two	أكثر من اثنين	4

Now just a few questions to help us understand more about you as a person and the support needs you may have.

الان سنلقي بعض الأسئلة لتساعدنا أكثر في فهمك كشخص وتحديد الرعاية والدعم اللازمين لك

31	What is your highest level of education? ما هو أعلى مستوى تعليمي حصلت عليه؟	No formal schooling	غير متعلم	1
		Primary school	تعليم ابتدائي	2
		Elementary School	تعليم متوسط	3
		High school	تعليم ثانوي	4
		College Graduate	تعليم جامعي	5
		Post Graduate	دراسات عليا	6
32	What is your current employment status? ما هو الوضع الوظيفي الخاص بك حاليا ؟	Currently self-employed	عمل خاص	1
		Currently government employee	موظف حكومي	2
		Currently employed by private sector	موظف في القطاع الخاص	3
		Unable to work due to illness	لا يعمل نتيجة المرض	4
		Retired	متقاعد	5
		Never worked	لم أعمل مطلقا	6
33	What is your average monthly household income? **Prompt:** If you don't know, or if you prefer not to answer, that is fine ما هو متوسط دخلك الشهري الحث: إذا كنت لا تعلم أو تفضل عدم الإجابة فلا بأس في ذلك.	Less than 2,000 Riyals	اقل من 2000 ريال	1
		2,000 – 4,999 Riyals	من 2000 – 4999 ريال	2
		5,000 to 10,000 Riyals	من 5000 – 10000 ريال	3
		More than 10,000 Riyals	أكثر من 10000 ريال	4
		Not sure	غير متأكد	5
		Prefer not to answer	أفضل عدم الإجابة	6

Participant ID # ________

These last few questions are about your thoughts on taking this survey. Please choose the response which best suits you.

هذه الأسئلة الأخيرة تتعلق بأفكارك خلال إجابتك على الأسئلة, فالرجاء اختيار أفضلها

34	Overall, was answering these questions: بشكل عام، كيف كانت الأسئلة في هذا الاستبيان ؟	Extremely difficult	صعبة جداً	1
		Somewhat difficult	صعبة إلى حد ما	2
		Neither difficult nor easy	لا أستطيع التحديد	3
		Fairly easy	سهلة إلى حد ما	4
		Extremely easy	سهلة للغاية	5
				6
35	Did you find the instructions I gave you easy to understand? هل تجد الارشادات التي اعطيتك ايها سهلة الفهم؟	Y	نعم	
		N	لا	
36	Are there any other issues related to your health care and support needs you feel we have missed out of this questionnaire? **هل هناك أي موضوعات اخري تخص رعايتك والدعم الصحي تشعر بأننا لم نذكرها في هذا الاستبيان؟**	Y	نعم	
		N	لا	

IF "YES", ASK RESPONDENT TO TELL YOU THE MOST IMPORTANT ISSUES

إذا كانت الاجابة بـ " نعم " فاسأل المريض أن يخبرك عن أهم الأشياء لديه

37 Please tell me which issues related to your needs, that you think should be included in this questionnaire.

Prompt: There are no right or wrong answers – feel free to say which other issues YOU think should be included.

الرجاء أن تخبرني ما هي الأشياء المتعلقة باحتياجاتك وتعتقد بأنه يجب إضافتها إلى هذا الاستبيان.

الحث : ليس هناك إجابات صحيحة أو خاطئة – فاشعر بالحرية في إطلاعي على تلك الأشياء التي يجب أن تضاف.

____

____

____

38	Would you be willing to take this same survey again in one to two week's time? **Prompt**: To help us develop and improve this new questionnaire هل أنت مستعد أن تملئ هذا الاستبيان مرة أخرى؟ حث: في أسبوع إلى أسبوعين لمساعدتنا في تطوير وتحسين هذا الاستبيان	Y	نعم
		N	لا

FINISH TIME: ___________

وقت الانتهاء: ______________

THAT WAS THE LAST QUESTION.

كان هذا السؤال الأخير.

ON BEHALF OF THE ONCOLOGY DEPARTMENT AT KING ABDULAZIZ MEDICAL CITY,
THANK YOU VERY MUCH FOR PARTICIPATING IN THIS SURVEY.

بالنيابة عن قسم الأورام بمدينة الملك عبد العزيز الطبية ،
نشكرك لمشاركتك في هذا الاستبيان.

KAIMRC Protocol # RC08/033
UAB Protocol #: XO81024009