UNIVERSITY OF SOUTHAMPTON

FACULTY OF HEALTH SCIENCES

Assessing variation in quality of care in ambulatory chemotherapy units: a feasibility study to develop and implement nurse-sensitive outcome indicators in the Kingdom of Saudi Arabia

by

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ABSTRACT

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ASSESSING VARIATION IN QUALITY OF CARE IN AMBULATORY CHEMOTHERAPY UNITS: A FEASIBILITY STUDY TO DEVELOP AND IMPLEMENT NURSE-SENSITIVE OUTCOME INDICATORS IN THE KINGDOM OF SAUDI ARABIA

By Dena Marwan A. Attallah

Background: The quality of patient care is a universal concern among healthcare managers, policymakers and consumers. In order to benchmark and improve patient outcomes and demonstrate the impact of high-quality care provided by ambulatory chemotherapy services (ACSs), it is important to develop patient-reported nurse-sensitive indicators, specific to chemotherapy-related symptoms and experiences of supportive care. This study builds on previous work by Armes et al. (2014) who developed the Patient-Reported Chemotherapy Indicators of Symptoms and Experience (PR-CISE).

Aims: This study aims to explore a range of methodological and feasibility issues that relate to the development and implementation of Nurse-Sensitive Outcome indicators (NSOIs) and associated tools in the Kingdom of Saudi Arabia (KSA). It also aims to establish whether variability exists in Nurse-sensitive Outcomes (NSOs) amongst ambulatory chemotherapy units in the KSA.

Methods: This study employed a descriptive, cross-sectional survey with two preparation stages. In Stage I, instrument items were developed. Two rounds of cognitive interviews were conducted with 10 patients to ensure the clarity, comprehensiveness and appropriateness of the proposed questionnaire (a translated Arabic version of the PR-CISE tool). In Stage II, the feasibility of delivering the protocol was evaluated and the questionnaire piloted with 30 cancer patients undergoing chemotherapy in a single centre. Moreover, a data collection tool that describes the characteristics of chemotherapy units and provides contextual data (on unit size, staffing, etc.) were tested. Finally, a small-scale survey was implemented. Survey data were collected from five ACSs located in the two largest regions in the KSA, using the last version of the questionnaire and the aforementioned tool developed for this study.

Results: The cross-sectional survey confirmed that survey processes were efficient. The Arabic PR-SICE questionnaire was acceptable and may be used to generate evidence about NSOs in ACSs in the KSA and inform future policy and practice. A total of 748 completed questionnaires were returned and the response rate was 93%. Significant differences were observed in the distribution of the severity of symptoms between ACSs in six out of seven studied symptoms. A large-scale survey of NSOs is feasible, acceptable and recommended, and can be largely implemented as planned.

List of Contents

List of Tables

List of Figures

List of Charts

List of Boxes

Declaration of Authorship

I, Dena Marwan A. Attallah declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

Assessing variation in quality of care in ambulatory chemotherapy units: a feasibility study to develop and implement nurse-sensitive outcome indicators in the Kingdom of Saudi Arabia

I confirm that:

This work was done wholly or mainly while in candidature for a research degree at this University;

Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;

Where I have consulted the published work of others, this is always clearly attributed;

Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;

I have acknowledged all main sources of help;

Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;

None of this work has been published before submission.

Signed:.....

Date: 25.12.2017

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This doctoral study is dedicated to my parents, sisters and brothers, who supported me throughout this long journey. They were always with me during my difficult times and encouraged me for my studies. They always boosted me with positive energy and hope. Words like "You can do it", “You are strong and able", "all pain will be from the past...it's a matter of time.” mean so much to me. Without this constant support, I would have never completed this journey. My sincere thanks especially to my dad, who would have been so proud and who made my dream true. He will live forever in my heart.

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Abbreviations

AC	Acute care
ACSs	Ambulatory Chemotherapy Services: outpatient chemotherapy
CI	Cognitive interviewing
IoM	Institute of Medicine
ISPOR	International Society for Pharmacaeconomics and Outcome Research
KSA	Kingdom of Saudi Arabia
MeSH	Medical Subject Headings
NREM	Nursing Role Effectiveness Model
NSIs	Nurse-sensitive indicators
NSOs	Nurse-sensitive outcomes
NSOIs	Nurse-sensitive outcome indicators
NWUCS	Nursing Workforce and Unit Characteristics Survey
PR-CISE	Patient Reported- Chemotherapy Indicators of Symptoms and Experience
PROM	Patients reports of outcomes relating to chemotherapy-related symptoms (a patient-reported outcome measure)
PReP	Experience of supportive care (which refers to as a patient-reported process
QoC	Quality of Care
RN	Registered Nurse
TCA	Translation and Cultural Adaptation
UK	United Kingdom
US	United States
VRAs	Volunteer research assistants
WHO	The World Health Organisation

Chapter 1: Overview

1.1 Introduction

For the past five decades, quality of patient care has been a major concern for health care managers, policy makers and consumers all over the world (Chitpakdee et al. 2008). The central goal of health care quality improvement is to maintain the existing good elements of a health care system while focusing on areas that require improvement. Symptom management, safe medication administration, and patients' experiences of supportive care have been identified as indicators of the quality of health care provided to patients in general (Department of Health 2010). Moreover, Donabedian (2003) indicated that outcome assessments could be used to determine the effects of care on patients' health and wellbeing. Usually, outcomes involve a change in the health status of the individual; however, outcomes also can include changes in behaviour related to health, increased knowledge of health conditions, or patient and family satisfaction with the care received, and its outcomes (Donabedian 1988).

In recent years, there has been a trend for the majority of cancer patients to receive their chemotherapy in nurse-led Ambulatory Chemotherapy Services (ACSs), rather than as inpatients, and this trend extends to the Kingdom of Saudi Arabia (KSA). The cancer care community focuses on achieving high-quality outcomes for patients undergoing chemotherapy in ambulatory care services. There is little literature about nurse-sensitive outcomes (NSOs) (also known as nurse-sensitive patient outcomes) in ambulatory care settings, especially in ACSs. Therefore, this scarcity of information on the quality of ambulatory care services concerning NSO in these settings needs rectifying.

As an oncology nurse specialist working in ACSs in the KSA, I have observed there to be a lack of national guidelines that relate to cancer treatment care. The absence of national guidelines has led to each ACS employing local management strategies that affect how its systems work, which could, it is argued, lead to diversity in access, outcomes and other important indicators. Such variations can have a major impact on the quality of health care that

cancer patients receive. The nature and amount of variation in the KSA remains unknown with respect to unit size, nurses working hours, staff mix, shift pattern and chemotherapy regimens used.

In nurse-led settings, including ACS, nurses are both the primary care providers and take responsibility for the co-ordination and management of the essential elements of care. Since the work they undertake in these settings is central to the management of patients, the focus of my thesis was on nurses, who are required to make evidence-based decisions to ensure the safety and quality of patient care. Given their involvement in almost every aspect of patient care and because their level of interaction with patients is greater than that of other healthcare professionals in the same setting, it is essential to examine the impact of nurses' work on patient outcomes. The impact of different patient assessment practices, the process of chemotherapy administration and protocols for symptom management are felt by patients and will vary as a result of differences in nursing practice. Moreover, my experience working in the KSA as a nurse in ACS motivated my interest to study the extent to which differences in nurse deployment patterns explain variations in symptom severity.

To date, no published study has characterised variations in the quality of nursing care provided by nurse-led ACSs in the KSA. Such a dearth may be due to several issues. The first is the fact that assessing the quality of care (QoC) is a complex and challenging process. Secondly, there is no accessible data about the symptoms experienced by patients that can be attributed to their chemotherapy treatment, nor is data available about their experience of supportive care. Thirdly, there are no regular data records available for Saudi ACSs that pertain to nursing workforce and unit characteristics. Fourthly, there is a lack of a valid and reliable tool to assess the quality of nursing care in the KSA. The final issue concerns the fact that there is no comprehensive information available about how to collect and record the required data.

In order to confidently design a study to address whether variability exists in NSOs amongst ACSs in the KSA, it was necessary to develop a valid and reliable instrument. Following the development of a new instrument, or when applying a pre-existing instrument in a new setting and before deploying it in a large-scale investigation, it is prudent to precede with a small-scale study to assess

the feasibility of the chosen instrument. In addition, feasibility work can address the question of whether such a study could be carried out in the KSA and provide the basis for planning a larger multi-centre survey to produce evidence that could be generalised more widely to other ambulatory care services in the KSA.

This study, therefore, set out to explore the range of methodological and feasibility issues that relate to the development and implementation of NSOs' indicators and associated tools to characterise ACSs and the nursing workforce in ambulatory chemotherapy settings in the KSA. It sought to address these issues in order to determine whether it would be feasible to proceed to a definitive study designed to answer the question: Is there variation in nurse-sensitive outcomes amongst patients with cancer who are undergoing chemotherapy in ambulatory chemotherapy units in the Kingdom of Saudi Arabia?

1.2 Thesis layout and contents

This thesis consists of eight chapters. **Chapters 1 and 2** provide the introduction, rationale and background. **Chapter 3** provides a critical literature review as supporting evidence for the study. This consists of two parts. The first, a narrative review, addresses the gap in the literature about quality of care in ambulatory chemotherapy settings. The second part, a meta-review, focuses on the impact of nurses and their work environment on patient experiences and outcomes of care in acute care (AC).

Chapter 4 justifies the methodological choice from a philosophical perspective. Also, it looks at the reasons for choosing the research methodology. Finally, it closes by providing a summary of the study design, setting, and participants. **Chapter 5** presents the methods used in the development and evaluation of the PR-CISE and associated tools, (stage 1 of the study) as well as the findings from this stage of the research.

Chapter 6 focuses on the pilot testing stage (Stage II). It gives a detailed description of the methods applied in testing the procedures to monitor recruitment, recruitment rates and the acceptability of the data collection tools

and sets out the findings of this stage. **Chapter 7** presents the methods used for, and the results of, the implementation of the developed quality of care indicators (PR-CISE/Arabic questionnaire and associated tools) through a small-scale cross-sectional survey.

Finally, **Chapter 8** discusses the findings in light of existing evidence. It initially evaluates how the aims and objectives of the study have been met, its originality and the applied methodology used whilst executing the three stages of the study. Also, it provides an interpretation of various aspects of the findings. Lastly, it concludes the thesis and sets out the study limitations and recommendations for future study.

Chapter 2: Background

2.1 Introduction

This chapter provides a justification for the study and illustrates where the research fits in relation to existing health care literature. It also clarifies and explains the need for this study, the focus of the study and the context used to inform the fieldwork. This chapter is divided into two parts. Part one aims to provide a contextual background to the study in the KSA. Part two will explore and define key terms around this topic.

2.2 Cancer incidence, services and information systems in the KSA

The total population of the KSA reached 31,742,308 people in 2016 (General Authority For Statistics: Kingdom of Saudi Arabia website 2017). In the last decade, the KSA government has given high priority to health care services, which has improved services significantly, particularly with regard to access and quality (Almutairi & Moussa 2014). As evidence of this improvement, the KSA health care system is ranked 26th among 190 of the world's health systems, according to the last WHO ranking (WHO 2000). Despite this achievement, several challenges still face the health care system which require new strategies and policies (Almalki et al. 2011). This includes cancer care services, which are primarily managed by the Government through the Ministry of Health and a number of semi-government organisations, which specifically operate hospitals and medical services for their employees, and several private hospitals.

The latest figures released by the Cancer Incidence Report Saudi Arabia (2016) show that the total number of adult cancer patients reached 14,796 cases in December 2013 (Saudi Cancer Saudi Cancer Registry 2016). As the incidence of cancer is rising, the number of patients receiving chemotherapy has increased, resulting in the need to increase the capacity of ACSs, while still maintaining patient safety and QoC. Currently, 15 specialist ACSs are the total available in the governmental and semi-governmental sectors. These are limited to the

main cities, located in different geographic regions across KSA. While, the rest of the cancer patients receive their chemotherapy either in inpatient wards or at day care units.

In reality, ACSs in the Kingdom offer services to a large segment of cancer patients. In the absence of national guidelines for cancer treatment, each ambulatory chemotherapy unit employs local management strategies that affect how its systems work, which can lead to diversity in access, staffing, outcomes and other important indicators. Such variations can have major impacts on the level and quality of health care that cancer patients receive.

In recent years, many steps have been undertaken by the health care system and health care researchers to reform the cancer care system in the KSA with the goal of improving cancer services. The Saudi Cancer Registry is a governmental system responsible for the collection, maintenance, and dissemination of high-quality population-based cancer data (Al-Eid & Quindo 2014). However, this system relies on routine data sets that have been devised for purposes other than measuring health outcomes, like mortality and morbidity rate. The available data cannot be used to address variation in the QoC provided in ACSs or to provide data that could be used to identify useful measures to improve patient outcomes.

Universally, routine collection of data to establish quality is recognised as an important component of a quality health care system. In developed countries, such as the US and the UK, the deployment of NSO indicators have enabled researchers to document the variation in patient outcomes for patients undergoing chemotherapy in order to demonstrate or monitor the quality of nursing care. At present, there is no published national patient-centred PROM in the KSA specific to chemotherapy, particularly indicators of symptoms and experiences. Thus, efforts must be devoted to securing instruments that can be used to collect relevant data in the KSA. Hence, in a developing country such as the KSA, it is essential to adapt and apply a valid outcome measure in order to extract data on patient reported outcomes to inform the provision of high-quality care across the Kingdom.

To achieve the goal of this study, the UK PR-CISE indicators were adapted and applied in the KSA context to monitor the symptoms and experiences of

patients undergoing chemotherapy in the ACSs. Additionally, there was the intention to refine this instrument to collect data on patient outcomes and develop methods to collect contextual data about the nursing workforce and unit characteristics that may help to explain any variation. These instruments could be used at some point in the future to routinely assess and manage symptoms prior to each chemotherapy cycle and to establish the adequacy of supportive care and, thus, contribute to efforts to improve the QoC in KSA.

2.3 Factors that influence and explain the healthcare context in the KSA

The KSA is divided into 13 regions. While Islam is undoubtedly the main factor that shapes Saudi culture, each region has its own traditions and norms that could influence patient care. Therefore, the basic concept of dignified treatment is an acknowledgement of each person's intrinsic worth as a unique individual (Downing 1998 cited in Al-Shahri 2002). A consideration of the social and cultural norms currently prevailing in Saudi society enables an understanding of the impact of these cultural aspects on individuals' response to illness and on research. The following paragraphs examine the influence of cultural and religious factors on health behaviours and patients, as well as the possible impact of these factors on the research process and findings in the Saudi context.

The holy book of the Muslims, the Quran, clearly explains that there are no differences between men and women and that both sexes are equal and capable of reaping the benefits presented by society (Wehbe-Alamah 2008). However, the gender differences that prevail in KSA are influenced by traditional, cultural and social practices. In the KSA, gender differences are known to impact both consumers and health providers (Aldosari 2017) based on cultural justification. Gender issues constitute one of the primary challenges relating to the provision of healthcare in the KSA, which is typically guided by religious values and cultural customs (Mobaraki & Söderfeldt 2010). Gender differences in healthcare can be discussed in terms of three concepts: gender segregation, guardianship and the caregiver role. Gender segregation can be observed in the separation of gender in worship and some public places

(Aldosari 2017). In the majority of hospitals in the KSA, separate treatment settings are provided for men and women, primarily in relation to inpatient settings. In waiting areas, women should be accompanied by a male relative or segregated from males by a partition. There are a few exceptions to segregation: the case of life-threatening situations, such as emergencies, and treatments, such as dialysis and chemotherapy.

Concerning gender differences in the context of health professionals dealing with patients, one of the core values in Saudi culture concerns situations where care is provided by practitioners of the opposite sex. There is a need to maintain modesty during medical procedures and examinations; for example, male healthcare professionals should not attempt to examine or interview a female patient without a nurse or an adult relative in attendance (Al-Shahri 2002; Aldosari 2017). In other words, a nurse or relative of a female patient should be present when a male healthcare provider is examining her. In parallel, when female healthcare providers examine a male patient, it is mandatory to have a chaperone present and to keep the door open during the examination (Aldosari 2017).

One of the key aspects of gender roles and relationships in Saudi society concerns the guardian and caregiver. The guardian is a fundamental concept concerning both genders, but is of greater significance for women. The male guardianship system is one of the critical aspects of Saudi culture because every Saudi woman must have a male guardian—usually her father or husband, and in some cases, an uncle, brother or even son—who has the power to make a range of critical decisions on her behalf. As caregivers, marriage and motherhood are highly valued institutions for women (Mobaraki & Söderfeldt 2010), who tend to spend all their time focusing on the needs of their family members before their own health needs. As compared to men, the guardianship role for women is one where they are caretakers. Thus, the male guardian may find themselves obliged and frequently allowed by the patient to take decisions on their behalf as well as to step forward and take over some or all of the patient's responsibilities (Aljubran 2010).

Male guardianship presents both disadvantages and benefits for women. One of the problems is that women suffering from cancer can experience a delay in investigations and treatment. For example, there might be a delay in treatment for breast cancer patients because their husbands or male guardians might object to a breast examination. Alternatively, for some women, cancer may be a matter of shame, affecting their marriage prospects as well as those of their female relatives. One of the benefits of guardianship is that the male members of a family spend their time attending to the needs of their relatives.

The role of the caregiver in the traditional Saudi family structure needs to be considered in the healthcare delivery process. In the KSA, people strictly follow conventions and maintain strong emotional bonds between family members. The caregiver is usually a family member or a friend who looks after the patient during treatment. However, the caregiver's involvement can influence patients' perceptions and influence patient care. Grove et al. (2012) stated that caregivers—which include family members, friends and sometimes other patients—might influence a patient's response to a questionnaire survey or interviews. For example, family members may not consent to a patient's participation in a study because it has no direct benefit for the patient; this may influence whether the patient participates in the study. Moreover, in some cases, a patient's responses may depend on her or his need to meet the caregiver's expectations. For instance, a male patient may respond to a question about the severity of chemotherapy-related side effects differently from a female patient, in order to convey a sense of resilience.

The second possible factor that is common, but not specific, to Saudi culture involves disclosing the diagnosis or prognosis to cancer patients. In Saudi society, cancer has been, and still is in many situations, viewed as a death sentence. Revealing the diagnosis or prognosis to a patient is considered unpleasant and inhumane. For many decades, Saudis have believed that having healthcare practitioners not disclose bad news directly to patients might protect them from losing hope (Karim et al. 2015). Instead, family members or the caregivers act as bearers of bad news, especially if poor clinical outcomes are expected. In some cases, the family requests that the diagnosis and prognosis not be disclosed to the patient. Likewise, disclosure can be a

challenge to healthcare providers in their daily clinical practice, possibly affecting the type of information shared between the patient and healthcare provider. For example, serious problems can arise from not disclosing the side effects of chemotherapy to patients. Before starting treatment, sharing with patients whatever they need to know about their treatment options will ensure that they pay attention to the serious side effects; failure to do so may result in an earlier death than may otherwise occur.

As per the norms of Saudi culture, men are expected to be assertive, tough and focused on material success. In contrast, women are supposed to be more modest, tender and concerned with the quality of life. Therefore, with regard to female health, Aljubran (2010: p. 142) stated that family members and, to a lesser extent, friends 'believe that patients are very vulnerable and should not be left alone to handle the stress of knowing the bad news or the stress of making decisions'. The last five years have seen an improvement in the process involving the disclosure of diagnosis, prognosis or treatment to patients with cancer. Recent studies by Karim et al. (2015) and Al-Amri (2016) support the evidence that most patients from the KSA prefer to be informed about their diagnosis and prognosis, despite their families' protective requests to withhold information from them. However, some patients still prefer the traditional disclosure approach.

The third possible factor that influences the healthcare context is patients' responses to illness. Islamic teachings urge Muslims to be patient and endure suffering because it has a purpose known only to Allah (the Arabic name for God). Muslims believe in the Hidden Blessings of Illness and Hardship. Hardships and difficulty are a trial for them, and benefits and rewards are only meant for those patients who receive the Decree of Allah. However, suffering from cancer-related illnesses or undergoing cancer treatments could be viewed as a punishment or reward. In view of the more significant reward of the afterlife, some patients might feel uncomfortable seeking help when suffering from chemotherapy-related side effects as they believe it is their duty to endure their condition.

The fourth factor that could influence the healthcare context is traditional medicine, which is used in most countries in the Arab world. In some cases,

patients rely on a combination of modern and traditional medicine. Traditional medicine is used as a treatment strategy or preventive modality. Traditional Islamic medicine includes alternative methods (such as cupping, phlebotomy (bloodletting) and cauterising); herbal medicine; and dietary treatments involving honey, olive oil and garlic (Al-Shahri 2002). Traditional approaches can be harmful for cancer patients undergoing chemotherapy. For instance, in the case of patients with febrile neutropenia, phlebotomy would lead to complications that may delay or stop the progress of treatment.

The status of women in Saudi society

Earlier, women played a limited role in larger society, especially in the workplace which would require them to work in the same environment as men. Women's employment has been limited mainly to the traditional domains, such as education, service-oriented businesses and healthcare. However, the status of women in Saudi society has undergone much change over the past decade. In 2011, King Abdullah bin Abdulaziz expanded women's rights in society, allowing women candidates to run for seats in the consultative assembly and to vote in the local elections. Nowadays, women in Saudi society are highly motivated to improve their situation with the ongoing changes that are transforming the male dominion. However, for some women, there are still barriers to break through.

With these considerable changes taking place in Saudi society and the growth in women's education, the role of Saudi women has extended to enable them to contribute in earnest to the development of the medical sector. As a result, Saudi women have made pioneering contributions in healthcare research, enabling improvements in patient care, especially nursing care and research.

In sum, this section provides a summary of the cultural and religious factors that could influence the provision of healthcare as well as research conducted in the KSA. Saudi society is characterised by a unique mix of religion and culture, which may pose challenges in providing healthcare to residents. It could therefore be argued that there may be challenges to conducting a study which aims to collect information from patients about the chemotherapy-related side effects they experience and their evaluation of care provided.

Accordingly, the researcher understands the need to be careful when designing this study, especially given the complexities of interacting with participants of the opposite sex. Within this context, the following section briefly describes oncology-related nursing in the KSA.

2.4 Oncology nursing in the KSA

The most recent figures from the Health Statistical Book of the Ministry of Health in the KSA in 2011 showed that the total number of nurses was 77,946, while the number of Saudi nurses was 40,437 (51.9% of the total) (Ministry of Health in SA 2011). In KSA the nursing workforce primarily relies on the recruitment of expatriate nurses from American, Asian, Australian, Canadian and European countries (Aboul-Enein 2002; Luna 1998 and Tumulty 2001, cited by (Aldossary et al. 2008). Two issues emerge from these figures: The first concerns nurse shortages, as the ratio of nurses to patients of 49 nurses per 10,000 populations compares unfavourably with other nations such as Qatar (118/10,000), Japan (115/10,000), Canada (93/10,000), and the UK (88/10,000) (WHO 2015). It could be anticipated that such a shortage would have some kind of an impact on the safety and quality of nursing care in ACSs. Secondly, variances in culture should be considered. Social values and language differences between patients and nurses can create barriers between expatriate nurses and native chemotherapy patients (AlYami & Watson 2014). These barriers might influence the supportive care and other care provided by this group of nurses. It could be argued that these barriers should be considered when evaluating the supportive care provided by ACSs and represent factors that could lead to variance in patient outcomes and experiences of care.

Apart from the shortage of nurses, how the health system is organised influences how nurses can use their skills effectively. Cancer (oncology) nurses play a vital role in coordinating the multiple and complex technologies employed in cancer diagnosis and treatment. It must be said that, within the KSA, oncology nursing is a relatively new discipline. Accordingly, there is a possibility that nurses will face challenges related to a lack of knowledge about providing QoC, which could affect patients experience of symptoms and provided care.

Interestingly, some hospitals mandate that nurses working with cancer patients must have either a Bachelor's degree or a specialized qualification in cancer care (Attallah 2008). Landon (2008), cited in Kendall-Gallagher and Blegen (2009), has simply defined certification as "the validation of cognitive knowledge" (2009: p.108). For this, obtaining certification in a speciality area from an accrediting organisation could be one way for nurses to obtain external confirmation of a certain level of competence. This could help them to advance in delivering care and is associated with high QoC. So far, globally, there has been little agreement on the impact of nurse certification on the QoC provided in the ACSs, including the KSA.

King Faisal Specialist Hospital and Research Centre, Jeddah, took the lead in educational provision through offering the first Oncology Nursing Diploma for Saudi Oncology Nurses (2001) in the KSA. This course lasts for one academic year and covers the practical and theoretical approaches surrounding cancer care. The Diploma is aimed at improving the skills of current employees, raising the quality of health care and, it is hoped, improving patient outcomes and satisfaction. Elsewhere in the Kingdom, nurse qualification levels in the other ACSs remain unknown. This raises the question of whether specialist nurses influence the provision of QoC in terms of patient outcomes and experiences of care. Lack of evidence about the ACSs patterns in the KSA provides some justification for monitoring data that could be used to examine the relationship between nurse education and patient outcomes.

In addition, at a national level (in the KSA), information and support for patients have become key issues in long-term strategic plans to improve the care of cancer patients. As in most other countries, there are concerns that factors affecting the quality of nursing care provided in ACSs (which could influence chemotherapy patient outcomes and their experiences of supportive care) remain unknown. To date, there is no national data about the cancer nursing workforce that could be used to estimate the impact of structural workforce factors on quality. This lack of information provides some of the justification for this study. Therefore, this study will be unique in that part of its focus will be to examine the characteristics of the nursing workforce in

ACSs in the KSA, which might explain variations in patient outcomes, and experiences of supportive care delivery in the ACSs.

2.5 Role of an oncology nurse

There is evidence to demonstrate that variations exist in the role of oncology nurses across institutions and between disease groups (Griffiths et al. 2013). Rieger and Yarbro (2003) identified six dimensions of a nurse's role in cancer care, namely; patient assessment, direct patient care, symptom management, supportive care, patient education, and coordination of care. To date there is no published evidence about the role of oncology nurses in the KSA, which could be used to compare between nurses' work with other care systems. In order to address the quality of nursing care in ACSs, it is important to highlight the role of nurses in this context. The following discussion on the role of the oncology nurse focuses on patient assessment, symptom management, supportive care and patient education, because these roles are the crucial aspects of care delivery in ACSs that may influence experience and outcomes.

A nurse-led ACS is an outpatient clinic that is run or managed by nurses that are embedded in the clinical pathway for patients during their chemotherapy. In these settings, nurses have an important role to play in assessing and managing chemotherapy side effects prior to chemotherapy administration. The purpose of assessing a chemotherapy patient before each cycle of chemotherapy is to identify any side effects experienced at home between cycles, assess the patient's fitness to continue, implement any planned changes in the treatment pathway, and determine the need for intervention (Roe & Lennan 2014).

Compared to acute care (AC) settings, it is expected that nurses be skilled in assessing and managing patient's symptom experiences, psychological distress, functional outcomes (self-care ability, daily activities) and both the patient's and their family's knowledge of the disease and its treatment, as these aspects are fundamental to formulating a care plan. Roe and Lennan (2014) indicated that assessing and managing chemotherapy related symptoms needs skilled nurses to obtain information on what a patient is feeling, rather than relying on what their eyes tell them.

Ream et al. (2008) define supportive care needs as care requirements arising during illness and treatment to manage symptoms and side effects that enable adaptation and coping, to optimise understanding and informed decision making, and to minimise decrements in functioning. Pelzang et al. (2010) indicate that modern healthcare systems are shifting toward a more patient-centred approach that is organised around the patient's needs, values, and preferences. Moreover, individual patients vary in their supportive care needs, and nurses are closely involved with many supportive care issues (Rieger & Yarbro 2003).

It could be argued that oncology nurses can take a leadership role in supportive care, including before, during, and beyond the treatment journey, which could help patients and their families to cope during the more challenging times. The involvement of nurses in supportive care strategies and interventions can include assessment (early detection of the problem) and provide education to manage chemotherapy-related symptoms and psychological distress.

Psychological distress includes several emotional, social, cognitive, and functional issues. It has been demonstrated that psychological support is a vital part of supportive care for both the patient and their family. Moreover, emotional support is one important aspect of treatment, as most patients experience anxiety and low mood (Rustøen et al. 2003; Takahashi et al. 2008). Therefore, it is essential to have access to comprehensible information and support required for self-care management. Literature review shows that adequately informed patients report lower levels of anxiety and better quality of life (Husson et al. 2010). A study from Australia showed that nurses recognised the need for such support, but felt they did not have the time or skills to provide it (Wilkes et al. 1998). This could be explained by the study of Frost et al. (1997) who indicated that many researchers have argued that the lack of nurse training hinders the health of patients through a lack of emotional and social support.

During chemotherapy treatment patients play an important role in managing their own symptoms. Consequently, a patient needs to be informed about the possible side effects of their treatment not only for consent purposes, but in

order to manage them and understand when they should seek help. A key goal of the nurse is to support the patient in self-care management and to enhance their ability to perform self-care, including recognition of severity of symptoms, which may result in improved patient-reported outcomes. This would be through educating patients and their caregivers about their chemotherapy treatment towards the recognition, reduction, and prevention of chemotherapy side effects. This requires nurses to understand the possible side effects of each chemotherapy drug and the self-care activities that might recognise, prevent, and/or reduce their severity (Rieger & Yarbro 2003).

This section has provided a commentary on the role of nurses and their contribution to patient outcomes and experience in the context of chemotherapy, and interventions that may influence the provision of high-quality care. In addition, it highlights the lack of published evidence about the nursing care provided by ACSs in the KSA. This means there is a lack of information by which to evaluate and improve QoC. In other words, the lack of published studies supports the existence of a gap between what nurses could possibly deliver and what is actually delivered. This raises a vital question: what kind of variations exist in the supportive care provided by nurses in ACSs in the KSA? The following sections address the QoC definitions, dimensions, indicators, and the framework underpinning this study.

2.6 Definitions of quality of care

The literature abounds with numerous definitions of “quality”, which are useful in understanding what ‘quality of care’ is. A current well-cited definition of QoC comes from Lohr and Schroeder (1990), who determine it to be “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (1990: p. 707). This kind of broad definition is useful in general contexts, but it is not particularly valuable for specific quality assessments. This definition has been criticised by Berwick (2009) as being technocratic and resulting from a professional, rather than a consumer's, view of quality. Castle et al. (1996) supported this point by indicating that operationalizing ‘*quality’* from the US Institute of Medicine (IoM) definition could be problematic, as it is

extremely general and subjective and, as such, resulting measures tend to be unable to realise the quality concept fully.

At a more detailed level, Donabedian (1980) insisted that “quality is a property that medical care can have in varying degrees” (1980: p. 3). Also, to Runciman et al. (2007) quality reflects “the extent to which a health care service or product produces a desired outcome/s” (2007, p. 297). These definitions simulate individual dimensions or components. These contrasting definitions tend to reflect the concerns of various interest groups. In a similar manner, as a research framework, QoC has been defined by Brook and Lohr (1991) as the "component of the difference between efficacy and effectiveness that can be attributed to care providers, taking account of the environment in which they work."(1991: p. 2). With regard to Campbell et al. (2000), components of QoC were identified as a combination of access and effectiveness. Access refers to whether an individual can access the health structures and processes of care that they need, while effectiveness reflects the extent to which care delivers its intended outcome and results. Therefore, in an attempt to generate a better understanding of the concept ‘quality of health care’, the most frequently used dimensions will be examined in the following section.

2.7 Dimensions of quality of care

One possible way of making the concept clearer is to break it down into smaller constituent variables. The National Health Service (NHS) of England identifies five domains that define QoC: effectiveness, access, capacity, safety, and patient-centeredness (Leatherman & Sutherland 2008). In ‘Crossing the Quality Chasm’, the IoM (2001) proposed the perspective of six complementary and synergistic dimensions of healthcare considered to be essential in achieving high QoC. These were: effectiveness, safety, patient-centeredness, timeliness, efficiency, and equity.

These dimensions can act as a framework for QoC that can help researchers to grasp the meaning and relevance of quality measures. Each individual component provides a partial picture of quality if viewed on its own, while it can offer a comprehensive picture of QoC when viewed in combination

(Campbell et al. 2000). This means that each dimension of QoC should be pursued to facilitate improvements in health care services.

For this study, three dimensions were considered; safety, effectiveness, and patient-centeredness. These dimensions are operational, tangible components that represent the broad construct "quality of care" (Department of Health 2008). The following paragraphs addresses the three dimensions that pertain to patient outcomes.

Safety

As a dimension of quality, safety refers to minimizing the risks of infection, injury, harmful side effects, or other dangers related to service delivery. Safety involves both the patient and the provider. Safety for the patients and health providers can be secured if an organisation is well designed, and the clinical structure and processes are sufficiently standardized to reduce uncertainty (Houdart et al. 2003). In view of this, Creel et al. (2002) stated that an organisation needs to develop safety measures to protect both patients and health providers.

Safety is fundamental to cancer care. Griffiths et al. (2009) Illustrated that safety "referred to processes where a number of potential adverse events could result from failures in critical aspects of care but the specific events were not necessarily highlighted (e.g. safe medication administration implied or was linked to a number of outcomes including infection and extravasation)" (2009: P.9). In ACSs, the safety of chemotherapy administration is an essential component in the delivery of quality health care. For cancer patients undergoing chemotherapy, safety refers to safe chemotherapy administration (e.g. errors in administration, or cannulation) and reducing outcomes relating to chemotherapy symptoms (for example; pain in the site of cannulation, extravasation, anaphylaxis reaction and other side effects). In addition, safety, is about patient assessment and suitability to receive treatment as well as education about side effects.

The indicator in this domain (safety) seeks to measure patient outcomes resulting from chemotherapy administration. This study is about refining and adapting an available instrument with the capacity to measure outcomes and experience that measures the number of incidents resulting from these

outcomes. This process may establish whether variability exists in safety outcomes amongst ACSs in the KSA.

Effectiveness

Effectiveness means delivering health care that is adherent to an evidence base and results in improved health outcomes for patients and their community, based on need (WHO 2006). In short, effectiveness has been defined as having the desired effect of health care (Kelly et al. 2011). For Campbell et al. (2000), the quality of health care depends on the effectiveness of service delivery norms and clinical guidelines to produce the intended results. it is essential to recognise that effectiveness includes both effective interpersonal and clinical care. In chemotherapy care, for example, this entails using chemotherapy and symptom management protocols that are known to be effective, such as giving patients information about how to reduce or prevent the side effects of their treatment. Moreover, according to Brown et al. (2001), assessing the dimension of effectiveness answers the following questions: "Does the procedure or treatment, when correctly applied, lead to the desired results?", and "Is the recommended treatment the most technologically appropriate for the setting in which it is delivered?"

Patient-centeredness

Castro et al. (2016) defined patient-centeredness as "a biopsychosocial approach and attitude that aims to deliver care that is respectful, individualized and empowering, which implies the individual participation of the patient and is built on a relationship of mutual trust, sensitivity, empathy and shared knowledge." (2016: p. 1930). In other words, patient-centred care is healthcare that establishes a partnership between practitioners, patients, and families; to ensure that any decisions made respect the patient's wants, needs, and preferences; and that the patient has the education and support they need to make decisions and participate in their own care (IoM 2001).

Within the area of patient-centeredness, the (IoM 2001) report "Crossing the quality chasm: A new health system for the 21st century" endorsed six domains of patient-centred care. These cover: 1) coordination and integration of care; 2) emotional support-relieving fear and anxiety; 3) information, communication, and expressed needs; 4) involvement of family and friends; 5) physical

comfort; and 6) respect for patient's values, preferences, and expressed needs. Contemporary thoughts on patient-centred care are consistent with those stated by the IoM in 2001, which emphasise quality and safety in health care.

In contemporary nursing, patient-centred care refers to prioritising the patient and their experience through the process of 'communication, discussion of treatment options, potential outcomes and possible psychological effects' (Royal College of Nursing 2013). In cancer care, patient-centred care is argued to be a vital component in the delivery of quality health care (Zucca et al. 2014), and has the potential to enhance a chemotherapy patient's experience that would help them to manage chemotherapy-related symptoms and possibly reduce the severity of adverse outcomes. Chemotherapy nurses are an integral component of supportive care for patients undergoing chemotherapy. They interact on a daily basis with patients to provide support and information, using evidence to improve patient knowledge. Therefore, the principles of person-centeredness must be adopted in research that has as its centre the intention to understand the key relationship between nursing practice and the quality of patient care (McCormack 2003).

The Department of Health (2010) In England has identified these three domains as key aims for quality improvement and suggests that health systems that make gains in these areas will better meet patient needs. Accordingly, high-quality ACSs means excellence in the three key dimensions of quality. Therefore, to assess the QoC that patients receive in ACSs, safety, effectiveness and patient-centeredness are domains that could be used as indicators of the success (or otherwise) of nursing interventions. However, there remains a paucity of evidence about the quality improvement agenda in the KSA.

2.8 Framework for assessing quality of care

In order to investigate phenomena and relationships in a valid and reasonable way, a theoretical framework is required. Following a theoretical framework is significant in terms of increasing understanding of what such sets of indicators mean, together with those aspects of care that ought to be covered and which are, and are not, being covered. As has been noted, QoC is a multidimensional concept, therefore no single area of assessment can alone afford an accurate

indication of quality (Mainz 2003). Further, Donabedian (1987) elucidated that the more valid the item as an indicator of quality, the more confidence can be placed in the quality assessment. Therefore, it was necessary to find a framework that could link QoC to my area of interest. Existing literature contains examples of several conceptual frameworks, with different pathways linking nursing as a resource and nursing education and skill mix to patient or nurse outcomes [see (Aiken et al. 1997; Doran et al. 2002; Doran et al. 2006; Leiter & Laschinger 2006; Tourangeau et al. 2007)]. Indeed, the most widely used conceptual model is that of Donabedian.

In 1966 Donabedian evolved a valuable model for defining and assessing QoC based on measurement of three quality elements, namely, structures, processes and clinical outcomes (Donabedian 1988). The author defined structural measures as "the attributes of the settings in which care occurs", processes as "what is actually done in giving and receiving care" and outcomes as "the effects of care on the health status of patients and populations" (1988: p. 1745). These elements were not attributed to quality per se, but they represented areas of focus when assessing QoC (Donabedian 1992). The three elements are linked, in that "good structure increases the likelihood of good process, and a good process increases the likelihood of good outcome" (Donabedian 1988). Moreover, this framework covers several levels where quality can be assessed: the care provided by health care settings, the care provided by health care providers (including nurses, physicians, etc.), the care implemented by patients and the care provided by the community. Since 1988, Donabedian's is a fundamental framework that has pervaded the quality improvement process and which has been used in different care settings, including oncology care.

Subsequently, in 1998, Irvine et al. developed the Nursing Role Effectiveness Model (NREM) (Figure 2-1), which was designed to articulate the link between the input of nurses and patient care outcomes. It was based on the dimensions of Donabedian's classical model of high-quality care; structure, process, and outcome. The NREM communicates nursing related contributions in NSOs for quality assurance purposes. In addition, Doran and Pringle (2011) stated that the model is supported by empirical evidence and can be used as a guide to

examine the links among nursing structures, processes, and patient outcomes. Therefore, this model was selected to guide the current study because it addresses the variables of structure, process, and outcome related to how nursing care affects patient outcomes.

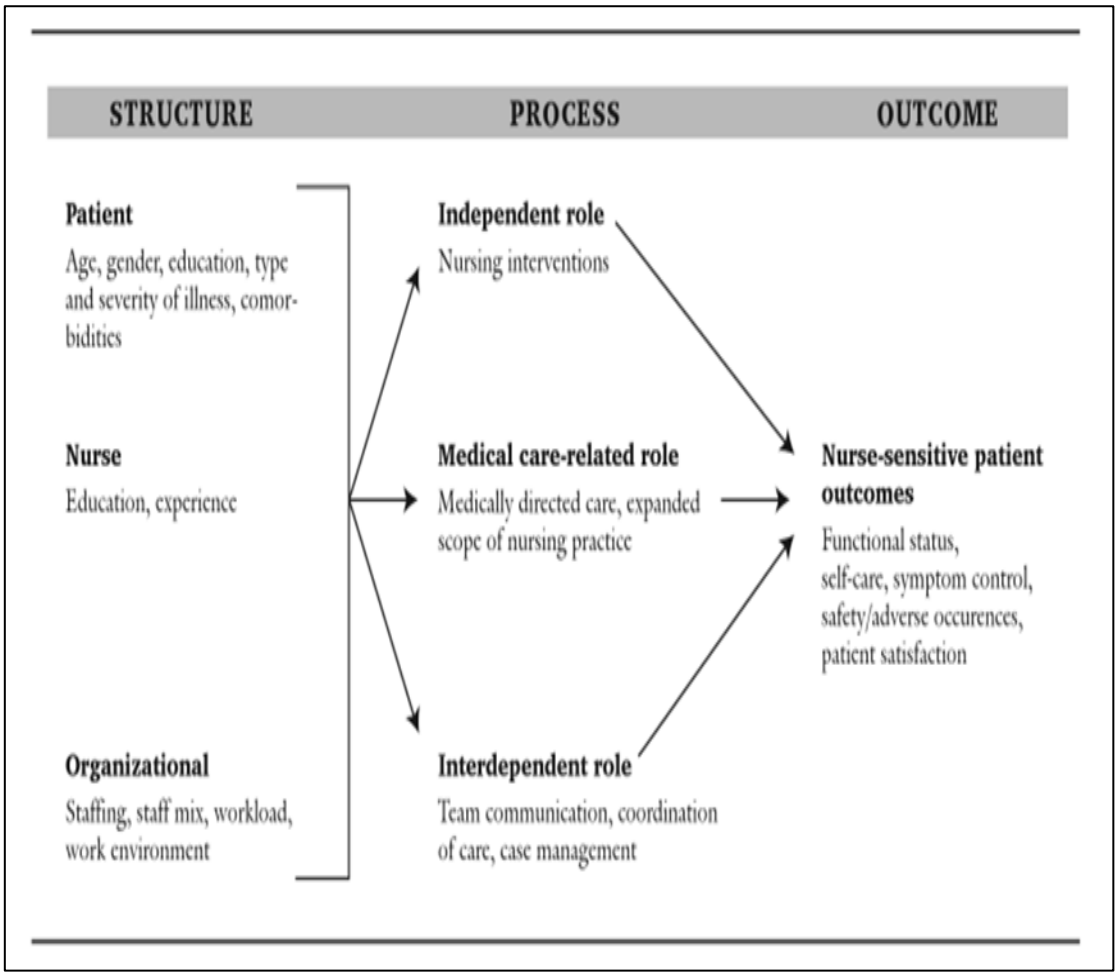


Figure 2-1 Nursing role effectiveness model. Source: (Doran & Pringle 2011)

Referring to NREM, the quality of health care can be measured by comparing the performance of an individual or a group of individuals with an ideal or benchmark. The next sections provide brief information about quality measures and indicators.

2.9 Measures versus quality indicators

Confusion persists about the difference between 'quality measures' and 'quality indicators', with these concepts often used interchangeably and

mistakenly. To Blegen (2006), measures could help to capture information on many aspects of quality, including: safety, effectiveness, and patient experience. While, "indicators serve to foster understanding of a system and how it can be improved, and to monitor performance against agreed standards or benchmarks" (Griffiths et al. 2008). Quality indicators usually develop to provide health care decision makers with tools to assess their data.

2.10 Classification of quality of care indicators

Quality indicators are essential to measure performance, benchmark, examine variations in care, allocate resources, and inform policy makers. Simply, quality indicators can indicate either problems or good quality in relevant care domains: safety, effectiveness, and patient-centeredness (Campbell et al. 2003). Importantly, indicators offer a mechanism through which care providers can take responsibility for the quality of their nursing services (Griffiths et al. 2008). Moreover, Mainz (2003) indicated that indicators of quality are not direct or definitive measures of quality. Rather, as their name suggests they indicate areas of care requiring greater scrutiny. Furthermore, quality indicators express quality at an aggregated level, usually the level of a health care service, or an institution, a region or a full country. For example, when an organisation assesses patient outcomes of a specific setting, professionals can use the results for internal quality improvements.

2.10.1 Structural indicators

Structure of care has been defined by the American Agency for Healthcare Research and Quality (AHRQ) as a "feature of a health care organisation or clinical related to the capacity to provide high quality health care". The structural indicators include patients, health care professionals, and organizational variables, all of which have an impact on the process and outcomes of care (Doran 2011). Referring to Doran's model (2006), these indicators provide essential information about a health care provider's capacity and organisational factors. Nurse variables focus mainly on qualification and experience, while organisational variables include the nursing work environment, staffing, skill mix, nursing assignment of patients, all of which can directly affect the delivery of nursing care. The use of structural indicators

is the support approach to monitoring and reporting of the quality of nursing care. In fact, structural measures have effects on the quality of nursing care. However, it is often influenced by the process of care and, thus, it is difficult to interpret its impact on the QoC (Donabedian 2005). This could support the need for a model that examines both structural and process components.

2.10.2 Process indicators

The process of care has been defined by the AHRQ as "a health care-related activity performed for, on behalf of, or by a patient" (AHRQ). Process measures are usually linked to treatments or procedures, which are known to improve health status or prevent future complications or health conditions (Cromwell et al. 2011). Process of care indicators measure the amount and type of care, including whether a specific intervention was provided to a patient and whether the care was based on evidence.

In NREM, the process component has been divided into three roles: nurses' independent, medical care-related, and interdependent roles. The author indicated that the independent role concerns activities and functions initiated by professional nurses. While, the medical care-related role concerns activities and functions initiated by nurses in response to medical order. Finally, the interdependent role concerns activities and functions in which nurses engage that are shared by other members of the healthcare team (Doran & Pringle 2011).

In ACSs, process of care indicators can be aligned with two components: the independent role and interdependent role. It could be argued that a patient's experience of nursing support can be assessed by asking whether chemotherapy-related side effects and severity were evaluated by nurses and whether they were educated on how to manage their symptoms via patient-reported measures. This can constitute an important step in gaining an understanding of the nurse's contribution to patient care in such settings.

2.10.3 Outcome indicators

Historically, until the 1990s, administrative databases held little available information about health outcomes that reflected the fundamental goals and levels of quality of nursing care (Doran et al. 2006). Nurse Sensitive Outcomes

(NSOs) have been characterised as those that are 'relevant, based on nurses' scope and domain of practice, and for which there is empirical evidence linking nursing inputs and interventions to the outcome' (Doran 2003: P. vii cited In Doran et al. 2006). Whereas, nursing-sensitive indicators (NSIs) are the data elements that are collected and analysed to identify nurse-sensitive outcomes (Doran & Pringle 2011). NSIs identify configurations related to care and care processes, both of which in turn influence patient outcomes, either directly or indirectly.

Referring to Donabedian's (1966) NREM framework for factors that influence patient care quality, NSIs are identified for the structure, process and outcomes of nursing care (Doran & Pringle 2011), nurse-sensitive patient outcomes are those that improve with more or higher-quality nursing care (NDNQI 2010). Several nursing reviews have helped to define the most common symptoms associated with chemotherapy, such as nausea and vomiting and fatigue, for example, (Griffiths et al. 2009; Griffiths et al. 2012; Wagland et al. 2015).

Oncology nurse researchers have contributed considerably to defining these outcomes and have developed tools to measure occurrence, distress, and individual experiences related to these symptoms (Rieger & Yarbro 2003; Armes et al. 2014).

Moreover, it could be argued that assessing patient experience through patient-reported measures is significant, as it may help to avoid misunderstanding and confused expectations around QoC. Additionally, this creates a global language of patient assessment.

2.10.4 Patient experience

Clinical outcome measures alone may not be able to include all relevant benefits, harms and characteristics of chemotherapy to the patient. Universally, researchers highlighted a need to gain more insight into the patients' perspectives and experiences during disease journey and treatment, to obtain information about the delivery and quality of care (WHO 2000; Kimman et al. 2017). To Jenkinson et al. (2002) patient experience is a reflection of what actually happened during the care process and therefore provide information

about the performance of healthcare workers. In other words, patient experiences refer to the way the patient evaluates health care outcomes, either in general or related to a specific treatment (Ahmed et al. 2014); which reflect the process of care provision (Suhonen et al. 2012).

2.10.5 Process versus outcome measures

In fact, no single type of quality measure can assess the QoC that is provided in ACSs. Rather, each type of quality measure addresses a key component of care. Generally, either processes or outcome indicators would be valid measures of quality of nursing care delivered in ACSs. The literature highlights that there has been considerable debate about whether process or outcome must be assessed as measures of the QoC (Brook et al. 1986; Davies & Crombie 1995). Process indicators focus on the way the service is delivered and outcome indicators focus on the result of care activity.

For Campbell et al. (2000), if the purpose of measurement is to influence the behaviour of the health care system, process measures are better indicators of QoC than other indicators, as they are a common measurement, under the control of health professionals and may more rapidly be altered. Furthermore, process measures have the ability to explore the manner in which the nurses interact with the patient; they are a measure of nurse skill. For a process to be a valid measure of quality, it must be closely related to an outcome that people care about. Also, there must be evidence that changes in the process result in improvements in patients' outcomes. Thus, it could be argued that process measures evaluate whether appropriate actions were taken and how well these actions were performed. Therefore, assessing patient outcomes, particularly patient experience of supportive care, will provide data about the nursing care process in ACSs. Patient outcomes, on the other hand, are widely accepted as being direct indicators of the quality of health care (Kane et al. 2007b). Likewise, for an outcome to be a valid measure of quality of nursing care, it should be closely related to processes of care that can be manipulated to affect the outcome.

In short, measures of quality in health care are generally accepted as those indicators representing structure, process, and/or outcomes (Doran 2011), they should all be included in questionnaires and interview protocols on

patient outcomes and experiences. Therefore, measures that reflect communications, collaboration, documentation, and teamwork may be important. A summary of types of quality measures is presented in Table 2-1.

In examining Donabedian's structure, process, and outcomes model in relation to the QoC provided by ambulatory chemotherapy settings, the expected health status outcomes for patients are chemotherapy-related symptoms (such as nausea and vomiting and oral mucositis), which cannot be linked directly to nurses' work. However, it could be argued that patient-centred care is an important component in the delivery of quality health and cancer care (Zucca et al. 2014), because nurses have control over the processes involved in nursing care delivery. In other words, it is clear that patient outcomes reflect the nursing contribution in terms of the support patients receive to manage chemotherapy related symptoms (which is known as self-care) and the quality of the administration process, which has an impact on safety and patient experience. Thus, more attention should be paid to the actual situation of care provided in ambulatory chemotherapy settings.

Table 2-1Summary of different types of quality measures

Type Quality measure	Indicators	Description	Example	Strength and limitations
Structure	Patient, nurse and organisational characteristics	Evaluate the infrastructure of health care settings; including the characteristics of a patient, nurse, and care setting; and whether those health care services can deliver care.	How many nursing shifts per day cover the unit?	Structure measures may be relatively straightforward to collect and interpret. While structure measures provide essential information about health care provider's capacity, these measures provide just one piece of the full picture of care.
Process	. Independent role . Medical care-related role . Interdependent role	Determine if the services provided to patients are consistent with routine clinical care. A process of care is a health care-related activity performed for, on behalf of, or by a patient.	Does a nurse document patients' side effects of chemotherapy resulting from the previous cycle? Do patients report that the nurse educates them about chemotherapy side effects?	Process measures are more sensitive to differences in quality of care and are direct measures of quality
Outcomes	- Nurse-sensitive patient outcomes And - Patient experience	Evaluating patient health as a result of the care received. Provides feedback on patients' experience of care. Experience of care is a patient's report of observations of, and participation in, health care, or assessment of any resulting change in their health.	What are the most reported symptoms by patient?	Measuring outcomes often requires detailed information, which some time is not available in the medical records, and this information is difficult and expensive to obtain.

2.11 Defining variation

Concerns about quality and variation cannot be separated because knowledge of variation is one of the foundations involved in improving quality. The term "variation" has been defined by the Oxford Advanced Learner's Dictionary as "a change or slight difference in condition, amount, or level, typically within certain limits" (Hornby 2015: p. 778). This definition expresses the natural condition of things to be different from each other or to depart from a pre-established target. In the context of QoC, variation in QoC is expected. Variability in care processes or outcomes is often taken as an indication of the need for quality improvement efforts (Selby et al. 2010). Therefore, understanding the differences in patient experience can help inform the priorities for improvement action and policies (Saunders et al. 2014).

In order for "variation" to exist, there must be at least two entities, for instance, individual patients or groups, nurse groups, health plans, or organisations being compared to each other or to a target. It is possible that differences in QoC are possibly based on justifiable causes, such as differences in patient characteristics or diagnoses and treatments, or through unjustifiable causes. Thus, to assess variation in patient outcomes, it is vital to investigate what factors cause this variation. As recommended by Armes et al. (2014), there is a gap in understanding about managing variation in ways that enable the delivery of high-quality care consistently over time and across patients. Therefore, refining the Patient Reported- Chemotherapy Indicators of Symptoms and Experience (PR-CISE) is required in tandem with work to develop standardised descriptors of workforce and unit characteristics, which will be the focus of the study.

2.12 Key terms for measuring quality

In literature, there were muddled about the definition of terms, such as domain, indicator, and measure, and measure, and were often not explicitly defined. Table 2-2 provides some definitions of the principal terms used in this study.

Table 2-2 Key terms for measuring quality

Term	Definition
Indicator	A summary measure that aims to describe in a few numbers as much detail as possible about a system, to help understand, compare, predict, improve, and innovate.
Metrics	Any set of data. An indicator is a particular sort of metric that identifies issues that may be worthy of further investigation
Outcome	A measurable change in health status, sometimes attributable to a risk factor or an earlier intervention
Patient experience	Is a quality indicator that can reflect what actually happened during the care process and therefore provide information about the performance of healthcare workers; it refers to the process of care provision.
Quality measure	A mechanism to assign a quantity to quality of care, by comparison to a criterion. The process of using data to evaluate the performance of health plans and health care providers against recognised quality standards.
Scales of measurement	A way to measure variables are defined and categorised within the context of a research study.
Patient-reported outcome measure	An indicator that provide an invaluable source of evidence for change in a patient's health status, knowledge or behaviour from the patient's point of view.
Nurse-sensitive indicators	'The data elements that are collected and analysed to identify nurse-sensitive outcomes' that 'identified for the structure, process and outcomes of nursing care'
Nursing-sensitive indicators	Are those that are "relevant, based on nurses' scope and domain of practice, and for which there is empirical evidence linking nursing inputs and interventions to the outcome."

2.13 Summary

The central goal of health care quality improvement is to maintain what is good about an existing health care system, whilst focusing on areas influencing patient outcomes and experience that require improvement. In recent years, patient outcomes have been widely accepted as direct indicators of the quality of health care (Kane et al. 2007b), and increasingly advocated as a means to demonstrate the impact of high-quality care (Armes et al. 2014).

The following chapter is the literature review, which presents an account of how quality of care was studied in ambulatory chemotherapy setting as well as the impact of nurses and their work environment on patient outcomes in acute care.

Chapter 3: Literature Review

3.1 Introduction

This review was carried out to identify sources of evidence that assess variation in QoC in ambulatory chemotherapy settings, and to provide an overview of nurse-sensitive indicators (NSIs) relevant to this context. This chapter consists of two parts. The chapter begins by giving a detailed description of the QoC in ambulatory chemotherapy units. It then goes on to present a meta-review that is used to examine the link between nurse-sensitive outcomes, nurse staffing, and nurse work environments in ambulatory care contexts.

3.2 Quality of care in ambulatory oncology care: narrative review

3.2.1 Introduction

A narrative review is a non-systematic technique that aimed at identifying and summarising what has been previously published and seeking new study areas not yet addressed (Grant & Booth 2009). A narrative review of QoC indicators has been conducted to identify nurse-sensitive outcome indicators (NSOIs) relevant to ambulatory oncology care. Firstly, this part discusses how ambulatory chemotherapy care quality can be assessed based on the framework introduced in the previous chapter framework. Then research studies pertinent to ambulatory chemotherapy care quality assessment were reviewed.

3.2.2 Aims and objectives

The aim of the narrative review was to identify indicators potentially sensitive to nursing that could be used to assess QoC in ambulatory care and to integrate these indicators into the theoretical framework of Doran (2006).

This literature review intended to answer the following questions:

1. What nurse-sensitive outcome indicators have been used to assess the quality of nursing care in ambulatory chemotherapy settings?

2. What aspects of nursing have been studied in the context of QoC in ambulatory chemotherapy settings?
3. How do nurses and their work environment contribute to quality patient care in ambulatory chemotherapy settings?

3.2.3 Strategies for identification of reviews

The main sources for identifying literature in this review relied on electronic databases, including CINHAL, Medline, Ovid, PsycINFO, the Cochrane Library, Saudi Medical Journal, and search engines (i.e., Google Scholar). In addition, manual searches of journals, articles, and books were undertaken to gather all relevant reviews. The strategy for literature searching used medical headings, keywords and their combinations. Search terms were adjusted from a preliminary literature review to account for those listed in the thesaurus of the databases searched, and MeSH terms were used where possible.

The keywords used in the search to identify relevant publications were: nurse, nurses, nursing, quality, quality of health care, quality assessment, quality indicator, outcome assessment, nursing sensitive outcomes, nurses sensitive outcomes, nursing-sensitive outcomes, patient outcomes, evaluation, measurement, and research, ambulatory chemotherapy care, outcomes, and cancer care (see Table 3-1).

Limits were applied to peer reviewed journals and only English language articles were retrieved. I wanted to identify papers of recognised quality and therefore confined the search to material in peer-reviewed journals. Also, this made it practical too. An example of a database search is given in Appendix B

Table 3-1 Search strategy of the narrative review

Main search terms	Keywords	Database
Cancer	"cancer" or "cancer care" or	• CINHAL • MEDLINE (EBSCO) • PsycINFO • Cochrane Library • Web of Science • Saudi Medical Journal • Delph (01 Jan 2002 - 02 March 2015)
Chemotherapy	"chemotherapy" or neoplasms" were combined with	
Nursing	"staff" or "staffing" and "nurse" and "nurse staffing" or "nursing staff" or "personnel staffing and scheduling" or "nurse-to-patient ratio" or "nurse-patient ratio" or "nurse to patient ratio" or "nurse/patient ratio" or "staffing ratio" or "nurse ratio" or "staffing levels" or "skill mix" were combined with	
Nurse certification	"nurse education" or "nurse certification" or "RN" or "BSN" or "cancer nurse" or "oncology nurse" or "oncology certified nurse" or "clinic nurse specialist"	
Organisational	"organisation" or organisation" or "workload" or "work environment" or "workforce" or workflow" or "shift" or "shift work" or capacity" or "environment or design or layout" or "health facility environment" or "patient acuity" or "bed occupancy" or "size" or patient volume" or "organisational culture" were combined with	
Patient education	"patient education" or "patient teaching"	
Patient outcomes	"patients" and "outcomes" or "outcome" or "patient outcome" or "patient outcomes" or "complications" or "treatment outcomes" or "patient-reported outcomes" or "outcome assessment" or "nursing sensitive outcomes" or "nurses sensitive outcomes" or "nursing-sensitive outcomes" were combined with	
Quality	"quality" or "quality of health care" or "quality assessment" or "quality indicator" or "outcome assessment" or "nursing-sensitive outcomes" or "nurses sensitive outcomes" or "nursing-sensitive outcomes" or "patient outcomes" or "evaluation" or "measurement" were combined with	
Relationship	"Relationship" or "relationship between" or "associations" were combined with	
Scale	"scale" or "scales" or "survey" or "questionnaire" or "self report" or "self-report" or "patient self-report" or "indicators" or "indicators" or "quality assessment" or "clinical assessment tools" or "evaluation" or "measurement" were combined with	
Unit labels	"ambulatory" or "ambulatory care" or "outpatients" or "ambulatory setting" or "ambulatory chemotherapy setting" or "ambulatory chemotherapy unit".	

Key: Some of these terms were used in isolation, but many were combined.

3.2.4 History of evaluating quality of nursing care

The issue of evaluating quality in health care has received increasing attention in recent years, and various measures have been identified as indicators of health care quality (Institute of Medicine 2001).

The quality of nursing care in inpatient hospital services has been found to depend on certain contextual and intervening conditions relating to the organisation involved, its work environment and personal factors relating to patients and nurses (Irurita 1999; Aiken et al. 2008). The history of inpatient care suggest that patient information, environmental factors, and organisational factors, (such as the type of hospital, skill mix, nurse-patient relationship, nurses being there when needed, and finally nurse staffing) have been thought of as key factors inhibiting or enhancing the quality of nursing care (Mukumbang & Adejumo 2014). What is not yet clear is to what degree these findings can be applied to the context of ambulatory care as opposed to inpatient care settings.

Indeed, quality measurement in ambulatory care has been slow to develop, compared to the acute care (AC) and long-term care contexts. In cancer care, the field of QoC assessment is relatively new. To date, few comprehensive attempts have been made to assess the quality of cancer care services generally and ambulatory chemotherapy specifically. Additionally, little is known about the QoC provided by ambulatory chemotherapy services in the Kingdom of Saudi Arabia (KSA), particularly nurse-sensitive outcomes. A good starting point is to discuss possible indicators that might be used to assess QoC in the ambulatory setting.

3.2.5 Quality measures to assess quality of care in the ambulatory setting

Quality indicators are significant since they are used to examine variations in care, measure performance, benchmark, allocate resources, and inform policy makers. Assessing QoC or a quality improvement project requires consideration of what to measure and how to measure an indicator, so that real relationships can be revealed. It is often said,

> "If we can not measure it, we can not improve it" Lord Kelvin.

Noting the compelling nature of the three quality measures, it is clear that each one of these approaches to quality assessment has its own strengths and weaknesses. Consequently, the decision to select one or another indicator depends on the context of the assessment, the target of quality assessment, and the available evidence upon which a valid judgment of quality can be made. The next section highlights evidence for nurse-sensitive outcome indicators (NSOIs).

3.2.5.1 Patient outcome measures sensitive to nursing care

Outcome indicators evaluate the results of care. This type of indicator has been used as one of the three main approaches to quality assessment (Donabedian 1988; Doran et al. 2006). Therefore, measuring variation in patient outcomes is a significant first step when assessing the quality of health care performance.

Historically mortality and morbidity have been widely used as the primary outcome indicators of health status, because of the availability of information about the rates of disease and death. For ambulatory chemotherapy settings, a measure of mortality is rather distal and may not reflect the effects of nursing care in these settings but, rather, reflects the performance of multi-professional teams as a whole (Armes et al. 2014). In other words, measuring mortality may not reflect an important variation in patient outcomes and experiences of care, which may be particularly sensitive to the input of nursing contribution in ambulatory chemotherapy settings.

Similarly, patients' perspectives and expectations about care received have been broadly incorporated into quality assessment, including the oncology outpatient setting (Brédart et al. 2014). Patient satisfaction or experience instruments are commonly used to assess patients' perspectives on the QoC received (Brédart et al. 2014). In fact, patient satisfaction of care has been used extensively to assess QoC from the perspective of patients. In Doran's (2006) model, patient satisfaction was used as a NSOI of quality. While this measure can shed light on some aspects of health care quality, it may not provide adequate information about elements of the processes of the delivery of care

or explain the actual experience of care that led to a patient being satisfied or dissatisfied with care provided in these settings.

One of the unique features of ambulatory chemotherapy care is its focus on the administration of chemotherapy and the prevention or reduction of its side effects, which should be considered when attempting assessing QoC provided in these settings. For this reason, and as mentioned earlier in the previous chapter, the current study focuses on NSOs as indicators of QoC. In order to conduct this study, it was vital to identify NSOIs that had the ability to assess symptom severity, supportive care, and care delivery.

Monitoring chemotherapy-related symptoms has been identified specifically as an area in which patient self-reporting might; 1) improve the efficacy of clinical operations, 2) improve the quality and completeness of the collected data, and 3) provide a more comprehensive picture of the patient experience (Basch et al. 2007). The scoping review by Griffiths et al. (2011), which aimed to identify patient outcomes sensitive to the quality of nursing services in ACSs, reveals that nausea and vomiting, oral mucositis, patient experience, and safe medication administration were the outcomes most likely to be sensitive to nursing in ACSs. Nationally, and up to now, there is no standard scale for NSO in ACSs that allows researchers to collect data on chemotherapy-related symptoms, including the KSA. The next section identifies the patient outcomes measurement scales that could be applied in the ambulatory chemotherapy-nursing context.

3.2.5.2 Scales assessing outcomes sensitive to nursing care in ambulatory chemotherapy services

A review of the literature revealed three studies that aimed to develop chemotherapy-related symptom assessment scales (Brown et al. 2001; Dy et al. 2010; Armes et al. 2014) (see Table 3-2). The three scales include a variety of health status from both physiological and psychological aspects.

Table 3-2 Summary of chemotherapy-related symptoms assessment scales sensitive to nursing care

Assessment scale; year; country; authors; settings	Aim	Target population	Outcomes	No. of items; response format; Descriptions of the indicators	Method of administration; Frequency of collecting data	strengths & limitations
Chemotherapy Symptom Assessment Scale (C-SAS) 2001 UK (Brown et al. 2001) Outpatient settings	The scale developed for the routine assessment of symptoms experienced by patients receiving chemotherapy, which is hoped to result in improvements in patient experience and in the quality of care provided.	Patients with common cancer	A range of chemotherapy-related symptoms including: Nausea, vomiting, Diarrhoea, constipation, pain, hair loss, shortness of breath, signs of infection, bleeding or bruising, problem with (skin, mouth or throat, eyes), change in appetite, weight loss or gain, headaches, feeling (weak, unusually tired, anxious or worried, low or depressed), changes in intimate and sexual relationship, and for women changes in periods.	24-item scale The scale was in 3 parts: 1) Frequency of the symptoms, 2) Severity, 3) The degree of discomfort.	Patient-reported survey Before each treatment	- The indicator was developed with the involvement of both patients and health professionals. - The patient rather than the health professional completes it. - Some of the symptoms included in this indicator are not sensitive to the work provided by nurses in the ambulatory chemotherapy settings (not nurse-sensitive outcomes)

Cancer Quality-ASSIST Supportive Oncology Quality Indicator Set 2009 US (Dy et al. 2010) Both inpatient and outpatient settings	The scale developed with the intention to evaluate the quality of supportive oncology care, which could be used to determine a common robust quality indicators set for future comparative studies and quality monitoring efforts.	Patients with advanced cancer.	Symptoms commonly related to cancer and its treatment (pain, depression, dyspnea, nausea, vomiting, fatigue, anorexia, and other treatment-related toxicities) and information and care planning (process of care)	41 indicators. Abstraction tool developed.	Medical record data abstraction.	While this scale concerns chemotherapy-related symptoms it is not specific to nursing work could not be used to evaluate their performance.

Patient-reported chemotherapy indicators of symptoms and experience (PR-CISE) 2011/ UK (Armes et al. 2014) Ambulatory chemotherapy settings	The aim of this study was to develop and test an outcome measure (patient-reported chemotherapy indicators of symptoms and experience [PR-CISE]) that is sensitive to the quality of nursing care for use in ambulatory chemotherapy settings	Patients with all types of cancer (oncology, haematology and palliative care)	Symptoms & experiences of supportive care (prevention of side effects) including: Nausea, vomiting, IV-line pain and irritation, Mouth problems, weakness, signs of infection, tiredness, feeling low/depressed	22-item with 2 parts. Part 1) To report on the severity of a range of symptoms experienced since the last cycle of chemotherapy (PROM) Part 2) focuses on the experience of care provided by chemotherapy nurses as reported by patients (PreP)	Patient reported survey Part 1 to be completed with each chemotherapy cycle. Part 2 indicators designed to be completed only once during the course of chemotherapy.	- The PR-CISE indicator was feasible and acceptable to patients. - Feedback from the indicators found to be useful for the stakeholders in each centre. Most stakeholders planned to use the information to make to care delivery in these settings. - It was not clear if the variation between centres was related to differences in the quality of nursing care or other modifiable factors such as workforce characteristics and deployment. - Further research is required to refine the indicator.

Key: ASSIST = Assessing Symptoms Side Effects and Indicators of Supportive Treatment

C-SAS

C-SAS is an outcome indicator developed for the routine assessment of symptoms experienced by patients receiving cytotoxic chemotherapy for common cancers in outpatient settings (Brown et al. 2001). This instrument is designed to assess the prevalence and characteristics of symptoms and the degree to which they cause distress or impair health, and evaluate the efficacy of treatments given for symptom relief. The scale underwent limited psychometric evaluation during development process (Lipscomb et al. 2004). Further tests to establish validity and reliability were performed by (Aslan and Vural (2006) Cited in Mollaoğlu & Erdoğan 2014). The C-SAS indicator was judged to be not suitable for the current study. While the scale is valid and reliable as an assessment instrument to collect data about chemotherapy-related symptoms, the scope of items has extended beyond those that are NSO in ACSs.

ASSIST

The Cancer Quality Assessing Symptoms and Side Effects of Supportive Treatment (ASSIST) scale measures quality. ASSIST is a scale developed in the US to address symptoms and symptomatic complications, treatment-related toxicities, and the information and care planning needs for adults living with cancer (Dy et al. 2010). Data are drawn from medical records. ASSIST can be used to evaluate the quality of supportive and end-of-life care for patients with advanced cancer, practice-level performance, multi-disciplinary care, and to identify areas for quality improvement.

A panel of healthcare professionals and social workers including oncology, palliative care, geriatrics, primary care, and nursing has evaluated this scale. Moreover, the face validity of the ASSIST was checked by clinician experts via a rigorous process of systematic review and expert panel consensus, and evaluated for feasibility, validity, and reliability at two sites.

For several reasons, this indicator was not suitable for the current study. Although medical records are a significant data source, chemotherapy-related symptoms are subjective and patients are the best reporters of their own experience. Moreover, unlike indicators that rely on process-based measures such as health screening measures (for example X-ray or laboratory test

results, specifically in outpatient settings), symptom assessment relies on patient report. Also, ASSIST was created to collect data about multi-disciplinary care and is not specific to nursing care. Furthermore, like the C-SAS scale, ASSIST evaluates a small number of symptoms, which do not fully reflect the range of symptoms experienced by patients undergoing chemotherapy in outpatient settings likely to be nurse sensitive.

PR-CISE

In the UK, a collaborative group of researchers from the Southampton University Hospitals NHS Trust, University of Southampton, and King's College London have successfully developed and tested indicators that assess the QoC provided in ACSs, which they refer to as patient-reported chemotherapy indicators of symptoms and experience (PR-CISE) (Appendix A) (Griffiths et al. 2011; Armes et al. 2014). This measurement system focuses on patient reports of outcomes concerning chemotherapy-related symptoms (involving a patient reported outcome measure, or PROM) and experiences of supportive care (patient reported process, or PreP). The indicators involved cover three domains of quality: symptom management, safe medication administration, and experience of supportive care (Department of Health 2010).

PR-CISE involves a 22-item self-report questionnaire that uses a Likert response format (none, mild, moderate, severe) and consists of two parts. Part A asks about the severity of the range of symptoms experienced since the last cycle of chemotherapy, including nausea, vomiting, IV-line pain and irritation, mouth problems, weakness, signs of infection, as well as support for the self-management of symptoms, and is designed for repeated administration with each chemotherapy cycle. Part B focuses on the experience of care provided by chemotherapy nurses and is designed to be completed once during a course of chemotherapy (Griffiths et al. 2011).

The feasibility, acceptability and utility of the PR-CISE tool has been tested in 10 specialist and non-specialist NHS cancer centres across the UK. The research team have stressed the PR-CISE questionnaire's potential for benchmarking among ambulatory chemotherapy centres, and for improving quality. It also recommended that future research should include exploration

of the extent to which variations in symptom severity are explained by differences in unit characteristics and nurse deployment patterns.

3.2.5.3 Summary of evidence on outcome scales sensitive to nursing care

In order to evaluate the quality of nursing care in ACSs, it is essential to use a valid and reliable scale. Patient-reported outcomes are frequently used as a measurement scale in inpatient settings. Therefore, using a patient-reported scale to document symptoms and experience outcomes in ACSs is a critical approach.

Nowadays, NSIs have become an increasingly valid and reliable means that support quality of nursing care and performance measurement in inpatient settings. Yet, NSIs are underdeveloped and minimally standardised in ambulatory care. Up to now, far too little attention has been paid to NSOIs in ACSs. Limited attempts have been made to develop valid and reliable NSOIs. The results show considerable variation in what, and how, chemotherapy-related symptoms are measured, and the available indicators remain under evaluation. Based on the lines of evidence considered, of the three instruments, only one, namely PR-CISE (Armes et al. 2014), was identified as being appropriate for use to assess nurse-sensitive outcomes in ACSs. However, further studies are required to refine and test the PR-CISE.

To sum up, as mentioned earlier, in view of the evidence demonstrating the effectiveness of using NSO alone as an indicator of the quality of nursing care in ACSs, there is an indication that variation in symptom severity might be explained by differences in workforce characteristics and deployment.

Accordingly, the use of an outcomes measure alone would not be likely to explain the variation in QoC. Having set out a potential scale to record outcome there is a need to consider variables that might account for variation and how to record these. To decide which aspects of nursing workforce should be included when developing a Nursing Workforce and Unit Characteristics Survey, a literature review of studies that had assessed the quality of nursing care was conducted. The following sections will therefore discuss variables

influencing patient outcomes studied in the context of QoC in ambulatory chemotherapy settings.

3.2.6 Variables influencing patient outcomes

As indicated in the NREM and related literature, several aspects of health care delivery systems have the potential to influence the quality of nursing care. These include: 1) the characteristics of health care systems and providers (nurses), such as certification, the level of training, years of experience and specialisation; 2) the capacities and resources of facilities, concerning aspects such as the volume of services, nurse staffing levels, the scope of services and access to technology, and finally; 3) the ways in which services are organised, financed, and delivered. Health service researchers have used established indicators to determine whether certain outcomes of care are influenced by 1) how care is delivered, and 2) who delivers it.

Research studies in quality assessment can be classified into three main approaches: studies that investigate relationships between the structure and outcomes of care, studies that investigate the link between the process of care and outcomes, and studies that investigate the relationship between structure and process of care. The next section discusses the studies examined and the variables included in the three approaches to quality assessment (structure, process and outcomes) in the context of ambulatory chemotherapy settings. The following section will focus on studies that examine the link between nurse and work environment characteristics, and patient outcomes in cancer care services.

3.2.6.1 Organisational characteristics and nurse-sensitive outcomes

Doran and Pringle (2011) pointed out that the focus of organisational variables is most often on staffing and nursing assignment patterns that directly influence the delivery of nursing care. The complexity of any inpatient or ambulatory care environment in terms of staffing, staff mix, workload, and work environment makes these characteristics important to consider when planning quality assessment or/and improvement. Nurse staffing levels have been examined in a variety of inpatient hospital settings, including critical care, ICU, medical and surgical units. More information about this is provided

in Section 3.3.6.3. However, very few studies have examined unit level variables in the ambulatory care environment, for example, the Emergency Room.

The nature of nurse-to-patient ratio, workload, and work environment in ACSs remains unclear. Little is known about how these variables influence patient outcomes and experience in ACSs. However, a few studies in this field have focused solely on skill mix, especially nurse certification. A gap in the evidence remains regarding the link between nurse staffing and patient outcomes sensitive to nursing service quality in the ambulatory cancer setting.

Nurse certification and patient outcomes

In 2010, the US Institute of Medicine (IoM) highlighted concerns about patient safety and adverse events, together with mandates for quality, and cost-effective care, which have been growing since the release of the 2001 report of the US IoM 'Crossing the Quality Chasm'. A growing body of evidence points to evidence that links the QoC nurses provide to patient outcomes and nurses' levels of qualification and expertise.

Landon (2008), cited in Kendall-Gallagher and Blegen (2009), has simply defined certification as "the validation of cognitive knowledge" (2009: p.108). For that, obtaining certification in a speciality area from an accrediting organisation could be one way for nurses to obtain external confirmation of levels of competence and has been demonstrated in some settings to be associated with high QoC. Research studies demonstrate a relationship between nurse certification and patient outcomes in medical-surgical and ICU services (Stalpers et al. 2015; Aiken et al. 2016); evidently, few studies have examined this relationship in oncology care settings.

Three studies Coleman et al. (2009), Frank-Stromborg et al. (2002) and Kim (2011) have attempted to document the association between oncology nursing certification and nurse-sensitive patient outcomes. Frank-Stromborg et al. (2002) used a retrospective chart review methodology to examine the impact of an oncology nursing certification on symptom management, pain and fatigue, adverse events, infection, and visits to the emergency department. The study comprised a sample of (n=20) nurses, of which 7 were certified and 13 were noncertified, and a review of 181 patient medical records. The authors

found no significant differences between patients cared for by certified nurses and those cared for by non-certified nurses.

Other studies have found that educational level did affect nurses' knowledge and abilities to manage chemotherapy symptoms. Coleman et al. (2009) compared certified nurses with non-certified nurses over knowledge and clinical behaviours related to symptom management of pain and chemotherapy-induced nausea and vomiting (CINV), in addition to patient and nurse satisfaction. The study included 93 oncology nurses, (38% of whom were oncology certified), and 270 cancer patients. Patients were asked to complete the Patient Pain Questionnaire (PPQ) and the Press Ganey Inpatient Survey (INVR). Nurses completed the Nurses Knowledge and Attitude Survey Regarding Pain (NKASRP), a questionnaire on work satisfaction, and lastly, a general demographic form.

Coleman et al (2009) indicated that patients had high satisfaction with their care, and that they believed that their pain was managed well. There was statistically no difference between the management of a patient's pain by certified nurses and noncertified nurses in this area. It was further revealed that nurses with more continuing education had good knowledge of nausea, while nurses in the Oncology Nursing Society had good knowledge of both pain and nausea. Compared to certified nurses, the results showed that non-certified nurses participated in less continuing education programs and lower percentages of non-certified nurses were members of Oncology Nursing Society. The findings of the study reveal that certification in oncology nursing improves patient care quality. Coleman et al (2009) concluded that the study provided some support for the hypothesis that certification in oncology nursing improved patient care quality, and that a multisite, large-scale study was needed to continue exploration to determine the effect of certification alone.

A more recent study Kim (2011) aimed to demonstrate the effect of Oncology Clinical Nurse Specialists' Interventions on NSOs on patients with cancer undergoing chemotherapy, in 7 hospitals in 3 cities in South Korea. NSO variables included pain, fatigue, anxiety, satisfaction, health-related quality of life, ease of access, and unexpected emergency room visits. This study

employed a quasi-experimental design. A sample of (n=65) patients was cared for by an Oncology CNS and 47 patients were cared for by noncertified nurses. Self-reported questionnaires and semi-structured interviews were used to appraise the performance of oncology CNSs in addition to a chart review to obtain medical characteristics. This study provided evidence of the effectiveness of oncology CNS; their interventions were found to diminish the intensity score in relation to pain and fatigue and also increased health-related quality of life. No significant effects were reported related to anxiety.

Summary of studies

The findings from this review provide inconclusive evidence for the effect of nursing certification on patient outcomes; studies have demonstrated some links between higher levels of nursing education and patient outcomes. Little attention has been given to measuring the influence of nurse certification on NSOs in oncology, and there is no published study with a focus on this association in ambulatory chemotherapy care. See Table 3-3.

Table 3-3 Summaries of studies exploring association between nurse certification and NSOs

Years/ Country	Aim	Theoretical framework	Design & data collection methods	Sample details	Results
(Frank-Stromborg et al. 2002) USA	To test hypothesis that patients cared for by Oncology certified Nurses have superior outcomes compared to those cared for by noncertified nurses.	Donabedian (1992)	Retrospective chart review: 181 Pts. Charts reviewed using a pilot-tested committee-drafted chart review form (Demographic Survey questionnaire)	20 Oncology RNs (7 certified and 13 noncertified) Medical records of 181 Pts.	The two groups did not differ with respect to: assessment of pain at admission, -number of pain assessments after admission, -assessment of fatigue at admission, number of unplanned visits to care facilities, admissions to care facilities, -number of unscheduled home visits. As hypothesized, the OCNs® documented a higher number of post admission fatigue assessments ($p < 0.05$). Contrary to hypothesis, patients of OCNs® had a greater number of infections and fewer documented instances of patient teaching regarding infection.
(Coleman et al. 2009) USA	Compare certified with noncertified nurses for knowledge and clinical behaviours related to symptom management of pain and chemotherapy induced nausea and vomiting, patient satisfaction, and nurse satisfaction.	Not specified	Survey of patients & nurses. Chart audits of symptom management.	93 nurses (n=35) certified in oncology nursing. 270 Pts.	Certified nurses scored higher than noncertified nurses on the Nurses' Knowledge and Attitudes Survey Regarding Pain as well as the Nausea Management: Nurses' Knowledge and Attitudes Survey. Certified nurses scored significantly higher ($p= 0.02$) than noncertified nurses on knowledge of pain management. Results from patients' surveys showed that cancer pain and CINV were managed well but improvements can be made.

(Kim 2011) Korea	The effect of oncology CNS interventions on patients with cancer undergoing chemotherapy.	Donabedian (1980)	Pt. Self-report questionnaire N. semi-structured interviews to appraise performance of oncology chart review for medical characteristic	1- (n=112) Patients undergoing chemotherapy (n=65) Pts. Cared for by an onco. CNS and (n=47) cared for by In 7 hospitals in 3 cities in South Korea Nov 2007- Apr 2008 2- Semi-structure interview (n=3) oncology CNSs, data on (n=14) Onco. CNS characteristic and role performance	Evidence of the effectiveness of oncology clinical nurse specialist. No significant effects were observed on anxiety or unexpected ER visits.

Keys: Onco. = Oncology, CNS= Clinical nurse specialist, Pts. = patients, RN= registered nurse, N. = nurses

3.2.7 Conclusions and recommendations

In summary, a narrative review of the literature was undertaken to establish the context and knowledge relevant to the use of Nurse-Sensitive Outcome Indicators (NSOIs) for quality monitoring and reporting in the present study. This narrative review identified a number of outcome indicators that have been used to assess the quality of nursing care provided by ACSs. One scale, namely PR-CISE, was found to be sensitive to nursing work and suitable for use in the current study.

Although NSOIs can detect certain problems and issues with care, they do not represent a systematic strategy for change and improvement in the quality of nursing care. However, quality indicators can be used to reveal information such as variations in outcomes that may be utilised during monitoring and to target improvements in care. In fact, it would be difficult to use a single set of indicators to assess the variation in the QoC nursing care provided in the ACSs. Other indicators, such as structural indicators, are required to explain variations in outcome measures.

It is clear there is little research addressing this area, and that which has been done has proved to be inconclusive; the evidence identified in this review does not provide substantive support for the link between structural indicators, such as nurse staffing, skill mix nurse-to-patient ratio, workload, and work environment indicators to QoC provided in ambulatory chemotherapy settings in national base (Saudi Arabia) or universally that would assess the QoC in this setting.

The quality of health care is often evaluated using patient outcomes. Since nurses deliver most of the direct patient care in hospital, nursing care is considered to be one of the most important areas of the quality of health care and patient safety (IoM 2011). The impact of nurses and their work environment on patient experiences and outcomes of care in AC will be explored in the next section.

3.3 Impact of nurses and their work environment on patient experiences and outcomes of care in acute care: Meta-review

3.3.1 Background

There is a growing concern about the impact of nurse staffing and other organisational variables on patient outcomes in adult health care. Over the past decade, several seminal studies, such as Aiken et al. (2002b), Needleman et al. (2002a), Cho et al. (2003), and Tourangeau et al. (2007), have examined the association between nurse staffing and nurse work environments and patient outcomes in different inpatient care contexts. The findings from these studies provide evidence to support an association (Lankshear et al. 2005; Kane et al. 2007b; Unruh 2008). Moreover, this area of research, which demonstrates the important role of nurses in the provision of high-quality, safe care (Brennan et al. 2013), has led to an improvement in both patient outcomes and care delivery in the context of in-patient care (Kane et al. 2007b).

In the nurse-led ambulatory chemotherapy services (ACS), nurses are the first-line healthcare providers, yet there appears to be no evidence about the association between staffing and organisational factors and patient outcomes. The absence of measures to characterise nurse staffing and the workforce in ambulatory care services in general, and specifically ACS, is a key challenge for healthcare researchers if they are to progress research in this area. Armes et al. (2014) highlighted the need to test the impact of differences in workforce characteristics on outcomes such as symptom severity, and recommended the development of standardized descriptors for the workforce and clinic organisation. In order to address these gaps, it is important to discuss the key measures and methodological issues that have emerged in this area of research to date.

3.3.2 Literature review process

Firstly, an initial search focused on the relationship between nurse characteristics and staffing on patient outcomes in ambulatory cancer chemotherapy and the findings presented earlier in chapter 3. The results of

this search revealed that no studies had examined these links in oncology units in general, or in ambulatory cancer chemotherapy in particular. The second step focused on the relationship between nurse staffing and patient outcomes in the context of medical/surgical settings and acute care (AC). In these types of care settings several patient clinical and patient-reported outcomes could be construed as being similar to the outcomes of patients receiving cancer chemotherapy, e.g. pain, satisfaction, and nausea and vomiting, which are considered to be patient outcomes sensitive to nursing care in ambulatory chemotherapy settings. Moreover, examining the available scientific literature related to medical/surgical settings and AC which studied the association between nurse staffing and patient outcomes, would enable the following questions to be answered:

1. What patient outcomes have been studied?
2. What aspects of nursing have been studied?
3. What organisational factors (e.g., staffing, staff mix, workload, and nurse work environment) have been studied?
4. How is the term “nurse staffing” defined?
5. Is there any evidence that patterns of nurse staffing and characteristics of the nurse work environment are implicated in patient outcomes?
6. What type of research designs and measurement of study variables have been deployed to examine the effect of nursing and organisational characteristics on patient outcomes?
7. What are the methodological issues in this area of research?

Several systematic reviews have been published about the association between nurse staffing and different patient outcomes in AC settings. As a result, a meta-review, i.e. a review of reviews, is most suited here. This will facilitate the understanding of the literature surrounding the inpatient context, without the need to undertake another review of individual studies. Notably, review articles tend to compare and contrast, summarising the findings of primary studies in addition to providing recommendations for future research.

3.3.3 Aims and objectives

This meta-review aimed to identify the review articles that have reported the relationship between NSOs and nurse staffing and other organisational factors in order to: 1) establish which patient outcomes have been studied in previous research; 2) identify the pool of structural factors in an organisation that might affect patient outcomes; and 3) investigate the research designs and methods of data collection used in this area of research, rather than summarise data on the impact of nurse staffing and work environments on patient outcomes in the context of inpatient care. Additionally, this meta-review was designed to create a resource to inform the development of the study-specific Nursing Workforce and Unit Characteristics Survey (NWUCS). This is intended as a tool to describe the features of the nursing workforce and unit characteristics in a uniform way (referred to here as NWUCS) that could be applied alongside the PR-CISE tool. The objectives of the meta-review were to:

1. Provide an overview of patient outcomes examined and the ways in which these outcomes have been measured in previous studies;
2. Provide an overview of the key review articles examining nurse staffing and organisational variables;
3. Identify nursing workforce characteristics, which have been identified as having an association with nurse-sensitive outcomes;
4. Identify key factors and issues that need to be considered by researchers who wish to examine organisational and nurse work environments;
5. Identify how data are collected about these characteristics;
6. Identify reasons for inconsistencies in the results across studies examining associations between patient outcomes and other organisation factors; and
7. Identify key methodological issues that have emerged from the research on nurse staffing and patient outcomes.

3.3.4 Conceptual framework

As mentioned earlier in Section 2.8, this review draws on Doran's (2006) framework of the nursing role effectiveness model (NREM).

3.3.5 Methods

As discussed above, the meta-review approach was selected to address the questions at hand. As the initial review activity revealed that a series of reviews existed, examining the association between nurse staffing and patient outcomes, a meta-review strategy, seemed more appropriate than undertaking another systematic review of studies. Moreover, meta-reviews are an appropriate strategy to describe whether the current evidence base is complete or incomplete, by synthesizing evidence from previous systematic reviews or meta-reviews.

3.3.5.1 Search strategy

The following electronic databases were searched: CINHAL, MEDLINE (EBSCO), PsycINFO, Cochrane Library, Web of Science, Saudi Medical Journal, and search engines (i.e., Google Scholar). Additionally, manual searches of journals, articles, and books were undertaken to gather all relevant reviews. The strategy for literature searching used medical headings and keywords as well as their combinations. Search terms were adjusted from a preliminary literature review to account for those listed in the thesaurus of the databases searched, and MeSH terms were used where possible. The main keywords used were: 'patient outcomes' and 'nurse staffing' (see Table 3-4).

Table 3-4 Search strategy

Topic	Keywords	Database
Patient outcomes	"patients" and "outcomes" or "outcome" were combined with "patient outcome" or "patient outcomes" or "complications" or "treatment outcomes" or "patient-reported outcomes" were combined with	• CINHAL • MEDLINE (EBSCO) • PsycINFO • Cochrane Library • Web of Science • Saudi Medical Journal (2002 -02 March 2015)
Nursing	"staff" or "staffing" and "nurse" and "nurse staffing" or "nursing staff" or "personnel staffing and scheduling" or "nurse-to-patient ratio" or "nurse-patient ratio" or "nurse to patient ratio" or "nurse/patient ratio" or "staffing ratio" or "nurse ratio" or "staffing levels" or "skill mix" were combined with	
Organisational	"organisation" or organisation" or "workload" or "work environment" or "work force" or work flow" or "shift" or "shift work" or capacity" or "environment or design or layout" or "health facility environment" or "patient acuity" or "bed occupancy" or "size" or patient volume" or "organisational culture" were combined with	
Unit labels	"medical/surgical units" or "intensive care units" or "intensive care" or "critical care"	
Relationship	were combined with "Relationship" or "relationship between" or "associations" were combined with	
Review	"Review" or "systematic review" or "review literature" or "peer review" or "meta-analysis"	

3.3.5.2 Inclusion criteria

- **Type of studies**

A review article was included if it was a systematic review (SR), a review of the literature (ROL), or a meta-analysis relevant to the field of enquiry. Reviews that attempted to examine or evaluate one or more nurse staffing measures and were related to data about NSO were also included. Moreover, a review was included if the organisational characteristic of nurse staffing formed at least one of the independent variables under examination.

- **Types of Settings**

The contexts of the reviews were hospital settings for adult acute care, intensive care, and medical and surgical care units.

- **Nurse variables**

An area of interest was nurse staffing (both nurse-to-patient ratio and the skill mix). The variability in definitions of nurse staffing utilised in the reviews was subjected to examination to inform the development of operational definitions of 'nurse-to-patient ratio' as well as 'nursing skill mix' for the current review.

- **Types of patient outcomes considered**

This review intended to examine clinical and patient-reported outcomes. Accordingly, all relevant outcomes examined in previous studies were included, as were any subjective measures of patient outcomes.

Focusing on a limited set of patient outcomes enabled the opportunity for closer scrutiny of NSOs that would be most suited to outpatient settings. Inpatient mortality rates and the length of hospital stay are common outcomes linked to nursing inputs and interventions and have been used as indicators of nursing quality. Reviews focused entirely on mortality and morbidity were omitted for two reasons. Firstly, while mortality can result from ambulatory care, patients do not die during that ambulatory care interaction. Moreover, mortality can be some days afterwards but related to the care provided in ambulatory settings. In other words, death during the inpatient admission to the ambulatory setting was not relevant.

Secondly, although there is an argument that death within 30 days could be related to aspects of nursing quality, mortality was not the focus of interest. In ACSs, mortality was not likely to feature as an indicator in an ambulatory setting, unless the education and self-care knowledge is poor, in which case causation can be attributed. In addition to mortality and length of hospital stay, reviews focusing on outcomes that were not considered subjective were excluded from this review, such as patient satisfaction, quality of life, and cost-effectiveness, as these outcomes are not of interest in this study.

3.3.5.3 Exclusion criteria

In summary, reviews were excluded if they fitted one of the following criteria

a) Reports, conference abstracts, discussion papers, dissertations, editorials, letters to editors, and Primary research articles.

b) Settings such as nursing homes, paediatrics or neonatal, because these populations and settings differ from the current focus.

3.3.5.4 Timeframe and language limitations

Wunderlich (1996) highlighted that in 1996 the Institute of Medicine (IoM) reported on the adequacy or otherwise of nurse staffing in hospitals and nursing homes and identified a need for empirical evidence regarding the association between nurse staffing levels, nursing staff mix, and the quality of patient care (cited in McGillis Hall et al. 2004).

Reviews and other evidence from 2002 to 02 March 2015 were selected. The year 2002 was marked as important following the publication of the IoM (2001) book "Crossing the quality chasm: A new health system for the 21st century" which investigated the components of quality of care. Three rounds of literature searching were conducted using the same keywords in each round. The first search was conducted during the development stage; a systematic search was carried out over a 10-year period between 2002 and 2012. The second search, was conducted in March 2012, aimed at updating the first search to consider any literature reviews that might constitute new evidence that might inform the content of the NWUC before approving it for pilot-testing. As a result, two more literature reviews were added to the primary results (Brennan et al. 2013 and Stalpers et al. 2015). The final update ran in February 2017 to include a wide range of literature and evidence for the discussion chapter. At this point no literature reviews were identified. The search was limited to review articles published in English only.

3.3.5.5 Selection of studies

The initial implementation of the search strategy yielded a total of 100 potential citations across all databases, which were then subjected to further screening. The initial results were evaluated against the inclusion/exclusion criteria; a review was identified from its title and abstract, and then a full text version of the publication was obtained and examined. As a result, only 10 reviews remained (see Table 3-5and Figure 3-1).

Table 3-5 Selection of studies

Database	Stage 1	Stage 2
CINAHL	30	10
PsycINFO	30	5
Medline Ovid	18	10
Cochrane Library	2	0
Saudi Medical Journal	0	0
IBSS	0	0
Web of Science	20	4
***Total**	100	29

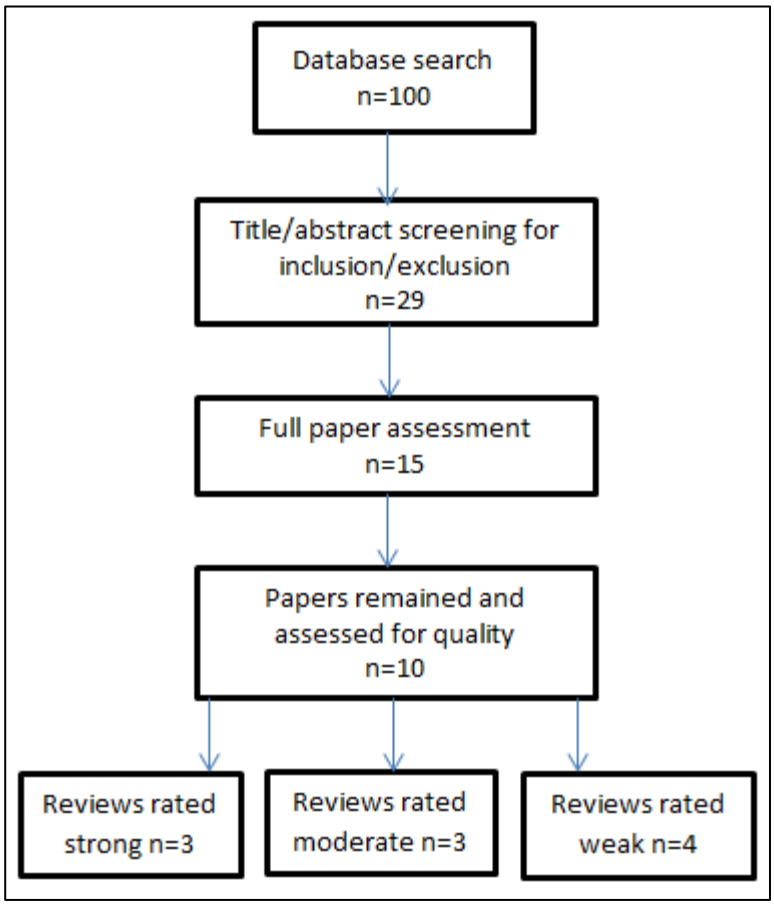


Figure 3-1 Search and retrieval process

3.3.5.6 Quality assessment

The methodological quality of each of the reviews was independently assessed using an AMSTAR quality assessment form, designed by Shea et al. (2007) (Appendix C). The AMSTAR checklist has been used in other meta-reviews in ordered to maintain methodological rigour in the meta-review. Also, the AMSTAR form has been shown to have excellent reliability (R2 = 0.96) and construct validity (Shea et al. 2007).

The AMSTAR checklist used these questions to evaluate the design, sample, measurement, and statistical analysis for a total of 11 possible points, with one mark given for a 'yes' response and zero marks for a 'no', 'can't answer', and 'not applicable' responses. Moreover, because AMSTAR comprises questions specific to meta-analysis, namely, questions 9 and 10, it was decided that reviews without a meta-analysis would have adjusted cut-off scores to reflect the fact that they could not receive points on these specific questions. Therefore, for reviews other than meta-analysis, only criteria relevant to a particular review were applied.

The total number of points that the study scored was divided by 11 or 9 depending on the review type. Papers that scored <0.5 were rated as weak, those scoring 0.50-0.74 were rated as moderate and studies that scored >0.75 were rated as strong (see Table 3-6).

Table 3-6 Outcomes of Methodological Quality assessment of the included reviews

Review article	Quality score	Total score on checklist	Outcome
Heinz (2004)	3 out of 9	0.33	Weak
Lang et al. (2004)	6 out of 9	0.66	Moderate
Lankshear et al. (2005)	7 out of 9	0.77	Strong
Kane et al. (2007b)	10 out of 11	0.90	Strong
Unruh (2008)	3 out of 9	0.33	Weak
Flynn and McKeown (2009)	2 out of 9	0.22	Weak
West et al. (2009)	6 out of 9	0.66	Moderate
Penoyer (2010)	3 out of 9	0.33	Weak
Brennan et al. (2013)	8 out of 9	0.88	Strong
Stalpers et al. (2015)	6 out of 9	0.66	Moderate

Key: < 0.5 Weak, 0.5 – 0.74 Moderate, > 0.75 Strong

3.3.5.7 Data extraction

Data extraction processes included the reverification of review eligibility and the creation of tables of the characteristics of included reviews. A data extraction form was created to extract data from the eligible reviews (Appendix D). This form aimed to gather data relevant to bias assessment and evidence tables.

3.3.6 Results

3.3.6.1 Description for reviews

The search yielded 100 reviews, 10 of which met the inclusion criteria, and included five systematic review (SR) articles, four review of the literature (ROL) articles, and one review of reviews (RR) article ((Heinz 2004), (Lang et al. 2004), (Lankshear et al. 2005), (Kane et al. 2007b), (Unruh 2008), (West et al. 2009), (Flynn & McKeown 2009), (Penoyer 2010), (Brennan et al. 2013) and (Stalpers et al. 2015)). Five review articles were excluded for the reasons for which are set out in Table 3-7.

Table 3-7 Excluded review

Author(s) and year	Reason(s) for exclusion
Burston et al. (2014)	The authors reviewed primary studies that covered both adult and paediatric settings without separating their findings.
Butler et al. (2011)	The aim was to explore the effect of hospital nurse staffing models on patient and staff-related outcomes
Shekelle (2013)	1. Outcome: focused on mortality, and 2. The authors reviewed primary studies that covered both adult and paediatric settings without separating their findings.
Twigg et al. (2010)	Outcome: mortality
Wilson et al. (2011)	Setting: Paediatrics

Three reviews presented a theoretical framework for assessing the association between patient outcomes and nurse staffing (Kane et al. 2007b; Unruh 2008; Brennan et al. 2013), whilst the review by (Stalpers et al. 2015) discussed a particular theory in the text, but did not clarify its use with regards to the

review. With regards to the primary studies included in the reviews, West et al. (2009) highlighted the lack of explicit discussion in the studies reviewing the theoretical basis of the link between nurse staffing and patient outcomes. Moreover, nine of the 10 reviews almost exclusively focused on structural characteristics regarding nurse staffing, such as nurse levels and skill mix, whilst one review article only, that by Stalpers et al. (2015), focused on the relationship between the characteristics of the nurse work environment and specific NSOs. Furthermore, eight of the 10 reviews indicated that the relationship between nurse staffing and patient outcomes would be affected by the omission or inclusion of other important factors, such as organisational factors, (Heinz 2004; Lang et al. 2004; Kane et al. 2007b; Unruh 2008; Flynn & McKeown 2009; Penoyer 2010; Brennan et al. 2013; Stalpers et al. 2015). The characteristics of the included reviews are presented in Table 3-8.

The following section presents the patient outcomes measured reported in the 10 review articles.

Table 3-8 Characteristics of included reviews

Author/year	Type of review	No. of primary studies	Research designs of included primary studies	Search periods	Databases searched	Quality of primary studies assessed and reported	Conceptual framework guiding data extraction and synthesis
(Heinz 2004)	ROL	16	6 Prospective & 10 Retrospective Designs: not specified	1998 - 2002	Not specified	No, no	No
(Lang et al. 2004)	SR	43	Unclear: 12 studies were considered "Key"	1980 – 2003	Medline, CINAHL, web of Science, ABI/Inform databases, and hand searches of the reference lists of the retrieved articles and reports.	No, no (largest studies were given more weight)	No
(Lankshear et al. 2005)	SR	22 Large studies	2 longitudinal, 19 cross-sectional	1990-present	Medline, CINAHL, EMASE, PsycINFO, HMIC, SIGLE, Cochrane Library, British Nursing Index, NLM Gateway Web of Knowledge, & grey literature	Yes, no	No
(Kane et al. 2007b)	SR & MA	28	4 case-control 7 cross-sectional 17 cohort	1990 - 2006	Medline, CINAHL, Cochrane Library, BioMed Central, fedral reports, American Nurses Association, and Digital Dissertations & unpublished dissertations and all studies	Yes, yes (quantitative)	Yes, created by the authors Kane et al. (2007)
(Unruh 2008)	ROL	26	21 primary studies 5 Reviews Designs: Not specified	1980 - 2006	Academic search Premier, CINAHL, EconLit, Health Source	No, no	Yes, created by author (Unruh 2008) Conceptual Model of Patient, Nurse, and Financial Outcomes Associated with

							Inadequate Nurse Staffing
(Flynn & McKeown 2009)	ROL	Not specified	2 SR 10 P. studies Design: Not specified	1998 – 2008	Not specified	No, no	No
(West et al. 2009)	SR	15	7 Quasi experiments 8 Observational used some form of risk adjustment	1990 - 2006	PubMed, Google Scholar, and bibliographies of articles	Yes, yes (quantitative)	No
(Penoyer 2010)	ROL	26	2 meta-analysis 2 case study 2 case-control 3 prospective surveillance 9 prospective 10 Large database or survey	Jan 1998-Dec 2008	Ovid Medline, PubMed, and Cumulative Index of Nursing and Allied Health Literature	No, no	No
(Brennan et al. 2013)	RR	29 reviews	8 SR 21 ROL	20 years Periods not specified	CINAHL, PubMed/MEDLINE, PsychINfO, and Cochrans	Yes, yes	Yes, Holzemer's Model for Health Care Research, based on Donabedian's structure, process, outcome theory

(Stalpers et al. 2015)	SR	29	1 RCT 9 longitudinal cohort 18 cross-sectional	2004 – 2012	PubMed/MEDLINE, Cochrane Library, Embase, and CINAHL	Yes, yes	Yes Donabedian's framework

Keys: MA= meta-analysis, SR= systematic review, ROL= review of literature, RR= Review of review, RCT= randomised control trial

3.3.6.2 Patient outcomes

The primary studies included across the 10 review articles linked various NSO to nurse staffing and other characteristics of the nurse work environment. The patient outcomes measured that have been reported in the review articles are presented in Table 3-8 and Table 3-9. These outcomes may be categorised as follows: 1) adverse patient events, including infections and postoperative complication; 2) length of hospital stay; 3) mortality; 4) failure to rescue; and 5) satisfaction.

In addition to in-hospital mortality and the length of hospital stay, the most frequently studied NSOs were infections and complications. In the review by Heinz (2004), the highest rates of NSOs were for failure to rescue, which was defined as the death of a patient with one of five life-threating complications: pneumonia, shock or cardiac arrest, upper gastrointestinal bleeding, deep venous thrombosis, or sepsis (Heinz 2004). In contrast, the incidence of failure to rescue was restricted to death within 30 days among patients who experienced complications in the review by (Lang et al. 2004). Moreover, failure to rescue has been measured as the number of deaths in patients who developed an adverse occurrence divided by the number of patients who developed an adverse occurrence (Kane et al. 2007b).

One review studied specific patient outcomes, such as malnutrition and delirium, in addition to the most commonly used NSO: patient falls, pain, and pressure ulcer (Stalpers et al. 2015). Lang et al. (2004) deployed 19 patient outcome measures, all of which were considered to be adverse events, except for satisfaction with nursing services. Moreover, the authors indicated that all the outcomes studied were events that occurred during the hospital stay (Lang et al. 2004). Similarly, the Kane et al. (2007b) review focused on a mix of 15 patient outcome measures, including hospital-related mortality, failure to rescue and adverse events.

The majority of primary studies used administrative data or screened patients' clinical records to identify patient adverse events. Moreover, data were usually abstracted from the clinical records by screeners, who used the records to decide whether or not adverse events had occurred, and to document and classify those events (Brennan et al. 2013). The majority of primary studies

lacked adjustments for the severity of patient outcomes when addressing the association between nurse staffing and patient outcomes (Lang et al. 2004). More information about methodological issues is presented in Section 3.3.6.6.

Table 3-9 Patient outcomes used in studies included in the reviews of the relationship between patient outcomes and structural and process variables

	Pain	Treatment outcome	Pressure ulcer	Gastrohemorrhage/ upper GI bleeding	Medication errors	Infection	Central line infection	Pneumonia	Respiratory Failure	Urinary tract infection	Wound infection	Nosocomial infection	Adverse event	Sepsis	Shock	Cardiac arrest	Deep vein thrombosis	CNS complications	Unplanned extubation	Surgical bleeding	Patient complaints	Patient satisfaction	Patient falls	Delirium	Malnutrition	Intravenous errors	Length of stay	Mortality	Failure to rescue
(Heinz 2004)				x				x		x			✓	x	x	x	x				✓						✓	✓	✓
(Lang et al. 2004)		✓	✓	✓	✓			✓		✓		✓	✓		✓	✓	✓				✓	✓	✓			✓		✓	✓
(Lankshear et al. 2005)					✓			✓		✓	✓	✓										✓					✓	✓	✓
(Kane et al. 2007b)			✓	✓				✓	✓	✓		✓			✓	✓	✓		✓	✓			✓					✓	✓
(Unruh 2008)			✓	✓	✓			✓		✓						✓	✓					✓	✓					✓	✓
(Flynn & McKeown 2009)			x		x	x									x						x		x				x	x	
(West et al. 2009)		x				x							✓								x						x	✓	
(Penoyer 2010)		✓				✓																					✓	✓	
(Brennan et al. 2013)													✓														✓	✓	✓
(Stalpers et al. 2015)	✓		✓																				✓	✓	✓				

Keys: ✓= primary focus of the review, x = patient outcomes reported in the review

3.3.6.3 Nurse staffing

This meta-review revealed a variety of different approaches used by the review authors whilst discussing nurse staffing, and definitions also varied across the primary studies depending on the purposes of each (Unruh 2008; Penoyer 2010). For example, in the review by Unruh (2008), 'nurse staffing' is discussed in terms of skill mix or ratio, while in the primary study by Jelinek and Kavois (1992) it is described as the method of establishing the appropriate mix and the number of nursing resources required to meet workload demands for nursing care on the patient care unit. 'Staff mix' has been defined by McGillis Hall (2005) as 'the combination of different categories of health care workers that are employed for the provision of direct patient care to the patient' (2005, p.30). Put simply, skill mix is expressed as varying levels of education and/or experience (Unruh 2008).

Although 'nurse staffing ratio' has been defined as 'the number of nurses or nursing hours per number of patients or patient-days, or vice versa' (Unruh 2008, p62), it might be difficult to generalise this definition to ambulatory care settings. For example, Unruh (2008) and Penoyer (2010) used the term 'nurse staffing' to refer to the hours of nursing provided per patient, or the number of patients or workload assigned to nurses (Penoyer 2010). In addition, she defined 'lower nurse staffing' as the condition of having fewer nurses per number of assigned patients, or a higher nurse workload. In contrast, higher nurse staffing is referred to a higher proportion of nurses for the assigned patients, or a reduced nurse workload (Penoyer 2010).

In addition, different operational definitions for the nurse-to-patient ratio were used by various authors, such as the number of patients cared for by one registered nurse (RN) per shift, or the number of RN Full-Time Equivalents (FTEs) per patient day, number of occupied beds, or 1,000 patient days (Kane et al. 2007b).

The literature revealed that nurse staffing was typically measured in one of three ways: 1) the number of hours of nursing care provided during a defined time period: total nursing staff Hours Per Patient Day (HPPD), such as RN, licensed practical nurse (LPN), nursing assistant (NA) (Lankshear et al. 2005;

Unruh 2008), 2) the proportion of staff that consisted of RNs (skill mix) (Lankshear et al. 2005; Unruh 2008) or, 3) the nurse-to-patient ratio (Kane et al. 2007b). There were more than 50 different measurements of nurse staffing identified within these broad categories. Also, data extraction procedures showed nurse staffing to involve different aspects, for instance, the type and level of patient care required, the mix and skill level of nurses, the number of patients that require nursing care, the appropriateness of the number of nurses, and cost efficiency and effectiveness (McGillis Hall 2005). The measure of the nurse-to-patient ratio usually detailed the number of patients cared for by each nurse. Also, there were more specific measures, including the RN-to-patient ratio, which measures the number of patients cared for by an RN, and the LPN-to-patient ratio. A more general description of the terms included was provided in two of review articles: the reviews by Unruh (2008) and Penoyer (2010). Additionally, there were variations in the ratios according to the shift, such as day, evening, and night shifts (West et al. 2009). Examples of the measures used in individual studies are presented in Table 3-10.

Table 3-10 Measures of nurse staffing

	Nurse staffing measures	Study
1	Ratio of registered nurses to patients	Kovner and Gergen (1998), Aiken *et al.* (2002b)
2	Nursing Hours Per Patient Day (HPPD)	Blegen and Vaughn (1998); Blegen et al. (1998), Cho et al. (2008)
3	Proportion of Registered Nurses	Blegen and Vaughn (1998), Blegen *et al.* (1998), Needleman et al. (2002b)
4	Number of Full-Time Equivalents (FTEs)	Blegen and Vaughn (1998), Blegen *et al.* (1998), Mark et al. (2000)
5	Nursing staff mix	McGillis Hall et al. (2004), Unruh (2003)

3.3.6.4 Measures other than nurse staffing

The report, Keeping Patients Safe: Transforming the Work Environment of Nurses (IoM 2004) raised serious concerns about the impact of hospital restructuring in the 1990s on patient safety outcomes and nursing work environments. In this report, the authors indicated that typical nursing work

environments were ‘characterised by many serious threats to patient safety’ (IoM 2004, p3). The authors then suggested that these conditions were caused by certain factors, such as work design issues, organisational cultures, organisational management practices, and the ways in which nurses were deployed in the (then) current inpatient settings (IoM 2004).

Stalpers et al. (2015) indicated that McClure (1983) has been identified to be the first to explicitly identify some of the major characteristics of the nursing work environment, such as nurse staffing, collaboration between nurses and physicians, and nurse autonomy. The authors highlighted that since then measurement of nursing work environments has been the focus of several studies, including the Practice Environment Scale (Lake 2002), the Nursing Work Index (Kramer & Hafner 1989), and the Essentials of Magnetism (Kramer & Schmalenberg 2004).

Schmalenberg and Kramer (2008) define a healthy work environment as one in which leaders provide the structures, practices, systems and policies that enable clinical nurses to engage in the work processes and relationships essential to safe and quality patient care outcomes.

Five of the 10 review articles summarised the results of the primary studies in terms of associations between the characteristics of the nurse work environment and patient outcomes (Lang et al. 2004; Lankshear et al. 2005; Kane et al. 2007b; West et al. 2009; Stalpers et al. 2015). These primary studies adjusted for the nurse/patient case mix and the skill mix, in addition to other organisational factors, such as the hospital type, the location and size, and the presence of special services in the hospital (Lang et al. 2004).

The review by Stalpers et al. (2015) extended the focus on the work environment to a broader set of characteristics than nurse staffing, to include the nurse level of education, nursing experience, and collaborative nurse-physician relationships. Moreover, in this review, the primary studies adjusted for several organisational factors, such as the nurse level of education, nursing experience, unit size, nursing care hours, unit type, acuity, the hospital system, and workload. To this end, the findings of this meta-review revealed that no reviews were identified that measured the association between nursing

workload or nurse work environment and patient outcomes. However, these factors have been used as a risk adjustment when studying the link between nurse staffing or the nurse work environment and NSOs.

3.3.6.5 Is there any evidence that patterns of nurse staffing and characteristics of the nurse work environment are implicated in patient outcomes?

Over the 10 reviews presented in this meta-review, the relationship between nurse staffing and patient outcomes has been studied extensively, and evidence has been provided to support this relationship. Kane et al. (2007b) indicate that nurse staffing is closely associated with patient outcomes, staff-related outcomes, and organisational outcomes. Many studies found that higher nurse staffing is associated with a decrease in adverse events and in-hospital mortality (Kane et al. 2007b). Other studies, however, such as the review by (Brennan et al. 2013) do not support this inverse relationship. For characteristics of the work environment other than nurse staffing, the findings of the 12 primary studies included in Stalper et al. (2015) showed the significant effects for collaborative relationships, education, and experience on patient outcomes. In fact, this meta-review was conducted to summarise the patient outcomes and factors that affect these patient outcomes, rather than to summarise data on the impact of nurse staffing and work environment on patient outcomes. A summary of the evidence about nurse staffing and patient outcomes reported by these review articles is provided in Table 3-11.

Table 3-11 Summary of reviews' aims, patient outcomes included, nurse staffing measures, and organisational factor findings

	Aim/objectives	Setting / country	Patient outcomes being investigated	Nurse staffing measure and nurse factors	Organisational factors	Findings
(Heinz 2004)	Review of effects of nurse staffing on patient outcomes.	Acute care/Not specified	Patient complications Mortality Length of stay.	-RN-to-Pt day ratios -RN as a percentage of total nursing care (skill mix) -Hours of direct patient care by RNs . -Nurse staffing levels	Not specified	Associations between nurse staffing and various patient outcomes are inconsistent.
(Lang et al. 2004)	The purpose was to determine whether the literature supports specific minimum nurse-patient ratios for acute care hospitals and whether nurse staffing is associated with	Acute care, rehabilitation or psychiatric hospitals	19patient outcomes : - nosocomial infections, - urinary tract infections , - pneumonia, - treatment errors, - adverse drug events, - cardiac arrests, - pulmonary compromise, - gastrohemorrhage, - unspecified complications, - intravenous errors , - venous thrombosis , - shock, - falls, - Pt injuries , - pressure ulcers , - patient satisfaction ,	Nurse-patient ratios Nurse staffing levels	Institutional support of nursing	- The literature offers minimal support for specific minimum nurse-patient ratios for nursing units especially without also adjusting for case mix and skill mix; although total nursing hours and skill mix do appear to affect some important patient outcomes. - Limited evidence supports probable relationships between higher levels of nurse staffing and lower rates of needlestick injuries (P.335). - A minimum nurse-patient ratio alone is probably not adequate to ensure quality of care. Patient acuity, skill mix, nurse competence, nursing process variables, technological sophistication, and institutional support of nursing should also be considered when setting minimum staffing requirements (P. 335).

	Patient ,nurse employee, or hospital outcomes.		- failure to rescue, - mortality, and - morbidity			- Mixed evidence for increased nurse staffing with pneumonia and UTIs. - This review reported that no guidance for setting N-to-Pt ratios.
(Lankshear et al. 2005)	To assess the evidence of a link between the nursing workforce and patient outcomes in the acute sector.	Acute sector/International research evidence	Patient mortality, complications (pneumonia, urinary tract infections, nosocomial infections, wound infections), failure-to-rescue, incidence of adverse events (falls, medication errors), length of stay, patient satisfaction.	- Nursing workforce (levels and skill mix) - Empowerment	- Shift - Rotation - Schedule - Organisational climate and culture - Number of trainees/physicians	- A positive relationship was found between nurse staffing and patient outcomes. - The findings suggested that higher levels of nurse staffing and richer skill mixes in qualified nurses are associated with improved patient outcomes. - The evidence of a link between nurse staffing and patient outcomes was mixed, and the researchers were not able to reliably estimate the effect of this association.
(Kane et al. 2007b)	To assess the evidence of an association between registered nurse staffing levels and patient outcomes.	Acute care hospital including intensive care units and medical surgical units /In the US &Canada	Mortality, failure to rescue, adverse events and complications including infection (nosocomial, urinary tract), cardiac arrest, shock, unplanned extubation ,respiratory failure, upper GI bleeding, surgical bleeding, DVT, patient falls, pressure ulcers and pneumonia.	Ratio of RN FTE per patient-day and nurse-to-patient ratios. Nurse staffing categorised as RN-to Pt ratios: 1) ratio of full time equivalents (FTEs) or RN per Pt day 2) no. of Pts assigned to 1 RN per shift in the unit - Education , - Experience, - Shift rotation,	- Unit/hospital size - Patient volume - Hospital type - Use of technology and computerized provider order entry systems - Organisation climate/culture - Error reporting systems - Shift schedule	- Statistical and clinical significant associations were found between higher number of qualified nurses and reductions in hospital-related adverse patient events. For example, high RN staffing was associated with 19% lower odds of developing hospital-acquired pneumonia for all patients, and 30% lower odds for ICU patients. - Reduced the number of nurse staffing was found to be associated with high incidence of adverse patient outcomes. - A consistent positive relationship was observed between the number of patients per RN shift and patient outcomes. - A simplified way of measuring the work of nurses is the number of patients a nurse cares for (ratio).

				- Employment status, and - Age		- The causal pathway to safe patient care includes other structure and process factors (P. 1202).
(Unruh 2008)	To assess the impact of hospital nurse staffing levels on patient, nurse, and financial outcomes.	Original US and international research studies	Mortality, medication errors, complications, patient satisfaction, falls, failure to rescue, and 17 specific adverse-event terms, including cardiac arrest , postoperative infections, pneumonia, and thrombosis .	- Nurse-patient ratios, - Nurse skill mix, - Nurse hours, - Nurse-to-patient days of care	Not specified	- The findings stressed the importance of hospitals acknowledging the influence that nurse staffing has on patient safety, staff satisfaction, and institutions' financial performance.
(Flynn & McKeown 2009)	To revisit published evidence relating to how nurse staffing levels influence patient, nurse and service outcomes. To consider the implications of this body of research for nurse managers in their quest to determine optimum nursing numbers.	International research in the acute service sector	No specific patient outcomes were studied. However, while searching databases, attention given to: Adverse effect, patient safety, Patient satisfaction, and Mortality	Nurse staffing levels and skill mix	Workload	- The result of this review shows the difficulty of conclusively demonstrating a causal relationship between nurse staffing levels, skill mixes and patient outcomes.
(West et al. 2013)	To evaluate the evidence linking nursing resources to patient outcomes as a framework for	Intensive care or critical care settings	- Adverse events, - Mortality	Characteristics of nursing workforce: Nursing resources: - N-Pt ratios	- Workload - Scheduling	- 1 author noted the nurses' role in pain control - Most included primary studies are observational and retrospective and varied in scope from 1 to 52 units.

	future research in this area .			- Skill mix - Nurses' level of education training and - Experience		
(Penoyer 2010)	To review literature evaluating the association of nurse staffing with patient outcomes in critical care populations over the past decade.	Critical care units and populations with critical illnesses International studies	Infections, Infection control, hospital mortality, length of stay, treatment outcome, postoperative complications and unplanned extubation and reintubation ,outcome assessment.	Nurse staffing including : - Number of Pts or workload assigned to Ns, or - Hours of nursing provided per patient (NS ratios) - Higher NS indicates more nurses (or higher proportion) for assigned Pts or less N workload . - Lower nurse staffing indicates fewer Ns (or lower proportion) for the number of assigned Pts or higher N workload.	- Workload - Professional engagement - Detection of quality of care	- NS levels are associated with patient outcomes. This finding is supported by earlier general research literature in other acute care settings. - Most studies suggested that decreased nurse staffing is associated with adverse outcomes in intensive-care unit patients. - Most included studies were observational, which would mean that causal relationship cannot be assumed. - In addition to numbers of nurses and nursing time, other factor such as nursing capability including skills, education, knowledge of nurses should be considered. - Also, need to consider the role of organisational factors in assessing or impeding nurses' ability to carry out specific process of care to prevent patient adverse events, and identify them and intervene in a timely manner when they do occur.

(Brennan et al. 2013)	To summarise review authors' findings and recommendations for future research focusing on reasons for inconsistencies across primary studies, and on how these inconsistencies have contributed to the lack of establishment of evidence-based nurse staffing guidelines to date.	Acute care	All available patient outcomes studied in primary studies including mortality and	All available nurse variables	- Acuity (intensity-nursing care needs, workload and complexity) - Staff availability, - Case mix, - Geographical	Inconsistencies in results across primary studies For future research in this area, the researchers should focus on conducting theoretically sound studies that favour strong internal validity and the ability to establish causal relationships among a variety of unit-level structures and processes of care and patient outcomes.
(Stalpers et al. 2015)	Systematically review the literature on relationships between characteristics of the nurse work environment and 5 NSOs in hospitals		- Delirium - Malnutrition - Pain - Patient falls - Pressure ulcer	Nurse work environment factors - Nurse staffing - Nurse education - Nursing experience, and - Collaborative relationships	- Work complexity, - Unit size, - Teaching status, - Acuity, - Staff category, - Hospital system, - Shift time, and - Pt census	- Scientific evidence was found on the effects of NS and other characteristics of the work environment (i.e. collaborative relationships, experience, and education) on falls, pain management & pressure ulcer (P.833). - There were mixed results regarding the association between NS and the outcomes measures of patient falls and pressure ulcer (P.832). - Significant effects were found related to nurse education: higher levels of education were related to fewer patient falls. - Specific work environment characteristics other than NS are related to NSO (P. 832).

3.3.6.6 Methodological issues

This meta-review has revealed that studying the influence of nursing and organisational factors on patient outcomes is difficult, and that the inconclusiveness and/or inconsistencies of the findings of the primary studies may be due to several method-related issues. These can be categorised into four main issues related to: 1) variations in measurement, 2) study design, 3) data sources and level of analysis for measurement and, 4) analytical methods.

1) Variations in measurements

Two measurement challenges related to variations were revealed. The first challenge was related to the variations in the definitions of variables. As mentioned in Section 3.3.6.2, across the 10 review articles, the primary studies assessed various patient outcome measures. However, the generalisability of results for the same patient outcomes was limited, because the primary studies varied in how the same outcome was defined and measured (Penoyer 2010; Brennan et al. 2013). Similarly, as mentioned above in Section 3.3.6.3, nurse staffing was measured and defined in several ways. The second challenge was related to the variations in the measurement of the same outcome. For example, Brennan et al. (2013) reported five different ways that have been used to measure hospital length of stay in 11 primary studies.

2) Study designs

The majority of primary studies presented in the 10 reviews took a quantitative approach. The centre for Evidence-Based Medicine (March 2009) considered randomised control trials (RCT) to be the research design with the greatest degree of rigour in the hierarchy of evidence to support causal relationships among the variables studied. The longitudinal and prospective cohort designs ranked as the next highest levels of evidence, while the observational and cross-sectional research designs came next (Medicine March 2009).

While, RCTs are the preferred research design, Stalpers et al. (2015) explain that it is almost impossible to use RCT design in this research area, because it requires randomisation of interventions that cannot be controlled. In other words, because nurses and patients cannot be randomly assigned to units or hospitals, the influence of nurse staffing on patient outcomes is a topic area that has not historically been studied by RCT methods (Brennan et al. 2013).

The majority of primary studies included in the reviews were observational designs with cross-sectional designs. Longitudinal and cohort designed studies ranked as the second-most favoured design among the reported studies. Only one randomised controlled trial (RCT) was included in the review articles. Brennan et al. (2013) report that the reason observational and cross-sectional designs dominated the literature in this area was mainly due to 'a function of the trade-offs among availability and reliability of data, internal and external validity, and costs in relation to both time and money' (2013: p 779).

3) Data sources and level of analysis for measurement

For observational research, the two potential sources of data are primary data, which are collected by the investigator for the purpose of the study, and secondary data, which has already been collected for another purpose but which is used by the investigator to examine a novel research question (Carlson & Morrison 2009). Over the 10 reviews, the authors of the primary studies tended to use large administrative databases (secondary data) when studying the effects of nurse staffing on patient outcomes. This was done for two reasons. Firstly, these databases were low cost in terms of the time and money required to obtain the data and, secondly, they were readily available, with potentially high external validity because of large sample sizes (Brennan et al. 2013). In contrast, the review authors remarked on the consequences and drawbacks of using large databases, as these generate potentially less reliable data (Lankshear et al. 2005; Unruh 2008; Penoyer 2010), due to minimal adjustment for confounding variables. According to Brennan et al. (2013), they were also subject to the underreporting of adverse events. In addition, secondary data may not include all the variables of interest, and it can be difficult to understand how and why the data elements were collected, as they were collected for purposes other than the investigators' study. Moreover, this type of data would include all the types of units and patients, rather than unit-level staffing (Unruh 2008; Penoyer 2010; Brennan et al. 2013).

The level of analysis was found to be another methodological issue. The review by Brennan et al. (2013) indicated that some administrative databases provided data solely aggregated to the hospital-level of analysis. This type of data omitted the unit-level context that limited researchers' abilities to identify the

amount of nursing care that could be attributed to specific patient outcomes, such as nurse characteristics (e.g. nursing experience and education), scheduling patterns, type of care provided on the unit, and variations in patient severity of illnesses (Lang et al. 2004; Lankshear et al. 2005; Kane et al. 2007b; West et al. 2009; Brennan et al. 2013).

The review authors point to the weaknesses and drawbacks of the primary studies that used unit-level of analysis, while the unit-level primary studies had more choice in the methods used for measuring and collecting data. The primary studies that used unit-level data tended to have smaller sample sizes and weaker external validity (Brennan et al. 2013). In addition, the unit-level of analysis proved to be an expensive method for collecting data. The variations in the definitions of variables led to inconclusive results across the primary studies, and generalisability was limited because these primary studies were conducted on a small number of units (Brennan et al. 2013).

4) Analytical methods

The synthesis of findings across the 10 review articles revealed three analytical issues that contributed to variations in the results in this area of research: 1) violation of the assumptions of statistical tests, 2) distinguishing between clinical and statistical significance, and 3) the timing of the data collection.

With regards to the first challenge, Lang et al. (2004) noted that a few of the primary studies lacked descriptions of the adjustments made, such as whether or how adjustments were made for multiple statistical comparisons, adjustment for severity of outcomes, and reporting of baseline rates of outcomes. For example, if the baseline adverse event rates were already low, increases in nurse staffing would not demonstrate any effect, while high rates of specific events would be largely affected by improvements in nurse staffing levels (Lang et al. 2004). Moreover, Lang et al. (2004) recommended that if the clinical implications of an adverse event are to be determined, the severity of the event must be reported, because interpreting the importance of an adverse event rate is confounded by a lack of knowledge about the severity of events. For example, the implications of pressure ulcers are confounded by the fact that the financial and clinical consequences of stage 1 or 2 ulcers may differ substantially from the consequences of deeper ulcers, such as those in stage 4 (Kane et al. 2007b).

Another statistical issue noted in the review articles was that the interpretations of the clinical importance of using regression or correlation coefficients were not expressed in the results. Instead, the authors of the primary studies usually judged the results to be positive or negative on the basis of ρ −values alone, independent of the effect size (Stalpers et al. 2015). Many primary studies used linear regression analysis with no assurance that the data actually showed linear relationships between patient outcome measures and various nurse staffing categories (Lang et al. 2004). The review by Kane et al. (2007b) attempted to test a number of hypotheses that included assumptions of nonlinear relationships between variables. The authors found that nonlinear relationships existed between nurse staffing and certain NSOs, such as medical complications and unplanned extubation in intensive care settings (Kane et al. 2007b).

The second challenge was related to distinguishing between clinical and statistical significance. Lang et al. (2004) and Unruh (2008) reported that the authors of primary studies usually did not report the effect size or the clinical significance, or the amount of change in patient outcomes that occurred because of changes in nurse staffing. Finally, the timing of data collection was found to be another challenge with regards to analytical methods. West et al. (2009) indicated that some primary studies collected data on nurse staffing information and patient outcomes at different times, thus making it difficult to interpret the influence of nurse staffing on patient outcomes.

3.3.7 Conclusion

The evidence reviewed identified that a number of patient outcomes could be linked to nurse staffing and nurse work environments. These outcomes can be grouped into the following categories: adverse patient events, in hospital mortality, length of hospital stay, and failure to rescue. While these patient outcome indicators have been linked to nurse staffing and other organisational factors in inpatient settings, there is a need to identify outcomes sensitive to nursing inputs and interventions in ambulatory care settings, as these categories are not especially relevant to the ambulatory setting.

Regarding nurse staffing, the review authors identified several definitions and measures of 'nurse staffing' across the primary studies. There is no scientific evidence to support specific definitions, and each depends on the patient and nurse characteristics, the work environment for nurses, and the type of unit where care is provided. Also, it is difficult to generalize these definitions in the context of ambulatory care because they were all designed to address the concept in in patient units. In brief, this meta-review identified different measurements of nurse staffing, with no standard methods of calculating either skill mix or nurse-to-patient ratio. Since a nurse ratio sufficient on one unit might not be on another, depending on the patient and nurse characteristics, definitions applicable to the patient care setting under study are desirable.

It must be acknowledged that some of the review articles outlined above have serious methodological flaws, which limit the generalisability and the power of their individual findings. Moreover, it is clear that the variations in reported patient outcomes and the adoption of different definitions and methods in identifying nurse staffing influenced the results of the primary studies. Therefore, comparisons, even among those that appear to be methodologically compatible, are open to debate.

In conclusion, many factors may affect patient outcomes, and nurse staffing is only one potential contributor. A large body of research recognises that there are factors beyond nurse staffing that may directly influence the outcome of patient care, such as nurse characteristics and organisational factors. This meta-review identified a pool of factors that could be considered when studying the relationship between patient outcomes and nurse staffing that would influence the quality of nursing care provided in ambulatory care. For example, unit size and layout, patient acuity, nurse experience and education, the type of hospital, and nursing care hours.

3.3.7.1 Evidence gaps

This meta-review identified important evidence gaps. Firstly, it points to the absence of studies that examine the relationships between nurse staffing or nurse work environment and patient outcomes in ambulatory care settings. Secondly, although this meta-review addressed the relationship between nurse

staffing and patient outcomes in AC, intensive care, medical and surgical settings, the findings cannot be generalised to ambulatory care settings. However, the findings from the meta-review can be used to inform future research to advance the science in this area, specifically in ambulatory settings.

3.4 Chapter summary.

To sum up, three main themes arose from the review of the literature: 1) The limitations of current nursing quality monitoring and reporting processes in Saudi Arabia, 2) Universally, researchers are just beginning to identify standards with meaningful indicators of quality for many aspects of care in ACSs – this is to say, a valid and reliable set of indicators and research methods must first be available – and 3) Information about ACSs' work environment should be documented and addressed prior to intervening further.

To date, there is no published evidence to quantify variations in the patient-reported outcomes (PROs) and patient reported process (PreP) of adult cancer patients receiving their treatment in ACSs in the KSA. This raises questions about symptom management and the quality of health care delivered to patients in the KSA. Establishing whether PROs in ACSs in the KSA vary can best be answered through a multicentre study in which chemotherapy patient-reported indicators of symptom and experience are measured in a valid and reliable manner, and factors that might potentially explain variation are also collected. Based on the results of the previous project of Armes et al. (2014), this study aims to explore a range of methodological and feasibility issues that relate to the development and implementation of NSOs indicators and associated tools to characterise unit and nursing workforce in ambulatory chemotherapy settings in the KSA. The next chapter provides an overview of the study design.

Chapter 4: Overview and introduction to design of the study

4.1 Introduction

The chapter starts by describing the research design, aim and objectives and research questions. Then, a summary of the study design and methods of the three different stages used to achieve the purpose and aims will be provided. Next, the setting, population and sample will be described along with how participants were approached, and the instruments for data collection will be presented. Finally, this chapter will end with a discussion of the ethical aspects of the study. Later chapters provide detail on each stage of the study.

4.2 Purpose of the research

The literature search revealed there is little literature on measures of Nurse-sensitive outcomes (NSOs) in ambulatory care settings, and that this is significantly more limited when focusing on NSOs in ambulatory chemotherapy settings.

In order to confidently design a study to address whether variability exists in NSOs amongst ambulatory chemotherapy services (ACSs) in the KSA, it was necessary to adapt a pre-existing instrument that had been demonstrated to be reliable and valid in the UK context. Following the development of a new instrument or when applied in a new setting a researcher should precede with a small-scale study to assess the feasibility of the instrument. In addition, this can address the question of whether such a study could be carried out in the KSA and provide the basis for planning a large multi-centre survey producing evidence that could be generalised more widely to other ambulatory care services in the KSA.

4.3 Aims and objectives of this study

The overall aims of this study were to explore a range of methodological and feasibility issues that relate to the development and implementation of Nurse-sensitive outcome indicators (NSOIs) and associated tools to characterise unit and nursing workforce in ambulatory chemotherapy settings in the KSA. It also

aimed to explore whether variability exists in the NSOs amongst ambulatory chemotherapy units in the KSA.

To achieve this, a 2-step development strategy was followed: 1) developing and validating the indicator set (PR-CISE and associated tools) and recruitment processes (Stages I and II); 2) Testing the feasibility of the indicator set in practice and preparing for implementation of the indicator set (Stage III).

Step 1: Developing and validating quality indicators for ambulatory chemotherapy settings. The objectives were:

1. To identify key methodological issues and challenges in developing and implementing nurse-sensitive outcomes measures and associated tools to characterise unit and nursing workforce in ambulatory chemotherapy
2. To adapt the PR-CISE (patient-reported outcome and process indicators that are sensitive to the quality of nursing care in ACSs) instrument for use in the KSA
3. To validate the PR-CISE Arabic version
4. To develop and validate the associated tools including a nursing workforce and unit characteristics (NWUCs) instrument for describing the structural characteristics of ACSs, and recruitment materials

Step 2: Test the feasibility of the indicator set in practice and preparing for implementation of the indicator set. The objectives were:

1. To estimate or clarify important parameters to inform how the proposed study design should be adapted to optimize data collection in any future large-scale study, specifically;
    i) Identify the number and characteristics of eligible patients that can be recruited within a one month timeframe, and the dropout rate
    ii) Time needed to recruit targeted sample
    iii) Estimate time needed to collect and analyse data
    iv) Perform a sample size calculation for definitive survey

2. To determine the acceptability of the PR-CISE and NWUCS measures and completion process with a sample of participants in the KSA through monitoring attrition, adherence and responses
3. Ascertain suitability of research methods for collecting data with the PR-CISE and NWUCS measures for use in a future survey
4. Identify any problems in the PR-CISE and NWUCS measures, design and process of conducting the survey
5. Assess the feasibility and suitability of planned analysis to examine variation in NSPOs

4.4 The research questions to be addressed in the large-scale study

Primary Question

1. Is there variation in nurse-sensitive outcomes amongst patients with cancer who are undergoing chemotherapy in ambulatory chemotherapy services in the Kingdom of Saudi Arabia?

2. Is it possible to use the planned research methods to collect routine data on nurse-sensitive outcome indicators in the KSA?

Secondary Questions

1. How do ambulatory chemotherapy services (ACSs) in the KSA vary in terms of working hours, unit size, staff mix, shift pattern, and chemotherapy regimens used?

2. What approaches to nurse staffing (e.g., skill mix patterns) are currently implemented in chemotherapy outpatient units in the KSA?

4.5 Design

This descriptive study was designed to investigate the feasibility of using NSO indicators (PR-CISE) and associated tools to assess the variation in QoC in ACSs. Results from the feasibility study were intended to inform the design of a large-scale survey to identify the variation in QoC and establish the link between NSO indicators and structural and process measures.

4.6 Summary of the three stages of the study

Stage I: Developing and validating the survey instruments

The key task in this stage was to translate, develop and adapt the PR-CISE measure to make it suitable for use in a population survey in the KSA. Also, work at this stage focussed on the development of associated tools to characterise unit and nursing workforce in ambulatory chemotherapy settings in the KSA, data collection process and recruitment materials.

Stage II: Testing acceptability and usability of data collection tools

To explore acceptability feasibility work addresses whether the measurement tool is judged to be suitable and attractive to both administrators and recipients. The purpose of this stage was to ensure that survey processes were acceptable. This was measured through analysis of attrition and adherence. This stage was an essential part of the feasibility study as it helped in assessing to what extent the survey could be implemented as planned and what elements would require revision.

Stage III: Implementation

For implementation, a feasibility study asks how the survey might be best delivered to the intended participants in a defined context. In this stage, four key tasks were planned. The first task was to evaluate the likelihood that the study could be fully implemented as planned and produce meaningful data. In addition the second task was to estimate or clarify important parameters to inform how the proposed study design might be adapted to optimize data collection in any future large-scale study. Thirdly, to identify any problems in the PR-CISE and NWUCS measures, design and process of conducting the survey. Finally, to assess the feasibility and suitability of planned analysis to examine variation in NSOs (see Figure 4-1 for a summary of the above).

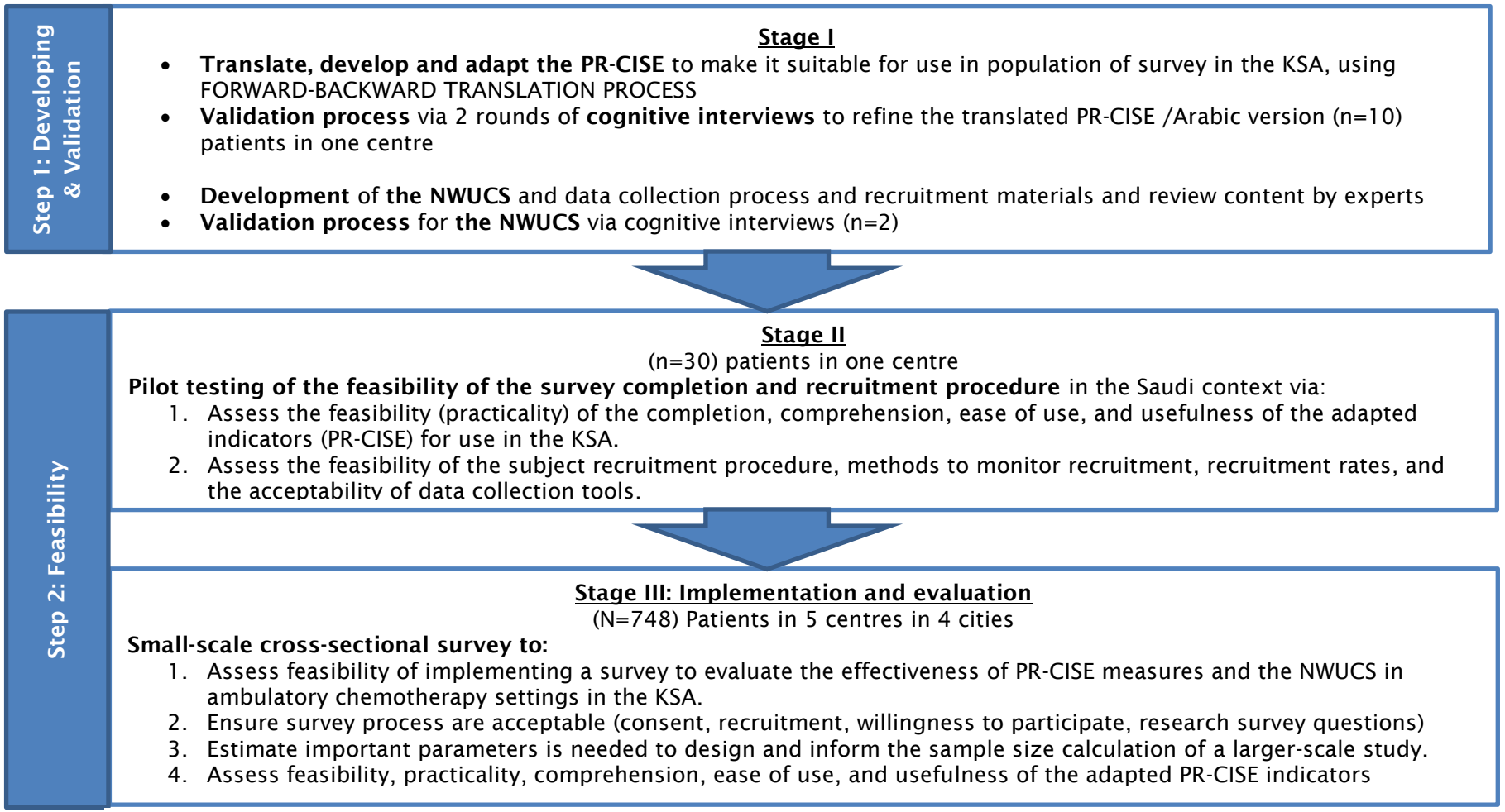


Figure 4-1 The two steps and three stages of the study

4.7 Setting

For the first two stages a single hospital Ambulatory Chemotherapy Service (ACS), was selected. This hospital delivers chemotherapy services to approximately 70 cancer patients a week, from different regions of the KSA. For Stage III, the two major provinces of KSA, Riyadh and Makkah, see Figure 4-2, were selected. These provinces were chosen due to their strategic location, transport and access, and large population. They include governmental and semi-governmental hospitals, which cover four different health care sectors (Armed forces, Medical Cities, National guard and Specialist Hospitals). All eight hospitals with ACSs located in these provinces were invited to take part. These hospitals represent a range of features present in the KSA health system and additionally treat a large number of chemotherapy patients. Ethics approval was ultimately obtained from five hospitals. These ACSs also vary in terms of the average number of patients receiving chemotherapy treatment per month. This variation was needed to represent a spectrum in terms of the size of the unit and likely complexity of chemotherapy delivered. This difference allowed the researcher to test the feasibility of implementing nurse-sensitive measures and associated tools, and data collection in the range of hospital types found in the KSA and incorporate ACS of different sizes.

Figure 4-2 Provinces of Saudi Arabia: the study areas comprised Riyadh and Makkah provinces

4.8 Participants

Patients: In all stages the target population was restricted to adult cancer patients undergoing chemotherapy in ambulatory services.

4.8.1 Inclusion and Exclusion Criteria for Sample Selection for all three stages

Inclusion criteria

a. All adult patients aged 18 years or older who were undergoing chemotherapy in an ACS in the chosen hospitals.

b. Patients who had received at least one cycle of chemotherapy in an ACS, with no specific eligibility criteria regarding the maximum number of previous chemotherapy cycles the patient received.

c. Patients who were able to respond to questions and can read and write in Arabic (for Stage I only).

Exclusion criteria

a. Patients who were receiving their first dose of chemotherapy.

b. Patients visiting the unit but who were not currently receiving chemotherapy.

Staff: all nurses, care assistants and secretary working on participating ambulatory chemotherapy services during 2nd and 3rd stages of data collection were invited to take part as volunteer staff, to support data collection process. In addition the unit head nurse managers or their representatives were invited to complete the NWUCS form.

4.9 Research Instruments

This study used an existing patient-reported questionnaire (PR-CISE) that incorporates specific indicators of quality (nurse-sensitive outcomes) (Griffiths et al. 2011a). Also, it used information collected through NWUCS (a data collection pro forma developed specifically for this study). See Table 4-1.

PR-CISE Measures

To assess the QoC delivered to patients, this study used an existing questionnaire; Patient-reported Chemotherapy Indicator of Symptoms and Experience (PR-CISE) developed by Griffiths et al. (2011a). With regard to NREM, this measurement tool incorporated the specific quality indicators related to the care process and nurse-sensitive outcomes, as well as the structural elements specific to patient demographic characteristics.

PR-CISE is a 22-item self-report survey consisted of three sections. Section A designed to collect structural and process indicators namely: chemotherapy regime and patient experience of informational support for self-management of symptoms. Section B, also, focuses on outcomes and process indicators. Patients were asked to report on the severity of a range of symptoms experienced that had been identified as potentially nurse-sensitive outcomes since the last cycle of chemotherapy, as well as patient experience of care provided by nurses at the setting in order to assess what nurses do. Section C requires information about structural indicators, specific to patient demographics. See Table 4-1.

Permission was sought, by email, from Professor Peter Griffiths to use the questionnaire for this study. Permission was granted on 10th April 2013. As the current study was conducted in the KSA, the PR-CISE questionnaire was translated into Arabic using a Forward-Backward technique (to be described in more detail in Section 5.2.3 page 102).

Associated tool: Nursing Workforce and Unit Characteristics Survey (NWUCS)

Various types of data collection forms to capture unit variables were considered for this study. However, none were found to be suitable for this particular research, as they did not fit the purpose of current study; specifically ACSs nurse staffing, or characteristics of units. Therefore, it was decided to develop a Nursing Workforce and Unit Characteristics Survey (see Appendix E) that would cover the areas of interest and help to answer the study questions by corresponding to the results of the PR-CISE. In addition, the researcher used

the information gained from this instrument to collect data about differences in workforce characteristics and deployment in the units involved in the study.

Table 4-1 The conceptual framework of the study

Structure	Source of data	Process	Source of data	Outcomes	Source of data
Patient	· Self-reported PR-CISE				
· Age · Gender · Chemotherapy cycle · Mode of chemo administration · Rote of chemo administration · *Diagnosis (site or type of primary cancer) · *Type of chemo	· *The unit patient log book	**Independent role** **Nursing intervention:** · Patient and family education · Assessment of chemotherapy side effects	· Self-reported PR-CISE	**Nurse-sensitive outcomes** **<u>Severity of subjective symptoms:</u>** · Nausea · Vomiting · IV-line pain/irritation · Oral problems · Weakness and tiredness · Sign of infection · Feeling low or depressed · Distress Thermometer	· Self-reported PR-CISE
Nurse · Certification	· NWUCS	**Interdependent role** **Coordination of care:** · Symptom management	& · NWUCS		
Organisation · Skill mix · Nurse-to-patient ratio · Working hours · Unit size · Shift pattern · Hospital type	· NWUCS				

4.10 Ethics

4.10.1 Ethical approval

First, ethical approval for the study was obtained from the University of Southampton, Faculty of Health Sciences Ethics Committee no. 8377 on 11/12/2013 (see Appendix F). In the KSA, each research site committee had different timelines for ethical review meetings, operating procedures, and requirements. Therefore, ethical approval was obtained from the Research Ethics Committee at the targeted hospital, on 08/04/2014, before proceeding with Stages I (CIs) and II (pilot testing) and before travelling to the KSA to collect data.

Whilst stages I and II were being conducted the researcher approached the ethical approval committees of the potential seven centres in the KSA, to gain permission before commencing Stage III of the study. Permission from five centres was eventually obtained.

4.10.2 Ethical considerations

It could be argued that strength and utility of research starts with a sound understanding of ethical considerations as they relate to the study. In this study, the researcher gave consideration to four ethical issues, including respect for persons/autonomy, justice, non-maleficence (do no harm), and beneficence (do good).

4.10.3 Respect

All potential participants were adult patients, and thus considered as autonomous persons with the capacity to make rational decisions. Participation in this study was not compulsory, meaning that the decision to refuse to take part or withdraw from the study would not affect the patient's relationship with their nurse, or their treatment plan. Moreover, via the information sheet, it was explained to participants, from all centres at each stage, that they must not feel obliged to fill in the questionnaire due to pressure from nurses or colleagues.

In Stage I, as stated earlier, potential interview participants were given the questionnaire packs and at least 24 hours to consider the information before they decided whether to participate in the interview. Consent forms were signed and collected at the beginning of the interviews. Each interview was digitally audio-recorded, if permission was granted. The researcher explained the purpose of recording the interview before the participants signed the consent form.

4.10.4 Non-maleficence

The questionnaire has been designed to present minimal risk to the participants. However, it may cause issues for some, such as anxiety or fatigue, and the researcher understood that some participants might feel that the topics covered by the questionnaire were too sensitive and/or personal. It was planned that, during the data collection process, if a participant was distressed and felt s/he may need treatment or care, the researcher would refer them to their general physician or another key worker, such as a social worker. Information regarding the measures to be used to reduce risk at each stage is presented in Table 4-2.

Table 4-2 Potential risks to participating in this study and measures to reduce these

Possible risk	Measures to reduce risk
In Stage I (the cognitive interviews): concerns about the burden on patients due to fatigue, anxiety or being upset	1 – If a participant feels upset, anxious or fatigued at any time they may stop the interview. The researcher will not proceed unless the participant wants to. 2 – The interview can be stopped at any time if a participant needs to take a break. 3 – If a participant is distressed and feels s/he may need treatment or care, the researcher will refer them to contact their General Physician or another key worker, such as a social worker. 4 – If any patients express concern about any indicator on the questionnaire, the researcher will report this to her supervisor and consider amendments or changes to the question.
In Stage II (pilot testing): concerns about the burden on patients due to fatigue, anxiety or feeling upset whilst filling in the questionnaire	1 – If participants feel upset or distressed due to the nature of the questions, they can stop and withdraw from the study without giving a reason, as participation is voluntary. 2 – If a participant is distressed, the volunteer staff will refer them to a specialised counsellor or another key worker, such as a social worker, who is available at the respective centre. 3 – If any patients express concern about any indicator on the questionnaire, the researcher will report this to her supervisor and consider amendments or changes to this question before starting the next stage.
In Stage III (the Feasibility survey study): **concerns about the burden on patients due to fatigue, anxiety or feeling upset whilst filling in the questionnaire**	1 – If participants feel upset or distressed due to the questions, they can stop and withdraw from the study without giving a reason, as participation is voluntary. 2 – If a participant is distressed then the volunteer staff will refer them to a specialised counsellor or another key worker, such as a social worker, available in that centre.

4.10.5 Confidentiality

Anonymity ensures confidentiality and data protection (Burns & Grove 2005). Accordingly, confidentiality of research data and anonymity of participants were assured during the research process (i.e. during the pilot testing, the study and data analysis). In stages II and III, no names were used on any documentation, apart from on the consent forms. Each of the five centres was assigned an identification letter from A to E, meaning that only the researcher was able to identify the centre. These letters were also be used when coding the questionnaires and unit profile forms. In Stage I each audio-recorded

interview and its data (transcript and notes) was assigned an identification number to ensure that only the researcher was able to identify the participants.

In stages II and III, the confidentiality of individual questionnaires was maintained to protect the rights of the participants to take part in the survey without fear of reprisal. Participants were asked to not include their names or other identifying marks anywhere on the survey, or in their responses. As mentioned previously, each questionnaire was number-coded to maintain the participants' anonymity for the purposes of data analysis and preserving confidentiality. Respondents were asked to put their completed questionnaires into a sealed brown envelope and to place it in a locked research box to ensure that only the researcher could view it.

All aspects of the study, including the results, remained strictly confidential. The data were only used for the intended explained purposes, in line with current UK, KSA, and University of Southampton data protection principles. When data were analysed and reported at the unit level, units were identified using alphanumeric codes. Participants were assured that no individual or centre would be identified in any report or publication derived from the study.

4.10.6 Beneficence

The results for each participating unit will be provided to the relevant UHNMs, thus allowing them to use the findings for their own purposes, such as improving the QoC provided in their ACSs. Moreover, the results had the potential to improve patient services and benefit healthcare policymakers. This is especially true in the case of nurse administrators, who require evidence-based information about the effectiveness and benefits of nursing interventions, particularly in managing the symptoms experienced by cancer patients. This could also affect decisions about nurse staffing for ambulatory settings. Moreover, the study results could provide basic data as a basis for future research into chemotherapy treatment in ambulatory settings, especially in the KSA.

Chapter 5: Development and validation stage (Stage I)

5.1 Introduction

This chapter offers a description of the methods used to arrive at a questionnaire suitable for pilot testing stage. The key task during this stage was to translate, develop and adapt the PR-CISE and associated tools to make it suitable for use in a population survey in the KSA. This chapter is divided into two parts. Part I reports the development process of PR-CISE/Arabic version, and findings. Part II presents work undertaken to develop he NWUCS. Finally, the chapter concludes with a summary of this chapter.

5.2 Part I: Developing and validating of PR-CISE/Arabic version

5.2.1 Design

Two processes were undertaken to finalise the PR-CISE/Arabic version: 1) Forward-Backward translation technique, and 2) survey validation process through cognitive interviews (CIs). The results from CIs were used to make final changes to the survey.

5.2.2 Process of developing the study instruments

For instrument development, it was necessary to follow a valid guideline that would result in a robust instrument. Creswell (2009) stated that using good procedures of scale development leads to the development of a rigorous instrument. In fact, there are various strategies used in scale construction. It was decided to rely primarily on (DeVellis 2011) guidelines as the most current resource which researchers can use when developing measurement scales. DeVellis (2011) recommends the following eight steps:

1. Determine clearly what will be measured;
2. Generate an item pool;
3. Determine the format for measurement;

4. Have the initial item pool reviewed by experts;
5. Consider inclusion of validation items;
6. Administer items to a development sample;
7. Evaluate the items; and
8. Optimise the scale's length.

As mentioned earlier in Section 4.9, the PR-CISE questionnaire was developed by a panel of experts from King's College London and the University of Southampton (Griffiths et al. 2011a; Armes et al. 2014). The contents and themes derived from their existing systematic scoping review (Griffiths et al. 2011) were supported by three specific reference groups (clinical, patient and technical references). The final version of the 22-item self-report measure PR-CISE was pilot-tested in 10 UK national Health Service centres (cancer centres) for feasibility, acceptability and utility checking. The findings supported the feasibility and acceptability of PR-CISE as an indicator assessing the quality of care provided in ambulatory chemotherapy services (Armes et al. 2014).

In this study, the Arabic version was developed based on the adaptations of relevant questions from the pre-existing PR-CISE scale. Therefore, it was not essential to follow all of DeVellis' (2011) steps, so four steps were undertaken in this study, as explained below:

Step 1: Generate an item pool

The starting point was to determine the contents for measurement, particularly the 22-item self-report measure PR-CISE (Griffiths et al. 2011a), with items being added, removed or adjusted.

Step 2: Determine the scale of measurement for the items and the physical construction of the instrument.

In this step, the researcher created multiple choice and Likert-type scale formats with the codes 1) none, 2) mild, 3) moderate and 4) severe. Then, the questionnaire was translated into the language of the participants in the study (Arabic). The Arabic version of the PR-CISE questionnaire was sub-divided into three sections including 23 items.

- Section A focussed on 2 dimensions, namely (1) chemotherapy classification and (2) supportive care. During the development, I added two questions to section A (A2 and A3);
- Section B focussed on the three domains of quality, specifically, effectiveness, safety and experience. Most of the questions focussed on the severity of subjective symptoms experienced since the last cycle of chemotherapy (symptom assessment). The only safety question included was B1.3, which asked about severity of pain and irritation at the infusion site, and reflected the safety of chemotherapy administration; and
- Section C recorded patient demographics and clinical characteristics which included sex, age, site of cancer and mode of administration, to assess the effect of mix and adjust for it.

Step 3: Have experts review the initial item pool

The first version of the PR-CISE/Arabic questionnaire was reviewed for content validity by two experts, who were bilingual (Arabic and English) senior oncology nurses, in addition to the study supervisors. When the contents of all revisions were agreed upon, the PR-CISE/Arabic was translated again by the same English editors, who finally confirmed that the questionnaire was ready to be pre-tested in the cognitive interview (CI) process. Details of the translation process are provided below in Section 5.2.3.2.

Step 4: Administer items to a sample for validation

The prototype of the PR-CISE/Arabic questionnaire was used with 10 respondents in two rounds of CIs to assess respondents' understanding of the questionnaire items. To evaluate the questionnaire, two CI techniques, namely think aloud and verbal probing, were used. A content analysis was employed to explore and analyse problems raised, to determine solutions and to generate the modified PR-CISE/Arabic questionnaire. After this process, the questionnaire was ready for use in the next stage, namely pilot testing. See Section 5.2.4.

5.2.3 Step I: Translation

The PR-CISE questionnaire was originally developed by a research team in the UK. For the purpose of this study it has been translated from the English to the Arabic language, in order to use it in the KSA.

In order to ensure that the data are not subjected to the effects of errors within translation it is important to have good quality translation of instruments (Maneesriwongul & Dixon 2004). Although, there are several factors influencing the quality of translation such as the translator, back translation, culture and language (Chen & Boore 2010), Granas et al. (2014) highlighted two significant factors when translating instruments. First, ensure semantic equivalence, which is that the meaning of each item remains the same after translation, keeping the original meaning of the words and sentence structure as the source language. Second, because translating relates not only to language but also to culture, the content of the items should be relevant to the adapted culture. Brislin (1970) (cited in Chen and Boore (2010) stated that English prose, resulting from translation, can be varied through sentence length, sentence construction and word choice. In addition, Granas et al. (2014) emphasised that the same statement may perhaps not carry identical meaning as a result of different countries possessing different levels of different health literacy and culture.

The review of Maneesriwongul and Dixon (2004) revealed that six popular translation processes can be used to translate a questionnaire into other languages including Forward-only translation, Forward-only translation with testing, Back-translation, Back-translation and monolingual test, Back-translation and bilingual test, and Back-translation and monolingual and bilingual test. The back-translation is a recommended process, which is used when scales are to be translated to different cultures (Maneesriwongul & Dixon 2004; Yu et al. 2004).

There are no standard guidelines for the translation of instruments, and quality and methods used vary widely. The Forward-Backward translation process has been used in this study. In 1999, a group within the International Society for Pharmacaeconomics and Outcome Research (ISPOR) formulated standardised guidelines for the translation process of instruments for research purposes

(Wild et al. 2005). The Translation and Cultural Adaptation (TCA) working group of ISPOR produced a ten step framework and set out principles of good practice in the translation and cultural adaptation of instruments (Wild et al. 2005). These steps are: 1) Preparation; 2) Forward Translation; 3) Reconciliation; 4) Back Translation; 5) Back Translation Review; 6) Harmonization; 7) Cognitive Debriefing; 8) Review of Cognitive Debriefing Results and Finalization; 9) Proofreading; and 10) Final Report. Additionally, the WHO (2013) issued guidelines relating to the translation process, which includes the following steps that are: 1) Forward translation; 2) Expert panel Back-translation; 3) Pre-testing and cognitive interviewing; and 4) Final version (WHO 2013). In order to produce a good translated version of the PR-CISE that was not only linguistically equivalent to the original instrument but also culturally and conceptually equivalent and acceptable, this study involved the necessary steps with careful consideration of both the ISPOR and the WHO recommendations.

5.2.3.1 Translation assistants

Potential translation assistants were contacted via phone or email to invite them to assist in the translation process. Seven bilingual translation assistants were recruited to work with the researcher through the translation process (Forward-Backward translation). These translation assistants were recruited for their fluency in Arabic and English. Moreover, the assistants were also Arab, in order to be familiar with cultural sensitivities. Five of the seven were Postgraduate students attending the University of Southampton, Faculty of Health Sciences. The expert panel comprised a (clinician) senior oncology nurse and a Head Nurse of Oncology Treatment Area (both working at KFSH-RC).

5.2.3.2 Procedure

As mentioned earlier, the researcher followed the recommended guideline procedures of TCA (2005) and WHO (2013) to produce a validated translation. The seven fluent Arabic and English translation assistants worked with the researcher, who acted as a project manager, in the Forward-Backward translation process as shown in Table 5-1.

Table 5-1 The Forward-Backward translation process

Phase	Step	Assistants	Procedure
Forward translation (FT)	Step 1	FT 1, FT2 & the researcher	Translation to target language, completed independently by the researcher and 2 translation assistants FT1 & 2 to produce one translation each in Arabic
	Step 2	FT 1, FT 2 mediator	Synthesised both forward translations into one with the help from the researcher (mediator)
	Step 3	2 Experts bilingual senior oncology nurses	The first version of PR-CISE/Arabic questionnaire was reviewed for content validity; content of all revision had been agreed The final
Backward translation (Blind)	Step 1	Backward Translator 1	Translation to target language, completed independently by 2 translation assistants to produce one translation each in English
	Step 2	Backward Translator 2	Synthesised both backward translations into one with the help from the researcher (mediator)
Expert review		2 Experts bilingual senior oncology nurses and the researcher's supervisors	The final English version of the PR-CISE/Arabic questionnaire was compared with the original PR-CISE

First, the researcher and two assistants translated the English version into Arabic. Another pair of assistants, one post-graduate and the senior oncology nurse, reviewed the translation. The researcher and the four assistants worked together to reconcile any obvious differences in the instrument items found within the forward translation and discussed these discrepancies to agree on an initial Arabic version of the PR-CISE. The first translated version of the PR-CISE/Arabic questionnaire was produced with consensus of all four bilingual assistants and the researcher. Then, the first translated version of the PR-CISE/Arabic questionnaire was given to an expert Arabic linguist to edit and proofread. The proofread version was then given to two different bilingual assistants, to translate the questionnaire from Arabic back to English. They were completely blind to the original PR-CISE to reduce any potential bias. Then the researcher compared the back-translated version with the original copy of the original English PR-CISE version. Reconciliation of any differences between

the back translated version and the original copy and any amendments necessary were made in discussion with both backward translators. Then the researcher met with the translators to agree on the final version of the PR-CISE/Arabic.

Furthermore, this process was repeated only with the items that had been changed following round 2 of CI, the translation team confirmed that the PR-CISE/Arabic second version was ready to be used in stage II (Pilot testing).

5.2.4 Validation: The cognitive interview technique

5.2.4.1 Design

In this stage, the CI method was employed to refine the translated PR-CISE/Arabic version of the questionnaire, as will be described here. This also helped the researcher to determine how respondents answered the survey questions and to identify potential challenges with prospective survey items. Two rounds of CIs were utilised with two major sub-types of CIs, namely the think aloud and verbal probing techniques. The first round of CIs was conducted to modify the overall PR-CISE/Arabic version of the questionnaire in terms of understanding, general comments and wording, as well as to ensure an appropriate format would be used in the questionnaire. Meanwhile, round 2 focused on specific problems raised from the questions in round 1. These problems included the possibility of changes in light of recommendations from the respondents, in addition to assessing the feasibility of asking patients to complete the questionnaire when they attend chemotherapy and amending the toolkit as necessary. Revisions to the prototype questionnaire were carried out after each round.

5.2.4.2 What is cognitive interviewing?

CI is a pretesting technique which has been widely used since the 1980s, which Willis (2005) explained as a methodology that provides tools for researchers to understand the processes through which respondents answer survey questions. In the early stages of a questionnaire development process, the CI technique is a popular method for refining and validating questionnaires (Buers et al. 2013), as it focuses mainly on the survey questions rather than on the

entire survey administration process (Willis 2005). CI techniques are methods aimed at enhancing data quality by improving questionnaires, and can be used for questionnaires administered to chemotherapy patients.

Furthermore, CI assesses respondents' understanding and interpretation of items to reduce potential measurement error and improve the validity of the questions (Dillman 2007). CI allows integration of cognitive theory and the survey methodology, as it grasps and elicits the respondents' understanding of the items. According to Tourangeau's (1984) cognitive processing model, answering survey questions involves four stages (Willis 2005) see Figure 5-1.

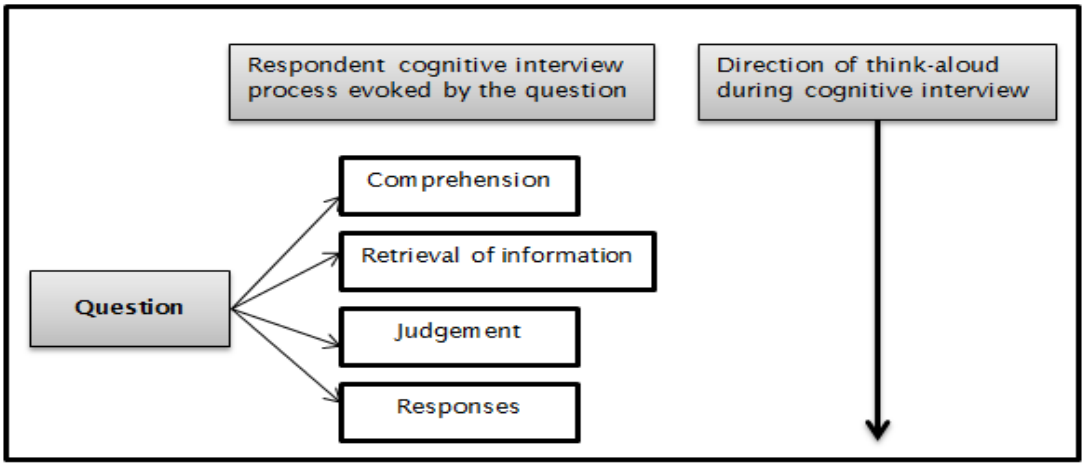


Figure 5-1 The four basic cognitive processes involved in answering questions

These stages are as follows: (a) comprehension, for example, understanding questions or following instructions as intended; (b) retrieval, such as remembering relevant information; (c) judgment, including final formulation of a response based on relevant memories; and (d) actual response, such as producing a response that is consistent with the individual experience (Collins 2003; Willis 2005) (see Table 5-2).

Moreover, Collins (2003) indicated that CI has the potential to improve the scientific quality of patient-reported outcomes, as it provides insight into various components of the response process. Unfortunately, there is no consensus on how to conduct, analyse or report CIs (Knafl et al. 2007).

Table 5-2 Cognitive Stages, Definitions, and Possible Response Errors

Stages	Definition and Possible Error
Comprehension	Respondent interprets question based on question intent and meaning of terms. Possible Errors: Unknown terms, ambiguous concepts, long and overly complex
Retrieval	Respondent searches memory for information needed to recall answers as well as the strategies used for information recollection. Possible Errors: Recall difficulties
Judgment/ Decision Process	Respondent evaluates response based on motivation and sensitivity/ desirability. Possible Errors: Biased or sensitive, estimation difficulty
Response	Respondent provides information in the format requested and considers the degree of difficulty experienced as s/he formulates an accurate response. Possible Errors: Incomplete response options

Think-aloud and verbal probing are the two common interviewing methods used in CI. Think-aloud is usually conducted as participants complete the survey; they are asked to read the questions out loud and verbalise their thought processes as they fill in the questionnaire. On the other hand, verbal probing is conducted once the participant has completed the survey. Here, the interviewer asks follow up questions to understand a respondent's interpretation more precisely and clearly. This process includes open-ended verbal probes, for example, 'Were any questions harder to answer than the rest?'. It is suggested that both techniques (think-aloud and verbal probing) be combined to elicit as much information as possible on participants' interpretations and thoughts about the questionnaire.

5.2.4.3 Setting

Because the interviews needed to be completed within a very short time period (approximately six weeks), a convenience sample of key informants (e.g. adult patients with cancer who had previously received chemotherapy in ambulatory settings, could read and write in Arabic and were cognitively able to

participate) was used. Willis (2005) recommends a sample size of 5 to 10 respondents for undertaking CIs. In this stage, the CI technique was used with a sample of 10 chemotherapy patients.

As mentioned in Section 4.7, this stage was carried out at one hospital over a four-week period (13/04/2014 – 10/05/2014). The researcher decided to choose this hospital because it is a government hospital with similar eligibility criteria to the main study sample population.

5.2.4.4 Eligibility criteria

The eligibility criteria for CIs were like the criteria for stages 2 and 3 (see Section 4.8.1).

5.2.4.5 Sample size

Recruiting began in early April 2014. In round 1, 11 potential participants, who met the inclusion criteria of the study, were recruited. Five of these respondents were willing to take part in this stage of the research, and were invited to participate in the CIs. In round 2, 15 eligible patients were invited to participate in the CIs, but only 5 did so. Overall, 10 eligible patients participated.

5.2.4.6 Recruitment materials

The questionnaire package was distributed to each potential participant by volunteer staff (research assistants). The package consisted of the invitation letter, the information sheet, consent form, and the questionnaire, (see Appendix G).

5.2.4.7 Recruitment strategy

After receiving the hospital's ethics committee approval, the researcher asked permission to recruit patients who attended a follow-up clinic, inviting them to participate in the CIs. First, when eligible patients arrived for their review or follow-up appointment, a volunteer member of staff at the desk informed them about the study. Second, when a patient agreed to a meeting or asked for more information about the study, the volunteer staff member introduced the researcher to the patient.

The researcher was available at the hospital, in a pre-booked room, during this stage to meet with patients who agreed to participate, and provide them with additional information about the study. In these meetings, the researcher arranged a convenient time to meet to conduct the interview. Potential participants were given time, at least 24 hours, to make a decision regarding whether they would like to participate in this pretesting stage. Finally, when a patient agreed to take part in the study, the researcher arranged for a mutually convenient time to conduct an interview.

5.2.4.8 Procedure

As mentioned earlier, two rounds of CI were conducted using the face-to-face, semi-structured interview technique. Five eligible patients participated in each round. CIs were conducted over a period of four weeks, with no more than two interviews per day. Based on Willis (2005), a maximum of one hour was determined as the limit for data collection, including both think aloud and verbal probing activities. Each interview employed both methods as follows. The CI protocol can be found in Appendix H.

In the first CI activity, the researcher instructed the participants to think aloud while they read and responded to the questionnaire, which helped the researcher to understand the participants' thought processes in arriving at an answer. In addition, they were instructed to mark items they found confusing/difficult to understand, upsetting/intrusive or annoying while completing the questionnaire. Although the participants were given space to complete the questionnaire without interference, the researcher was available in the room to answer any additional questions raised by the participants. When a participant indicated that he/she was finished, the researcher began the second activity.

In the second activity, each participant was interviewed to determine the appropriateness and clarity of the items in the questionnaire, and both concurrent and spontaneous verbal probing were used. In other words, at the end of the think-aloud activity, the participants were asked follow-up questions (probing) focusing, for instance, on how they chose their answers (more examples can be found in (Table 5-3). Such probing is an effective technique

for use in testing self-administered surveys (Willis 2005), as it helped the researcher to learn where and how she could improve this questionnaire. In addition, using retrospective and concurrent verbal probing helped the researcher to encourage participants to elaborate on their responses when necessary.

Following the first round, changes were made to the questionnaire to reflect on the feedback received on the content, clarity and design, as necessary. Then, the revised questionnaire was ready for the second round of CIs, which was conducted to test the changes made to the prototype of the PR-CISE/Arabic questionnaire. In addition, it helped to identify further necessary changes that could be made to the questionnaire to improve clarity prior to its distribution to the study subjects (Dillman 2007; Izumi et al. 2013). At the end of this stage, the Arabic version of the PR-CISE questionnaire was ready for pilot testing.

Table 5-3 Probing examples used during the cognitive interviews classified according to Beatty and Willis (2007)

Approach	**Type of probing**	**Probing example addressed during the interview**
Concurrent		
Pre-scripted	General Paraphrasing Comprehension Judgment Recall	How did you arrive to that answer? Was this easy or hard to answer? Can you repeat the question in your own words? What does the term 'symptoms' mean to you?
Spontaneous	General Comprehension	How well do you remember this? Why do you chose 'Mild' and not 'severe'? What do you mean with 'this question is difficult? How could this question be more comprehensible? Could an extra response category provide a solution?
Retrospective		
Pre-scripted	General	Are all things addressed during this interview that is important to you regarding your chemotherapy symptoms management and care?
Spontaneous	General	What do you think about this questionnaire? Would you like to add an extra question about that? Was there any difficult question to answer?

5.2.4.9 Data processing and analysis

In round 1, the goal of the preliminary analysis of the data was to identify incomprehensible or inconsistent items in terms of understanding, wording, general comments and format in the PR-CISE/Arabic version. Such items were then deleted or modified to reduce potential response errors and improve the quality of data obtained using the PR-CISE/Arabic questionnaire. In round 2, the content analysis of the data mainly focussed on the following three areas: 1) specific problems raised in the questionnaire in round 1; 2) changes made to the items in light of respondents' recommendations and 3) undetected problems.

The analytical process chosen for this stage was a content analysis based on recommendations for CIs developed by Willis (2005). A content analysis has the ability to detect the content and context of difficulties in questionnaire responses and to elucidate emerging themes (Creswell & Clark 2011) and the frequency of those themes (Ritchie & Lewis 2003). Due to the small sample size, and to save the researcher time that would be spent, for instance, learning a new technology like NVivo, a thematic analysis of the data was carried out, and codes and themes were identified and extracted manually.

The process was conducted as follows. First, the researcher listened to the tape recordings of the interviews, and then the interviews were transcribed. Transcripts and notes collected from the CIs were examined individually, line by line. Then, problematic items were marked with problem codes using the coding systems of Levine et al. (2005) and Willis (2005). Each code is briefly described in Table 5-4. Moreover, the problem codes were used to consider potential sources of errors in questionnaire development and to classify problems with the questionnaire. Next, problem codes were tallied for each section of the questionnaire to assist in identifying what changes are required. It should be stated that while coding assisted in determining the frequency with which problems were identified, examining only the frequency of problem codes does not necessarily indicate the seriousness of problems. Moreover, items revealed as problematic were discussed with the supervisor, which helped to confirm corrective actions when issues with the questionnaire did arise.

Table 5-4 Coding systems for classifying questionnaire problems from Levine et al. (2005) and Willis (2005)

Levine et al. (2005)	Willis (2005)
Comprehension: Items with unclear or ambiguous terms, failed to understand the questions consistently	**Clarity:** Problems with the intent or meaning of a question *Subcategories:* wording, technical term, vague and lack of reference periods
Knowledge: Items for which respondents lacked information to answer a question	**Knowledge:** Likely to not know or have trouble remembering information *Subcategories:* knowledge, recall, computation
Inapplicable: Items measuring construct that are inapplicable for many respondents (e.g. made assumptions)	**Assumptions:** Problems with assumptions or underlying logic *Subcategories:* inappropriate assumptions, assuming constant behaviour and double-barrelled
Construct: Items failed to measure the intended construct	**Response categories:** Problems with the response categories *Subcategories:* missing, mismatch question-answer, vague, open-end questions, overlapping and illogical order
Subtle: Items making discriminations that are too subtle for many respondents	**Sensitivity:** Sensitivity nature or wording/bias *Subcategories:* Sensitive content (general), sensitive wording (specific) and socially acceptable
General: Several other general issues associated with the development of a questionnaire	**Instructions:** Problems with introductions, instructions or explanations
	Formatting: Problems with layout or question ordering

5.2.4.10 Corrective actions

In response to problems reported by respondents in completing the questionnaire, there were several potential corrective actions to take. In this study, the types of corrective action were adapted from Willis (2005), as described below.

1) Change in wording: This action was taken when the original intent of the indicator was not captured adequately, or when particular words were unclear or confusing.

2) Change in the instruction or introduction of indicators: This action was taken when problems in the introduction or instruction were identified.

3) Improve the response categories: Response options were refined when the responses provided by respondents did not match the response options available on the questionnaire.

5.2.4.11 Linking problem codes to corrective actions

The problem codes and corrective actions assisted in identifying when changes to the questionnaire were required. After round 1 significant changes were made to the questionnaire, and all changes were reviewed by the researcher's supervisor and two bilingual (English and Arabic) senior oncology nurses prior to CIs round 2. This was done to ensure ample justification for making the suggested change. The final questionnaire at end of the CIs reflected the layout and wording determined to be clearest in the cognitive interviews.

5.2.4.12 Findings from stage I: Development and validation of the PR-CISE/Arabic version

5.2.4.12.1 Introduction

This section begins with the findings of the recruitments and demographic characteristics of the respondents. This followed by an illustration of the findings from interviews conducted from two rounds of CIs consecutively.

5.2.4.12.2 Recruitment

In round1, eleven chemotherapy patients were recruited to take part at this round, eight agreed to be interviewed. Of the eight patients, three cancelled their interviews as they were afraid of contracting the coronavirus infection. Therefore, five patients participated in this round.

In round two, an effort was made to recruit older-aged patients (70+ years old) as there were none in round 1. During the recruitment stage, four 70-year-old patients were deemed eligible to participate in this round; however, three were excluded because they were not able to read and it would have been insensitive to have them participate in this study. Whereas, one participant agreed to take part in a different way, by using the think-aloud activity with interviewer administration. This reflects the high Saudi illiteracy rate among the group aged 60 to 70+, and is more prevalent among females than males.

Overall, 15 eligible patients were invited to participate in this round 2, of which eight (53%) refused to take part in this round of the interviews. The reasons behind refusing to participate were that three were happy to fill in the self-report questionnaire but not to participate in a CI. Three patients reported transportation as the reason for not taking part, while the other two patients were not aware of their diagnosis and their carers refused to include them in this study. One participant provided no explanation.

Furthermore, seven of the 15 patients agreed to take part in this round. However, two patients were excluded, with one potential participant withdrawing on the same day of the interview after being given more information about the nature of the CI. The other participant did not provide any explanation, but chose not to show at the scheduled time. Consequently, at this round, five patients were interviewed.

5.2.4.12.3 Demographic characteristics

Table 5-5 details the demographic characteristics of the participants in stage I, rounds 1 and 2. In round 1, of the five participants, three were males. The participants were aged between 18 and 70 years. There were no participants aged 70+ years in this round. Table 5-5 shows that at least one participant from each age group participated in this round, except for the oldest age

group (70+ years), of which there were no participants. One of the five participants was having 12+ cycles of chemotherapy, two were having three cycles and two were having four cycles.

In round 2, in total, five patients with ages ranging from 31 to 70+ years participated in the interviews. As indicated in Table 5-5, two (n = 2) participants were having more than 12 cycles of chemotherapy. In addition, 20% of the participants lacked data related to the cancer, one of whom was unaware of their diagnosis. The majority of patients (80%) asked their chemotherapy nurses about the names of their chemotherapy drugs, while one (n =1) participant knew the name of their chemotherapy.

Table 5-5 Demographic and clinical characteristics of the participants in round 1 and 2

Question		Round one n (%)	Round two n (%)
C1. Chemotherapy cycle			
	2	0	0
	3	2 (40)	0
	4	2 (40)	0
	5	0	1 (20)
	6	0	0
	7	0	1 (20)
	8	0	1 (20)
	9	0	0
	10	0	0
	11	0	0
	12+	1 (20)	2 (40)
	Missing data	0	0
C2. Type or site of the primary cancer (diagnosis)			
1.	**Bladder/Urological (not prostate)**	0	0
2.	**Blood (Leukaemia)**	1 (20)	2 (40)
3.	**Bowel**	0	1 (20)
4.	**Brain/central nervous system**	0	0
5.	**Breast**	1 (20)	1 (20)
6.	**Gynaecological (womb, ovaries)**	0	0
7.	**Head or neck**	1 (20)	0
8.	**Lung**	1 (20)	0
9.	**Lymphomas**	1 (20)	0
10.	**Mouth or oesophagus**	0	0
11.	**Prostate**	0	0
12.	**Stomach**	0	0
13.	**Other**	0	0
14.	**Don't know**	0	0
15.	**Missing data**	0	1 (20)
C3. Mode of chemotherapy administration			
1.	**IV**	5 (100)	4 (80)
2.	**IV and tablets**	0	1 (20)
3.	**Tablets**	0	0
4.	**Missing**	0	0
C4. Device for chemotherapy administration			
1.	**Temporary IV needle (Peripheral cannula)**	4 (80)	5 (100)
2.	**PICC line**	0	0
3.	**Central venous catheter (Portacath or Hickman)**	1 (20)	0
4.	**Missing**	0	0
C5. Age of the subject in years			
	18-30	1 (20)	0
	31-40	1 (20)	1 (20)
	41-50	1 (20)	1 (20)
	51-60	1 (20)	1 (20)
	61-70	1 (20)	1 (20)
	71+	0	1 (20)
	Missing	0	0
C6. Gender of the subject			
	Male	3 (60)	3 (60)
	Female	2 (40)	2 (40)
	Missing	0	0

5.2.4.12.4 Completions and duration of the CIs

The completion time was reduced from 8-16 minutes in round 1 to 5-8 minutes in round 2, which was judged to be more acceptable for a self-report questionnaire intended to be completed by patients while receiving treatment. Duration of the ten CIs were provided in Table 5-6 below.

Table 5-6 Length of the cognitive interviews in round 1 and 2

Participant	Introduction and preparation	Think-aloud technique	Concurrent probing technique	Total	Interview status
			Round 1		
Participant 1	30 min	16 min	21 min	67 min	Recorded
Participant 2	32 min	9 min	35 min	76 min	Notes taken
Participant 3	12 min	8 min	22 min	42 min	Recorded
Participant 4	19 min	11 min	20 min	50 min	Recorded
Participant 5	11 min	9 min	24 min	44 min	Notes taken
			Round 2		
Participant 1	15 min	8 min	17 min	40 min	Recorded
Participant 2	15 min	5 min	12 min	32 min	Recorded
Participant 3	13 min	5 min	16 min	34 min	Notes taken
Participant 4	10 min	6 min	11 min	27 min	Recorded
Participant 5	12 min	7 min	10 min	29 min	Notes taken

5.2.4.12.5 Findings from round 1 of the CIs

During the first interview activity, think-aloud, careful observation was undertaken and notes were collected. In fact, a problem found in a CI was not necessarily a problem reported by the respondent. For example, one respondent, after reading the indicator, said:

> "Well . . . this didn't happen when I met with the chemotherapy nurse . . . really, I can't remember if my nurse did this . . . well, it's 'No'."

Patients provided other comments during this activity:

> "Things look important; I don't remember being asked about side effects by the nurses here (she checked 'No')."
>
> ". . . I don't understand this question . . ."
>
> ". . . This question is not clear."
>
> ". . . What do you want me to do!"

The response problems were categorised based on coding scheme systems for classifying questionnaire problems by Levine et al. (2005) and Willis (2005). Problem schemes were used to code the comments made by respondents and from the interview transcripts. Issues raised from round 1 were classified into three categories relating to: 1) lack of knowledge; 2) comprehension: unclear items or ambiguous terms; and 3) items with instruction or clarification issues. These issues made respondents feel unsure and confused and resulted in them not understanding and needing explanations or re-wording. The following paragraphs provide an overview of these problems.

1) **<u>Issues in knowledge:</u>**

Items for which the respondents lacked the information needed to respond

The researcher found that patients lacked the information they needed to answer question A1, which posed a serious issue. This question asked about the name/s of the chemotherapy being administered, and was designed to identify classifications of extravasation risk which has a direct impact on patient-reported outcomes.

Of the five respondents in round one, 60% of the participants (n= 3) knew the name/s of their chemotherapy, whereas two (n = 2) participants did not know, but one (n = 1) asked the nurse about it. The respondents used a heuristic:

> ". . . I don't know, I will ask the nurse . . ."

Another respondent said:

> "Remove this question . . . It would be better if you ask the doctor or check the medical record . . . I don't know the name . . . It's chemo, that's all that I know."

This item was problematic because many patients were hesitant to say that they wanted to ask the chemo nurses about the name of their treatment.

To conclude, patients were not knowledgeably informed about this matter. Therefore, after careful consideration and as a result of these CIs, to avoid bias in the future stages, a volunteer researcher will be asked to write the name/s of the chemotherapy on the questionnaire prior to giving it to the potential patient.

Items with issues of retrieval of information

A minor issue featuring in the analysis was the retrieval of information. When subjects comprehended a question, they had to retrieve the relevant information from long-term memory. In question A1, the respondents had difficulty recalling the name/s of the chemotherapy taken. One respondent verbalised:

> "Oh, don't remember . . . let's see if I could find . . . many chemo names look like each other . . . names look the same . . . I should be careful."

A solution to this matter has been discussed in the previous paragraph.

2) <u>Comprehension: unclear items or ambiguous terms</u>

Cognitive testing is also an effective way of detecting comprehension problems such as concepts or terms that are understood incorrectly or inconsistently by respondents. Two specific questions, B3.5 and B4, were considered difficult for respondents to understand and interpret.

Question B3.5 in question 3.5 in Appendix I, Table B asked patients if they were confident in their ability to manage the chemotherapy symptoms experienced after their chemotherapy treatment. The results showed that the majority of participants, four (80%), found question B3.5 difficult to understand and asked for it to be re-worded, stating that this question could be shortened. Comprehension probe questions were used: "Could you tell me in your own words what this question is asking?" Respondents suggested that this question could be asked as follows:

> P04: "Can you manage your chemo side effects?"

While others suggested a different context:

> P05: "Do you have the ability to deal with the side effects caused by your chemotherapy?"

In response to this identified difficulty and following a discussion with the academic supervisor, question B3.5 was revised in the second round of the CI from "Are you confident in your ability to manage the symptoms you are experiencing?" to "Do you have the ability to deal with the side effects caused by your chemotherapy?"

Once again, serious comprehension issues arose with question B4, which asked about the patient's perspective of their health. Respondents failed to generalise the construct. In response to a comprehension probe, all of the respondents indicated that they would consider re-wording the question. Of the respondents, 100% (n=5) asked for the question to be paraphrased and for the meaning of the numbers included in the scale to be clarified. One respondent commented:

> P01: ". . . what do you mean by 'how are you doing overall'? I don't understand . . . Because you need to specify the reason behind this format . . . It is too vague a question."

Another respondent commented:

> P03: ". . . in what context? . . . Financial, psychological or what?"

The respondents' comments raised clarity issues represented in the wording and technical terms. For the second round of cognitive testing, question B4 was revised from "How are you doing overall?" to "We would like to know about your health today. Is it good or bad?"

Failure to comprehend medical terms

The researcher was interested in the respondents' comprehension of symptom-specific terms as they are the main pillar of this study. In both rounds, nine of the 10 respondents were able to give a synonym or description that captured the implications of these terms, and none felt that new wording was needed for these expressions. Although one respondent identified the phrase "Feeling unusually tired" as unclear. However, when probed about what feeling unusually tired meant to her, she defined it as "comprehensive fatigue". After discussion with the supervisor, no changes were made and the sentence was kept as is.

2. Items with instruction or clarification issues

From this researcher's observation, the respondents did not always take the time to read the directions prior to completing the PR-CISE. In addition, two respondents expressed that they did not read the directions at all or discontinued reading the instructions if they were long or not understood.

One respondent revealed that:

"I wasn't paying attention . . . the questions are clear and the response as well."

Two minor incidents with missing information were detected during data analysis of the first three respondents that fell under the instruction problem in questions B2 and B4. Information that the interviewee needed to address the question was missing in question B2; this could be proved as one respondent was confused and asked for clarification:

> P02 ". . . what if I don't have any other symptoms, do I need to write anything or what?"

Therefore, it was decided to add an additional instruction to further clarify the question. Question B2 could be skipped if the patient did not experience any other symptoms. In round two of the CIs, question B2 was adjusted from "Are you experiencing any other symptoms? (List up to 3)" to "Do you suffer from any other symptoms? If yes, please describe it and indicate how severe it is. If no, please go to question B3.

1. ☐Yes 2. ☐No

(List up to 3)".

Another minor comprehension issue emerged in question B4 which was missing information. In forming judgments, no problem with response categories was reported by respondents. However, information was added because one patient asked for clarification of the meaning of the numbers included in the scale. Therefore, prior to round 2, in response to the respondents' comments, the researcher added additional information to the question, "Please circle the number that describes your health and write this number in the box below. Zero (0) means that your health is weak; the higher the number, the better health you experience with 10 being the best health."

Overall, respondents reflected positive feedback about:

1. **Formatting:** Overall, the respondents found the questionnaire font size clear and easy to read, with no problem reported regarding question order.
2. **Sensitivity/bias:** Of the five respondents tested, none appeared to find any items annoying or upsetting.

3. **Response period:** In response to a question about the length of the questionnaire, all respondents (n=5) felt that the questionnaire was not too long or burdensome, which took approximately 8 to 16 minutes to complete. One respondent commented:

> "P03: "This questionnaire looked full of details . . . busy . . . however, all good aspects of care were looked at. This questionnaire isn't long at all; it's very organised . . . it is easy to follow."

Conclusion from round 1

A variety of cognitive problems was identified in this round, and can be categorised in issues related to: (1) clarity, (2) knowledge, (3) comprehension, (4) instruction, and (5) response categories. All the comments from patients were reviewed with one of the supervisors following the completion of round 1. The corrective actions were taken in response to comments from the respondents. Details of specific question modification whilst developing the PR-CISE/Arabic questionnaire can be found in the Appendix I in Tables A, B and C.

5.2.4.12.6 Findings from round 2 CIs

Based on recommendations derived from the first five CIs, this round was conducted to test the changes made to the prototype of the PR-CISE/Arabic questionnaire, as well as to provide additional testing of questionnaire segments that were not changed. Also, this round was planned to gain insight into the cognitive processes by which members of the target population of adults undergoing treatment in ambulatory chemotherapy settings answer the survey questions. Although the reports from the CIs are qualitative, and only five interviews were completed, several themes did emerge from the interviews. Probes were planned to illuminate lexical, temporal and logical problems within the survey questions.

Of the five patients interviewed, four were able to correctly complete the PR-CISE without any assistance, while one interview used a different technique, with the interviewer-administer conducting think-aloud activities for a 74-year-old man who was illiterate. Whereas the four self-administered, when interviewed, did not identify any cognitive process difficulties. There were no

similarities among the four respondents regarding demographic characteristics or clinical characteristics (see Table 5-5).

1) **Response processes related to survey layout and design**

All five respondents reported that the questions were clear, with comments such as “all fine” and “questions are pretty well thought out”. They also found that the response categories allowed them to get the answers they needed and was “easy to use”.

2) **Issues in comprehending the instructions**

Issues in comprehension of the instructions and the ability to communicate an answer in round 2 were assessed by asking participants to paraphrase the directions in the instrument. Respondents were then asked to describe the thought process by which they arrived at their answers. In general, the respondents found the questions easy to understand and answer. Also, the respondents did not find indicators confusing or bothersome.

During the interviews, non-scripted probing questions were used to identify navigational issues and computation problems as underlying reasons for some of the errors that were observed in the completion of the PR-CISE. Navigational errors resulted from the use of arrows in the layout of the PR-CISE which was confusing to one respondent. She had a problem with the logic of the horizontal arrow’s directions to answer. Although she indicated that she found the indicator in this question confusing, her comments describing her response did not support the claim. Therefore, in response to comments from the respondents, it was decided to keep the question and its answer as is.

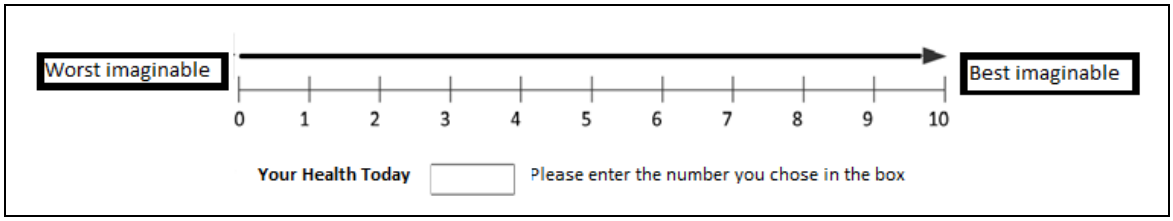


Figure 5-2 Question B4 (overall distress)

The CI probe results revealed that participants did not always take time to read the information sheet and the survey instructions prior to completing the PR-CISE questions. One participant stated that she did not read the instructions at all or discontinued the reading if the instructions were not understood. She did complete all of the questions or all of the requested demographic information.

Conclusion from round 2

In summation, the comments on round two were overall positive, and no additional problems were detected. For that reason, it could be said that the five respondents were able to answer the questions in a way that truly reflects the objective of each question, obtaining answers related to the intended meaning and also reflecting what they thought and believed. Since this questionnaire was demonstrated to be feasible in this population, similar results would be expected in a larger patient population. A summary of changes made to the PR-CISE in the development stage is presented in Table 5-7.

Table 5-7 changes to question content during the development stage

	Question that reveal problem in round 1	Revised question asked in round 2	Findings from round 2	Solutions
1.	A1. Please tick the names of the chemotherapy drugs that you are receiving from the drugs listed below.	Question remain the same	4 of 5 respondents were not aware of the name/s of their chemotherapy.	In the pilot study the nurses were asked to write the name/s of chemotherapy and number of the cycle on the top of the questionnaire prior to providing it to the targeted patient.
2.	A3. Do you feel that you are fully informed about the side effects that might result from your chemotherapy?	Before starting your treatment, did you felt that you are fully informed about the side effects that may result from your chemotherapy treatment?	Questions were clear, easy to understand and answer No difficulties with specific wording (medical terms) or phrasing/terminology	No additional changes
3.	B1. Since your last chemotherapy treatment, have you experienced any of the symptoms listed below? How severe was the symptom? 1. Nausea 2. Vomiting 3. Pain and irritation at the intravenous injection 4. Problems with mouth or throat (e.g. dry or sore mouth or sore, mouth ulcers) 5. Feeling unusually tired 6. Signs of infection like feeling unusually hot or cold, flu	Question remain the same	Questions were clear, easy to understand and answer No difficulties with specific wording (medical terms) or phrasing/terminology	No additional changes

	like feelings, high temperature, pain when urinating. Feeling low or depressed			
4.	B2 Do you suffer from any other symptoms? (List up to 3)	Do you suffer from any other symptoms? 1. ☐yes 2. ☐No If yes, please describe it and indicate how severe it was. If no, please go to question B3.	Questions were clear, easy to understand and answer NO difficulties with specific wording (medical terms) or phrasing/terminology	No additional changes
5.	B3.5 Are you confident in your ability to manage the symptoms you are experiencing? Response categories 1. Yes 2. Somewhat 3. No	Do you have the ability to deal with the side effects caused by your chemotherapy?	Questions were clear, easy to understand and answer NO difficulties with specific wording (medical terms) or phrasing/terminology	No additional changes
6.	B4. How are you doing overall? Please circle one number that best describes how much distress you have been experiencing since your last chemotherapy treatment till today.	We would like to know about your health. How much distress have you been experiencing since your last chemotherapy treatment till today? Please circle one number on the scale that best describes your health and please write this number in the box Below. Zero (0) means that your health is weak; the higher the number, the better health you experience with 10 being the best health."	Questions were clear, easy to understand and answer NO difficulties with specific wording (medical terms) or phrasing/terminology	No additional changes

5.2.4.13 Limitations

In this study, there were a few limitations to using cognitive testing alone, as a way of evaluating questions. First, as is always the case with CI data, the small number of interviews was a concern. Despite this fact, CI is not a method for obtaining statistical estimates and sample size in studies using this method, are typically small. However, the small sample of respondents will not be entirely representative of the entire population to be surveyed. Therefore, there may be item-related issues within sub-groups of the chemotherapy population that were missed and not identified.

Second, there was also the possibility that an item that appeared to be problematic during CIs might not actually adversely affect the resulting data. For example, a particular misunderstanding of an instruction sometimes does not have a substantive effect on most answers.

Finally, identifying a problematic item or question does not in itself ensure that a revised instruction or question will be better than the original. The CI is not a stand-alone method of item evaluation; rather it is a step before large-scale testing to increase the likelihood of developing valid and reliable survey items. While the results of CI testing helped the researcher to examine the extent to which tools of inquiry validly and reliably capture respondents' experiences, it proved that the scale is feasible to administer, the burden on patients is reasonable, and the range of the responses received point out that the scale is usable. This questionnaire also seems to be able to detect variations in patient outcomes. However, it is felt that pilot testing would reveal any additional problems with the questionnaire. The next part presents the development process of the associated instrument NWUCS.

5.3 Part II: Developing and validating of NWUCS

The attempt to develop standardized descriptors of workforce and clinic organisational was difficult, since the process of measuring these potential variables is complex. It could be argued that different methods of measuring these variables can produce variation in the results of statistical analysis.

Like PR-CISE instrument development, the process involved in developing the NWUCS was guided by the recommended eight steps by DeVellis (2011). Only the steps that were actually used are described below:

1. **Determine clearly what will be measured**

This phase included a comprehensive literature review on nurse staffing and unit characteristics. The definitions were developed based on the selected frameworks NREM (definitions can be found on Section 3.3.6.3).

2. **Generate an item pool**

The study framework NREM identified four main initial pool of items (organisational components) to be considered when developing the instrument. Within this framework the focus of organisational variables is on staffing and nursing assignment patterns which were found to be directly influencing the delivery of nursing care. Furthermore, in this phase, several items in each subscale were identified, and mini control items that have similar meanings as the real items were created.

3. **Determine the format for measurement**

Based on prior theoretical and previous research, the researcher developed and designed the NWUCS instrument. The final version of the NWUCS was a 28-item self-report measure. The survey questions are shown in Appendix E. The NWUCS variables were classified a priori into one of three parts; unit characteristics, nurse staffing characteristics and general information. The researcher created multiple choice and open-end questions as response formats.

4. **Have the initial item pool reviewed by experts**

Obtaining content validation is also an important part in the scale development process (DeVellis 2011). The researcher's supervisors reviewed the content validity of the first version of NWUCS scale and the clarity and conciseness of each item. Based on these expert comments and feedback, revisions were made.

5. **Administer items to a development sample**

The instrument was designed to be completed once by the ACSs Head Nurses or their representatives. Therefore, the instrument was piloted with 2 ACSs Head nurses in two different hospitals.

5.3.1 Validation of NWUCS

5.3.1.1 Design

Face-to-face, semi-structured interviews with a CI focus were conducted with two Unit Head Nurse Managers (UHNMs) to check for potential misunderstandings, ambiguity or problems in completing the NWUCS, as well as to ensure the validity of the survey findings and make them suitable for research administration.

5.3.1.2 Recruitment strategy and materials

After receiving approval from the participated hospital's ethics committee, the researcher contacted the UHNM of the two participating ACSs to arrange for data collection. The NWUCS packages were emailed to the targeted participants. Each package was individually labelled with a unique ID, each containing a letter of invitation and the NWUCS. Then, the researcher arranged for a convenient time to interview the UHNM of the ACS or their representative.

5.3.1.3 Data collection procedure

During the interviews, the researcher used the NWUCS interview protocol (see Appendix H), which allowed for two activities. In the first activity, the participants were given space to complete the survey without interference. In addition, they were instructed to mark items they found confusing/difficult to understand or annoying while completing the survey. Moreover, in this time, the researcher was available in the same room to answer any additional questions raised by the participants. When the participant indicated that he/she was finished, the researcher began the second activity.

In the second activity, a CI method with a verbal probing activity was used to determine the appropriateness and clarity of the items on the survey where necessary, and both concurrent and spontaneous verbal probing were used. This activity aimed to help the researcher learn where and how she could improve this survey. As mentioned earlier, data were collected only once from each participating ACS.

5.3.1.4 Findings from stage I: development and validation of NWUCS

After completing the NWUCS, the researcher went through the survey with the participants to discuss any ambiguities or misinterpretation. The list of interview questions and the results of the two sets of interviews are presented below in Table 5-8.

In addition, the instrument was reviewed in terms of content validity, especially the relevance and adequacy of items. Detailed individual interviews were conducted to ensure the NWUCS had an in-depth understanding of aspects of nurse staffing and patient education. No further changes were required at this stage. As a result, the NWUCS was ready to be used in the pilot testing stage.

Table 5-8 Summarises of specific question answers whilst developing the NWUCS.

Question asked	Responses	Action taken
1. How easy was it to read the NWUCS?	Both participants indicated that the questionnaire was *'very easy'* to read.	No action was taken
2. How easy was it to answer the questions?	One participant commented: P02: *"Some questions 20 & 21 needed to go off and look through staff files … this takes time."*	In the implementation stage, the head nurses were instructed that the questionnaire would take about 45 minutes depend on the availability and easy access to the required information.
3. Where the response options clear? If no or somewhat, could you please tell me what the question was?	The response options were clear for both.	No action was taken
4. Where these instructions clear to you?	Both participants answered *'yes'* it was clear.	No action was taken
5. Were there any questions that were difficult to understand? If yes, could you please tell me what the questions were? And how can I improve it?	Both answered 'No'	No action was taken
6. Where there any questions that, you particularly disliked. If yes, please tell me what these questions were. And how can I improve it?	For both participants, there were no disliked questions.	No action was taken
7. Do you think that there is anything else that I should have included in this questionnaire, which I might have missed out?	One participant P02: "*perhaps include a question about staff years of experience in oncology and/or chemotherapy unit*".	Suggestion will be added to the recommendation for future large-scale study
8. Do you have any suggestions?	Both answered 'No'	No action was taken

5.4 Summary of the work conducted at this stage

- Refinement of the PR-CISE questionnaire and development of an Arabic version (forward translation)
- Back translation and validation of the questionnaire by an expert panel.
- Pretesting of the PR-CISE/Arabic questionnaire (preliminary validation of the questionnaire using CI techniques).
- Thematic analysis of findings and Finalisation of the prototype of the PR-CISE/Arabic questionnaire for pilot testing.
- Development of the NWUCS, which can assist in interpreting the results of the PR-CISE.
- Test of the content validity of the associated tool (NWUCS)

The pilot testing stage will be reported in the next chapter, including the method of recruitment and administration, an examination of response rates and the identification of redundant data items.

Chapter 6: Pilot testing stage (Stage II)

6.1 Introduction

To test the extent to which the nurse-sensitive outcome measures were suitable to participants, a pilot test of the final version of PR-CISE/Arabic questionnaire that emerged from the CIs was conducted with patients undergoing chemotherapy at a single ambulatory chemotherapy service (ACS).

Details of the research design, objective, and sampling are provided in following sections.

6.2 Design

For Parahoo (2006), piloting is a key stage in the development of the questionnaire, allowing the careful evaluation of the instrument before the main study is conducted. In social science research, the term 'pilot study' is used in two different ways, either a small-scale version or a trial run designed to test the methods to be used in a larger, more rigorous study (Polit & Beck 2004). Because the intent of a pilot study is not to answer the researcher's questions, but rather to focus on improving the study techniques and avoiding serious pitfalls for this reason, pilot studies are sometimes referred to as feasibility studies (Polit & Beck 2004).

6.3 Objective

As noted in Stage I, the PR-CISE questionnaire was translated and validated through CIs. The data collection process then needed to be piloted on a small sample of patients before being used in the main study.

According to Hertzog (2008), there are several purposes for pilot studies. Stage II of this study conducted a trial-run design of the pilot survey to evaluate methods and tools for a proposed larger study (Gardner et al. 2003). The objectives of the pilot-test were to:

1. Monitor the methods of recruitment, recruitment rates, and the acceptability of data collection tools (testing the appropriateness of instruments used during the study);
2. Monitor the administration process, average time for filling out the Arabic versions of the PR-CISE questionnaire, and the response rate;
3. Assess the practicality of the completion, comprehension, ease of use, and researcher usefulness of the adapted indicators (PR-CISE) for employment in a population survey in the KSA; and
4. Identify redundant data items and further refine the instruments (e.g. the Arabic version of the PR-CISE and the unit profile form) as necessary.

Additionally, tasks like development of data collection material and confirmation of sample size for the main study were completed.

6.4 Sample and Setting

The pilot study was conducted on a small sample of the population in the same manner anticipated in the main study. Therefore, the final Arabic version of PR-CISE questionnaire was pilot-tested on a convenience sample of adult chemotherapy patients in a single ACS (the same unit where Stage I was conducted).

6.5 Eligibility criteria

The inclusion and exclusion criteria were similar to that used in Stage I, except the criterion; “Patients who are able to respond to questions and can read and write in Arabic”. The decision to exclude this criterion was taken after data were collected for Stage I as it would result in a large proportion of people being excluded due to the high illiteracy rate in KSA.

6.6 Sample size

Burns and Grove (2005) make no specific recommendations with respect to sample size for pilot studies, while approximately 10 participants are

recommended by Nieswiadomy (2011). Others like Hertzog (2008) found a sample size of 10-20% of the main study sample was a reasonable number of participants to consider enrolling in a pilot. Hertzog (2008) concluded that the decision on final sample size is ultimately guided by both cost and time constraints and the size and variability of the population.

During the period between 1 February and 30 April 2014, the average number of chemotherapy patients receiving their treatment in the targeted ACS was 89 patients monthly. Therefore, pragmatism suggested recruiting a convenience sample of 30 patients who met the study's inclusion criteria study and were available during the four-week data collection period.

6.7 Recruitment materials

Like stage I, the questionnaire package was distributed to each potential participant by volunteer staff (research assistants). The package consists of the invitation letter, the information sheet, and the questionnaire, (see Appendix F).

A return of the questionnaire is indicative of their consent to participate in the study. Therefore, the information sheet clearly stated that no specific consent form will be requested as completion of the questionnaire will be taken as consent.

A questionnaire return box was used to collect the completed sealed questionnaires. This box was locked with a secure padlock and placed at the nurse's station of the participated ACSs.

The researcher introduced the process of data collection to volunteer staff to identify potential patients who were due to receive chemotherapy treatments on the data collection days. This was done with the use of the Unit Patient Log Book and the guidelines for recruiting potential participants.

6.8 Data collection

In this stage, data were collected by a self-administered questionnaire.

6.8.1 Procedures

6.8.1.1 Patient survey

When eligible patients arrived at the reception desk, the trained volunteer staff gave them the information sheet for the study. They gave the patient questionnaire packages, each with a unique study ID, to all eligible patients in the participating unit. The patients were asked to read the information sheet before completing the self-reporting survey. Then, participants were asked to complete the questionnaire, seal it in the brown envelope provided, and return it by dropping it in the research box on the same day. A four-week period (11May to 13 June 2014) was allocated to collect the required data.

To reduce the risk of sampling errors, volunteers were asked to instruct patients orally to complete only one questionnaire, even if they visited the unit more than once during the data collection period. It is important to note that during this period, the researcher presented a schedule for distributing the patient questionnaire packages to the patients in the selected unit. This allowed the researcher to monitor issues in the data collection procedure. An example would be to record reasons for non-participation or withdrawal and observe how patients fill in the questionnaire in case of inability to read and write Arabic.

6.8.1.2 Nursing Workforce and Unit Characteristics Survey (NWUCS)

In this stage, the researcher arranged for face-to-face interviews with the Unit Head Nurse Manager and expert senior oncology charge nurse to examine the content validity of the first version of the NWUCS. At first, participants were asked to complete the questionnaire. Then, when the participant indicated that he/she was finished, the researcher began the second activity. Each participant was interviewed to determine the appropriateness and clarity of the items on the survey, and both concurrent and spontaneous verbal probing were used. For example, “Were the response options clear?”; “How would you suggest that we re-word this statement?”; and “Were there any words which were difficult to understand?”.

These interviews helped the researcher to learn where and how she could improve this survey. At the end of this stage, a revised NWUCS version was

ready for distribution to the targeted Unit Head Nurse Managers in the other hospitals selected.

6.8.2 The instrument

1- In this stage, the adapted PR-CISE/Arabic version was used to collect the data. Following the testing in Stage II, the PR-CISE/Arabic version consisted of three sections as follows:

- Section A focussed on 2 dimensions: 1) chemotherapy classification and 2) supportive care. During development, I added two questions A2) and A3) to section A; (3 items)
- Section B focussed on the three domains of quality, specifically effectiveness, safety, and experience of care provided. Most of the questions focussed on the severity of subjective symptoms experienced since the last cycle of chemotherapy (symptom assessment). The only safety question included was B1.3, which asked about severity of pain and irritation at the infusion site and involved the safety of chemotherapy administration; (14 items) and
- Section C recorded patient demographics and clinical characteristics like sex, age, site of cancer, and mode of administration in order to assess the effect of the mix and adjust for it. (6 items)

The overall length of the questionnaire was four-pages, and the total number of questions in the questionnaire was 23.

2- The developed NWUCS form was created to collect data on Nursing Workforce and Unit Characteristics. This measure consisted of three sections as follows:

- Section 1 focused on the unit characteristics (9 items)
- Section 2 focused on Nurse Staffing characteristics including: skill mix, nurse-to-patient ratio and the level of nursing education. (11 items)

- Section 3 contained of General Information including: chemotherapy regimens provided in this unit and process of proving chemotherapy education to the patient and their caregiver. (8 items)

The overall length of this form was 6-pages with 28 items.

6.9 Data checking

This focused on data checking rather than analysis, as the purpose of pilot testing is to evaluate methods and tools for the main study. However, to model the process of data entry for the later survey, the researcher entered data from the completed questionnaires into password-protected SPSS Access databases. The original paper questionnaires were then reviewed, and errors in the database corrected as necessary.

The response rate, average time of filling out the Arabic version of the PR-CISE questionnaire, and the percentage of missing values were used as indicators of feasibility of the questionnaire. The response rate was calculated using the total number of eligible patients treated with chemotherapy who completed the measure each week. By the end of the pretesting stage, the researcher had a chance to revise the recruitment materials prior to the main survey study.

6.10 Findings from Stage II

This stage focused on evaluating the feasibility and acceptability of 1) the methods for recruitment 2) the process for identifying patients and administering the questionnaire and responses to this.

Data collection for Stage II took place between 11 May and 13 June 2014. This four-week period allowed testing of the data collection process in an ambulatory chemotherapy setting (ACS). Data were collected by one volunteer member of nursing staff who worked as the chemotherapy administrator in the selected ACS in the KSA.

6.10.1 Methods and outcomes of recruitment procedures

6.10.1.1 Recruitment

Feasibility of recruitment unit, manager, and volunteer staff

The Unit Chairman and Head Nurse Managers gave their consent to include their unit in the study. Three available staff who spoke Arabic during the data collection period were approached by Unit Head Nurse and the researcher to see if they were willing to volunteer to support questionnaire distribution and one nurse agreed.

Feasibility of recruiting a representative sample

The importance of testing the sampling and recruitment process in detail was emphasised in the literature (Arain et al. 2010). The pilot revealed the volunteer nurse was able to follow the sampling instructions and carry out the necessary checks, such as ensuring patients were not included in the sample if they were due to receive their first cycle of chemotherapy.

During the pilot it became clear that not all patients were aware of their diagnosis of cancer. So, it was decided it would be necessary to adjust the sampling guidance notes for the main study advising volunteer staff to exclude patients who were not aware they had cancer.

Feasibility of recruitment strategies and screening method

Overall, the recruitment strategy was effective. The recruitment procedure was completed as planned. A One-month period (20 working days) was scheduled to recruit 30 patients. During this time, the volunteer nurse was able to recruit the required number of patients on only 14 of those days. One reason for this was that there was not enough time for volunteer staff member to screen and identify eligible patients and recruit them in the missed 6-days.

The unit logbook records identified seventy-three patients were due to have chemotherapy treatment over the period of recruitment. After de-duplication, fifty-five patients were screened for eligibility. Of these twelve patients declined to take part in the survey. The reasons for refusal were not recorded. Of the 43 patients who initially agreed, 33 patients participated in this stage. See Figure 6-1for the participant flow chart.

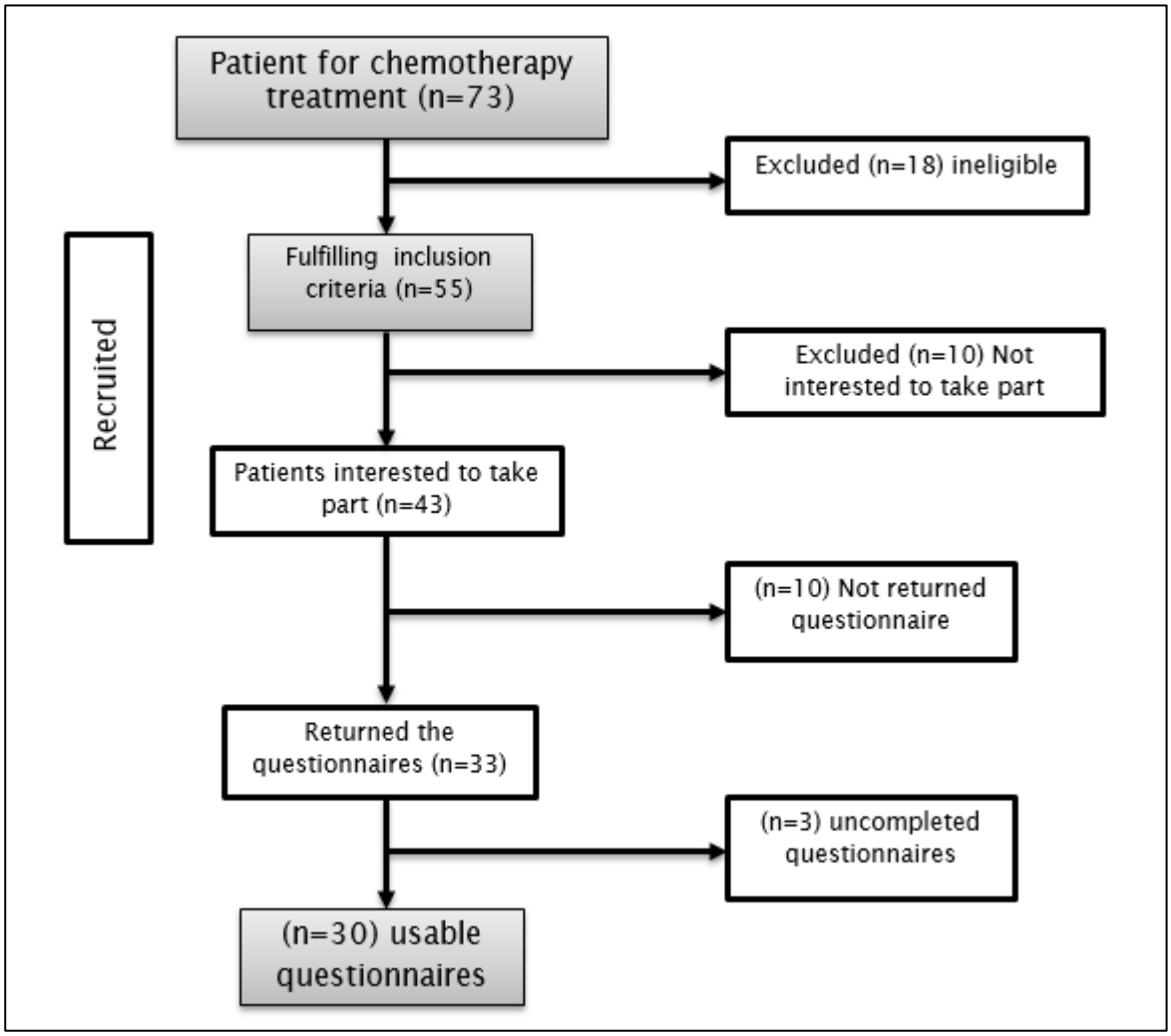


Figure 6-1 Flowchart of outcome of screening & recruitment process in Stage II

Acceptability of data collection process and materials

Acceptability of the data collection process was an important focus of Stage II. Therefore, after completion of screening period, volunteer staff completed an evaluation form that included seven acceptability statements. The Volunteer staff member was asked to indicate whether:

1. The instructions were easy to follow;
2. The recruitment instructions were easy to follow;
3. Volunteer had enough time to screen for eligible patients;
4. Volunteer had sufficient time to distribute the questionnaire to eligible patients;
5. The questions were easy to understand by patients;

6. Volunteer felt comfortable following all the process; and
7. Volunteer would be willing to participate in a similar survey in future.

Patients were not unduly anxious about participating and the volunteer staff member confirmed patients understood the nature of the survey. The volunteer staff member reported she enjoyed the process of conducting the study. As well as the helpfulness of training on the purpose of the survey and the procedures she indicated the clarity of the instructions for recruiting potential participants'. However, the workload to screen for eligible patients and recruit patients for the survey was reported as the greatest challenge faced in collecting data. The volunteer staff member indicated that it was difficult to participate as volunteer data collector because it affects nursing hours.

6.10.1.2 Suitability of research methods.

Assessing the suitability of the research design and method used in this stage focused on the response rate to the questionnaire and acceptability of the questionnaire.

Potential participants and Response rate / completion

Of the original 43 who were given a questionnaire to complete 33 were returned, the response rate was 76.7%. Ten patients (23.3%) did not return the questionnaire and counted as withdrawn from the study; reasons for this are unknown. Moreover, of the 33 returned, 3 were not useable as they had not been completed.

6.10.1.3 Baseline data for participants

The age of participants ranged from 18 to over 71 years old. Table 6-1 below describes demographic information of the patients.

Table 6-1 Characteristics of the participants (n=30)

Characteristic	N	(%)
Gender of the participant		
Male	14	(42.4)
Female	16	(48.5)
Age of the participant (years)		
18-30	3	(9.1)
31-40	8	(24.2)
41-50	11	(33.3)
51-60	2	(6.1)
61-70	5	(15.2)
71+	1	(3)
Type or site of the primary cancer		
Bladder/Urological (not prostate)	3	(9.1)
Blood	2	(6.1)
Bowel	5	(15.2)
Breast	9	(27.3)
Gynaecological (womb, ovaries)	1	(3)
Head or Neck	1	(3)
Lung	1	(3)
Lymphatic (lymphoma)	4	(12.1)
Oesophagus or Tung	1	(3.0)
Stomach	2	(6.1)
Other	1	(3)

6.10.2 Administration of, and responses to, the questionnaire

6.10.2.1.1 Acceptability of the PR-CISE questionnaire for a population undergoing chemotherapy in ACS

Acceptability of the indicators had already, to some extent, been addressed during the development stage through cognitive interviews, and conversation with experts senior bilingual oncology nurses (translation process) and the research supervisors.

The method of questionnaire collection was easy for both participants and the volunteer staff. Over the 43 patients interested in taking part in the survey 33 (76.7%) returned the questionnaire in the research box.

The acceptability of the PR-CISE was assessed by asking participants three short questions, at the end of the questionnaire:

1. If they had found the completion of the questionnaire to be tiring;
2. How long it had taken them to answer the questionnaire; and
3. Whether they would participate in the survey on another occasion.

Over 90% of participants did not find it tiring. One participant suggested,

"this questionnaire must be repeated with each cycle.".

Similarly, another participant suggested that

"It might be helpful to fill in the questionnaire before starting the chemotherapy. So the nurses will be aware of what we experience last time to help us cope with these side effects."

All participants reported that they would be willing to answer the questionnaire on another occasion.

Missing data can be a problematic issue for researchers across many different fields. Conducting a pilot test proved useful in highlighting the questions that appeared to cause respondents the most difficulty or confusion and/or where the layout or structure of the questionnaire could be improved. Knowledge about the nature of the missing values can help identify the most appropriate method for dealing with missing data (Little & Rubin 2014).

Across all the 23-item on the questionnaire, there were only 10 data omissions giving a 98.55% was the completion rate. The most missing answers were accounted for by questions A1 and C1, which concerned the name of chemotherapy received, and the cycle of chemotherapy.

"A1 what is the name of chemotherapy that you are receiving?"

"C1 which cycle of chemotherapy will you receive today?"

For the other missing answers, these were all randomly missing; Table 6-2 summarises the completeness of each measure.

Table 6-2 individual item omissions in the questionnaire

Variable	Observed		Missing	
	N	%	Count	%
A1	27	90	3	10
A2	29	96	1	3.3
A3	29	96	1	3.3
B1_1	30	100	0	0
B1_2	30	100	0	0
B1_3	29	96	1	3.3
B1_4	29	96	1	3.3
B1_5	29	96	1	3.3
B1_6	30	100	0	0
B1_7	30	100	0	0
B2	30	100	0	0
B3_1	30	100	0	0
B3_2	30	100	0	0
B3_3	30	100	0	0
B3_4	29	96	1	3.3
B3_5	30	100	0	0
B4	30	100	0	0
C1	27	90	3	10
C2	30	100	0	0
C3	30	100	0	0
C4	30	100	0	0
C5	30	100	0	0
C6	30	100	0	0

Time duration

On the evaluation sheet participants were asked to estimate how long it took to complete the task in minutes. Participants indicated that the length of the questionnaire was acceptable. The mean length of time for respondents to complete the 23-item version of the PR-CISE ranged from 10 to 23 minutes, with a mean of 16 minutes.

6.11 Discussion and conclusion

This stage sought to evaluate the feasibility and acceptability of implementing a pilot survey for patient undergoing chemotherapy in ACSs. In this pilot-testing stage, 33 participants returned a questionnaire from a single ACS over

a four-week period. The questionnaire packages were distributed to all eligible patients. However, it was hard to determine the total number of eligible patients, because reasons for non-participations and non-eligibility were not recorded. As a result, I developed forms to record this information for the main study.

The findings inform this phase supported the content validity of the PR-CISE Arabic version indicators particularly the relevance, adequacy, and clarity of the survey questions. At this stage, no revisions to the PR-CISE Arabic scale were required. Where 10% of participants do not know the name of the chemotherapy received and the chemotherapy cycle (questions A1 and C1), an adjustment was made to the process of collecting data for these two questions in Stage III. It was determined to write the name and cycle of chemotherapy on the top of the questionnaire before hand it to the targeted participants.

The use of instructions for recruiting potential participants had, in the researcher's view, helped the volunteer staff member recruit and supported screening of eligible participants. No changes to the patient recruitment strategy were planned for the implementation stage. But, as the volunteer staff member who participated at this stage reported it was difficult to manage the workload of the survey alongside clinical duties. It was decided to deploy volunteer research assistants (VRAs) in Stage III, to support the data collection process. It was planned that these volunteers would not be working in the units identified for data collection, but would be recruited from medical and health sciences schools.

The next chapter presents the implementation stage (stage III) – the main study.

Chapter 7: Implementation stage (Stage III)

7.1 Introduction

The implementation of the survey evaluated the likelihood that the study could be fully implemented as planned and proposed. For implementation, a feasibility study asks how the survey can be successfully delivered to the intended participants in a defined context. Additionally, work at this stage focuses on identifying possible barriers to completing the survey and solutions.

As mentioned earlier in Sections 4.5, this stage used a cross-sectional survey. This approach enabled collection of data on variability in terms of patients' experience of subjective symptoms and the support nurses provide to patients at ACSs. Data were collected from five ACSs in four cities, within the targeted provinces, in the KSA.

7.2 Population and sampling

7.2.1 Patients

As this was a feasibility study, no formal sample size calculation has been carried out. Because the focus of the study is on estimating parameters such as 1) Identify the number and characteristics of eligible patients that can be recruited within a one-month timeframe, and the dropout rate. And 2) the percentage (proportion) of eligible patients who are willing to participate, of participants who drop out of the trial for a future large-scale study, not on formal testing of hypothesises. Therefore, this study aimed to recruit a consecutive sample of adult cancer patients undergoing chemotherapy in the targeted ACSs, who met the inclusion criteria. Consecutive sampling is a non-probability sampling technique that involves all subjects from the accessible population over a particular time interval (Polit & Beck 2013), which makes the sample a better representation of the entire population.

Eligibility criteria:

The eligibility criteria for the feasibility study were similar to the criteria for stage II.

Measures to reduce the risk of errors and minimize bias in sampling

- Patients identified via the Unit Patient Log Book.
- Non-identifiable data regarding reasons for non-entry collected about those who choose not to participate.
- Non-identifiable socio-demographic data collected about those who consented to CIs.
- The researcher instructed patients to complete only one questionnaire, even if they visited the unit more than once during the data collection period.

NB. In the KSA, conducting research requires that the researcher consider the broad factors that might influence the study. While caregivers (including family members or friends) are critical partners in the provision of care to patients, this study did not involve them as a source of data, because PR-CISE is a self-reported questionnaire.

7.2.2 Staff

The Unit Head Nurse Managers or their representatives were invited to complete the NWUCS form.

7.2.3 Volunteer research assistants (VRAs)

Being a feasibility cross-sectional study, it was impossible for the researcher to collect data in the five ACSs by herself. Therefore, student healthcare professionals, hospital staff (including all nurses and unit clerks working in participating ACSs, and researchers working in research departments, were invited to take part as VRAs, to support the data collection process, where possible.

NB. The hospital staff were included where appropriate, depending on the research ethics policy in each hospital.

Moreover, the VRAs roles were to:

1) Identifying potential patients: The VRAs were instructed to refer to the instructions for recruiting potential patients and to follow the script when introducing the study to patients;

2) Distribute the questionnaires. Also, to

3) Collect data on the number of eligible patients, reasons for non-eligibility and non-participation or withdrawal by using associated tools; and

4) Assist potential participants who need help in completing the questionnaires.

7.2.3.1 The criteria for sample selection were:

Inclusion criteria

- Medical or health sciences students or male and female interns
- Aged 21 years and above (with no upper age limit)
- Written and spoken communication skills in Arabic
- Students from schools affiliated with the targeted hospitals

Students who met the above criteria were considered eligible to work with oncology patients and selected for the study.

Exclusion criteria

Those who could not speak Arabic were excluded from the study.

7.2.3.2 Methods of drawing the sample

In stage III, the VRAs were recruited to handle data collection in the four centres. In two of the four centres, volunteer lists were obtained from the hospital research committees. The lists included the names and numbers of medical or health sciences students. The researcher selected the VRAs using a simple randomised sampling method via the lottery method. Accordingly, each member on a list is assigned a unique number, and tags containing these numbers are placed in a hat and thoroughly jumbled. The researcher, blind-folded, then picks the numbered tags from the hat. All the students corresponding to the numbers picked from the hat were chosen as VRAs. This

strategy ensures that every participant gets an equal chance of being chosen, thus minimising selection bias. Subsequently, the selected VRAs were sent an invitation to participate in the study. In the other two centres, the VRAs were recruited from the medical and health sciences schools affiliated with the centres via a leaflet placed on the internship bulletin boards. The leaflet contained the researcher's email address to enable interested students to get in touch.

7.3 Procedures

The researcher had overall responsibility for recruitment and data collection, however, when possible VRAs took on aspects of this. A meeting with the recruited VRAs was held at each centre to ensure uniformity of the process and adequate understanding of the study's purpose, procedures that were undertaken and VRAs roles and responsibilities throughout data collection days.

7.3.1 Strategy for accessing the VRAs

To access the potential VRAs, it was necessary to use a well-defined strategy. This strategy comprised five stages.

1) An invitation letter was emailed to each potential VRA. In this email, the researcher emphasised to the potential VRAs that participation was entirely voluntary and that no reply was necessary if they did not wish to support the study.
2) With the help of the Unit Head Nurse Managers from each centre, the researcher then determined a time and place to meet with the potential VRAs within the centre.
3) A meeting with the recruited VRAs was held at each centre to ensure that the data collection process would be followed consistently and that the VRAs sufficiently understood the research objectives, the procedures to be undertaken as well as their roles and responsibilities throughout the data-collection process. At the meeting, the prospective VRA participants were also given a study package (comprising the invitation letter, an explanation of their

role in the study, instructions for recruiting potential participants and a script to introduce the study to patients), see Appendix L.

4) The participants were asked to read the information sheet in the package to ensure that they understood the role of a volunteer researcher. The researcher also informed the VRA's that they could decline to contribute at this point.
   One reason for the meeting was that the researcher was acutely aware that needed an opportunity to ask questions and understand processes to be asked too. The researcher provided the VRA's with the necessary instructions regarding their roles as well as the process to select potential patients and return the questionnaires to the researcher.
5) Towards the end of each meeting in the centre, before data collection commenced, the VRAs who wished to contribute were asked to specify their preferred date for the next meeting; this meeting was used to provide the necessary training relating to their study participation. Refreshments were provided for participants in appreciation of their attendance.

7.3.2 Overview of the VRAs' training process

The researcher believes that the success or failure of all data-driven projects hinges on the team's ability to collect data consistently from the targeted patients. In each centre, a one-day training workshop for all potential VRAs was held prior to data collection. The workshop aimed at engaging the VRAs in a simulatory real work environment and consider communication between themselves and the patients. The objective was also to train them to use the associated tools to characterise the targeted patients.

Following the training workshop, the researcher was available in person for a week to observe and help in the process of data collection as needed. This also enabled the researcher to gauge the VRAs' understanding of their role.

7.3.3 Data collection materials

The data were collected using the final version of self-administered PR-CISE/Arabic questionnaire and NWUCS instruments. Like Stage II, a questionnaire returns box was used to collect the completed sealed questionnaires. A research box was placed at the nurse's station at each participant's ACSs and locked with a secure padlock. Each return box was allocated a unique site identifier (ID) in addition to the research title.

7.3.4 Data collection

Data collection was undertaken in a period between December 2015 and August 2016; each ACS was asked to run the study for a four-week period. All study instruments were printed and despatched to the participating centres, along with other relevant documentation. Data collection procedures similar to those in Stage II were used (see section 6.8.1).

7.3.4.1 Patient survey

For the feasibility survey, a patient information sheet, like those in Stage II, was used. All participants were asked to read the information sheet before making a decision about whether or not they would like to participate. Also, the recruitment procedures remained the same as those in stage II.

Non-participation and withdrawal

Patients who decided not to take part in the study were asked, if possible, by the researcher/VRAs for their permission to record their reasons for non-participation. The log of recruitment activity (Appendix J) created for recording the number of eligible patients who accepted and declined and reasons for non-participation in the survey (Appendix K) was completed by the researcher/VRAs.

7.3.4.2 Nursing Workforce and Unit Characteristics Survey

After receiving the hospital's ethics committee approval, the researcher contacted the UHNM of the ACSs or their representatives at each participating ACS to arrange for data collection. The NWUCS packages handed to the targeted participants. Each package was individually labelled with a unique ID;

each contains a letter of invitation and the NWUCS. The researcher asked the UHNM to fill in the NWUCS only once and drop it in the research box.

7.3.4.3 Feasibility parameters

To collect useful text-based information that might inform a large-scale study, volunteer staff were asked to fill in the Log of recruitment activity (Appendix J) and the reason for non-participation form (Appendix K) and to write down any comments they had about the associated tools or their roles in recruiting patients. Table 7-1 shows the feasibility parameters

Table 7-1Parameters for feasibility study

Parameter	Assessment	Comment
Baseline for patient participants PR-CISE	Estimates of the variance of patient characteristics across the proposed units, symptoms, patient experiences.	To determine sampling strategy to ensure findings are reliable and valid. To inform outcome measure selection and calculate the level of clustering, target effect size and sample size for future study.
Baseline for NWUCS	Estimates of the variance of staff profiles, chemotherapy regimens used in each unit, and local practices around administration patient management.	To inform future study design
Unit participation	Proportion of managers invited on behalf of eligible unit to take part: who agree versus those who refuse	To identify reason for not participating. Inform future study design and recruitment strategy.
Recruitment: selection bias	Compare rates and characteristics of patients invited to take part, and those recruited	To identify bias to inform design and implementation of future study.
Patient participation in survey	Register of number of chemotherapy patients attending for treatment in unit log book, number of patient eligible as proportion of all patient attending, proportion of patient surveys distributed to eligible individuals that are completed and returned, versus those not completed/returned. Level of non-response in surveys.	Document reason for not participating. Inform future study design, recruitment strategy, and choice of survey completion.
Patient assistance required to complete survey	Proportion of patients who wish to complete a survey who require researcher or other help to complete the survey and reasons for this.	Document nature of help, who helped, how long survey took to complete. Inform future large-scale/outcome. Measure selection.
Patient/nurse survey: time take to complete	Written record of time taken to complete on each survey copy.	Resource implications for future study.
Data collection process	Document issue identified during recruitment and data collection procedures	To identify bias to inform design and implementation of future study.
Data analysis issues	Document issues identified during data analysis procedures: data quality issues, time for analysis, database issues, etc.	To determine which analysis techniques to use to give a robust answer to research question in the future survey and/or suitability of proposed analysis techniques
Adherence to protocol	Document instances of non-compliance with protocol and rationale. Document changes made to study protocol and rationale.	To identify bias to inform design and implementation of future study.

7.3.5 Data analysis

The primary aim of this study was to assess the feasibility of data collection and analysis methods. Lancaster et al. (2004) indicate that the analysis of any feasibility study should be mainly descriptive and/or focus on confidence interval estimation. Descriptive statistics were used to address feasibility parameters, including frequency and percentage distributions. This information helped to estimate relevant design parameters to inform any future study design, such as; recruitment rate, completion rate, and dropout rate. The numbers were displayed in a log of recruitment activity (see Appendix J) to show how many eligible patients presented in each ACS, how many patients were approached, participated, dropped out, and included in the primary data analyses.

To assess feasibility and suitability of the planned analysis that aimed to examine variation in nurse-sensitive outcome indicators (NSOIs), I followed the same statistical analysis strategy provided by Armes et al. (2014). Initially descriptive statistics including; means, standard deviation (SD), and percentages; and χ^2 tests, were used to summarise patient demographics, reported frequency and severity of problems, and experience of supportive care. In addition, the baseline characteristics of centres and nurses were established to assess the variability across different centres. In order to compare between centres variation in symptom prevalence and severity, multiple logistic regression models were used. Data analysis will be discussed in great detail throughout the results sections.

All analyses were carried out using SPSS software, version 20 (SPSS Inc., Chicago, IL). Colour coding was applied using Microsoft Excel 2013. A level of significance of 0.05 together with 95% confidence intervals was used for all hypothesis testing.

7.4 Results

7.4.1 Feasibility parameters

7.4.1.1 Recruitment and retention parameters

7.4.1.1.1 Hospital participation

During this stage, seven hospitals were approached to participate. Requests for ethical approval were sent to each hospital's ethics committee. The outcome of the request and time required to gain approval varied by hospital. Of the seven hospitals approached, five agreed to take part and ethics approval given. One hospital was excluded because the ethics approval process took more than three months to process, leaving limited time to complete the study. The other hospital ethics committee declined to give approval to conduct the study because of high nursing workload.

7.4.1.1.2 Volunteer staff

Eighteen volunteer staff were recruited to support data collection from the volunteer lists of the participating hospital research committees. Volunteers were medical or health sciences students. Twelve students agreed to take part in the data collection, and none of the recruited volunteer staff dropped out from the study. Out of the 12 VRAs, three participants were male. Table 7-2 shows the recruitment process and the number of VRAs in each centre.

Table 7-2 VRAs recruitment process per site

Centre	No. of requited VRAs	No. of VRAs agreed to participate	No. of VRAs received training	No. of VRAs participated in data collection process	No. of VRAs collected data/day
A	10	7	7	7	2
B	Not applicable, the primary researcher collected data.				
C	2	2	2	2	1
D	2	1	1	1	1
E	4	2	2	2	1
Total	**18**	**12**	**12**	**12**	

7.4.1.1.3 Feasibility of deploying VRAs to support the data collection process

The time required to recruit the VRAs was fairly short in the two centres which had volunteer lists. In the other two centres, the process was time consuming, taking about two months to complete.

Centre A had the largest number of potential patients. Therefore, a team leader was appointed among the VRAs to communicate with the rest of the team (namely, the VRAs). The team leader was responsible for preparing the data collection schedule for the VRAs. The team leader was responsible for allocating two VRAs per day for data collection and to communicate with the researcher at the beginning of each week and whenever needed.

The VRA participants were asked to share their opinions and the challenges they encountered while recruiting patients for this study. When asked specifically about recruitment issues associated with the caregivers, no major conflicts were noted. However, the VRAs stated that in some cases, it was necessary to communicate with the caregiver before accessing patients.

7.4.1.1.4 Flow of patient participants during the study

Table 7-3 shows the number of participants across sites and numbers eligible, approached and declined and Figure 7-1 below depicts a flow chart showing participant flow through the study.

Table 7-3 Recruitment process and response rates by site

	A	B	C	D	E	Total
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Patients receiving chemotherapy	524	690	331	-	68	1613
No. of eligible patients	399	425	266	-	43	1133
No. of approached patients	329	398	231	102	43	1103
Declined participation	51 (15.5)	159 (39.95)	15 (15.15)	27 (26.47)	2 (4.65)	254 (23.03)
No. of patients received questionnaire package	278	239	216	75	41	849
Returned questionnaire	267	237	171	74	41	790
Excluded	8	4	9	21	0	42 (5.32)
Questionnaire completed (useful questionnaire)	259	233	162	53	41	748
Response rate %	96.04	99.16	79.17	98.67	100	93.05 %

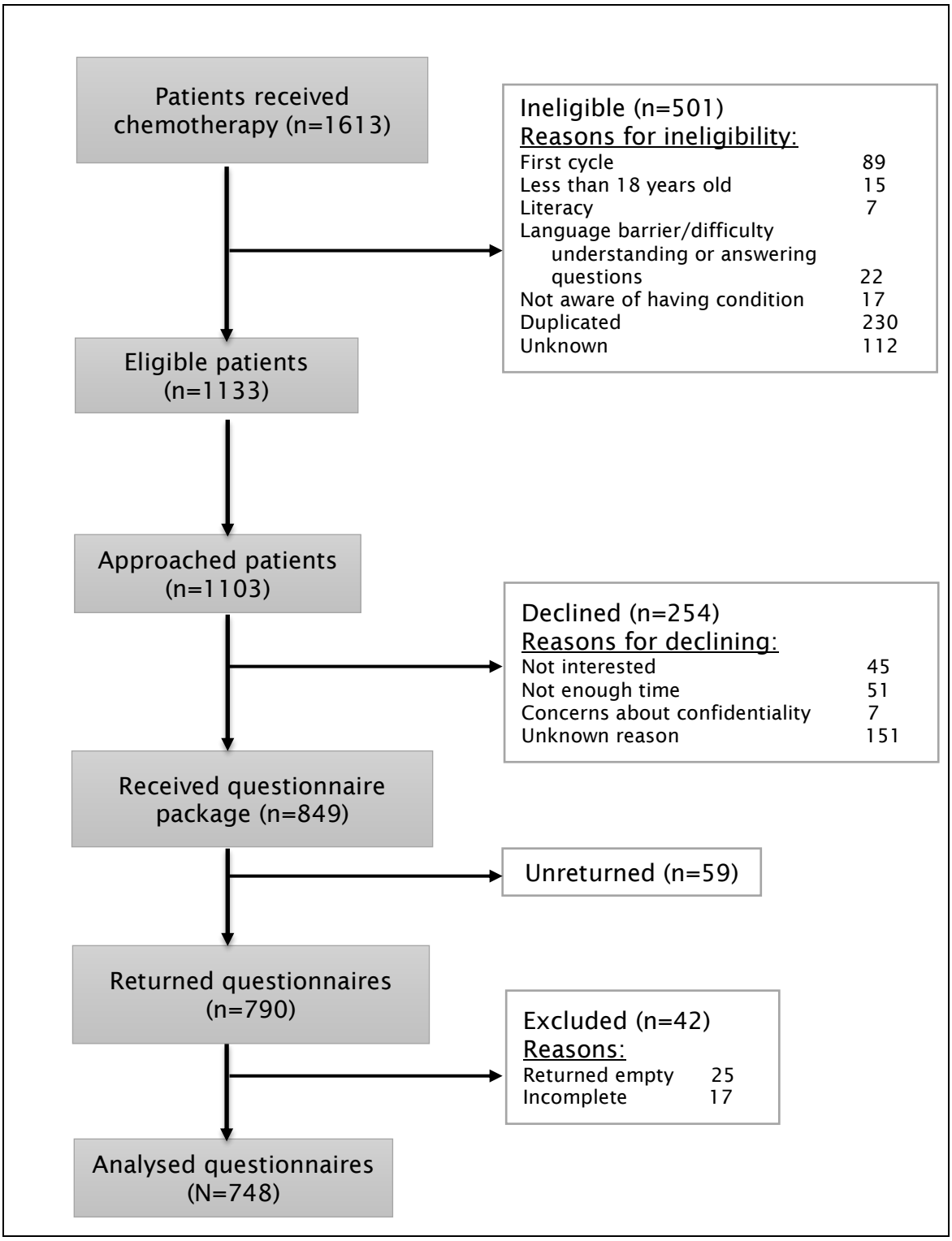


Figure 7-1 Flowchart of outcome of screening & recruitment process in Stage III

7.4.1.2 Feasibility and Effectiveness of data collection protocol

7.4.1.2.1 Recruitment strategy and screening method

The intention was to ask each centre to recruit for a four-week period (one month). In other words, data collection was intended to take 20 working days in each centre. However, due to variation in calendar order of collecting data over religious and school holidays, only two centres achieved this, Centres C and E recruited patients for 16 days only. In Centre D, the data collectors did not provide any data on recruitment time as they did not complete the log of recruitment activity.

Seven hundred and forty eight patients who were undergoing chemotherapy were ultimately recruited out of a total of 1613 patients attending the targeted centres, over the data collection period, and who were screened for eligibility. Of those undergoing chemotherapy, 70% (n=1133) fulfilled the inclusion criteria for the study.

7.4.1.2.2 Feasibility of exclusion criteria

Of the 1613 patients receiving chemotherapy, 501 were not considered to meet the inclusion criteria for the study, an exclusion rate of 31%. Records on reasons for ineligibility show that most were ruled ineligible either for being duplicate patients (45.9%, n=230) or for unknown reasons (patient did not give an explanation) (22.35%, n=112), but not being the first cycle. First cycle patients came third, 19.56% (n=98) of the ineligible population. Twenty-two patients (4.39%) had a language barrier (non-Arabic speakers) or difficulty understanding or answering questions. A further 3.39% (n=17) were not aware of having cancer, 2.99% (n=15) were reported to be younger than 18 years old, and the remaining 1.39% (n=7) of ineligible patients were illiterate.

7.4.1.3 Patient interest/participation in the survey

Out of the 1103 patients who were approached to participate in the study, 23.03% (n=254) declined to participate for reasons including not having enough time (n=51), not being interested in taking part (n=45), and concerns about confidentiality (n=7). The remaining (n=151) did not want to participate for unknown reasons.

7.4.1.4 Determining recruitment rate

Of those approached (n=1103), 849 agreed to participate and received the questionnaire package. It was planned to collect the required data over the course of a six-month period. However, potential participants were approached in person between 5 September 2015 and 10 August 2016. This delay was caused by two reasons: the spread of coronavirus during the recruitment period, and gaining a response from ethics committees, which took varying lengths of time to consider the study.

Five out of seven hospitals ultimately agreed to take part in this study, a recruitment rate of 71.4%. The data collection process began immediately after each hospital granted approval for the study.

Table 7-4 presents and compares the number of days devoted to the participant recruitment process in each centre. Each volunteer research assistant was asked to complete a log of recruitment activity daily. However, one volunteer research assistant failed to record these data. Overall, the study identified 1133 eligible participants in the five participating centres, who were approached over the course of 92 working days over a 12-month period (20 working days in each centre). The average number of approached patients per day varied between centres from 19.9 to 2.86. Of the 849 who received the questionnaire package (after screening for eligibility), 790 returned the questionnaire to the research boxes, a participation rate of 93.05%. In summary, an average of around eight participants were recruited per day.

Table 7-4 Flow chart for daily recruitment process

	Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Total	Average (SD)	Maximum (Minimum)	Range
A	No. of eligible patients	22	23	19	17	26	19	22	16	21	22	15	18	19	22	22	21	19	18	22	16	399	19.95 (2.79)	26 (15)	11
	No. of approached patients	16	22	12	14	26	11	22	11	19	21	15	15	18	19	22	16	18	16	9	7	329	16.45 (4.90)	26 (7)	19
	No. of patients received questionnaire package	16	22	12	14	23	10	17	11	12	17	10	15	16	15	15	12	11	15	8	7	278	13.9 (4.11)	23 (7)	16
	Returned questionnaire											-										267	-	-	-
B	No. of eligible patients	18	21	25	19	25	18	22	25	21	22	23	22	21	17	22	19	18	25	20	22	425	21.25 (2.55)	25 (17)	8
	No. of approached patients	16	21	25	19	24	17	22	25	19	21	22	22	19	17	22	19	16	17	19	16	398	19.9 (2.93)	25 (16)	9
	No. of patients received questionnaire package	13	18	19	17	17	13	17	18	14	12	9	8	10	10	7	3	8	10	9	7	239	11.95 (4.55)	19 (3)	16
	Returned questionnaire											-										233	-	-	-
C	No. of eligible patients	9	8	11	18	19	21	20	21	22	16	-	-	9	20	18	19	19	16	-	-	266	16.625 (4.71)	22 (8)	14
	No. of approached patients	9	6	11	17	19	19	18	14	17	16	-	-	7	18	15	17	19	9	-	-	231	14.4375 (4.53)	19 (6)	13
	No. of patients received questionnaire package	8	5	10	15	19	19	16	14	17	15	-	-	6	17	15	16	17	7	-	-	216	13.5 (4.69)	19 (5)	14
	Returned questionnaire																					171	-	-	-
D	No. of eligible patients	Unknown																							
	No. of approached patients	102																					Cannot be calculated		
	No. of patients received questionnaire package	75																							
	Returned questionnaire																					74	-	-	-
E	No. of eligible patients	0	8	3	2	9	13	0	2	0	-	4	0	0	2	0	0	-	-	-	-	43	2.86 (4.03)	13 (0)	13
	No. of approached patients	0	8	3	2	9	13	0	2	0	-	4	0	0	2	0	0	-	-	-	-	43	2.86 (4.03)	13 (0)	13
	No. of patients received questionnaire package	0	8	3	2	9	12	0	2	0	-	4	0	0	1	0	0	-	-	-	-	41	2.73 (3.88)	12 (0)	12
	Returned questionnaire											-										41	-	-	-

7.4.1.5 Response rate

Overall, the recruitment rate was high, and the number of responses received was greater than expected, because during the pilot stage the response rate was 76.7%. Although questionnaires were not offered to all eligible patients, 2.91% (n=30) were missed from a total of 1133 eligible patients due to the busy working clinic, and data were not collected for the full period in some centres (Table 7-4).

Response rates were calculated by dividing the number of returned questionnaires by the total sample that received the questionnaire package. Overall, the response rate was 93.05%, with one centre achieving 100% and the lowest percentage was in Centre C who achieved over 79% (see Table 7-5). In total, 790 people returned the questionnaires. Of these 790 questionnaires (n= 42, 5.316%) had to be excluded as patients returned them uncompleted or without fully answering questions about symptoms. As a result, 748 questionnaires were analysed. This indicates the PR-CISE was acceptable to patients and data collection feasible.

Table 7-5 Response by study site

Centre	N	%
Centre A	267	96.04
Centre B	237	99.16
Centre C	171	79.16
Centre D	74	98.66
Centre E	41	100
Total	790	93.05

7.4.2 Frequencies of missing data

Of those included in the analysis, missing data varied according to the question being asked. Data were classified as missing when no value was observed for a variable where there should have been a response. The proportion of missing data in each completed questionnaire was less than

10 %. The percentages of missing information ranged from 0.13% to 2.12% depending on the variable. The percentage of missing data for demographic data was low. Moreover, the percentages of missing data for the side effects variables was as follows: (B1-3) the highest number of patients experienced pain or irritation at the injection site (2.12%), (B1-5) weakness (1.33%), and (B1-6) signs of infection (0.93%). While in the nursing support variables, the percentage of missing data ranged from 0.26% to 2% in across the 748 participants. A summary of the frequency and percentage of missing data for each variable can be found in Table 7-6.

Table 7-6 Frequency and percentage of missing data for each variable

Variable	N	Mean	Std. Deviation (SD)	Missing	
				N	%
A1	744			4	0.5
A2	739	1.39	0.48	9	1.2
A3	736	1.57	0.76	12	1.6
B1_1_Nausea	744	2.14	1.04	4	0.5
B1_2_Vomiting	743	1.59	0.91	5	0.7
B1_3_Pain or Irritation	732	1.59	0.93	16	2.1
B1_4_Mouth or Throat	744	2.06	1.08	4	0.5
B1_5_Feeling weak	738	2.65	1.07	10	1.3
B1_6_Infection	740	1.97	1.07	8	1.1
B1_7_Feeling Low or Depressed	745	2.18	1.09	3	0.4
B2	748	1.61	0.52	0	0
B3_1	741	2.2	0.92	7	0.9
B3_2	739	2.26	0.89	9	1.2
B3_3	737	2.04	0.89	11	1.5
B3_4	733	2.07	0.90	15	2
B3_5	746	1.49	0.66	2	0.3
B4	747	7.5	2.07	1	0.1
C1	737	5.76	3.56	11	1.5
C2	744	6.28	3.29	4	0.5
C3	744	1.16	0.38	4	0.5
C4	747	1.19	0.54	1	0.1
Age	741	3.32	1.39	7	0.9
Gender	747	1.66	0.47	1	0.1
Total				**144**	**19.8**

7.4.3 Descriptive analysis of participants' demographic, clinical and treatment characteristics

Table 7-7 presents the demographic and clinical characteristics of the sample used in the analyses. In the whole sample, there were more women (65.77%, n=492) than men (34.09%, n=255). Of those recruited, the highest proportion (n=194, 25.93%) were aged between 41-50 years, while the lowest proportion (n= 46, 6.15%) were 71 years or older.

The researcher or volunteer research assistants wrote the type of chemotherapy, diagnosis and treatment cycle on each questionnaire before passing it to targeted patients. Because of this, diagnosis data were missing from only four patients (0.53%). This figure indicates the feasibility of the data collection process.

A wide variety of cancer diagnoses were reported, especially in centres that recruited large numbers of patients. Across the whole sample, the highest proportion of patients had breast cancer (32.75%), and the proportion varied between centres ranging from 18.9% to 53.7%. The most frequently identified types of cancer other than breast cancer varied between centres. For example, lymphoma came second on the list of identified diagnoses (n= 90, 12%) (see Table 7-7), although in Centre A and E different types of cancers were identified.

Table 7-8 summarises clinical and treatment data. Almost 59% of those surveyed had received cycles 2, 3, 4 or 5 of their chemotherapy treatment. The most widely administered classes of chemotherapy drugs were vesicants (64.57%), and the proportion of exfoliants and highly emetogenic treatments each were approximately 25%. Across the sample, the majority of participants (87.29%) received their treatment via peripheral cannula and a small proportion 12.6% through a central venous catheter.

Analysis of variation between centres found significant differences in gender ($\chi^2_{(4)} = 17.36, \rho = .002$), age groups ($\chi^2_{(20)} = 40.70, \rho = 0.004$), site of cancer ($\chi^2_{(44)} = 101.16, \rho = .000$), and the cycle of chemotherapy ($\chi^2_{(44)} = 62.07, \rho = 0.037$).

Table 7-7 Participants' demographic and clinical characteristics by centre

Centre		A	B	C	D	E	Total	Association with centres
N		259	233	162	53	41	748	
Gender N (%)								$\chi^2_{(4)} = 17.363, \rho = 0.002$
	Male	87 (33.6)	64 (27.5)	72(44.4)	23(44.23)	9 (22)	255 (34.09)	
	Female	172 (66.4)	169 (72.5)	90(55.6)	29(55.77)	32 (78)	492 (65.77)	
	Missing	0	0 (0)	0 (0)	1 (1.886)	0 (0)	1 (0.133)	
Age N (%)	18-30	34 (13.1)	30 (12.9)	17 (10.5)	6 (11.3)	2 (4.9)	89 (11.89)	$\chi^2_{(8)} = 40.696, \rho = 0.004$
	31-40	48 (18.5)	36 (15.5)	18 (11.10)	10 (18.9)	10 (24.4)	122 (16.3)	
	41-50	58 (22.4)	75 (32.2)	34 (21.0)	19 (35.8)	8 (19.5)	194 (25.93)	
	51-60	71 (27.4)	56 (24.0)	39 (24.1)	7 (13.2)	9 (22)	182 (24.33)	
	61-70	29 (11.2)	23 (9.9)	39 (24.1)	8 (15.1)	9 (22)	108 (14.43)	
	71+	18 (6.9)	13 (5.6)	12 (7.4)	1 (1.9)	2 (4.9)	46 (6.15)	
	Missing	1 (0.4)	0 (0)	3 (1.9)	2 (3.8)	1 (2.4)	7 (0.93)	
Site of Cancer	N (%) Bladder/Urological (not prostate)	4 (1.5)	4 (1.7)	0 (0)	3 (5.7)	1 (2.4)	12 (1.60)	$\chi^2_{(52)} = 101.164, \rho = 0.000$
	Blood	33 (12.7)	20 (8.6)	9 (5.6)	5 (9.4)	0 (0)	67 (8.95)	
	Bowel	24 (9.3)	24 (10.3)	24 (14.8)	9 (17.0)	6 (14.6)	87 (11.63)	
	Brain/Central Nervous System	4 (1.5)	4 (1.7)	2 (1.2)	1 (1.9)	2 (4.9)	13 (1.73)	
	Breast	87 (33.6)	87 (37.3)	39 (24.1)	10 (18.9)	22 (53.7)	245 (32.75)	
	Gynaecological (womb, ovaries)	24 (9.3)	23 (9.9)	8 (4.9)	3 (5.7)	5 (12.2)	63 (8.42)	
	Head or Neck	8 (3.1)	6 (2.6)	3 (1.9)	1 (1.9)	0 (0)	18 (2.40)	
	Lung	14 (5.4)	8 (3.4)	17 (10.5)	1 (1.9)	1 (2.4)	41 (5.48)	
	Lymphatic (lymphoma)	30 (11.6)	26 (11.2)	24 (14.8)	10 (18.9)	0 (0)	90 (12)	
	Oesophagus or Tung	3 (1.2)	3 (1.3)	0 (0)	1 (1.9)	0 (0)	7 (0.93)	
	Prostate	3 (1.2)	0 (0)	3 (1.9)	0 (0)	2 (4.9)	8 (1.06)	
	Stomach	3 (1.2)	5 (2.1)	9 (5.6)	3 (5.7)	0 (0)	20 (2.67)	
	Other	22 (8.5)	21 (9.0)	24 (14.8)	3 (5.7)	1 (2.4)	71 (9.5)	
	I don't know	0 (0%)	2 (0.9)	0 (0)	0 (0)	0 (0)	2 (0.26)	
	Missing	0 (0%)	0 (0)	0 (0)	3 (5.7)	1 (2.4)	4 (0.53)	

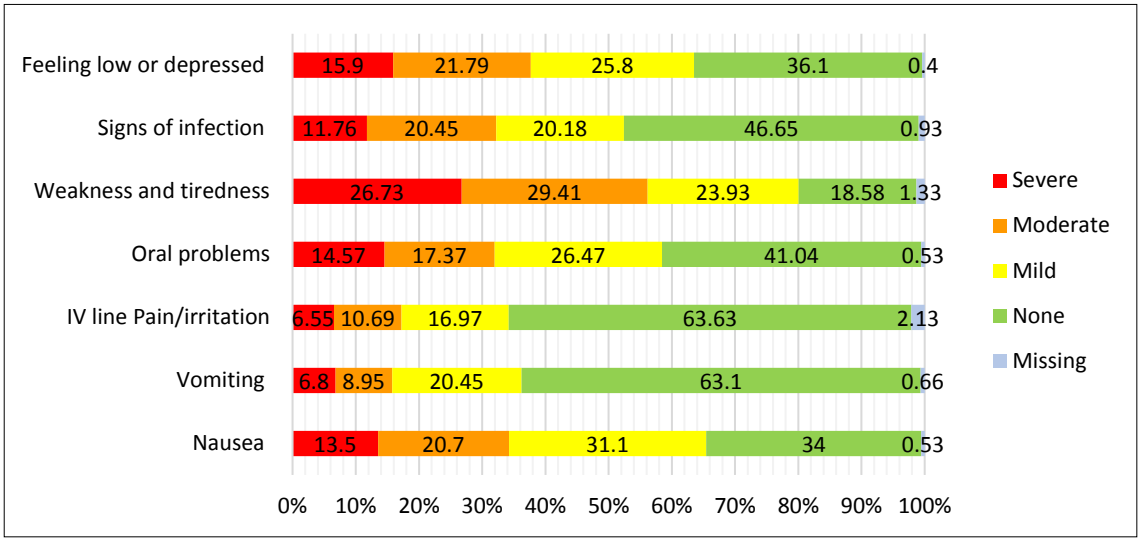
Table 7-8 Cycle, classification, mode, and device of chemotherapy by centre

Centre	A	B	C	D	E	Total	Association with centres
N	259	233	162	53	41	748	
Chemo cycle N (%)							
2	49 (18.9)	46 (19.7)	19 (11.7)	5 (9.4)	9 (22)	128	$\chi^2_{(44)} = 62.073, \rho = 0.037$
3	39 (15.1)	44 (18.9)	39 (24.1)	9 (17)	4 (9.8)	135	
4	32 (12.4)	30 (12.9)	24 (14.8)	8 (15.1)	4 (9.8)	98	
5	23 (8.9)	23 (9.9)	20 (12.3)	6 (11.3)	6 (14.6)	84	
6	16 (6.2)	18 (7.7)	7 (4.3)	2 (3.8)	11 (26.8)	54	
7	19 (7.3)	13 (5.6)	13 (8)	2 (3.8)	1 (2.4)	48	
8	19 (7.3)	9 (3.9)	8 (4.9)	1 (1.9)	2 (4.9)	39	
9	10 (3.9)	7 (3.0)	6 (3.7)	1 (1.9)	0 (0)	24	
10	11 (4.2)	6 (2.6)	7 (4.3)	2 (3.8)	1 (2.4)	27	
11	3 (1.2)	3 (1.3)	5 (3.1)	1 (1.9)	0 (0)	12	
12	3 (1.2)	7 (3.0)	1 (0.6)	0 (0)	1 (2.4)	12	
13+	34 (13.1)	27 (11.6)	13 (8.0)	6 (11.3)	2 (4.9)	82	
Missing	1 (0.4)	0 (0)	0 (0)	10 (18.9)	0 (0)	11	
Received vesicant chemotherapy N (%)	153(59.07)	149 (63.94)	108 (66.66)	36 (67.92)	37 (90.24)	483 (64.57)	$\chi^2_{(4)} = 15.845, \rho = 0.003$
Received irritant chemotherapy N (%)	28 (10.81)	34 (14.59)	39 (24.07)	6 (11.32)	1 (2.43)	108 (14.43)	$\chi^2_{(4)} = 20.134, \rho = 0.000$
Received exfoliant chemotherapy N (%)	36 (13.89)	80 (34.33)	38 (23.45)	16 (30.18)	23 (56.09)	193 (25.8%)	$\chi^2_{(4)} = 48.681, \rho = 0.000$
Received inflammitant chemotherapy N (%)	14 (5.4)	55 (23.6)	21 (12.96)	4 (7.54)	0 (0)	94 (12.56%)	$\chi^2_{(4)} = 45.059, \rho = 0.000$
Received highly emetogenic chemotherapy N (%)	52 (20.07)	76 (32.61)	45 (27.77)	10 (18.86)	6 (14.63)	189 (25.26%)	$\chi^2_{(4)} = 14.507, \rho = 0.006$
Mode of chemo administration N (%)							
Intravenous Injection (IV)	229 (88.7)	191 (82)	138 (85.2)	48 (90.6)	27 (65.9)	633 (84.5)	$\chi^2_{(8)} = 50.171, \rho = 0.000$
IV and Tablets	29 (11.2)	42 (18)	22 (13.6)	4 (7.5)	11 (26.8)	108 (14.4)	
Missing	1 (0.4)	0 (0)	2(1.2)	1 (1.9)	0 (0)	4 (0.53%)	
Chemotherapy administration N (%)							
IV cannula	237 (91.5)	198 (85)	140 (86.4)	45 (84.9)	33 (80.5)	653 (87.3)	$\chi^2_{(8)} = 17.168, \rho = 0.028$
PICC	9 (3.5)	23 (9.9)	9 (5.6)	1 (1.9)	3 (7.3)	45 (6)	
Portacath or Hickman	13 (5)	12 (5.2)	13 (8)	6 (11.3)	5 (12.2)	49 (6.6)	
Missing	0 (0)	0 (0)	0 (0)	1 (1.9)	0 (0)	1 (1.33%)	

7.4.4 Severity of subjective symptoms

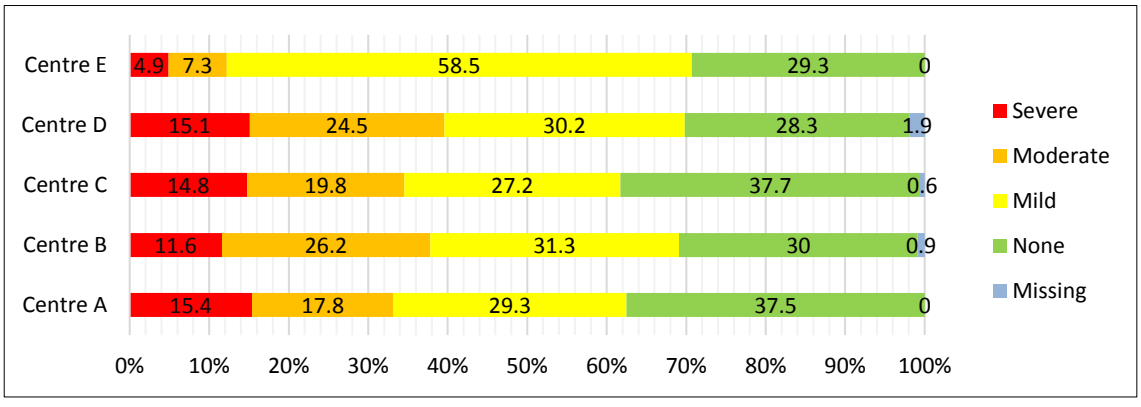
This analysis groups outcomes into (none & mild) and (moderate & severe). Results show a considerable variation regarding the percentage of patients experiencing symptoms across the five centres. The most frequently identified symptom was 'weakness and tiredness', with 56.14% of participants reporting it as experiencing moderate or severe symptom, see Chart 7-1.

Chart 7-1Percentage of participants experiencing symptoms



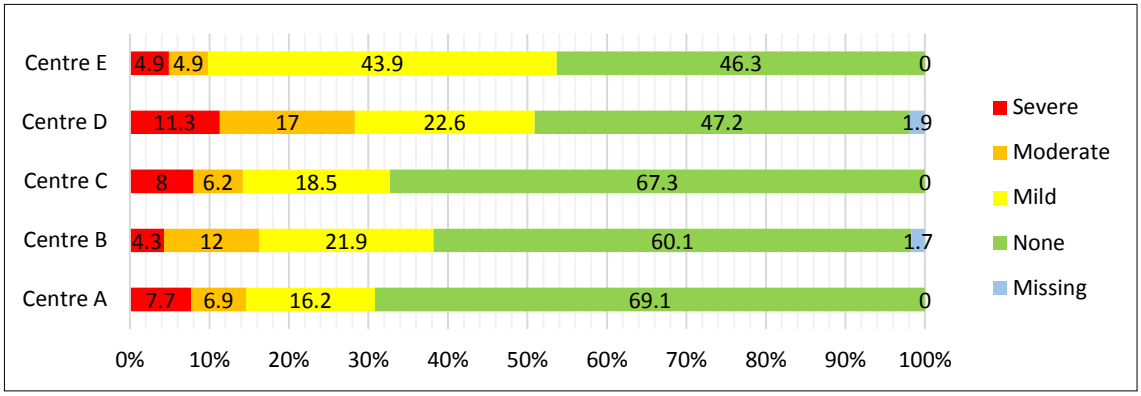
The severity of nausea reported by patients varied among centres (see Chart 7-2). Sixty-five percent of patients reported experiencing mild or no nausea, while 24.5% of patients reported moderate or severe nausea.

Chart 7-2 Percentage of participants experienced nausea by centre



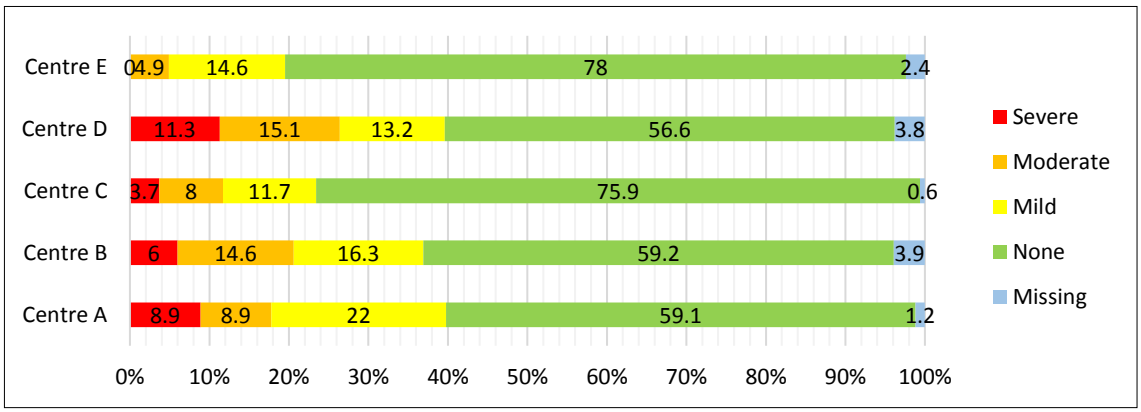
Across the whole sample, a significant number of respondents (approximately 63%) reported they had not experienced any vomiting with their previous cycle of chemotherapy (see Chart 7-3). Across all five centres, the rate of severe vomiting was 11.3% or less.

Chart 7-3 Percentage of participants experienced vomiting by centre



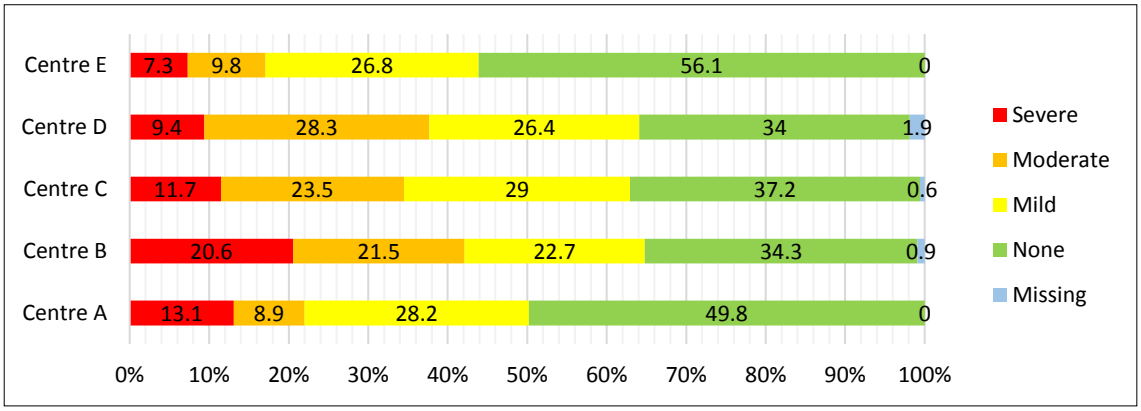
The majority of participants (80.6%) reported experiencing mild or no pain or irritation at the injection site (see Chart 7-4). Those reporting severe or moderate pain or irritation at the injection site ranged from 4.9% in Centre E to 26.4% in Centre D. In Centre E, no-one reported experiencing severe pain or irritation at the injection site.

Chart 7-4 Percentage of participants experienced IV-line pain or irritation by centre



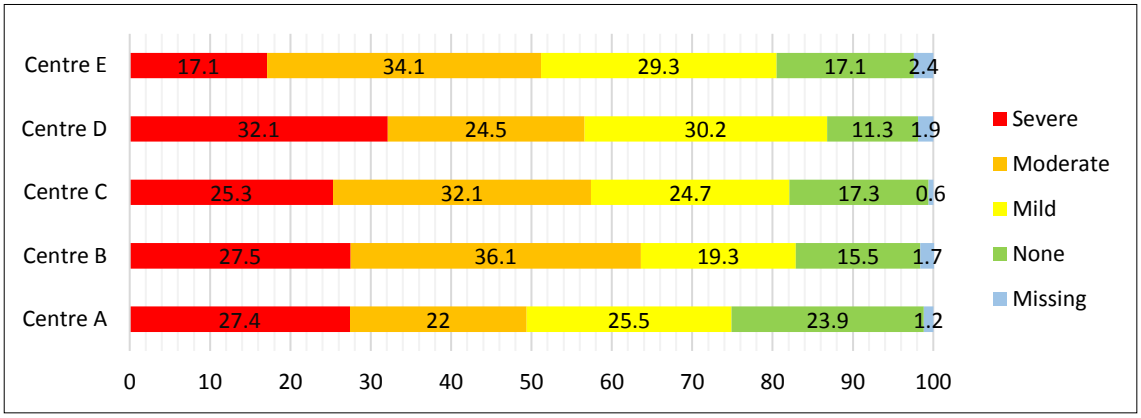
Across the whole sample, 67.51% of respondents reported zero or mild oral problems (see Chart 7-5). There was variation in oral problems between centres, with the lowest proportion of severe problems being 7.3% in Centre E, and the highest being 20.6% in Centre B.

Chart 7-5 Percentage of participants experienced oral problems by centre



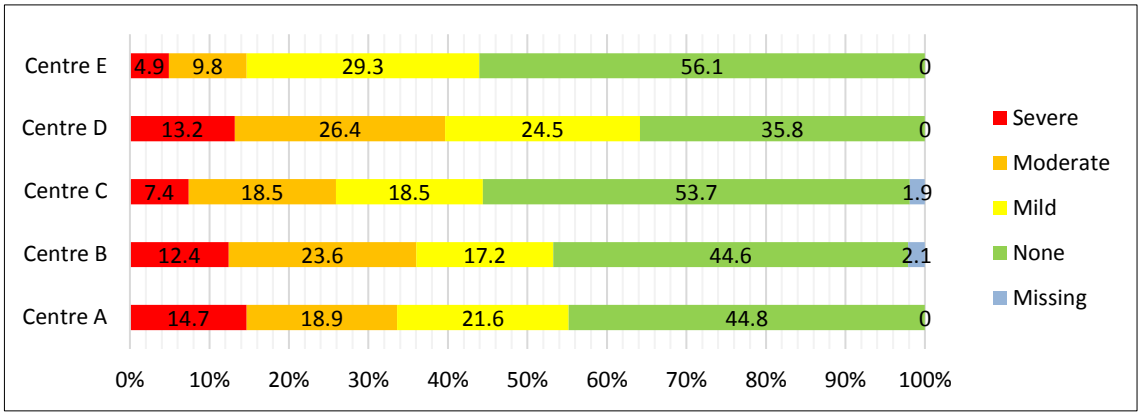
Results about weakness and tiredness revealed that 56.14% of the sample reported moderate or severe weakness (see Chart 7-6). In Centres A and E, equal numbers of participants reported severe/moderate and mild/no weakness. The proportion of participants reporting severe issues was consistently highest across all centres. The percentage of those with moderate symptoms of weakness was highest at Centres B and C, with more than 30% at each.

Chart 7-6 Percentage of participants experienced weakness and tiredness by centre



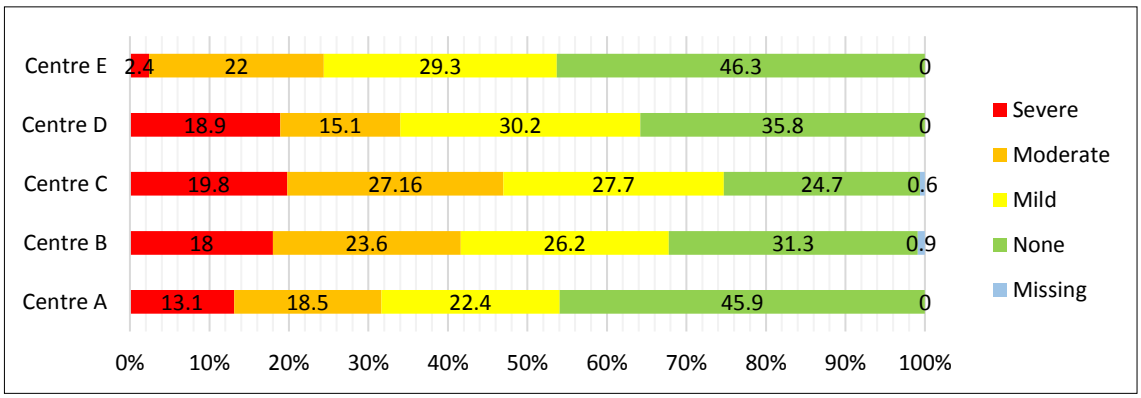
Overall, the majority of patients (approximately 67%) reported either an absence, or only mild signs, of infection during their previous cycle of chemotherapy (see Chart 7-7).

Chart 7-7 Percentage of participants experienced s*igns of Infection* by centre



Moderate or severe feeling low or depressed was reported by 37.8% of the whole sample. Across the centres the rate of severe distress was 20% or less (see Chart 7-8). Centre E reported a substantially different figure from the other centres, with less than 2.5% reporting severe problems.

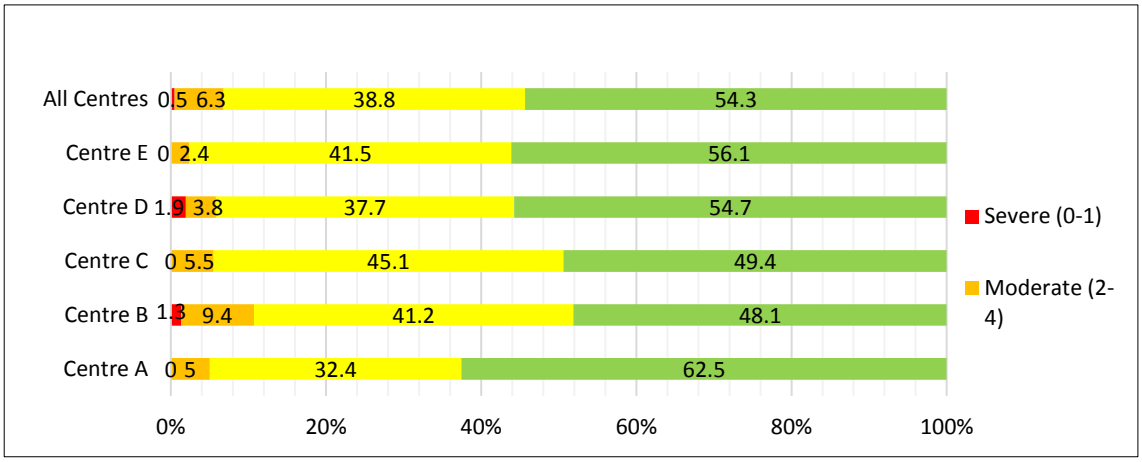
Chart 7-8 Percentage of participants experienced feeling low or depressed by centre



As it appears in Chart 7-9 there was less variability reported between centres on the distress thermometer item. The majority of respondents, 54.3%, reported experiencing no distress. The proportion reporting they experienced

moderate or severe distress was 6.8%. There was no evidence from the study that respondents experienced severe distress in three centres (Centres A, C and E), while negligible results ranged from 1.3% (Centre B) to 1.9% (Centre D).

Chart 7-9 Percentage of participants experienced distress by centre



Significant differences were observed in the distribution of severity of symptoms between centres in six out of the seven studied symptoms. Chi-square tests confirm significant associations between the centres and severity of the following problems: Nausea ($\chi^2_{(12)} = 26.65, p = 0.009$); Vomiting ($\chi^2_{(12)} = 34.34, p = 0.001$); Pain or irritation at injection site ($\chi^2_{(12)} = 30.29, p = 0.003$); Oral problem ($\chi^2_{(12)} = 44.52, p = 0.0001$); Feeling weak ($\chi^2_{(12)} = 22.36,\ p = 0.034$); and Feeling low and depressed ($\chi^2_{(12)} = 30.62, p = 0.002$). Prevalence of Signs of infection ($\chi^2_{(12)} = 19.09, p = 0.087$) does not seem to differ between centres.

Additional problems

Respondents were asked to report any additional problems they were experiencing other than the seven symptoms listed in the PR-SICE questionnaire. Across the whole sample N=748), 377 additional problems were reported by 303 respondents (40.5%). These additional problems have been categorised into 13 categories, and presented in Table 7-9. The most commonly reported additional problems were bone pain (n=68) and alopecia (n=49), while the least common was impotence (n=3).

Frequencies of these additional reported items were less likely to occur than symptoms listed in the PR-CISE questionnaire. It could argue that the relative infrequency with which they occur mean that variations would be hard to pick up.

Table 7-9 Additional problems

Additional problems	N
Impotence	3
Oedema	4
Vision problem	6
Bleeding	8
Chest pain	15
Constipation	29
Loss of appetite	29
Numbness	36
Diarrhoea	40
Itching/skin problem	44
Headache	46
Alopecia	49
Bone pain	68
Total	377

7.4.5 Association between severity of symptoms and patient demographics

Spearman's (rho) technique was used to investigate whether symptom severity was influenced by patient demographics, clinical diagnosis, and treatment; types and cycles. Overall, the correlations were weak between symptoms and the variables of interest (see Table 7-10). Gender was correlated with the majority of symptoms ($p< 0.025$), most strongly with nausea (rho= 0. 0.123). There was no statistically significant effect between Vesicant or Exfoliant and all symptoms.

Table 7-10 Correlation coefficients (rho) for symptom severity and patient demographics

Symptoms		Association with								
		Patients demographics		Clinical diagnosis	Treatment type					Treatment cycle
		Age groups	Gender	Cancer site	vesicant	irritant	Exfoliant	Inflammitant	Emetogenic	
Nausea	rho	-0.126**	0.123**	0.009	0.050	-0.101**	-0.047	-0.003	-0.076*	-0.069*
	P-value	0.000	0.000	0.407	0.085	0.033	0.099	0.468	0.019	0.031
Vomiting	rho	-0.087**	0.047	0.013	-0.006	-0.147**	-0.051	-0.003	-0.018	-0.039
	P-value	0.009	0.100	0.359	0.436	0.000	0.084	0.472	0.311	0.149
IV-line pain/irritation	rho	-0.072*	0.089**	-0.120**	0.040	0.019	-0.038	0.009	0.010	-0.051
	P-value	0.026	0.008	0.001	0.139	0.305	0.154	0.400	0.390	0.086
Oral problems	rho	0.058	0.073*	0.020	0.055	0.003	-0.046	-0.094**	-0.024	-0.067*
	P-value	0.058	0.023	0.294	0.066	0.467	0.105	0.005	0.258	0.035
Weakness and tiredness	rho	0.011	0.102**	-0.001	0.013	-0.018	-0.035	-0.043	-0.019	-0.010
	P-value	0.379	0.003	0.489	0.359	0.317	0.171	0.120	0.304	0.390
Signs of infection	rho	-0.044	0.072*	-0.091**	0.012	-0.049	-0.009	-0.010	-0.011	-0.023
	P-value	0.119	0.025	0.007	0.370	0.091	0.402	0.391	0.381	0.271
Feeling low or depressed	rho	-0.043	0.115**	0.000	-0.004	-0.047	0.012	0.073*	-0.008	0.052
	P-value	0.120	0.001	0.498	0.458	0.100	0.369	0.024	0.417	0.080
Distress thermometer	rho	-0.012	-0.030	0.077*	0.011	-0.025	0.002	0.023	-0.038	-0.018
	P-value	0.367	0.210	0.018	0.384	0.251	0.477	0.268	0.151	0.317

** Correlation is significant at the 0.01 level (1-tailed), * Correlation is significant at the 0.05 level (1-tailed).

7.4.6 Support with managing symptoms

This part of the analysis assesses participants' perceptions of nurses' support in response to symptoms they experienced (see Chart 7-10). In this sample, there were large variations between centres. Across the whole sample from Centres A to D, approximately half (53%) of patients reported that nurses did not ask about their symptoms or were not aware of the severity of their symptoms, while about 78% of respondents from Centre E reported that nurses did ask about their symptoms. More than 40% of respondents across all centres said that nurses did not provide useful information or practical advice for symptom management. The majority of participants (59.2%) reported they felt confident about managing their symptoms, while only 9% of participants were not fully confident in their ability to manage their symptoms.

Table 7-11 and Chart 7-10 gives a summary of variations in the distribution of patients' responses to items about symptom management between centres. While all the support variables were statistically significantly associated with centres, the Chi-square tests suggest that the provision of useful information and practical advice by nurses were strongly associated with centres. This highlights the need to further investigate the importance or impact of nursing staff and centre specific characteristics on quality of cancer care and symptom management.

Table 7-11 Support to manage symptoms

CENTRE	A		B		C		D		E		Total		Association with centres
	N	%	N	%	N	%	N	%	N	%	N	%	
DO THE NURSES WHO GIVE YOU CHEMOTHERAPY ASK ABOUT YOUR SYMPTOMS?													
Yes	111	42.9	53	22.7	44	27.2	14	26.4	32	78	254	33.9	$\chi^2_{(8)} = 81.207, \rho = 0.000$
Somewhat	21	8.1	38	16.3	14	8.6	15	28.3	0	0	88	11.8	
No	123	47.5	141	60.5	102	63.0	24	45.3	9	22	399	53.3	
MISSING	4	1.5	1	0.4	2	1.2	0	0	0	0	7	0.93	
ARE THE NURSES WHO GIVE YOU CHEMOTHERAPY AWARE OF THE SEVERITY OF THE SYMPTOMS?													
Yes	96	42.9	48	20.6	23	19.8	11	20.8	30	73.2	208	27.8	$\chi^2_{(8)} = 71.419, \rho = 0.000$
Somewhat	36	8.1	44	18.9	28	17.3	15	28.3	0	0	123	16.4	
No	126	47.5	139	59.7	99	61.1	26	49.1	11	26.8	401	53.6	
MISSING	1	1.5	2	0.9	3	1.9	1	1.9	0	0	7	0.93	
ARE THE NURSES WHO GIVE YOUR CHEMOTHERAPY PROVIDING USEFUL INFORMATION TO MANAGE YOUR SYMPTOMS?													
Yes	131	50.6	48	20.6	56	34.6	9	17.0	39	95.1	283	37.8	$\chi^2_{(8)} = 133.388, \rho = 0.000$
Somewhat	36	13.9	44	18.9	45	27.8	19	35.8	0	0	144	19.2	
No	86	33.2	139	59.7	59	36.4	24	45.3	2	4.9	310	41.4	
MISSING	6	2.3	2	.9	2	1.2	1	1.9	0	0	11	1.4	
ARE THE NURSES WHO GIVE YOUR CHEMOTHERAPY PROVIDING PRACTICAL ADVICE TO MANAGE YOUR SYMPTOMS?													
Yes	125	48.3	50	21.5	53	32.7	7	13.2	39	95.1	274	36.6	$\chi^2_{(8)} = 132.057, \rho = 0.000$
Somewhat	35	13.5	37	15.9	47	29.0	14	26.4	1	2.4	134	17.9	
No	94	36.3	143	61.4	58	35.8	29	54.7	1	2.4	325	43.4	
MISSING	5	1.9	3	1.3	4	2.5	3	5.7	0	0	15	0.13	
ARE YOU CONFIDENT IN YOUR ABILITY TO MANAGE THE SYMPTOMS YOU ARE EXPERIENCING?													
Yes	175	67.6	135	57.9	85	52.5	17	32.1	34	82.9	446	59.6	$\chi^2_{(8)} = 59.416, \rho = 0.000$
Somewhat	49	18.9	87	37.3	61	37.7	28	52.8	7	17.1	232	31	
No	35	13.5	10	4.3	16	9.9	7	13.2	0	0	68	9	
MISSING	0	0	1	0.4	0	0	1	1.9	0	0	2	0.26	

Chart 7-10 Support to manage symptoms

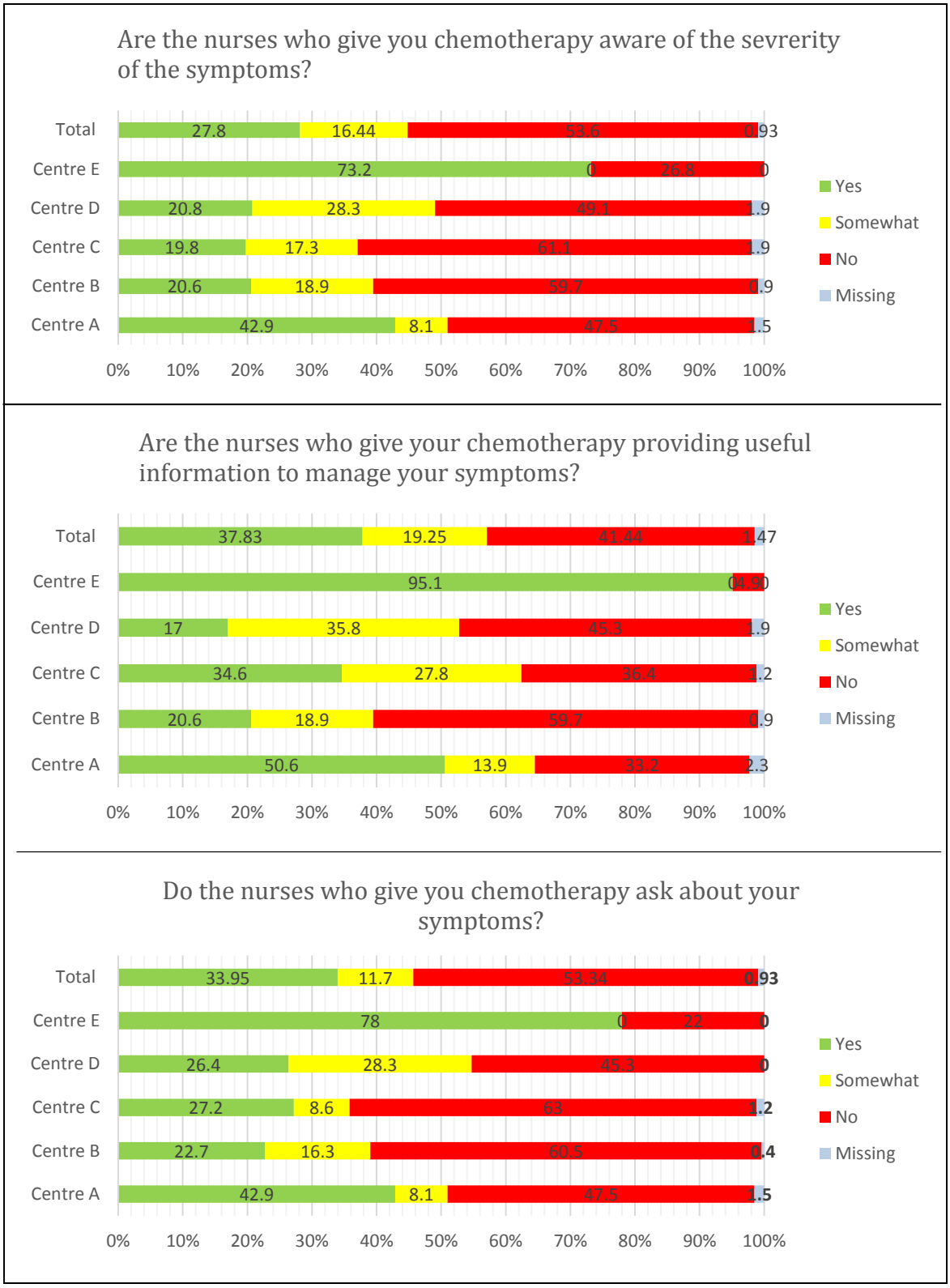
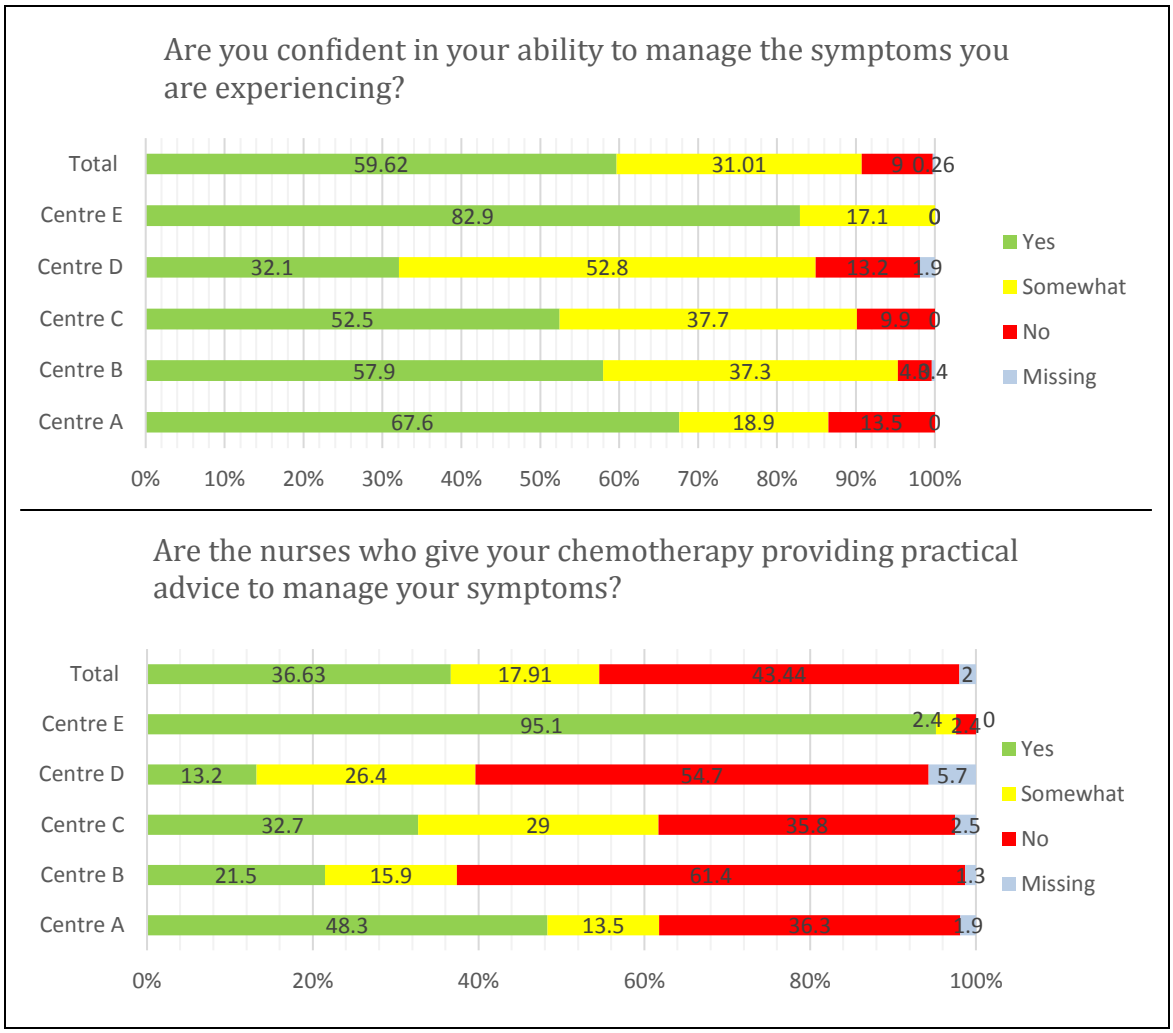


Chart 7-10 Continued



7.4.7 Correlations between support to manage symptoms and symptom severity

Evidence on the correlation between support to manage symptoms and symptom severity were calculated, using Spearman's rank correlations coefficient rho technique. While this study is not intended to establish causal relationships, it does contribute data which to be used in estimating correlation between support to manage symptoms, and symptom severity.

There was only weak evidence of a correlation between a centre's ranking of performance on support to manage symptoms and symptom severity (see

Table 7-12). The strength of the relationship between the variables was assessed, and the weakest negative correlation was observed in vomiting (rho= -0.023, rho= -0.052, rho= -0.053, rho= -0.047), and infection (rho= -0.002).

Table 7-12 Correlation between support to manage symptoms and symptoms severity

	Nausea	Vomiting	IV-line pain or irritation	Oral problems	Weakness and tiredness	Signs of infection	Feeling low or depressed	Distress
Nurses ask about symptoms	0.053	-0.023	0.061	0.072	0.079*	-0.002	0.089*	-0.015
Nurses aware of symptoms	0.001	-0.052	0.044	0.027	0.027	0.004	0.048	0.001
Nurses give useful information	0.012	-0.053	0.094*	0.053	0.022	0.000	0.029	0.013
Nurses give practical advice	0.039	-0.047	0.091*	0.047	0.012	0.001	0.044	0.007
Confidence in self-care ability	0.115**	0.090*	0.028	0.051	0.037	0.013	0.089*	0.138**

7.4.8 Patient experience of informational support

Participants were asked to complete two questions about their experience of informational support (awareness of chemotherapy side effects), see

Table 7-13.

Centre E ranked as giving the highest proportion (92.7%) of participants a clear explanation about what their treatment will involve, while Centre B was ranked the lowest with 30.9%. Across the sample, 58.28% of participants reported that they were fully informed about the possible side effects they might experience because of their chemotherapy treatment. However, almost a quarter of the sample reported (24%) felt that they were to some extent informed about possible side effects of their treatment.

Table 7-13 Patient awareness of chemotherapy side effects

		A	B	C	D	E	Total	Association with centres
		N (%)	N (%)	N (%)	N (%0	N (%)	N (%)	
Before starting your treatment, did you get a clear explanation by your chemotherapy nurse of what treatment will involve?	Yes	191 (73.7)	72 (30.9)	126 (77.8)	26 (49.1)	38 (92.7)	453 (60.56)	$\chi^2_{(4)}$ =155.677, $\rho = 0.000$
	No	65 (25.1)	161 (69.1)	35 (21.6)	25 (47.2)	0 (0)	286 (38.23)	
	Missing	3 (1.2)	0 (0)	1 (0.6)	2 (3.8)	3 (7.3)	9 (1.2)	
Do you feel that you are fully informed about the side effects that might result from your chemotherapy?	Yes	147 (56.8)	138 (59.2)	93 (57.4)	23 (43.4)	35 (85.4)	436 (58.28)	$\chi^2_{(8)} = 26.320$, $\rho = 0.001$
	To some extent	58 (22.4)	56 (24)	45 (27.8)	19 (35.8)	2 (4.9)	180 (24)	
	No	51 (19.7)	37 (15.9)	22 (13.6)	9 (17)	1 (2.4)	120 (16)	
	Missing	3 (1.2)	2 (0.9)	2 (1.2)	2 (3.8)	3 (7.3)	12 (1.6)	

7.4.9 Descriptive analysis of unit profile and nurse workforce

Descriptive information on the variables of interest is provided in Table 7-14, which shows how centre size, total nursing personnel, skill mix, and nurse education vary across participating centres.

7.4.9.1 Centre characteristics

Four of the 5 centres (A, B, C and E) are located in tertiary hospitals, with only one of these a teaching hospital (centre C). The 5th centre (D) was a secondary hospital. The centres show considerable variability in Centre size and capacity in terms of beds or chairs, which ranged from 10 to 22 beds/chairs. Table 7-14 confirms that the centres show likeness in the number of working shifts, shifts length, and types of cancer treated in the centre. Although the numbers of treated patients were varied.

Centres D and E are primarily small centres with fewer patient participants than the rest of the centres. This meant reliable estimates of the effect of centre and nursing characteristics of interest on patient outcomes was not possible to calculate.

7.4.9.2 Nurse characteristics

The centres ranged broadly on nursing characteristics. Overall, nursing personnel staffing were 52 professional nurses, and the majority were female with 84.6 %. And the proportion of male nurses was very few.

7.4.9.3 Nursing skill mix

In the participating centres, all nursing personnel were professional nurses (RN) with no Licensed Practical Nurses (LPNs). It is not possible with the collected data to determine the effect of nursing skill mix on the prevalence of reported severity symptoms in the different centres.

7.4.9.4 Total staffing

Three of the five centres' participant nurses were assigned to the patient, not the bed.

7.4.9.5 Nurse education

Overall, the percentage of nurses holding bachelor degrees was 73%, and ranged widely from 0% in centre E to 100% in Centre A. Only Centre C reported to have 42.1% of nursing personnel holding a specialised diploma in cancer care nursing. Centre E was the only centre with 100% of its nurses holding a diploma (see Table 7-14).

Table 7-14 Participating centres: organisational characteristics, staffing and nursing interventions

	A	B	C	D	E
Centre characteristics					
Hospital type	Tertiary	Tertiary	Tertiary and teaching hospital	Secondary	Tertiary
How many years/months this centre opened?	5 Years	11 years			
Unit capacity (chair/bed number)	22	22	20	15	10
Chairs	10	16	15	15	7
Beds	12	6	5	0	4
No. of working days/week	5 days no weekends	5 days no weekends	5 days no weekends	5 days no weekends	5 days no weekends
No. of nursing shifts	1 shift	1 shift	1 shift	1 shift	1 shift
Shift length	9-hour	9-hour	9-hour	9-hour	9-hour
Start and finish time for each shift	07:30 am-16:30 pm	07am-16pm	08 am–17 pm	07:30 am-16:30 pm	07:30 am-16:30 pm
Type of cancer treated in the centre	All types of cancer	All types of cancer	All types of cancer	All types of cancer	
Staffing					
Total No. of nurses working in the centre N	6	14	19	10	3
No. of nurses administer chemotherapy N (%)	6 (100)	14 (100)	19 (100)	5 (50)	3 (100)
No. of female nurses' N (%)	4 (66.6)	13 (92.8)	14 (73.6)	10 (100)	3 (100)
No. of male nurses' N (%)	2 (33.3)	1 (7.1)	5 (26.3)	0 (0)	*0* (0)
Optimal No. of nursing staff per shift N (%)	6 (100)	10 (71.4)	14 (73.6)	8 (80)	3 (100)
Optimal No. of nurses who speak Arabic/ shift N (%)	4 (66.6)	2 (14.2)	6 (31.5)	3 (30)	1 (33.3)
No. of nurses holding Bachelor Degree N (%)	6 (100)	10 (71.4)	13 (68.4)	9 (90)	0 (0)
No. of nurses holding Diploma N (%)	0 (0)	4 (28.5)	6 (31.5)	1 (10)	3 (100)

No. of nurses holding Diploma in cancer nursing N (%)	0 (0)	0 (0)	8 (42.1)	0 (0)	0 (0)
No. of nurses with pre-work preparation course for cancer care N (%)	6 (100)	14 (100)	11 (57.8)	10 (100)	3 (100)
No. of nurses with no preparation or speciality in cancer care n (%)	0	0	0	0	0
Do you use a standardised approach to measure acuity when allocating chemotherapy patients to particular nurses?	Yes	No	No	No	No
Allocate by chair or patient	Patient	Patient	Chair	Chair	Patient
Nurse-to-chair ratio	-	-	1:3	1:3	
Nurse-to-patient ratio	1:8	1:5-6	-	-	1:4-5
Patient education and assessments					
Patient and family education provided	· Before the first cycle · As needed	· Before the first cycle · By request	· Before the first cycle · By request	· Before the first cycle only	· Before the first cycle · As needed
Format of patient education	One on one	One on one	· One on one · Patient information leaflets	· One on one · Patient information leaflets	One on one Group discussion
Who give patient education	Nurse Educator	Patient educator	Nurse Educator	Physician	Physician
Points of patient education	· Possible side effects · How to reduce or prevent the occurrence of the side effects	· Possible side effects · How to reduce or prevent the occurrence of the side effects · Nutrition plan · Daily activity	· Possible side effects · How to reduce or prevent the occurrence of the side effects · Nutrition plan · Daily activity	· Possible side effects · How to reduce or prevent the occurrence of the side effects	· Possible side effects · How to reduce or prevent the occurrence of the side effects · Nutrition plan · Daily activity
Do nurses assess patients' side effects resulting from the previous cycle?	Before each cycle	If not seen by physician & Before some cycle	If not seen by physician before each cycle	If not seen by physician before each cycle	Before each cycle
Do nurses document patients' side effects of chemo	Before each cycle	If not seen by the physician	If not seen by the physician	Before each cycle	Before each cycle
Do you use a particular nursing documentation tool?	No	No	No	Yes Checklist	No

7.4.10 Factors that influence patient outcomes

To compare between centres variation in symptom prevalence and severity was then estimated before and after adjusting for case mix using multiple logistic regression models.

7.4.10.1 Risk adjusted symptoms

The initial step was grouping outcomes into (moderate & severe) and (none & mild). Then, I calculated of the unadjusted proportion of symptoms severity for each centre. I then calculated a standardised symptom ratio (SSR). The SSR is the ratio of the number of patients reporting moderate or severe symptoms to the number predicted for that ACS from a regression model based on the entire sample. Variables included in the regression model to calculate the SSR were patient demographics, clinical, treatment types, and treatment cycle data. Predictor variables were entered as independent variables in a multiple logistic regression analysis (see Box 7-1), and the sum of predicted probabilities was used to calculate the expected number of cases. Iezzoni (1997) stated risk adjustment aims to account for the effects of differences when comparing outcomes across groups of patients. The overall purpose of risk adjustments made to each experienced symptom by each centre was to standardise the impact of patient characteristics and other factors to isolate the remaining effects of treatment efficacy and quality of care.

Each centre was assigned a rank based on their relative performance on each of the measures, and the researcher assessed the correlation between the raw score ranking and the ranking based on the SSR. Centre performance was correlated with patient-reported symptom severity (rank) and with the performance on patient-reported supportive care (rank). A traffic light colouring system has been applied to the ranks, with red indicating higher prevalence scores and green lower prevalence scores.

Box 7-1 Predictive variables used to calculate the standardised symptom ratio

Patient Demographics:
- Age (18-30, 31-40,41-50, 51-60, 61-70, 71+)
- Sex (male, female)

Clinical Diagnosis:
- Diagnosis (Colorectal, breast, lung, gynaecological, haematology, other cancers)

Treatment type:
- Emetogenic treatments
- Inflammitant treatments
- Exfoliant treatments
- Vesicant treatments
- Treatment cycle (1, 2, 3, 4, 5, 6, 7, 12+)

Centre characteristics
- Hospital type (secondary, tertiary, teaching)
- Centre size (capacity)

Nurse characteristics
- Nurse education (diploma, bachelor)
- Total staffing
- Skill mix (RN, LPN)

Table 7-15 shows the ACSs rank of the prevalence of symptoms experienced and the variables of interest before and after adjusting for differences across participated ACS. Before adjustment (or without controls), with the unstandardized symptoms ratio, it was clear that Centre E ranked as the best centre regarding the least proportion of patients experiencing severe or moderate symptoms, except for feeling weakness and tiredness. Overall, risk adjustment made a difference to the ranking of centres in terms of the proportion of patients experiencing moderate or severe symptoms, see Table 7-15. For example, risk adjustment made enormous differences to the ranking of Centre E. In Centre B, it was evident that the SSR was significantly above 100% for all symptoms except for overall distress. Changes in ranks suggest that the differences observed could be a matter of differences in case mix on variables measured.

Correlations between adjusted and unadjusted rankings were varied across items and ranged from ($\rho = -0.4\ to\ 0.5$).

Table 7-15 Standardised and unstandardized symptom rates

Centre	Rate per 100 patients	Rank	SSR %	Rank	Correlation of standardized rank and SSR rank
Nausea					
A	33.204	4	81.430	4	- 0.1
B	37.7682	2	104.999	1	
C	34.567	3	99.311	2	
D	39.622	1	71.095	5	
E	12.195	5	91.488	3	
Vomiting					
A	14.671	3	82.565	4	- 0.3
B	16.309	2	103.116	1	
C	14.197	4	96.120	2	
D	28.301	1	65.927	5	
E	9.756	5	91.704	3	
IV-line pain/irritation					
A	17.7606	3	83.561	4	- 0.4
B	20.600	2	103.373	1	
C	11.728	4	92.049	3	
D	26.415	1	74.073	5	
E	4.878	5	93.550	2	
Oral problems					
A	22.007	4	81.030	4	0.3
B	42.060	1	108.410	1	
C	35.185	3	99.709	2	
D	37.735	2	67.195	5	
E	17.073	5	92.176	3	
Weakness and tiredness					
A	49.420	5	82.725	4	0.5
B	63.519	1	105.668	1	
C	57.407	2	99.157	3	
D	56.603	3	68.622	5	
E	51.219	4	100.324	2	
Signs of infection					
A	33.590	3	83.661	4	- 0.4
B	36.051	2	102.457	1	
C	25.925	4	97.273	3	
D	39.622	1	64.429	5	
E	14.634	5	97.846	2	
Feeling low or depressed					
A	31.660	4	81.856	4	0.5
B	41.630	2	101.976	1	
C	46.913	1	95.141	2	
D	33.962	3	68.270	5	
E	24.390	5	94.574	3	
Distress					
A	5.019	4	6.917	3	0.2
B	10.729	1	7.543	2	
C	5.555	3	17.457	1	
D	5.660	2	5.028	5	
E	2.439	5	6.599	4	

Rank 1= highest standardised symptom ratio and 5= lowest symptoms ratio. Traffic light colouring system has been applied to the ranks, with red indicating higher prevalence scores and green lower prevalence scores.

7.4.10.2 The effects of different patient demographics and treatment type and cycle on patient outcomes

In order to investigate the extent to which patient characteristics influenced the variations in patient outcomes (symptoms experienced), multiple logistic regression models were fitted. Three separate multiple logistic regression models were used to estimate the factors associated with symptom experiences and the effects of predictive variables (see Box 7-1) on each experienced symptom.

First, each experienced symptom was fitted to a regression model with patient characteristics; age, sex, diagnosis, cycle, and potential to cause emesis or necrosis. To explore the potential influence of nursing workforce and centre characteristics on the variations of symptom severity, the second regression model was used. The second regression model included workforce and centre characteristics, centre and nurse characteristics were adjusted for in addition to predictive variables included in the first model. Finally, all possible predictive variables of patient and unit characteristics were combined in a regression model.

Interpretation of Odds ratio less than 1

The interpretation of odds ratios greater than 1 is straightforward but when odds ratios are less than 1 its interpretation becomes less intuitive. In this study, I have adopted the reverse approach of interpreting odds less than 1 as suggested by McHugh (2009). For instance, using age group 18-30 as reference in Table 7-16, the odds ratio of age group 41-50 years was 0.48. A straight forward interpretation will be that the odds of patients aged 41-50 years was 0.48 time the odds of those aged 18-30 or that 41-50 years have 52% lower odds than patients aged 18-30 years. But I have reversed the odds to obtain how many times the odds were greater in age group 18-30 compared with 41-50 years. Thus, I have used 1/0.48 = 2.08 to say that the odds in the group 18-30 years were at least twice as large as the odds for patients aged 41-50 years. The outputs of the models are shown in following paragraphs.

Nausea

The result of the analysis suggests that patients' age was a strong negative predictor of nausea even when the effects of all other variables were accounted for. The effect of age was strongest among the youngest age group (18-30 years). The odds of reporting nausea for patients this age group were on average, at least twice as large as the odds for the older age groups (31-40, 41-50, 51-60, 61-70 and 70+). Surprisingly, this younger age group's odds of nausea symptoms were about 6 times (CI = 2.50 – 20.0, $p < 0.0001$) greater than that of patients aged 70+ years.

Nausea was also significantly associated with patient gender. Odds of nausea experience for female patients were 1.8 times (CI = 1.18 – 2.78, $p = 0.01$) larger than that of male patients. The site of cancer was not a statistically significant predictor of nausea. Treatment types were likely to influence the experience of nausea negatively, apart from inflammitant drugs. Patients treated with an irritant drug had 1.72 times (CI = 1.04-2.86. $p = 0.03$) less odds of experiencing nausea than those who were not exposed to the same treatment. Also, exposure to emetogenic treatments had a negative effect on nausea. The odds for patients exposed to the treatment were 1.59 (CI =1.04 – 2.44, $p = 0.03$) times less than that of those not exposed to it. However, there was no statistical evidence that treatment with an exfoliant, vesicant and inflammitant drugs were associated with nausea experience.

Table 7-16 Results of multiple logistic regression models that fitted the nausea against some Patients' characteristics

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	-0.07	0.52	0.89	0.93	0.33	2.57
18-30 years	0.00			1.00		
31-40 years	-0.56	0.31	0.07	0.57	0.31	1.04
41-50 years	-0.73	0.3	0.01	0.48	0.27	0.86
51-60 years	-0.88	0.3	0.00	0.41	0.23	0.74
61-70 years	-0.76	0.32	0.02	0.47	0.25	0.88
71+ years	-1.84	0.51	0.00	0.16	0.05	0.40
Male	0.00			1.00		
Female	0.59	0.22	0.01	1.80	1.18	2.78
Vesicant No	0.00			1.00		
Vesicant Yes	0.08	0.21	0.70	1.09	0.71	1.65
Irritant No	0.00			1.00		
Irritant Yes	-0.54	0.25	0.03	0.58	0.35	0.96
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.07	0.22	0.76	0.93	0.61	1.45
Inflammitant No	0.00			1.00		
Inflammitant Yes	0.21	0.26	0.43	1.23	0.74	2.06
Emetogenic No	0.00			1.00		
Emetogenic Yes	-0.46	0.22	0.03	0.63	0.41	0.96
Blood	0.00			1.00		
Bowel	0.75	0.41	0.06	2.13	0.97	4.77
Breast	0.36	0.35	0.30	1.43	0.73	2.88
Gynaecological	0.68	0.43	0.12	1.97	0.85	4.65
Lungs	-0.14	0.5	0.79	0.87	0.31	2.30
Lymphatic	0.14	0.39	0.72	1.15	0.54	2.47
Other types of cancer	0.49	0.36	0.17	1.63	0.82	3.35

Vomiting

Vomiting was negatively associated with patient's age – the younger the patient, the higher the odds of reporting moderate or severe vomiting. Patients aged 61-70 years had 2.50 (CI = 1.04 – 6.25, p = 0.04) times lower odds of experiencing moderate or severe vomiting compared with younger patients aged 18-30 years. Female patients had on average 1.06 times greater odds of reporting moderate or severe vomiting than male patients however, this gender difference was not statistically significant. Odds of vomiting experience

were 3.85 (CI = 1.24 – 13.71, p = 0.03) times higher among patients with gynaecological cancer and 3.03 (CI: 1.01 – 10.46, p = 0.05) time higher in bowel cancer patients than patients with blood cancer. There was no strong indication that the experience of severe or moderate vomiting differs between blood and the other types of cancer. Treatment with irritant drugs had a reducing effect on the severity of vomiting. Patients treated with an irritant drugs had 2.50 times (CI = 1.37-4.35, p < 0.001) lower odds of reporting severe vomiting than patients not exposed to the treatment.

Table 7-17 Results of multiple logistic regression models that fitted vomiting against some Patients' characteristics

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	-1.26	0.7	0.07	0.28	0.07	1.05
18-30 years	0.00			1.00		
31-40 years	0.06	0.39	0.87	1.06	0.5	2.3
41-50 years	-0.42	0.38	0.27	0.66	0.31	1.41
51-60 years	-0.44	0.37	0.24	0.64	0.31	1.36
61-70 years	-0.91	0.45	0.04	0.40	0.16	0.96
71+ years	-1.02	0.62	0.1	0.36	0.09	1.13
Male	0.00			1.00		
Female	0.06	0.29	0.84	1.06	0.59	1.89
Vesicant No	0.00			1.00		
Vesicant Yes	-0.09	0.28	0.73	0.91	0.52	1.57
Irritant No	0.00			1.00		
Irritant Yes	-0.89	0.29	0.00	0.41	0.23	0.73
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.01	0.28	0.98	0.99	0.57	1.74
Inflammitant No	0.00			1.00		
Inflammitant Yes	0.18	0.33	0.59	1.2	0.64	2.38
Emetogenic No	0.00			1.00		
Emetogenic Yes	-0.3	0.28	0.28	0.74	0.43	1.29
Blood	0.00			1.00		
Bowel	1.11	0.59	0.05	3.03	1.01	10.46
Breast	0.89	0.54	0.10	2.42	0.91	7.81
Gynaecological	1.35	0.6	0.03	3.85	1.24	13.71
Lungs	0.02	0.78	0.98	1.02	0.19	4.59
Lymphatic	0.33	0.59	0.58	1.39	0.45	4.78
Other types of cancer	0.68	0.54	0.21	1.98	0.73	6.38

IV-line pain or irritation

IV-line pain or irritation do seem to be negatively associated with the age of patients. Odds of experiencing pain or irritation decreased with increasing age. Patients aged 18-30 years appear to be disproportionately affected by IV-line pain or irritation relative to older patients aged 61-70 years with odds 3.70 (1.54, 10.00) times higher in the younger age group. IV-line pain or irritation was higher among female patients compared with their male counterparts. Females had about two times (CI = 1.10-3.29, p-value =0.02) higher odds of experiencing IV-line pain or irritation than males. The site of cancer, when considered together, is a predictor of IV-line pain or irritation. However, the distribution IV-line pain or irritation on these locations, when considered relative to each other, appears to be fairly equally distributed. The analysis did not seem to support any association between IV-line pain or irritation and treatment types.

Table 7-18 Results of from multiple logistic regression models that fitted the IV-line pain or irritation against some Patients' characteristics and treatment type

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	-1.78	0.65	0.01	0.17	0.04	0.59
18-30 years	0.00			1.00		
31-40 years	-0.46	0.38	0.23	0.63	0.30	1.33
41-50 years	-0.27	0.36	0.44	0.76	0.38	1.55
51-60 years	-0.31	0.35	0.38	0.73	0.37	1.48
61-70 years	-1.31	0.46	0.00	0.27	0.10	0.65
71+ years	-0.38	0.52	0.47	0.69	0.23	1.84
Male	0.00			1.00		
Female	0.64	0.28	0.02	1.90	1.10	3.29
Vesicant No	0.00			1.00		
Vesicant Yes	0.47	0.27	0.08	1.6	0.94	2.73
Irritant No						
Irritant Yes	-0.03	0.34	0.94	0.97	0.51	1.94
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.24	0.28	0.40	0.79	0.45	1.38
Inflammitant No	0.00			1.00		
Inflammitant Yes	0.38	0.33	0.26	1.46	0.78	2.91
Emetogenic No	0.00			1.00		
Emetogenic Yes	0.02	0.28	0.94	1.02	0.6	1.77
Blood	0.00			1.00		
Bowel	0.88	0.47	0.06	2.41	0.98	6.17
Breast	-0.15	0.41	0.71	0.86	0.39	1.97
Gynaecological	-0.65	0.55	0.24	0.52	0.17	1.55
Lungs	-0.53	0.64	0.41	0.59	0.15	1.95
Lymphatic	-0.48	0.47	0.30	0.62	0.25	1.55
Other types of cancer	-0.51	0.46	0.26	0.6	0.25	1.49

Oral problems

Oral problems were significantly positively associated with the overall age of patients. However, the distribution of severity of oral problems was not the same across age categories. The severity of oral problems in age groups 51-60 and 61-70 was about twice (CI range = 1.09 – 4.18, p <= 0.03) that of patients aged 18-30 years, respectively. While severity was slightly higher among

female patients relative to their male counterparts; analysis indicates that this difference was not statistically significant. The site of cancer does not seem to be associated with severity of oral problems. Treatment with an inflammitant and exfoliant drugs had negative effects on oral problems.

Table 7-19 Results of from multiple logistic regression models that fitted oral problems against some patients' characteristics and treatment types

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	-0.88	0.54	0.1	0.41	0.14	1.17
18-30 years	0.00			1.00		
31-40 years	0.03	0.35	0.92	1.04	0.53	2.06
41-50 years	0.60	0.32	0.07	1.81	0.97	3.47
51-60 years	0.79	0.32	0.01	2.20	1.19	4.17
61-70 years	0.75	0.34	0.03	2.11	1.09	4.18
71+ years	-0.1	0.48	0.84	0.91	0.34	2.27
Male	0.00			1.00		
Female	0.06	0.22	0.79	1.06	0.68	1.64
Vesicant No	0.00			1.00		
Vesicant Yes	0.48	0.22	0.03	1.62	1.06	2.47
Irritant No	0.00			1.00		
Irritant Yes	0.01	0.27	0.96	1.01	0.6	1.73
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.44	0.22	0.05	0.64	0.42	1.00
Inflammitant No	0.00			1.00		
Inflammitant Yes	-0.57	0.25	0.02	0.56	0.35	0.92
Blood	0.00			1.00		
Bowel	-0.4	0.42	0.34	0.67	0.29	1.53
Breast	0.44	0.35	0.21	1.55	0.79	3.13
Gynaecological	0.14	0.45	0.76	1.15	0.48	2.76
Lungs	-0.33	0.5	0.51	0.72	0.26	1.89
Lymphatic	0.26	0.39	0.50	1.30	0.61	2.80
Others	0.26	0.35	0.46	1.30	0.66	2.65
Emetogenic No	0.00			1.00		
Emetogenic Yes	0.08	0.22	0.71	1.08	0.71	1.67

Patients not treated with inflammitant drugs had 1.8 times higher odds of experiencing severe oral problems compared with those exposed to the treatment. However, odds were 1.62 times (CI: 1.06, 2.47, p =0.03) higher among patients treated with vesicant compared to those not exposed to the treatment.

Weakness and tiredness

The odds severity of weakness was 1.54 times (CI = 1.03 – 2.30, p = 0.03) higher among female patients compared to male patients. Weakness was not significantly associated with age, cancer site, and treatment. However, there were indications that weakness increased with increasing age but this relationship was not statistically significant.

Table 7-20 Results of from multiple logistic regression models that fitted Weakness against some patients' characteristics

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	0.38	0.49	0.44	1.46	0.56	3.85
18-30 years	0.00			1.00		
31-40 years	-0.01	0.30	0.97	0.99	0.55	1.78
41-50 years	0.03	0.29	0.92	1.03	0.58	1.81
51-60 years	-0.20	0.28	0.47	0.82	0.47	1.42
61-70 years	0.30	0.31	0.34	1.35	0.73	2.48
71+ years	0.18	0.39	0.64	1.20	0.56	2.59
Male	0.00			1.00		
Female	0.43	0.20	0.03	1.54	1.04	2.30
Vesicant No	0.00			1.00		
Vesicant Yes	0.16	0.20	0.43	1.17	0.79	1.75
Irritant No	0.00			1.00		
Irritant Yes	-0.22	0.25	0.37	0.80	0.49	1.3
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.25	0.21	0.25	0.78	0.51	1.19
Inflammitant No	0.00			1.00		
Inflammitant Yes	-0.24	0.25	0.34	0.78	0.47	1.28
Emetogenic No	0.00			1.00		
Emetogenic Yes	-0.17	0.21	0.42	0.85	0.56	1.27
Blood	0.00			1.00		
Bowel	0.23	0.36	0.53	1.26	0.61	2.57
Breast	0.49	0.32	0.12	1.64	0.88	3.05
Gynaecological	0.04	0.40	0.92	1.04	0.47	2.31
Lungs	0.14	0.41	0.74	1.15	0.51	2.59
Lymphatic	-0.09	0.35	0.80	0.92	0.46	1.81
Other type of cancer	0.48	0.32	0.13	1.62	0.87	3.03

Signs of Infection

The chi-square goodness of fit test indicates that modelling infection as a dependent variable against patient characteristics as the independent variable was not significantly different from the baseline model that did not include the independent variables. All the variables – age, gender, cancer sites, treatment and cycle of treatment – did not significantly predict infections. Variations in the distribution of infection among the different categories of age, cancer site and treatment types were not significantly different.

Table 7-21 Results of from multiple logistic regression models that fitted Infection against some patients' characteristics and treatment type

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	0.28	0.5	0.58	1.32	0.49	3.54
18-30 years	0.00			1.00		
31-40 years	-0.07	0.31	0.82	0.93	0.51	1.71
41-50 years	-0.46	0.30	0.13	0.63	0.35	1.14
51-60 years	-0.46	0.30	0.12	0.63	0.35	1.14
61-70 years	-0.39	0.32	0.23	0.68	0.36	1.28
71+ years	-0.02	0.40	0.97	0.98	0.45	2.13
Male	0.00			1.00		
Female	0.16	0.22	0.46	1.18	0.77	1.80
Vesicant No	0.00			1.00		
Vesicant Yes	-0.06	0.21	0.78	0.94	0.62	1.43
Irritant No	0.00			1.00		
Irritant Yes	-0.48	0.25	0.06	0.62	0.38	1.03
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.01	0.22	0.97	0.99	0.64	1.54
Inflammitant No	0.00			1.00		
Inflammitant Yes	-0.02	0.26	0.94	0.98	0.6	1.64
Emetogenic No	0.00			1.00		
Emetogenic Yes	-0.18	0.22	0.42	0.84	0.55	1.29
Blood	0.00			1.00		
Bowel	-0.14	0.38	0.71	0.87	0.42	1.83
Breast	0.00	0.32	0.99	1.00	0.53	1.89
Gynaecological	-0.15	0.42	0.72	0.86	0.38	1.97
Lungs	-0.49	0.45	0.27	0.61	0.25	1.45
Lymphatic	-0.50	0.37	0.17	0.60	0.29	1.24
Other type of cancer	-0.65	0.34	0.05	0.52	0.27	1.01

Feeling low or depressed

Treatment with an irritant drug has a significant inverse association with depression. Those treated with an irritant had 1.79 (CI = 1.09, 2.94, p-value = 0.013) times lower odds of being depressed compared to those not exposed to the treatment. Also, treatment with an inflammitant drug had a significant positive effect on depression. Patients exposed to the inflammitant treatment had 1.84 times (CI = 1.11, 3.13, p-value = 0.02) greater odds of being depressed relative to those not treated with an Inflammitant drugs. Gender also positively predicted feeling low or depressed.

Females had 1.85 times (CI = 1.23, 2.79, p-value < 0.001) greater odds of being depressed than males. The burden of depression was significantly lower among patients with gynaecological cancer relative to those with blood cancer. Gynaecological patients had about 2.56 times (CI = 1.11, 5.88, p-value = 0.017) lower odds of being depressed compared to leukaemia patients. Feeling low or depressed was not significantly associated with age and cycle of treatment.

Table 7-22 Results of from multiple logistic regression models that fitted feeling low or depressed against some Patients' characteristics and treatment type

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	-0.24	0.5	0.63	0.79	0.29	2.1
18-30 years	0.00			1.00		
31-40 years	-0.22	0.31	0.47	0.8	0.44	1.46
41-50 years	-0.18	0.29	0.54	0.84	0.47	1.49
51-60 years	-0.34	0.29	0.24	0.71	0.40	1.25
61-70 years	-0.24	0.31	0.45	0.79	0.42	1.46
71+ years	-0.26	0.40	0.51	0.77	0.34	1.68
Male	0.00			1.00		
Female	0.61	0.21	0.00	1.85	1.23	2.79
Vesicant No	0.00			1.00		
Vesicant Yes	-0.01	0.21	0.97	0.99	0.66	1.49
Irritant No	0.00			1.00		
Irritant Yes	-0.58	0.25	0.02	0.56	0.34	0.92
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.13	0.22	0.56	0.88	0.58	1.35
Inflammitant No	0.00			1.00		
Inflammitant Yes	0.61	0.26	0.02	1.84	1.11	3.13
Emetogenic No	0.00			1.00		
Emetogenic Yes	-0.24	0.21	0.26	0.79	0.52	1.19
Blood	0.00			1.00		
Bowel	-0.41	0.38	0.28	0.66	0.31	1.4
Breast	-0.03	0.32	0.94	0.98	0.52	1.83
Gynaecological	-0.94	0.43	0.03	0.39	0.17	0.9
Lungs	-0.25	0.43	0.57	0.78	0.33	1.81
Lymphatic	-0.53	0.36	0.15	0.59	0.29	1.2
Others	-0.03	0.33	0.93	0.97	0.51	1.85

7.4.10.3 The effects of different organisational and nursing features on patient outcomes

I considered several organisational and nursing variables as input into the multiple logistic regression models that examined the unit characteristics as predictors of the seven outcomes. Due to strong correlations between some of the variables, some of them were dropped from the final models. Caution should be exercised in relation to the use of these estimate of odds as the

distribution of patients in these hospitals might have affected the estimates. Particularly as only one secondary healthcare unit participated in the study, the other units were tertiary or teaching hospitals. Table 7-23 show the adjusted odds ratios and their corresponding 95% confidence intervals for each of the outcomes.

Table 7-23 indicates that the type of hospital was significantly negatively associated with all the seven outcomes. Also, the degree of severity of each outcome varied depending on the hospital type. The odds of experiencing any of the outcomes were significantly higher in secondary compared with tertiary and teaching hospitals. For instance, the odds of a patient experiencing nausea were 4.17 (CI: 1.45, 12.5, p = 0.01) and 3.45 (CI: 1.20, 10.00, p = 0.02) times higher in secondary healthcare compared to that of tertiary and teaching hospitals respectively. This was also true for the experience of vomiting with odds 4.0 (1.14, 14.29, p = 0.03) and 4.17 (CI: 1.10, 14.29, p=0.03) times higher in secondary healthcare units relative to tertiary and teaching hospitals respectively. The odds of a patient in secondary healthcare unit experiencing oral problems were 14.29 (4.76, 33.33, p< 0.001) and 11.11 (3.70, 33.33, p<0.001) times greater than the odds of experiencing the problems in tertiary and teaching hospitals respectively.

The capacity of each healthcare unit (centre) was positively associated with all the seven outcomes. Thus, the higher the unit's capacity, the higher the odds of experiencing moderate or severe levels of each outcome. Except for vomiting, unit capacity was a significant positive predictor of the other six outcomes. Increasing unit capacity by one resulted to and increased odds of between 8% and 20% in the experience of the six outcomes.

Table 7-23 indicates that the percentage of nurses with a bachelor was negatively associated with the odds of experiencing all the seven outcomes variables. Hence, the higher the percentage of nurses with a bachelor degree, the lower the odds of experiencing any of the outcomes. The percentage of nurses with a bachelor degree was statistically significant predictors particularly for experiencing oral, weakness and Depression with odds decreasing by between 2 and 3% for every percentage point increase in nurses with bachelor degree.

Table 7-23 Results of multiple logistic regression models that fitted the outcomes against some hospital characteristics

Outcome	Covariate	Log Odds	Std. Error	Sig	OR	Lower	Upper
Nausea	Intercept	-2.24	0.68	0.00	0.11	0.02	0.37
	Secondary	0.0			1.0		
	Tertiary	-1.41	0.54	0.01	0.24	0.08	0.69
	Tertiary & teaching	-1.24	0.54	0.02	0.29	0.10	0.83
	Unit capacity	0.17	0.06	0.01	1.18	1.05	1.34
	% nurses with Bachelor	-0.01	0.01	0.26	0.99	0.98	1.01
Vomiting	Intercept	-1.66	0.76	0.03	0.19	0.04	0.75
	Secondary	0.0			1.0		
	Tertiary	-1.37	0.64	0.03	0.25	0.07	0.88
	Tertiary & teaching	-1.41	0.67	0.03	0.24	0.07	0.91
	Unit capacity	0.08	0.08	0.29	1.08	0.93	1.27
	%nurses With Bachelor	-0.01	0.01	0.56	0.99	0.98	1.01
IV-line pain Or irritation	Intercept	-3.02	0.98	0.00	0.05	0.00	0.26
	Secondary	0.0			1.0		
	Tertiary	-1.75	0.69	0.01	0.17	0.04	0.64
	Tertiary & teaching	-2.12	0.68	0.00	0.12	0.03	0.45
	Unit capacity	0.18	0.08	0.03	1.20	1.03	1.44
	%nurses With Bachelor	-0.01	0.01	0.34	0.99	0.98	1.01
Oral problems	Intercept	-2.04	0.61	0.00	0.13	0.04	0.41
	Secondary	0.0			1.0		
	Tertiary	-2.60	0.54	0.00	0.07	0.03	0.21
	Tertiary & teaching	-2.39	0.55	0.00	0.09	0.03	0.27
	Unit capacity	0.31	0.06	0.00	1.36	1.21	1.53
	%nurses With Bachelor	-0.03	0.01	0.00	0.97	0.95	0.98
Weakness and tiredness	Intercept	-0.30	0.51	0.56	0.74	0.27	2.04
	Secondary	0.0			1.0		
	Tertiary	-1.27	0.49	0.01	0.28	0.11	0.73
	Tertiary & teaching	-1.29	0.52	0.01	0.28	0.10	0.75
	Unit capacity	0.17	0.05	0.00	1.18	1.06	1.32
	%nurses With Bachelor	-0.02	0.01	0.00	0.98	0.97	0.99
Signs of Infection	Intercept	-1.95	0.64	0.00	0.14	0.04	0.47
	Secondary	0.0			1.0		
	Tertiary	-1.13	0.53	0.03	0.32	0.11	0.90
	Tertiary & teaching	-1.37	0.54	0.01	0.25	0.09	0.73
	Unit capacity	0.13	0.06	0.03	1.14	1.01	1.29
	%nurses With Bachelor	0.00	0.01	0.45	1.00	0.98	1.01
Feeling low or depression	Intercept	-1.66	0.56	0.00	0.19	0.06	0.55
	Secondary	0.0			1.0		
	Tertiary	-1.07	0.51	0.04	0.34	0.13	0.93
	Tertiary & teaching	-0.59	0.53	0.27	0.56	0.20	1.57
	Unit capacity	0.16	0.06	0.00	1.17	1.05	1.31
	%nurses with Bachelor	-0.02	0.01	0.02	0.98	0.97	1.00

7.4.10.4 Combining Patient, nurse and unit characteristics

This section examines the simultaneous effects of patients', nurses' and centre characteristics on the reported patient outcomes. The aim was to adjust for all possible confounding factors in the same model in order to obtain more precise estimates of factors that influence the quality of care.

However, the estimates of the odds ratios are similar in the combined patients and hospital models when compared with those obtained from modelling (patient's characteristics and treatment type) and (nurse and organisational characteristics) separately. The fact that some of the variables remained statistically significant when both the patient and unit's characteristics were adjusted for simultaneously in the models indicates that they are strong predictors of the outcomes for which they remained statistically significant.

Therefore, given that the estimates of the odds ratios are similar in the separate models and the combined models, I shall not give detailed interpretation of the combined model results as shown in Table 7-24 – 7-30. Readers are referred to the interpretations in the patients' models and the organisational models respectively.

Nausea

Age, gender and treatment with emetogenic drugs were strong predictors of nausea after adjusting for organisational variables. While age, treatment with emetogenic and hospital type were negatively associated with nausea, unit capacity was positively associated with nausea and the female patients had greater odds of experiencing nausea relative to the male patients.

Table 7-24 Output of combining nausea and multiple logistic regression models

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	-1.85	0.93	0.05	0.16	0.02	0.93
18-30 years	0.00			1.00		
31-40 years	-0.55	0.31	0.08	0.58	0.31	1.06
41-50 years	-0.78	0.30	0.01	0.46	0.25	0.82
51-60 years	-0.91	0.30	0.00	0.40	0.22	0.72
61-70 years	-0.72	0.33	0.03	0.49	0.25	0.92
71+ years	-1.85	0.51	0.00	0.16	0.05	0.41
Male	0.00			1.00		
Female	0.61	0.22	0.01	1.83	1.19	2.83
Vesicant No	0.00			1.00		
Vesicant Yes	0.05	0.22	0.81	1.05	0.69	1.60
Irritant No	0.00			1.00		
Irritant Yes	-0.47	0.26	0.07	0.63	0.38	1.04
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.16	0.23	0.49	0.85	0.55	1.34
Inflammitant No	0.00			1.00		
Inflammitant Yes	0.31	0.27	0.24	1.37	0.81	2.34
Emetogenic No	0.00			1.00		
Emetogenic Yes	-0.47	0.22	0.03	0.63	0.41	0.96
Blood	0.00			1.00		
Bowel	0.77	0.41	0.06	2.16	0.98	4.90
Breast	0.44	0.35	0.21	1.55	0.79	3.14
Gynaecological	0.8	0.44	0.07	2.23	0.95	5.33
Lungs	-0.12	0.51	0.82	0.89	0.32	2.37
Lymphatic	0.12	0.39	0.75	1.13	0.53	2.44
Other type of cancer	0.53	0.36	0.14	1.71	0.85	3.52
Secondary	0.00			1.00		
Tertiary	-1.32	0.58	0.02	0.27	0.08	0.82
Teaching	-1.05	0.59	0.07	0.35	0.11	1.11
Unit capacity	0.15	0.07	0.02	1.16	1.02	1.33
%nurses With Bachelor	-0.004	0.01		0.61	0.98	1.01

Vomiting

There are some indications of a negative association between age and experience of vomiting with younger age group (18-30 years) being disproportionately affected compared with patients aged 61-70 years old. Treatment with irritant drugs had a negative effect on vomiting experience and

odds of vomiting were greater among gynaecological patients relative to leukaemia patients.

Table 7-25 Output of combining vomiting and multiple logistic regression models

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	-0.99	1.13	0.38	0.37	0.04	3.16
18-30 years	0.00			1.00		
31-40 years	0.02	0.39	0.95	1.02	0.48	2.23
41-50 years	-0.49	0.39	0.20	0.61	0.29	1.32
51-60 years	-0.43	0.38	0.25	0.65	0.31	1.37
61-70 years	-0.90	0.45	0.05	0.41	0.16	0.98
71+ years	-0.98	0.62	0.12	0.38	0.10	1.19
Male	0.00			1.00		
Female	0.07	0.30	0.81	1.07	0.60	1.92
Vesicant No	0.00			1.00		
Vesicant Yes	-0.10	0.28	0.73	0.91	0.52	1.58
Irritant No	0.00			1.00		
Irritant Yes	-0.92	0.3	0.00	0.4	0.22	0.72
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.05	0.29	0.86	0.95	0.54	1.68
Inflammitant No	0.00			1.00		
Inflammitant Yes	0.18	0.35	0.60	1.20	0.62	2.43
Emetogenic No	0.00			1.00		
Emetogenic Yes	-0.34	0.28	0.23	0.71	0.41	1.25
Blood	0.00			1.00		
Bowel	1.12	0.59	0.06	3.07	1.02	10.69
Breast	0.99	0.55	0.07	2.68	0.99	8.73
Gynaecological	1.41	0.61	0.02	4.11	1.31	14.81
Lungs	0.13	0.78	0.87	1.14	0.21	5.16
Lymphatic	0.27	0.6	0.65	1.31	0.42	4.57
Others	0.70	0.55	0.20	2.02	0.73	6.54
Secondary	0.00			1.00		
Tertiary	-1.39	0.70	0.05	0.25	0.06	0.97
Teaching	-1.36	0.72	0.06	0.26	0.06	1.06
Unit capacity	0.06	0.08	0.48	1.06	0.9	1.25
%nurses With Bachelor	-0.001	0.01	0.86	1.00	0.98	1.02

IV-line pain or irritation

The experience of IV-line pain or irritation was inversely associated with hospital type. The more technically advanced the hospital, the lower the odds

of pain or irritation experience. Also, the higher the unit's capacity, the higher the odds of experiencing pain or irritation. Female patients had higher odds of experiencing pain or irritation compared to their male counterparts.

Table 7-26 Output of combining IV-line pain or irritation and multiple logistic regression models

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	-4.14	1.54	0.01	0.02	0	0.23
18-30 years	0.00			1.00		
31-40 years	-0.44	0.39	0.26	0.65	0.3	1.38
41-50 years	-0.34	0.37	0.36	0.71	0.35	1.48
51-60 years	-0.27	0.36	0.45	0.76	0.38	1.56
61-70 years	-1.21	0.47	0.01	0.3	0.12	0.73
71+ years	-0.30	0.53	0.57	0.74	0.25	2.01
Male	0.00			1.00		
Female	0.61	0.28	0.03	1.84	1.07	3.22
Vesicant No	0.00			1.00		
Vesicant Yes	0.45	0.27	0.10	1.57	0.92	2.69
Irritant No	0.00			1.00		
Irritant Yes	-0.03	0.35	0.92	0.97	0.5	1.96
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.31	0.29	0.28	0.73	0.42	1.30
Inflammitant No	0.00			1.00		
Inflammitant Yes	0.50	0.35	0.14	1.66	0.86	3.36
Emetogenic No	0.00			1.00		
Emetogenic Yes	0.01	0.28	0.96	1.01	0.59	1.77
Blood	0.00			1.00		
Bowel	0.95	0.47	0.05	2.57	1.04	6.68
Breast	-0.02	0.41	0.96	0.98	0.45	2.27
Gynaecological	-0.58	0.56	0.31	0.56	0.18	1.69
Lungs	-0.40	0.65	0.54	0.67	0.17	2.28
Lymphatic	-0.48	0.47	0.31	0.62	0.25	1.57
Others	-0.46	0.46	0.32	0.63	0.26	1.58
Secondary	0.00			1.00		
Tertiary	-2.35	0.84	0.01	0.10	0.01	0.44
Teaching	-2.48	0.79	0.00	0.08	0.02	0.37
Unit capacity	0.24	0.11	0.02	1.28	1.06	1.66
%nurses With Bachelor	-0.01	0.01	0.39	0.99	0.98	1.01

Oral problems

The positive effects of age, unit capacity and treatment with vesicant on oral problems are depicted in Table 7-27. Hospital type and percentage of nurses with bachelor degree were inversely associated with odds of experiencing oral problems.

Table 7-27 Output of combining oral problems and multiple logistic regression models

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower	Upper
Intercept	-2.72	0.93	0.00	0.07	0.01	0.39
18-30 years	0.00			1.00		
31-40 years	0.06	0.35	0.87	1.06	0.53	2.13
41-50 years	0.51	0.33	0.12	1.67	0.89	3.22
51-60 years	0.84	0.32	0.01	2.31	1.24	4.43
61-70 years	0.74	0.35	0.03	2.11	1.07	4.24
71+ years	-0.13	0.49	0.79	0.88	0.32	2.23
Male	0.00			1.00		
Female	0.08	0.23	0.73	1.08	0.69	1.69
Vesicant No	0.00			1.00		
Vesicant Yes	0.50	0.22	0.02	1.65	1.07	2.55
Irritant No	0.00			1.00		
Irritant Yes	0.15	0.28	0.58	1.17	0.68	2.03
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.39	0.23	0.09	0.68	0.43	1.07
Inflammitant No	0.00			1.00		
Inflammitant Yes	-0.33	0.26	0.21	0.72	0.43	1.21
Emetogenic No	0.00			1.00		
Emetogenic Yes	0.18	0.23	0.43	1.20	0.77	1.87
Blood	0.00			1.00		
Bowel	-0.4	0.43	0.35	0.67	0.29	1.56
Breast	0.49	0.36	0.17	1.63	0.82	3.36
Gynaecological	0.24	0.46	0.60	1.27	0.52	3.13
Lungs	-0.35	0.51	0.49	0.70	0.25	1.89
Lymphatic	0.18	0.40	0.64	1.20	0.56	2.65
Others	0.27	0.36	0.45	1.31	0.65	2.72
Secondary	0.00			1.00		
Tertiary	-2.77	0.59	0.00	0.06	0.02	0.20
Teaching	-2.39	0.59	0.00	0.09	0.03	0.29
Unit capacity	0.31	0.07	0.00	1.36	1.19	1.55
%_nurses with Bachelor	-0.03	0.01	0.00	0.97	0.96	0.98

Weakness and tiredness

Most of the patients' characteristics do not significantly predict weakness. Put differently, there seem to be no differences in severity of weakness experienced by patients irrespective of their age, treatment type and cancer site. What stands out in the model result was the weakness experienced by males, females, and patients' hospital characteristics. The females had greater odds of experiencing moderate or severe weakness than male patients. Odds of weakness were greater in secondary healthcare units relative to tertiary and teaching hospitals.

Table 7-28 Output of combining 'weakness and tiredness' and multiple logistic regression models

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	-0.32	0.79	0.68	0.72	0.15	3.46
18-30 years	0.00			1.00		
31-40 years	-0.01	0.30	0.99	1.00	0.55	1.82
41-50 years	-0.03	0.29	0.91	0.97	0.54	1.71
51-60 years	-0.19	0.29	0.51	0.83	0.47	1.45
61-70 years	0.29	0.31	0.35	1.34	0.72	2.48
71+ years	0.18	0.39	0.65	1.19	0.55	2.6
Male	0.00			1.00		
Female	0.43	0.2	0.03	1.54	1.04	2.31
Vesicant No	0.00			1.00		
Vesicant Yes	0.17	0.21	0.41	1.18	0.79	1.77
Irritant No	0.00			1.00		
Irritant Yes	-0.17	0.25	0.49	0.84	0.51	1.37
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.21	0.22	0.34	0.81	0.52	1.24
Inflammitant No	0.00			1.00		
Inflammitant Yes	-0.11	0.26	0.67	0.9	0.53	1.49
Emetogenic No	0.00			1.00		
Emetogenic Yes	-0.12	0.21	0.56	0.89	0.58	1.34
Blood	0.00			1.00		
Bowel	0.25	0.37	0.5	1.28	0.62	2.64
Breast	0.51	0.32	0.11	1.66	0.89	3.12
Gynaecological	0.07	0.41	0.86	1.07	0.48	2.4
Lungs	0.14	0.42	0.73	1.15	0.51	2.63
Lymphatic	-0.14	0.35	0.69	0.87	0.44	1.73
Others	0.48	0.32	0.14	1.61	0.86	3.03
Secondary	0.00			1.00		
Tertiary	-1.43	0.52	0.01	0.24	0.09	0.67
Teaching	-1.36	0.55	0.01	0.26	0.09	0.75
Unit capacity	0.15	0.06	0.01	1.17	1.04	1.31
%nurses With Bachelor	-0.02	0.01	0.01	0.98	0.97	1

Signs of infection

Infection does not seem to depend on patient characteristics but there is a strong suggestion that infection experienced by patients can be significantly

explained by hospital type and capacity. Odds of infection were higher in secondary compared with tertiary and teaching healthcare units. Also, the higher the capacity of the healthcare unit, the greater the odds of infection.

Table 7-29 Output of combining signs of infection and multiple logistic regression models

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	-0.97	0.9	0.28	0.38	0.06	2.12
18-30 years	0.00			1.00		
31-40 years	-0.06	0.31	0.85	0.94	0.51	1.74
41-50 years	-0.50	0.3	0.1	0.61	0.33	1.1
51-60 years	-0.44	0.3	0.14	0.64	0.36	1.15
61-70 years	-0.30	0.33	0.36	0.74	0.39	1.41
71+ years	0.03	0.4	0.95	1.03	0.46	2.24
Male	0.00			1.00		
Female	0.16	0.22	0.47	1.17	0.76	1.8
Vesicant No	0.00			1.00		
Vesicant Yes	-0.09	0.22	0.68	0.92	0.60	1.4
Irritant No	0.00			1.00		
Irritant Yes	-0.5	0.26	0.06	0.61	0.36	1.02
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.07	0.23	0.77	0.93	0.6	1.47
Inflammitant No	0.00			1.00		
Inflammitant Yes	0.07	0.27	0.79	1.07	0.64	1.82
Emetogenic No	0.00			1.00		
Emetogenic Yes	-0.19	0.22	0.39	0.83	0.54	1.28
Blood	0.00			1.00		
Bowel	-0.07	0.38	0.85	0.93	0.44	1.97
Breast	0.11	0.33	0.75	1.11	0.59	2.13
Gynaecological	-0.08	0.43	0.85	0.92	0.40	2.13
Lungs	-0.38	0.45	0.40	0.68	0.27	1.64
Lymphatic	-0.47	0.37	0.20	0.62	0.30	1.28
Others	-0.59	0.34	0.08	0.55	0.28	1.08
Secondary	0.00			1.00		
Tertiary	-1.20	0.56	0.03	0.30	0.10	0.9
Teaching	-1.38	0.58	0.02	0.25	0.08	0.79
Unit capacity	0.13	0.06	0.05	1.14	1.00	1.29
%nurses With Bachelor	-0.004	0.01	0.61	0.99	0.98	1.01

Feeling low or depressed

Depression depends on patient gender, treatment with inflammitant, unit type, unit capacity and proportion of nurses with a bachelor degree. Being a female

or being treated with inflammitant increases the odds of depression. Also, the higher the unit's capacity, the greater the odds of a patient being depressed. Odds of being depressed decreases with availability of more advanced facilities in hospitals and more educated nurses.

Table 7-30 Output of combining 'feeling low or depressed' and multiple logistic regression models

Covariate	Log Odds	S.E.	Sig	Odds Ratio	Lower CI	Upper CI
Intercept	-1.79	0.84	0.03	0.17	0.03	0.86
18-30 years	0.00			1.00		
31-40 years	-0.19	0.31	0.53	0.82	0.45	1.52
41-50 years	-0.25	0.30	0.40	0.78	0.44	1.4
51-60 years	-0.36	0.29	0.23	0.70	0.39	1.25
61-70 years	-0.3	0.32	0.35	0.74	0.39	1.39
71+ years	-0.3	0.41	0.46	0.74	0.33	1.64
Male	0.00			1.00		
Female	0.64	0.21	0.00	1.90	1.25	2.89
Vesicant No	0.00			1.00		
Vesicant Yes	-0.02	0.21	0.93	0.98	0.65	1.48
Irritant No	0.00			1.00		
Irritant Yes	-0.43	0.26	0.10	0.65	0.39	1.08
Exfoliant No	0.00			1.00		
Exfoliant Yes	-0.14	0.22	0.53	0.87	0.56	1.34
Inflammitant No	0.00			1.00		
Inflammitant Yes	0.78	0.27	0.00	2.18	1.29	3.76
Emetogenic No	0.00			1.00		
Emetogenic Yes	-0.18	0.22	0.41	0.84	0.55	1.28
Blood	0.00			1.00		
Bowel	-0.47	0.39	0.23	0.63	0.29	1.35
Breast	-0.03	0.32	0.94	0.98	0.52	1.85
Gynaecological	-0.87	0.43	0.04	0.42	0.18	0.97
Lungs	-0.37	0.44	0.40	0.69	0.29	1.63
Lymphatic	-0.63	0.37	0.09	0.53	0.26	1.1
Others	-0.06	0.33	0.86	0.94	0.50	1.81
Secondary	0.00			1.00		
Tertiary	-1.59	0.55	0.00	0.20	0.07	0.59
Teaching	-1.00	0.56	0.08	0.37	0.12	1.11
Unit capacity	0.19	0.06	0.00	1.21	1.08	1.37
%nurses with Bachelor	-0.02	0.01	0.02	0.98	0.97	1

7.5 Summary of the work conducted at this stage

This chapter has discussed the process of implanting a small-scale cross-sectional survey in 5 ambulatory chemotherapy setting. This stage was required to ensure the feasibility of implementing a survey to evaluate the effectiveness of the self-report measure PR-SICE/Arabic version and associated tools in the KSA. Also, this survey was conducted to estimate critical parameters that are needed to ensure the acceptability of the survey process and inform a large-scale study.

The findings of this survey including the method of recruitment and administration, response rates confirmed the feasibility of using the planned research methods to collect routine data on nurse-sensitive outcomes indicators in the KSA.

There was variability across centres regarding symptom experience, support provided and nurse and centre characteristics. The results of this study are a starting point to understand the relationship between how nurses deliver the care and how do patients experience their chemotherapy symptoms and how do they experience the care provided to them. Next chapter, presents a general discussion of the findings from the three stages of the study.

Chapter 8: General Discussion

8.1 Introduction

The findings of this study represent a necessary first step toward improving quality aspects of nursing care by developing a clinically valid set of quality indicators. In practice, these can be used to measure, report and improve the quality of care provided in ambulatory chemotherapy services (ACSs). Nursing-sensitive outcomes (NSOs) are advocated as ideal indicators for quantifying the quality of nursing care. The increased demand for the delivery care of a certain quality by those accessing ACSs has encouraged the development and further advancement of valid and reliable quality indicators for such services. Despite the obvious need, however, no quality indicators have yet been developed for Saudi ACSs. This study contributes to addressing this gap through the development and validation of an Arabic Patient Reported- Chemotherapy Indicators of Symptoms and Experience (PR-CISE) indicator set for ACSs and an assessment of various feasibility parameters in the Kingdom of Saudi Arabia (KSA). In addition, it explores whether such data can be collected easily and practically. This incorporates a cross-sectional survey, which has been carried out to evaluate the possible existence of variation in the selected NSOs.

In this concluding chapter, the originality of the research is highlighted. Then, the main findings of the study and how these link to other relevant studies are discussed. The findings are presented in the context of the existing research. Following this, an overview of the strengths and limitations of the study is provided, along with implications for practice and policy and future avenues of research. Recommendations for areas of future research are delineated. A personal reflection that considers the process of conducting the cross-sectional survey and the potential effect that the researcher had in terms of the context in which these data were collected are provided. Finally, a concluding statement about the contribution of the study is offered.

8.2 Originality of the research

In the KSA, there is no substantial body of literature on the quality of nursing care in general, and even less literature that pertains to ambulatory chemotherapy care. Given that the KSA, like all nations, has a legitimate need for evidence-based patient standards, there is a clear imperative to address this issue. The intention of this study was to assess the feasibility and acceptability of implementing a cross-sectional survey in the KSA to estimate the variances in NSOs for adult patients treated in ACSs. The rationale for the study lay in the need for evidence-based information to support evaluation and contribute to efforts to improve the quality of care. A three-stage study was designed to address this gap in the literature by validating a comprehensive quality indicator set and assessing the acceptability of the protocol and accompanying implementation strategy for ACSs. These represent significant contributions when it comes to providing guidance for healthcare professionals on translating best practice into clinical practice and ensuring the consistent delivery of high-quality patient care.

8.3 Summary of the main findings

This study successfully developed, adapted and tested Arabic PR-CISE indicators and associated tools. The indicators were found to be suitably useful, feasible and acceptable, and they can now be used to generate evidence about NSOs in ACSs to inform future policy and practice in the KSA and other Arab countries. The cross-sectional survey confirmed that the survey processes were efficient. This supports the argument that the adoption of a large-scale survey of NSOs is feasible, acceptable and recommended; moreover, it showed that such a survey can also be fully implemented (with some minor adjustments). The results provided preliminary evidence of considerable variation among centres concerning various factors. These included severity of patients' symptoms, perceived support from nurses to manage chemotherapy-related symptoms and differences in characteristics between nurses and centres.

8.4 Framework

The use of a robust theoretical framework to design and test quality indicators is recommended to develop a coherent knowledge base. In this study, the Nursing Role Effectiveness Model (see section 2.9.1) was used as a framework to characterise the factors that can influence the quality of care in ACSs.

Referring to NREM, the structural indicators component involves patients, nurses, and organisational variables that can have an impact on the process and outcomes of care (Doran 2011). These components were used to develop the NWUC survey, and as such represented factors that might influence patient outcomes.

In this study, three structural variables were excluded, namely; nurses' years of experience, workload, and the work environment. Two reasons led to this exclusion, 1) a limited time frame, and 2) data on these components would have needed to be collected from the nurses themselves. However, these types of organisational factors have been associated with patient outcomes in ICU settings. Additional research is needed to establish whether these relationships exist in the ambulatory environment.

The process indicator components were limited to the independent and interdependent roles. These two components were used to assess the nurses' contribution and its impact on patient outcomes.

The present study adds to the literature by offering a method that enables hospital sites to be evaluated and contrasted with one another in relation to the QoC they provide. If a system for periodic data collection is established it will be possible to build a national picture (both in the KSA and other Arabic speaking countries) of the standards that pertain to patient care.

8.5 Development and validation of the quality indicator set

In the first stage of the development process, it was essential to determine which quality indicators already existed in the international field of ambulatory chemotherapy care; this made it possible to develop quality indicators for the

ACSs in the KSA. Therefore, it was decided to conduct a systematic literature review, as described in Chapter 3 of this thesis. This systematic review gave an overview of all published quality indicators unique to NSOs for ambulatory chemotherapy care and focussed on the number and type of indicators developed, in addition to the methodology applied. The literature review revealed that previous research conducted by established the development of the PR-CISE indicators for patient symptoms and care experience within the healthcare system. In addition, the PR-CISE had been validated as an indicator assessing the quality of care provided in ACSs in the UK (Armes et al. 2014).

This study developed and adapted patient-reported indicators of chemotherapy symptoms and experience (PR-CISE). The PR-CISE was chosen because it represents a useful diagnostic tool that can measure a variety of symptoms that are relevant to this clinical group. The components were also used to assess the nurses' ability to collect data about the support provided to help patients manage their symptoms as well as the patients' experience of such informational support. The Arabic version of the PR-CISE instrument was developed to fulfil a need for ambulatory chemotherapy measures that can be applied in the clinical setting to promote quality care. In line with a previous study (Armes et al. 2014), cognitive interviews with patients confirmed the adequacy of the content covered by the adapted PR-CISE indicators, while simultaneously providing initial information pertaining to the completion of the questionnaire. After conducting the pilot survey, the Arabic version of the PR-CISE instrument was accepted without further changes to the structure. This provided evidence that (a) previous work on developing PR-CISE indicators was a sufficient starting point for this study and (b) the indicators are suitable for adoption in practice settings in the KSA. The cross-sectional survey findings have added evidence in support of the content validity of this indicator.

As suggested by Armes et al. (2014), associated tools, which explore the extent to which variation in symptom severity is explained by differences in workforce and clinical organisation characteristics, are needed. In this study, the Nurse Workforce and Unit Characteristics Survey (NWUCS) was developed using a systematic appraisal method (see Chapter 3). The development of this survey revealed several previously unmeasured factors about nurse staffing and support provided to patients in the ACSs. The cognitive interviews

involving two expert panels (senior chemotherapy nurses) gave nurses the opportunity to provide their input into the development of a tool intended for routine nursing practice application; at the same time, these experts' involvement strengthened the validation process.

The findings of this study confirmed that the NWUCS content and format were acceptable and relevant to the evaluation of the nursing workforce at different centres; the survey also provided valuable information about patients' care while receiving chemotherapy. Although the NWUCS helped in gathering information about nurse and centre characteristics, it may require further evaluation to fully assess the validity and reliability surrounding the interpretation of the results. Specifically, further research should explore whether the nurse staffing levels affect the severity of patients' symptoms. This could possibly be determined by including a larger sample of centres and considering other potentially relevant variables (e.g. nurse-to-patient ratios) with the Arabic PR-CISE indicators adapted as necessary. To summarise, the findings of this study provided evidence in support of the content validity of the Nurse-sensitive outcome indicators (NSOIs) and their associated component factors, especially the relevance, adequacy and clarity of the instruments.

8.6 Feasibility parameters

8.6.1 Settings

The number of ACSs in the KSA amounts to 15 centres distributed across all regions of the country. This study was conducted in five ACSs located in four cities in the two largest regions. These locations were chosen because they represent a range of features present in the KSA health system and treat many chemotherapy patients. The processes developed for the study could be applied consistently in the different ACSs, regardless of size or complexity.

8.6.2 Recruitment

The target population was adult chemotherapy patients in five ACSs who met the inclusion criteria (see section 6.5). The intention was to recruit a

consecutive sample from each of the five ACSs for inclusion in the implementation stage. Overall, the recruitment strategy and screening methods were effective, as sufficient numbers of patients were recruited who met the eligibility criteria. This study achieved a high response rate (*N*= 748, 93%) in a short period were the data collected. This rate is comparable to the rates in other studies of patient outcomes in cancer centres. For instance, the recruitment rate for the first reported UK-based studies testing chemotherapy patient outcomes in ACSs was not detailed; however, the researchers gave an estimated response rate of 40–87% (Armes et al. 2014). They acknowledged that not all centres had been able to collect data on eligibility or refusal to participate. Moreover, the second UK study to examine the prevalence of cancer chemotherapy-related problems reported a recruitment rate of 43% (Wagland et al. 2016). In addition, the sample size of patients (N=748) in the KSA study was large enough to obtain a substantial amount of useful information, and it proved adequate for establishing the variation in symptom severity among participating centres. The number of participants reflects the effectiveness of the screening methods and recruitment process.

8.6.3 Data collection

As in Armes et al. (2014) study, in this research, most information about patient outcomes was gathered through patient self-reporting at the point of chemotherapy delivery. This mechanism was shown to be feasible and acceptable for UK and KSA patients. However, the data gathered during the pilot-testing stage (Stage II) offered significant information on the eligibility process, thereby verifying the applicability of the inclusion criteria planned for this study. Moreover, the pilot-testing results showed that there was a potential disadvantage in the initial data collection strategy. Specifically, nursing staff experienced a great deal of difficulty in the data collection process. As mentioned earlier, the volunteer staff member found it hard to manage the workload of the survey alongside clinical duties. On reflection, this suggested that some changes were warranted in terms of implementing the developed indicators in the Saudi ambulatory chemotherapy care setting. Thus, for the implementation stage (Stage III), it was proposed that volunteer research assistants (VRAs) should be responsible for the recruitment and distribution of the survey to the eligible patients. The VRAs' assistance in the real-time

distribution of the survey enabled a log of recruitment activity and identified reasons for non-eligibility to be compiled. These initial revisions provided additional credibility to the data collection process. Moreover, in stage III, data on patients' diagnoses and chemotherapy regimens were collected from the unit log book by the researcher or VRAs. This method helped to reduce the percentage of missing data.

In terms of the amount of time required for data collection, this study took place over a considerably shorter period than previous studies did. While this study evaluated 5 centres with the aim of completing the data collection in 20 days, Armes et al. (2014) conducted a 3-month study across 10 centres. This resulted in almost triple the responses, at 2466, compared to 849 who received the questionnaire package in the current study. Considering that cross-sectional methods offer a snapshot at a point in time for the evaluation of certain factors for a given population, it is beneficial to maximise the number of participants reached.

8.6.4 Analysis plan

Risk adjustment was the chosen standardised comparison technique that supported the investigation of the potential causes of differences in NSOs between centres. Multiple logistic regression models were developed, which helped in explaining this variation. Regression models were found to be feasible for analysing relevant factors; however, unexplained variation remained after case-mix adjustment of patient demographics and nurse and unit characteristics.

8.6.5 The impact of cultural aspects and the influence of the study location on the research process and findings

As discussed in the background provided in Section 2.3, gender differences could be an issue that should be considered when planning a study in the KSA. One of the gender-specific considerations relates to transportation. In Saudi society, women who wish to travel must have a male chaperone, and until recently, they were not permitted to drive (Mobaraki & Söderfeldt 2010; Aldosari 2017). In this study, the issue of transport did not present a problem

as the female patients were already present in the ACS for their treatment rather than for the study specifically. The same rule applies to female employees, including those working in the health sector, who cannot travel within or outside the Kingdom without their guardian's permission. Some of my Saudi female classmates who have studied outside the Kingdom (in the UK) faced some problems when it came to travelling within the Kingdom for data collection. Their male guardians would only allow them to collect data from their own city.

As mentioned earlier, the current study was conducted in four cities located in the two of the largest regions in the KSA, and the researcher faced no difficulty travelling within or outside the kingdom. Furthermore, after training the VRAs, I communicated with them via phone or emails and was ready to travel to collect data if required. Regarding the female VRAs, Saudi law requires a male relative's consent before a woman can seek employment, start education, travel or obtain identity documents (Mobaraki & Söderfeldt 2010). For this study, I recruited female volunteers from the volunteer lists available at the targeted hospitals or via leaflets placed on internship bulletin boards. In this manner, I ensured that the female VRAs had received permissions from their male guardians before participating in this study; accordingly, they faced no problem with transportation. Besides, the male guardians were assured of the safety of the place where data was collected as it was also where these women worked. Additionally, consideration was given to the fact that gender differences might influence data collection. Therefore, both male and female VRA participants were asked to report any issues encountered with the caregivers or the patients themselves during the recruitment process. The VRA participants did not report any conflicts with patients of the opposite sex.

Furthermore, as stated in the introduction Section 2.3, Saudi society is built on cultural and Islamic affiliations. Therefore, a patient's response to the survey might be influenced if the caregiver is present with the patient whilst the study is in progress. The patient might discuss questions they have about the PR-CISE questionnaire with the caregiver accompanying them during treatment; in this case, the data recorded would not reflect the patient's own experiences and sentiments but that of the caregiver. While PR-CISE is a self-reported questionnaire, future studies should consider exploring who actually answers

the questionnaire (the patient, caregiver, the researcher, or a combination of parties).

8.6.6 Feasibility of recruiting volunteer research assistants to support the data collection process

It was feasible to invite VRAs to take part in this study to support the data collection process. The recruitment strategy and training workshop of the potential VRAs were effective. Overall, the VRAs training process developed for this study could be used in a future large-scale survey. Recruiting both male and female VRAs helped in identifying issues regarding gender-specific considerations.

8.7 Severity of subjective symptoms

The survey found that in the Saudi population, 'weakness and tiredness' were the most troublesome symptoms, in that over 50% of participants rated them as moderate or severe. This result is consistent with the findings of the previous UK studies; Wagland et al. (2016) studied the prevalence of cancer chemotherapy-related problems and found that 48% of patients experienced moderate or severe 'tiredness, fatigue or [lack of] energy'. Concerning Wagland et al. (2016) study, a previous study on outpatients by Armes et al. (2014) found that a higher proportion of patients reported moderate or severe tiredness, at 65%. While fatigue is one of the most common symptoms of cancer and its treatment, no clear evidence has been published to support the assertion that weakness and tiredness are directly linked to the quality of nursing (Griffiths et al. 2009); therefore, they are not sufficient as NSOIs. Therefore, more research needs to be done to establish this link.

A picture emerged of considerable numbers of participants experiencing moderate or severe symptoms across all symptoms assessed in this study. For instance, overall, 34.2% of participants experienced moderate or severe nausea; however, this figure varied among centres, ranging from 33% to 39%. This is consistent with the study by Armes et al. (2014), who reported that

nausea was found to be the most prevalent physical symptom of chemotherapy patients (41%). As well as Janelsins et al. (2013) study who indicated that nausea is known as a common and distressing symptom associated with most chemotherapy regimens.

8.8 Support to manage symptoms

In addition to the questions about the severity of symptoms, the survey included five items exploring aspects of patient support to manage their symptoms. These items were endorsed and validated by Armes et al. (2014). In their study, 90% of patients answered 'Yes' to the question, 'Do nurses ask you about your symptoms?' across all 10 data collection sites, and the range was 72–97%.

Surprisingly, in the present study, just over half (53%) of the patients in four centres stated that nurses did not enquire about their symptoms. Compare to Centre E, less than a quarter (22%) of the patients reported that nurses did not enquire about their symptoms. In Centres B, C and D, the nurses sought to assess patients' side effects resulting from the previous cycle of chemotherapy if they had not been seen by a physician. Centres B, C and D reported low nurse enquiries about patient symptoms (22.7%, 27.2% and 26.4%, respectively) and correspondingly low enquiries about symptom severity (22.6%, 19.8% and 20.8%, respectively). Only in the final centre (Centre E) did most patients state that nurses enquired about their symptoms (78%) and their severity (73.2%). This appeared to be a common theme for this centre, with other factors, such as the amount of information provided, being reported as extremely high, with up to 95% of patients stating that they had received advice. An explanation for the general trend is that doctors, and not nurses, are usually the ones who enquire about patient symptoms in the KSA.

8.9 Patient experience of informational support

Research evidence suggests that nurses and physicians are the most preferable sources of information on the management of chemotherapy-related symptoms (Nair et al. 2000), as this helps patients in adequately performing self-care and coping with the side effects of their treatment. In this study,

items related to patients' experiences with information support offered before and during treatment and the administration process were recorded.

As with the other outcomes, patients appeared to show considerable differences in the experience of care they had received. For instance, over 60% of patients answered 'Yes' when asked, 'Before starting your treatment, did you receive a clear explanation from your chemotherapy nurse of what the treatment would involve?'. However, this ranged from just 30% of participants at Centre B stating they received informational support compared to nearly 92% at Centre E.

As with managing symptoms, Centre E showed higher levels of patient care, pointing to at least one nursing team that offered superior care relative to the others.

Ventura et al. (2013) studied patients' experiences of chemotherapy in an ambulatory cancer care unit, and they provided evidence that being cared for at an ACS triggers patients' self-care potential. Their findings highlighted the need for models that facilitate self-care and patient empowerment, especially in the ambulatory setting. Therefore, future research needs to be directed at how to encourage patients to identify their information needs while incorporating their goals and wishes into the delivery of care at the ambulatory care.

8.10 Factors that influence patient outcomes (variation in nursing and unit characteristics)

The results of this study suggested that across centres, patients can experience variability in the quality of care they receive. Differences in care quality can have a direct effect on patients' recovery and experience as they receive treatment for cancer. Moreover, there were significant differences observed in the distribution of the severity of symptoms across most centres. To disentangle whether between-centre variation in symptom severity and perceived support from nurses was related to differences in patient demographics alone or could be explained by differences in workforce and

centre characteristics, the author adjusted for the case mix. Multiple logistic regression models were developed that explained this variation. The survey analysis allowed the effects of patient demographics (age, gender, diagnosis, chemotherapy type and cycle) on participants' experiences to be explored. This, however, was weakly correlated when evaluated relative to aspects like demographics and the type of diagnosis. Interestingly, gender had a significant correlation ($p < 0.025$) with the overall number of symptoms experienced.

When adjusted for nursing and centre characteristics, the results gave some confidence (see Section 7.4.10), although the risk adjustment model was limited. Given that most nurses were registered nurses (RNs), it was not possible to calculate the influence of the nurse skill mix. Due to differences in data availability on nurse staffing levels (nurse-to-patient ratios) in some participating centres, it was not possible to take the effect of differences between the studied centres into account. A study by Aiken et al. (2016) found that nurse staffing factors were associated with patient outcomes in inpatient environments. The authors argued that hospitals that employed a larger population of professional nurses experienced better patient outcomes and staff work performance. In contrast, they attributed higher rates of avoidable errors and deaths among patients to hospitals that employed a mix of nurses with lower skill sets. The results of my study showed that in the hospitals with a greater proportion of nurses with higher education (bachelor's degrees), nurses were more likely to be rated highly by patients on measures like support to manage the symptoms and severity of the experience. In addition, participating centres with a greater proportion of nurses who had achieved a higher qualification, such as a bachelor's degree, recorded lower rates of symptoms like IV-line pain and irritation.

Centre A used a standardised approach to measuring acuity when allocating patients to nurses, and patients had a likelihood of experiencing nausea that was 1.24 times lower than they did at other centres; however, the difference was not significant. However, variation in nausea may be explained with further analysis and identification of mediating factors along the causal pathway. This trend continued in terms of the experience of vomiting episodes, with those in the standardised acuity approach centre experiencing 1.16 times lower odds of vomiting. However, this was not statistically

significant between hospital types. The most significant finding of this study was that there is some evidence that centre and nurse characteristics have a direct influence on NSOs, and they translate directly into the nature of patient care received and accompanying symptom reports for those receiving chemotherapy.

8.11 Strengths and limitations

One strength of this study relates to the unique area of investigation. This study represents the first in the KSA to collect comprehensive data about NSOs using NSOIs. Feasibility testing is a significant step that must be taken before recommending further applications, rather than first evaluating the effectiveness of the indicators. This study validated the acceptability and reliability of conducting this type of study in the KSA. Now, the services will have the opportunity to use the quality indicators for internal quality monitoring and improvement.

Another strength of this study is its high response rate, the nationwide sampling approach enabled the participation of centres that treat patients from around the KSA. This gave an important opportunity to look at the Saudi demographic on a national level to better gauge how, if implemented, a larger future programme may be received. Other strengths include the insight provided from this large sample; the inclusion of patients with any type of cancer (all adult age groups were studied) and the relatively low level of missing data (from incomplete questionnaires).

Like other studies, the present study had some limitations; these can be categorised into the two general areas of the study design and data collection approaches. The first limitation is the modest number of participating centres (N = 5). The feasibility study (Stage III) was undertaken in 5 ACSs that volunteered to participate. While this represented an adequate number for a feasibility study, the centres can be seen as forerunners, and they may not be representative of all chemotherapy ambulatory care services in the KSA. The limitations in the NWUCS make nursing care's contribution to patient outcomes difficult to evaluate and report in relation to the performance of the ACSs.

Therefore, further development of approaches to characterising and measuring the nursing workload, staffing and skill mix would provide greater insight into ACS performance.

This study used a cross-sectional design. This was suitable and cheaper than longitudinal methods, while providing a snapshot at a select point in time. However, the limitations of such a design need to be acknowledged. The approach limits the possibility of drawing definitive conclusions about the causal relationships of the variables of interest and patient outcomes. In other words, no causal inferences can be established from cross-sectional data. Moreover, the cross-sectional design did not allow the researcher to conduct test-retest procedures, which would have tested this aspect of the validity of the scale. Specifically, efforts to further improve validity components would have been particularly helpful.

Another limitation involved the delays in ethical approval, which were attributed to the way in which each hospital processed such requests. In some hospitals, approval was granted by the unit head nurse; the approval process could be made more efficient by making the nursing affairs ethics committee responsible for it. This would help to support ongoing research by reducing the time spent waiting to engage in primary data collection, especially for studies with tight time and resource restrictions.

8.12 Implications

NSO measures are widely accepted as quality indicators; the indicators that were developed and adapted in this study have many potential implications, especially in terms of research, clinical practice and policymaking. This may offer ways for organisations to look how staff members assess and respond to patient symptoms and concerns and reveal services committed to patient-centred care. This, in turn, may further hospital initiatives directed at safety and quality by developing staff who actively act to promote choice, independence and a holistic approach to treatment. In addition, these quality indicators represent a relatively low-cost addition, yet they offer real potential for the improvement of care standards in the hospital environment. Indicators such as these may be able to tap directly into strategies that aim to foster

patient outcomes that are centred around the quantity and quality of nurses in these units. Given that the work environment is a factor that has a major influence on behaviours, existing studies have linked hospitals that exhibit high safety and patient care quality with nursing standards (Aiken et al. 2012). In this schema, the results for quality indicators in countries in Europe and North America (Armes et al. 2014) have an exciting potential to be translated to the KSA.

8.12.1 Messages for researchers

NSOs are considered as a growing body of work for researchers and quality measurement specialists. However, while research on nurse staffing and patient outcomes has surged in the last decades, few studies have applied the Nursing role effectiveness model (NREM) to examine the nature of these relationships in ambulatory care settings, especially ACSs. This presents some exciting avenues for future research. Specifically, two main directions can be investigated to explain the variation in patient outcomes. First, more information about nurse characteristics could be acquired. This could comprise factors measured using a nurse survey, including nurses' years of experience and information about the number of patients they cared for on their last shifts. The findings of such a survey could result in a deeper understanding of the causes that contribute to variation in patient outcomes across different ACSs. Further analysis of these data may reveal whether the adjustment of nurse workforce and unit characteristics will promote less variation in the quality of care received.

The second direction that may be explored could involve repeating the present study with a larger number of centres. This may add further insight and increase generalisability across centres through access to a far wider demographic, especially if sampling methods are used that incorporate hospitals nationwide.

8.12.2 Recommendations and challenges for policy makers

At present, little can be said with confidence about the quality of care provided in ACSs in the KSA. There is no national system focus on the quality

monitoring and improvement necessary to guarantee high-quality cancer care for Saudi cancer patients, specifically for patients undergoing chemotherapy in ACSs. Therefore, policy makers in the KSA, need to be encouraged to set out a national monitoring and improvement strategy for chemotherapy care. Regarding recommendations for policy makers, the present findings suggest that the PR-CISE indicators and associated tools can be used in future to inform: a) national improvement strategy, to measure and monitor the quality of nursing care in ACSs comprehensively and explicitly, and b) a national nursing workforce for cancer care.

In order to make a successful plan to progress towards a national systematic quality monitoring and improvement system, three goals should be considered: 1) implementing a quality monitoring system, 2) building a database that has the capacity to capture and display the data, and 3) establishing a national quality monitoring and improvement initiative. The first goal of a national improvement strategy would be to implement a quality monitoring system. Implementing the quality indicator set that was developed during this PhD into all ACSs in the KSA would generate a large pool of data. This set of indicators would enable the accumulation of a range of structure, process and outcome data.

To progress towards a systematic quality monitoring and improvement system for ambulatory chemotherapy settings, the second goal of a national improvement strategy would be to establish a national registry system to collect data on chemotherapy care practices. This would comprise the development of a database to include all quality measures in chemotherapy care. Such an extensive database would provide policymakers, healthcare managers and researchers, the possibility to assess, evaluate, and make a fair comparison of quality of care between and across different types of chemotherapy care services possible in the KSA. The primary sources to delineate the items to be included in the database can be drawn from the results of my own work and the evaluations of patient outcomes of chemotherapy-related side effects that. I hope that the descriptions provided here, and a growing body of similar resources in the literature, will assist policymakers and healthcare systems as they develop and implement the tools needed to provide the national database.

The third and last goal of the national improvement strategy would build on identifying the best ACSs practices via quality measurement, to assess and address issues of inequalities in quality of care, especially when it comes to patient experiences of symptoms and supportive care. In order to help services to improve their practice, policy makers in cooperation with researchers should set out a national improvement strategy. This might extend to areas such as activity and procedure standards (procedural) to address clinical and administrative activities or interventions carried out within the ACSs in the care of patients or the management of the hospital or its staff. Examples include patient assessment, patient education, medication administration, and the like. Moreover, outcome standards could be developed to provide information about whether predicted outcomes are being realised.

Evidently, this study found evidence of variation in the ACS profiles and the characteristics of nurses in the studied centres. The results underline the need to develop a nursing workforce strategy for oncology nursing in the KSA. The KSA would also benefit from the design of patient acuity tools for the ACSs. The implementation of the quality indicators and associated tools would lead to the creation of an extensive database of quality indicator scores for a range of ambulatory chemotherapy care units. Based on such data, analyses could be performed and evaluated for signs of improvement or declining standards. Since chemotherapy is a dynamic area of cancer care, there is a need to debate modes of practice and future direction of chemotherapy services. Once the direction has been debated and agreed, issues such as who delivers the service, in which way, in which location and the nature of the service may be planned together with models of support and supervision for optimum physical and psychological patient care. Following the implementation of a national systematic quality monitoring and improvement system, the improvement effect can then be measured by making use of the quality indicators and database.

With the above in mind, there are still three main significant challenges that remain for policy makers. First, to move from purely researcher-driven processes, which summarise research, to co-production processes, which allow policy makers and healthcare managers to join with researchers in interpreting

implications for the healthcare system. This can be done by providing opportunities for sharing experiences and learning from success as well as failure. Second, to keep investigating how policy makers can contribute to meeting the needs of the managers and caregivers to conduct quality evaluation and improvement repeatedly within their services. In other words, policy maker needs to make further investigation about which structural improvements are needed for ambulatory chemotherapy services and caregivers which can be achieved by incorporating the existing quality indicators set within the ACSs. Third, to consider the attitudes and experiences of healthcare managers and caregivers when implementing the quality indicators into ACSs and investigate how to continue to involve all other possible stakeholders when progressing towards a systematic use of the quality indicators in these settings care.

In conclusion, the developed and adapted chemotherapy indicators of symptoms and experience and its associated tools are worthy of serious consideration by policymakers and programme managers in the KSA and elsewhere.

8.12.3 Messages for clinical practice

Based on the results of this study, the PR-CISE indicators are ready to be used in individual ambulatory chemotherapy care settings in the KSA, with the opportunity to evaluate and improve the quality of care provided in this setting. It is recommended that every ACS measure the quality indicators no less than twice a year in order to generate representative quality data about the care delivered.

Second, there is a need to improve patient outcomes and experience of supportive care, especially in terms of chemotherapy-related symptoms. The developed and adapted indicators can provide structured data on patients' symptoms and supportive care that could be used by the local authority to identify plans for action and design interventions. Moreover, every participating hospital will receive a copy of the study results, in which they will only be identified by the assigned identification letter. This will allow them to accomplish the following: 1) confirm known issues, 2) identify unknown issues

and 3) compare centres to determine potential differences in care quality. Then, the manager with the help of the team needs to interpret and analyse the quality indicator scores and distillate practical point for the team. When the team members have agreed on possible explanations on what might have caused the issues, they can then together decide on all working points if action needs to be taken to improve this issue.

Last, empirical data to support decisions about unit and nursing characteristics are needed in Saudi ACSs. This is important, as nurse staffing has been identified as one of the factors influencing patient outcomes in inpatient settings. The NWUCS is intended to be used in clinical practice and drive quality-improvement efforts. I suggest that ambulatory chemotherapy practice staff assess their compliance with each of the standards. For areas requiring improvement, practice healthcare professionals should prioritise time and resources and set achievable goals. To help practices rapidly comply with the standards, the developed set of indicators might provide a source to assist in practical implementation. Once compliance has been maximised, practices should create a mechanism for periodic surveillance.

This study focussed on patients' experiences of chemotherapy-related symptoms and support for managing symptoms. In the results, 63.49% of participants reported mild, moderate or severe feelings of low or depressed mood. This alarmingly high result presents an essential area that must be addressed; this can be done by reducing stress and alleviating feelings of low mood and depression among patients undergoing chemotherapy. For the KSA, this may highlight the need for psychological support services for patients and their families during such a tumultuous time. This would suggest the need to gather information on the causes of these distress factors and enable the creation of strategies to improve patient outcomes. It is anticipated that while the life-threatening issue of cancer would be a major factor, perceived levels of support and access to available services and information must also be prioritised.

8.13 Recommendations for future surveys using the PR-CISE indicators

Much can be done to enhance the quality of care provided in the ACSs in the KSA. The resulting development of valid PR-CISE indicators and associated tools in this study may be applied elsewhere. It is argued that one of the main contributions of this study to the current literature regarding these indicators is that they could be implemented directly in different ACSs in Arabic speaking countries. In terms of understanding and managing variation, future researchers may replicate this study in different ACSs and regions to allow for generalisation to the nation's population. This should include refining the NWUCS.

The findings also identified associations between the study variables. Future researchers can use this result as a basis from which to evaluate whether the associated variables have a causative relationship.

In terms of issues relating to data collection, some patients were ineligible to participate. One reason for this ineligibility was insufficient literacy. Considering that the experience of patients is fundamental to this research, future research should consider the inclusion of VRAs to support the administration of the questionnaire. It may also be possible to consider having VRAs directly support patients as they complete the survey. This would need to be carefully considered, as it would generate a potential for bias (e.g. if researchers somehow influenced or altered the truthful responses of participants due to their own cognitive biases).

The study developed useful tools and instructions that supported the data collection process. It would be beneficial for these tools to be used in any large-scale survey, including the eligibility criteria, log of recruitment activity and instructions to identify eligible participants. A sample size calculation would be required for a future large-scale survey. Findings on number of eligible patients over 1 month (Table 7-2) may be used as the basis for sample size calculations for the large-scale study.

Recommendations on how the future survey should be conducted

The inclusion of VRAs would provide more up-to-date feedback and articulate the number of eligible patients relative to those who have agreed to participate. This would highlight the rates of participation across sites and potentially flag early issues for the lead researcher to address. As in the implementation stage, it is suggested that noting the type of chemotherapy, diagnosis and treatment cycle on each questionnaire should be undertaken prior to passing the survey to the selected patient. The VRAs should follow the developed recruitment strategy and screening methods. This may initially be more time consuming (and costly), as they would need to be introduced to patients and gain approval to communicate with them directly. However, it would also improve the fidelity of the research by ensuring that participants are actively engaged in the data collection process. In addition, the VRAs would be able to provide frequent feedback to the lead researcher via progress reports, thereby highlighting any challenges that emerge.

8.14 Personal reflection

Collecting these data gave me first-hand experience of both the anticipated and unforeseen challenges that come with any form of primary data collection. The author was especially struck by the generally supportive nature of participants in giving their time to further this body of work. Considering that these individuals are going through a particularly strenuous life experience, the author was extremely aware of and grateful for their participation. Aspects of inclusion and exclusion strongly highlighted the need for innovative thinking when attempting to capture the widest possible demographic. As individuals who were illiterate could not participate in the current study, the author was aware that this loss may somewhat skew the demographic of respondents, as those from older generations and poorer backgrounds are more likely to have poorer literacy. The author did observe that the tangle of policies and regulations that needed to be navigated could be both time consuming and confusing without adequate preparation. This gave me an appreciation of the need to foster working alliances with stakeholders across

the healthcare spectrum. For future research, such alliances would assist in developing a diverse network of support when engaging with such studies.

8.15 Conclusion

This study aimed to investigate the feasibility and acceptability of undertaking a cross-sectional survey using NSOIs as a step toward assessing variation in quality of care in ambulatory chemotherapy units in the KSA. This aim was achieved, and the results were encouraging, demonstrating that recipients viewed PR-CISE and its associated tools as valuable, feasible and acceptable. The set of tools developed show a great deal of potential in terms of the assessment of variation in the severity of patients' subjective symptoms in the KSA, and the instruments may be applied in other Arabic-speaking nations. The study measure and processes can now be used (with minor adjustments) in a large-scale survey. Moreover, the NWUCS represents one of the first attempts to characterise ACS nursing services, and it has applicability beyond the KSA. Future application of these tools has the potential to contribute to improvements in the quality of patient care in ambulatory cancer services.

Given that patient outcomes are increasingly being linked to the quality of professional care they receive, the use of tools like the PR-CISE set is expected to grow. For the KSA, this offers real opportunities to not only incentivise organisational learning but also provide a benchmark of care standards across the country. While tools like these can highlight patient dissatisfaction with care, it is vital to employ them. By actively engaging with staff across hospital sites, they can be empowered to use such tools in the KSA, and in so doing, support the standardised evaluation of quality standards.

Appendices

Appendix A: PR-CISE

Original

Nurse Sensitive Indicators

Appendix F: Final self-report/self-assessment questionnaire

How are **you**? ...and how are we doing?

The questions overleaf ask about how you are feeling and whether or not the support you are getting from the nurses in the chemotherapy day unit is helping. We would like to get an overall picture from all our patients about how well nurses are supporting you.

It is important for us to understand how you are doing and what works for you.

- We hope that the doctors and nurses looking after you have given you a chance to tell them about how you are doing and whether the care you are getting is meeting your needs
- Because things change over time, we would like you to complete this questionnaire every time you come in for chemotherapy treatment
- We hope that it will also help you to think about questions that you might still have or support that you might still need

You might want to make a note of any issues that you want to discuss with your chemotherapy nurse after completing the survey - the back page has been left blank for this purpose.

General instructions

- Most questions are answered by putting a tick clearly inside a box.
- Please use a blue or black pen.
- Don't worry if you make a mistake; simply cross out the mistake and put a tick in the correct box.
- DO NOT write your name or address anywhere on the questionnaire.
- Taking part in this survey is voluntary. Your answers will be treated in confidence unless you decide to share them with your chemotherapy nurse. Otherwise they will only be fed back anonymously as part of a report to the hospital that cared for you.
- This work is being developed in partnership with your NHS Trust by Professor Peter Griffiths and a research team at King's College London and the University of Southampton. It is being undertaken on behalf of the National Cancer Action Team at the Department of Health.

Please put this questionnaire in the box at reception before you leave today

Thank you ☺

Nurse Sensitive Indicators

A. Do you know about the drugs you are getting?

Please tick any of the chemotherapy drugs listed below that you are receiving as part of your chemotherapy regimen.

For each drug ticked please also tell us if you feel fully informed about the side effects. We realise that your answers to these questions may change as you progress through treatment because:

- You have been told more about your drugs
- Your drugs have changed
- You experienced side effects that you hadn't been prepared for

If you don't know what drugs you are getting please ask the doctor who prescribes your chemotherapy or the nurse who sets up or administers it to tell you. If you are not receiving any of these drugs please tick "none of the above" and tell us if you feel informed about the side effects of the drugs you are on by ticking the box.

We have only listed drugs that most commonly cause nausea or vomiting or can irritate veins. However we know that many of you will be taking drugs that don't appear on this list.

	I am receiving this drug	*I was told about the side effects*
1. Aclarubicin	☐	☐
2. Amsacrine	☐	☐
3. Carboplatin	☐	☐
4. Carmustine	☐	☐
5. Cisplatin	☐	☐
6. Cyclophosphamide (less than 1500mg)	☐	☐
7. Cyclophosphamide (more than1500mg)	☐	☐
8. Dacarbazine	☐	☐
9. Dactinomycin	☐	☐
10. Daunorubicin	☐	☐
11. Doxorubicin	☐	☐
12. Docetaxel	☐	☐
13. Etoposide Phosphate	☐	☐
14. n. Floxurudine	☐	☐
15. Fluorouracil	☐	☐
16. Idarubicin	☐	☐
17. Irinotecan	☐	☐
18. Methotrexate	☐	☐
19. Mitroxantrone	☐	☐
20. Mustine	☐	☐
21. Mytocycin	☐	☐
22. Oxaliplatin	☐	☐
23. Paclitaxel	☐	☐
24. Raltitrexed	☐	☐
25. Streptozocin	☐	☐
26. Teniposide	☐	☐
27. Topotecan	☐	☐
28. Treosulfan	☐	☐
29. Vinblastine	☐	☐
30. Vincristine	☐	☐
31. Vindescine	☐	☐
32. Vinorelbine	☐	☐
None of the above	☐	☐

60

Appendix A

B. How are you feeling and how are we doing?

Please look at the list of symptoms below, which are commonly experienced by people undergoing cancer chemotherapy. Tell us which symptoms you experienced since your last chemotherapy treatment. If you experienced a symptom, please tell us how severe the symptom was by ticking the boxes.

B1 Since you last chemotherapy have you experienced...

	None	Mild	Moderate	Severe
Nausea	☐1	☐2	☐3	☐4
Vomiting	☐1	☐2	☐3	☐4
Pain and irritation at the injection / infusion (needle) site	☐1	☐2	☐3	☐4
Problems with mouth or throat (e.g. sore or dry mouth/throat, mouth ulcers)	☐1	☐2	☐3	☐4
Feeling weak	☐1	☐2	☐3	☐4
Signs of infection (e.g. feeling unusually hot or cold, flu like feelings, high temperature, pain when urinating)	☐1	☐2	☐3	☐4
Feeling unusually tired	☐1	☐2	☐3	☐4
Feeling low or depressed	☐1	☐2	☐3	☐4

B2 Are you experiencing any other symptoms?

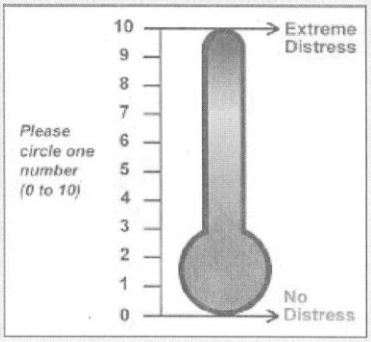
	Mild	Moderate	Severe
.....	☐1	☐2	☐3
.....	☐1	☐2	☐3
.....	☐1	☐2	☐3

B3 Please tell us about the support you receive to manage your symptoms

	Yes	Somewhat	No
Do the nurses who give you chemotherapy ask you about your symptoms?	☐1	☐2	☐3
Are the nurses who give your chemotherapy aware of the severity of the symptoms?	☐1	☐2	☐3
Are the nurses who give your chemotherapy providing useful information to manage your symptoms?	☐1	☐2	☐3
Are the nurses who give your chemotherapy providing practical advice to manage your symptoms?	☐1	☐2	☐3
Are you confident in your ability to manage the symptoms you are experiencing?	☐1	☐2	☐3

B4 How are you doing overall?

Please circle the number (0-10) on the 'thermometer' to the right, that best describes how much distress you have been experiencing in the past week including today.



61

C. About you and your treatment

Because this questionnaire is anonymous and we won't look at your medical records it would help us if you could give us some additional details about yourself and your treatment.

C1 Which cycle of chemotherapy will you receive today? Please circle one number

1 2 3 4 5 6 7 8 9 10 11 12+

C2 What is your diagnosis?

C3 How are you receiving your chemotherapy? Please tick one box

- Injection or infusion (drip) ☐ 1
- Injection or infusion (drip) and tablets ☐ 2
- Tablets only ☐ 3

C4 What is the device used for giving injections/infusions? Please tick one box

- Cannula (needle) ☐ 1
- PICC line (long flexible tube that runs up a vein, inside your arm & ends up in a large chest vein) ☐ 2
- Hickman/Central line/Portacath (tube that goes directly into one of the large veins in the chest) ☐ 3

C5 What is your age?

- 18-30 ☐ 1
- 31-40 ☐ 2
- 41-50 ☐ 3
- 51-60 ☐ 4
- 61-70 ☐ 5
- 71+ ☐ 6

C6 Are you:

- Male? ☐ 1
- Female? ☐ 2

C7 How would you describe your ethnic background? Please tick one box

- White British ☐ 01
- White Irish ☐ 02
- White Other ☐ 03
- Mixed-White & Black Caribbean ☐ 04
- Mixed-White & Black African ☐ 05
- Mixed-White & Asian ☐ 06
- Mixed Other ☐ 07
- Asian or Asian British-Indian ☐ 08
- Asian or Asian British-Pakistani ☐ 09
- Asian or Asian British-Bangladeshi ☐ 10
- Asian or Asian British-Other ☐ 11
- Black or Black British-Caribbean ☐ 12
- Black or Black British-African ☐ 13
- Black or Black British-Other ☐ 14
- Chinese ☐ 15
- Any other background ☐ 16
- Do not wish to disclose ☐ 17

62

Appendix A

D. Are we getting it right?

Instructions: Think about the care you have received from the chemotherapy nurses since you started receiving your treatment in the chemotherapy day unit and read the statements below. Please tick the box that most matches your experience.

C8	**Before starting my treatment I was given a clear explanation by a chemotherapy nurse of what the treatment would involve**	*Yes* ☐ 1 *Yes, to some extent* ☐ 2 *No* ☐ 3
C9	**If you are taking chemotherapy tablets at home, did the chemotherapy nurse give you an explanation about what you should do in a way you could understand?**	*Yes* ☐ 1 *Yes, to some extent* ☐ 2 *No* ☐ 3 *I don't take chemotherapy tablets at home* ☐ 4 ☐ 5
C10	**Are you able to talk with a chemotherapy nurse when you need to?**	*Yes* ☐ 1 *Yes, to some extent* ☐ 2 *No* ☐ 3
C11	**Since your last cycle of chemotherapy treatment, did you contact a chemotherapy nurse about a problem?**	*Yes and they sorted it out* ☐ 1 *Yes but they didn't sort it out* ☐ 2 *No, because I didn't know who to contact* ☐ 3 *No I didn't need to* ☐ 4
C12	**I feel that the treatment was rushed and that the chemotherapy nurses do not have enough time**	*Yes, always* ☐ 1 *Yes, sometimes* ☐ 2 *No* ☐ 3
C13	**I spend an unnecessary amount of time in the chemotherapy day unit waiting to receive my chemotherapy**	*Yes, always* ☐ 1 *Yes, sometimes* ☐ 2 *No* ☐ 3
C14	**The nurses are gentle and skilful when they place the cannula (needle) in my arm**	*Yes* ☐ 1 *Yes, to some extent* ☐ 2 *No* ☐ 3 *Not applicable* ☐ 4

PR-CISE/Arabic Version

Health Sciences

UNIVERSITY OF Southampton

الرقم التعريفي		

استبيان لمرضى وحدة العلاج الكيميائي الخارجية

في الصفحات التالية اسئلة مطروحة عن الاعراض الجانبية التي واجهتها منذ اخر جلسة علاج كيميائي و عن ما إذا كان الدعم المقدم لك من الممرضات في وحدة العلاج الكيميائي مفيد أم لا.

- تعبئة الاستبيان تستغرق حوالي ١٠ الى ١٥ دقيقة.
- هذه الدراسة تحت اشراف جامعة ساوثمبتون ببريطانيا.

تعليمات عامة:

- معظم الأسئلة يمكن الاجابة عليها بوضع علامة X واضحة داخل المربع.
- من فضلك استخدم القلم المرفق مع الاستبيان.
- لا تقلق اذا أخطأت، ببساطة اشطب الخطأ وضع علامة x في المربع الصحيح.
- لا تكتب اسمك أو عنوانك في أي مكان على الاستبيان لضمان الخصوصية.
- مشاركتك في الدراسة تطوعية وسيتم التعامل مع اجوبتك بسرية الا إذا قررت مشاركتها مع الممرضة المسؤولة عن علاجك.
- سيتم استخدام اجوبتك كجزء من التقرير المقدم للمستشفى المعالج لك.

من فضلك ضع هذا الاستبيان في الصندوق المخصص للدراسة والموجود في استقبال وحدة العلاج الكيميائي قبل مغادرتك اليوم

شكراً لتعاونكم

Appendix A

القسم الاول (أ): ما هو اسم العلاج الكيماوي الذي تأخذه؟ وهل تعرف اعراضه الجانبية المحتملة؟

أ١/ من فضلك اختر اسم العلاج الكيميائي الذي تأخذه من بين الادوية المذكورة بالأسفل.

- إذا لم تكن تعلم اسم العلاج الكيميائي الذي تأخذه من فضلك اسأل الممرضة المسؤولة عن اعطائك للعلاج الكيميائي لإخبارك.
- في حال عدم وجود اسم العلاج الكيميائي الذي تأخذه في قائمة الادوية المذكورة بالأسفل الرجاء وضع علامة x على "لا شيء مما سبق".

	اسم الدواء	الاسم باللغة الانجليزية	انا اخذ هذا الدواء
١	اكلاروبيسين	Aclarubicin	☐
٢	اليمتا (بيميتريكسيد)	Alimta (Pemetrexed)	☐
٣	امساكرين	Amsacrine	☐
٤	بليومايسن	Bleomycin	☐
٥	كابسايتابين (زيلودا)	Capecitabine (Xeloda)	☐
٦	كاربوبلاتين	Carboplatin	☐
٧	كارموستين	Carmustine	☐
٨	سيسبلاتين (بلاتينول)	Cisplatin (Platinol)	☐
٩	سايكلوفوسفاميد (سايتوكسان)	Cyclophosphamide (Cytoxan)	☐
١٠	سايتارابين (آرا- سي)	Cytarabine (Ara-C)	☐
١١	داكربازين (دي تي أي سي)	Dacarbazine (DTIC)	☐
١٢	داكتينوميسين (كوزميجين)	Dactinomycin (Cosmegen)	☐
١٣	داونوروبيسين	Daunorubicin	☐
١٤	دوكسوروبيسين (أدرياميسين)	Doxorubicin (Adriamycin)	☐
١٥	دوسيتاكسيل (تاكسوتير)	Docetaxel (Taxotere)	☐
١٦	ايتوبوسايد (في بي 16)	Etoposide (VP-16)	☐
١٧	فلودارابين (فلودارا)	Fludarabine (Fludara)	☐
١٨	فلورايوراسيل (5 أف يو)	Fluorouracil (5 FU)	☐
١٩	جيمسايتابين (جيمزار)	Gemcitabine (Gemzar)	☐
٢٠	ايداروبيسين	Idarubicin	☐
٢١	ايرينوتيكان	Irinotecan	☐
٢٢	ميثوتريكست	Methotrexate	☐
٢٣	ميتومايسين	Mitomycin	☐
٢٤	ميتوزانترون (نوفانترون)	Mitoxantrone (Novantrone)	☐
٢٥	مستين	Mustine	☐
٢٦	اوكسالوبلاتين (ايلوكساتين)	Oxaliplatin (Eloxatin)	☐
٢٧	باكليتاكسيل (تاكسول)	Paclitaxel (Taxol)	☐
٢٨	رالتيتريكسد (تاموديكس)	Raltitrexed (Tomudex)	☐
٢٩	ستربتوزوسين	Streptozocin	☐
٣٠	تينيبوسايد	Teniposide	☐
٣١	توبوتيكان (هيكامتين)	Topotecan (Hycamtin)	☐
٣٢	تريوسلفان	Treosulfan	☐
٣٣	فينبلاستين (فيلبان)	vinblastine (Velban)	☐
٣٤	فينكريستين (في سي آر)	Vincristine (VCR)	☐
٣٥	فينديسين (إلديسين)	Vindesine (Eldesine)	☐
٣٦	فينوريلبين (نافيلبين)	Vinorelbine (Navelbine)	☐
٣٧	لا شي مما سبق	None of the above	☐

أ٢ / قبل بدء العلاج، هل حصلت على شرح واضح من قبل ممرضة العلاج الكيميائي عن علاجك والاعراض الجانبية الناتجة عنه؟

١ ☐ نعم ٢ ☐ لا

أ ٣/ قبل بدء العلاج، هل شعرت بأنك على علم تام بالأعراض الجانبية التي قد تنجم عن علاجك الكيميائي؟

١ ☐ نعم ٢ ☐ بعض الشئ ٣ ☐ لا

القسم الثاني (ب): ماهي الأعراض الجانبية التي واجهتها منذ اخر جلسة علاج كيميائي تلقيتها؟ وما هو الدعم الذي تلقيته للتعامل معها؟

يرجى القاء نظرة على قائمة الأعراض الجانبية المذكورة في الاسفل، والتي عادة ما يعاني منها المرضى الذين يخضعون للعلاج الكيميائي.
أخبرنا أي الأعراض واجهت منذ آخر جلسة علاج كيميائي تلقيتها ومدى شدة الأعراض وذلك بوضع علامة X في المربعات المناسبة.

ب ١/ منذ الجلسة الماضية هل شعرت بأحد الأعراض المذكورة بالأسفل، وما مدى شدتها؟

		لا	خفيف	متوسط	شديد
١	غثيان	☐ ١	☐ ٢	☐ ٣	☐ ٤
٢	قيء (استفراغ، طراش، ترجيع)	☐ ١	☐ ٢	☐ ٣	☐ ٤
٣	الم و تهيج في مكان حقن الإبرة الوريدية	☐ ١	☐ ٢	☐ ٣	☐ ٤
٤	مشاكل في الفم او الحلق (مثل: جفاف أو التهاب في الفم أو الحلق، تقرحات الفم)	☐ ١	☐ ٢	☐ ٣	☐ ٤
٥	الشعور بالضعف (إعياء)	☐ ١	☐ ٢	☐ ٣	☐ ٤
٦	علامات الالتهاب مثل: الشعور بحرارة أو برودة غير معتادة، شعور مشابه للإنفلونزا، ارتفاع في درجة الحرارة، الم عند التبول.	☐ ١	☐ ٢	☐ ٣	☐ ٤
٧	شعور بالاكتئاب أو تدني الحالة المزاجية.	☐ ١	☐ ٢	☐ ٣	☐ ٤

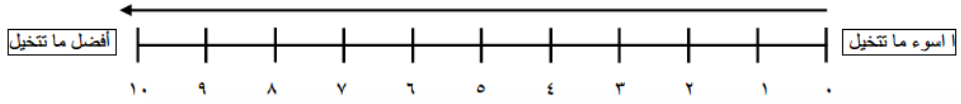
ب٢ / هل عانيت من أي اعراض أخرى لم تذكر في الأعلى؟
إذا كانت الاجابة بنعم يرجى ذكرها وبيان شدتها اما اذا كانت الاجابة ب لا الرجاء الانتقال للسؤال ٣.

		خفيف	متوسط	شديد
٨	.....	☐ ١	☐ ٢	☐ ٣
٩	.....	☐ ١	☐ ٢	☐ ٣
١٠	.....	☐ ١	☐ ٢	☐ ٣

ب ٣/ من فضلك أخبرنا عن دعم الممرضات الذي تلقيته للتعامل مع الأعراض الجانبية للعلاج الكيميائي (للتخفيف من شدتها أو تجنب حدوثها)

		نعم	بعض الشيء	لا
١	هل سألتك الممرضة المسؤولة عن إعطاءك العلاج الكيميائي عن الأعراض الجانبية التي واجهتها بعد اخذك للجرعة السابقة؟	☐ ١	☐ ٢	☐ ٣
٢	هل تعلم الممرضة المسؤولة عن علاجك بمدى شدة الأعراض الجانبية التي تعرضت لها منذ اخر جرعة؟	☐ ١	☐ ٢	☐ ٣
٣	هل أعطتك الممرضة المسؤولة عن علاجك الكيميائي معلومات مفيدة للتحكم في شدة الأعراض الجانبية الممكن حدوثها أو تجنبها؟	☐ ١	☐ ٢	☐ ٣
٤	هل أعطتك الممرضة المسؤولة عن علاجك الكيميائي نصائح عملية للتحكم في شدة الأعراض الجانبية الممكن حدوثها أو تجنبها؟	☐ ١	☐ ٢	☐ ٣
٥	هل لديك القدرة على التعامل مع الأعراض الجانبية الناجمة عن علاجك الكيميائي؟	☐ ١	☐ ٢	☐ ٣

ب ٤/ نود ان نعرف كيف هي صحتك اليوم، هل هي جيدة ام سيئة.
من فضلك ضع دائرة حول الرقم الذي يصف صحتك ويرجى كتابة هذا الرقم في المربع أدناه. الرقم ٠ يعني ان صحتك ضعيفة وكلما اقترب الرقم من١٠ تكون صحتك أفضل.



صحتك اليوم: ☐ يرجى وضع الرقم في المربع

Appendix A

القسم الثالث (ج): عنك وعن علاجك

لان هذا الاستبيان سري ومجهول الهوية نحن لن ننظر الى سجلك الطبي لذلك نرجو التكرم بإعطائنا بعض المعلومات الاضافية عن نفسك وعلاجك.

ج ١/ ما هو رقم جلسة (جرعة) العلاج الكيميائي التي ستأخذها اليوم؟ يرجى وضع دائرة على رقم واحد فقط.

٢	٣	٤	٥	٦	٧	٨	٩	١٠	١١	١٢+

ج ٢/ اخبرنا عن نوع أو مكان الورم الذي يتم علاجك منه؟

١	☐	المثانة / المسالك البولية (وليس البروستاتا)	٦	☐	أمراض النساء (الرحم، المبايض)	١١	☐ البروستات
٢	☐	الدم (لوكيميا)	٧	☐	الرأس أو الرقبة	١٢	☐ المعدة
٣	☐	الأمعاء	٨	☐	الرئة	١٣	☐ آخر
٤	☐	المخ/ الجهاز العصبي المركزي	٩	☐	الغدد اللمفاوية	١٤	☐ لا أعرف
٥	☐	الثدي	١٠	☐	البلعوم		

ج٣/ كيف تأخذ علاجك الكيميائي؟ ضع علامة x على الاجابة المناسبة.

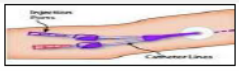
١ ☐ حقن وريدي

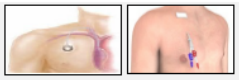
٢ ☐ حقن و أقراص (حبوب / كبسولات)

٣ ☐ أقراص فقط.

ج ٤/ بالنظر الى الصور الجانبية أدناه، ما هي الاداة المستخدمة لإعطائك الحقن ؟

١ ☐ إبرة وريدية مؤقته 

٢ ☐ خط القسطرة المركزي المغروس من وريد طرفي (أنبوب طويل مرن يمتد من وريد داخل ذراعك وينتهي في وريد كبير في الصدر) 

٣ ☐ خط القسطرة الوريدي المركزي (أنبوب يخرج من الصدر بورتاكاث أو هيكمان) 

ج ٥/ كم عمرك؟

١ ☐ ١٨ـ ٣٠ ٤ ☐ ٥١ـ ٦٠

٢ ☐ ٣١ـ ٤٠ ٥ ☐ ٦١ـ ٧٠

٣ ☐ ٤١ـ ٥٠ ٦ ☐ ٧١+

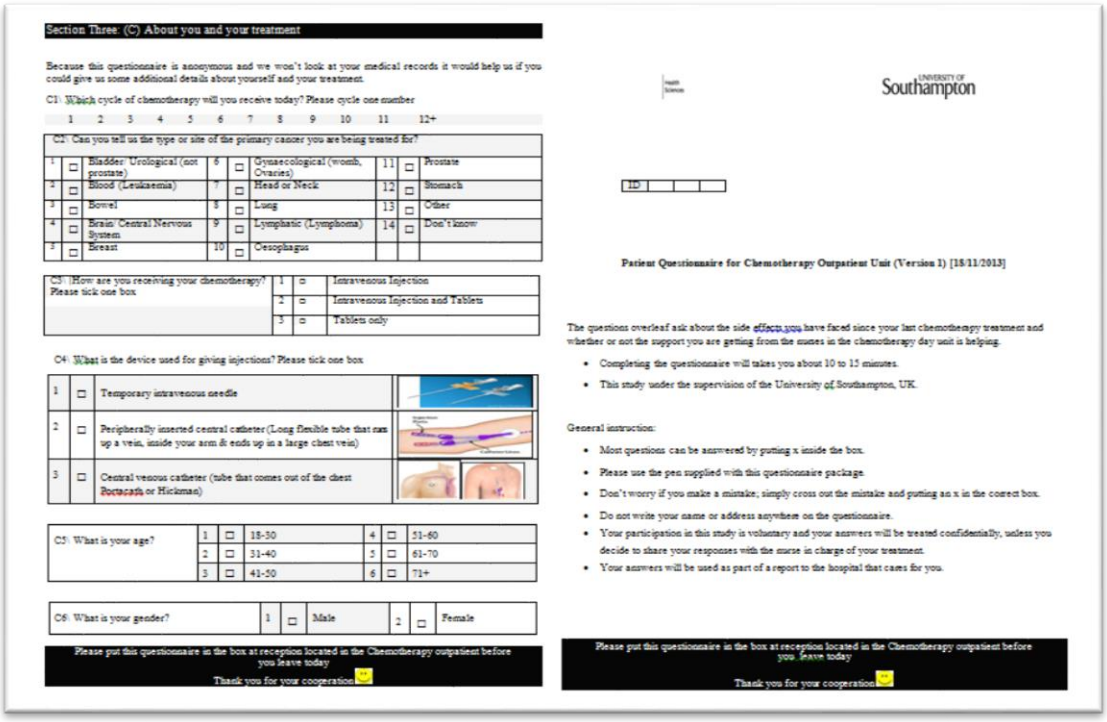
ج ٦/ ما هو جنسك

١ ☐ ذكر ٢ ☐ أنثى

من فضلك ضع هذا الاستبيان في الصندوق المخصص للدراسة والموجود في استقبال وحدة العلاج الكيميائي قبل مغادرتك اليوم

شكراً لتعاونكم

PR-CISE/Arabic version (English translation)



Section Three: (C) About you and your treatment

Because this questionnaire is anonymous and we won't look at your medical records it would help us if you could give us some additional details about yourself and your treatment.

C1: Which cycle of chemotherapy will you receive today? Please cycle one number

1 2 3 4 5 6 7 8 9 10 11 12+

C2: Can you tell us the type or site of the primary cancer you are being treated for?

1	☐	Bladder/ Urological (not prostate)	6	☐	Gynaecological (womb, Ovaries)	11	☐	Prostate
2	☐	Blood (Leukaemia)	7	☐	Head or Neck	12	☐	Stomach
3	☐	Bowel	8	☐	Lung	13	☐	Other
4	☐	Brain/ Central Nervous System	9	☐	Lymphatic (Lymphoma)	14	☐	Don't know
5	☐	Breast	10	☐	Oesophagus			

C3: How are you receiving your chemotherapy? Please tick one box	1	☐	Intravenous Injection
	2	☐	Intravenous Injection and Tablets
	3	☐	Tablets only

C4: What is the device used for giving injections? Please tick one box

1	☐	Temporary intravenous needle	
2	☐	Peripherally inserted central catheter (Long flexible tube that ran up a vein, inside your arm & ends up in a large chest vein)	
3	☐	Central venous catheter (tube that comes out of the chest Portacath or Hickman)	

C5: What is your age?	1	☐	18-30	4	☐	51-60
	2	☐	31-40	5	☐	61-70
	3	☐	41-50	6	☐	71+

C6: What is your gender?	1	☐	Male	2	☐	Female

Please put this questionnaire in the box at reception located in the Chemotherapy outpatient before you leave today

Thank you for your cooperation

Southampton

ID

Patient Questionnaire for Chemotherapy Outpatient Unit (Version 1) [18/11/2013]

The questions overleaf ask about the side effects you have faced since your last chemotherapy treatment and whether or not the support you are getting from the nurses in the chemotherapy day unit is helping.

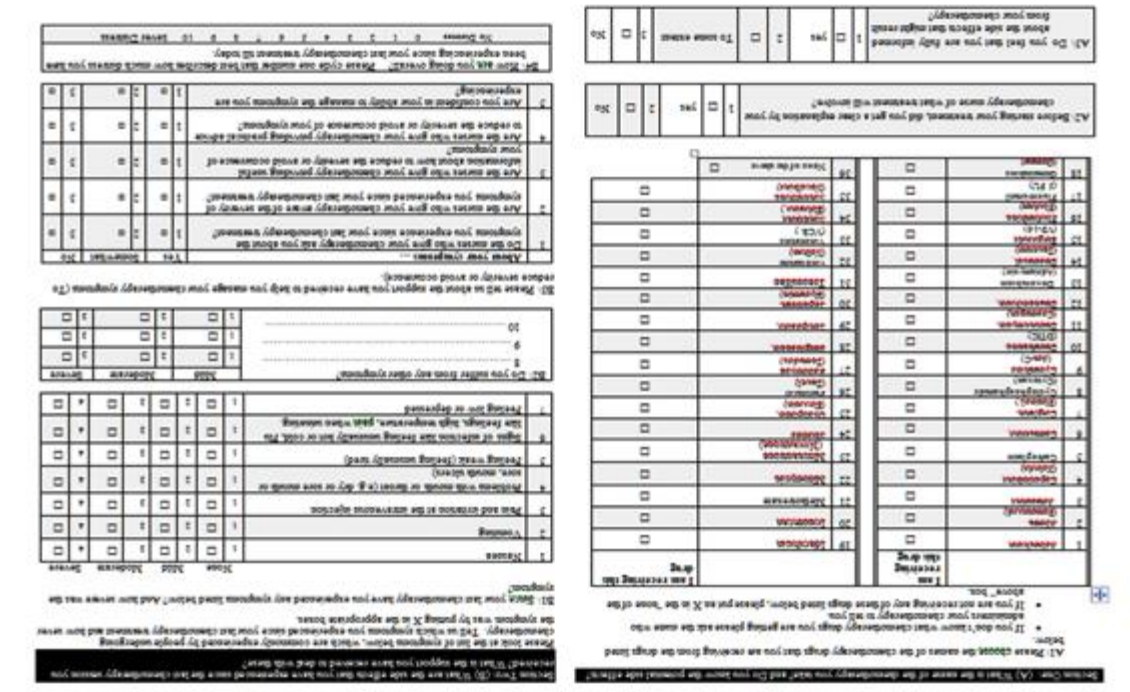
- Completing the questionnaire will takes you about 10 to 15 minutes.
- This study under the supervision of the University of Southampton, UK.

General instruction:

- Most questions can be answered by putting x inside the box.
- Please use the pen supplied with this questionnaire package.
- Don't worry if you make a mistake, simply cross out the mistake and putting an x in the correct box.
- Do not write your name or address anywhere on the questionnaire.
- Your participation in this study is voluntary and your answers will be treated confidentially, unless you decide to share your responses with the nurse in charge of your treatment.
- Your answers will be used as part of a report to the hospital that cares for you.

Please put this questionnaire in the box at reception located in the Chemotherapy outpatient before you leave today

Thank you for your cooperation



Appendix B : Sample of the search

#	Query	Limiters/Expanders	Last Run Via	Results	Action
S41	S35 and S40	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	0	Edit S41
S40	S36 or S37 or S38 or S39	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	1217	Edit S40
S39	oncology units$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	365	Edit S39
S38	oncology outpatient units$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	14	Edit S38
S37	chemotherapy ambulatory units$	Search modes - SmartText Searching	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	862	Edit S37
S36	chemotherapy ambulatory units$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	0	Edit S36
S35	S33 and S34	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	6	Edit S35
S34	review$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	194525	Edit S34

S33	S29 and S30 and S31 and S32	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	14	Edit S33
S32	relationship$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	100979	Edit S32
S31	skill mix$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	1204	Edit S31
S30	staffing levels$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	904	Edit S30
S29	S12 and S28	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	38313	Edit S29
S28	S15 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	93621	Edit S28
S27	nurse ratio$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	1914	Edit S27
S26	staffing ratio$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	97	Edit S26
S25	nurse/patient ratio$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	1787	Edit S25

S24	nurse to patient ratio$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	91	Edit S24
S23	nurse-patient ratio$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	1787	Edit S23
S22	nurse-to-patient ratio$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	54	Edit S22
S21	personnel staffing and scheduling$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	13327	Edit S21
S20	personnel staffing$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	13355	Edit S20
S19	nursing staff$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	18696	Edit S19
S18	nurse staffing$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	1340	Edit S18
S17	S15 and S16	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	18423	Edit S17
S16	nurse$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	143671	Edit S16

S15	S13 or S14	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	92731	Edit S15
S14	staffing$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	17069	Edit S14
S13	staff$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	80067	Edit S13
S12	S3 or S6 or S8 or S9 or S10 or S11	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	1007006	Edit S12
S11	patient-reported outcomes$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	657	Edit S11
S10	complications$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	273504	Edit S10
S9	treatment outcomes$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	140742	Edit S9
S8	S3 and S7	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	64293	Edit S8
S7	outcome$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	112847	Edit S7

Appendix B

S6	S4 or S5	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	15162	Edit S6
S5	patient outcomes$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	11126	Edit S5
S4	patient outcome$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	4561	Edit S4
S3	S1 or S2	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	788369	Edit S3
S2	patients$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	517127	Edit S2
S1	patient$	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL Plus with Full Text	442724	Edit S1

Appendix C: Quality assessment form

AMSTAR is a measurement tool created to assess the methodological quality of systematic reviews.

1. Was an 'a priori' design provided? The research question and inclusion criteria should be established before the conduct of the review.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
2. Was there duplicate study selection and data extraction? There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
3. Was a comprehensive literature search performed? At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
5. Was a list of studies (included and excluded) provided? A list of included and excluded studies should be provided.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
6. Were the characteristics of the included studies provided? In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
7. Was the scientific quality of the included studies assessed and documented? 'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
8. Was the scientific quality of the included studies used appropriately in formulating conclusions? The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
9. Were the methods used to combine the findings of studies appropriate? For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I^2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
10. Was the likelihood of publication bias assessed? An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable
11. Was the conflict of interest stated? Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.	☐ Yes ☐ No ☐ Can't answer ☐ Not applicable

Appendix D: Data extraction form

Date of data extraction __/__/____
Paper details
Author(s)
_____
Paper title :
_____
_____
Journal_____
Year _____Volume ____ Issue ____ Pages____
Database(s)_____

Extraction Result

□Include in review

□Exclude from review، Reason

_____
_____
_____

Brief Summary

_____
_____
_____

Brief methodological critique

_____
_____
_____

1	Main aim(s) / objective(s)	
2	Setting(s)	
3	Design (tick more than one if applicable) □ Review of literature (ROL) □ Systematic Review (SR) □ Meta-analysis (MA) □ Review of Reviews (RR) □ Other _____	
4	Inclusion criteria of the review:	
5	Exclusion criteria of the review:	
6	Number of studies included in the review	
7	Types of studies included in the review (tick more than one if applicable): □ Randomized control Trial (RCT) □ Cross-sectional □ Observational □ Reviews □ Not specific □ Other, specify _____	
8	Is quality of primary studies assessed and reported? □Yes □No	
9	Measures of patient outcomes investigated in the review:	

	a. Number of the patient outcomes included in the review ( ) b. Mention them _____ _____ _____ _____ □ Physical domain □ Emotional □ Patient satisfaction □ Global quality of life domain □ Other
10	Nurse staffing measured in the review: Number of the patient outcomes( ) □ Nurse-to-patient ratio, specify _____ □ Skill mix, specify _____ □ Other, specify _____
11	Organizational factors included in the review: □ Nurse work environment, specify _____ □ Workload, specify _____
12	Is there a relationship between skill mix (RNs and /or licensed nurses) and patient outcomes?
13	Is there a consistent association between higher ratios of nurse to patients and better patient outcomes?
14	Are variations in nurse-to-patient ratios associated with differences in patient outcomes?
15	Terms used to describe organisational characteristics (nurse staffing) in the review:
16	Definition of terms used to describe skill mix if applicable:
17	Definition of terms used to describe nurse-to-patient ratio if applicable:
18	Results:
19	Authors conclusions and recommendations of the review:
20	Comments:

Appendix E : Nursing Workforce and Unit Characteristics Survey

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Appendix 2: Nursing Workforce and Unit Characteristics Survey

TO: Nurse Managers of Selected Units

Please complete the following questions to provide background information about your unit, which will take approximately 15 minutes. This information will be used to profile your unit, and to understand the differences and similarities between ambulatory chemotherapy units involved in the study. Only a code number that identifies the hospital and unit will be used for the data file and any identifiers that associate your answers to your unit will be destroyed upon completion of the study. In accordance with the University of Southampton's Data Protection Policy data will stored securely for 10 years after the end of the project. Questions can be left blank if you prefer but complete data is always more helpful in the analysis.

Unit code xx	Date

How many years/months this unit is opened: ……. Year ……. Month

Hospital characteristics: ☐ Tertiary hospital ☐ Secondary hospital ☐ Teaching hospital

V3 15/10/2015

Questions	Answers
Unit Characteristics	
1. What is the usual number of chairs/beds used to give chemotherapy in this unit?	…… Chairs …… Beds
2. How many patients are treated with chemotherapy per day, in the last week?	Sunday | Monday | Tuesday | Wednesday | Thursday ( ) | ( ) | ( ) | ( ) | ( )
3. How many patients are treated with chemotherapy per month, in the last 3 months?	Month 1 | Month 2 | Month 3 ( ) | ( ) | ( )
4. What are the hours that this unit is open?	Start ……. Finish ……
5. What is the number of working days per week in this unit?	☐ 5 days per week, no weekends ☐ 7 days per week ☐ Other, please specify ……
6. How many nursing shifts per day cover the unit?	☐ 1 shift ☐ 2 shifts ☐ 3 shifts ☐ Other, please specify ……
7. What is the usual shift length that nurses work in this unit?	☐ 8-hour day shift ☐ 9-hour day shift ☐ 12-hour day shift ☐ Other, please specify……
8. What is the start and finish time for each shift?	8-hour shift | 9-hour shift | 12-hour shift | Other Shift Start ……. Finish …… | Start ……. Finish …… | Start ……. Finish …… | Start ……. Finish ……
Nurse Staffing Characteristics	
9. What is the total number of nurses working in this unit?	……
10. What is the number of nurses who administer chemotherapy in this unit?	……
11. What is the optimal number of nursing staff member per shift?	8-hour shift | 9-hour shift | 12-hour shift | Other Shift …… | …… | …… | ……

Appendix E

	8-hour shift	9-hour shift	12-hour shift	Other Shift
12. On each shift, what is the usual staff mix/proportion of nurses, please specify. a. Number of Registered Nurse with bachelor degree b. Number of Registered Nurse with Diploma degree c. Number of Licensed practical nurse (LPN)	a. …… b. …… c. ……	a. …… b. …… c. ……	a. …… b. …… c. ……	a. …… b. …… c. ……
13. Do you use a standardised approach to measure patient acuity when allocating chemotherapy patients to particular nurses on different shift? **If you use a particular patient acuity scale I will be grateful if you send it to me.**	☐ Yes ☐ No			
14. Nurse-to-patient ratio What is the usual number of patients assigned to each nurse per shift?	……			
15. Do you ever allocate by chair? **If no, please go to question 17.**	☐ Yes ☐ No			
16. On a shift basis, how do you allocate the patients to the available chairs and beds?	……			
17. What is the number of female nurses in the unit?	……			
18. What is the number of male nurses in the unit?	……			
19. What is the optimal number of nurses who speak Arabic per shift?	……			
20. Overall, what is the post-registered qualification of nursing staff in this unit? a. Number of nurses holding **Bachelor's** Degree b. Number of nurses holding **Diploma** Degree	a. …… b. ……			
21. Of the total number of nurses who give chemotherapy, how many nurses had: a. Diploma in cancer nursing b. Pre-work preparation course for cancer care c. Non d. I don't know	a. …… b. …… c. …… d. ……			

General Information	
22. What type of cancer you are treating in your unit?	☐ All types of cancer ☐ Oncology ☐ Haematology ☐ Specific types of cancer please specify …… …… …… …….
23. In your unit, do you provide patient and family education that helps them to manage or reduce the severity of their chemotherapy side effects?	☐ Never ☐ Before the first cycle only ☐ Before some cycles ☐ Before each cycle ☐ Other, please specify ……..
24. In what format does this education take? (please check all that apply)	☐ One on one ☐ Group discussion ☐ Other, please specify ……
25. Please state the most important points that you include when educating patient and family about chemotherapy side effects? (please tick all that apply)	☐ Possible side effects ☐ How to reduce or prevent the occurrence of the side effects ☐ Nutrition plan ☐ Daily activity ☐ Other
26. Do you assess patients' side effects of chemotherapy resulting from the previous cycle?	☐ Never ☐ Before some cycles ☐ Before each cycle ☐ Other
27. Do you document patients' side effects of chemotherapy resulting from the previous cycle?	☐ Never ☐ Before some cycles ☐ Before each cycle ☐ Other
28. Do you use a particular tool? I will be grateful if you send it to me	☐ Yes ☐ No

29. Chemotherapy regimens (protocols) provided in this unit.

Please check all relevant regimens. We have only listed regimens that are most commonly administered; however, we know that in your unit you may administer other regimens that don't appear on this list

☐ ABVD ☐ AC ☐ BEP ☐ CAP ☐ Carboplatin/ Topotecan ☐ CHOP-R ☐ CVP
☐ ESAP ☐ 5FU/ Leucovorin ☐ ICE ☐ MAID ☐ TAC ☐ TCH ☐ XELOX
☐ XILIRI ☐ Other, please specify…….

Thank you for your efforts to support the implementation of this study

Please email, fax or mail the completed Unit Profile to Dena Attallah:
Email: dma1e11@soton.ac.uk
Fax 00966 2 6925004

Appendix F : Ethics approvals

University of Southampton Ethics Approval

Ethics and Research Governance Online

ERGO

Accessibility toolbar | Help

Logged in as : dma1e11 | Logout

University of Southampton

Main Menu

- My Research
- Submissions to review
- Downloads
- Adverse Incident

View all my research

Using nurse-sensitive outcome indicators to assess variations in the quality of care provided by ambulatory chemotherapy services in the Kingdom of Saudi Arabia: A descriptive cross-sectional study

Submission ID:8377

Submission Overview | IRGA Form | Attachments | Peer Feedback | History | Adverse Incident

Approved by the Ethics Committee in 5 day(s) on 11/12/2013

Date	Activity	Comments	Attached Documents
11/12/2013 4:32 pm	Reviewed and approved by the ethics committee		
9/12/2013 5:02 pm	Approved by supervisor and sent to ethics committee		
9/12/2013 2:09 pm	Submitted to supervisor Alison Richardson (ar2y08)		
5/12/2013 7:05 pm	Revision requested by the ethics committee		
5/12/2013 7:05 pm	Possible problems were found by 1 member of the committee	Please see the comments agreed by myself and the lead reviewer who has identified the issues which you are advised to consider and revise before approval can be granted. Thank you Margaret Millburn	
5/12/2013 6:40 pm	Possible problems were found by 1 member of the committee	Thank you for your submission. We would like you to clarify the following issues and make amendments accordingly: * Although the researcher has not worked as an oncology nurse in one of the research unit since 2005, presumably some of the same staff could be there. Please clarify whether some of the staff will be the same, whether the researcher's former employment could have any impact on recruitment, data collection and analysis, and if so, how this will be managed. * Please clarify whether patients receiving palliative chemotherapy will be eligible to participate, and if so, how this will be managed. * Please clarify whether there are any eligibility criteria concerning how long ago previous chemotherapy was received, and whether there is a maximum number of	

Appendix F

Permission to use the self-report questionnaire (PR-CISE)

From: Griffiths P. (Health Sciences)
Sent: 10 April 2013 13:16
To: Attallah D.M.
Cc: Richardson Alison; Lennan, Elaine (Elaine.Lennan@uhs.nhs.uk)
Subject: RE: Requesting your permission to use self-report questionnaire instrument (Quality in cancer care: Nurse sensitive indicators for ambulatory chemotherapy)

Dear Dena

It is fine for you to use the instrument as a student of Southampton, provided that appropriate copyright and acknowledgements are put on to any version that you use.

Essentially we cannot give you copyright for a translated version (it is owned by NCAT) and any requests to use your translation would need to come back to us in the first instance. In any publications and reports could you refer to our peer reviewed publication (pending) in preference to the report. Please check back with us for full bibliographic details

Peter

Professor Peter Griffiths
Chair of Health Services Research
Faculty of Health Sciences, University of Southampton
Executive Editor International Journal of Nursing Studies

Room E4015, Building 67
Highfield Campus (click for campus map and travel directions)
SO17 1BJ
Tel: +44(0)2380597877

Appendix G: Recruitment materials

Sample of instruction for recruiting potential participants

Health Sciences

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Instructions for recruiting potential participants

Dear Sir/Madam:

Please distribute a patient survey package to any patient who meets all of the following criteria:

1. Patients aged 18 and over who are undergoing chemotherapy in an ambulatory chemotherapy unit.
2. The participants must be patients receiving their chemotherapy in an ambulatory chemotherapy unit.
3. Patients who have received at least one cycle of chemotherapy in an ambulatory unit.
4. Potential participants are patients who are due for chemotherapy on the day of data collection, or who come in the day before for blood test or assessment check.
5. The participants must be able to participate in this study (e.g. not ill, enough time).
6. The participants must be willing to participate in this study.
7. The participants must be able to read and write in Arabic. If not, patient relative or nurse would help the patient in this matter.

Please follow these guidelines to help you recruit potential patient participants

1. Potential patients will be identified through the ambulatory chemotherapy unit's patient log book.
2. You will recruit eligible patients who have arrived for their chemotherapy sessions.
3. You will give potential patients information outlining the study. You can use the provided guidelines (a script for staff to introduce the study to patients.)
4. Please write the diagnosis and chemotherapy regimen at the top of the questionnaire, and before giving it to patient.
5. Please supply the potential patient with the questionnaire package
6. Instruct patients to complete only one questionnaire, even if they visit the unit more than once during the data collection period.
7. Instruct the potential patient to put the completed questionnaire in the envelope, and seal it before placing it in the research box in the nursing office. Regardless of whether they have filled it in or not.

General instruction:
Patients have a right to refuse and/or withdraw at any time without given a reason. However, please use the flow chart, Reasons for non-participation in the surveys and Reasons for non-eligibility forms and list the number where possible.

Dena Attallah

Sample of letter of invitation: patient questionnaire

(English translation)

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Letter of Invitation: Patient questionnaire (English translation)

Date

Dear Sir/Madam

My name is Dena M. Attallah. I am currently studying for a PhD at the Faculty of Health Sciences, University of Southampton in the UK. As a part of the programme, I am conducting a research study entitled: **Using nurse sensitive outcome indicators to assess variations in the quality of care provided by ambulatory chemotherapy services in the Kingdom of Saudi Arabia: A descriptive cross-sectional study.**

The purpose of this study is to gain information about patients experience with the side effects of chemotherapy, and whether or not the support they are getting from the nurses in the chemotherapy outpatient unit is helping them.

Therefore, I would like to invite you to take part in this study, which will involve you completing a questionnaire that is enclosed with this questionnaire package in order to test it before it is used in a much larger survey.

If you are interested in this study, please read the information sheet enclosed with this letter. This will help you to decide whether you would like to take part or not. Please do not hesitate to contact me if further information is needed. Please contact me on 00966505616828 or e-mail: dma1e11@soton.ac.uk

I hope you find this study interesting and thank you very much in advance for your cooperation.

Faithfully,

Dena M. Attallah

PhD student
Faculty of Health Sciences
University of Southampton
Southampton, SO17 1BJ.
Tel: 02380594283(UK)/0505616828 (KSA)
Email: dma1e11@soton.ac.uk

Appendix G

Sample of letter of invitation: patient questionnaire

(Arabic version)

Health Sciences

UNIVERSITY OF Southampton

خطاب دعوة: استبيان المرضى (النسخة العربية)

تحية طيبة وبعد،،

أوجه لكم هذا الخطاب باسمي أنا دينا مروان عطاالله، أدرس حاليًا للحصول على درجة الدكتوراه من كلية علوم الصحة بجامعة ساوثامبتون في المملكة المتحدة. وأعمل على إجراء دراسةٍ بحثية، كجزء من البرنامج، تحت عنوان: استخدام مؤشرات النتائج الحساسة للمرضين لتقييم الاختلافات في جودة الرعاية التي تقدمها وحدات العلاج الكيميائي الخارجية في المملكة العربية السعودية: دراسة مستعرضة وصفية.

الغرض من هذه الدراسة هو الحصول على معلومات حول تجربة المرضى مع الأعراض الجانبية للعلاج الكيميائي، وما إذا كان الدعم التي يتلقونه من الممرضات في وحدة العلاج الكيميائي للمرضى الخارجيين يساعدهم ام لا.

لذلك، أود أن أدعوكم للمشاركة في هذه الدراسة، والتي ستشمل اكمال استبيان تم تضمينه مع حزمة الاستبيان هذه.

إذا كنت مهتماً بهذه الدراسة، يرجى قراءة ورقة المعلومات المرفقة مع هذه الرسالة. هذا سيساعدك على أن تقرر ما إذا كنت ترغب في المشاركة أم لا. من فضلك لا تتردد في الاتصال بي إذا كان هناك حاجة الى مزيد من المعلومات. الرجاء الاتصال بي على 00966505616828 أو البريد الإلكتروني: dma1e11@soton.ac.uk .

أرجو أن تجد هذه الدراسة مثيرة للاهتمام ولك جزيل الشكر مُقدمًا على تعاونك معنا.

مع خالص التقدير،

دينا مروان عطا الله

طالبة دكتوراة
كلية علوم الصحة
جامعة ساوثامبتون
ساوثامبتون،
SO171BJ
هاتف: 02380594283 (المملكة المتحدة)/ 0505616828 (المملكة العربية السعودية)
البريد الإلكتروني: mailto:dma1e11@soton.ac.ukdma1e11@soton.ac.uk

Sample of participant information sheet: Patient survey

(English translation)

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UNIVERSITY OF Southampton

Participant Information Sheet: Patient Survey (English translation)

Title of the study: Using nurse sensitive outcome indicators to assess variations in the quality of care provided by ambulatory chemotherapy services in the Kingdom of Saudi Arabia: A descriptive cross-sectional study

Researcher name: Dena M. Attallah Ethics number:

Dear Patient

You are being invited to take part in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and, if you wish, discuss it with others. This information sheet states the purpose of the study and what will happen if you take part. Furthermore, it gives more detailed information about how the study will be conducted. Please contact me if there is anything that is not clear or if you would like further information. I encourage you to take time in deciding whether you wish to participate.

What is the purpose of the study?

The quality of patient care is a major universal concern among healthcare managers, policymakers and consumers. A small survey is being conducted to test a questionnaire designed to survey patients' experience of nursing care in outpatient settings. Following this testing and amendment of the questionnaire, this study will include information gained from patients from seven hospitals in the two largest cities in the Kingdom of Saudi Arabia.

The questionnaire asks about your experience with the side effects of chemotherapy, and whether or not the support you are getting from the nurses in the chemotherapy outpatient unit is helping you. I would like to get an overall picture from patients about how well nurses are supporting them.

The information you provided will contribute towards the investigation of the quality of care in ambulatory chemotherapy services in the Kingdom of Saudi Arabia. It is hoped that this will help to identify target areas for improving the quality of care in the future, which will likely benefit future patients in outpatient services.

Why have I been invited?

You have been invited to take part in this study because you have been identified as a patient undergoing chemotherapy at outpatient setting. This study plans to recruit all patients who are treated in adult chemotherapy outpatient settings.

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Do I have to take part?

Participation in this study is voluntary, so you do not have to take part. The decision is solely yours. This information sheet describes the study so that you can make your decision. If you do decide to take part, you can withdraw at any time without giving a reason.

What will I have to do?

Taking part in this study will involve answering a questionnaire, which will take approximately 15 minutes. You will be asked to complete an anonymous questionnaire once and drop this questionnaire in the research box available at the nurses' station, before you leave the hospital today. Submission of the questionnaire implies consent to participate.

What are the possible disadvantages of taking part?

While I do not foresee any harm or disadvantages to you by taking part in this study, I do understand that you may feel uncomfortable to answer several questions about your feeling towards the support you are getting from the nurses in this unit. These questions are not intended to be upsetting, but they may raise issues for you. If you feel you would like some additional help after filling the questionnaire I will be able to advise you who to contact, for example GP, nurse advisor, or another key worker.

What are the possible benefits of taking part?

The benefit of participating in this study is that the information gained may help me understand the quality of services provided to patients undergoing chemotherapy in outpatients at hospitals throughout the country. Additionally, the results of this study could be used to make recommendations for best practice and will offer insight about the patient experiences.

Will my taking part in this study be confidential?

Yes. No names will be used on any documentation—questionnaires are entirely anonymous. All research documents and completed questionnaires will be stored in the research box, which is locked with a secure padlock. After collection of all research boxes from all units, each questionnaire will have special codes that allow the investigator to recognise the hospital name only. When travelling back to the UK, the completed questionnaires will be stored in the researcher locked hand luggage. Questionnaires will be stored in a locked cabinet at the University of Southampton. All information from the questionnaire will be anonymous and treated with sensitivity.

How will the information I provide be used?

The data will be held in a secure computer, access to which will be restricted with password protection; the data will be accessible only to myself and my supervisors. The original questionnaires and the data in the computer will be stored for 10 years. The information from the questionnaires will be converted into figures for analysis. Some of the information may be used to develop future research ideas.

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What will happen to the results of the research study?

The findings may also be written in the form of reports or research articles and published at local or international conferences or in academic journals. If this happens, your information will not be identifiable.

Who has reviewed this study?

This study has been reviewed by the Ethics Committee of the faculty of Health Sciences at the University of Southampton, UK (ethics number: ...). Also the study has been reviewed by the local ethics committee of the ... Hospital.

What if there is a problem or I have a compliant?

If you have a concern or a complaint about this study you should contact

In ..., Kingdom of Saudi Arabia:

You could speak or write to the Head nurse of the Chemotherapy Treatment Area, ... (name of the hospital), on telephone number provided below;

Tel: xxxxxxx

In the UK

Martina Prude, Head of the Governance Office, at the Research Governance Office (Address: University of Southampton, Building 37, Highfield, Southampton, SO17 1BJ ; Tel: +44 (0)23 8059 5058; Email: rgoinfo@soton.ac.uk . If you remain unhappy and wish to complain formally Martina can provide you with details of the University of Southampton Complaints Procedure.

Thank you for taking the time to read this information sheet. This information sheet is for you to keep.

For further information please feel free to contact the researcher

Researcher:
Dena M. Attallah,
PhD Student
Faculty of Health Sciences
University of Southampton
Southampton, SO17 1BJ.
Tel: 02380594283(UK)/0505616828 (KSA)
Email: dma1e11@soton.ac.uk

Appendix G

Sample of participant information sheet: Patient survey

(Arabic version)

Health Sciences

UNIVERSITY OF Southampton

ورقة معلومات المشاركين: استبيان المرضى

عنوان الدراسة: استخدام مؤشرات النتائج الحساسة للممرضين لتقييم الاختلافات في جودة الرعاية التي تقدمها وحدات العلاج الكيميائي الخارجية في المملكة العربية السعودية: دراسة مستعرضة وصفية.

اسم الباحثة: دينا م. عطا الله **رقم الأخلاقيات:** xxx

عزيزي المريض،

نتشرف بدعوتك إلى المشاركة في دراسةٍ بحثية، ولكن قبل أن تقرر المشاركة من عدمها من المهم أن تفهم لماذا يتم إجراء هذا البحث وماذا سيتضمن. ونرجو أخذ الوقت الكافي لقراءة المعلومات التالية بعنايةٍ ومناقشتها مع الآخرين إذا كنت ترغب بذلك. حيث توضح ورقة المعلومات هذه الغرض من الدراسة وماذا سيحدث إذا شاركت أنت فيها، وبالإضافة إلى ذلك فهي تمدك بمعلوماتٍ أكثر تفصيلاً عن الكيفية التي سيتم بها إجراء الدراسة. ونرجو منك التواصل معنا إذا كان هناك أي شيءٍ غير واضح أو إذا كنت ترغب في المزيد من المعلومات. وننصحك بالتمهل وأخذ الوقت الكافي لاتخاذ قرار ما إذا كنت ترغب في المشاركة أم لا.

ما الغرض من الدراسة؟

تشغل جودة رعاية المرضى اهتماماً عالمياً رئيسيًا بين مديري الرعاية الصحية وصناع القرار والمستهلكين. سيتم إجراء دراسة استقصائية صغيرة لاختبار الاستبيان الذي صمم لجمع معلومات حول تجربة المرضى مع الرعاية التمريضية في وحدات العلاج الكيميائي الخارجية. بعد اختبار وتعديل الاستبيان، سوف تشتمل هذه الدراسة على معلوماتٍ يتم الحصول عليها من مرضى من سبع مستشفياتٍ في أكبر مدينتين بالمملكة العربية السعودية.

الاستبيان يسأل عن تجربتك مع الأعراض الجانبية للعلاج الكيميائي، وعما إذا كان الدعم الذي تحصل عليه من الممرضات في وحدة العلاج الكيميائي الخارجية يساعدك. أود الحصول على صورة شاملة من المرضى حول كيفية جيدا الممرضات ودعمها. ومن المؤمل أن تساعد هذه المعلومات في تحسين جودة رعاية المرضى في وحدات العلاج الكيميائي الخارجية.

لماذا تمت دعوتي؟

نحن نوجه إليك الدعوة للمشاركة في هذه الدراسة لأنك مريض تخضع للعلاج الكيميائي في وحدة العلاج الخارجية للكبار. وتعتزم هذه الدراسة إلى إشراك جميع المرضى الذين يعالجون في هذه الوحدات.

هل يستلزم الأمر مشاركتي؟

تُعد المشاركة في هذه الدراسة أمرًا تطوعيًا، لذلك فأنت لست مضطراً للمشاركة. القرار يرجع لك وحدك. وتساعدك هذه الورقة بما تحويه من معلومات ووصف للدراسة في اتخاذ قرارك بالمشاركة او لا. وفي حال قررت المشاركة في هذه الدراسة، يمكنك الانسحاب في أي وقتٍ بدون توضيح الأسباب.

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ما الذي يجب أن أقوم به؟

تشتمل المشاركة في هذه الدراسة على الإجابة على الاستبيان الذي سوف يستغرق حوالي 15 دقيقة. سيطلب منك تكملة الاستبيان مرة واحدة ووضع هذا الاستبيان في صندوق البحوث الموجود في مكان الممرضات قبل مغادرة المستشفى اليوم. وتقديم هذا الاستبيان يعني الموافقة على المشاركة.

ما هي مساوئ المشاركة المحتمل مواجهتها؟

في حين أنني لا أتوقع أي أضرار أو مساوئ لك من خلال المشاركة في هذه الدراسة، أنا اتفهم كثيرًا احتمالية شعورك بعدم الارتياح للإجابة على بعض الأسئلة حول مشاعرك تجاه الدعم الذي حصلت عليه من الممرضات في هذه الوحدة. ولا يُقصد من هذه الأسئلة أن تكون مصدر إزعاجٍ لك، لكنها قد تثير مسائل مهمة بالنسبة لك.

إذا شعرت بأنك تود الحصول على المساعدة بعد ملء الاستبيان أو كنت ترغب في التحدث مع شخص ما عن شعورك، فسأكون على استعداد لإرشادكم على الشخص المناسب الذي يمكن التواصل معه، على سبيل المثال الطبيب، الممرضة أو موظف رئيسي آخر.

ما هي فوائد المشاركة المحتملة؟

تتمثل فوائد المشاركة في هذه الدراسة في المعلومات التي سوف تقدمها والتي قد تساعد على فهم جودة الخدمات المقدمة للمرضى الذين يخضعون للعلاج الكيميائي في الوحدات الخارجية في جميع أنحاء البلاد. بالإضافة إلى ذلك، يمكن استخدام نتائج هذه الدراسة إلى تقديم توصيات للحصول على أفضل رعاية تمريضية، كما ستقدم فكرة عن تجارب المريض.

هل ستكون مشاركتي في هذه الدراسة أمرًا سريًا؟

نعم، ولن تُوضع أية أسماء على أية مستندات سوف تكون الاستبيانات مجهولة تمامًا. سيتم حفظ جميع مستندات البحوث والاستبيانات المكتملة في صندوق البحث المُقفل بقفل آمن. وبعد جمع كافة صناديق البحث من جميع الوحدات، سوف يكون لكل استبيان رمز خاص يسمح للباحثة بالتعرف على اسم المستشفى فقط. وعند العودة إلى المملكة المتحدة، سيتم حفظ الاستبيانات المكتملة في حقيبة اليد المقفلة الخاصة بالباحثة. سيتم حفظ الاستبيانات في خزانة مقفلة في جامعة ساوثهامبتون. وتكون جميع المعلومات الواردة من الاستبيان مجهولة المصدر ويتم التعامل معها بحساسية.

كيف سيتم استخدام المعلومات التي أقدمها؟

سيتم حفظ البيانات في جهاز حاسب آلي آمن، يقتصر الوصول إليه عليّ مع الحماية بكلمة السر، ولن يمكن لأحد سوى فريق البحث الوصول للبيانات. كما سيتم تخزين الاستبيانات والبيانات الأصلية في جهاز الحاسب الآلي لمدة 10 سنوات وذلك تمشيا مع سياسة حماية البيانات في كلية العلوم الصحية في جامعة ساوثهامبتون. سيتم تحويل المعلومات من الاستبيانات إلى أرقام لتحليلها. كما يمكن استخدام بعض المعلومات في تطوير الأفكار البحثية المستقبلية.

ماذا سيحدث لنتائج دراسة البحث؟

يمكن كتابة هذه النتائج في شكل تقارير أو مقالات وبحوث وتُنشر في المؤتمرات والمحلية أو الدولية أو في المجلات الأكاديمية. وإذا حدث ذلك، لن يمكن التعرف على هويتك.

Appendix G

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من الذي قام بمراجعة هذه الدراسة؟

تمت مراجعة هذه الدراسة لجنة الأخلاقيات في كلية العلوم الصحية في جامعة ساوثهامبتون، المملكة المتحدة (رقم الأخلاقيات: ...). كما تمت مراجعة الدراسة من قبل لجنة الأخلاقيات المحلية التابعة للمستشفى الخاصة بك (اسم المستشفى: ... ، رقم الأخلاقيات: ....).

ماذا لو كانت هناك مشكلة أو لدي شكوى؟

إذا كان لديك قلق أو شكوى حول هذه الدراسة، عليك الاتصال بـ:

في (مستشفى ...)، المملكة العربية السعودية:

يمكنك التحدث أو إرسال خطاب إلى رئيس الممرضين في منطقة العلاج الكيماوي، مستشفى ...، على رقم الهاتف التالية:

هاتف: XXXXXXX

في المملكة المتحدة:

مارتينا بريود، رئيس مكتب الإدارة، في مكتب إدارة الأبحاث (العنوان: جامعة ساوثهامبتون، مبنى 37، هايفيلد، ساوثمبتون، SO17 1BJ؛ هاتف: 5058 8059 23(0) 44+؛ البريد الإلكتروني: rgoinfo@soton.ac.uk.
إذا لا تزال تشعر بعدم الرضا وترغب في تقديم شكوى رسمية، فسوف تزودك مارتينا ببيانات قسم إجراءات الشكاوى التابع لجامعة ساوثامبتون.

نشكركم على ما أتحتم لنا من ثمين وقتكم لقراءة هذه المعلومات.

لمزيد من المعلومات لا تتردد في الاتصال بي.

الباحثة: دينا م. عطاالله، طالب دكتوراه
كلية العلوم الصحية
جامعة ساوثامبتون
SO17 1BJ
المملكة المتحدة
هاتف: 02380594283 (المملكة المتحدة) /0505616828 (المملكة العربية السعودية)
البريد الإلكتروني: dmalell@soton.ac.uk

Sample of letter of invitation: Nurse Workforce and Unit Characteristics Survey

Health Sciences

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Letter of Invitation: Nurses Workforce and Unit Characteristics Survey

Date

Dear Sir/Madam

My name is Dena M. Attallah. I am currently studying for a PhD at the Faculty of Health Sciences, University of Southampton in the UK. As a part of the programme I am conducting a research study entitled: **Using nurse-sensitive outcomes indicators to assess variations in the quality of care provided by ambulatory chemotherapy services in the kingdom of Saudi Arabia: a descriptive cross-sectional study.**

The aim of this study is to establish whether variability exists in nurse-sensitive outcomes amongst ambulatory chemotherapy units in the KSA. In addition to explore a range of methodological and feasibility issues that relate to the development and implementation of nurse-sensitive outcomes measures and associated tools to characterise unit and nursing workforce in ambulatory chemotherapy settings in the KSA.

Therefore, we would like to invite you to take part in this study. It will involve you participating in a face-to-face or telephone interview to complete the survey enclosed with this survey package. Also you will be asked about issues related to the survey questions, such as: the clarity of the questions, the appropriateness of the questions and if any items are missing. The interview will take approximately 30 minutes to complete. This survey would be completed by you or your representative.

We hope you find this study interesting and thank you very much in advance for your cooperation. Please do not hesitate to contact me if further information is needed, I am available to answer any question you may have about this study or the survey.

Sincerely,
Dena M. Attallah
PhD student
Faculty of Health Sciences
University of Southampton
Southampton, SO17 1BJ.
Tel: 02380594283(UK)/0505616828 (KSA)
Email: dma1e11@soton.ac.uk

Appendix H: Interviews protocols

Cognitive Interview Protocol

Study title: Using nurse-sensitive outcome indicators to assess variations in the quality of care provided by ambulatory chemotherapy services in the Kingdom of Saudi Arabia: A descriptive cross-sectional study

Sample Cognitive Interview Protocol (Version 1)

Introduction

This interview will help us to test this questionnaire and identify problems. The questionnaire asks about your experience with the side effects of your last treatment of chemotherapy. And whether or not the support you are getting from the nurses in the chemotherapy outpatient unit is helping to reduce severity or avoid occurrence. This information will contribute towards an investigation of the quality of care provided by ambulatory chemotherapy services.

Usually when we read we read silently, to ourselves. But today I am going to ask you to read in a different way. At the end of each question or sentence, I'd like you to comment out loud about your understanding of the text at that point. At the end of each section, I'll ask you follow-up questions like how you chose your answer. These questions will help us to learn where and how we can improve this questionnaire. The interview should take approximately about 45 to 60 minutes, depending on you and your health experiences. If you need to take a break at any time, let me know.

Before we begin, I want to reassure you that we will keep the information you give us confidential. Your doctors and health plan do not know you are taking part in this interview. Your name is not written on this interview. Your name will not appear in the report we write summarising these interviews. It would be helpful to me if I taped our interview. Is that OK with you? But if you prefer not to record this interview, I will write notes as we go along.

1 YES → START TAPE RECORDER

2 NO

Before we start please sign the consent form.

ENTER START TIME: _____ AM/PM

The questions overleaf ask about the side effects you have faced since your last chemotherapy treatment and whether or not the support you are getting from the nurses in the chemotherapy day unit is helping.

- Completing the questionnaire will takes you about 10 to 15 minutes.
- This study under the supervision of the University of Southampton, UK.

General instruction:

- Most questions can be answered by putting x inside the box.
- Please use the pen supplied with this questionnaire package.
- Don't worry if you make a mistake; simply cross out the mistake and putting an x in the correct box.
- Do not write your name or address anywhere on the questionnaire.
- Your participation in this study is voluntary and your answers will be treated confidentially, unless you decide to share your responses with the nurse in charge of your treatment.
- Your answers will be used as part of a report to the hospital that cares for you.

PROBES: Were these instructions clear to you?

Did you feel that you understood what you were asked to do?

Section One: (A) What is the name of the chemotherapy you take? and Do you know the potential side effects?

A1\ Please choose the names of the chemotherapy drugs that you are receiving from the drugs listed below.

- If you don't know what chemotherapy drugs you are getting please ask the nurse who administers your chemotherapy to tell you.
- If you are not receiving any of these drugs listed below, please put an X in the "none of the above" box.

PROBES: Were the response options clear? How would you suggest that we re-word this statement? Was it tiring to answer this question? I notice you hesitated before responding to that question. Is there something that is confusing to you?

Appendix H

Would you prefer that I ask this in a different way? For example use the regimen name instead of the medication. How hard was this to answer?

A2\ Before starting your treatment, did you get a clear explanation by your chemotherapy nurse of what treatment will involve?	1	□	yes	2	□	No

A3\ Do you feel that you are fully informed about the side effects that might result from your chemotherapy?	1	□	yes	2	□	To some extent	3	□	No

PROBES: Were the response options clear? How would you suggest that we re-word this statement? Was it tiring to answer this question? I notice you hesitated before responding to that question. Is there something that is confusing to you? Would you prefer that I ask this in a different way? For example use the regimen name instead of the medication. How hard was this to answer?

Section Two: (B) What are the side effects that you have experienced since the last chemotherapy session you received? What is the support you have received to deal with these?

Please look at the list of symptoms below, which are commonly experienced by people undergoing chemotherapy.

Tell us which symptoms you experienced since your last chemotherapy treatment and how sever the symptom was by putting X in the appropriate boxes.

PROBES: Is there something that is confusing to you? What, to you, is meant by "symptoms"? Were these instructions clear to you? Did you feel that you understood what you were asked to do?

B1\ Since your last chemotherapy have you experienced any symptoms listed below? And how severe was the symptom?

		None		Mild		Moderate		Severe	
1	Nausea	1	□	2	□	3	□	4	□
2	Vomiting	1	□	2	□	3	□	4	□
3	Pain and irritation at the intravenous injection	1	□	2	□	3	□	4	□
4	Problems with mouth or throat (e.g. dry or sore mouth or sore, mouth ulcers)	1	□	2	□	3	□	4	□
5	Feeling weak (feeling unusually tired)	1	□	2	□	3	□	4	□
6	Signs of infection like feeling unusually hot or cold, Flu like feelings, high temperature, pain when urinating.	1	□	2	□	3	□	4	□
7	Feeling low or depressed	1	□	2	□	3	□	4	□

PROBES: Were there any words which were difficult to understand?

How would you suggest that we re-word this statement?

Were the response options clear?

Were there any symptoms that we forgot to include in this question?

Would you prefer that I use different words?

B2\ Do you suffer from any other symptoms?	Mild		Moderate		Severe	
8	1	□	2	□	3	□
9	1	□	2	□	3	□
10	1	□	2	□	3	□

PROBES: Would you prefer that I use different words?

B3\ Please tell us about the support you have received to help you manage your chemotherapy symptoms (To reduce severity or avoid occurrence).

	About your symptoms ...	Yes		Somewhat		No	
1	Do the nurses who give your chemotherapy ask you about the symptoms you experience since your last chemotherapy treatment?	1	□	2	□	3	□

2	Are the nurses who give your chemotherapy aware of the severity of symptoms you experienced since your last chemotherapy treatment?	1	□	2	□	3	□
3	Are the nurses who give your chemotherapy providing useful information about how to reduce the severity or avoid occurrence of your symptoms?	1	□	2	□	3	□
4	Are the nurses who give your chemotherapy providing practical advice to reduce the severity or avoid occurrence of your symptoms?	1	□	2	□	3	□
5	Are you confident in your ability to manage the symptoms you are experiencing?	1	□	2	□	3	□

PROBES: Were the response options clear?

I notice you hesitated before responding to that question.

Can you repeat the question in your own words? How would you suggest that we re-word this question?

Was it tiring to answer this question?

Is there something that is confusing to you?

How hard was this to answer? Why do you believe this?

B4\ How are you doing overall?
Please tick one box that best describes how much distress you have been experiencing since your last chemotherapy treatment till today.

PROBES: Were the response options clear?

Would you prefer that I use different measurement method?

I notice you hesitated before responding to that question.

Is there something that is confusing to you?

How hard was this to answer?

Section Three: (C) About you and your treatment

Because this questionnaire is anonymous and we won't look at your medical records it would help us if you could give us some additional details about yourself and your treatment.

PROBES: Were these instructions clear to you?

I notice you hesitated before responding to that question. Is there something that is confusing to you?

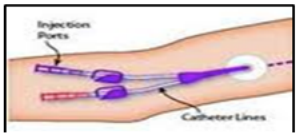
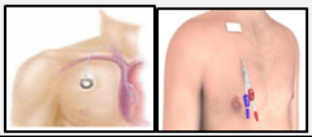
C1\ Which cycle of chemotherapy will you receive today? Please cycle one number

2 3 4 5 6 7 8 9 10 11 12+

C2\ Can you tell us the type or site of the primary cancer you are being treated for?								
1	□	Bladder/ Urological (not prostate)	6	□	Gynaecological (womb, Ovaries)	11	□	Prostate
2	□	Blood (Leukaemia)	7	□	Head or Neck	12	□	Stomach
3	□	Bowel	8	□	Lung	13	□	Other
4	□	Brain/ Central Nervous System	9	□	Lymphatic (Lymphoma)	14	□	Don't know
5	□	Breast	10	□	Oesophagus			

C3\ |How are you receiving your chemotherapy? Please tick one box	1	□	Intravenous Injection
	2	□	Intravenous Injection and Tablets
	3	□	Tablets only

C4\ What is the device used for giving injections? Please tick one box

1	□	Temporary intravenous needle	
2	□	Peripherally inserted central catheter (Long flexible tube that runs up a vein, inside your arm & ends up in a large chest vein)	
3	□	Central venous catheter (tube that comes out of the chest Portacath or Hickman)	

Appendix H

C5\ What is your age?	1	□	18-30	4	□	51-60
	2	□	31-40	5	□	61-70
	3	□	41-50	6	□	71+

C6\ What is your gender?	1	□	Male	2	□	Female

PROBES: Were the response options clear?

Is there something that is confusing to you?

How hard was this to answer?

Were there any words which were difficult to understand?

Now we've reached the end of this interview, thank you for your cooperation.

ENTER END TIME: _____ AM/PM

Sample of nursing workforce and unit characteristics survey protocol

Health Sciences

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Nursing Workforce and Unit Characteristics Survey **(NWUCS)**: Sample cognitive interview protocol

Introduction

This interview will help us to test this questionnaire, identify problems and improve our survey. The questionnaire asks about your Nursing Workforce and Unit Characteristics. This information will contribute towards an investigation of the variation in quality of care provided by ambulatory chemotherapy services in the KSA.

This interview will include two activities. In the first activity, you will be asked to answer the survey questions without interference. Also to mark items they found confusing/difficult to understand or annoying, while completing the survey.

In the second activity, I would like to tell us what you what items you found confusing/difficult to understand or annoying in this survey. As well as, I'll ask you follow up questions that would help in gaining clarification, elaboration, and verification of the survey.

The interview should take approximately about 45 to 60 minutes, depending on you and the information you give.

Please let me know if you need to take a break at any time.

It would be helpful to me if I taped our interview. Is that OK with you? But if you prefer not to record this interview, I will write notes as we go along.

1 YES START TAPE RECORDER
2 NO

ENTER START TIME: _____ AM/PM Date

TO: Nurse Managers of Selected Units

Please complete the following questions to provide background information about your unit, which will take approximately 15 minutes. This information will be used to profile your unit, and to understand the differences and similarities between ambulatory chemotherapy units involved in the study. Only a code number that identifies the hospital and unit will be used for the data file and any identifiers that associate your answers to your unit will be destroyed upon completion of the study. In accordance with the University of Southampton's Data Protection Policy data will stored securely for 10 years after the end of the project. Questions can be left blank if you prefer but complete data is always more helpful in the analysis.

PROBES: were these instructions clear to you?

Did you feel that you understood what you were asked to do?

1

Questions	Answers
Section One: (A) Unit Characteristics	
1. What is the usual number of chairs/beds used to give chemotherapy in this unit?	…… Chairs …… Beds
PROBES: • Were the response options clear? • How would you suggest that we re-word this question and its responses? • Is there something that is confusing you? • Would you prefer that I ask this in different way?	
2. How many patients are treated with chemotherapy per day, in the last week?	Sunday | Monday | Tuesday | Wednesday | Thursday ( ) | ( ) | ( ) | ( ) | ( )
3. How many patients are treated with chemotherapy per month, in the last 3 months?	Month 1 | Month 2 | Month 3 ( ) | ( ) | ( )
4. What are the hours that this unit is open?	Start …… Finish ……
5. What is the number of working days per week in this unit?	☐ 5 days per week, no weekends ☐ 7 days per week ☐ Other, please specify ……
PROBES: • Were the response options clear? • Is there something that is confusing to you?	
6. How many nursing shifts per day cover the unit?	☐ 1 shift ☐ 2 shifts ☐ 3 shifts ☐ Other, please specify ……
7. What is the usual shift length that nurses work in this unit?	☐ 8-hour day shift ☐ 9-hour day shift ☐ 12-hour day shift ☐ Other, please specify……
8. What is the start and finish time for each shift?	8-hour shift | 9-hour shift | 12-hour shift | Other Shift Start ……. Finish…… | Start …. Finish … | Start …. Finish … | Start ……. Finish ……

Section Two: (B) Nurse Staffing Characteristics				
9. What is the total number of nurses working in this unit?	……			
10. What is the number of nurses who administer chemotherapy in this unit?	……			
11. What is the optimal number of nursing staff member per shift?	8-hour shift	9-hour shift	12-hour shift	Other Shift
PROBES: • Would you prefer that I use different words?	……	……	……	……
12. On each shift, what is the usual staff mix/proportion of nurses, please specify. a. Number of Registered Nurse with bachelor degree b. Number of Registered Nurse with Diploma degree c. Number of Licensed practical nurse (LPN)	8-hour shift a. …… b. …… c. ……	9-hour shift a. …… b. …… c. ……	12-hour shift a. …… b. …… c. ……	Other Shift a. …… a. …… b. ……
PROBES: • Is there something that is confusing to you? • Would you prefer that I use different words?				
13. Do you use a standardised approach to measure patient acuity when allocating chemotherapy patients to particular nurses on different shift? **If you use a particular patient acuity scale I will be grateful if you send it to me.**	☐ Yes ☐ No			

PROBES: • I notice you hesitated before responding to that question. • Is there something that is confusing to you? • Would you prefer that I use different words? • What, to you, is meant by "patient acuity"? • Would you please tell me how can I improve it? • Were there any words which were difficult to understand?	
14. Nurse-to-patient ratio What is the usual number of patients assigned to each nurse per shift?	……
PROBES: • Was this question clear to you? • If no, how would you suggest that we re-word this question?	☐ Yes ☐ No
15. Do you ever allocate by chair? **If no, please go to question 17.**	☐ Yes ☐ No
PROBES: • Was this question clear to you? • If no, how would you suggest that we re-word this question? • What, to you, is meant by "allocate by chair"?	☐ Yes ☐ No
16. On a shift basis, how do you allocate the patients to the available chairs and beds?	……
PROBES: • Could you please tell me more about… how do you allocate your patients to the nurses? • I'm not quite sure I understood …Could you tell me about that some more?	
17. What is the number of female nurses in the unit?	……
18. What is the number of male nurses in the unit?	……
19. What is the optimal number of nurses who speak Arabic per shift?	……
PROBES: • Was this question clear to you?	

20. Overall, what is the post-registered qualification of nursing staff in this unit? a. Number of nurses holding **Bachelor's** Degree b. Number of nurses holding **Diploma** Degree	a. …… b. ……
PROBES: • Was this question clear to you? • If no, how would you suggest that we re-word this question?	
21. Of the total number of nurses who give chemotherapy, how many nurses had: a. Diploma in cancer nursing b. Pre-work preparation course for cancer care c. Non d. I don't know	a. …… b. …… c. …… d. ……
PROBES: • I notice you hesitated before responding to that question. • Is there something that is confusing to you?	

Section Three: (C) General Information	
22. What type of cancer you are treating in your unit?	☐ All types of cancer ☐ Oncology ☐ Haematology ☐ Specific types of cancer please specify ……
23. In your unit, do you provide patient and family education that helps them to manage or reduce the severity of their chemotherapy side effects?	☐ Never ☐ Before the first cycle only ☐ Before some cycles ☐ Before each cycle ☐ Other, please specify ……
PROBES: • Is there something that is confusing to you? • Were the response options clear? • How would you suggest that we re-word	

5

this response options? • Would you prefer that I ask this in a different way?	
24. In what format does this education take? (please check all that apply) PROBES: • Is there something that is confusing to you? • Would you prefer that I ask this in a different way? • Were the response options clear? • Do you think that there is anything else that I should have included in these responses which I might have missed out?	☐ One on one ☐ Group discussion ☐ Other, please specify ……
25. Please state the most important points that you include when educating patient and family about chemotherapy side effects? (please tick all that apply) PROBES: • Were the response options clear? • Do you think that there is anything else that I should have included in these responses which I might have missed out?	☐ Possible side effects ☐ How to reduce or prevent the occurrence of the side effects ☐ Nutrition plan ☐ Daily activity ☐ Other, please specify …… …… ……
26. Do you assess patients' side effects of chemotherapy resulting from the previous cycle? PROBES: • Were the response options clear? • Do you think that there is anything else that I should have included in these responses which I might have missed out?	☐ Never ☐ Before some cycles ☐ Before each cycle ☐ Other
27. Do you document patients' side effects of chemotherapy resulting from the previous cycle? PROBES: • Was this question clear to you? • Is there something that is confusing to you? • Were the response options clear?	☐ Never ☐ Before some cycles ☐ Before each cycle ☐ Other
28. Do you use a particular tool? I will be grateful if you send it to me PROBES: • Was this question clear to you? • I notice you hesitated before responding to that question. • Is there something that is confusing to you?	☐ Yes ☐ No

29.Chemotherapy regimens (protocols) provided in this unit.
Please check all relevant regimens. We have only listed regimens that are most commonly administered; however, we know that in your unit you may administer other regimens that don't appear on this list

☐ ABVD ☐ AC ☐ BEP ☐ CAP ☐ Carboplatin/ Topotecan ☐ CHOP-R
☐ CVP
☐ ESAP ☐ 5FU/ Leucovorin ☐ ICE ☐ MAID ☐ TAC ☐ TCH ☐ XELOX
☐ XILIRI ☐ Other, please specify……

7

Appendix H

Questionnaire evaluation of the NWUCS

Questionnaire evaluation

We would appreciate if you could please take some time to give us some feedback on the questionnaire. We anticipate this will take no more than 10 minutes to complete.

Question	Response Options
1. How easy was it to read the NWUCS?	☐ Very difficult ☐ Somewhat difficult ☐ Neither difficult nor easy ☐ Somewhat easy ☐ Very easy
2. How easy was it to answer the questions?	☐ Very difficult ☐ Somewhat difficult ☐ Neither difficult nor easy ☐ Somewhat easy ☐ Very easy
3. Were the response options clear? If no or somewhat, could you please tell me what is this question is this? And how can I improve it?	☐ Yes ☐ No ☐ Somewhat clear
4. Where these instructions clear to you?	☐ Yes ☐ No ☐ Somewhat clear
5. Was there any question that was difficult to understand? If yes, could you please tell me what is this question is this? And how can I improve it?	☐ Yes ☐ No
6. Where there any questions that you particularly disliked? If yes, please tell me what is this question is this? And how can I improve it?	☐ Yes ☐ No
7. Do you think that there is anything else that I should have included in this questionnaire- which I might have missed out?	☐ Yes ☐ No
8. Do you have any suggestions?	☐ Yes ☐ No

Now we've reached the end of this interview, thank you for your cooperation.

ENTER FINISH TIME: _____ AM/PM

Thank you for your time ☺

8

Appendix I : Details of specific question modification whilst developing the PR-CISE/Arabic questionnaire

Table A Details of specific question modification whilst developing the PR-CISE/Arabic questionnaire: section A. Demographic data

PR-CISE Items	Changes in the Adapted PR-CISE (Before Round 1)	Translation of the adapted PR-CISE/Arabic version (Round 1)	Difficulties with specific wording (medical terms) or phrasing/terminology / Difficulties regarding the response categories	Interview findings	Action taken: Items to be adjusted, Included or deleted from the adapted PR-CISE (preparing for Round 2)	Reasons to ask, change or add questions
A list of drugs, classified by their potential to cause toxicity in terms of nausea/vomiting and tissue necrosis if extravagated, was presented in PR-CISE	NA	A1\ Please tick the names of the chemotherapy drugs that you are receiving from the drugs listed below.	The question formatting was clear and easy to understand. But respondents found it difficult to answer. The reasons for this because respondent were not a knowledgeable informant; Comprehension issues. They spent long time to find the name of their chemotherapy	3 (60%) of the participants knows the names of their chemotherapy. While (n=2) participants does not know, but (n=1) asked the nurse about it.	*In the pilot study the nurses will be asked to write the name of the chemotherapy and number of the cycle on the top of the questionnaire before providing it to the targeted patient.	To know the type of chemotherapy based on classifications of extravasation risk *To avoid bias and reduce the missing data
	This question was added to the original PR-CISE	A2\ Before starting your treatment, did you get a clear explanation by your chemotherapy nurse	Question was clear Easy to understand and answer	Most the chemotherapy patients got the first information from their	NA	To find out the patient experience of the process of care

		of what treatment will involve?	NO difficulties with specific wording (medical terms) or phrasing/terminology	physicians not from their chemo nurse. 3 (60%) participants reflected that they get a clear explanation by their physicians. 1 participant (20%) received information through chemo nurse and 1 participant (20%) get the information from the patient educator.		To find out do patient receive information about what to expect possible side effects (nursing Support)
For each drug ticked please also tell us if you feel fully informed about the side effects	This question was a part of the first question in the PR-CISE,	A3\ Do you feel that you are fully informed about the side effects that might result from your chemotherapy?	Question was clear Easy to understand and answer	No comments	Before starting your treatment, did you felt that you are fully informed about the side effects that may result from your chemotherapy treatment?	To find out that if the patients get enough information about the possible side effects result from their chemotherapy

Table B Details of specific question modification while developing the PR-CISE/Arabic questionnaire: Section B. (Quality indicators)

PR-CISE Items	Changes in the Adapted PR-CISE (Before Round 1)	Translation of the adapted PR-CISE/Arabic version (Round 1)	Difficulties with specific wording (medical terms) or phrasing/terminology/ Difficulties regarding the response categories	Round 1 CIs findings	Solutions Action taken: Items to be adjusted, Included or deleted from the adapted PR-CISE (preparing for Round 2)	Reasons to ask, change or add questions
Effectiveness: symptom severity. And safety*: chemotherapy administration \ PROM B1. Since your last chemotherapy treatment, have you experienced… 1. Nausea 2. Vomiting 3. Pain and irritation at the injection/infusion (needle) site 4. Problems with mouth or throat (e.g. sore or dry	Change was in the wording of the question and not in substance. However, one item has been removed B1.5 The response categories remain the same	B1. Since your last chemotherapy treatment, have you experienced any of the symptoms listed below? How severe was the symptom? 1. Nausea 2. Vomiting 3. Pain and irritation at the intravenous injection	Question was clear Easy to understand and answer No difficulties with specific wording (medical terms) or phrasing/terminology	One participant (P01) recommended that in the points 4 & 6 items need to be separated one by one for example: 6. Sign of infection a) high temperature b) pain when urinating c) flu like feeling	Following discussion with the supervisor, the question remains the same Because, the purpose of the question is to know whether the patient was experience mouth or sore problems or not. And to describe how severe it was.	To find out patient experience of subjective symptom severity, this would explain the possible variation in quality of care

mouth/throat, mouth ulcers) 5. Feeling Weak 6. Signs of infection (e.g. feeling unusually hot or cold, flu like feelings, high temperature, pain when urinating). 7. Feeling unusually tired 8. Feeling low or depressed Response categories 1- Non 2- Mild 3- Moderate 4- Sever		4. Problems with mouth or throat (e.g. dry or sore mouth or sore, mouth ulcers) 5. Feeling unusually tired 6. Signs of infection like feeling unusually hot or cold, flu like feelings, high temperature, pain when urinating. 7. Feeling low or depressed Response categories 1. Non 2. Mild 3. Moderate 4. Sever				
B2\ Are you experiencing any other symptoms? (list up to 3)	Question remain the same	Do you suffer from any other symptoms? (list up to 3)	Clear and Easy to understand, but this question can be skipped if the patient didn't experience any other symptoms.	P02 … what if I don't have any other symptoms, do I need to write anything or what??...	*Question B2 can be skipped if the patient didn't experience any other symptoms. So, it would be adjusted to: Do you suffer from any other symptoms?	To find out any other symptoms that might be specific to chemotherapy nurses work

					1. ☐yes 2. ☐No If yes, please describe it and indicate how severe it was. If no, please go to question B3.	*To give clarity
B3\ Experience: supportive care and care delivery PreP 1. Do the nurses who give you chemotherapy ask you about your symptoms? 2. Are the nurses who give you chemotherapy aware of the severity of your symptoms? 3. Are the nurses who give you chemotherapy providing useful information to	Response categories remain the same	1. Do the nurses who give your chemotherapy ask you about the symptoms you experience since your last chemotherapy treatment? 2. Are the nurses who give your chemotherapy aware of the severity of symptoms you experienced since your last chemotherapy treatment?	Questions 1-4 were clear Easy to understand and answer There are no problems in interpreting	4(80%) participants reflected that they found question B3.5 difficult to understand, need to be re-wording, and can be shortened. Participants recommendations were Re-wording of the question P02: Can you deal with the chemotherapy side effects that you are experiencing? P03: Can you deal with the symptoms	Question B3.5 has been adjusted to: Do you have the ability to deal with the side effects caused by your chemotherapy?	To assess patient's perceptions of what nurses do in response to symptoms they experience. Reason for changes: This form of the question will make it more understandable.

manage your symptoms? 4. Are the nurses who give you chemotherapy providing practical advice to manage your symptoms? 5. Are you confident in your ability to manage the symptoms you are experiencing? Response categories 1. Yes 2. Somewhat 3. no		3. Are the nurses who give your chemotherapy providing useful information about how to reduce the severity or avoid occurrence of your symptoms? 4. Are the nurses who give your chemotherapy providing practical advice to reduce the severity or avoid occurrence of your symptoms? 5. Are you confident in your ability to manage the symptoms you are experiencing? Response categories 4. Yes 5. Somewhat 6. no	However, B3.5 was confusing and difficult to understand	you are experiencing? P04: Can you manage your chemo side effects? P05: Do you have the ability to deal with the side effects caused by your chemotherapy?		

B4\ How are you doing overall? No distress		How are you doing overall? Please circle one number that best describes how much distress you have been experiencing since your last chemotherapy treatment till today.	Considered difficult to understand, needs paraphrasing Conflicting in answering instruction	5 participants (100%) asked for paraphrasing (re-wording) the question and clarification of the meaning of the number included in the scale. **P01:** … what do you mean by how are you doing overall? I don't understand … … Because you need to specify the reason behind in this format It is too vague question. **P02:** …It would be better to paraphrase this question … like How would you describe your health in general since the last dose of chemotherapy till today? **P03:** … in what context??... Financial psychological or what?? …	The question has been adjusted to: We would like to know about your health. How much distress have you been experiencing since your last chemotherapy treatment till today? Please circle one number on the scale that best describes your health and please write this number in the box Below. '10' means the more distress health you have been experiencing and '0' means no distress.	Clarity Instruction was added to this question to help the respondents understand the way of answering

Table C Details of specific question modification whilst developing the PR-CISE/Arabic questionnaire: section C

PR-CISE Items	Changes in the Adapted PR-CISE (Before Round 1)	Translation of the adapted PR-CISE/Arabic version (Round 1)	Difficulties with specific wording (medical terms) or phrasing/terminology/ Difficulties regarding the response categories	Interview findings	Action taken: Items to be adjusted, Included or deleted from the adapted PR-CISE (preparing for Round 2)	Reasons to ask, change or add questions
C1 Which cycle of chemotherapy will you receive today? Please circle a number C2. What is your diagnosis? C3. How are you receiving your chemotherapy? Please tick one box. 1. Injection or infusion (drip) 2. Injection or infusion (drip) and Tablets 3. Tablets only	C1 remain the same no changes C2 has been changed before round 1 because it felt be easier for patient to respond to this type question C3. Remain the same Changes have been in the use of medical terminology from Injection or infusion (drip) To Intravenous injection	C1. Which cycle of chemotherapy will you receive today? Please circle a number C2. Can you tell us the type or site of the primary cancer you are being treated for? C3. How are you receiving your chemotherapy? Please tick one box. 1. Intravenous injection 2. Intravenous injection and Tablets 3. Tablets only	Questions in this section were clear and easy to understand and answer There are no problems in interpreting	N/A	N/A	To assess the effect of case mix, and adjust for it, information about sex, age, ethnicity, and class of chemotherapy and mode of administration were added. Question C2. Has been adjusted for clarity C6 This format is conventional among patients in the Kingdom.

Appendix I

C4. What is the device used for given injection/infusions? Please tick one box. C5. What is your age? 1. 18-30 2. 31-40 3. 41-50 4. 51-60 5. 61-70 6. 71+ C6. Are you 1. Male 2. Female C7. How would you describe your ethnic background	C4. Pictures were added to facilitate the selection C5. Remain the same with no changes C6. Change was in the wording of the question and not in substance. C7. This question has been removed before Round 1	C4. What is the device used for giving injections? (Use the pictures as a guide.) Please tick one box. C5. What is your age? 1. 18-30 2. 31-40 3. 41-50 4. 51-60 5. 61-70 6. 71+ C6. What is your gender? **7.** Male **8.** Female	Questions were clear, easy to understand and answer NO difficulties with specific wording (medical terms) or phrasing/terminology	N/A	N/A	**C7.** Because ethnicities reference group were not used to determine assess patient symptoms in the KSA, ethnicity items were omitted from the adapted PR-CISE

Appendix J : Log of recruitment activity by site

Flow Chart

Hospital code #__

Starting Date: __/__/2015
Finishing date: __/__/2016

Data collected by:	☐	The researcher	☐	Volunteer staff

		Number of patients for chemotherapy	Number of eligible patients	Number of approached patients	Number of patients received questionnaire package	Number of patient decline to take part
Week 1	Day 1					
	Day 2					
	Day 3					
	Day 4					
	Day 5					
Week 2	Day 1					
	Day 2					
	Day 3					
	Day 4					
	Day 5					
Week 3	Day 1					
	Day 2					
	Day 3					
	Day 4					
	Day 5					
Week 4	Day 1					
	Day 2					
	Day 3					
	Day 4					
	Day 5					

Appendix K: Reasons for non-participation in the survey

Hospital Code: #
Date starting data collection: __/__ /2015
Date finishing data collection: __/__ /2016

Data collected by: ☐ The researcher ☐ Volunteer Staff

Reasons for non-participation in the surveys

Reason	Week 1					Week 2					Week 3					Week 4					Total
	D1	D2	D3	D4	D5	D1	D2	D3	D4	D5	D1	D2	D3	D4	D5	D1	D2	D3	D4	D5	
1. Not enough time																					
2. Don't want to participate in research																					
3. Don't like completing questionnaires																					
4. Don't think the study is worthwhile																					
5. No personal benefit																					
6. Concerns about confidentiality																					
7. Questions not relevant/few symptoms																					
8. Difficulty understanding or answering questions																					
9. Dislike questionnaire – other reason																					
10. Other reason/don't know																					
11. Wanted more information about the study																					
12.																					

Researcher: Dena Attallah
V3 28/08/2015

Hospital Code: #
Date starting data collection: __/__ /2015
Date finishing data collection: __/__ /2016

Data collected by: ☐ The researcher ☐ Volunteer Staff

Reasons for non-eligibility

Reason	Week 1					Week 2					Week 3					Week 4					Total
	D1	D2	D3	D4	D5	D1	D2	D3	D4	D5	D1	D2	D3	D4	D5	D1	D2	D3	D4	D5	
1. First-cycle patient																					
2. Literacy																					
3. Difficulty understanding or answering questions																					
4. Is not aware of having condition																					
5. Patients visiting the unit but not currently receiving chemotherapy																					
6. Language barrier (non-Arabic speaker)																					
7. Patient age (less than 18 year)																					
8. Repeated patient																					

Researcher: Dena Attallah
V3 28/08/2015

Appendix L : Volunteer research assistants package

Health Sciences

UNIVERSITY OF Southampton

Letter of invitation: volunteer researchers meeting

Date 29/05/2016

Dear Madam,

My name is Dena M. Attallah. I am currently studying for a PhD at the Faculty of Health Sciences, University of Southampton in the UK. As a part of the programme I am conducting a research study entitled: **Using nurse-sensitive outcomes indicators to assess variations in the quality of care provided by ambulatory chemotherapy services in the kingdom of Saudi Arabia: a descriptive cross-sectional study.**

The aim of this study is to establish whether variability exists in nurse-sensitive outcomes amongst ambulatory chemotherapy units in the KSA. In addition to explore a range of methodological and feasibility issues that relate to the development and implementation of nurse-sensitive outcomes measures and associated tools to characterise unit and nursing workforce in ambulatory chemotherapy settings in the KSA.

Therefore, we would like to invite you to take part in this study as a volunteer re. It will involve you participating in:

1- Identify potential patients,
2- Distribute the questionnaires, and
3- Offer assistance to potential participants who need help in completing the questionnaires.

Also you will be asked about issues related to the process and tools of conducting this survey.

We hope you find this study interesting and thank you very much in advance for your cooperation. Please do not hesitate to contact me if further information is needed, I am available to answer any question you may have about this study or the survey.

Sincerely,
Dena M. Attallah
PhD student
Faculty of Health Sciences
University of Southampton
Southampton, SO17 1BJ.
Tel: 02380594283(UK)/0505616828 (KSA)
Email: dena.attallah@gmail.com

Health Sciences

UNIVERSITY OF Southampton

Instructions for recruiting potential participants

Dear Sir/Madam:

Please distribute a patient survey package to any patient who meets all of the following criteria:

1. Patients aged 18 and over who are undergoing chemotherapy in an ambulatory chemotherapy unit.
2. The participants must be patients receiving their chemotherapy in an ambulatory chemotherapy unit.
3. Patients who have received at least one cycle of chemotherapy in an ambulatory unit.
4. Potential participants are patients who are due for chemotherapy on the day of data collection, or who come in the day before for blood test or assessment check.
5. The participants must be able to participate in this study (e.g. not ill, enough time).
6. The participants must be willing to participate in this study.
7. The participants must be able to read and write in Arabic. If not, patient relative or nurse would help the patient in this matter.

Please follow these guidelines to help you recruit potential patient participants

1. Potential patients will be identified through the ambulatory chemotherapy unit's patient log book.
2. You will recruit eligible patients who have arrived for their chemotherapy sessions.
3. You will give potential patients information outlining the study. You can use the provided guidelines (a script for staff to introduce the study to patients.)
4. Please write the diagnosis and chemotherapy regimen at the top of the questionnaire, and before giving it to patient.
5. Please supply the potential patient with the questionnaire package
6. Instruct patients to complete only one questionnaire, even if they visit the unit more than once during the data collection period.
7. Instruct the potential patient to put the completed questionnaire in the envelope, and seal it before placing it in the research box in the nursing office. Regardless of whether they have filled it in or not.

General instruction:

Patients have a right to refuse and/or withdraw at any time without given a reason. However, please use the flow chart, Reasons for non-participation in the surveys and Reasons for non-eligibility forms and list the number where possible.

Dena Attallah

Health Sciences

UNIVERSITY OF Southampton

Script to introduce the study to patients

Study title: Using nurse-sensitive outcome indicators to assess variations in the quality of care provided in ambulatory chemotherapy services within the Kingdom of Saudi Arabia: A descriptive cross-sectional study

The following is a script that can be used to introduce the study to patients when you provide them with patient survey packages. Feel free to use any part of this script; you need not follow it exactly.

"Our unit is participating in a research study being conducted by the School of Health Sciences at the University of Southampton. We are handing out this survey to all of our patients and would like to encourage you to take time now to read the information and decide whether or not you would like to participate.

All of our patients are being asked to complete a short questionnaire to get an overall picture of how well our nurses support them. The questions overleaf asks if you have experienced a particular symptom since your last chemotherapy session and whether or not the support you are getting from the nurses in the chemotherapy day unit is helping. Patients from seven hospitals across the kingdom are participating in this study.

Completing the survey is voluntary. Your individual answers are confidential and will be seen only by the researcher. It should take about 10 minutes to complete, and there is a pencil in this envelope for you to use and keep.

I will leave this with you to complete before you leave today. Regardless of whether you complete it or not, please place the questionnaire in the envelope and seal it. Then place it into the research box at the nursing desk. You will not receive any further mail or call about this study; this is the only time it will be offered to you.

Thanks in advance for considering participation in this study."

Dena Attallah

Glossary of terms

ACS: Ambulatory Chemotherapy nit: outpatient chemotherapy**.**

Content validity: evidence from qualitative research demonstrating that the instrument measures the concept of interest including evidence that the items and domains of an instrument are appropriate and comprehensive relative to its intended measurement concept, population, and use.

Face validity: whether, on the face of it, the instrument appears to be assessing the desired qualities.

Licensed practical nurse (LPNs)**:** nurse who care for people who are sick, injured, convalescent, or disabled under the direction of physicians and registered nurses (Bureau of Labor Statistics, 2009).

In the KSA, LPNs/ non-registered nurses are nurses graduated from diploma nursing program who care for ill person, injured, convalescent, or disabled under the direction of physicians and registered nurses.

Nurse-led Ambulatory chemotherapy service: is an outpatient clinic that is run or managed by nurses that are embedded in the clinical pathway for patients during their chemotherapy.

Nurse-sensitive patient outcomes: The term 'Nursing sensitive outcomes' has been described as "relevant, based on nurses' scope and domain of practice, and for which there is empirical evidence linking nursing inputs and interventions to the outcome" (Doran 2006, p. S77). In other words, Gobel et al. (2006) defined it as "outcomes that are attained through or are significantly impacted by nursing interventions" (2006, p.621).

Nurse-to-patient ratio: the number of patients for whom one nurse has direct responsibility at any one time (Lankshear et al. 2005).

Nurse (RN)-to-patient ratio: the term 'ratios' has been express in two different ways; one method uses the number of patients assigned to one nurse per shift in the unit, whereas the second uses a ratio of full time equivalents (FTEs) of RNs per patient ways (Kane et al. 2007a). In this study ratio of interest is the first method of use.

Patient Safety: "The process by which an organisation makes patient care safer. This should involve: risk assessment; the identification and management of patient-related risks; the reporting and analysis of incidents; and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring" (2004 p.17) (Agency July 2004).

PR-CISE: Patient Reported- Chemotherapy Indicators of Symptoms and Experience

Practicality: describing the feasibility of using an instrument in its intended population and clinical setting.

Think-aloud interviewing: the term describes a very specific type of activity, in which subjects are explicitly instructed to "think aloud" as they answer the survey questions (Willis 1999).

Registered nurse (RN): a nurse graduated from a nursing programme college or nursing school and holds a professional nursing qualification. A RN provides nursing care to patients and the patient's family. In the KSA, RN are defined as nurse who hold a bachelor degree from an university or equivalent college, and engage in providing nursing care to or assisting in the medical treatment of persons with injuries and/or illnesses or postal women.

RN skill mix: can be defined as the proportion of RN hours of care to the total hours of nursing care workers in acute care units (American Nurses Association 1996). Unlicensed staff skill mix is defined as the proportion of unlicensed staff hours of care to the total hours of nursing care workers in acute care units (American Nurses Association, 1996).

Skill mix: According to the UK Royal College of Nursing (Royal College of Nursing 1992) the term 'skill mix' can be defined as 'the number and mix of staff within the nursing/midwifery team who have the appropriate skills and knowledge to deliver quality patient-centred nursing care' (Royal College of Nursing 1992: p. 1) In this study by "Skill mix" I mean variation in skill and educational background of nursing staffing in nursing homes. By nurse education I mean the percentage of nurses with a bachelor degree.

Unit: the word "Unit" refers to centres/services of chemotherapy outpatient.

Unit characteristics: in this study, it refers to the characteristics of the participated centres including; hospital type and unit size.

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