Enhancing knowledge:
the impact of experience and information

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Declaration of Originality

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Hedyeh Hedayati
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Abstract

Background

The last two to three decades has seen a shift towards patients taking a more active role in treatment decision making. One way of enabling patients to give true informed consent prior to medical treatment is to give them adequate information from which to make a reasonable decision. Research highlights that lack of knowledge or poor recall of information may result in negative consequences for the patient. A plethora of studies have been conducted on improving the type and manner in which this information is given to ultimately improve patient knowledge. Assuming there is a limit to how much information can be imparted prior to treatment, the main purpose of this research was to assess the impact that the experience of treatment in addition to the standard pre-treatment information has on patients’ eventual knowledge of chemotherapy treatment information, a unique area of research.

Methods

Part One: A literature review was conducted to determine all possible tools and methods that have been implemented for development of an improved consent process, including their effectiveness and their success in improving patient knowledge of the information given. A large number of studies were identified in assessing the effectiveness of a variety of interventions, in different populations. The main finding of this review suggests that although some of these tools may be beneficial at improving patient knowledge of the information given, patient recall was still poor. Furthermore, a majority of these studies were found to be methodologically flawed, have limited external validity, and were often conducted on small samples questioning reliability of results. Therefore, considering these limitations and the potential cost in implementing such interventions, it is believed that alternative research is necessary. Therefore, a novel area of research would be to assess the impact of treatment experience on patient knowledge of the standard pre-treatment consent information given.
**Part Two:** A second literature review was conducted to identify studies assessing the impact of patient experience with surgical or non-surgical treatment and its effect on patient knowledge of the informed consent information. Overall, the evidence suggested that despite having experienced treatment, a high proportion of patients still did not recall or recognise aspects of the procedure they undertook. However, scarce data indicated that further research was necessary especially in different patient populations.

**Part Three:** Gaps identified in part two aided the design of a longitudinal study to assess whether patient knowledge improves when the experience of chemotherapy is added to the standard pre-treatment information used for informed consent. The assessment of knowledge was based on the information given to patients on their information sheet and consent form. Some factors that may be associated with patient knowledge of treatment information given were identified from the literature reviews, either as not being, or scarcely being evaluated. Therefore, the level of patient satisfaction, trust for the physician, and social support were chosen to be measured and their changes over the chemotherapy treatment period were determined. Lastly, particular demographic or psycho-social variables were assessed as predictors of knowledge of pre-treatment information given. Seventy one consecutive men and women due to receive adjuvant chemotherapy treatment for breast or colorectal cancer participated in the study. Eligible patients who consented were visited to complete structured questionnaires at three time points.

**Part Four:** Six women with breast cancer agreed to participate in the in-depth qualitative interview regarding information given at the time of consent. This additional study was conducted to help triangulate findings from the longitudinal study and provide a richness of responses regarding the topics of interest.

**Results**

Patient knowledge of the number, name and potential side effects of chemotherapy drugs were evaluated and found to vary greatly. First, patient knowledge of the number of drugs given for chemotherapy was found to be the most highly recalled aspect of consent information.
(ranging from 59.6% correct at Time 1 to 68.4% correct at Time 2) although experience over the three time points showed no significant increase in knowledge (p = .33). Second, patient knowledge of the names of drugs given, showed a significant increase over the course of chemotherapy (p = .01) although the highest proportion of correct recall was still low at only 26.3% at Time 3. Finally, an analysis of patient knowledge of chemotherapy side effects also found participants did not have significantly increased knowledge of potential side effects despite experience (p = .52) with the highest proportion of correct recall being 21.1% at Time 2.

Patient satisfaction significantly reduced over time (p = .04) although satisfaction remained moderate-to-high. The same result was found for social support with experience (p = .02). However, although trust remained high across all three time points, there was a non-significant worsening trend over the course of chemotherapy (p = .61). A number of predictors appeared to correlate with variables assessing patient knowledge of the information given. A regression model was found to be significant for the knowledge of the number of drugs \( \chi^2(8, 70) = 30.72, p = .000 \) with predictors accounting for 47.8% of the variance. The model for the name of drugs received was also significant \( \chi^2(5, 70) = 12.61, p = .03 \) with predictors accounting for 32.4% of the variance. Being female and being a private patient were found to be significant, individual predictors of knowledge of the name of drugs. However, no other predictors in the two models were strong enough to be individually significant. The patient’s age and the extent that they read the information given were the only factors found to be associated with all three measures of knowledge. The most prominent themes of the qualitative analysis included patients having a high level of trust for their physician and that the consent information form given was seen, by patients, as a reinforcement tool which they could refer to if needed.

**Conclusion**

The experience of chemotherapy treatment in addition to the standard pre-treatment information initially given to patients at consent does not appear to be sufficient at improving patient knowledge of chemotherapy. However findings suggest that different components of
the consent process are predicted by different variables. People differ in their ability to understand information, and have different circumstances and priorities that can influence their memory and interpretations. This leads to recognition of the complexity in improving the consent process and suggests that an individualised or multi-faceted approach is necessary.
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Chapter 1: Introduction

Setting the scene

Decisions made about health care take place in each one of our lives on a daily basis. Some decisions may be regarded as trivial because of their limited consequences such as taking headache medication while others relate to more complex matters that are often associated with greater risks. Examples of such decisions include undertaking surgery or chemotherapy treatment for cancer. Every diagnostic and therapeutic procedure in health care involves the exchange of information between the physician and the patient and obtaining the patient’s informed consent. Informed consent is the patient’s decision to have or not have a procedure or treatment once the patient has been given all of the necessary information, understands it, has had time to deliberate on it, and is free from coercion. The concept of informed consent has been evolving over the past 100 years and has its origins in both ethical and legal theory. In ethical terms, informed consent maintains respect for patients by acknowledging that patients are autonomous and therefore have the right to make decisions about their own medical treatment. Legally, the health care professional is obliged to inform the patient of material risks, benefits, and alternatives to treatment to which the patient provides autonomous authorisation (Beauchamp & Childress, 2001). Literature in the fields of law, philosophy, medicine, and psychology define informed consent by five components: (1) competence, (2) disclosure, (3) understanding, (4) voluntariness, and (5) consent (Beauchamp & Childress, 2001; Milton, 2000). These components are discussed in more detail later in this chapter.

Information is fundamental in assisting people to make informed health decisions. The goal of providing patients with information on their diagnosis, prognosis, and treatment, as well as potential risks and side effects, is so that patients understand the relevant and necessary information given in order to make an informed decision about whether to go ahead or not. The importance of making an informed decision to consent to medical treatment, and remembering and understanding this information, is crucial as it plays a number of roles.
They include allowing patients to gain control of their condition (Gaston & Mitchell, 2005; Mills & Sullivan, 1999) improving compliance with treatment (Fallowfield, 2008), reducing anxiety (Gaston & Mitchell, 2005), enabling patients to create realistic expectations (Gaston & Mitchell, 2005; Mills & Sullivan, 1999), reducing uncertainty and decision delay (O’Connor, Llewellyn-Thomas, Sawka, Pinfold, To, & Harrison, 1997), and increasing patient satisfaction (Hinds, Streater, & Mood, 1995; Mills & Sullivan, 1999). However patients may have difficulty in processing and retaining a large amount of information and/or they may find the information too complex to understand. Evidence indicates that a significant number of patients are not entirely aware or are completely unaware of important factors associated with their treatment (Craft, Burns, Smith, & Broom, 2005; Olver, Turrell, Olszewski, & Willson, 1995). A limited or lack of knowledge of medical information does not allow patients to make informed choices. It may also impact on the physicians who may not feel comfortable that the patients do have knowledge of the information. In addition, it may deem patients ill-equipped to make the psychological adjustment necessary for their treatment, and may also lead to other major consequences. For instance, although strictly advised against for medical safety, cancer patients may become pregnant during chemotherapy treatment due to a lack of knowledge. Similarly patients who are not aware that having a heart problem can be a complication of a treatment may not know the course of action to take if such signs occur.

There are several reasons that patients may not have knowledge of the information given. One of the reasons may be that patients, once given their diagnosis, may be psychologically distressed and therefore unable to absorb the information given to them (Hogbin & Fallowfield, 1989). Age related cognitive changes may also impact on patient knowledge as may communication barriers between the patient and the physician possibly as a result of substandard communication skills training (Fallowfield & Jenkins, 2006). Similarly it has been suggested that cognitive dysfunction due to the treatment may also lead to a lack of recall of important information during and after treatment (Olin, 2001; Tannock, Ahles, Ganz, & van Dam, 2004).

There are several approaches that have dominated the field of research to address the issue of lack of knowledge of the procedural or treatment information given. This includes the use of
strategies to improve the format in which the information is provided to patients. There are a number of vehicles of information delivery that have been evaluated and these include:

- Video recordings (Everett, Novoseletsky, Cole, Frank, Remillard, & Patel, 2005; Street, Voigt, Geyer, Manning, & Swanson, 1995)
- Written information in various formats (Bruera, Pituskin, Calder, Neumann, & Hanson, 1999; Damian & Tattersall, 1991; Rees, Ford, & Sheard, 2003; Sepucha, Belkora, Tripathy, & Esserman, 2000; Tattersall, Butow, Griffin, & Dunn, 1994)

The second approach is to identify the patients’ information needs, perceptions, and preferences to ultimately improve the quality of informed consent. The aim of such research is to guide researchers to approaches that may improve treatment information given to patients. Exploratory studies have measured patient information needs regarding therapeutic procedures at one or more time points, often in the form of questionnaires containing treatment relevant items. Patients indicate the importance of each item listed with item examples including medical test results, dealing with an emergency, duration of treatment, management of treatment side effects, precautions, and diet (Iconomou, Viha, Koutras, Vagenakis, & Kalofonos, 2002; Rees & Bath, 2000). If patient information needs are met, in view of legal and ethical requirements of informed consent, their knowledge of the information given may be positively influenced.
A third approach to improve the way information is given in order to improve patient knowledge is effective communication between doctors and patients. Good communication is believed to lead to increased patient knowledge, which in turn results in better adherence to treatment, increased patient satisfaction, decreased anxiety, and the decreased likelihood of litigation (Fallowfield, 2008).

Delivering treatment information in an appropriate and timely manner can be difficult with time pressures and patient numbers leading to short consultations in which there may be an information overload. Physicians may also overestimate the level of patient knowledge of treatment information resulting in dissatisfied or confused patients, which can create problems, as patients need to be clear about the benefits and risks before consenting to a medical treatment. Therefore improving communication skills of physicians may improve patient outcomes including knowledge of the information given about their diagnosis, prognosis, and/or treatment. There have been many developments in providing communication skills training for physicians which suggest that communication skills can be taught and if taught well, the effect is seen in the clinic (Dimoska, Butow, Dent, Arnold, Brown, Tattersall, et al., 2008; Fallowfield, 2008; Fallowfield & Jenkins, 2006; Gysels, Richardson, & Higginson, 2004).

One concept that has been overlooked in the previous strategies, in reference to complex treatment that occurs over time, is that patients may need to experience elements of the treatment in order to take in and understand some of the necessary information given at the time of consent. Therefore, one fundamental question that remains to be answered is whether patient knowledge of the information given at the time of consent naturally improves with experience of the treatment. Although such a finding would not help improve the process at the time of consent, it would influence both researchers and clinicians in the way informed consent to complex treatment is conducted and assessed. Put simply, it may show that although poor knowledge and understanding of consent information does occur, repeating and layering necessary information over time may be sufficient to (1) ensure that patients know and understand what is happening and what to expect, (2) ensure that clinicians have provided
the best information they can to patients, and (3) ensure that legal and ethical obligations are better met.

Informed consent in oncology is especially important because treatment decisions balancing potential life-saving efficacy with serious side effects have a great impact on life and its quality. The oncology setting is a relatively broad and complex area for conducting psycho-social research. There are several reasons for this including the numerous types of known cancers for which psycho-social research on informed consent needs to be explored. Secondly, the sensitive nature of cancer at the patient level, and the physical and psychological wellbeing of patients that research deals with can be problematic. The lack of patient knowledge of the information given about the treatment they are undertaking may diminish their ability to manage their condition and the inevitable side effects. In addition, with the ever increasing research on cancer, many advances have been made regarding cancer detection and treatment and thus, cancer patients are surviving for longer periods of time. This makes the informed consent information very relevant for knowledge of any late side effects or complications that may occur in the time post-treatment. Consequently patients have to live with the experience of their treatment for many years thereafter which highlights another factor that makes informed consent in the oncology area a key process. As such, informed consent may impact on patient satisfaction and quality of life post-treatment.

**Purpose of the thesis**

This thesis, based on psycho-oncological theory and methodology, is composed of two distinct literature reviews, one longitudinal quantitative study, and one qualitative study aimed at investigating the impact of the experience of chemotherapy treatment in addition to standard pre-treatment information on patient knowledge of chemotherapy information. In other words, does a patient’s experience of having treatment help them to improve their knowledge of the important information given to them at the time of consent? If it is not possible to fully inform patients about their chemotherapy treatment prior to their commencement, as much of the literature suggests, this dissertation aims to explore whether patients eventually acquire the
requisite information with experience. The experience of patients that occurs during their chemotherapy treatment (over the course of several cycles) may take the form of many things including education, the acquisition of knowledge over and above the standard information given pre-treatment, and communication with the health care professionals, among other things. If the experience of chemotherapy treatment increases patient knowledge of the vital information, it implies that patients can take better control of the risks and side effects associated with their treatment. It may also reassure physicians to know that patients will have improved knowledge of the consent information with experience, if they showed poor understanding at the initiation of treatment. Therefore this thesis aims to explore this novel concept in the following format: the remainder of Chapter One focuses on the purpose of informed consent, its elements, and the history from which it originated. This research relates to informed consent to non-surgical treatment even though it is recognised that the literature on informed consent covers consent to medical treatment as well as experimental studies such as clinical trials for new drug treatments, as discussed further in this chapter.

Chapter Two outlines the societal burden of breast and colorectal cancer. The current research focuses on early stage breast and colorectal cancer for a number of reasons. Firstly, early stage breast and colorectal cancer patients undertake similar modalities of treatment, for example, adjuvant chemotherapy to eliminate micrometastatic disease is used with local treatments such as surgery or radiotherapy to improve cure rates. In addition, breast and colorectal cancer constitute a large proportion of cancer patients as a whole, making research findings generalisable to a large population. Also, a large portion of research undertaken in the area of informed consent has been carried out with breast and colorectal cancer patients, hence making this research comparable to previous work. This research evaluates whether patient knowledge improves in breast and colorectal cancer patients undergoing adjuvant chemotherapy. Patients undertaking adjuvant chemotherapy are generally in a reasonable physical and psychological state to participate in a longitudinal study. Therefore, in Chapter Two, the impact of chemotherapy treatment on these patients and its potential side effects is discussed.
Specific to the interests of this thesis, two literature reviews were conducted as shown in Chapter Three and Four. Chapter Three reports a literature review that was conducted on studies assessing tools (often format modifications) implemented for delivery of consent information and their effectiveness in improving the informed consent process pre-treatment. A second literature review is presented in Chapter Four focusing on studies conducting longitudinal research to identify the impact of treatment experience, if any, (rather than the use of tools) on patient knowledge. The chapter also highlights several demographic and psycho-social variables that were assessed in the studies and their impact on patient knowledge.

Chapter Five further elaborates on the demographic and psycho-social variables outlined in Chapter Four but also outlines further novel psycho-social variables that have been overlooked in the literature so far that may impact on patient knowledge. Chapter Six summarises the gaps in the literature identified in Chapters Three, Four, and Five and provides a rationale for the current empirical studies. This evaluation highlights the necessity for an empirical examination into what impact the overall experience of chemotherapy has on patient knowledge of information given regarding chemotherapy treatment. It also underlines the necessity for assessment of novel measures that may impact on patient knowledge of information given. Furthermore in this chapter, the aims of the empirical studies are outlined using a psycho-oncological perspective, as commonly taken in the field of informed consent research. This includes a detailed rationale for the selection of the design and psychological methods.

Chapter Seven and Eight form the empirical component of this thesis. Chapter Seven reports on the approach and results from a longitudinal, quantitative investigation in 71 breast and colorectal cancer patients measuring the impact of chemotherapy treatment experience on patient knowledge of consent information. In addition, results of changes to patient satisfaction, trust for the physician, and social support with the information are presented as are the findings of the impact of certain demographic or psycho-social variables believed to impact on patient knowledge. In Chapter Eight, an account of the qualitative component of the research conducted on a subset of the original sample is given including the findings drawn
from the thematic analysis undertaken. Finally, Chapter Nine summarises the findings from the series of reviews and empirical studies, and highlights directions for future research.

**Informed consent**

Informed consent, as briefly defined above, is the patient’s decision to undertake a preventative, diagnostic, or therapeutic procedure when the patient has all of the requisite information, understands it, has had time to deliberate, and is free from coercion. Obtaining a patient’s informed consent is a mandatory process required by patients undergoing any medical test or procedure such as mammography screening for breast cancer or treatment like chemotherapy. The definition of an informed decision appears simple in theory but is complex in operation.

**History of Informed consent**

**Medical treatment consent**

The history of informed consent originates from the practice of Hipprocates. Hippocratic medicine was based on benevolent paternalism where the idea was to disclose as little as possible as it was considered harmful. The aim was to benefit the patient and to avoid harming them. Teuton and Taylor (2001) cited a quote from Hippocrates regarding treatment consent: “..Perform your medical duties calmly and adroitly, concealing most things from the patient while you are attending to him….” (p. 894, Teuten & Taylor, 2001).

Following this, in the eighteenth century, Benjamin Rush, an American physician, who later became a professor in medical theory, believed that patients should be educated to the point that they could understand and comply with the physician’s recommendations. In 1786, Rush stated “Yield to patients in matters of little consequence, but maintain an inflexible authority in matters essential to life” (p.65; Faden & Beauchamp, 1986).

More than a decade later, Thomas Percival, an English physician, published ‘Medical Ethics’ in which he claimed (as quoted in Thomas, 2001):
‘To a patient who makes enquiries which, if faithfully answered, might prove fatal to him, it would be a gross and unfeeling wrong to reveal the truth. His right to it is suspended and even annihilated.’ (p. 8). Percival felt that beneficent deception for the purpose of protecting the hope of the patient was a prior duty to truth (Thomas, 2001). In 1847 the American Medical Association (AMA) adapted its code of ethics to follow Percival’s ethical code of conduct. Today, this is known as therapeutic privilege.

In the history of informed consent there have been two landmark cases that have essentially defined the informed consent process. The first of the two, previously mentioned, occurred in United States in 1914: Schloendorf vs. Society of New York Hospital tried before Justice Benjamin Cardozo. In this case, the ‘right of self-determination’ was used to justify enforcing the requirement for obtaining consent from the patient. In other words, the freedom to determine one’s own act. Forty three years later, the second landmark case: Salgo vs. Leland Stanford, Jr. University saw the first use of the term informed consent. In this case, it was apparent that the physician failed to provide necessary information beyond the basic nature of the procedure, hence the case focused not merely on whether consent had been given but whether the patient had been adequately informed (Syse, 2000). The decade to follow saw the emerging sense of duty to disclose appropriate information to patients and to obtain consent for treatment. The legal doctrine of informed consent communicated this concept to the medical community. By 1970 most physicians were recognising both a moral and legal duty to provide informed consent for procedures. Evidently, patients and their families have become increasingly responsible partners in their healthcare.

As it stands today, the definition covers legal, ethical, and clinical factors and needs to be appreciated as a process involving the patient and the health care provider, rather than the outcome of signing a form. This process has been recognised as comprising five fundamental elements (1) disclosure, (2) competence, (3) understanding/comprehension, (4) voluntariness, and (5) consent (Beauchamp & Childress, 2001; Milton, 2000). Figure 1 visually represents the informed consent process and its components. The clinical, ethical, and legal implications will be discussed within the five elements that structure the informed consent process.
Figure 1: Flow diagram detailing the process of informed consent for medical treatment

**CONSENT PRE-CONDITIONS**

- Adult patient
  - Competent patient
    - Patient given adequate information
      - Yes
        - Patient understands all treatment aspects
          - Yes
            - Treatment initiation
          - No
            - Patient decision to consent/refuse absent of external influences
              - Yes
                - Alternative process
              - No
                - Further clarification
                  - Authorisation by signing consent
                    - Yes
                      - Treatment initiation
                    - No
                      - Refuse treatment
                        - Alternative procedures
  - Non-adult patient
    - Parental/Paediatric consent
      - Yes
        - Surrogate consent
        - No
          - Seek more information
Disclosure

In order to make a decision whether or not to undertake treatment, the patient requires adequate information disclosure including the risks, benefits, and alternatives to the proposed treatment. The standard legal procedure involves the health care provider’s *a priori* duty to inform patients about all aspects regarding the procedure (e.g., surgery) or therapy (e.g., chemotherapy, radiotherapy) to be undertaken (Bernat, 2001). The information that health care providers are legally required to give patients prior to treatment or surgery has been debated for several decades. Essentially, the requirement is to disclose ‘material’ (significant) information that is likely to influence the patient’s decision when making an informed choice. There are two known forms of material information which the law has presented (Studer, 1987)

- **The professional point of view:** the health provider's responsibility is limited to the disclosures that a health professional practicing in your community would make under the same or similar circumstances.

- **The patient's point of view:** the health provider is required to disclose all facts, risks, and alternatives that a reasonable person in the patient's situation would consider important in deciding to have, or not to have, a recommended treatment.

Regardless of the type of information disclosure, it is duty of the health care professional that in addition to the disclosure explained above, to provide specific information that the patient may request and clarify any questions which may be asked.

The landmark case of *Roger vs. Whitaker* in Australia in 1992 confirmed that Australian courts would not be bound by common professional practice, that is, the first of the two forms of material information stated above. The question in this particular case was whether an ophthalmic surgeon should have warned his patient of the one in 14,000 chance of a complication, sympathetic ophthalmia (blindness in the other eye) and subsequent risk of total blindness, arising from a proposed procedure. The High Court declared that it was the doctor’s duty to warn his patient of this remote risk because it may have materially influenced her decision as to whether to have the procedure.
The following statement was made by the joint judgment of the majority of the court and was to be considered as the standard to be adopted by doctors when advising patients of risk (McPhee, 2002).

The law should recognise that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient’s position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it. (p.114)

This stems from the recognition that ultimately patients have the choice to undergo a procedure as they will have to shoulder the risk. This will be discussed further in the section on voluntariness. Although, the information given to the patient is the key issue in any consent process, there are other aspects that need to be fulfilled before it is considered a valid consent process. The requirement for informed consent has also shifted from just providing the information to ensuring that the patient has understood the information.

**Competence**

Competence is one of two necessary pre-conditions in the informed consent process because in clinical practice, the informed consent doctrine allows for shared decision making. While the physician contributes information about medical treatments or procedures, patients interpret the recommendations with their health care and values in mind. Competence for decision making is comprised of several elements, including the ability to comprehend the information, appreciate the nature of the situation, the ability to weigh the options rationally, and finally to communicate the choice (Grisso & Appelbaum, 1998). The patient is considered incompetent when he or she is not able to comprehend the risks and benefits of the proposed treatment due to temporary or permanent mental or physical limitations and as a result is unable to provide consent (Cohn & Azzara, 1998).
Some patients undertaking treatment do lack the capacity to make an informed decision whether to consent to or refuse the proposed medical treatment. In these situations, there is the requirement that someone aid in their decision-making process. This is known as surrogate consent. In this case, health professionals should communicate in the same manner as they would have done with the competent patient. The legally recognised surrogate for the patient is initiated when the patient loses decisional capacity. It is the right and duty of the patient to choose a surrogate decision maker, also known as durable power of attorney, whom they trust and believe will make decisions that are of the best interest to the patient, hence understanding the patient’s health goals and treatment preferences. Some jurisdictions invoke a neutral body to consent for the patient, such as the Guardianship Board in South Australia (Office of the Public Advocate, 1997). This is due to the potential for surrogates to have their own interests, such as relatives desiring early access to their inheritance, and hence put these before the interests of the patient.

In the case where the patient has lost capacity prior to appointing a surrogate decision maker (in jurisdictions that allow this), it seems logical to refer to the close relatives of the patient as they would best know the patient’s preferences. Nevertheless, the law behind this also varies across countries and even jurisdictions (NHMRC, 2005). There are three standards with regards to determining the process of surrogate consent. These will however not be discussed as the interest of this thesis is in circumstances where patients’ informed consent is given without the need for a surrogate.

In Australia, patients under the age of 16 years undertaking a medical procedure require the consent of a parent or guardian as they cannot legally consent independently. This is known as paediatric consent. In this situation, there is the requirement for the minor’s ‘assent’ or ‘dissent’, where possible, in addition to the parent or guardian’s permission. Therefore in the case of adolescents, physicians are required to discuss components of the medical procedures with adolescents, in the presence of their parents or guardians. Different countries or even states may have different laws with regards to treatment of children. In South Australia, a medical practitioner may administer medical treatment to a child, which is defined as a person under the age of 16 years (Government of South Australia, 2004) if:
• the parent or guardian consents; or
• the child consents and
  o the medical practitioner who is to administer the treatment is of the opinion that the child is capable of understanding the nature, consequences, and risks of the treatment and that the treatment is in the best interest of the child's health and well-being; and
  o that opinion is supported by the written opinion of at least one other medical practitioner who personally examines the child before the treatment is commenced (p.8)

**Comprehension**

Comprehension is defined as the ability to understand the meaning or importance of something (or the knowledge acquired as a result). Therefore, in the context of the consent process, in order to trade off the survival benefits and side effects of adjuvant treatment, patients must have knowledge of the information that has been disclosed. Similarly, patients must retain the information regarding side effects of treatment in order to be able to manage or even prevent them from occurring or have knowledge of the treatment options if they do occur. For example, if a patient about to undergo chemotherapy treatment is told that fertility may be compromised, the patient should know what this statement entails. This example highlights that a lack of comprehension, is foremost, a problem affecting the patient.

In studying the literature on patient knowledge of the information given, an inconsistency was identified in both the use of the term ‘knowledge’ and the complexity with which it was measured. An array of terms have been used interchangeably in the literature to refer to knowledge of the information given. These include but are not limited to understanding, comprehension, memory, recall, and recognition. Each of these terms, while related to the term ‘knowledge’ have different meanings, in some cases varying only slightly, while in others quite vastly. There is no single agreed definition of any of these related terms however some definitions are presented below.
The Oxford English Dictionary defines knowledge as:

(1) expertise and skills acquired by a person through experience or education; the theoretical or practical understanding of a subject, (2) what is known in a particular field or in total; facts and information or (3) awareness or familiarity gained by experience of a fact or situation (paragraph 1, Wikipedia, 2010a).

The term knowledge is also used to refer to the confident understanding of a subject with the ability to use it for a specific purpose, if appropriate. Knowledge acquisition involves complex processes: perception, learning, communication, association, and reasoning [http://en.wikipedia.org/wiki/Reasoning](http://en.wikipedia.org/wiki/Reasoning). Similar to this is the term comprehension which is the ability to understand the meaning or importance of something (or the knowledge acquired as a result).

Understanding is complex to measure so is not often assessed in research. To date, no standard definition of understanding has been made nor has there been any agreement on how to accurately measure it. Understanding is believed to be a psychological process related to an abstract or physical object, such as a person, situation, or message whereby one is able to think about it and use concepts to deal adequately with that object (paragraph 1, Wikipedia, 2010b). In order to understand, one must receive, encode, retain, and process the information (p. 596, Dunn & Jeste, 2001).

Measured more commonly in research is recall – that which represents the recollection of memory. There are two types of recall including free recall where no clues are given to assist retrieval. An example would include asking someone to remember a list of items they had previously read without showing them the list again, or giving them hints about the items contained in the list. For example, Olver, Whitford, Denson, Peterson, and Olver (2009) refer to measuring recall of informed consent information in their study of a CD-ROM format modification. These authors have measured recall using this most superior method of free recall where patients were not guided in their responses to questions, rather the questions were open-ended so patients have to retrieve all the information from the back of their minds (Olver, Whitford, Denson, Peterson, & Olver, 2009).
**Cued recall** is a less difficult process, referring to when some clues are given to assist retrieval (also known as prompted recall). Recalling is a requisite to understanding but does not imply understanding. In the study by Layton and Korsen (1994), written warnings were compared with verbal warnings to improve patient recall of the information. A structured interview was conducted to ask about warnings however patients were prompted for the answers therefore this method of assessment would be considered cued recall (Layton & Korsen, 1994). As can be seen, in comparison to free recall, prompted recall requires less complex processes.

Lastly, **recognition** is the ability to identify something previously seen, heard, or known. Recognition is considered inferior to the ability to recall as it involves heavily prompting memory retrieval. For example, for a patient to recognise what side effects they had previously been informed about from a written list is much easier than to recall the side effects freely. For example, Langdon, Hardin, and Learmonth (2002) conducted a large randomised controlled trial, considered the gold standard research design, to measure whether written information improved recall of the consent process. Although the authors reported recall to be assessed by 11 multiple-choice questions, each with three options, this was actually indicative of assessing patients’ recognition as the patients could see the correct answer amongst the incorrect ones (Langdon, Hardin, & Learmonth, 2002).

Measures for recall or understanding cannot often be standardised in research as they are made to assess something that is specific to a study. Therefore there is lack of validated assessment tools in the literature dedicated to assessing knowledge of consent information. Despite this lack of a standardised means of measuring these factors, difficulties in patient knowledge have been widely researched. Although many studies wish to measure knowledge or understanding, what they actually measure is recall and/or recognition. Although, from the definitions it is clear that neither recall nor recognition completely imply knowledge, they are less complex to measure and give some indication of a person’s knowledge. In other words, they act as a surrogate measure of knowledge. In this study, the term knowledge was purposefully chosen. Knowledge, defined previously as, ‘experience of a fact or situation and also expertise and skills acquired by a person through experience or education’ (paragraph 1, Wikipedia, 2010)
can be related to the information acquired through chemotherapy treatment. Specifically, patients are firstly given the necessary information for gaining informed consent to chemotherapy treatment using a standard written information sheet and consent form. The physician and the nursing staff attempt to clarify this important information to help patients make an informed decision about whether to have the treatment or not, a kind of educative process where interaction takes place between the parties. This initial consent information may be recalled by patients in the future without necessarily comprehending it. However, the experience of having the chemotherapy itself, together with the initial education, is believed to constitute knowledge.

Consistent with most previous research, the empirical research forming this thesis has also used recall as a measurable surrogate for an aspect of knowledge. Free recall was believed to be the most superior surrogate of knowledge (compared to recognition) as it is involves retaining and freely bringing back the information from one’s mind without any prompting. It is believed that the longitudinal nature of the study captures the impact of patients’ experience of the treatment. Therefore, in this study, knowledge is defined as a patient’s ability to free recall the information given at the time of consent following some experience of the chemotherapy treatment. As, previously mentioned, the experience of patients that occurs during their chemotherapy treatment (over the course of several cycles) may include such things like education, the acquisition of knowledge over and above the standard information given pre-treatment, and communication with the health care professionals. Therefore any reference to treatment experience in this thesis relates to the definition outlined here.

Knowledge can be gained by different means: incidental, accidental, and purposeful. Incidental knowledge may arise from watching television or reading the newspaper, an activity which may have not been planned. Accidental knowledge comes about in the course of doing something else such as catching up with a friend who happens to be diagnosed with cancer. These two factors will no doubt impact on the knowledge of patients in this study and in any other study as they are hard to identify and eliminate. The most common form of knowledge is purposeful, that is the focus is cancer information and learning is active in accessing information.
This research is interested in knowledge gained from both the information given as part of the informed consent process and from the experience of chemotherapy treatment. Therefore the type of knowledge that is of interest in this study is purposeful, as recall of the information specifically given on the information sheet and consent form is being assessed. However the knowledge captured in this study is incidental, accidental, and purposeful as it is not possible to separate purposeful knowledge from the knowledge patients gain incidentally or accidentally.

**Voluntariness**

Voluntariness is where a decision is based on no coercion and the patient is free to accept or reject the advice. This stems from the principle of respect for patient autonomy which underpins the requirement for valid consent to treatment. Two philosophers who influenced the current explanation of respect for autonomy were Immanuel Kant and John Stuart Mill who both agreed on its moral importance. Kant believed that respect for autonomy stems from the recognition that everyone has unconditional value thus each having the capacity to determine his or her own moral destiny. Mill was focused on individuals being liberal making them develop and be happy but also benefiting society as a whole (Beauchamp & Childress, 2001) (Brazier & Lobjoit, 1991). Autonomy acknowledges the right of ‘self-determination’ as was identified by Justice Cardozo in 1914, in the case of *Schloendorf vs. Society of New York Hospital* in which a surgeon failed to obtain consent for a hysterectomy ("Schloendorff v. The Society of the New York Hospital, 105 N.E 92," 1914).

Cardozo stated that:

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages (p.93).

Although this is a valid statement, in practice, the majority of people cannot always make completely autonomous choices, especially in situations such as that of undergoing treatment. While some may autonomously decide to forgo information and allow the treatment decision
to be made by the doctor, others may not be able to decide due to the inability to understand and evaluate the options in order to make a choice. Evidently, autonomous decisions become more difficult and often are less likely to occur when the choice is complex and may be life altering. The autonomous decision becomes increasingly challenging, the more impaired our ability to understand. Although, health professionals are required to endeavour to ensure patient autonomy, this can be difficult as patients may see this act as implicit coercion and impeding valid informed consent. Therefore the ethical principle of beneficence and nonmaleficence as well as the fiduciary principle become significant factors in informed decision making. Beneficence refers to an action that benefits others while non-maleficence is the obligation not to inflict harm on others. Medicine is based on non-maleficence because beneficence may be too hard to achieve not so much in being able to do some good but having to do limitless good. The Fiduciary principle focuses on the significance of the patient-physician relationship of trust. This is essential when psychiatrists take action on behalf of the patient to benefit them and maintaining respect for the autonomous decision of the patient (McMurray, 2002).

**Consent**

This last element involves patients giving written authorisation that they understand all of the components of the procedure they are undertaking and wish to go ahead with it. Apart from the situation with incompetent patients previously discussed, there are three exceptions to this rule; (1) in emergency settings, where patients are not capable of giving informed consent and who do not have a family member or guardian who is legally authorised and willing to make this important decision on their behalf, (2) therapeutic privilege, which may happen if the doctor believes that information disclosure will be detrimental to the patient’s health, and (3) waiver, where patients may waive the rights to be given information however again, physicians must still explain the basic aspects of the proposed treatment and patients may still be required to sign a consent form. These patients may receive treatment without consent (Bernat, 2001; McMurray, 2002).
Each country or even jurisdiction may vary in the regulation of consent to emergency medical treatment. The following outlines the legislation act in South Australia (Government of South Australia, 2004):

A medical practitioner may lawfully administer medical treatment to a person (the patient) if—

- the patient is incapable of consenting; and
- the medical practitioner who administers the treatment is of the opinion that the treatment is necessary to meet an imminent risk to life or health and that opinion is supported by the written opinion of another medical practitioner who has personally examined the patient; and
- the patient (if 16 years of age or over) has not, to the best of the medical practitioner's knowledge, refused to consent to the treatment.
- if the patient is a child, and a parent or guardian of the child is available to decide whether the medical treatment should be administered, the parent's or guardian's consent to the treatment must be sought but the child's health and well-being are paramount and if the parent or guardian refuses consent, the treatment may be administered despite the refusal if it is in the best interests of the child's health and well-being. (p. 8).

Clearly, the key point in this regulation is that if the physician is aware of any valid advance refusal, there should be respect for patient autonomy. In addition, the patient should be made aware of what has been done, and why, as soon as they have recovered (General Medical Council, 1998).

**Informed consent: constraints**

There are a number of constraints to the process of informed consent and consequently the value of the consent process remains a highly debatable yet important topic in medical practice. These debatable issues evident in the large and complex body of research include the following:
**Full disclosure of information**

The impracticable nature of being able to give complete information disclosure is exemplified by the case where there may be long-term risks of a new method of treatment that may not be known. With respect to such consent, health care providers need to ensure that patients are aware of the potential for unforeseeable events to occur. This limitation is rarely encountered in common medical treatments, however may be apparent with medical treatment research such as with a new cancer drug where patient volunteers are involved.

**Patient preference in taking a passive role in decision making**

After the changes in the nature of medical practice since the eighteenth century, there has been a shift from basic informed consent which was considered to be solely a legal requirement to what is now commonly referred to as informed choice or informed decision-making. This transition has meant that patients are encouraged to participate in decision-making and this involvement is based on being given full information together with effective communication between health professionals and patients (Fallowfield & Jenkins, 1999; Gysels et al., 2004). Many studies have been conducted on what patients believe that information consists of and studies showed that cancer patients desire similar information, regardless of cancer type (Beaver, Bogg, & Luker, 1999; Davidson, Brundage, & Feldman-Stewart, 1999; Gaston & Mitchell, 2005). This information has included cure, spread of disease, treatment options, side effects, and survival. However, Gaston and Mitchell (2005) found that while information needs may be similar across patients with different cancer types, variability may be evident for decision-making preferences.

A recent study examined decision-making preferences for gynaecological cancer patients and compared the finding to previous work involving breast and colorectal cancer patients (Beaver & Booth, 2007). Amongst 53 gynaecological cancer patients, almost half preferred a passive role (47.2%) followed by one third preferring a shared role (32.1%). Previous research reported that breast cancer patients were more likely to want to participate than colorectal cancer patients (Beaver et al., 1999).
Regardless of the differences across the patient groups, all three preferred a passive followed by a shared role in decision-making (Beaver & Booth, 2007). There may be other factors that impact the decision-making preferences of patients such as age (Pinquart & Duberstein, 2004), status of the disease (Butow, McLean, Dunn, Tattersall, & Boyer, 1997) and the sex of a patient (Salkeld, Solomon, Short, & Butow, 2004). Patient autonomy gives the patients the right to decide not to be informed, that is, waive the right to receive the information. This process is legally valid just as long as the physician ascertains that the patient does not want the information, rather than not disclosing it.

**Health professional disbelief in informing patients**

Only a minority of health care professionals oppose the ideas of valid informed consent and patient autonomy. While some still believe in Hippocratic traditions in that there may be harmful effects of informing patients, others believe autonomy is only valuable in healthy minded and educated patients (Wear, 1998).

**Complete patient knowledge of the information**

The shift from the passive to the active role of the patient, discussed above, has changed the view of consent from an emphasis on the process of obtaining consent to one where the quality of the patient’s knowledge of the information has become paramount. Nevertheless, complete patient knowledge of the information given appears to be unattainable in some cases. Evidence indicates that patients have poor recall and understanding when they have been questioned about the information given (Cassileth, Zupkis, Sutton-Smith, & March, 1980; Muss, White, Michielutte, Richard, Cooper, Williams, et al., 1979). In any health care setting, the patient’s lack of knowledge of a procedure that will be, or has been conducted on them, may have minor and major implications. A closer assessment of these implications will be carried out in the next section and will concentrate on the oncology setting as this is the focus of this thesis.

**Research participant consent**

The informed consent process not only plays a role in considering a particular procedure or treatment but also in research as in participation in clinical trials. International recognition of
the research consent process dates back to the time when Nazis forced concentration camp prisoners to serve as participants in extremely harmful and often lethal experiments. The court responsible for convicting the German doctors and scientists laid down a set of principles of informed consent for future research involving human subjects. This procedure emerged in 1947 and is known as the Nuremberg code (Appendix A). This together with the 1964 declaration of Helsinki by the world medical association formed the first record of guidelines set out for informed consent (Shuster, 1997).

Informed consent for research has been developed from the necessity to protect individual participants’ rights even though the participant is contributing towards research that may significantly impact on improving global health and future practice, making it a highly significant process. Several authors have reported that individuals who have given their informed consent do not fully understand their rights as participants or the methods of their treatment allocation in trials (Heitanen, Aro, Holli, & Absetz, 2000; Harth & Thong, 1995; Williams, French, & White, 2003).

**Research versus medical treatment consent**

The literature covers research on informed consent issues associated with both consent to research and medical treatment, however while there are similarities between the two, there are also distinct differences between these situations and this has been noted by several authors (Appelbaum & Roth, 1982; Taub, Baker, & Sturr, 1986). The difference lies in the additional elements that accompany informed consent to research including explanations of the study nature and purpose, any benefits and risks involved, but also patient appreciation that the study outcomes are not clear. In the research setting, patients need to comprehend the difference between individualised treatment and research protocols such as the occurrence of random allocation, the fact that placebos may be given and most importantly, participants taking part in research are not guaranteed that their involvement will benefit them, but may benefit future patients. These are key factors that are additional to treatment consent and need to be understood by the patient.
Research into improving the informed consent process for treatment or research have addressed similar issues and assessed similar strategies such as modifications to written information, and computer-based and audio-visual presentation of the information. Studies assessing informed consent to research may also focus on improving participant recruitment rates (Mapstone, Elbourne, & Roberts, 2007). In this thesis, studies in both treatment and research settings will be reviewed. However the main aim of the empirical studies in the thesis is to concentrate on informed consent to chemotherapy treatment in breast and colorectal patients.

**Summary**

To summarise, in the past, giving information to patients was regarded as a simple process and patients did not question aspects of the consent process once the doctor suggested specific treatments. With the increasing emphasis on self-determination of the patient, there was an obvious change in the patient-doctor relationship from paternalism to respect for patient autonomy. This change affected the importance of several factors, the legal pressures of obtaining informed consent being prominent. This meant that the quality of the information provided as well as patient understanding of such information became paramount. As a result, a substantial increase in research in this area surfaced and ways to improve the quality of the information and its impact on patient outcomes such as patient knowledge, dominated the informed consent literature and continues to do so. While much of the research has focused on assessing novel interventions on information provision aimed at improving patient knowledge, there is scant research assessing the impact of treatment experience in addition to the pre-treatment education on patient knowledge which forms the primary aim of this research.

The next three chapters will delve into the foundations that form the empirical studies in Chapters Seven and Eight. This includes the provision of information regarding breast and colorectal cancer burden of disease, benefits of adjuvant chemotherapy as a treatment option, and side effects of adjuvant therapy. Subsequently, two literature reviews present evidence on different approaches aimed at improving patient knowledge of the information given for the informed consent process and effectiveness, if any, of the methods.
Chapter 2: Cancer and its medical context

Cancer was identified as one of the national health priority areas, in 1996, due to its impact in Australia with regards to morbidity, mortality, and costs (Department of Health & Ageing, 2005). Eight priority cancers were identified: lung cancer, colorectal cancer, melanoma, non-melanocytic skin cancer, prostate cancer, breast cancer, cervical cancer, and non-Hodgkin's lymphoma. Amongst these, the most frequently occurring cancers in men and women combined are colorectal cancer followed by breast cancer, although this excludes non-melanocytic skin cancer which is not a notifiable cancer, hence accurate incidence data is not available (Australian Institute of Health and Welfare (AIHW) & Australasian Association of Cancer Registries (AACR), 2004). This chapter will give an overview of the epidemiology of breast and colorectal cancer. The burden of disease in Australia resulting from these two cancers will also be discussed.

Definition of cancer

Cancer comprises a collection of diseases related to changes or mutations in genes. These mutations lead to abnormal proliferation of cells and may develop in the many different tissues in the body. Other terms for cancer include neoplasm or tumour however these are also referred to as non-cancerous growths. Tumours can be qualified as benign\(^1\) or malignant\(^2\) growth. Although the different cancers have common characteristics, they each have their own specific profile consisting of risk factors, severity levels, treatment options, and survival rates (Olver, 1998).

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\(^1\) Benign tumours do not invade surrounding tissues and do not spread to other parts of the body.
\(^2\) Malignant tumors possess the ability to invade adjacent tissues and spread distantly (metastasis).
Breast cancer

Breast cancer usually develops in the breast tissue, either in the cells that line the breast ducts (ductal cancer) or lobes (lobular cancer; NHMRC, 2001). Breast cancer is at an early stage if it is confined to the breast and axilla only. This disease is predominantly found in women. Many factors have been identified as possible contributors to its development. They include age (in particular over the age of 50 years), race, socioeconomic status, family history, previous breast cancer in the same individual, and exposure to female hormones (NHMRC, 2001).

Incidence and mortality

Breast cancer is the most common cancer in women in Australia and this is followed by colorectal cancer (excluding non-melanocytic skin cancer [NMSC]; AIHW & NBCC, 2006). The incidence of breast cancer has risen from 80 cases per 100,000 population in 1983 to 117 cases per 100,000 population in 2002. This constitutes an increase of 1.9 per cent per annum in the nineteen-year period (AIHW & NBCC, 2006). In Australia, 11,791 women were diagnosed with breast cancer in 2001 constituting 29.1 per cent of all cancer cases. In males, breast cancer is rare with a total number of 84 new cases in 2002 and 20 deaths in 2004.

The mortality rate of breast cancer in women was 2,641 in 2004 which, among women, is the most common cause of cancer-related death annually as shown in Figure 2 (AIHW & NBCC, 2006). However amongst males and females, it constitutes 7.2 per cent which follows lung cancer (19.4%), colorectal (13.1%), and prostate cancer (7.5%; Australian Institute of Health and Welfare (AIHW) & Australasian Association of Cancer Registries (AACR), 2004). Nevertheless there has been a decline in female deaths due to breast cancer from 1990 which saw an age-standardised rate of 31.0 deaths per 100,000 to 23.4 deaths per 100,000 population in 2004 (Figure 2; AIHW & NBCC, 2006). This is believed to be partly attributable to commencement of the BreastScreen Australia program and the increased use and access to the program, leading to earlier detection of breast cancer. Another contributory factor to the declining death rate is the increased effectiveness of adjuvant therapy. This program will be further discussed later.


**Survival**

Survival rates in females after a breast cancer diagnosis has significantly increased between the four-year periods 1982-1986 and 1998-2002 with five-year survival increasing from 70.9 per cent to 86.6 per cent (Figure 3). This increase was seen across all age groups from 20-29 years to 80-89 years of age. Survival in women in different stages of breast cancer is undoubtedly different however no Australian data is available on this. Data from the United States of America suggests that women in stage 0 and I breast cancer have five-year survival rates of 100 per cent but only 20 percent survival rates in stage IV breast cancer patients (AIHW & NBCC, 2006).
NOTE:
This figure is included on page 28 of the print copy of the thesis held in the University of Adelaide Library.

Figure 3: Relative survival proportions of females with breast cancer, Australia 1982-1986 to 1998-2002
**Colorectal cancer**

The bowel is part of the gastrointestinal tract and is made up of three main components involved in completing food digestion by the absorption of water and nutrients. These three parts consist of the small bowel, colon, and rectum each with specific roles in the digestion of food as shown in Figure 4 (Anonymous, 2007). The colon and rectum form the large bowel hence bowel cancer is often referred to as colorectal cancer, implying cancer of the colon or rectum (NHMRC, 2000).

![Figure 4: Diagram illustrating the colon and rectum](image)

Colorectal cancer is a malignant tumour that originally develops from non-cancerous (benign) growth, or polyp. Cancer occurs in the colon (large bowel) or the rectum and requires many years to develop and may spread to other parts of the body. The majority of colorectal cancers are adenocarcinomas from the gland-forming cells lining the bowel wall which produce and secrete mucus (American Cancer Society, 2007). Several risk factors have been associated with developing colorectal cancer, including the following (American Cancer Society, 2007; The Cancer Council South Australia, 2007)

- personal history of colorectal cancer or polyps or inflammatory bowel disease
- getting older with rapidly increasing risk from the age of 50
- family history of colorectal cancer
- diets that are high in fat and calories and low in fibre
**Incidence and mortality**

In males, colorectal cancer is also the second most common cancer with prostate cancer currently the most common (excluding NMSC). Colorectal cancer resulted in diagnoses of 6,961 new cases in males in 2001 which contributed to 14.6 per cent of all new cancer cases in males (Australian Institute of Health and Welfare (AIHW) & Australasian Association of Cancer Registries (AACR), 2004). Females are also commonly affected by colorectal cancer with 5,883 new cancer cases diagnosed in 2001. This is the second most common cancer diagnosed in women impacting on 14.5 per cent of women in 2001.

Colorectal cancer is the third leading cause of death in both males and females. In males this follows lung cancer and prostate cancer, while in females colorectal cancer is third to breast and lung cancer in mortality rates. There were 2,601 deaths due to colorectal cancer in males and 2,153 deaths in females resulting in 12.7 per cent and 13.5 per cent of cancer-related deaths in males and females, respectively. Similar to breast cancer, there has been an increase in colorectal cancer cases however to a smaller extent with an increase of 0.3 per cent in males over the ten year period from 1991 to 2001 and an increase of 0.1 per cent in females (Figure 5). Mortality rates have also fallen since 1991 as seen in the breast cancer population, with a 1.2 per cent decrease per annum in males from 1991 to 2001 and a 1.6 per cent decrease in females during the same period (Australian Institute of Health and Welfare (AIHW) & Australasian Association of Cancer Registries (AACR), 2004).

**NOTE:**
This figure is included on page 30 of the print copy of the thesis held in the University of Adelaide Library.

**Figure 5:** Age-standardised incidence and mortality rates for colorectal cancer, Australia
Prevention, detection, and treatment strategies

Cancer control programs and tools are often developed to improve three main areas; prevention, detection, and treatment of cancer. Different mechanisms are implemented for the various types of cancer with primary prevention and early detection programs for breast and colorectal cancer focusing on changes in behavioural and lifestyle factors and regular screening tests. Behavioural and lifestyle factors common to both breast and colorectal cancer include: a diet low in fat and high in fibre and vegetables, moderate levels of alcohol consumption, avoidance of smoking, and adequate physical activity. Additionally, late age of first pregnancy (over 30) may be an influential factor in the development of breast cancer (Gerber, Müller, Reimer, Krause, & Friese, 2003; National Cancer Institute, 2007).

Screening is a form of secondary prevention, that is, an early detection mechanism developed for both breast and colorectal cancer. Each of these cancers has different screening methods and these will be discussed below. These screening methods all involved an informed consent process. There has been a vast amount of research on informed consent for screening procedures (Edwards et al., 2006; O'Connor., Stacey, Entwistle, Llewellyn-Thomas, Rovner, Holmes-Rovner, et al., 2003).

Breast cancer screening

In 1990 a program was established in Australia for the early detection of breast cancer, known as BreastScreen Australia which is jointly funded by the Australian state and territory governments. This screening program involves x-rays of the breasts to examine asymptomatic people for any preinvasive or early stage development of the disease. This is called a mammography, which is recommended and provided as a free service biennially for women aged 50-69 years. It is also available for women 40-49 years and over 70 years old who wish to attend. The program provides for screening, follow-up of any suspicious lesions, and diagnosis of breast cancer. The service is available at fixed and mobile units to cater for both urban and rural areas capturing as much of the population as possible. Such provisions in addition to the latest advances in mammographic technology means that there has been, and hopefully continues to be, an increase in screening participation rates. The age-standardised
participation rate has risen from 52.3 per cent in the two-year period 1996-1997, to 56.1 per cent in 2002-2003 (AIHW & NBCC, 2006).

**Colorectal cancer screening**

A screening program for colorectal cancer has been introduced in Australia. During the period from November 2002 to June 2004, a pilot program was conducted for bowel cancer screening using faecal occult blood test (FOBT). This test involved collection of faecal samples, which are used for detection of blood in the faeces. This procedure does not identify whether cancer cells are present but allows for the identification of lesions that bleed. The pilot program aimed to determine the acceptability, feasibility, and cost-effectiveness of faecal occult blood testing as a screening service for bowel cancer. The assessment was shown to be acceptable by the target population as well as feasible and cost-effective in early detection of bowel cancer. Following this, there was commencement of the National Bowel Cancer Screening program in August 2006. Initially people turning 55 or 65 years old between 1 May 2006 and June 2008 who hold a Medicare or Department of Veteran Affairs (DVA) card, as well as those who participated in the pilot program were allowed to attend for screening. The reason for this is to slowly introduce the program and ensure that increased demands for health services such as colonoscopy can be met (The Cancer Council SA, 2007). The second phase of the program commenced on the 1st July 2008 and will offer testing to people turning 50 years of age between January 2008 and December 2010, and those turning 55 or 65 between July 2008 and December 2010. Approximately 1 in 25 people have a positive FOBT and this means further tests such as a colonoscopy is undertaken to investigate the cause of the bleeding (NHMRC, 2000).

Colonoscopy is more complex but the most sensitive and specific process. Prior to the procedure, preparation takes place to empty the bowel and if required sedatives are administered for the process. This involves a colonoscope, an elongated instrument with an attached camera, being inserted into the large bowel for identification of any polyps and if present, they are removed.
Cancer treatment

Lastly, upon development of the disease, there needs to be consideration of treatment options available. The potentially curative local treatment options are surgery with or without radiotherapy.

Additional treatments which may be recommended after surgery to try to prevent relapse are local radiotherapy or systemic treatments which circulate in the blood stream and reach the whole body such as chemotherapy and hormonal therapy. These latter treatments are used also for widespread disease. The choice depends on the type, size, and stage of cancer. Patients should be informed of the risks and benefits of each treatment in making their decisions about therapy (NHMRC, 2001). In addition to this, patients need to be informed about the therapeutic intent including the survival and recurrence rates of the cancer based on the different treatment options available as well as the process that it involves. Equally as important to these factors, in making an educated and rational treatment decision, are the patients’ personal preferences.

Breast cancer treatment is commonly initiated by surgery to remove breast tissue either in the form of lumpectomy, which constitutes removal of a lump of breast tissue or a mastectomy, which refers to removal of all breast tissue including skin and the nipple (NHMRC, 2001). Following surgery, routinely after a lumpectomy, radiotherapy may be conducted. This makes use of radiation to destroy any remaining cells locally. Furthermore, chemotherapy or hormone therapy can be given in addition to surgery and/or radiotherapy and this is known as adjuvant chemotherapy. This mechanism makes use of drugs to destroy cancer cells that may have spread and not have been detected and may help in alleviating the risk of breast cancer recurrence and hence improve survival (NHMRC, 2001).

Similarly, the primary treatment choice for colorectal cancer patients includes removal of the cancer containing part of the intestine by surgery. Likewise, to achieve curative results, surgeons may make use of other treatment methods after surgery such as chemotherapy (NHMRC, 2000). In this study, breast and colorectal cancer patients were undertaking
chemotherapy in addition to surgery or radiotherapy. The type of chemotherapy varied among patients however were all combination of drugs which is discussed in the next section.

**Systemic adjuvant therapies**

Systemic adjuvant therapy includes cytotoxic therapy and hormonal therapy to reduce systemic recurrences and overall mortality. Statistics to highlight these benefits of adjuvant chemotherapy in breast cancer have been identified from a meta-analysis of randomised controlled trials shown in Table 1, and reported by the Early Breast Cancer Trialists’ Collaborative Group (Early Breast Cancer Trialists' Collaborative Group, 2005).

<table>
<thead>
<tr>
<th>Table 1: Adjuvant treatment benefits for breast cancer patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>&lt;50yrs</td>
</tr>
<tr>
<td>50-69yrs</td>
</tr>
</tbody>
</table>

*Combination chemotherapy refers to cyclophosphamide, methotrexate, and fluorouracil or a doxorubicin-containing regimen

Similarly, adjuvant chemotherapy has been found to be beneficial for the treatment of colorectal cancer. Fluorouracil has been the leading agent in the treatment of colorectal cancer for over four decades and has been used alone and in combination with other drugs (Ragnhammar, Hafström, Nygren, & Glimelius, 2001). The standard adjuvant treatment for colorectal cancer in Australia is fluorouracil (FU) plus leucovorin (otherwise known as folinic acid [FA]) and oxaliplatin (André, Boni, Mounedji-Boudiaf, Navarro, Taberner, Hickish, et al., 2004). Recent evidence from a phase III clinical trial has suggested that the addition of oxaliplatin to FU/FA improves the efficacy of adjuvant treatment (André et al., 2004). The multi-centre trial involved 2,246 patients with Stage II and III colon cancer and compared oxaliplatin 5FU/LV (n = 1,123) with infusional 5FU/LV alone (n = 1,123). The results of this
study reported a significant increase in disease free survival at four years (Hazard ratio 0.76, 95% CI 0.64, 0.89).

Chemotherapy regimens undertaken at the hospitals of patients in this study are listed in Table 2. Treatment plans of some patients included a combination of these different types of chemotherapy (for breast, for example. AC plus CMF, AC plus Paclitaxel).

<table>
<thead>
<tr>
<th>Table 2: Chemotherapy taken by patients in the study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemotherapy Composition</td>
</tr>
<tr>
<td>---------------------------</td>
</tr>
<tr>
<td>5-Fluorouracil, Epirubicin, Cyclophosphamide</td>
</tr>
<tr>
<td>Doxorubicin, Cyclophosphamide</td>
</tr>
<tr>
<td>Oxaliplatin, Folinic Acid, 5-Fluorouracil</td>
</tr>
<tr>
<td>5-Fluorouracil, Folinic Acid</td>
</tr>
<tr>
<td>Cyclophosphamide, Methotrexate, 5-Fluorouracil</td>
</tr>
<tr>
<td>Doxorubicin</td>
</tr>
<tr>
<td>Docetaxel</td>
</tr>
<tr>
<td>Paclitaxel</td>
</tr>
</tbody>
</table>

Although these benefits of adjuvant treatment are invaluable for men and women with breast or colorectal cancer, there are side effects that accompany these cytotoxic or hormonal drugs. Patients need to be informed about these side effects prior to treatment commencement in order to help them make treatment decisions. This process involves weighing up the benefits with the potential side effects of the particular treatment. More importantly, remembering this aspect of the informed consent process, i.e. the side effects, is vital. This is explained further as an overview of side effects associated with adjuvant therapy is given below.

**Chemotherapy side effects**

Chemotherapy may be associated with both short-term and long-term side effects. Short-term side effects commonly occur during the course of chemotherapy treatment and are often not prolonged for more than a few months after treatment completion. In fact, most side effects
are transient and have resolved by the time the next cycle of chemotherapy is given. On the other hand, long-term side effects often develop later but may persist for many years (Partridge, Burstein, & Winer, 2001).

**Short-term side effects**

Common short-term side effects include nausea, vomiting, fatigue, diarrhoea, stomatitis, alopecia, and neutropenia. Side effects that occur less frequently include systemic infections, neutropenic sepsis\(^3\), neuropathy\(^4\), thrombo-cytopenia\(^5\), and myalgias\(^6\). Partridge and colleagues (2001) conducted a review that highlighted side effects following common chemotherapy regimens including their frequency and severity. The following table (Table 3) is replicated from their review.

---

\(^3\) Neutropenia is characterised by an abnormally low number of neutrophil granulocytes (a type of white blood cell) making patients with neutropenia more susceptible to bacterial infections

\(^4\) Neuropathy is any disease that affects any part of the nervous system often resulting in numbness.

\(^5\) Thrombo-cytopenia is the presence of relatively few platelets in blood.

\(^6\) Myalgia means muscle pain
<table>
<thead>
<tr>
<th>Chemotherapy regimen</th>
<th>Nausea</th>
<th>Vomiting</th>
<th>Diarrhoea</th>
<th>Stomatitis</th>
<th>Alopecia</th>
<th>Neutropenia or infection</th>
<th>Thrombocytopenia</th>
<th>Neuropathy</th>
<th>Myalgias</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMF (oral cyclophosphamide)</td>
<td>Frequent +++</td>
<td>Common +</td>
<td>Common +</td>
<td>Frequent Partial-total</td>
<td>Frequent +++</td>
<td>Rare</td>
<td>Frequent +</td>
<td>Almost never</td>
<td>Almost never</td>
</tr>
<tr>
<td>CMF (all intravenous)</td>
<td>Common +++</td>
<td>Frequent +</td>
<td>Common +</td>
<td>Uncommon +</td>
<td>Frequent Partial-total</td>
<td>Frequent +++</td>
<td>Rare</td>
<td>Uncommon +</td>
<td>Almost never</td>
</tr>
<tr>
<td>MF</td>
<td>Common +</td>
<td>Common +</td>
<td>Common +++</td>
<td>Uncommon, minimal</td>
<td>Rare +</td>
<td>Almost never</td>
<td>Almost never</td>
<td>Almost never</td>
<td>Almost never</td>
</tr>
<tr>
<td>AC</td>
<td>Frequent +++</td>
<td>Common +++</td>
<td>Uncommon +</td>
<td>Common +++</td>
<td>Almost always, total</td>
<td>Frequent +++</td>
<td>Rare</td>
<td>Uncommon +</td>
<td>Almost never</td>
</tr>
<tr>
<td>AC-tamoxifen</td>
<td>Rare +</td>
<td>Rare +</td>
<td>Rare +</td>
<td>Rare +</td>
<td>Almost always, total</td>
<td>Common +</td>
<td>Rare</td>
<td>Almost never</td>
<td>Uncommon +++</td>
</tr>
<tr>
<td>CEF/FAC (oral cyclophosphamide)</td>
<td>Frequent +++</td>
<td>Frequent +++</td>
<td>Common +++</td>
<td>Frequent +++</td>
<td>Almost always, total</td>
<td>Almost always +++</td>
<td>Common</td>
<td>Frequent +++</td>
<td>Uncommon +</td>
</tr>
<tr>
<td>CAF/FAC/FEC 100 (all intravenous)</td>
<td>Common +++</td>
<td>Common +++</td>
<td>Common +++</td>
<td>Frequent +++</td>
<td>Almost always, total</td>
<td>Frequent +++</td>
<td>Common</td>
<td>Frequent +++</td>
<td>Uncommon +</td>
</tr>
</tbody>
</table>

CMF= cyclophosphamide, methotrexate, and 5-fluorouracil, MF= methotrexate, and 5-fluorouracil, AC= doxorubicin and cyclophosphamide, CEF= cyclophosphamide, epirubicin, and 5-fluorouracil, FAC= 5-fluorouracil, doxorubicin, and cyclophosphamide, FEC= 5-fluorouracil, epirubicin, and cyclophosphamide; Frequency: Almost never=<1%; Rare=1-5%; Uncommon=6-20%; Common=21-50%; Frequent=51-95%; Almost always=>95% Severity: +=mild; ++=moderate; +++=severe. Permission was granted from the authors to replicate this table from (Partridge et al., 2001)
Long-term side effects or complications

There has been much written on the long term sequelae of treatment of cancer which is termed survivorship (Demark-Wahnefried, Aziz, Rowland, & Pinto, 2005). This includes the late effects of chemotherapy such as the organ toxicities, particularly cardiac, neurological and renal depending on the drugs given and probably the most unfortunate side effect of a second cancer caused by the chemotherapy (Olver, 2009). For example, patients may develop a cardiomyopathy, peripheral neuropathy or permanent cognitive dysfunction secondary to the chemotherapy. Survivorship also encompasses the long term psychosocial impact of having been through cancer treatment. The details are beyond the scope of these studies but the knowledge that they may occur post treatment can lead to pre-emptive treatment.

Common long-term side effects include weight gain, fatigue, amenorrhoea, and complications include sexual dysfunction, and cognitive dysfunction. Noticeably, fatigue has been reported in both short- and long-term side effects. Recent research has shown that fatigue is recognised as a short-term side effect nevertheless limited evidence has suggested that women have experienced fatigue up to many years after treatment. It is not clear, though, to what extent this is associated with chemotherapy treatment (Partridge et al., 2001).

Weight gain

Weight gain appears to affect 50% or more of women receiving adjuvant chemotherapy treatment, with a mean gain of 2.5-5kg (Goodwin, Ennis, Pritchard, McCready, Koo, & Sidlofsky., 1999). This is commonly found in pre-menopausal women, and women who become menopausal as a consequence of chemotherapy treatment also appear to be at an increased risk of gaining weight (Goodwin et al., 1999). No doubt this is a cause of distress for women, yet women who remain aware of this during and after treatment may be able to act on this, such as, through exercise.

Amenorrhoea

Amenorrhoea is the absence of a menstrual period in a woman of reproductive age. The duration of this absence varies amongst studies in the breast cancer literature. This is a result
of direct toxicity to the ovaries (Lin, Aikin, & Good, 1999) and can be temporary or permanent and is dependent on a number of factors including age, the chemotherapy regimen, and the dosage administered (Partridge et al., 2001). Therefore premature menopause may impact on the fertility of women after breast cancer, which may be of particular concern in younger women who wish to become pregnant after their treatment. It is also associated with a series of menopausal symptoms occurring. This information can be crucial in treatment decision-making and as a long-term concern, requires women to continue to be informed after treatment completion.

**Sexual dysfunction**

Many women undergoing chemotherapy treatment report reduced sexual desire, and painful sexual intercourse also known as dyspareunia (Barni & Mondin, 1997). This has been found to persist for months or years after treatment completion, in women experiencing sexual dysfunction (Ganz, Rowland, Desmond, Meyerowitz, & Wyatt, 1998). Undoubtedly, women need to understand that this may impact on their sexual life as well as their partners’, and they need to know this so that both the woman and her partner are prepared to and can prevent the problem and seek advice on its management.

**Cognitive dysfunction**

Adjuvant chemotherapy has been found to impair cognitive abilities of women with breast cancer. Women have reported deficits in memory and concentration as well as comprehension (Anonymous, 2006). This sensation is talked about by patients as ‘chemobrain’ or ‘chemofog’. There is limited evidence on the true effects of chemotherapy on cognition, however controlled studies are suggestive that there are cognitive deficiencies ranging between 16% and 50% (Tannock et al., 2004). In most cases these changes seem to resolve over time however deficits of up to 10 years after treatment have been reported (Tannock et al., 2004). This is a major challenge for women who continue to work during treatment or initiate work after treatment. Additionally, it may influence what information as part of the informed consent process women remember and more importantly, may hinder the effect of chemotherapy experience on patients’ recall abilities. For instance, patients may need to avoid certain foods due to interactions with drugs they are receiving or avoid the sun (or at the very
least use sun block) as certain chemotherapy drugs may cause the skin to be sensitive to the sun. If these are not remembered or not understood, it may lead to other detrimental effects.

**Summary**

Breast and colorectal cancer are no doubt of major concern in today’s society as seen from the incidence and mortality data. Therefore it cannot be forgotten that large numbers of people are still affected by this condition every day, not only directly in the case of patients with cancer but relatives or friends are indirectly affected as well.

With the ever increasing advances in prevention, detection, and treatment methods, one cannot ignore the importance of conducting research to better the process of providing information about these methods for those involved. It is important to understand that both cancer screening and treatment require information and patient decision-making hence are equally important in the informed consent process.

Decisions about adjuvant chemotherapy are complex. The patient needs to have knowledge of short- and long-term impacts of the treatment. The short-term impact of treatment may include the risk of transient side effects such as nausea, vomiting, and fatigue, amongst others. Long-term impacts may include the organ toxicities, and even the potential side effect of a second cancer caused by chemotherapy. Key statistics stated previously suggest that survival rates are improving hence more patients now live for longer periods of time. This indicates that they will have to live longer with the experience of their cancer diagnosis and treatment. However, for patients who have a low rate of survival potentially due to advanced cancer, it still remains important to maximise their well-being and satisfaction during the diagnosis and treatment stages.
Chapter 3: Literature review One

As discussed in Chapter One, informed consent consists of five main components, two of which are ‘disclosure’ and ‘comprehension’. The patient requires disclosure of adequate information including the risks, benefits, and alternatives to the proposed treatment but also patients must have comprehension of the information that has been disclosed to be truly informed. Research has shown that a considerable number of patients do not understand some to all of the information provided. This, as previously discussed, has several consequences for the patient including dissatisfaction, anxiety, and lack of adherence to treatment. Stemming from this, several approaches have been researched to improve patient comprehension of the information given for informed consent, as outlined in Chapter One.

This literature review will focus on one of these approaches, which is to identify effective formats of information delivery for informed consent. This chapter provides a summary of comparative studies evaluating the effectiveness of interventions that aim to improve patients’ knowledge for making an informed decision and consenting to a particular procedure or treatment. Many studies have assessed the effectiveness of these format modifications on a variety of outcomes including information recall, patient satisfaction, patient anxiety, compliance, and physical coping, amongst others.
Methods

The objective of the present review was to determine all possible tools/methods that have been implemented for development of an improved consent process, their effectiveness, and success in practice on improving a patient’s knowledge of the information given. The specific review questions to be addressed were:

1. What tools/methods have been used to improve patient knowledge of the information given to obtain consent to medical treatment?
2. How have these tools been implemented?
3. Have these tools been successful, that is, effective in improving patient knowledge of the information given?

This review identified studies including participants who were adults undergoing some form of treatment i.e. surgical or non-surgical, in a health care setting provided they had consented to such before commencing treatment. Health care settings could include hospitals, hospices, clinics, and/or medical centres. Interventions that aimed at improving the treatment consent process and patient outcomes were included and a description of the method implemented was needed. Comparators included standard care or an alternative comparable intervention also designed to improve the consent process. Types of outcomes measured in this review include primarily assessment of patient knowledge with the pre-treatment information given. Patient satisfaction with the information provided was also assessed as were other variables measured in the studies such as anxiety. Studies other than English were not translated for two reasons; firstly, this reduced generalisability of non-English studies to the Australian population and the feasibility of translating numerous studies with the knowledge that many may not be relevant to the review.

The method of identifying studies included searching the medical and health literature for relevant systematic reviews (Table 4) conducted in the last decade (1999 onwards). This cut off only applied to when the systematic review was conducted but there were no restrictions on when the study was conducted (within the limitations of the electronic database coverage of
articles). A ten year time frame was chosen as it was believed that in this period all of the relevant studies would be included in the systematic reviews. The reference lists of all included studies were searched for additional sources that may have not been identified in the systematic reviews. The search terms that were used to search the databases are as follows. Mesh Terms: Informed consent, disclosure, consent forms, comprehension, mental competency, memory, longitudinal studies, follow-up studies, prospective studies, and text words: longitudinal stud*, longitudinal survey*, follow-up stud*, follow-up survey*, prospective stud*, prospective survey*.

Upon retrieval of the studies that met the inclusion criteria for this review, data was extracted by a single researcher. A profile was developed for each systematic review, outlining the review’s characteristics, study design, study authors, year and setting, target population, and outcomes assessed in the follow-up period. Studies were excluded if they included populations under 18 years of age because their consent processes are different and often parents provided surrogate consent.
<table>
<thead>
<tr>
<th>Systematic review author</th>
<th>Number of papers included</th>
<th>Patients</th>
<th>Intervention</th>
<th>Outcomes measured</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Agre, Campbell, Goldman, Boccia, Kass, McCullough, et al., 2003)</td>
<td>Seven RCTs, one quasi-RCT</td>
<td>Variety of medical conditions</td>
<td>Variety of interventions (video, computer multimedia, audiotape, decision aid)</td>
<td>- Knowledge</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Satisfaction</td>
</tr>
<tr>
<td>(Dunn &amp; Jeste, 2001)</td>
<td>34 controlled studies</td>
<td>Surgical, psychiatric and medical patients</td>
<td>Wide variety of approaches</td>
<td>- Patient understanding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Personalised risk information</td>
<td>- Risk knowledge</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Accurate risk perception</td>
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<td></td>
<td></td>
<td></td>
<td>- Anxiety</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Satisfaction with decision</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Decisional conflict</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Uptake of and adherence to tests</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>- Quality of life</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Patient understanding</td>
</tr>
<tr>
<td>(Edwards et al., 2006)</td>
<td>22 RCTs</td>
<td>People making decisions to undergo screening</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Flory &amp; Emanuel, 2004)</td>
<td>42 trials (randomised and non randomised)</td>
<td>Variety of medical conditions</td>
<td>Variety of interventions (video, computer multimedia, enhanced consent form, test/feedback)</td>
<td>- Informed needs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Knowledge</td>
</tr>
<tr>
<td>(Gaston &amp; Mitchell, 2005)</td>
<td>47 controlled &amp; uncontrolled studies</td>
<td>Advanced, non curable cancer patients</td>
<td>Any intervention to improve information giving and decision making</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systematic review author</td>
<td>Number of papers included</td>
<td>Patients</td>
<td>Intervention</td>
<td>Outcomes measured</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>---------------------------</td>
<td>------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>(Gysels &amp; Higginson, 2007)</td>
<td>Nine RCTs</td>
<td>Diagnostic screening patients</td>
<td>Patient education using videotapes or computer programs in cancer care</td>
<td>Patient knowledge, Satisfaction, Decision making, Treatment choice or care management, Knowledge</td>
</tr>
<tr>
<td>(Jeste, Dunn, Folsom, &amp; Zisook, 2008)</td>
<td>37 RCTs</td>
<td>Variety of medical conditions</td>
<td>Video or computer based programs to inform patients about their medical evaluation or management</td>
<td>Knowledge</td>
</tr>
<tr>
<td>(McPherson, Higginson, &amp; Hearn, 2001)</td>
<td>10 RCTs</td>
<td>Various cancer types</td>
<td>Methods of information giving to cancer patients, their families and carers aimed primarily at educating</td>
<td>Knowledge acquisition, Preferences for information, Attitudes toward the intervention, Uncertainty, Satisfaction</td>
</tr>
<tr>
<td>(Pitkethly, MacGillivray, &amp; Ryan, 2008)</td>
<td>16 RCT or quasi-RCTs</td>
<td>Cancer patients and their families</td>
<td>Providing recordings (e.g. audio-tapes) or summaries (e.g. letter) of consultations</td>
<td>Satisfaction, Information access, use &amp; understanding, Satisfaction, Health &amp; wellbeing, Patient understanding &amp; recall of information, Satisfaction, Level of anxiety, Decision to participate</td>
</tr>
<tr>
<td>(Ryan, Prictor, McLaughlin, &amp; Hill, 2008)</td>
<td>Three RCTs and one quasi-RCT</td>
<td>Individuals or the guardians of individuals asked to participate in a clinical trial</td>
<td>Audio visual information for informed consent for participation in clinical trials</td>
<td></td>
</tr>
</tbody>
</table>
Table 4 continued…

<table>
<thead>
<tr>
<th>Systematic review author</th>
<th>Number of papers included</th>
<th>Patients</th>
<th>Intervention</th>
<th>Outcomes measured</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Skinner, Campbell, Rimer, Curry, &amp; Prochaska, 1999)</td>
<td>13 RCTs</td>
<td>Variety of participants</td>
<td>Individual tailored print information</td>
<td>• Knowledge</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Satisfaction</td>
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<td></td>
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<td></td>
<td></td>
<td>• Attendance</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>• Knowledge retention</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Correct performance of postoperative activities</td>
</tr>
<tr>
<td>(Stern &amp; Lockwood, 2005)</td>
<td>19 RCTs</td>
<td>Adults in a hospital setting as inpatients or same day surgical patients</td>
<td>Variety of interventions (written information sheet, audio-visual aids, computer-assisted instruction, learning packages)</td>
<td>• Patient understanding</td>
</tr>
<tr>
<td>(Trevena, Davey, Barratt, Butow, &amp; Caldwell, 2006)</td>
<td>10 systematic reviews and 30 RCTs</td>
<td>Variety of medical conditions</td>
<td>Communication tools in most formats (verbal, written, video, provider-delivered, computer-based)</td>
<td>• Recall of medical information</td>
</tr>
<tr>
<td>(van der Meulen, Jansen, van Dulmen, Bensing, &amp; van Weert, 2008)</td>
<td>10 RCTs &amp; CCTs</td>
<td>Cancer patients</td>
<td>Variety of interventions (audiotape, videotape, letter, question prompt sheet)</td>
<td></td>
</tr>
</tbody>
</table>
**Results**

Over the decades there have been a plethora of studies assessing the effect of providing patients with consent information in a different format to the standard way which is usually a written information sheet and consent form. Between 1999 and 2009, there were 14 systematic reviews identified that included studies assessing the effectiveness of format modifications on patient knowledge, satisfaction, anxiety and more. It was recognised that the format modifications researched fell under five main types: additional or modified written information, audio-tapes of the consultation, educational video-tapes, interactive multimedia, and decision aids (Table 4). The systematic reviews did not capture all of the relevant studies, however through a comprehensive search these studies were also identified and formed part of this literature review.

**Written information**

Written information, second to verbal information, is the most common form in which treatment procedures, risks, benefits, side effects and the like, is presented to patients. Therefore, modifications of written medical information have resulted in a large amount of research in an attempt to improve patient knowledge, and satisfaction amongst other factors. In addition to the plethora of studies on this topic, the research has highlighted that there are many ways in which modified written information can be presented to patients to enable informed consent to be given. In some studies, the modified information is aimed to replace the standard treatment information given while in others, the modified written information is given in addition to the standard information. In this literature review the studies have been categorised into several different areas making an effort to group together the similar studies for ease of comparison and discussion. The breakdowns presented are (1) detailed versus non-detailed information (also including specific versus non-specific information), (2) written versus verbal information, (3) varying readability of the written information, and (4) question prompt sheets.
Detailed versus non-detailed information

The earliest study identified that compared the effect of the standard format of the consent form with a modified consent form on comprehension levels was conducted in the United States of America (USA) in 1969 (Epstein & Lasagna, 1969). The authors conducted a hypothetical randomised trial of 66 female hospital or medical school employees who were asked if they were willing to take two tablets of ‘acetylhydroxybenzoate’ or a placebo when they next had a headache.

The participants were divided into three groups (22 participants in each group) and given varyingly detailed descriptions of the actions and hazards of the drug, that is, long versus medium versus short consent form. Some participants in the group receiving the long form appeared to have misunderstood that fatal reactions may occur and it was found that this group had lower understanding scores than those receiving less detailed information, such as the short consent form (45% vs. 67%, respectively). The study concluded that the information provided to participants should be brief to maximise comprehension.

The main limitation of this study was that it was simulated therefore it was likely to be less realistic than if real consent forms were being compared. All patients in the study were female which is not generalisable to the greater population. With the primary study of this thesis in mind, consenting to chemotherapy treatment is considered to be more significant to patients than consenting to headache medication therefore the study participants in this research may not have read the information seriously. Finally, there was no indication of significance testing.

Following this, in the early 1980s, a randomised study by Dodd (1982) was conducted, also in the USA, to assess the effectiveness of varying types and levels of information in an attempt to improve knowledge of chemotherapy of 48 non-terminal cancer patients (Dodd, 1982). Patients enrolled in the study were currently undergoing chemotherapy treatment, for at least two weeks and varied in their cancer diagnoses with the majority having breast or genitor-urinary, followed by gastro-intestinal but also had small numbers with head and neck, lung,
lymph, and blood cancers. Three types of information were presented to four groups of 12 patients: drug information (including drug names, and potential side effects), information about the management of side effects (including information about managing the 44 potential side effects of chemotherapy), a combination of drug information and side effect management information, and no systematic information (control group). Patient knowledge of the information was measured twice: firstly at the pre-intervention interview and between four and nine weeks later at the post-intervention interview. Knowledge was assessed by a 23-item pre-intervention questionnaire and a 15 item post-intervention questionnaire which were adaptations of previously used questionnaires (Dodd & Mood, 1981; Muss et al., 1979). Questions included patient knowledge of names of drugs they were receiving, and possible side effects of the drugs. A list of 27 chemotherapy drugs was given and patients were asked to identify which ones they were receiving, with both trade and generic names given to aid recognition. Patients were then shown a list of 44 potential side effects of chemotherapy and asked to identify those believed to be a result of chemotherapy.

Dodd (1982) found that among all patients, accuracy in stating drug names was 33% pre-intervention which improved to 69% post-intervention. Similarly there was poor recognition of lethal side effects pre-intervention (19%) which improved by more than double (39%) post-intervention. Patients in groups receiving drug information (n = 24) were found to significantly increase their drug name accuracy and knowledge of potential side effects (p < .01), and knowledge of potential lethal side effects (p < .002) post-intervention. The chemotherapy knowledge score was significantly higher for patients who received drug information as compared to the patients who did not (p < .01). The study also identified that the more educated the patients, the higher their chemotherapy knowledge pre-intervention (p = .006) although at the post-intervention interview, this only remained significant for patients who did not receive drug information. There was no indication of any differences between the group receiving more information (drug and side effect information) and the groups receiving one of these types of information. Regardless, significant changes on patient knowledge need to be considered with caution as the patients were being tested on recognition by being given a list of drug names and side effects. This recognition task requires less cognitive processing and therefore if patients were asked for free recall of the potential side effects, the
performance of patients may have been poorer. The study showed that retention of drug information without reinforcement is short-lived. An interesting finding reported by the authors was that the drug information did not significantly help patients to correctly recognise experienced side effects of chemotherapy (no p value). In other words, the majority of side effects experienced were not attributable to the chemotherapy but other medical conditions or medicines being taken.

The sample size of 12 patients in each group was limiting, otherwise the study followed up patients four to nine weeks post intervention assessing long-term knowledge. However, the assessment four to nine weeks post-intervention may have resulted in inconsistent findings among patients. This is because of the large time range at which knowledge was assessed although authors reported that the original plan was to measure knowledge between four and six weeks post intervention. This time range was modified due to the health status of several patients. Additionally, the mean duration of chemotherapy time at pre-test was six weeks which means that patients had forgotten information between initiation of treatment and the pre-test. The study did have the advantage that it was blinded to the data collectors at the post-intervention which minimizes bias. While the study was not conducted to assess the effectiveness of information given for informed consent, the results can be extrapolated to such a setting.

Wallace (1986) also conducted an oncology based study to assess the effectiveness of different pre-operative preparatory booklets on knowledge, expectations, and anxiety of patients (Wallace, 1986). The study based in the UK included patients who were undergoing minor elective gynaecological surgery but the information was not believed to be for informed consent to surgery rather just for preparation. Sixty three women were sequentially allocated to three groups: routine care (n = 26), routine care plus a minimally informative booklet (n = 17), or routine care plus a maximally informative booklet (n = 20).

The minimally informative booklet contained globally reassuring statements while the maximally informative booklet contained procedural, sensory, and temporal information as well as suggestions for cognitive-behavioural coping strategies. The authors stated that the
groups were separated to prevent contamination by patients transferring information across groups. Patients were recruited to the study six to eight weeks pre-admission to hospital, interviewed on the purpose of the study, asked for baseline demographic data, and given one of the two booklets, or nothing, if in the control group. Other measures at this time included expected affiliations such as who they expected to talk to about their operation and from whom they expected to receive any form of information and emotional support. Patients were also asked about their information preferences and knowledge about surgery. Knowledge was measured using a 5-item subscale of a 20-item multiple choice questionnaire used in a previous study (Wallace, 1985). The scale measured whether patients understood that they would be having a general anesthetic, the number of cuts on the abdomen, the duration of discomfort, the expected time of recovery, and the nature of the procedure of sterilisation or infertility investigations. This subscale measuring knowledge had an alpha coefficient of .60 which the authors believed was low internal consistency and therefore chose to use individual items.

On the morning of surgery, patients were interviewed on their worries, concerns, and again on their knowledge about surgery. Worries and concerns were measured using ten aspects of surgical care of which six were specific to sterilization or infertility investigations. Patients were asked ‘are you worried about this?’ and ‘are you concerned about this’? Unlike the reliability of the knowledge questionnaire, the reliability of the questionnaire on their worries and concerns was unknown. The group receiving maximally informative booklets stated that less items regarding the surgery worried them (p = .02) compared with the other groups. Knowledge was measured using an extended multi-item open choice questionnaire measuring correct knowledge about surgery (alpha coefficient = .75) and number of misconceptions held (alpha coefficient = .64).

It was stated that at pre-admission no differences were between the groups on patient characteristics, preferences for information and knowledge about surgery. However no results were presented on these pre-admission differences. Post-intervention (pre-operation) results revealed that the group receiving maximally informative booklets (M = 22.2, SD = 5.6) had greater knowledge than those receiving minimally informative booklets (M = 17.3, SD = 4.9)
and no booklets (M = 15.3, SD = 4.9; p = .002). They did not, however, significantly differ in their awareness of the potential impact of the surgery.

Similar to Dodd’s (1982) study, Wallace (1986) measured patient knowledge long-term and protected against contamination between patient groups. However, the study was made up of a small sample but did not report effect sizes therefore possible Type II errors could have been made. Also recognition was used to measure knowledge which again is inferior to the use of free recall. Pre-intervention knowledge was measured using individual items of the scale due to a low alpha coefficient despite there being just as many reliability concerns with doing such. Knowledge of surgery such as recovery or future investigations were not measured post operation. Also, it was unclear what the possible range of scores was for the knowledge questionnaire given post-intervention, pre-operation. Therefore it was not clear whether the maximally informative group actually had a high level of recognition.

The effectiveness of pre-admission self-instructional information given to surgical patients was also conducted by Rice and Johnson (1984) in the USA (Rice & Johnson, 1984). The purpose of the study was to assess whether self-instructional booklets would result in less teaching time during hospitalization compared to standard practice. This randomised study of 130 adult patients undergoing elective cholecystectomy or herniorrhaphy received preadmission instruction which was either in the form of specific or non-specific booklets focusing on coughing, deep breathing exercises, leg movements, and ambulatory behaviours. These instructions were mailed to patients preadmission after random selection six to 10 days prior to surgery. A third group received a post admission non-specific booklet. Patients in the pre-admission booklet groups were visited by a nurse blind to booklet allocation who asked patients to perform exercises. The mean age of cholecystectomy patients was 48 years old and 47 years in hernioorhaphy patients.

Knowledge was assessed through the level of performance of exercise behaviours. The study found that most patients could learn exercise behaviours prior to hospital admission however more knowledge was gained when the specific information was given (62%) compared with non-specific information (53%) although statistical significance was unclear. This result was
found to be independent of the type of surgery performed. The study did not report how many patients comprised each of the three groups.

Several studies have assessed patient knowledge of information given to consent to general anaesthesia. One of these studies was conducted in Australia by Inglis and Farnill (1993) on 40 consecutive patients consenting for their own operation or consenting for surgery on a child and therefore making a decision to undergo general anesthesia (Inglis & Farnill, 1993). At baseline, demographic information was obtained from patients and their trait anxiety was assessed using the Spielberger State-Trait Anxiety Inventory (STAI). Patients were then randomly allocated to one of two groups: a routine information group in which they were given an explanation of the anaesthetic, theatre procedures, and expectations for the recovery room (n = 20), or a detailed information group who were given additional information on incidence of nausea and vomiting, sore throat, death, brain and teeth damage, and awareness (n = 20). The mean age of patients was lower in the routine information group (M = 42 years, SD = 16, range 21 – 77 years) compared with the detailed information group (M = 51 years, SD = 18, range 26 – 80 years) however was not significantly different. No other demographic differences were found between the two groups.

Immediately after the information was given, patient’s state anxiety was measured using the same inventory, a widely used scale measuring dispositional and situational anxiety. The comparison of the groups for state anxiety was adjusted by using the patient’s predetermined trait anxiety scores as a covariate. Also, assessment of cued recall of the various general anaesthetic risks (i.e. risk of sore throat, death, serious damage to teeth, nausea, vomiting, waking during the operation, or suffering brain damage) and their incidence was done using a visual analogue scale which was developed for this study. Each response was scored right or wrong according to whether it fell within an arbitrary one centimeter of the correct point.

Results showed that there were no statistically significant differences between the state or trait anxiety scores of the two groups before or after receiving the information and therefore receiving detailed information did not increase the anxiety level of the study group. In fact, the mean anxiety levels of patients in both groups were similar to those reported for adults who
are tested under relatively non-stressful conditions and lower than general medical and surgical patients, as reported by the authors.

There were also no significant differences between groups on recall of common complications such as nausea and sore throat, however the detailed information group better recalled the risk of death compared with the control group (p < .001). Eleven of the 20 patients in the detailed information group were able to give the correct answer about the risk of death compared with three of the 20 in the routine information group. Also, the authors reported a significant difference between groups on recalling serious damage to teeth, favouring the detailed information group (p < .05). However, the numbers recalled correctly were low in each group (three in the detailed information group, zero in the routine information group), therefore should be considered with caution. The recall that was measured was cued, which, as mentioned previously, impacts the strength of findings as patients were not asked to free recall information. There is a limitation to measuring anxiety immediately after the information is given because patients are not given enough time to consider the information and become anxious or have their anxiety allayed by the information. This was a small study and therefore may not have had enough power to detect significance, and the study did not report effect sizes, therefore Type II errors were possible.

A more recent randomised study conducted in the UK was interested in comparing an original consent leaflet that has been used in the gynaecology clinic for over ten years, with a modified more detailed consent leaflet (Garrud, Wood, & Stainsby, 2001). The forty one patients were undergoing elective laparoscopy and using a randomised block design, 21 received the old leaflet and 20 received the new detailed leaflet. The patients’ ages ranged between 23 to 41 years of age but no mean age was given. The modifications to the old leaflet included the omission of a diagram, the addition of two paragraphs, and arrangement of the leaflet content into eight sections for better visual presentation. The two additional paragraphs added more information on possible risks or complications. After their consultation patients were given their leaflet and were followed up two to three days later by means of a telephone interview to measure knowledge, anxiety, and satisfaction with the information.
Knowledge of the leaflet was measured using five open-ended questions and scoring was based on the presence of certain factual elements in the patients’ answers, with a maximum score of 23. Therefore, knowledge was measured using a free recall test, being the most stringent method. Statistically significant effects were seen for patient knowledge in the intervention group compared with the control group receiving the old leaflet ($M = 10$ vs. $6.55$ respectively, $p < .001$), however the results may be biased. This is because it is not clear how many different people scored the patient data and hence it may have been scored differently.

Satisfaction was also measured using a modified form of the Medical Interviews Satisfaction Scale cognitive subscale. Possible scores ranged from nine to 45 with higher scores reflecting greater satisfaction. Satisfaction was found to be significantly higher in the new leaflet group ($M = 41.6$ vs. $36.8$, $F(1, 39) = 10.7$, $p = .002$). Anxiety was measured using the STAI on which scores ranged from six to 24, with higher scores indicating greater anxiety. There were no significant differences in anxiety between the two groups ($M = 8.90$ new leaflet, vs. $M = 8.95$ old leaflet).

Elective laparoscopy is a safe and minimally invasive procedure and therefore providing such detailed risk information for more threatening procedures may lead to different results. This, together with the lack of validity of the questions suggests the results should be considered with caution.

**Summary**

In summary, of the six studies reported, four measured detailed versus non-detailed information or usual care, and two measured specific compared with non-specific information or usual care. Only two of the six studies measured knowledge using the most superior form of recall, that is, free recall (Garrud et al., 2001; Rice & Johnson, 1984). Although one study compared specific versus non specific booklets (Rice & Johnson, 1984), and the other compared detailed versus non-detailed information (Garrud et al., 2001), these studies were both conducted on surgical patients and recall was assessed a short time after the intervention was given. Both studies found the experimental group to have significantly better recall than the control group. In Garrud and colleagues’ study, a mean recall of 11 of a possible score of 23 was achieved in the detailed information group. Similarly, Rice and Johnson found 62% of the patients in the specific information group to have knowledge of the exercises.
This suggests that patients had knowledge of about one half to two fifths of the information given. Regardless of this low to moderate level of recall, Garrud et al. found that patients receiving the detailed information had a significantly higher level of satisfaction than the non-detailed booklet group.

Rice and Johnson (1984) who measured free recall on a larger sample of 130 adult surgical patients did this through a novel method, that of, performance of learnt behaviours. Surgical patients were informed that certain exercises were beneficial for recovery which may have been the motivation for patients to learn them. Another motivation to learn the exercises may be by correctly performing exercises to please the physician or nurse. This process does not work in all settings such as chemotherapy where patients, more than anything, need to be aware of side effects in the case that they occur. However identifying an intervention which allows patients to please their physician or allows for better recovery may motivate patients, indirectly improving their knowledge. Regardless this found the patients receiving the specific booklet to have more knowledge of the exercises.

In all but one of the other studies measuring detailed versus no detailed information, knowledge was also found to be higher in patients receiving the detailed information and there appeared to be no impact of the modified information on worries and anxiety of patients. However this overall finding needs to be considered with caution for several reasons. Firstly, the studies used cued recall or recognition to measure knowledge which inevitably reduces the strength of the results compared to if they utilized free recall. The studies were conducted on a variety of different populations including surgical and non-surgical patients and all of the studies were made up of small samples and although significance was achieved, effect sizes were not reported therefore the possibility of a Type II error was difficult to ascertain.

The study with conflicting results was conducted by Epstein and Lasagna (1969) and found less detailed information was beneficial to improve patient recall or knowledge. The fact that the oldest study showed brief information to be more effective may be due to the more passive nature of patients during the consent process back in the late 1960s, prior to the transition in general of patients now playing a more active role. Nonetheless, the study was a simulated
trial which may underestimate the true effects of the intervention. Epstein and Lasagna (1969) was also the only study that looked at decision making for a minor procedure, namely, taking headache medication.

**Written versus verbal information**

The desirability of obtaining written informed consent for low risk radiologic procedures has been a topic of controversy for several decades. Winfield, Ford, James, Heller, and Lamballe (1986) studied a group of 80 patients referred for excretory urography in Tennessee, USA who were randomized to one of two groups: a detailed informed consent form group (n = 42) or a control group who were interviewed but not provided with a written consent form (n = 38) (Winfield, Ford, James, Heller, & Lamballe, 1986). The purpose of the study was to evaluate the effect of informed consent for excretory urography on the incidence of adverse reactions to the administered contrast agent, the degree of discomfort experienced by the patient, the level of the patient’s anxiety before and after the procedure, the patient’s perception of the examination, the desirability of obtaining informed consent from the patient’s viewpoint, and the patient’s willingness to proceed with the examination after receiving knowledge necessary to grant informed consent. The two groups had similar demographics including the number of men and women, similar age ranges (no mean age given), and comparable educational background. The patients in both groups were treated in the same way and the attending radiologist was not aware of the group assignment.

The level of discomfort, fear and apprehension of the test, as well as patients’ perception of their understanding of the examination were categorized on a scale of zero to three. All reactions and side effects were recorded but no statistically significant differences were found between the two groups regarding adverse reactions of patients (no p value given). Similarly, the study reported a similar level of fear and anxiety in the two groups (no p value given). Authors reported that eight multiple choice questions were asked of the patients as a measure of acquired information concerning the nature of the procedure and its risks. Patients were interviewed between 24 to 48 hours after the examination either in person or by telephone. Six of the questions to assess understanding were presented and included understanding of different anatomical structures that the test can evaluate, name of the chemical element in the
contrast material, common sensations that people experience after the injection of the contrast material, percentage of patients experiencing a skin rash in response to the contrast material, and experiencing a life-threatening reaction in the procedure.

Results showed that the level of patient understanding of the procedure and its risks differed, with the control group reporting a mean score of 48% while the detailed consent form group reported a mean of 73% (p < .001). No other results or statistical methods were given. Patients in the study group were specifically asked if they found the written consent form helpful and desirable and most of the patients (83%) found it to be so. None found it harmful.

There are several limitations to this study including the lack of reporting of the validity and reliability of the scales used. Although this is common when study specific measures are needed for informed consent studies as we’ve seen above this also included the lack of using standardised questionnaires that are available to measure anxiety. Also, understanding was measured using multiple choice questions which is believed to measure recognition, not as stringent as free recall and definitely not a true measure of ‘understanding’. The authors also do not present statistical methods used or any of the actual scores of understanding and only an overall average was given. The study does, however show that there are benefits to information recall of the consent process in terms of knowledge of the procedure and risks, at least within a day or two immediately after treatment. While this study is over 20 years old, in recent times there is believed to be diversity in the practice for gaining informed consent for radiological procedures and there was no evidence identified that there is a standard practice to give written information and have a consent form signed.

On the other hand, Damian and Tattersall (1991) conducted an Australian study of 48 patients attending an oncology clinic for a follow-up consultation (Damian & Tattersall, 1991). While this was not assessing the information for the purposes of informed consent, as in the previous study, patients were randomised to receive a letter outlining their consultation (n = 24) versus not receiving the letter after completion of their consultation (n = 24). The letter was written specifically for each patient with the use of medical terminology kept to a minimum. The content of the letters varied with each consultation but mostly included details of treatment
choices and strategies, test results, current disease status, clinical findings, and follow-up/referral arrangements. There were no differences between the two groups regarding median age, however both groups comprised mainly of women (letter group: n =20, no letter group: n =19).

All patients were followed up with a structured telephone interview three to 19 days after the consultation. Patients were asked to recall the consultation, both prompted and spontaneous although details of the questions asked to measure recall were unclear. There were no significant differences in the percentage of items recalled by the two groups, although patients receiving the letter were given more items to remember than the control group. High levels of information were recalled in both groups (Letter group: 85%, range 50 -100; Verbal group: 75%, range 50 – 100, no p value given).

Patients were also asked to indicate satisfaction on eight aspects of the consultation using a 5-point scale. Patients were generally satisfied with the consultation although those receiving the letter were more satisfied with the information received (p = .01). Also most patients with bad news consultations found the letter significantly more useful to help understand and remember what they had been told compared to patients receiving good news (p < .001) perhaps due to the overwhelming nature of receiving negative information at the consultation. Although half the patients receiving bad news found their letter distressing to some extent and were significantly more anxious (p = .002), this was not measured by a reliable scale. Of the patients who received the letter, 83% found it useful and most control group patients (67%) thought that a letter outlining their consultation would be useful. Patients read their letters an average of 2.6 times and most showed it to at least one other person. As mentioned above, this study was limited in that no details of the questions measuring recall were given and similarly no reliability coefficients were given for the other scales used. The sample in each group was also small and no effect sizes were reported therefore there was the potential to make Type II errors. However, the findings showed that individualised letters may be beneficial and acceptable to patients although at this stage, the difference to patients receiving no letters is not sufficient enough for implementation. This method does, however, deserve further
investigation, especially around what happens to the patient after this letter (choice of treatment, etc).

In a prospective randomised study of 269 surgical patients, written versus verbal preoperative warnings about the risks of surgery were assessed on their effects in improving the recall of information postoperatively (Armstrong, Cole, & Page, 1997). The authors reported that motivation of the study derived from patients who stated that much of the information given to them was forgotten before they had been able to absorb it or discuss it with family. The study conducted in the UK included patients undergoing cosmetic surgery, elective hand surgery, and excision of minor skin tumours. On admission, patients were randomly allocated to a verbal warnings only group (n = 132) or a group receiving the same verbal warnings plus written warnings including a sheet listing the warnings (n = 137). There was a good gender balance and the mean age in each of the groups was 46 years old. The groups were also balanced for educational achievements with the majority having left school without any formal qualifications.

Approximately one week after surgery patients were interviewed and their recall of information was measured by a nurse who was not aware of the group allocation. It was unclear whether recall was cued or free recall however results were shown for the warnings that patients recalled. The written warning group remembered four of the seven preoperative warnings significantly better than the verbal warning group. The four warnings remembered better included infection, haematoma, wound, and scar, while the serious warnings regarding anaesthesia were remembered by less than half of the patients in each group. The mean number of warnings recalled in the written warning group was about half (M = 3.64), less than one warning compared with the verbal warning group (M = 2.95, p = .006). The relevance of a difference in recall of less than one warning between the two groups may not be clinically meaningful. Regardless, the study groups were generalisable to surgical patients however they were not dangerous surgical procedures. The study did not follow up the patients for further recall during the postoperative recovery period. The study was limited in that no details regarding the recall measure were given such as whether it was free recall and whether it was a valid and reliable questionnaire.
Layton and Korsen (1994) also conducted a UK study, compared written warnings with verbal warnings about risks and outcomes, as in Armstrong et al.’s (1997) study, to improve recall and recognition (Layton & Korsen, 1994). Layton and Korsen’s study was prospective and measured recall and recognition of warnings for patients undergoing surgical removal of lower third molar teeth under general anaesthesia. The patients were divided into two groups: verbal warnings (n = 100) or written warnings (n = 94). It was unclear whether the allocation to the groups was random. The written warning group was also divided by the timing of being given the information: one group received the written information one to two weeks pre-admission and patients were able to take the written warnings home while the other group only saw the information on admission. Patients were interviewed by a different clinician to the one who had consented the patients, on average 12 days after the operation.

Warnings of five possible risks associated with the operation were given and included: altered sensation (dysaesthesia) of the lower lip, dysaesthesia of the tongue, facial swelling, trismus (stiffness and limitation of opening of the mandible), and pain. The clinician asked questions in a structured interview requiring cued and free recall. Results obtained post-operatively identified that written information significantly improves patient recall of important warnings such as the risk of dysaesthesia of the lip (p < .01) and tongue (p < .001) compared with verbal warnings. However there were no statistically significant differences between the two groups for the other risks and no significant differences between the subgroups receiving written warnings. This study did not report on the reliability of the questionnaire given or patient blinding, allocation concealment, and follow up of patients. Therefore the results need to be considered with caution.

More recent studies also evaluating the effectiveness of written versus verbal communication about risks included a US study conducted by Makdessian, Ellis, and Irish (2004). This prospective randomised study assessed recall in a group of patients undergoing cosmetic surgery (rhinoplasty, rhitidectomy, laser resurfacing) receiving only the standard consultation i.e. oral discussion of the risks of the procedure (n = 57) compared with a group receiving a pamphlet outlining surgical risks in addition to the standard consultation (n = 63) (Makdessian, Ellis, & Irish, 2004). The majority of patients participating were female (n = 88),
the average age was 41 years (range 14-72 years), and almost half of all the patients (n = 54) had a university or higher degree.

The average follow-up was two weeks after the procedure and recall was assessed by means of contacting the patients in each group and asking them to repeat the risks and complications which they were informed about in their initial consultation. The answers were entered into a standard checklist and analysed. The mean number of risks recalled in the intervention group compared with the control group was 2.5 versus 1.5 out of 5 potential risks (no SD provided) which was found to be statistically significant (p < .001). This still implies that even in the intervention group, on average only half of the risks were being recalled, which may not be considered as sufficient.

Patients undergoing rhinoplasty or laser resurfacing appeared to significantly recall more risks when given the pamphlet compared to those who were not (p < .001, p = .02, respectively). However recall success in the face-lift group (n = 22) was not statistically significant (p = .19). Educational background also appeared to influence the recall of information with patients with a university or higher education recalling 2.3 of 5 risks while patients without a university education recalling 1.8 of the risks (p = .02). When comparing the two groups, the pamphlet appeared to influence risk recall in patients who did not have a university education, recalling 2.2 of the risks versus 1.1 risks in the patients not receiving the pamphlet (p < .001). Risk recall was also improved in patients who had a university education (p = .001).

There were no statistically significant differences in recall of males either receiving the pamphlet or not, however there was a difference among females with the pamphlet group recalling significantly more risks (2.7 risks) than those not receiving the pamphlet (1.5 risks, p < .001). Females also recalled significantly more than males when receiving the pamphlet (p = .02) however no differences were seen in gender in patients not receiving the pamphlet. This study conducted some in-depth analyses of the impact of a pamphlet on patient recall of risks however was limited in that patients were called on the phone and could have had the sheet in front of them.
Langdon and colleagues (2002) conducted a relatively large randomised controlled study (N = 126) on a group of patients who were given information in the form of a written sheet and appropriate explanation of the information (n = 61) to a group receiving verbal information alone (n = 65; Langdon et al., 2002). The study objective was to determine whether written information was acceptable to patients and whether it improved recall of the consent interview. The population consisted of patients undergoing hip arthroplasty (M = 68 years, no SD) typically an older patient group due to the type of surgery, and hence differences in the recall abilities of this population are likely to differ when compared with a younger population. Demographic characteristics were found to be similar across the two groups.

Recall was assessed on admission by a researcher unaware of the randomisation results who used a questionnaire with eleven questions: one assessing the usual length of postoperative stay and ten assessing the risk of postoperative complications. These questions were in the form of multiple choice questions each with three options, which, as previously discussed, is indicative of recognition rather than recall as they can see the correct answer amongst the incorrect ones. Recall was assessed on admission to the hospital however it was unclear how long before admission the patients received the information. The written information group had a significantly higher ‘total questionnaire score’ (p = .004). Of the questions that assessed patient recall, only one question was found to have statistically significant results with which the written information group recalled more information than the verbal consent group regarding the risk of deep vein thrombosis: 31% vs. 11% (p = .01). Besides the fact that recognition being measured, this study was limited in its explanation of statistical analysis as there is no indication of the reliability of the scale used.

Summary

Overall, a further six studies measured the effectiveness of written information compared with verbal information on patient outcomes including knowledge, satisfaction, and anxiety. Five of these studies were conducted on surgical patients all of which were conducted in the USA or UK. In all of these studies, there was some form of improvement in patient knowledge in the group receiving written information. However in several studies less stringent methods of
recognition or cued recall were only measured. The most recent study conducted by Makdessian et al. (2004) measured free recall in an RCT of 120 cosmetic surgical patients receiving either oral information or pamphlets outlining the surgical risks. The findings showed that after two weeks patients receiving the pamphlet recalled significantly more information than the group receiving oral information. However the pamphlet group only recalled half of the five surgical risks. Other studies measuring recall of similar patients also found patients to recall only half of the information (Armstrong et al. 1997).

Makdessian and colleagues (2004) also measured the impact of demographic variables on the recall of information. Patients undergoing cosmetic surgery were found to recall more if they had a university or higher education. When comparing the two groups, the pamphlet group appeared to influence the recall of risk in patients with or without a university education. Similarly a significant difference was also seen in the gender breakdown, with females recalling more than males when receiving the pamphlet and also recalling more than females not receiving the pamphlet. A reason for this may be that females read the pamphlets thereby impacting their recall compared to males or those not receiving any reading material.

In all of the studies, recall was measured between one and 19 days post treatment therefore long-term recall or recognition was not measured. This may be because these studies were mainly in surgical patients who have the treatment once off rather than non-surgical treatment which may be over several months.

Most interestingly, Damian and Tattersall (1991) found that the majority of non-surgical patients with bad news consultations found a letter significantly more useful to help, understand, and remember what they had been told compared to patients receiving good news (p < .001). It may be that the patients paid more attention to the information given and what they had to do and be aware of.
Varying readability of consent forms

The readability of information may be another factor relating to patient recall and subsequent understanding of information. Earlier studies assessing varying levels of readability of the consent form were identified. One of these studies, conducted by Taub (1980), was a simulated trial that involved 90 elderly volunteers for research (Taub, 1980). The author was particularly interested in identifying the impact of age on memory of the information. Therefore a group of elderly patients was created with 56 community dwelling female adults (57 to 83 years) recruited from local senior citizen centres. The comparison younger group was made up of 34 female adults aged 22 to 35 years who were housewives, clerks, or secretaries. Two versions of the information forms were tested, one which was considered to be fairly difficult to read, being at the 12th grade reading level, and a revised information form which was designed to be fairly easy to read requiring only 6th to 7th grade reading levels. The first version of the form was read by 34 of the older adults and all members of the younger group while the revised form was evaluated by 22 participants of the older sample. The authors state that this two step process could protect the rights of the potential volunteers by eliminating those who do not understand the procedures and/or may have ‘volunteered’ under pressure. Volunteers were also grouped on the basis of scores on a vocabulary test as memory was believed to be affected by vocabulary levels.

Apart from the readability level, the forms were otherwise the same which includes the length, font, and content. Two to three weeks after signing the consent form, participants answered multiple choice questions, each with five alternatives, relating to the main points presented in the information forms (suggesting recognition was assessed). However the different versions of the information form had no effect upon memory performance either alone or in connection with vocabulary level and these results were not presented. Therefore the authors combined the data for the two forms for age group comparisons. They identified that amongst the elderly groups, the number of correct scores increased with an increase in vocabulary level (p < .01). Age was also found to be a significant factor to the total number of correct responses (p < .05) with younger adults performing better.
This study had several limitations with the key concern being the complex design of the study. Firstly, bias was created by the two step process eliminating participants due to concerns of not understanding the procedure or being pressured to volunteer. The authors based the scores on the vocabulary test as memory was believed to be affected by vocabulary levels, however this introduces another confounding variable. It is unclear from the study what differences in the groups were relevant and not measured. Also, no results were shown to compare the impact of the different versions of the form on correct responses, and the small sample size in each of the subgroups analysed maybe a limiting factor.

Almost two decades later, Davis, Holcombe, Berkel, Pramanik, and Divers (1998) conducted a non-randomised study to test the hypothesis that a simplified consent form would be less intimidating and more easily understood by individuals with low to marginal reading skills (Davis, Holcombe, Berkel, Pramanik, & Divers, 1998). A total of 183 adults were tested including 18 from a private oncology clinic, 28 at a low income housing complex, and 137 at a university oncology clinic.

Two types of consent forms were assessed: the first, known as the Southwestern Oncology Group (SWOG) consent form at a 12th grade reading level was for a phase III breast cancer clinical trial, which was seven pages long, single spaced, with an average sentence length of 21 words, and no graphics. The second was a simplified booklet-style form (5th grade level) developed at the Louisiana State University Medical Centre (LSU). This was also seven pages but fewer words, an average sentence length of 13 words and using colored headers, with seven instructional graphics. The two groups were similar in demographics and the reading ability of patients was on average at a 7th – 8th grade level. Patients were given one consent form and were then interviewed using an oral questionnaire that assessed attitudes and comprehension of the form read. On the following day the patients were given the alternate consent form and were again interviewed, therefore the order of initial forms given to patients was alternated to prevent bias. Sixty nine adults were initially given the SWOG form and 114 initially given the LSU form. Fewer people were recruited for the SWOG as their interview took 25 minutes compared to 10-12 minutes using the LSU form.
The simplified form (LSU) was rated as significantly preferred (62%, \( p < .0001 \)), less frightening (13%, \( p = .008 \)), and easier to read (97%, \( p < .0001 \)). Patient comprehension was almost the same for both forms (58% LSU form; 56% SWOG form) with no significant differences on any of the 10 individual questions used to assess this. Comprehension was found to be related to patients’ reading ability which was measured by the Rapid Estimate of Adult Literacy in Medicine (REALM) which is a reading recognition test. Reading recognition tests indicate people’s ability to read aloud words in isolation, and authors reported that they are accepted as useful predictors of general reading ability. Participants reading at or below a 3rd grade level had an average comprehension score of 21%, those reading at a 4th–6th grade level averaged 39%, those at a 7th–8th grade level scored 54%, while those reading at or above a 9th grade level scored 72% (\( p = .04 \)).

Several limitations to the study included non-randomization of the study which meant more participants were given the LSU form as it took less time to read and therefore more questionnaires could be completed. Secondly, none of the participants were candidates for the phase III breast cancer trial for which the consent form was designed and again, as in previous studies, none of the participants were dealing with an actual recent diagnosis of cancer. Another potential problem reported by the authors was that, although the questionnaire was pilot-tested for comprehension, the validity of the questionnaire was not extensively tested to determine the appropriateness of the questions.

**Summary**

In conclusion, both of these studies showed no impact on patient knowledge of information by modifying the information to a 7th grade reading level from a 12th grade level. However, findings from the more recent study indicated that simplifying informed consent material alone makes the forms more appealing and easier to read but may not improve comprehension (Davis et al., 1998). Similar to the recall found in studies measuring other interventions discussed in the previous sections, Davis and colleagues also found patients to recall about half of the information. These studies also found a higher reading level, higher vocabulary level, and younger age were related to increasing levels of comprehension. However in both
studies the measure of recall was questionable and the methods employed were somewhat flawed. Neither of the studies randomly allocated patients to the comparable groups and as a result there were considerable differences in their demographics.

**Question prompt sheet**

Another novel method to improve the consent process or the success of consultations is through the use of question prompt sheets. The primary idea of this method is to promote patients to ask questions during the consultation and is believed to have the added benefit of increasing knowledge and satisfaction. Butow, Dunn, Tattersall, and Jones (1994) studied the effectiveness of a question prompt sheet to encourage cancer patients to ask questions and participate in the consultation (Butow, Dunn, Tattersall, & Jones, 1994). The study was restricted to patients of a single oncologist to control for the impact of clinical style. The 142 patients were randomised to receive either a handout encouraging question asking or a handout informing patients of services available through the Cancer Council. The mean age of patient was 51 years (range 19 – 83 years), the majority were females (84%) with breast cancer (43%), and married or de facto (63%). Half of the patients had localized cancer while 35% had metastatic cancer, with the remaining unknown or no evidence of the disease. Patients were not all newly diagnosed as 44% of patients had recurring cancer. The question prompt sheet (QPS) was given to patients 10 minutes prior to the consultation, giving them time to think about questions. Also prior to the consultation, the Spielberger State Anxiety Inventory (SAI) and two questions regarding involvement and information preferences from the Information Styles Questionnaire were completed by patients. Following this the consultation was audio-taped and these were analysed using a computer based program, CT-LOGIT.

Patients were telephoned one to three weeks after the consultation to assess recall. Recall of information, which was reported to be cued, was assessed by comparing each item recalled by the patient with the specific information presented by the oncologist. It was then reported as the percentage of facts recalled accurately in total and within each category of information. Patient satisfaction with the amount and quality of the information received, the doctor’s
communication skills, and patient participation was also assessed at follow-up using 22 items adapted from previous research (Korsch, Gozzi, & Francis, 1968; Roter, 1977). Patients also completed a 21-item Psychological Adjustment to Cancer scale which has two subscales: the impact of cancer on daily life and the feelings of being worthwhile and in control of the cancer. The two subscales had high Cronbach’s alpha coefficients (.80 and .85, respectively) as measured in a validation study. Questionnaires assessing patient satisfaction and adjustment to cancer were sent separately by mail.

There were limited differences between groups regarding the number and duration of questions asked or the patients’ consultation and no relationship between the question prompt sheet versus general information sheet on recall or patient satisfaction. Patient scores on the SAI were not reported and there was no indication of whether there were any differences between groups at baseline. Both groups recalled approximately a quarter of the information presented in the consultation (25% and 27% in the QPS and general information group respectively) however most were satisfied with the consultation (87% and 89% in QPS and general information group respectively). Results of statistical analyses were not shown. Multiple regression analyses were conducted to explore the predictors of the duration and number of patient questions during the consultation. There was no relationship found between the duration and number of patient questions during the consultation and patient satisfaction, psychological adjustment, or recall. The main limitation of this study was the use of prompted recall. The sample population was also rather mixed but there was no indication whether there were any differences in these demographic and disease factors between the two groups. The fact that 56% of the patients had just been diagnosed and 44% had recurrent cancer may have impacted on assessment of knowledge due to the previous exposure of the information in recurring cancer patients, however this was not evaluated in the study.

In 2001, a similar study was conducted by the same research group in New South Wales, Australia (Brown, Butow, Dunn, & Tattersall, 2001). This was an extension of the previous study to see if results could be replicated results across oncologists rather than only assessing patients from one medical oncologist. This study measured the effects of a question prompt sheet provided 15-20 minutes prior to the initial consultation with one of nine oncologists.
Factors assessed included patient question asking, length of the consultation, recall, anxiety, and satisfaction. Patients were randomly allocated to one of two groups: one group receiving the prompt sheet (n = 160) and the other usual care (n = 158).

There were no differences between groups on demographic and disease characteristics indicating successful randomisation. Oncologists of patients in the group receiving the prompt sheet were given protocols to be proactive regarding the prompt sheet by reassuring them that the questions would be answered to the best of their ability. The prompt sheet group was further divided into subgroups. Half of the patients received a prompt sheet that was actively endorsed (n = 81) and half received a prompt sheet that was not actively endorsed (n = 79, 25% of total sample). Prior to the consultation, all participants completed a questionnaire measuring anxiety, using the Spielberger State Anxiety Inventory (SAI) and information preferences, using an adapted form of the Information Styles questionnaire. The consultation was audio-taped and immediately after the consultation, anxiety was reassessed. Within 10 days post consultation a structured telephone interview took place and recall was assessed. Recall was assessed by asking questions on specific areas covered during the consultation. Similar to the previous study, the percentage of facts recalled was calculated for total accuracy and the number recalled accurately within each category.

On the other hand, satisfaction, anxiety, and information needs were assessed by a questionnaire that was mailed to patients seven to 10 days post consultation. Similarly, satisfaction was measured as in the previous study (described above). This, however, was a larger study, with 318 consultations taking place, patients had a mean age of 56 years, and there was a similar female to male ratio. One concern was the contamination effects of proactive doctors maintaining their standard practice in the control group and passive doctors behaving in their standard manner with all patients, whether receiving a prompt sheet or not. However based on the audio-taped consultations, no significant differences were identified.

In patients who had a prompt sheet, there were no significant differences in the total number of questions asked between those who saw a passive or proactive doctor. However, patients who had a prompt sheet and a proactive doctor (M = 52%) significantly recalled more
information in total than those patients receiving prompt sheets but a passive doctor (M = 44%, p = .04).

With regards to the specific categories, it was found that patients with a prompt sheet whose doctor was proactive recalled significantly more information regarding treatment issues (p = .01) and side effects (p = .009) than those with a prompt sheet and passive doctor. The group not receiving a prompt sheet was reported not to have significantly different recall to the two prompt sheet groups however the specific results were not stated. Patient age, gender, and whether the patients had listened to the consultation audiotape prior to the recall interview were associated with recall below the .20 level of significance. Age, gender, and endorsement of the prompt sheet were included in a multivariate regression which indicated that gender and endorsement of the prompt sheet remained in the model. This indicated that males whose doctor endorsed the prompt sheet recalled more information, however this was not true for females.

Anxiety levels prior to the consultation were no different in the groups. However immediately after the consultation, patients in the prompt sheet group which was not actively endorsed were significantly more anxious than patients in the other two groups. Similarly no differences were found in satisfaction with receiving the prompt sheet or the active endorsement. It was unclear whether the control group patients were asked about their satisfaction with their consultation and if so, whether there were any differences with the two prompt sheet groups. This was a well conducted study despite raw figures not being shown for recall, satisfaction, and anxiety. Admittedly the primary outcome of the study was the effect of prompt sheets on question asking for which the results were presented. Also, it was unclear if patients had access to the prompt sheet when interviewed on the phone, as this may have impacted on their recall.

**Summary**

Neither of the studies assessing the effectiveness of question prompt sheets on patient knowledge found significant differences between patients receiving the question prompt sheet
or not. The two studies presented in this review were based in Australia and from the same research team. The more recent of the two studies was a much larger study aimed to overcome limitations from the first study and also measure additional factors. Brown and colleagues (2001) assessed free recall however this was via telephone which means that patients may have the information sheet and consent from in front of them to refer to correct answers so results should be considered with caution. Regardless of this, a significant difference was found in the recall of patients who received proactive doctors compared to those receiving passive doctors. In both groups, though, about half of the information was only recalled. Also, recall was assessed a short time after the consultation therefore the long-term knowledge of the information given is unclear.

**Audiotapes**

The next section reviews studies that assessed audiotapes being used to reinforce information that has already been delivered verbally in person. Audiotapes may be more suitable for communicating information about treatments for a wider range of patients such as those with low health literacy.

In the late 1970s, Butt (1977) conducted a study in the USA to ascertain if giving patients a tape recording of the consultation between the patient and the physician was an acceptable form of communication for patients (Butt, 1977). Forty eight consecutive patients who either had functional problems or an illness and wished to take part in the study, were recruited from outpatient clinics. Their tape recorded consultation included the patients’ history, physical examination, laboratory findings, diagnosis, and prescribed treatment. A total of 45 patients responded to the questionnaire sent to them three months after the consultation which included a series of questions. However, there was no indication of these questions being reliable or valid. The sample had a mean age of 55 years (range 26 to 77 years) and 58% were females. The response rate was unclear however the results revealed that 91% of the patients were ‘helped’ or ‘helped considerably’ in understanding the physicians’ discussion. Also, the majority of patients (86%) believed that the taped communication improved their health care. Spouses of elderly patients were particularly grateful to be able to listen to the summary. Overall, this research showed that the tape was acceptable for patients to enhance the
communication process. The study was relatively broad in its inclusion criteria with the patients having a range of illnesses however for the purposes of this study, this may be acceptable, increasing generalisability. This was a reasonably simple study which showed positive findings however the recommendation to conduct larger, well controlled randomised studies was made by the author given there was no control group to compare findings with.

Stemming from Butt’s (1977) study, Reynolds, Sanson-Fisher Poole, Harker, and Byrne (1981) conducted a study in Australia to investigate to what extent patients awaiting cancer treatment wanted information about their illness (Reynolds et al., 1981). Furthermore, the study was designed to determine the amount and type of information patients are given, and the effects of two techniques, i.e. providing patients with an audio-recording of the consultation and explicit categorization of patient recall of information. Group one patients were informed about their illness and its treatment by direct questioning and explicit categorization. In other words, patients were given an information handout with a list of categories which could be discussed such as: ‘what is wrong with you and what is the diagnosis,’ ‘what the treatment will be,’ ‘what sort of symptoms you may have’ etc. If the patients asked about one of the questions on the list, they were given detailed information on that topic. Patients were given the handout to take home as well as a tape-recording of the consultation. Group two patients were given the same information as group one patients except they were not given a tape-recording of the consultation. Lastly, group three patients acted as controls and were given standard information about their diagnosis, parts of the body affected, proposed treatments, possible side effects, and examinations necessary.

A total of 67 patients with various types of cancer who were referred to the medical oncology clinic for treatment were randomly allocated to one of three groups. However, the randomisation process was not stated in the study. Five days after the consultation each patient was contacted by an independent interviewer and a structured interview was conducted. Patients were asked to rate, on a 5-point scale, how satisfied they were with the amount of information they received. Patient knowledge about each aspect of the illness and its management was also assessed however the authors did not report any details on how knowledge was assessed. Six weeks later interviews with the same content were conducted.
with the patients, so there were two follow-up interviews over time. Recall was measured by calculating the number of facts presented to the patients during the consultation obtained from the tape-recording and then determining the number that were recalled by the patient. The two intervention groups were presented, on average, a similar number of facts (Group 1: M = 29.6, SD = 5.8; Group 2: M = 28.1, SD = 5.9) whereas the control group (Group 3) received much less information (M = 18.2, SD = 5.3). Findings show that at five days the control group patients recalled a greater percentage of presented facts (80%) than the intervention groups (69%) which was statistically significant (p < .05).

Also, at six weeks the control patients were found to have better knowledge (84%) than the intervention groups (69%) which was statistically significant (p < .05). The control group patients actually had an improvement in recall over time, while information recall in the intervention groups remained the same, however no significance testing was provided. Regardless, all three groups of patients remained highly satisfied and no significant differences were found between the three groups with regards to satisfaction.

The oncologists conducting the consultation were not blinded to the study as only one of two oncologists conducted consultations for all three groups. This may mean that there may have been some inconsistency in the information provided to patients within the same group. Also the measure of recall was via a telephone interview which may allow patients to refer to their notes in answering the questions. This study did not specify whether it was cued or free recall which may impact on the findings. There is also some confusion in the study with regards to the terms recall and knowledge, as these were used interchangeably.

Hogbin, Jenkins, and Parkin (1992) assessed the effectiveness of audiotape recordings on patient knowledge in 67 early breast cancer patients who were randomized to one of two groups: either receiving a tape of the diagnosis and treatment consultation or not (Hogbin et al., 1992). Three questionnaires were administered and completed by the patients prior to randomisation. Firstly, an understanding questionnaire designed for the purpose of this study proposed to measure whether the patient understood the different aspects of the treatment information for e.g. which type of operation would be performed. Secondly, additional
measures were used including the Hospital Anxiety and Depression Scale (HADS) questionnaire to measure anxiety and depression, and the Rotterdam Symptom Checklist (RSCL) was used to measure the patients’ psychological and physical distress. The last two questionnaires were standardised and were reported to have good reliability (not stated). These three questionnaires were again given to patients two to three days pre-operation (approximately two weeks after the first assessment) and only the HADS and RSCL were also given six weeks later.

Correct responses for understanding were calculated on an individual basis by listening to the consultation as the information given varied but ultimately patients were informed that they needed to provide an answer to all questions therefore giving all patients a maximum score of 18. The results showed that patients who received the tape showed a significantly higher level of understanding at the second time point (M = 16.66, range 14 – 18) compared with the initial assessment (M = 15.09, range 11-18, p < .01) however no significant increase was evident in the group not receiving the tape from the initial assessment (M = 15.70, range 12-18) to the second assessment (M = 16.35, range 15- 18, p > .05). Anxiety and depression did not significantly differ at any stage between the tape and no tape groups. As with most study-specific questionnaires, the understanding questionnaire was not believed to be validated and it was unclear whether recall was free or prompted therefore these findings need to be considered with caution.

Another similar randomised trial also conducted in the UK assessed the effect of an audio-taped consultation on knowledge of the information given and anxiety compared with not receiving an audio-tape (North et al., 1992). A sample of 34 advanced carcinoma patients newly referred to the medical oncology outpatient clinic was included in the study. On arrival, patients were given the HADS questionnaire (to assess anxiety and depression) and were asked a series of 11 questions on their knowledge regarding their diagnosis, severity of illness, treatment choice, etc. The patients were then randomly allocated to either receive the tape or not. In the consultation, the oncologists used a standard checklist for both groups to ensure patients received the same information and this was validated by an independent person who checked that the same information was given to the patients thus increasing the accuracy of
the study. All patients returned one week later and were asked to repeat the HADS and an information questionnaire. After one week, the mean HADS anxiety scores improved in both groups but the scores improved significantly more in the tape group than the control group (p < .001).

Depression scores also improved in both groups but this was not found to be statistically significant, perhaps due to compromised power due to the low sample size. However, effect sizes were not provided so the possibility of Type II errors occurring was difficult to ascertain. Information at the first time point was not different between the groups with both recalling a mean of three items. After the intervention, the tape group recalled significantly more information (M = 9.33, SD = 1.64) compared with the control group (M = 4.44, SD = 2.13; p < .001). North and colleagues did not mention the randomisation process or whether the clinician was blind to the group the patient was allocated to. The study did not provide methods for the statistical analyses and the small sample size also limits the generalisability of the results. No information was given on the questionnaire used to measure knowledge, therefore it was unclear whether free or prompted recall or recognition was being assessed. Also the authors did not report validity or reliability testing on the questionnaire.

Similarly, Dunn, Tattersall, Jones, Sheldon, Taylor, and Sumich (1993) conducted a randomised controlled study of cancer patients attending their first consultation with a medical oncologist (Dunn et al., 1993). This study, however, had a larger sample size of 142 patients who were randomised to one of three groups: (1) audiotape of the consultation, (2) audiotape of cancer in general, or (3) no tape. The oncologist was blind to the group assignment. Prior to the consultation, patients were asked to complete the 20-item Spielberger State Anxiety Inventory (SAI) measuring situational anxiety and two questions from the Information Styles questionnaire regarding involvement and information preferences, as in previous studies by this same group mentioned in the prompt sheet section above.

Information recall was assessed four to 20 days after the consultation by means of a telephone interview. Free recall was assessed by an open-ended question asking patients to report what the doctor said in the consultation. They were then given standardised prompts of 13
categories based on topics commonly discussed in consultations and asked whether the doctor mentioned any of them. Free and cued recall were analysed separately and total recall was also measured as an aggregate of both the scores which was then converted to a proportion as different consultations contained different amounts of information. There was a loss to follow up with only 92 patients (65%) assessed at time two, with 30 patients in the group receiving an audiotape of the consultation and 31 patients in the other two groups thus limiting power for between group analyses.

The patients lost to follow up were found to be on average 8.6 years younger (p < .005) and more likely to have presented with a first diagnosis of cancer (p < .005). Multiple regression analyses showed that these factors were not confounders to satisfaction, recall, or psychological adjustment. The mean total recall was 26% and this did not increase in the group that received the consultation tape relative to the control group (p value not provided). However the general tape group recalled less than both groups which was significantly less than the consultation tape group when only including those who listened to the tape (p < .05). There were no significant differences in the patients’ salient recall across the three groups with an average salient recall of 41.9% (range, 0% to 100%). Similarly, there were no significant differences in the mean free recall across the three groups. The authors did not report an overall mean for free recall but it was low in all three groups with the consultation tape reporting the highest mean free recall of 12.4% (SEM 2.2). This is further confirmation of the difference in free versus cued recall and the superiority of free recall.

Patient satisfaction was measured by a validated 22-item satisfaction questionnaire and those in the tape groups received seven additional questions relating to the satisfaction with the tape, which were all sent by mail. Results showed that there was a significant difference in the groups, with patients in the group receiving the consultation tape being more satisfied with the tape itself (M = 61, SE = 5.7) than those receiving the general tape (M = 43, SE = 4.9). Satisfaction with the consultation was also highest in the consultation tape group (91%) followed by the general tape group (87%), and the no tape control group (85%) and this was marginally significant (p < .05). Patients also completed the Psychological Adjustment to Cancer (PAC) scale covering six adjustment factors: hope, confidence in the medical system,
stigma associated with cancer, perceived personal control, acceptance, and denial. In this study the Cronbach’s alpha was .86 and test-retest reliability was .92. Psychological adjustment to cancer was found to be similar across all three groups at follow up. This study was well written, randomization was explained, and was based on an intention-to-treat analysis, an advantage over other studies. While the loss to follow up may be a limitation, authors conducted attrition analyses that showed this did not impact on the findings of the study. This study was good in that they reported and compared free versus cued recall and an aggregate of both recall measures. However it did not report on whether there were any differences in demographic or disease characteristics between the groups.

In the UK, McHugh and colleagues (1995) conducted a study that focused on patients who were receiving bad news of their diagnosis (primary) or unsuccessful treatment in patients with an established diagnosis (secondary; McHugh et al., 1995). The study examined the effect of providing patients with an audiotape of a previous consultation on their level of participation during a subsequent consultation. The study was a randomised trial including 117 diagnosed patients from a medical oncology clinic. All consultations were audio taped and patients were randomly allocated to a group that received the tape to play at home (n = 63) or not (n = 54). The clinician was blind to the group allocation. Each patient had two clinical interviews, one prior to the group allocation (stage 1) and the second an average of four weeks afterwards (stage 2). Both interviews involved completion of the 30-item General Health Questionnaire (GHQ-30) and the HADS questionnaire (to assess anxiety and depression). Following this, an average of five months after the baseline questionnaire, there was a postal follow-up (stage 3) which included the GHQ-30 (Goldberg & Williams, 1988), the HADS questionnaire, and an information retention questionnaire. The information retention questionnaire asked patients to recall what was said during the consultation with regards to aspects of their diagnosis and treatment however it was unclear whether free or prompted recall was being assessed.

Information recall was measured by comparison of patient responses to the transcript of the consultation audio-tape and then a proportion of accurate recall was calculated. Those in the tape group also completed an ‘attitudes to tape’ questionnaire specifically designed for the
study. Demographic characteristics were similar in both groups. There were losses to follow up in each group so at stage 3 there were 32 patients in the intervention group and 46 control group patients. Nevertheless, the study was conducted using an intention-to-treat analysis meaning that scores could still be analysed from drop outs making the analysis more conservative.

Tape group patients correctly recalled more of the facts they had been given concerning their diagnosis and treatment than did control group patients and this was found to be statistically significant for five out of the nine items at stage 3 (p < .05). The percentage recalled by patients varied based on the topic for example 100% of the tape sample recalled the name of treatment at five months however in this group only 73% recalled the effect of treatment on daily life. In fact the effect of treatment on daily life was the factor recalled by the least number of patients in the tape group and the no tape group (50%).

No significant differences were found in mean GHQ-30 and HADS scores between tape and control groups at stage two or three. Subgroup analyses were conducted to see if any particular type of patients benefited from the tape. Therefore patients were categorised into good prognosis (greater than 70%) or poor prognosis. When considering the subgroup analysis, it was identified that from stage one to two, generally, good prognosis patients (Mean change - 5.1, 95% CI -8.9 to -2.3) had a greater improvement in general health than the poor-prognosis group (Mean change 0.2, 95% CI -2.8 to 3.2; p = .02). From stage two to three, the change in mean scores continued but was not found to be significant, perhaps due to compromised power due to the small samples being compared. No effect size analyses were provided to ascertain the magnitude of change. Most patients receiving the tape thought that it was helpful (76%). Overall this was believed to be a well conducted study however there were some concerns with the information retention questionnaire. Firstly, it was not reported to have been validated (as many questionnaires in this area of research) and it was posted to patients, which reduces the reliability of the responses provided. Type II errors were also likely given the small sample size for between subject analyses.
As a result of conflicting findings from studies, Hack, Pickles, Bultz, Degner, Katz, and Davison (1999) aimed to assess the impact of offering breast and prostate cancer patients with an audiotape of their primary oncology treatment consultation (Hack et al., 1999). This randomised controlled trial consisted of 36 patients allocated to three groups: group one did not receive the audiotape, group two received the audiotape, and group three were given the choice of receiving or not receiving an audiotape (all accepted).

Prior to the consultation (Time 1), patients were given the consent form, demographic form, STAI, and Control Preferences scale. The Control Preference scale uses a card sort procedure to determine whether patients want to play an active, collaborative, or passive role in decision-making. After the consultation (Time 2), the State Anxiety Inventory (SAI) was given again in addition to a modified version of the Patient Perception scale, the Physician’s Perceived Likeability, and Technical Expertise scale. The Patients Perception scale is a standardized tool used to assess patients’ satisfaction regarding patient centeredness of the physicians’ interaction using 4-point scales (1 = completely to 4 = not at all). The Physician’s Perceived Likeability and Technical Expertise scales both developed for the study were each a 5-point scale (1 = strongly agree to 5 = strongly disagree). Reliability or validity of the questionnaire was not reported.

Six weeks after the consultation (Time 3), a follow up telephone call was made and patients completed all questionnaires. At time 3 an information recall questionnaire was also given, which was developed for the study, and contained 5-point scales (1 = we definitely did not discuss to 5 = we definitely did discuss) regarding five items: treatment alternatives, treatment side effects, likelihood of cure, extent of disease, and type of illness information available. Again, there was no mention of reliability or validity of the questionnaire. Lastly, the audiotape questionnaire asked how often they and their significant others had used the tape, and what other sources they had obtained regarding their illness.

Results revealed that there were no significant differences in anxiety over the three time points. Half of the women were found to prefer a collaborative role before the consultation while half of the men were found to prefer a passive role. Six weeks later, the majority of men
(55%) and 44% of women assumed they played an active role during the consultation. Patients were highly satisfied with the physician-patient communication immediately after the consultation. This dropped slightly but still the patients remained satisfied six weeks later. Also patients who were given the choice to receive the audiotape were significantly more likely to listen to a portion of the tape (83% vs 55%) and listened to the whole tape an average of 2.5 times more than the group routinely given the tape (p value not given). This interesting finding suggested that when patients were given the choice of additional information (in the form of a tape), they not only took the option 100% of the time, but they utilized the information more than those who were given the tape without making the choice.

Recall of the discussion at the six week follow up was high with a mean score of 4.3 per items on the 5-point scale, although this does not show the specifics of the information but rather that the five categories of information were discussed. Amongst the small sample of prostate cancer patients hence male, there was a statistically significant difference in recall when comparing the three groups. Those being offered the tape recalled more followed by those given the audiotape and then those not given the tape (p < .05). Thus the choice of taking the audiotape for this subgroup also impacted recall. For the whole sample, there was a significant correlation between recall and satisfaction with the consultation. Patients who had high recall were most highly satisfied with the patient-physician communication and this was found to be significant for males (p < .05) but not for females. Limitations of this study included the reliability of the questionnaires used, the unclear process of randomisation, and the impact of the small sample size compared between three groups, low generalisability of the results, and the lack of reporting of effect sizes making Type II errors hard to determine. This study showed some interesting and positive findings which should be explored in future research.

While most of the studies have, to date, assessed the effectiveness of being given an audiotape versus not being given the tape, or different forms of the audiotape, several have assessed the effectiveness of an audiotape being given compared to another intervention. One of these studies was conducted by Tattersall, Butow, Griffin, and Dunn (1994) who compared audiotapes with summary letters of their consultation (Tattersall et al., 1994). A randomized cross over trial of 187 cancer patients attending their first consultation was conducted. Eligible
patients completed the HADS questionnaire and two items on involvement and information preferences from the Information Styles Questionnaire, as in previous studies by this group discussed throughout this review. Following this, patients were randomized to receive the audiotape then letter (TL) or letter then audiotape (LT). The oncologist was blind to the group to which patients were randomized. Ten days after the consultation patients were contacted to determine recall and use of the first intervention.

Recall was assessed using a technique developed in a previous study by comparing patient recall against salient points nominated by the doctor (Dunn et al., 1993). Following this, the second intervention was given to patients and approximately ten days afterwards, a second telephone interview was conducted. Patient satisfaction, anxiety, and depression were also assessed using questionnaires which were sent by mail at both follow-up time points. Satisfaction was assessed using 10-point linear analog scales assessing the degree to which the intervention aided their understanding, annoyed them, helped recall, embarrassed them, or helped family and friends understand, amongst others. The sum of the scales was used to derive the scores which were expressed as a proportion of the maximum possible score.

Patients who received the tape first listened to it on average 2.8 times and read the letter 2.2 times. Patients who received the letter first read it 3.4 times and listened to the tape 1.8 times. Therefore both groups used the first intervention more than the second but more so if the letter was received first (p < .0001). Anxiety and depression scores were not affected by receiving a tape or letter but anxiety decreased significantly for both groups over time (p < .01). Satisfaction scores were high in both groups (greater than 80% for all items) with the only significant difference between the groups being that patients felt the tape to be more effective in reminding them of what the doctor said (p < .05) compared to the letter. Audiotapes, however, were the clear preference as a communication aid over letters (82% versus 38% respectively). Patients recalled (after being cued) an average of 2.43 of the 5.04 points nominated as salient by the doctor and an average of 4.58 items in all. Recall of salient points was similar for TL and LT groups (no results shown).

The telephone interview to measure recall may be a limiting factor to the findings as patients may have had the letter or other relevant information (such as notes from the tape) with them.
Despite the letter being read more, the audiotape was the preferred method for receiving the information. Letters may have been read more simply because they are a more convenient method that can be accessed anytime compared to audiotapes which require equipment to access. Future studies could assess why audiotapes were found to be preferred over letters and how to modify it so that recall is also improved.

The last decade has seen a diminishing number of studies assessing audiotapes, which may be attributed to advances in technology. Nonetheless, some Canadian researchers have continued to conduct studies to assess the impact of consultation audiotapes on cancer patients (Hack, Pickles, Bultz, Ruether, Weir, Degner, et al., 2003; Hack, Pickles, Bultz, Ruether, & Degner, 2007; Hack, Whelan, Olivotto, Weir, Bultz, Magwood, et al., 2007). The last of these studies was designed to enhance informed consent to a clinical trial in breast oncology. Patients included 69 women newly diagnosed with invasive breast cancer across five Canadian cancer centres who were considering participation in a trial comparing breast irradiation alone to breast irradiation plus regional nodal radiation in women with a moderate risk of regional recurrence after breast conserving surgery. After the consultation, patients completed a socio-demographic questionnaire and were randomized to one of three groups: standardized audiotape (n = 22), consultation audiotape (n = 20), or both audiotapes (n = 27).

The standardized audiotape was 15 minutes in length and detailed patients’ rights, benefits, and risks and was developed after much piloting. On the other hand the consultation audiotape was an average of 32 minutes. Outcomes measured included perception of being informed about clinical trials, knowledge of clinical trial related information, and satisfaction. The Informed Consent Questionnaire was adapted and used in the study including the Patient Perception of Being Informed (PPBI) and the Patient Knowledge of Information Relevant to Informed Consent to Clinical Trials (PKI) subscales. Each subscale consisted of 17 items, with a 5-point scale used for each item in the PPBI (strongly agree to strongly disagree) and true/false items in the PKI. The PKI also included four multiple choice questions but were not used in this study. Satisfaction was measured using the Patient Perception Scale which includes 9-items rated on a 4-point scale and has been found to have a Cronbach’s alpha of .88 in previous studies. An Audiotape Use Questionnaire was also used to assess the number of
times the patient listened to the tape, the perceived benefits/drawbacks associated with the audiotape, and preference of audiotape format: standardized or consultation. This questionnaire was adapted from a similar questionnaire used in previous audiotape studies (Hack et al., 1999; Hack et al., 2003).

The trial nurse contacted the patients one week after the consultation to determine whether they wanted to take part in the radiation trial and regardless of their participation were contacted within three days to assess outcomes of the audiotape trial. There were no statistically significant differences found for demographic variables across the three groups. There were also no differences in the average number of times each tape was listened to. The mean scores of the PPBI, PKI, and patient satisfaction questionnaires were generally high but no statistically significant differences were found between the three groups (M = 14.2, SD 2.0). Almost half the patients (48%) preferred to have both audiotapes and two fifths (39%) of patients preferred the consultation audiotape. Amongst patients who received both audiotapes, half preferred the consultation audiotape and a further one third did not have a preference (32%) with the remainder preferring the standardized audiotape (18%). The test of difference in those patients expressing a preference was marginally significant (p = .07), suggesting that patients preferred the consultation audiotape over the standardized audiotape.

This study lacked reporting of the reliability coefficients of the PPBI and PKI subscales of the Informed Consent questionnaire, especially given that in some circumstances, this standardized instrument was changed for this study. It also included 21 oncologists across five cancer centres which can result in differences in consultation audiotapes, yet greater generalisability. Future studies should use larger sample sizes to replicate findings and also consider including a control group to determine the impact of the consultation on patient knowledge of the clinical trial. As the current sample size was low, effect sizes should have been reported to help identify the magnitude of change and any possibility of Type II errors. As it stands in this study, the reason for a high level of recall is unclear and may be attributed to the written information given or other sources rather than the consultation or standardised audiotapes.
Summary
The nine studies identified in this review found mixed results regarding the effectiveness of using an audiotape of the consultation to improve patient knowledge of the information given. Only one of these studies clearly reported to have measured free recall but this by means of a telephone interview therefore it still remains unclear whether patients referred to the information sheet and consent form for assistance (Dunn, et al. 1993). This randomised controlled trial of 142 cancer patients who either received an audiotape of the consultation, a general audiotape, or no tape measured free and prompted recall between four and 20 days and found no differences between the groups on free recall. The groups had a low mean level of free recall with the highest mean found in patients receiving the consultation tape being 12.4% (SEM 2.2).

Three studies, all of which were conducted in the UK, of which two were randomised controlled trials, found the audiotapes to significantly improve the recall of cancer patients compared with patients not receiving a tape. Two of these RCT studies focused on bad news consultations and a third study included advanced cancer patients (Hogbin et al., 1992; McHugh et al., 1995; North et al., 1992). This suggests that in such conditions patients may benefit from an audiotape of the consultation. In two of the studies, short-term recall was measured, that is, one to three weeks after, while in McHugh and colleagues (1995), long-term recall was assessed, 5 months after the consultation. All of these studies showed a high level of recall ranging between 73% and 100%. However, the method of measuring recall was unclear in all three studies therefore results should be considered with caution. Also, while significant differences were found, two of the three studies had a small sample size which increases the likelihood of Type II errors. No effect sizes were given to determine the magnitude of change.

Anxiety was also measured in these three studies however only North and colleagues’ (1992) study showed an improvement in anxiety levels, which was seen in both groups although more so in the audiotape group. The other two studies did not find anxiety to increase over time. In addition, patients receiving audiotapes of the consultation found them to be helpful (McHugh et al., 1995). Patient satisfaction was found to be high in all patients regardless of the group
that they were allocated to (Dunn et al., 1993; Tattersall et al., 1994). In one study patient satisfaction was associated with recall, in that patients who had a high level of recall were most satisfied with the consultation. Males were also found to be more satisfied than females when they had a higher level of recall (Hack et al., 1999). Overall while some positive findings were found for the effects of audiotapes on patient recall of the information given, further research would be necessary as evidence shows that there are still some mixed findings but also poor measures and/or reporting of recall were found in most studies. However more advanced technologies may preclude audiotapes from further assessment.

**Videotapes**

In this next section, the effectiveness of providing patients with a videotape outlining treatment related information and whether this format improves patient knowledge is assessed. Moldofsky, Broder, Davies, and Leznoff (1979) conducted one of the earlier studies identified that assessed the impact of a videotape on improving the knowledge of patients (Moldofsky, Broder, Davies, & Leznoff, 1979). A 55 minute educational videotape program was designed for adult asthma patients and consisted of a dialogue between a physician and a professional sports player who had asthma. Adults attending an asthma clinic were randomised to either a control group receiving no videotape (n = 39) or an intervention group who received the videotape (n = 40). After the intervention group viewed the video post-consultation, they were assessed on their knowledge by a 23-item questionnaire, and also on their attitudes to medicine, and asthma. A medical assessment was also conducted. The control group completed the knowledge questionnaire after their consultation. A second assessment of knowledge was conducted an average of 16 months later, however 17 people were lost to follow up therefore results were based on the 62 participants who were assessed at both time points.

The two groups were similar in demographics, medical symptoms, and attitudes towards medicine, and asthma. Findings showed that the video group had a significantly higher mean total score (M = 17.9, ± 0.7) than the control group (M = 14.7, ± 0.6) at the first assessment (post-consultation) of the knowledge questionnaire (p = .006). At the second post-intervention assessment, the video patients scored significantly lower than their first assessment (M = 15.0,
± 0.7, p = .02) returning to a similar knowledge level to that of the control group. The patients not receiving the video did not show any differences in their knowledge over time (M = 14.4, ± 0.7). The superior retention of the information was short-lived for those viewing the videotape suggesting that the length of time (an average of 16 months) eroded the new knowledge gained. The study was well written, however lacked details of how patient knowledge was assessed (i.e., was it recall and/or comprehension of the information). The authors reported that the limitation to videotapes to improve knowledge is their failure to encourage active involvement of the participant (interaction). The authors suggested that to improve this shortcoming, adding a discussion with a physician in addition to the videotape may show improved knowledge retention.

In 1994, a study that did assess the effectiveness of a discussion with a physician along with the videotape to improve patient knowledge was conducted (Agre, Kurtz, & Krauss, 1994). Agre, Kurtz, Beatrice, and Krauss (1994), a US based study, aimed to identify the role of a videotape in increasing colonoscopy patients’ knowledge in preparation for giving informed consent and also whether increased knowledge resulted in increased anxiety. The study compared three groups (1) the educational videotape on its own, (2) video combined with a discussion with a physician, and (3) a discussion alone in preparing colonoscopy patients for informed consent.

Two hundred and one colonoscopy patients were recruited to a stratified, randomised three-arm study (video plus discussion, n = 68; video alone, n = 66; discussion alone, n = 67). Stratification was based on no colonoscopy or previous colonoscopy. The videotape, which was assessed a priori by a specialist panel of physicians, was a five minute presentation by a physician with on-screen graphics and summaries of the most important information for reinforcement. This intervention was delivered prior to the consultation after which physicians confirmed that patients understood the information and obtained informed consent. A 13-item multiple choice questionnaire, developed by the investigators and piloted on colonoscopy patients, was used to assess patient knowledge immediately afterwards. The internal consistency of the 13-item questionnaire was .65, showing moderate internal reliability. The STAI was used to test anxiety. Mean correct answers revealed that the two video groups had
better knowledge than the discussion only group (p < .01). The video plus discussion group had a mean of 11.0 (SD 2.18), the video only group had a mean of 10.7 (SD 1.58) and the discussion only group had a mean of 9.6 (SD 2.18). However no significant differences were found between patients receiving discussion with the video or the video alone nor were effect sizes reported. The similar finding in the two intervention groups may be because the discussion was a verbal repetition of the same material presented by the video, not a personalised discussion. Similarly the groups did not differ with regards to levels of anxiety. This study also assessed age and education as mediating variables and found these variables to significantly correlate with knowledge, with subjects who were younger and more educated appearing to be more knowledgeable. Patients who had previous colonoscopies did not have better knowledge than patients hearing the information for the first time. This study was limited in that it was measuring recognition, and the questionnaire had moderate internal consistency. Also, the authors did not report effect sizes.

Another randomised study assessing the impact of an information video on knowledge and anxiety of patients undergoing a colonoscopy was conducted in Australia (Luck, Pearson, Maddern, & Hewett, 1999). Prior to randomisation, all patients were given two information sheets, one outlining the purpose and requirements of the study, and the other focusing on colonoscopy. Baseline anxiety, similar to Agre and colleagues’ study (1994), was assessed by the STAI, however only state anxiety was assessed. Patients were then randomly allocated to the video (n = 72) or no video group (n = 78) with those in the video group taken to a room to view a 10 minute video. In the video, an Australian actor described the procedure, in non-medical language, with the colonoscopist and a patient who had previously had a colonoscopy. This was followed by viewing of a filmed procedure. On average, the colonoscopy procedure took place one week later, prior to which patients were asked to complete the SAI again and a knowledge questionnaire. The knowledge questionnaire was designed by the investigators who categorized it into three sections: knowledge of the purpose (maximum 4 points), procedural details (maximum 5 points), and potential complications (maximum 3 points). There was no further information given on the details of the knowledge questionnaire or how it was measured.
No demographic differences were found between the two groups at baseline. The effect of the demographic characteristics on anxiety at enrolment was assessed and it was identified that females had higher state anxiety at baseline than male patients (p < .001). In addition, patients who had not had a previous colonoscopy had higher state anxiety at baseline than those who had previous experience of the procedure (p < .001). The factors significantly affecting anxiety immediately before colonoscopy included anxiety scores at enrollment and whether or not the patient had watched the video or not (p value not provided). Pre-colonoscopy anxiety was less for patients who had viewed the video but greater for patients who had higher anxiety at enrollment. Patients with low initial anxiety were even less anxious if they had watched the video, and this was statistically significant (p value not provided). Patients who had watched the video scored a significantly higher number of correct responses to questions about the purpose of the colonoscopy (p < .001), the details of the procedure (p = .005), and the potential complications (p = .003). Overall, the video group had a mean of 9.88 (95%CI 9.53 – 10.23) while the non-video group had a mean of 8.31 (95%CI 7.96-8.66, p < .001) of a maximum score of 12.

A sub group analysis of the 20% of patients most anxious at enrolment identified that those in the video group had the highest mean scores for all factors (total mean = 10.4, 95% CI 9.74 – 11.1), whereas the patients who did not watch the video had the poorest results for all factors (total mean = 7.36, 95%CI 6.56 – 8.16; p value not provided). In other words, the video was of greater benefit to severely anxious patients compared with not receiving a video.

This study did not report questionnaire validity or reliability. Again, it was unclear whether ‘knowledge’ was being measured, as reported in the study, or in fact information recall. In addition, some of the results were not supported by significance testing or not even reported. Despite these limitations, this was believed to be a good quality study which showed some interesting findings. In particular, patients with severe anxiety were found to have the greatest improvement in knowledge and reduction in anxiety because of the video. However the question still remains whether the decrease in anxiety allows increased knowledge acquisition or whether the knowledge gained by watching the video results in the reduction in anxiety.
Done and Lee (1998) attempted to answer this question by similarly evaluating the effectiveness of a video to assess patient knowledge of the anaesthetic information for patients undergoing elective procedures. Similar to Agre et al.’s (1994) and Luck et al.’s (1999) study, this assessed anxiety using the STAI which was completed by patients prior to randomisation into a video (n = 63) or non-video group (n = 64). Following this patients in the intervention group were taken into a room to see the video, which was a seven minute video that comprised a series of slides with voice-overs, developed by the Australian Patient Safety Foundation. Patients in the non-video group went directly to the admission area while the video group did so after viewing the video. The medical staff were blind to whether the patients viewed the video or not. At discharge, patients repeated the STAI and an 18-item knowledge questionnaire which was based on true/false questions on procedure, monitoring, and observation of anaesthesia as well as follow up care, and side effect treatment thus suggesting the questionnaire measured recognition of information. These questions were categorized into three main groups: process, risk, and misconception. The study provided a detailed description of the statistical analyses conducted.

No significant differences were found in the demographic characteristics between the two groups. The majority of patients in both groups correctly responded to the five process questions however there was a significant difference for one of these questions whereby video group participants were better informed than non-video group patients that the anesthesiologist would stay the whole time they were asleep (95% vs. 81% respectively, p = .01). On the other hand, the questions on risk showed more disparity in the correct responses with the video group showing significantly higher scores in five of the eight questions. Only one third of patients in the non-video group knew that they may feel a tube coming out of their windpipe when they woke up, while more than three quarters of patients in the video group understood this (p < .001). Similarly only half of the patients in the non video group were aware that their teeth may be damaged because of the instruments placed in their mouth compared to 80% aware in the video group (p < .001). Two of the five questions on misconceptions about the anaesthetic procedure were also found to be better understood by patients in the video group although there was still a high rate of correct responses in the non-video group.
After adjusting for preoperative state and trait anxiety, the study found a relative risk of 6.36 times more likely for the video group patients to answer all questions correctly (95% CI 2.01-15.82, p < .01). Also the video group patients were three times more likely to identify misconceptions (95% CI 1.94 - 4.29, p < .001) after adjusting for preoperative state and trait anxiety, and previous anaesthesia experience.

Nevertheless, the predictors of correct risk knowledge were those who had a video intervention (RR 7.12, 95% CI 3.70 – 10.07) and low trait anxiety scores (RR 5.88, 95% CI 1.69 – 25.00), after adjusting for state anxiety and previous anaesthesia experience. There was no difference between the intervention groups in the change from pre- to post-state anxiety scores (p = .42) and trait anxiety scores (p = .44). Overall the study found the video to be effective in improving correct responses.

As pointed out above, knowledge was assessed using true/false questions which suggests that recognition (a less stringent form of assessment) was used, as the answers are written out for the patients to recall. Also patients had a 50% chance of guessing the answer correctly. Therefore this may not be the most reliable and valid questionnaire to use which reduces the confidence in the findings shown. Also, limited details of the video were given making it impossible to replicate the findings of this study.

Several other studies have evaluated the impact of a video about anaesthesia for educating surgical patients. One of these studies was conducted in the US in which patients attending the North Carolina Baptist Hospital for an anaesthesia preoperative visit during a two-week period were randomly assigned to one of two groups (Zvara, Mathes, Brooker, & McKinley, 1996). The first group of patients received a 10 minute video about anaesthesia and surgery prior to seeing the anaesthesiologist (n = 91) while the second group did not view the video (n = 87). After their interview, all patients completed a questionnaire on information received, patient perceptions about anaesthesia, and the interview. Six multiple choice questions were used to assess knowledge of anaesthetic information, suggesting recognition was measured.
Patients in the video group knew what to do if they did not feel well before outpatient surgery significantly better than patients who did not see the video (99% vs. 86% respectively, p = .03). No other differences were found for the other five knowledge based questions or the patient perceptions questions between the two groups. There was no explanation of the video content, which could be the reason for the lack of differences between the groups, although 85% of patients viewing the video rated it as a very helpful part of the interview. It may be that it did not add anything more than the information given during the interview. However the questionnaire used to measure knowledge was also non-validated, and the reliability of it was unclear and therefore may not have been sensitive enough to detect differences.

The beginning of the new decade saw an increase in studies assessing the impact of videotapes on knowledge and satisfaction in a variety of settings. The study took place in a gynecology clinic in Nottingham, UK and looked at a population of women undergoing elective procedures, that is, sterilisation (Mason, McEwan, Walker, Barrett, & James, 2003). Patients were randomly allocated to either an intervention group (n = 15) who watched the video before the standard consultation or a control group (n = 16) who just received the standard consultation. The video was comprised of information about the procedure including its risks, advantages, disadvantages, and alternatives and took approximately five minutes to complete. The video consisted of diagrams, text, shots of the day theatre, and laparoscopic equipment.

A sterilisation knowledge questionnaire, designed by the authors was given to the 31 patients across both groups after their consultation. No information was given on the questionnaires validity or reliability. The sterilisation knowledge questionnaire consisted of questions either requiring true/false or yes/no responses. Essentially, this may be considered as assessing recognition because the patients are not required to provide answers based on the free recall of information but are given options they have been exposed to before. The authors aimed to justify the validity of this by asking staff to also fill in a questionnaire about their perception of the patients’ understanding. However there is always the possibility of the doctor or nurse having incorrect judgment too. This knowledge questionnaire, together with the Spielberger
State Anxiety Inventory-Short Form, which consisted of six items, was completed by both groups after the patient’s consultation.

The mean age of the sample was 34 years old and none of the demographic characteristics were different between the two groups. Data were presented as medians which are a less commonly used form of analysis compared with means when measuring outcomes such as recall or knowledge. Median scores are more representative of the population where there is high variance in the population, i.e. one or more deviant cases, however the variance in recall scores is likely to be small therefore the mean is a better indicator (Swinscow, 1997). Therefore authors must have had highly skewed data to warrant use of this method.

Nevertheless, the authors reported that patients receiving the intervention had better median scores for the knowledge questionnaire than the control group, and the study found this to be statistically significant (p < .001). The median score in the intervention group was 18 out of a maximum of 20 whereas the control group had a median score of 11.5 out of 20. All but one patient scored over 16/20 in the intervention group while 13 out of 16 patients in the control group scored below 16/20. The anxiety levels were not significantly different between the two groups. The limitation of this study, was again, measuring recognition as a form of knowledge. Also, for the reasons mentioned above, using the mean to assess knowledge would have been a better indicator.

Thomas, Daly, Perryman, and Stockton (2000) conducted an RCT in the UK of a videotape intervention on patients with different cancers (Thomas, Daly, Perryman, & Stockton, 2000). Patients were randomized to either receive the educational video or undergo routine verbal information with the aid of the British Association of Cancer United Patients (BACUP) booklets. This study did not assess information recall but rather satisfaction with the style and level of information given as well as depression and anxiety. The style and level of information to be presented in the video was determined after six focus groups consisting of doctors, nurses, pharmacists, radiographers, patients, and their relatives. A 20 minute film was professionally produced and narrated by two popular UK TV personalities with the video containing a description of chemotherapy, radiotherapy, and their risks. It also featured patients describing their own experiences, side effects, and the methods used to alleviate them.
Patients who were recommended radiotherapy or chemotherapy were given routine verbal and written information, and then were randomised to receive or not to receive the educational video which was designed to be taken home and used more independently. In addition, at the time of randomization, all patients completed a HADS questionnaire (to measure anxiety and depression). Following this, three weeks into chemotherapy or radiotherapy treatment, patients completed the HADS questionnaire again as well as an information satisfaction questionnaire. All the patients in the video group (n = 113) watched the video at least once and an average of 2.3 times. These patients were more satisfied with the information than patients in the non-video group (93% vs. 64%, p < .001). Patients better prepared for treatment through the use of the video had lower levels of anxiety during treatment than at the initial pretreatment assessment (p < .001) whereas there was no significant difference in patient anxiety in the non-video group. Depression also decreased in the video group (p < .001) while there was a significant increase in depression compared to the pretreatment level in the non-video group (p < .001). Although before the intervention, control patients had lower levels of anxiety and depression compared with the video group, no significance testing was conducted on this.

Depression has also been linked to prolonged adverse side-effects of chemotherapy including fatigue and nausea (Maguire, 1995). It therefore appears likely that better preparation for such side-effects using the video program may overcome the risk of developing the symptoms of depression during treatment. The study aimed to minimise bias in a number of ways: (1) the video was given to take home so that patients could not discuss it with other patients and therefore gave no opportunity for other patients to obtain it, and (2) the initial questionnaire was given prior to randomisation therefore no bias from the assisting nurse was possible. The questionnaire used, although a simple questionnaire, was not validated and based patient satisfaction on one question raising issues of reliability. Other limitations to the study included no reporting of effect sizes and the use of a screening tool for anxiety and depression (HADS). However, as results using the HADS were found, it suggests this questionnaire was sensitive enough for this purpose.

Another study based in an oncology setting evaluating the effectiveness of a videotape was conducted in the US (Orringer, Fendrick, Trask, Bichakjian, Schwartz, Wang, et al., 2005).
Newly diagnosed patients with melanoma were eligible for the study and therefore 217 patients were randomly assigned to an intervention group (n = 112) or a control group (n = 105). Randomisation in this study, unlike the others, was not computer generated but rather sequentially alternated patient assignments to one of the two groups which may introduce bias. This bias is in the form that one can predict the group which the next patient will be allocated. The video used in this study was also professionally produced and narrated by professional actors and was just under 11 minutes in length. The video included an overview of melanoma, its incidence, its risk factors, and clinical presentation.

Outcomes in this study, unlike Thomas and colleagues’ (2000) study, included knowledge of information given and anxiety levels. Prior to the consultation visit, patients in the intervention group received the educational videotape, a set of melanoma knowledge questionnaires, and emotional distress questionnaires. Patients were asked to complete one set of questionnaires prior to watching the video and the second set after viewing the video. On the other hand, control patients were just sent the same questionnaires and asked to complete them prior to the visit. The second set of questionnaires was completed by these patients after the visit before leaving the clinic. This method removed any possible contamination bias of the video being seen by control patients. The knowledge questionnaire, developed by physicians at the study centre, contained 23-items, was multiple choice but had been validated. The multiple choice format suggests that the authors assessed recognition of information rather than free recall. There was a significant difference in the knowledge scores of intervention patients from pre (M = 11.63 ± .93) to post video (M = 20.38 ± .47, p < .001). However the same statistically significant results were seen in the control group with knowledge improving from pre-visit (M = 10.78 ± .95) to post-visit (M = 15.95 ± .81, p < .001). Nonetheless, knowledge improved to a greater extent for patients in the intervention group with a mean change of 8.81 (± 0.91) versus 5.11 (± 0.78).

Anxiety was measured using two validated instruments, the STAI and the Distress Thermometer. Although, the Distress Thermometer, as a one-item tool cannot be checked for reliability. However, both instruments showed a significant decrease after viewing the videotape (p < .001) and in the control group (p < .001). Conversely, the decrease in anxiety
levels was greater in the control group than in the intervention group with a mean change of 10.21 (SD = 2.18) versus 3.20 (SD = 1.45).

Kinnane, Stuart, Thompson, Evans, and Schneider-Kolsky (2008) also conducted a recent study in an oncology setting. This Australian-based study aimed to assess recall of information regarding self care and side effects in patients who watched the video as part of their pre-chemotherapy education with those who received standard care (Kinnane, Stuart, Thompson, Evans, & Schneider-Kolsky, 2008). Eligible patients were those newly diagnosed with colorectal cancer or breast cancer and receiving adjuvant chemotherapy. Three quarters of the patients recruited were females with a diagnosis of breast cancer. Patients were randomised to receive either standard information (n = 29), which included a one hour education session including written and verbal information provided by nursing staff, or to receive the standard information with the addition of the 10 minute video (n = 31). This video was not available for loan and was only allowed to be seen once prior to their first chemotherapy treatment by the patient and an accompanying family member but without the presence of medical staff.

After consenting to chemotherapy treatment, but prior to receiving it, all patients completed a demographic questionnaire. There were no statistical differences between the groups. Recall was measured on the day of the second cycle of chemotherapy whereby patients were given 20 minutes to complete the 15-item multiple choice questionnaire. At 20 weeks or at the completion of chemotherapy, patients in the intervention group were asked to complete a questionnaire to provide feedback on the video. There were no statistically significant differences between the two groups on any of the recall items. Recall in the video group ranged between 26% and 100%, while the non video group had recall of items ranging between 21% and 100%. The lowest level of patient recall referred to patients not knowing how often they should take their temperature. It may be that if the video was allowed to be taken home or viewed more than once, an improvement in recall may have been seen. The authors believed that with a large sample in each arm of the study, significant differences in the groups may become clear. However, as effect sizes were not reported it is difficult to say what magnitude of change was present and whether Type II errors were made. Also, feedback from the patients revealed preference for the nurse to be present when the video was watched.
to answer any questions. Patients may forget the answers to these questions by the time the video is finished.

Nonetheless, all of the video group patients were very to extremely satisfied and all of them perceived that the video helped them remember the information given to them by the nurse, despite the actual outcomes. The study was well designed and reported however it was limited in that the study consisted of a small sample compromising power and generalisability. Also, the recall questionnaire was given at the second chemotherapy cycle which means that both groups had been exposed to the actual treatment and therefore the impact of this experience may have confounded the results and this was not discussed by the authors. In addition, giving a 10 minute video only once suggests that there is a chance that it would not have impacted patients when they were anxious right before the procedure. One way to overcome this question was for the study to measure anxiety.

Studies on the effectiveness of videotapes were also assessed in clinical trial settings such as Agre and Rapkin’s (2003) randomised study assessing three tools to improve informed consent: a videotape, computer, and booklet which were compared with a standard written consent form (Agre & Rapkin, 2003). Patient populations included those considering participation in existing clinical trials (n = 204) such as phase I, II, III clinical trials, and three non-therapeutic trials, family and friends who accompanied the patients to the consent discussion for those trials (n = 109), and individuals the authors labeled as surrogate subjects, who were waiting for patients in a surgical day hospital waiting area (n = 128). This was a complex study not only comparing different samples and different consent tools, but it included testing recall of information from 18 different clinical oncology trials that were modified in format and reading level. The study results were also condensed into this paper, so some details are not present. As Agre and Rapkin’s (2003) primary target was the patient group, and because patient groups are the focus of this review, only these results will be highlighted here to help clarify outcomes.

First of all, Agre and Rapkin (2003) classified each of the 18 protocols as ‘easy’, ‘moderate’, or ‘hard’ to comprehend depending on the number or seriousness of the side effects, and the
complexity of the procedures involved, among other components. Second, all 18 protocols were assessed for reading level. Protocols were amended (if necessary) so all content was comparable at an 8th grade reading level. Third, once the content was similar, protocols were converted from standard written forms to all three alternative formats including a booklet, videotape, and computer. In other words, the content was identical in all interventions. Finally, review sections were also added to the computer, video, and booklet formats.

Patients were randomly allocated to an intervention, and after consenting, they completed a demographic information form and knowledge quiz. Patient participants also completed the validated Functional Assessment of Cancer Treatment-General (FACT-G), which is a measure of cancer patients’ quality of life. Knowledge was measured by a 12-15 item post-intervention only multiple choice quiz based on each of the elements of informed consent provided in each specific protocol once again suggesting that recognition rather than free recall was assessed. Amongst all participants, on average 69% of responses were correct which did not differ significantly among the different populations (i.e. booklet, video, computer, or control groups).

A hierarchical regression analysis of the patient only group revealed that knowledge scores were higher for patients in trials with complex protocols. Better education was a significant predictor of patient knowledge in the model but other factors such as age, gender, and minority status were not significant predictors. There were no significant main effects for the different formats. However, there were significant interaction effects where the computer and video formats produced improvements in knowledge over the booklet and standard versions, but the video format was not superior to the computer format (as in analyses of the whole sample). Furthermore, patients who completed the video or computer formats without a family member present performed better and they were more satisfied. The authors stated that this result concerning family members was hard to explain suggesting family may have distracted patients, or perhaps such patients who were accompanied by family were more vulnerable to misunderstanding. Patients who were more distressed according to the FACT-G Emotional Wellbeing subscale also appeared to benefit from the video and computer formats.
Agre and Rapkin (2003) concluded that their study did not show any consistent improvements from alternative informed consent formats. Computer and video formats did improve knowledge in some cases, but made knowledge worse in other cases. Some other important findings of this study include that no one group or one demographic recalled more than two-thirds of the informed consent information suggesting that further research is necessary to understand this result and hopefully improve it; although, this result in itself points to the complexity of the possible outcomes. As knowledge also appeared to be superior for the complex protocols compared to the simpler protocols, this brings into question the amount of time being spent with patients (by physicians) having less complex procedures. The authors suggest that these results may have occurred for other reasons such as less attention or motivation by patients (for understanding simple procedures). Furthermore, surrogates did not perform as well as patients or family members on the knowledge quiz (and also showed lower reliability on scales) raising the question of the validity of using non-patients in studies to test methods for improving informed consent knowledge. This was an interesting study highlighting many complex results in the area of informed consent in oncology. However, some of the results of this study are questionable, mainly due to the lack of detail presented. Numerous analyses were utilized to answer different questions about the complex groups and formats bringing into question Type I error. Another questionable conclusion is that Agre and Rapkin (2003) stated that those patients with high scores on the FACT-G Emotional Wellbeing subscale were more distressed when high scores on this scale usually refer to the less distressed as the subscale is mainly reverse scored.

Other studies conducted in a clinical trial setting included a randomised study of cancer patients newly referred to a phase I clinic conducted in Canada (Strevel, Newman, Pond, MacLean, & Siu, 2007). This study included 49 patients who considered phase I clinical trials due to metastatic disease for which standard treatment options had either failed, had a low chance of success, or did not exist. The intervention was an eight minute educational DVD, which discussed essential aspects of phase I clinical trials including graphics, text, dialogue, and enacted scenes (n = 22).
On the other hand, the control group received a placebo DVD, also eight minutes, including research achievements of scientists and investigators at the health institute attended (n = 27). The DVD was non-interactive therefore it was like viewing a video rather than a form of interactive multimedia. Immediately after viewing the DVD, patients completed a questionnaire of demographics, knowledge, and satisfaction. Knowledge was assessed using multiple choice and true/false questions (obviously assessments of patient recognition of information) and patient satisfaction was assessed using 5-point Likert scales of ‘strongly disagree’ to ‘strongly agree’. Physicians were blinded to the study and after consultation with the patient, completed a questionnaire on their perceptions of the patients’ understanding of phase I clinical trials. Similar demographics were found for patients in the two groups.

Of the seven questions evaluating knowledge of phase I clinical trials, the experimental group correctly responded to three questions which reached statistical significance compared with the control group. They were less likely to believe that the goal of phase I clinical trials was to decide if a new drug is more effective than an old drug (p = .02), more likely to know that the study drug had been tested in animals but not thoroughly in humans (p = .003), and less likely to believe phase I drugs have proven activity against cancers in humans (p = .008).

Intervention patients were more satisfied with the educational DVD as three quarters believed that it provided useful information compared with one fifth of the control DVD group (p < .001). Sixty percent agreed that they had a good knowledge of what was involved in a phase I clinical trial, 35% more than the control patients (p = .03), also agreeing that it prompted them to ask more questions of the physician (p = .02), and helped in their decision-making process (p = .011). No statistically significant difference in physician perceptions was observed between the two study arms. This was a good study in that the authors used a placebo DVD rather than a control group that did not receive anything. Again, recognition rather than free recall was measured and the questionnaire was not validated and there was no mention of its reliability. Long term retention of DVD content was also not assessed. Effect sizes were not reported given the sample size was very small and therefore the possibility of Type II errors was difficult to ascertain.
Patient satisfaction of an informational video was also investigated by Pager (2005) on cataract surgery patients in an Australian private hospital (Pager, 2005). There was random assignment of 141 cataract surgery patients into one of two nine-minute video groups. Both videos were professionally produced and edited, one explained what to expect from the surgery and a mention of the potential risks while the other video detailed the anatomy of the cataract and no mention of what patients should expect. The second video was to protect from the Hawthorne effect in that patients may merely be satisfied by just taking part in the study. Following the viewing of the video, patients were interviewed on their satisfaction and expectations and their responses were recorded on a 12 centimetre visual analogue scale from ‘not at all’ to ‘extremely’. The interviewer was blinded to each patient’s videotape allocation. Prior to discharge, the patient was asked about the experience of the cataract surgery in terms of anxiety, discomfort, and risk using identical visual analogue scales.

Also, patients were asked to rate how their experience compared with what they were expecting, their level of understanding, and overall satisfaction. Preoperatively, patients in the intervention group expected the surgery to be uncomfortable and painful \( (p = .008) \) and risky \( (p = .009) \) but this had no effect on anxiety. Postoperative findings revealed patients in the intervention group were more satisfied with the experience \( (p = .04) \) and believed they understood what was happening more than the control group \( (p < .001) \). Limitations to these findings include the validity and reliability of the scale, which is not mentioned, but also the subjective nature of the questions. Anxiety, unlike in previous studies, is not measured using a validated scale such as the HADS or STAI and therefore needs to be considered with caution. Also, understanding was measured by means of one question that asked patients about their perceived understanding. Nevertheless this study provides a superior RCT design comparing two interventions that were slightly modified using a decent sample size. Although inclusion of a third control group would have been beneficial it is understandable that this may have not been feasible as it would make the study larger and hence more time consuming and costly.

One patient group not assessed in the studies reported so far is that of psychiatric patients. Wirsching, Sergi, and Mintz (2005) conducted a randomised study to evaluate a structured instructional video designed to enhance the informed consent process for psychiatric patients.
considering participation in treatment research (Wirsching, Sergi, & Mintz, 2005). Eighty-three schizophrenic patients, medical patients without self-reported psychiatric illness, and university students gave consent to take part in the study. Most of the patients were men (82%) due to the heavy reliance of Veteran Affairs (VA) clinical research settings. The experimental videotape was generic to allow for wide applicability and it focused on three main areas: optimal behavior during the treatment session, the content covered by the informed consent session covers, and good decision-making. Patients in the control group received a general educational video, only presenting information about human subject research. Both videotapes were 16 to 18 minutes in length, and written at a fifth-grade reading level. Therefore all of the patients recruited were randomly allocated to one of these groups.

Knowledge, measured using an 80-item quiz believed to be assessing recognition, was measured at two time points, before and after watching the videotape. The reliability of this measure (Cronbach’s alpha) in the schizophrenia group was .90 and .85 in both the medical and student groups suggesting high reliability. The proportions of correct responses were calculated for each group of patients in each of the groups at each time point. Statistically significant improvements were found in the experimental group compared with the control video group in all three patient groups ($p < .005$) and standardized effect sizes were large (medical patients partial $\eta^2 = 0.77$; university students partial $\eta^2 = 1.43$; schizophrenia patients partial $\eta^2 = 0.70$).

The study was reported in considerable detail with the only unclear element being how many medical patients and university students took part. This was one of relatively few studies that reported effect sizes and measured a large amount of knowledge (80 questions). However it was unclear whether all of the questions were based on free recall. It is likely that many were measuring recognition.

**Summary**

Among the 11 studies that measured and reported on recall or knowledge of the information given, nine found videotapes to increase recall of at least some, if not all aspects. The studies
were conducted in a variety of settings including both surgical and non-surgical patients but also on a mixture of patients including psychiatric patients, clinical trial participants, and family and friends of patients, among others. Videotapes used were also diverse, with the length of the videotape ranging from five to 20 minutes, with only Moldofsky et al.’s (1979) study using a 55 minute videotape suggesting they were usually a quick intervention. This was one of the earliest studies found and since then patients play a more active role in their health decisions and therefore may not require such a lengthy explanation. It may also be that an excessive amount of information does not allow patients to absorb any specific information thereby reversing the impact of the video. Other differences between the studies included some studies comparing the video to usual care (n = 7) while in others it was another video, another intervention such as a booklet, or in one case the design included three groups; two video groups compared to usual care.

Many of the studies reviewed did not adequately assess patient knowledge as they provided patients with multiple choice formats suggesting they relied on patient recognition of information rather than the more stringent test of free recall. Specifically, nine studies used recognition and a further two studies did not adequately report the method used. Very few measures were validated or were assessed for reliability, however, as often pointed out, this is an unavoidable problem in the area of informed consent as questionnaires of knowledge and satisfaction often need to be study/treatment-specific. Therefore none of the studies reported findings based on the most superior form of recall which is that of free recall. Also, recall or recognition was measured within a short time frame of viewing the video in all of the studies, usually immediately after or maybe after their consultation, on the same day, or at discharge-at most a couple of days afterwards. Only Luck and colleagues (1999) measured recall one week after having colonoscopy. Therefore, future studies should assess recall at a number of time points to determine whether the video has any benefit over usual care or other interventions.

Other limiting factors that were found in the studies included the sample size being small in a number of studies, making Type II errors likely. In addition, there was a lack of effect sizes being calculated with only one study reporting them (Wirsching 2005).
It was difficult to pool the findings in order to give an estimate of patient recall of the information from the studies due to the differences discussed above, that being, the vastly different populations, the different forms of measuring recall and exactly when recall was assessed. Also, it was difficult because of differences in the way that recall was calculated and reported such as many studies didn’t provide overall results for patient recall in each of the groups. However the results indicated that recall was as low as 26% for some aspects in patients receiving the video.

Patient satisfaction and anxiety levels were also measured in these studies although only in a limited number of studies. Satisfaction was only measured in three studies although all of which were studies that compared the video to another video or another intervention. Satisfaction was not measured in studies that compared the video to usual care. Nonetheless patients viewing the experimental video were found to be more satisfied than the patients receiving a placebo video (Strevel, 2007), a general educational video (Pager, 2005) or routine care plus a booklet (Thomas, 2000).

Mixed results were found for the effectiveness of the videos on anxiety levels which were all measured using validated questionnaires (i.e. STAI and HADS). The three studies that showed a reduction in anxiety levels from pre-intervention to post-intervention assessed videotapes that were longer (10 to 20 minutes) than those in the two studies showing no difference in anxiety levels (5 to 7 minutes). One of the interesting results on anxiety was found in Luck and colleagues’ (1999) study that conducted a sub group analysis of the 20% of patients most anxious at enrolment. They identified that those in the video group had the highest mean scores for all factors whereas the patients who did not watch the video had the poorest results for all factors. In other words, the video was of greater benefit to severely anxious patients compared with not receiving a video.

Videotapes, in some instances, appear to be a successful choice of intervention for incorporation into patient education or the informed consent process. The combining of vision and sound in a video is attractive for most patients as it gives interesting form to the written word. Not all randomised trials of video education, however, have had similarly consistent
results. The variation in these trial results suggests that, like all educational materials, the quality and type of the content is paramount, the way outcomes are assessed need to be very specific, and how the video is used is vital to success. Involving patients in the development of the video to show previous patients recounting their personal experience may help new patients relate. Using respected TV personalities offers the familiar face of respectability and professionalism and using physicians adds an element of authority. The studies assessing the effectiveness of videos that used TV personalities found them to increase recall or recognition of patients. While this is not to say that there was a causal relationship but there may be some association which can be further evaluated in future studies. Also the advantage of patients taking the video home is that it allows them to gather information at their own pace overcoming the variation in time individuals take to understand similar issues. It also allows reinforcement by repetition which may not be possible if it is not given to take home. In addition, the use of a video guarantees consistency of information and potentially saves on consultation time.

On the other hand, not all videotapes in the studies reviewed above used the advantage of providing video information from previous patients or celebrities. Furthermore, some studies did not allow patients to take their videos home and yet others found that even when patients had access to the videos, as with other information formats, they did not necessarily view them very often, if at all. All studies should attempt to measure how often patients access their information formats in this area given the results of some studies suggesting this impacts patients’ recall and varies considerably. Perhaps one of the major setbacks to using videotapes as an alternative information format in informed consent situations is that it is simply not feasible. Specifically, professional videos are not easy to create, and they are probably not cost effective, especially as they need to be individualized for different treatments or procedures. Videotapes, like audiotapes, are also a fading technology that is being replaced by different DVD formats, especially interactive formats.
Interactive Multimedia

Technology has evolved rapidly over the last few decades and no doubt this has received a great deal of attention for improving informed consent. Interactive multimedia, as the name suggests, is presentation through the use of more than one medium (for example, on CD-ROM or a Web site) which is designed to be interactive. Commonly, multimedia can include such combinations as text, audio, still images, motion video but the key is the interactive nature of the media formats. Therefore, videotapes may also have these features, however interactive videotapes are designed in such a way to respond to choices made by the individual user. This format allows the process to be interactive and personalized and also allows for the pace of information provision to be tailored for each patient. Multimedia programs may more effectively assist learning and retention of information because several media are used to stimulate viewer interest and to arrange and highlight important information (Webber, Summers, & Rinehart, 1994). In addition, some argue that tailoring information is important to meet patients’ different backgrounds (Harris, 1998).

The first comparative study identified to assess the effectiveness of interactive multimedia on patient knowledge of information given was in the early 1990’s. This is probably explained by the fact that in the 1980s, interactive multimedia was probably not commonly used and most certainly expensive. Therefore the use of such in research was not deemed to be feasible. In the early 1990’s, Ader, Angel, Bhaskar, and Melamed (1992) conducted a US based study on the effect of an interactive videodisc on patient knowledge and information seeking for third molar extraction (Ader et al., 1992). Thirty five patients attending a consultation on third molar extraction were recruited to the study. Prior to the consultation, a short 6-item questionnaire was completed by patients on their general knowledge of the procedure. Information seeking style was measured by the Miller Behavioural Style Scale (MBSS) and the Krantz Health Opinion Survey (HOS). State anxiety was assessed using the SAI form previously discussed. At this time a demographic questionnaire was also completed. Patients were then randomly assigned to receive either the interactive videodisc (n = 18) or the non-interactive video (tape group, n = 17).
The videodisc ‘Preparing for dental extractions’ consisted of four sections: Wisdom teeth, Extractions, Risks, and Recovery, each with a submenu. This allowed patients to choose what menu to view and in what order. Immediately after viewing the videodisc, a 15-item multiple choice knowledge questionnaire and the SAI were again administered to patients. This was then repeated prior to surgery which was several weeks after the consultation, so overall, data was collected at three-time points. One week after the surgery patients were asked to rate their satisfaction on a 7-point scale and were also asked to state their preference of method (e.g. written information, videotape, etc.) for future consultations. In order to compare the effectiveness of the video compared with usual care, an additional 25 patients attending a third molar extraction consultation were asked to complete the knowledge questionnaire immediately after their consultation.

The two initial videodisc groups did not significantly differ with respect to demographic characteristics, pre-video knowledge, or anxiety. On average, 64% of the total video was viewed by the interactive videodisc group patients (group one) while the whole video was viewed by all of the patients in the non-interactive video group (group two) most likely due to the inability to move around and view different aspects of the information. After the consultation, patients in group one correctly responded to an average of 73% of the quiz compared with 85% of group two and 40% in the usual care group (p < .001). Also, there was a significant difference in the association between self-reported information seeking and group allocation (p < .01). Inconsistent with the study hypothesis, an increase in self-reported information seeking in the interactive videodisc group resulted in a decrease in knowledge while greater reported information seeking in the non-interactive videotape group led to an increase in knowledge. Almost two thirds of the patients (n = 22) were followed up after surgery and of these it was found that patients in group one were in general, more satisfied than those in group two (p < .02).

Overall, patients in group two were more knowledgeable than patients in the other two groups although group one patients only viewed an average of 64% of the disc which could have affected this outcome. The mean initial anxiety score for the entire sample was 36.1 (no SD), but no further information regarding mean anxiety levels in each of the groups were given.
Despite this, authors reported that there were no significant differences in state anxiety between the groups or time. Overall, the non-interactive video group appeared to be the most successful group in terms of knowledge however this does not mean they were the most satisfied group.

This study is limited in that the usual care patients did not form part of the randomisation process potentially introducing biases in this group but also these patients were only assessed on knowledge after the consultation therefore a baseline level of knowledge before the procedure was not obtained to compare with the other two groups. Knowledge at baseline and after the intervention was measured using different questionnaires therefore changes in knowledge over time were not able to be ascertained. Knowledge was also measured in the form or recognition through the use of multiple choice questions, for which the answer could be recognised from the choices given. Also, the knowledge and satisfaction questionnaire were not reported to be validated and also the sample size was small compromising power. Effect sizes were not provided despite this possibility of Type II error.

A larger study to evaluate an interactive computer-based informed consent method was also conducted in the USA (Hopper et al., 1994). A sample of 160 consecutive patients referred for imaging examination requiring the use of intravenously administered contrast were included and evenly randomized into one of two groups stratified by previous use of intravenous contrast material, age, and gender. The first group received written information on the procedure which was at an eighth grade level while the second group received the information by means of an interactive video on the computer. The interactive video included all the same information as the written form, but was spoken on-screen by a physician and included video images of techniques, radiographs, equipment, graphs, and diagrams. The interactive video group had the choice of not receiving further information on the risks reported or receiving the detailed information on every risk reported. The majority of patients chose to be informed about the detailed information for every risk.
Immediately after watching the interactive video or reading the written information, patients were tested on the risks of contrast material with the test made up of seven multiple choice questions, with questions one and two assessing the purpose of the examination and intravenous contrast material, while questions three to seven assessed the risks of the contrast material. Another two questions asked patients if the information was sufficient and whether they were satisfied with the information provided. Patients in the written group were provided with written correction for their incorrect responses while the video group received immediate feedback for incorrect responses as part of the interactive video program on the computer. Furthermore, patients could be receiving different informed consent procedures based on whether they were due to receive high or low risk ionic contrast material (based on previous screening procedures), so there were essentially two differences in the groups’ experiences, and one further difference in individual patient experiences.

Findings indicated that the average number of correct responses to the first two questions (on purpose) was significantly better for the interactive video group (M = 1.8) compared to the written group (M = 1.6, p = .003). The average correct responses for all seven questions combined was slightly higher in the interactive video group compared to the written group but this was not statistically significant (M = 5.2 versus 4.8 correct responses, respectively, no p value). Only females showed significant differences in correct responses. Specifically, females in the interactive video group responded to the questions on risk (questions three to seven) significantly better than females in the written group (M = 3.5 versus 3.0 respectively, p = .02). Similarly, females in the interactive video group (M = 5.4) scored significantly more correct responses on all seven items compared to females in the written group (M = 4.6, p = .002). The authors suggested these superior responses from women could have been due to several reasons including women being more interested in health concerns, more open to communication, or the fact that women responded better to the young male physician in the video.

Most patients thought the information provided was sufficient, however patients in the written group were significantly more satisfied with the informed consent process than the interactive video group (p = .049).
The amount of time necessary for risk assessment was an average of 0.7 minutes longer in the written group compared with the video group (p = .0001). However, the informed consent process took significantly longer in the interactive video group, an average of 5.2 minutes compared with 2.9 minutes in the written group (p = .0001). This difference in time was shown in the report to be due to request of additional information by patients in the interactive video group.

The authors did not provide any information on the length of the video itself, but they did suggest it was superior to written consent not only because the purpose of the procedure as understood better by all and women generally performed better, but it allowed further screening of patients and collected further history about the patients that was useful for the technologists (such as information on renal disease and diabetes). Findings were only specific to English speaking patients and those well enough to be involved in the study, so results are difficult to generalize to other groups, despite their importance. Similarly, the authors suggested that outpatients, such as those tested in this study do have enough time before their procedure to undergo video consent. However inpatients do not because they arrive just in time to undergo the procedure, therefore eliminating them from involvement. Furthermore, although randomised to be split evenly between the intervention and control groups (and statistically analysed), 65% of patients had previously had contrast material before this study, possibly confounding recall of information in this case. As in many other studies, only recognition was assessed in this study rather than free recall due to the multiple choice format of the knowledge questionnaire.

Jones et al. (1999) conducted a large study in the UK to compare the effect of providing personalized computer-based information compared with general information booklets on the psychological status of the patients, their use, and satisfaction, as well as doctors’ perceptions. Three days prior to starting radiotherapy treatment, 525 patients with breast, cervical, prostate, or laryngeal cancer agreed to take part in the study and therefore were randomized to one of three groups.
Two groups received computer-based information using a touch screen computer, one of which was given general information about cancer (n = 167) while the other group received personalized information including a summary of their medical records as well as links to information about all the concepts and terms mentioned in the record (n = 178). Half of the personalised group patients were also given access to the general information system to identify which method was preferred. Printouts of the information viewed in each group were also given to patients. A third group of patients were given as many booklets of information as they wanted from a folder of booklets (n = 180).

Shortly after randomization, patients completed the HADS questionnaire and the Mental Adjustment to Cancer (MAC) scale. Three weeks later, at their consultation, patients completed the HADS and MAC scale again and there was also assessment of the patients’ participation, knowledge, and time spent in consultation. Three months later, patients completed a third HADS and MAC scale and were asked about their information preferences and their use of the printed material at home. At three months, 83% responded to the questionnaires - a reasonably high follow-up rate. The participants lost to follow up were more likely to be in the general computer information group than the other groups (23% vs. 13%, p = .004).

Results showed that at the three week assessment, almost two-thirds (65%) of the personal information group patients who were offered both systems chose the personalized one first and overall this group also had higher satisfaction scores compared with the general information group (p = .04) which were based on seven related questions. The booklet group was more likely to feel more overwhelmed than the personal information group (p < .001) which may be due to the choice they had in taking as many booklets as they wished.

Knowledge was assessed by the doctors however details of how knowledge was assessed were not reported. They perceived that more patients in the general computer information group (35%) were above average in knowledge compared with the personal information group (25%) and booklet information group (20%; p = .01). No further information was given regarding tests to show where this difference lies.
In addition, this was not considered a standardised form of testing knowledge and therefore these findings need to be considered with caution. Printed material was used more by patients who were offered booklets (83%) than by the personalized information group (70%) and lastly the general information group (57%; p < .001).

The personal information group was less anxious at three weeks and then again at three months with a mean difference of 18% (95% CI 3.7% - 26.5%) improvement from the start of treatment to three months later. However the general information group was less anxious at three weeks (28%) compared to the start of treatment (37%) but then anxiety increased to baseline levels again (37%, no significance testing stated). There were no significant changes in the patient’s depression scores or mental adjustment scores between the start of the treatment and follow up at three weeks and three months and no effect sizes were given.

While there were no major differences in doctor’s perceptions of the patients’ knowledge in the two groups, personal information was the preferred method by patients, and patients using the general information seemed more anxious at three months follow up. The main limitation of this study was that knowledge was assessed by the doctors’ assessments. Doctors may overestimate the knowledge of patients and this is a very subjective form of assessment that was not clearly discussed. This was not considered a standardised form of testing knowledge and therefore these findings need to be considered with caution.

More recent studies on the effectiveness of interactive videodiscs included one conducted by Phelan et al. (2001) in the US in a group of potential candidates for back surgery. Eligible patients included those who had received non-surgical therapy for at least four weeks and were candidates for lumbar spine surgery but had not had prior low back surgery. One hundred patients were randomized to receive a videodisc and a booklet (n = 47) or a booklet only (n = 53). No one was blinded in the study and no attempt was made to standardize processes in the consultation.

The videodisc included presentation of the spine anatomy, risks and benefits of surgical and non-surgical procedures, and interviews with patients who had good and bad experiences of
surgery. This touch screen program allowed patients to tailor the information to their diagnosis, age, and could also stop, repeat, or explore specific information from a menu. Patients in this group also received a printed handout of the outcome probabilities. The booklet included information on the spine in general, problems that can cause low back pain, treatment alternatives, and a self-test on the material. Patients in the videodisc group viewed it prior to the second visit.

Prior to randomization, baseline information was obtained from patients. Patient knowledge was assessed by 17 true/false questions suggesting recognition was assessed. This questionnaire was designed for the study through a pilot process of nurses validating the questions. Knowledge was assessed at randomization (pre-test) and again after patients viewed the videodisc and attended the second physician visit (post-test). The post-test questionnaire was conducted by telephone between 27 and 56 days after randomization and the knowledge score was calculated by totaling all of the correct responses (no Cronbach’s alpha was provided to assess reliability). An eight-item questionnaire was also completed by patients at the post-test on usefulness of treatment decisions, amount of information, treatment preferences, and understandability of the information. The only significant difference identified was that more patients receiving the videodisc and booklet found the material easy to understand (93%) compared with the booklet only group (72%, p = .04). No effect sizes were given to determine the magnitude of change so the possibility of Type II errors were difficult to ascertain considering it was not a large sample. An intention-to-treat analysis was conducted and findings revealed that the mean knowledge was similar in the groups at the pre-test but the difference in scores from pre-test to post-test were significantly different with a 4.4 point improvement in the videodisc-booklet group compared with 2.9 points in the booklet only group (p = .08). The two groups were further stratified into patients who had low, medium, and high score improvements from pre-test to post-test. This revealed a significant difference in the low score group in that the improvement in the videodisc group (8.8 points) was significantly greater than the booklet group (5.5 points; p = .02). Clearly those with initially high scores could not obtain large improvements due to a ceiling effect. The low score group patients were identified to be older than the other groups’ participants (mean age of 60 years vs. 45 years, p = .001) and less educated (78% high school graduates vs. 91%, p = .05).
Therefore younger age and a higher level of education may be predictors of knowledge although this was not assessed in the study. Overall, the study showed that both formats were beneficial for improving the knowledge of patients although the videodisc was more effective, particularly in poorly informed patients, and was also easier to understand. This was a well conducted study with concealment of treatment allocation, intention-to-treat analysis, low loss to follow up, and a reasonable sample size (although effect sizes were not provided and possible Type II errors could have occurred). However knowledge was measured using recognition and the follow up time across patients varied considerably which may impact on knowledge scores.

The last decade has seen an increase in studies assessing the effectiveness of multimedia formats on a range of outcomes. This increase, no doubt, has risen as a result of more exposure and dependence on computers and the Internet. In the US, Shaw, Beebe, Tomshine, Adlis, and Cass (2001) examined the effect of a multimedia computer assisted instruction (CAI) program with patients undergoing colonoscopy who had never undergone the procedure before (Shaw et al., 2001). Patients were randomized to standard education (n = 70) or CAI plus standard education (n = 63). Those in the latter group were asked to visit the clinic three to seven days before the examination to view the CAI. The endoscopist and the nurse were blinded to the assignment. After consenting to colonoscopy, patients completed an anxiety and comprehension questionnaire. Prior to leaving the colonoscopy unit, they were given a satisfaction and computer usage questionnaire to complete at home and return on the following day. The CAI was developed by the authors and was comprehensive in nature with eight main topics provided at two levels of complexity and wording of the script was at an eighth grade level.

Comprehension was measured using a 14-item test developed for the study, covering the purpose of colonoscopy, alternative ways to study the colon, potential complications of the colon and their treatment, limitations of the procedure, and appropriate post sedation behaviour. It was unclear whether the items were measuring free recall or recognition however the authors stated that responses were incorrect if patients checked items that should not have been checked or failed to check items that should have been checked. This implies that the
comprehension test was probably measuring recognition. Scores were based on the total count of incorrect responses (no Cronbach’s alpha was provided). Anxiety was measured by a 12-item questionnaire, four of the items which were taken from the HADS scale and the remaining eight were specifically developed. Cronbach’s alpha for this scale was .90 which is considered high.

A follow up rate of 65% was achieved but no significant differences were found between the groups in the baseline assessment of demographics. There were also no statistically significant differences between the anxiety of patients in the two groups prior to the procedure. On the other hand, the CAI had a significant effect on comprehension overall with a mean of 4.57 (SD = 2.69) incorrect responses compared with 7.67 (SD = 3.26) in the standard education group (p < .001).

Satisfaction figures showed that more patients in the CAI group were more likely to indicate that they did not need more information about colonoscopy as compared with patients in the education group (82.5% vs. 42.5%, respectively). In other words, the CAI group were more likely to indicate satisfaction with the amount of information provided when compared with the standard education counterparts (p = .001). This study had several limitations that should be considered when assessing the findings. This includes the 35% loss to follow up which is a large proportion of patients. The comprehension questionnaire was specifically developed for the study without previous testing and it was unclear whether comprehension was actually being measured. In addition, it is unknown why the authors designed a study specific anxiety questionnaire when there are many validated measures available that could have been used, perhaps they were measuring anxiety specific to the educational program.

As discussed in the section on videotapes, Agre and Rapkin (2003) also conducted a study assessing three tools to improve informed consent: a videotape, computer, and booklet were compared with a standard written consent form. To re-iterate, patient populations included those considering participation in existing clinical trials (n = 204) such as phase I, II, III clinical trials, and three non-therapeutic, family and friends who accompanied the patients to
the consent discussion for those trials (n = 109), and individuals labeled surrogate subjects, who were waiting for patients in a surgical day hospital waiting area (n = 128).

The computer-assisted instructional (CAI) program was developed for the study and included the same information as the other interventions, however no further information on the content was provided. Knowledge was the primary outcome measured by a 12-15 item multiple choice quiz on each of the elements of informed consent based on the details provided in each specific protocol. This included how involved the research procedure was and the number of side effects, and was completed by patients after the consent intervention. Overall in all groups of patients, the computer intervention patients correctly recalled 66% of the knowledge of the information given compared with 68% of patients undergoing standard care, 70% receiving the booklet, and 73% viewing the video. No significance was reported for these findings. Correlation analyses revealed that computer and video formats were weakly associated with the proportion of correct responses which was not found to be statistically significant. This was a complex study reporting some interesting findings however several of the results were questionable often due to a lack of detail presented.

A recent, well conducted study was undertaken in Germany in the form of a randomised controlled trial of 56 patients undergoing cardiology or endoscopy procedures (Enzenhofer et al., 2004). It aimed to identify the impact of computerised picture material and a leaflet (visualisation group, n = 28) on improving informed consent as opposed to a patient-physician conversation, considered usual care (control group, n = 28). The assessed intervention, known as ‘Dr Topf’s patient information system’ was designed to be used as an active system together with the patient. It has the benefit of allowing the physician to decide what pictures to show and how to present the information instantly.

Dr Topf’s patient information system was developed in conjunction with physicians in Heidelberg. This was to set up the computer-based information system with correct medical explanations and supporting two-dimensional graphical presentations. This system was piloted with 28 patients and consisted of information and pictures used in cardiologic and gastroenterological procedures. The presentation consisted of a maximum of five pictures and
intended to take no more than five minutes to go through. On the other hand, the control group, considered usual practice in Germany was a standardised conversation by the physician. The different groups received the same information and the sole difference between them was the format of the information given (Enzenhofer et al., 2004).

Descriptive characteristics of the sample suggested that no significant differences were identified between the two groups with regards to age, gender, and level of education. The authors used a structured questionnaire to assess knowledge which was in the form of ten questions each with five probable statements (it does not apply, it applies partly, it applies, it applies very well, or it could not be better). Patients had to indicate whether the statement was correct or incorrect, which indicates that recognition was being measured. A score of zero to 10 was obtainable with a higher score indicating a greater level of patient knowledge. The patients had to answer these questions approximately three days after the intervention which meant that there were minimal losses to follow-up (88% complete). It appears from the results that patients in the intervention group (M = 7.21, 95% CI 6.5-7.9) had a greater level of knowledge than those who consented based on a patient-physician conversation (M = 5.04, 95% CI 3.3-6.2) and this was found to be significant with a large effect size (p = .006, partial $\eta^2 = .19$).

Satisfaction was also assessed using a patient satisfaction questionnaire that was designed for the study. Cronbach's alpha coefficient for the internal consistency of the patient satisfaction questionnaire was .94 which is very high. Five possible answers ranging from ‘it does not apply’ (one point) to ‘it could not be better’ (five points) were arranged on an ordinal scale. A total score of five to 25 points could be reached. Higher scores indicated greater satisfaction. The visualization group had significantly higher satisfaction (M = 21.2, 95% CI 19.2 to 23.8) compared with the control group (M = 15.8, 95% CI 14.1 to 17.5, p < .001). This good quality study found the computer based information system to be very effective in improving patient knowledge and patients were highly satisfied. Limitations of the study included that the authors did not indicate whether the questionnaire used to assess patient knowledge was validated or whether the authors had carried out reliability tests. Additionally, as suggested above, the use of multiple choice questions meant that it assessed recognition, which
undoubtedly is not as good an indicator of recall as the patient being asked to recall freely. Physicians raised concern during the pilot phase of testing that the visualization could increase patients' anxiety however no formal assessment of this was conducted which can be considered for future research. Finally, the sample size was quite small, however, significance was still found and effect sizes were reported hence Type II error was unlikely suggesting the impact of the intervention was very strong.

The last couple of years have seen yet more studies assessing multimedia effectiveness in improving education and/or informed consent in a variety of medical settings. One of these studies was conducted in an oncology setting in Australia (Olver, Whitford, Denson, Peterson, & Olver, 2009). Cancer patients undertaking chemotherapy who were not involved in clinical trials and had a life expectancy of at least 12 weeks were included. Patients were randomly allocated to one of two groups: CD-ROM (n = 47) or standard care (n = 54) and the clinician was blinded to this group allocation. The study had a 76% follow-up rate however, intention-to-treat analyses were provided.

At the time of consenting to chemotherapy but prior to being given the information, patients were assessed on psychological (immediate and delayed recall and thematic recall, short-term memory, concentration, and pre-morbid IQ) and emotional factors (anxiety, depression, and coping styles). Thematic recall is the ability to recall the main themes of the study while general recall represents the ability to recall each factor within these themes. Following this, patients in the CD-ROM group were given the interactive, multimedia CD-ROM which could be taken home but also viewed on computers at the hospital with a nurse available to help patients. Patients could also print sections of the CD-ROM to take with them. The control group was given standard written information and both groups were provided with verbal information and were permitted to ask any questions, as in usual care. At the second chemotherapy visit (three to four weeks later), patients provided demographic information and completed a multiple-choice questionnaire on where they obtained their information, satisfaction with the information, and the extent of information accessed and understood. Also they were asked to recall the number of drugs, name of drugs, side effects expected, goal of the treatment, and length of the treatment was assessed and compared to their initial
information sheet and consent form for the patients’ specific chemotherapy regimen. Therefore, the recall questions asked of patients were not standardized as they needed to be study-specific, however, they did measure free recall, the most stringent form of recall.

The ‘Understanding Cancer’ CD-ROM was designed for the study by local media producers and the content developed by the researchers. The CD-ROM included text, audio, graphics, and links to the Internet broken up into nine sections including type of cancer, nutrition, patient’s perspective, further information, prevention, help, frequently asked questions, glossary, and informed consent form. The CD-ROM also included videotaped interviews of patients, doctors, and dieticians. The information included all the standard information that patients receive but also additional information about cancer and its treatment, however recall was not assessed on the additional information, and due to the interactive nature of the CD-ROM patients did not have to view all information, only the parts they desired.

Results showed that the groups were comparable based on descriptive information. The majority of patients said they received most of their information from their doctors (63%) and a similar number thought the purpose of the information and consent form was to explain treatment (61%). There were however no significant differences in three recall variables that were considered: number of drugs, treatment length, and treatment goal between the two groups. The proportion of correct responses to these questions ranged between 47% and 55% across all patients indicating in the best case, only half of the patients correctly recalled the information given. Effect sizes indicated a small difference between groups for correct recall of treatment length, favouring the CD-ROM group.

This study conducted further analyses after collapsing the two groups (CD-ROM and control groups) to determine predictors of recall of these three factors and found three significant models, showing the complexity of predicting recall of the different aspects of informed consent. Recall of the number of drugs was found to be predicted by reading comprehension, depression, and fatalism (p = .008) with only depression being found to be an independent predictor. Recall of length of treatment found a significant model based on five variables that predicted recall including gender, anxiety, depression, fatalism, and helplessness/hopelessness
(p = .005) however no significant individual predictors were found. Similarly, recall of the treatment goal did not have any individual predictors but a significant model based on immediate recall, immediate thematic recall, concentration, and depression was found (p = .03). All three models had the addition of format of delivery to the model (CD-ROM versus written information) which was not found to be a strong predictor and in fact the weakest predictor in two of the three models suggesting that the format of the information was not a good predictor of recall, but that depression was the most consistent predictor at varying degrees of strength. At their second chemotherapy cycle, satisfaction was also measured however there were no differences found between the groups and overall 66% of patients found the information very or somewhat helpful.

Overall, this study was well conducted and reported however was limited mainly in the loss to follow-up. However, the authors did provide attrition analyses where possible. Analyses of missing data revealed a significant difference between those who completed all assessments and those who only completed pre-randomisation assessment. These analyses showed that thematic recall was poorer in those who dropped out, showing evidence of a possible bias in the study sample.

**Summary**

The eight studies assessing the effectiveness of interactive multimedia in improving patient knowledge of information given were found to be divided. Half of the studies found some form of interactive multimedia to be effective when compared with usual care (Ader et al., 1992; Enzenhofer et al., 2004; Shaw et al., 2001) or booklets (Phelan et al., 2001). The remaining four studies showed either no significant differences in knowledge of the information given when patients received some form of interactive multimedia were compared with patients receiving another intervention or usual care (Agre & Rapkin, 2003; Hopper et al., 1994; Olver et al., 2009), or another intervention was found to be more effective (Jones et al., 1999). Ader et al. (1992) who compared three groups of patients also found a non-interactive intervention to be more effective than the interactive version.
However the main concern with these findings was that three of the four studies that showed an interactive intervention to be more effective in improving patient knowledge of the information given, measured recognition as a form of knowledge rather than free recall. The fourth study did not clearly report how knowledge was assessed although the description implied that it was recognition (Shaw et al. 2001). On the other hand, findings from the only studied that measured free recall, which was also the most recent study conducted on the effectiveness of interactive multimedia did not find significant differences between receiving a CD-ROM or usual care. Although calculation of effect sizes in this study indicated that there was a small difference between groups for correct recall of treatment length favouring the CD-ROM group. Regardless, only half of the patients receiving the CD-ROM correctly recalled the length of treatment.

There were also a range of factors that varied across studies, including the populations in which the interventions were examined ranging from imaging examination to cardiology procedures indicating patients were recalling information with different levels of complexity. The methods used by these studies were also vastly different. One major difference was that Enzenhofer et al. (2004) had an interactive program which was seen by the patient together with the physician. In this way it allowed the physician to decide what pictures to show and how to present the information instantly. Interactive multimedia in the other studies was designed for patients to view on their own and each had the options of choosing what menus to view. Phelan et al. (2001) also included interviews of patients who had good and bad experiences of surgery. In addition, the timing of assessment ranged between immediate recall to recall months after the intervention. Although, in three of the four studies showing the interactive methods to be effective, recognition was assessed a short time after, that is up to one week post-intervention.

Patient satisfaction was also measured in six studies, with the majority finding the interactive program to be beneficial. All of the satisfaction questionnaires were believed to be designed for the study however only two of the studies measured or at least reported the reliability of the questionnaire (Enzenhofer et al., 2004; Shaw et al., 2001). Both of these studies reported
high Cronbach's alpha coefficients for the internal consistency of the patient satisfaction questionnaire suggesting excellent reliability.

Another main outcome measured in the studies reported here was anxiety. Four studies reported on anxiety in the different groups (Ader et al., 1992; Jones et al., 1999; Olver et al., 2009; Shaw et al., 2001). All of these studies used some form of reliable measure although in one study, a combination of items from a reliable questionnaire (HADS) and items designed specifically for the study were used (Shaw et al., 2001). The questionnaire was tested for reliability which was found to be considerably high. It appeared from the studies that there was no difference in anxiety between groups at baseline. One of the two studies that measured anxiety after the intervention found the personal computer group to be significantly less anxious than the other groups receiving general computer information or booklet information. While Shaw and colleagues found no differences between the two groups, Jones and colleagues found patients receiving personalised information had lower anxiety at three weeks and three months. Both of these studies used the HADS scale which has been validated and is reliable although as mentioned above, Shaw et al. 2001, also included some study-specific questions.

Based on the findings, it is difficult to make any definitive conclusions regarding the effectiveness of interactive multimedia in improving patient knowledge of the information. Most studies appear to be measuring recognition and therefore more studies need to replicate these findings using better methods of measuring recall, namely free recall. However in the one study found to measure free recall, findings did not show the intervention to be successful therefore it does not seem feasible to implement such technology which can be costly and time consuming to implement.

**Decision Aids**

Informed decision making (IDM) and shared-decision making (SDM) have been of increasing interest in recent decades. This has been particularly evident since the shift from the patient’s passive role, in which providers make the decisions about treatment with minimal patient
contribution, to their more active role in which patients are informed in decision-making. Informed decision-making involves patient knowledge and understanding of the information given regarding the treatment, including risks, benefits, alternatives, and uncertainties, consideration of his or her own preferences, and participation in decision-making at a desired level (Rimer, Briss, Zeller, Chan, & Woolf, 2004). Recent advances from informed decision-making to shared decision-making include the addition of personal values and preferences of patients. Shared decision-making is particularly important when there is more than one possible medical recommendation. With the fast growing availability of new treatments it is likely that patients have an increased number of options which no doubt makes the decision-making process more challenging.

Informed consent and informed and shared decision-making are often used interchangeably. Although there is a complex overlap between informed decision-making and informed consent, differences between them also exist. At a simple level both lead to patients being informed on a particular procedure however IDM and SDM are more focused on a decision based on patient preferences and values and have more flexibility with the amount of patient participation they involve. Patient knowledge of the information given is an outcome commonly measured in studies assessing both informed consent and informed decision-making, such as those involving the use of decision aids.

There has been a vast amount of research into IDM and SDM but the size and complexity of such is beyond the scope of this thesis. While decision aids are intended for informed and shared-decision making, the relevance of studies on decision-making to this particular research project is that decision aids are designed to aid in recall and understanding of the information given for consenting to non-surgical treatment. For this reason, studies conducted in this specific area were reviewed and studies falling outside of these constraints were not included. It should be noted that the specific interest of this thesis, that is, knowledge of information given regarding adjuvant chemotherapy treatment, there is often a limited number of choices therefore the decision made is often less complex. Patients often only have to decide whether or not have such treatment as opposed to some settings where the type of treatment can be
chosen, for instance, breast cancer patients deciding between breast conserving surgery or mastectomy.

To facilitate decision-making for patients, there has been extensive development of decision aids. Decision aids have been defined by the Cochrane Collaboration (O'Connor et al., 2003) as “interventions designed to help people make specific and deliberative choices among options by providing information on the options and outcomes relevant to the person’s health status.” (p.2). They are designed to assist patients to understand the possible outcomes of the options, consider personal values on the harms and benefits associated with the options to clarify preferences, feel supported in decision-making, and participate in decision-making.

Decision aids are more detailed and personalized interventions aimed at preparing people for decision-making than patient education materials (O'Connor et al., 2003). They also focus on alternatives, descriptions of risks and benefits, and the use of explicit probabilities in presenting risks and benefits (Goel, Sawka, Thiel, Gort, & O'Connor, 2001; O'Connor, Wells, Jacobsen, Elmslie, & Tugwell, 2001). Indicators of informed decision making have been suggested to include improved knowledge, more realistic expectations, reduced uncertainty, improved clarity of values, reduced decision delay, improved adherence, and increased satisfaction with the decision (O'Connor, 1995; O'Connor et al., 1997).

Following the transition between the passive to the active role of patients, a large number of studies have assessed the effectiveness of decision aids on the outcomes mentioned above. A considerable proportion of these were found to be pre/post-test designs or pilot studies that solely assessed the effectiveness of the decision aid. More recently, there have been comparative studies being conducted on decision aids with other interventions.

Decision aids have been developed in multiple formats including pamphlets and booklets (Gattellari & Ward, 2003), audiotapes (O'Connor et al., 1998; Man-Son-Hing, Laupacis, O'Connor, Biggs, Drake, Yetisier, et al., 1999; Goel et al., 2001), computer-based formats (Molenaar, Sprangers, Rutgers, Luiten, Mulder, Bossuyt, et al., 2001; Kaner, Heaven, Rapley, Murtagh, Graham, Thomson, et al., 2007) and web-based formats (Krist, Woolf, Johnson, & Kerns, 2007). These may be self-administered decision aids (O'Connor et al., 1998) or interactive (Whelan, Levine, Willan, Gafni, Sanders, Mirsky, et al., 2004).
A number of systematic reviews on studies assessing the effectiveness of decision aids have been performed (Gaston & Mitchell, 2005; Feldman-Stewart, Brennenstuhl, McIssac, Austoker, Charvet, Hewitson, et al., 2006; O'Connor et al., 2003; O'Brien, Whelan, Villasis-Keever, Gafni, Charles, Roberts, et al., 2009). Some of these reviews focus on specific medical areas, such as cancer-related decision aids, while others may focus only on decision aids for screening or treatment across different settings. Also, some focus just on randomised controlled studies while others have reported on non-randomised and even non-controlled studies.

In the most recent systematic review conducted by O'Brien et al. (2009) which focused on randomised controlled trials assessing cancer-related decision aids (DAs) for screening or treatment, 34 studies were identified. Of these, 22 were in screening, five in high risk prevention, and seven in treatment. Potentially fewer studies concentrate on decision making for treatment because often there is little choice. Like in the case of adjuvant chemotherapy, people don’t often choose between different types of chemotherapy, but rather they just have it or don’t have it, making the decision less complex. Most of the studies involved decisions on prostate and breast cancer (n = 11 each) and the majority of studies evaluated a decision aid versus usual practice (n = 24), six trials compared two types of decision aids, and a further four compared two types of decision aids with usual practice. Outcomes considered in this review included patient knowledge, anxiety, support for decision-making, and the patient’s decision or intention.

The effect of decision aids compared to usual practice on knowledge acquisition was measured in 15 studies with 21 comparisons in which standardised effect sizes could be calculated and therefore reported in the review. The overall finding across screening, prevention, and treatment studies showed that decision aids improved knowledge over control groups (weighted average effect size 0.49, 95% CI 0.43 - 0.55). Similar findings were found on subgroup analyses based on the type of decision (i.e. screening, treatment). Among the 12 screening studies that measured knowledge there was significant heterogeneity therefore a random effects model was used giving a weighted average effect size of 0.67 (95% CI, 0.40 to 0.94, p < .0001). The three studies evaluating decision aids by women for prevention or
treatment that measured knowledge also showed significant benefits of the DAs compared with usual care (weighted average effect size, 0.50, 95%CI, 0.31 to 0.70, p < .001). The way that knowledge was measured in these studies was not reported in the review however examination of the original studies revealed that two of the three studies were actually measuring recognition by means of true/false and multiple choice questions (Whelan, Sawka, Levine, Gafni, Reyno, Willan, et al. 2003, Whelan et al. 2004).

Anxiety was also measured in the screening, prevention, and treatment studies which revealed that overall there were no significant differences between the two groups. However, when pooling results from three screening studies, the group that received the DA had significantly less anxiety than the group that received usual care (weighted average effect size -0.30; 95% CI, -0.53 to -0.08, p = .008). Another outcome measure was decisional conflict which had significant heterogeneity across five screening comparisons available and the random effects estimate was not significant (-0.15; 95% CI, -0.44 to 0.13; p = .28).

The review also identified studies that compared the effectiveness of different types of decision aids. Ten comparisons were found of which seven were for screening and three in prevention or treatment. Overall there appeared to be limited differences in effectiveness of the different types of DAs. There were, however, significant differences found in the prevention/treatment studies on knowledge which favoured more intensive (e.g. computer program) rather than less intensive DAs (e.g. brochure) with a weighted average effect size of 0.33 (95% CI, 0.10 to 0.56, p = .002). Pooled analyses showed that anxiety and decisional conflict were not significantly different between DA and control groups.

The limitations with such reviews include the limited commonality in outcome measures reported across studies and the restriction to studies for which data was obtainable and extractable. This review found limited evidence on the effectiveness of DAs in the prevention and treatment setting compared with screening which can be considered for future DA research. Decisions made for screening, prevention, and treatment are vastly different and are also made under different circumstances. For example, a decision about undergoing adjuvant chemotherapy may be less complex than taking up a preventative treatment like hormone
replacement therapy which can prevent but also cause cancer. Regardless the studies showed positive findings regarding DAs in improving knowledge and not increasing anxiety.

Other studies which did not make the inclusion criteria of O’Brien and colleagues’ (2009) review are also reported here. However in line with the review by O’Brien and colleagues, the studies reported here will also be limited to those that are based in the oncology setting. Goel and colleagues (2001) conducted a randomized controlled study based in a community setting in Canada, to evaluate a decision aid compared with an educational pamphlet for the choice of the surgical management of early breast cancer on decisional conflict, knowledge, and anxiety. This study focused on patients who were newly diagnosed with stage I or II breast cancer, suitable for either mastectomy or breast conservation therapy with no prior history of cancer. Unlike most other studies, this study used surgeons rather than patients as the unit of randomization. There is no reason reported for this but it is assumed that this is to minimize bias with the physicians’ communication style. During the consultation, patients who consented were given an enrollment questionnaire which was completed prior to leaving. The patients were then given the decision aid or pamphlet to take home with them as well as a second questionnaire to review prior to surgery.

The decision aid given was developed using focus groups of women with breast cancer and consultations with experts and piloted before use in this study. The format of the decision aid was an audiotape and workbook, the tape was 26 minutes in length and supplemented the workbook which was at an eighth grade reading level and included colour photos as well as a values clarification exercise for decision-making.

The values clarification exercise was a three step process involving reviewing advantages and disadvantages of each procedure (i.e. lumpectomy and mastectomy), then considering the value of these advantages and disadvantages, and finally assessing which decision seemed more likely. The pamphlet group (control) had identical information given without the photos, numbers, or values clarification exercises. The enrollment questionnaire included a demographic questionnaire, current choice of therapy, surgeon’s recommendation, and a state
anxiety measure (SAI). No significant differences were found for any of the factors measured at this baseline assessment time between the pamphlet and decision aid group.

Two to three days later, patients were contacted to make sure the questionnaires were completed. A follow-up questionnaire was also sent six months after enrollment. A total of 57 surgeons participated in the study, 28 in the decision aid arm and 29 in the pamphlet arm. These surgeons enrolled 136 patients, 86 in the decision aid arm and 50 in the pamphlet arm. The preoperative questionnaire included the same anxiety inventory, a knowledge questionnaire: the 18-item true/false Breast Cancer Information Test-Revised (BCIT-R) and the Decisional Conflict Scale, as discussed in the previous study. Finally, the last questionnaire six months later assessed decisional regret and repeated the anxiety inventory. Most of the patients (93%) completed the preoperative questionnaire. Anxiety did not differ between the two groups at enrollment and preoperatively with both at very high levels (above 50 points). At the six month follow up, anxiety was found to be lower than at the pre-operative stage, although this was consistent across both groups, equally to about 35 points which is reported to be within the normal population range.

At the pre-operative stage, the mean knowledge score was found to be similar in both groups (Pamphlet group: M = 14.4, SD = 2.2; Decision aid group: M = 14.2, SD = 2.0, NS). Similarly, at this time point, decisional conflict was not found to be significantly different between the two groups. Overall, the decision aid in this study showed limited benefit to decisional conflict, knowledge, and anxiety. It should be noted that there were losses to follow up at the pre-operative stage (time two) and six month follow up (time three). At time two, 93% were followed up which is reasonably high (decision aid, n = 77; pamphlet, n = 48) however at time three this dropped again in both groups. The questionnaire was completed by 73% (n = 63) in the decision aid group and 88% (n = 44) in the pamphlet group. The loss to follow up in the decision aid group was of borderline significance (p = .04). Other limitations to this study included the knowledge questionnaire being completed at home at which time the patients had access to the information given, perhaps biasing results. The questionnaires were also given even before the DA was viewed therefore it could have influenced them even more
than if it was posted at the end. Also, no effect sizes were reported but with a small sample, especially by the six month follow up there is the possibility of Type II errors occurring.

In the screening setting, Gattellari and Ward (2003) conducted a randomised controlled trial to evaluate the effectiveness of an evidence-based (EB) booklet in educating men on prostate cancer screening and to promote informed decision-making. Male patients aged between 40 and 70 years old and who had not been diagnosed with prostate cancer were included in the study. Prior to the consultation, participants were randomised and blinded to allocation to either the EB booklet (n = 126) or a comparison pamphlet (n = 122). The 32 page EB booklet was developed by experts in the area, included quantitative questions, and had a Flesch-Kincaid reading level of 7.3. The Flesch–Kincaid readability tests are designed to indicate comprehension difficulty when reading a passage of contemporary academic English. The comparison pamphlet was shorter, and non-numerical and had a Flesch-Kincaid reading level of 11.2.

Prior to the consultation a questionnaire was also completed on the men’s estimates of lifetime risk, level of worry, interest in having a screening PSA test within the next year, and perceived ability to make an informed choice. In addition, a 10-item true/false questionnaire was used to assess knowledge about prostate cancer and screening and the total percentage of correct responses was computed to obtain a composite score suggesting this was a measure of recognition rather than free recall. Three days after the consultation, another questionnaire was sent out again measuring men’s estimates of lifetime risk, level of worry, interest in having a screening PSA test within the next year, and perceived ability to make an informed choice and also decisional conflict using subscales of the Decisional Conflict Scale.

Demographic characteristics were not found to be significantly different between the two groups. There was a high follow up rate in the two groups (84% in the EB booklet group, 89% in the pamphlet group). Groups were comparable at pre-test with no significant differences. However, knowledge scores significantly increased from pre-test to post-test for both groups (p < .001). More specifically, at post-test the EB booklet group was significantly more likely to correctly estimate the lifetime risk of developing and dying from prostate cancer (57% vs.
The EB booklet group also had a higher knowledge score compared with the pamphlet group \( (p = .049) \) at this time point however there was only a small difference between mean percentage of items correctly answered in the two groups \( (50\% \text{ versus } 45\% \text{ in the EB and pamphlet group, respectively}) \). This however only shows that patients had knowledge of half of the information provided.

Interest in prostate cancer screening was similar in the two groups as was decisional uncertainty. More patients found the EB booklet \( (75\%) \) acceptable than the pamphlet \( (50\%) \). Despite the lengthy booklet which was three times that of the pamphlet, it was just as likely to be read in full. Overall, there appeared to be benefits to the evidence based booklet in informing men about prostate cancer screening. These benefits need to be further researched to confirm the findings. A limitation to the study included lack of provision of the reliability and validity of the knowledge questionnaire used, and the use of recognition assessment rather than free recall.

A more recent study on patient education before a health maintenance examination and involvement in decision-making for prostate cancer screening was conducted (Krist et al., 2007). This compared a paper-based \( (n = 196) \) with a web-based decision aid \( (n = 226) \) and included a control group \( (n = 75) \) who received no pre-visit educational material. The randomised controlled study, stratified by physicians to ensure that each physician’s patients were similarly distributed across the three study groups, and based on an intention-to-treat design, included men, 50 to 70 years of age who had scheduled a health maintenance examination. The web-based decision aid presented information about prostate cancer, screening concepts, potential screening benefits, and known risks. The paper-based decision aid was a print-out of the website which was mailed. There was no further information regarding the content of the brochure. Control patients received usual care which did not include any educational material. The web-based and paper-based groups were provided with and asked to review the material before their visit.

Outcomes were measured at two time points, one by means of a telephone interview prior to the visit and one immediately after the visit. Patient outcome measures included patients
reported locus of decision making control using the Control Preferences Scale (CPS), time spent discussing screening, topics covered in the discussion, Decisional Conflict Scale, which measures patients’ levels of conflict in making medical decisions, and whether a PSA test was ordered. Patient knowledge of prostate cancer screening was also measured using a questionnaire used in a previous study, which was by means of multiple choice questionnaires, implying that recognition was measured. Physicians also completed a questionnaire on all measures except knowledge and decisional conflict.

Baseline demographic characteristics were similar across the three groups. The CPS scores revealed that about one third (36%) of patients in each of the three groups reported that a collaborative decision was made. Patients receiving either of the decision aids were significantly more involved in the decision making process (p = .03). Patients receiving the decision aids were also significantly more knowledgeable than the control group on prostate cancer screening after receiving the intervention (69% in both decision aid groups versus 54% in the control group, p < .001). It was unclear whether patient knowledge pre-visit was not measured or just not reported.

Other findings included no apparent differences in the time spent discussing prostate cancer screening or the number of topics covered between the groups. There was also low decisional conflict in all three groups with no differences between the groups. This may be explained by three quarters (74%) of patients wanting a PSA test prior to enrollment. Overall, the differences between patient and physician responses were not significant, although physicians believed that they had greater control over the decision than the patients. On the whole, both decision aids were found to be equal in effectiveness of educating patients and involving them in decision making. They were both found to be more effective for improving patient knowledge than for the control patients. The study was limited again to a specific population and also the knowledge questionnaire was assessed using recognition rather than recall and even so, its validity and reliability was not clear.

The patient population was highly educated in both groups and therefore the sample may be more likely to present themselves to the clinic and likely to receive PSA testing. Although the
authors reported no differences between the groups, there was a large difference in the
numbers randomised to each of the decision aid groups compared with the control group. In
addition, the authors reported that their study was underpowered to detect differences between
the brochure and Web site groups and like in many other studies, no effect sizes were reported
so the possibility of Type II error was likely.

With technological advances, other forms of decision aids have been developed in recent
times. These include video-based, CD-based, and interactive decision aids. A CD-ROM was
assessed in a study by Molenaar et al. (2001) with newly diagnosed stage I and II breast cancer
patients in three Dutch hospitals, one cancer, and two general hospitals. A CD-ROM on
choosing between mastectomy and breast conserving therapy (BCT) was designed and piloted
and was found to be feasible, acceptable, and helpful for the patients.

The Interactive Breast Cancer CD-ROM included a combination of still images, video, and
text. Written summaries of potential pros, cons, and uncertainties of the two surgical options,
as well as selected parts, were printable. There were eight underlying menus which patients
could select from and each represented different factors of the two surgical alternatives.
Unlike other studies, patients in this study were not randomised to a group as the authors
believed randomizing individual patients or surgeons may lead to an underestimation of the
effect of the CD-ROM and also if patients in the control group learned of such a CD-ROM,
they may have wanted a copy and it was believed to be unethical to have denied them the
access. Therefore a pretest/posttest design was conducted whereby one hospital (Hospital B)
used the CD-ROM for a period of six months and the other two hospitals (Hospitals A and C)
acted as controls. Following this, Hospitals A and C used the CD-ROM and Hospital B was
the control for a period of six months. Finally, it was reversed again so that Hospital B patients
received the CD-ROM. In other words, this was an ABA design for Hospital B and a BAB
design for Hospitals A and C.

Patients receiving the CD-ROM (n = 92) were scheduled an appointment, about one week
after diagnosis to view the CD-ROM in the presence of a breast cancer nurse specialist. After
the consultation but prior to the CD-ROM viewing, patients completed a baseline
Patients in the control group (n = 88) returned the questionnaire by mail before admission to the hospital. At baseline, socio-demographic and clinical variables, treatment preference, decision style, decision uncertainty, and quality of life were assessed. Outcomes measured after implementation of the study included generic quality of life, breast cancer specific functioning and symptoms as well as satisfaction with the information, the decision making process, the treatment decision, and care. Only results of satisfaction were of interest to this review, and therefore reported, as other variables are beyond the scope of this research. Different scales were used for the different types of satisfaction assessed, of which only satisfaction with the decision made and satisfaction with the care used questionnaires reported to be validated. These were the ‘effective decision making’ subscale of the Decisional Conflict Scale and the Patient Satisfaction Questionnaire. Follow up was at three and nine months after the surgery and analyses were conducted on an intention-to-treat basis.

At baseline, satisfaction was found to be significantly different between the hospitals with Hospital B scoring a higher patient satisfaction score (p = .03). Therefore ‘hospital’ was entered as a covariate when the effectiveness of the CD-ROM program was tested. No other differences were found at baseline for patients receiving the CD-ROM or usual care.

An overall positive effect was found on satisfaction for patients receiving the CD-ROM (p < .01). This however was not found to be different at three months compared with nine months. At three months, patients receiving the CD-ROM were found to report higher satisfaction with information (p < .01) and their treatment decision (p = .03). At nine months, CD-ROM patients were more satisfied with the information (general, p < .01 and specific, p = .03), the decision-making process (p = .02), the treatment decision (p < .00), and communication with physicians (p = .04) than control patients. Overall, the Interactive Breast Cancer CD-ROM improved satisfaction with various aspects of decision-making in early stage breast cancer patients.

A limitation of the study included the use of study-specific instruments to measure satisfaction with the information and the decision making process as they were not standardized. However, as seen in much of the previous research, this is not uncommon in this area due to the types of questions needed to be addressed. Also, the authors reported the reliability of these measures as being good (Cronbach’s alpha > .76). Another limitation was that there may have been
contamination of the intervention when physicians changed their communication with patients in the usual care groups due to events in consultation with the CD-ROM patients. This may be evaluated in future studies by audio-taping consultations. A third limitation was that the study was not randomised which may impact on the selection of patients, although baseline factors were reported to be similar across the two groups. This study, unlike most other studies, had a long follow up of nine months.

**Summary**

This review identified four recent studies on DAs in oncology apart from those that were identified in the systematic review by O’Brien and colleagues (2003). Three of these studies measured patient knowledge of the information given, although all of them were actually measuring knowledge in the form of recognition. None of the studies reported on a higher level measurement of recall therefore findings are reported on recognition of the information given hence should to be considered with caution.

Two of the three studies measuring recognition of the information found a significant improvements using the decision aid (Gattellari & Ward, 2003; Krist et al., 2007). Both studies were based in the screening setting, and both were specifically for prostate cancer, which means the studies were based on males with an age limit of between 40 and 70 years of age. The decision aids used in these studies included web based decision aids, paper based decision aids, and evidence based booklets. The most recent study found both the paper based and web based decision aid to be more effective than no pre-visit educational material however the decision aids themselves found the same mean level of recognition. The paper based and web based decision aids both had mean recognition of 69% compared to 50% recognition in the pre-visit educational material (Krist et al., 2007). On the other hand, Gattellari and colleagues (2003) compared an evidence based booklet with a comparison booklet which was shorter, reporting no numbers and had a higher reading level, hence making it harder. The evidence based pamphlet resulted in a mean recognition of 50% compared to 45% in the comparison group.
The research identified in this review focused on decisions that cancer patients need to make for screening or surgical treatment. No study was found to assess effectiveness of decision aids for non-surgical treatment such as chemotherapy. This may, as suggested above, be due to such treatment having a limited choice and therefore a less complex decision to be made, although of no less importance. Despite showing decision aids to be effective for recognition of the information given, the studies only measured this shortly after the intervention. No long-term knowledge of the information given was assessed.
Discussion

Evidently, there is much published evidence available on the effectiveness of interventions aimed at improving the informed consent process. The evidence-base that forms this review shows that limited high quality research has assessed the effectiveness of interventions intended to improve patient knowledge of the medical information given. In other words, most studies had methodological flaws or reporting was unclear. Although the majority of the included studies conducted randomised controlled trials (n = 43, 86%) which are considered level II evidence, minimization of bias is lacking.

Among the studies, there was considerable variation in the design, content, presentation, and delivery of interventions examined by the included studies. The populations studied, and the purpose of the studies also varied but most importantly the measure of patient knowledge of the information differed vastly across studies. The literature did not show evidence of any standardised approaches in measuring patient knowledge of the information given, with all of the research designing study specific questionnaires to measure knowledge. This appears to be an unavoidable approach in the kinds of studies reviewed as the main aim of such research is to measure specific patient knowledge related to specific procedures or treatment regimens tailored for individuals or small homogenous groups. The most superior surrogate for the measurement of knowledge is to assess free recall where patients are asked to retrieve information from the back of their minds without prompting. However this was sparingly found in the literature. Most studies used recognition as a form of measuring knowledge but it is clear that patients’ recognising potential treatment side effects from a list does not show that they can freely remember the side effects to watch out for or understand what it means and what they need to do if they result. Furthermore, when scales were used to measure free or cued recall, or recognition they were often not reported to be valid or reliable so it is unclear whether such testing was not done or just not reported. Regardless, it was not considered feasible or valid to pool the results of these studies statistically such as using a meta-analytic approach. Combining such scales would make the meta-analysis inaccurate, therefore a
narrative meta-synthesis of the results was attempted to answer the review’s questions to the greatest extent possible.

The main finding of this review suggests that the use of format modifications to surgical or non-surgical treatment information given to patients to provide informed consent may be beneficial at improving patient knowledge of the information given. Based on findings from the studies that measured free recall of the information given, the review highlighted only a limited number of format modifications that were potentially more effective than routine care currently provided as part of the informed consent process. These included a pamphlet outlining procedural risks in addition to the standard consultation (Makdessian et al., 2004); a modified consent leaflet incorporating better layout (Garrud et al., 2001); and specific preadmission instructions (Rice and Johnson, 1984). These studies were all based in surgical settings and free recall was measured a short time after, with the longest measurement being two weeks after receiving the information. Across these studies, recall of the information given was found to be between two and three fifths with the format modifications, compared to one third to a half recalled by patients receiving usual care. The amount of information recalled by patients is still believed to be low even with the format modifications making clinically meaningful improvements questionable. In addition, the three studies had samples with ages in the range of 14 to 72 years of age but two studies reported the mean age of patients to be in the 40’s which shows that recall was measured in young populations. Previous studies have shown that increased age is related to decreased memory (Lavelle Jones, Byrne, Rice, & Cuschieri, 1993), hence age may be a confounding variable. As a result, the consent tools used in these studies need to be assessed on older populations before effectiveness is determined. Also, two of the three studies included populations that comprised all or mostly females, however there has been no association established between gender and recall of the information given.

When studies utilizing less than ideal measures of cued recall or recognition (or even those using unclear measures) are taken together, there appears to be greater success in applying the interventions.
The stand out intervention was believed to be videotape formats as the findings were most consistent across studies. Three quarters of the studies assessing the impact of videotapes that measured and reported on recall or recognition of the information given found videotapes to increase patient knowledge of at least some if not all aspects.

The studies were conducted in a variety of settings including both surgical and non-surgical patients but also on a mixture of patients including psychiatric patients, clinical trial participants, and family and friends of patients, among others. In addition, the types of videotapes used were also diverse, with the length of the videotape ranging from five to 55 minutes. Recall or recognition was measured within a short time frame of viewing the video in all of the studies, usually immediately after or sometimes after their consultation on the same day or at discharge, at most a couple of days afterwards. This may not capture the patient’s long term knowledge of the information so may show different results than those demonstrated in Moldofsky and colleagues’ study (1979). Future studies should measure free recall or knowledge of information when given the videotape at longer periods than within one to three days.

Other interventions showed less consistent findings. Less than one third of the studies found audiotapes to significantly improve recall or recognition of information in patients when compared to patients receiving usual care. Two of these studies focused on bad news consultations and a third study included advanced cancer patients (Hogbin et al., 1992; McHugh et al., 1995; North et al., 1992). This suggests that in such conditions patients may benefit from an audiotape of the consultation. Patient recall of the information given was found to be good in these studies, ranging between 73% and 100%. Recall in the two studies assessing recall in the short term found a recall rate of between 85% and 90% (Hogbin et al., 1992; North et al., 1992). These studies however were conducted in relatively small samples increasing the possibility of Type II errors and neither of the studies reported effect size calculations or clinically meaningful change. A study comparing audiotapes with summary letters showed that patients recalled the same amount of information with the audiotapes and letters, yet audiotapes were the preferred method by patients (Tattersall et al., 1994). This may be because it is easier to listen to a tape than read information that is given. Tapes may also be
a more convenient method as they can be listened to at any time, even while doing other things, however patients need to find time to sit and read the letter.

Like studies assessing audiotapes, there were also inconsistent findings across studies that were reviewed regarding the effectiveness of interactive multimedia for improving patient knowledge of information given. Half of the studies reported here found statistically significant increases in recall or recognition of information given (Ader et al., 1994; Enzenhofer et al., 2004; Phelan et al., 2001; Shaw et al., 2001). The populations that constituted these studies varied considerably; three were non-surgical treatments ranging from imaging examinations to cardiology procedures and one study focused on patients who were undergoing back surgery. Three of these studies measured recognition of the information given and in one study the form of recall measured was unclear. An estimate of the percentage of information recalled or recognised by patients receiving the interactive multimedia was between two-thirds and just under three-quarters. The comparison group of patients receiving usual care or a booklet in the case of Phelan et al. (2001) recalled between two and three-fifths of the information given. Enzenhofer and colleagues found a computer based system to have a large effect size for recognition of information given to cardiology and endoscopy patients. Future studies could consider replicating this good quality study using superior assessments of free recall.

While there is a plethora of studies and systematic reviews on the effectiveness of decision aids on a variety of outcomes, for the purposes of this thesis, only studies focusing on the effectiveness of decision aids (DAs) in cancer patients were reported here. Three studies aimed to measure the impact of DAs on patient knowledge of the information given. In fact all three measured recognition of the information given which is a major flaw of these studies as discussed above. Two of these studies found a significant difference between patients receiving interactive multimedia and those receiving no decision aid (Krist et al., 2007) or a booklet (Gattellari & Ward, 2003). Patients recognised between half and nearly three quarters of the information given in these two studies, a significant finding, compared to the control group (45%-54%). The interesting point that was identified regarding DAs was that no studies were found to assess effectiveness of decision aids for non-surgical treatment such as
chemotherapy. Does this imply that patients do not need decision aids for such treatment as it is not a complex decision? Compared to other decisions such as deciding to take HRT, there are limited choices with regards to deciding to undertake chemotherapy treatment therefore patients would potentially not benefit from such an intervention.

Comparatively, the results obtained in this review were somewhat consistent with other systematic and non-systematic reviews. In a non-systematic review of informed consent research, Agre and colleagues (2003) aimed to investigate the impact of audio-visual (video and computer-based) interventions in eight studies with outcomes on participant understanding and informed decision-making. This review found that across different groups of participants, most interventions did not significantly improve the knowledge of patients and no particular way of presenting informed consent information was superior to the other forms.

Similarly, Flory and Emanuel (2004) conducted a systematic review on interventions to improve research participants understanding of informed consent. Of the 12 video and multimedia interventions assessed in nine studies, only three were found to significantly improve participants’ understanding. The authors concluded ‘multimedia and enhanced consent form interventions do not consistently improve research participant’s understanding (pg. 1596; Flory & Emanuel, 2004).’

Other than knowledge, several studies measured patient anxiety and satisfaction. There was also scarce literature on factors that may be associated with patient knowledge or information such as age, gender, and education. This review found about one third of the studies identified measured anxiety and in most studies, validated questionnaires such as the STAI and HADS were used. Some of these studies only measured anxiety at baseline while others measured anxiety prior to and after the intervention. Findings from the majority of studies showed no differences between experimental and control groups at baseline and/or after interventions. Therefore there were limited studies from those identified that showed improvements in patient anxiety (Luck et al., 1999; North et al., 1992; Olver et al., 2009). In Luck and colleagues’s study, a sub group analysis of the 20% of patients most anxious at enrolment identified that those receiving a video had the highest mean scores for all aspects of
knowledge, whereas the patients with severe anxiety who did not watch the video had lower mean knowledge scores (no p value given. Less anxious patients, as the literature suggests, have been shown to recall information to a greater extent because anxiety may result in difficult assimilating the information given (Jepson & Chaiken, 1990; Ley, 1979).

Satisfaction was also measured in a similar number of studies to that of anxiety. Most studies found high levels of satisfaction in patients. Therefore, while patients have poor recall or knowledge of the information given, they remain highly satisfied. In most studies satisfaction levels were found to be over 75% (Enzenhofer et al., 2004; Shaw et al., 2001; Strevel et al., 2007; Tattersall et al., 1994; Thomas et al., 2000). This may suggest an inverse relationship between these two factors, with low recall being associated with high satisfaction. Although one study found the opposite of this, specifically an increase in patient recall of the information given led to an increase in patient satisfaction (Hack et al., 1999). There may be a reporting bias associated with patient satisfaction of information or care received. In other words, patients may state that they are satisfied as they believe it may impact on their care, or this may be a socially desirable response consciously or subconsciously given by patients. However the main concern with measuring satisfaction is that there are not many standardised questionnaires and often authors need to measure satisfaction with a specific factor, therefore many researchers have to develop their own study specific satisfaction questionnaire raising questions of validity and reliability.
Summary of the limitations

One limitation of this review concerns the included studies themselves. The included studies were heterogeneous in terms of both patients and interventions. Although the interventions may have fallen in the same category, that is, written versus verbal information, or audiotapes, the actual tools varied considerably amongst the studies. In addition, there were several limiting aspects seen in the studies such as the way findings were presented. Very few studies provided sufficient data to conduct subsequent statistical testing in order to gain some consistency between the studies. Much of the research was conducted on small sample sizes which reduced external validity and hardly any studies conducted or at least reported effect size calculations. A large proportion of the studies measured recall of the information given immediately or a short time after implementation of the intervention. Assessment of interventions on long-term recall of the information given, especially when procedures or treatments carry long term side effects or possible future complications is vital.

In addition the use of comprehension, understanding, knowledge, memory, and recall were used interchangeably when they differ considerably as discussed extensively in Chapter One. Very few studies distinguished between these when assessing the effects of information recall on the informed consent process. As mentioned above, some studies did not specifically measure free recall of information, but rather prompted recall or recognition making results incomparable. In most studies, recognition was used as a surrogate to assess patient knowledge which as previously mentioned requires less cognitive processing than more difficult assessments of memory such as free recall. A large number of these studies also lacked any mention of validity or reliability of recall questionnaires. Although this is a problem of the studies, it is also a general issue as there is no ‘gold standard’ assessment method of knowledge. It is understood that because of the nature of these kinds of studies, unstandardized questionnaires need to be used for measuring recall, making validity and reliability hard to assess as with any necessary study-specific designed assessments.
This also leads onto the question of ‘what constitutes adequate recall or knowledge of information given?’ As components that form the information given to patients varies considerably, is this question even possible to answer? Is it that a certain proportion of correct responses represents adequate recall regardless of the information? For example, one study considered recognition of one of the four major risks acceptable and recognition of three major risks as a good level of information recall (Kriwanek, Armbruster, Beckerhinn, Blauensteier, & Gschwantler, 1998). This study further raises the question ‘Should adequate recall be based on a number as demonstrated in this study or should it be based on the level of importance of that information such as the seriousness of side effects?’ Evidence from this review shows that despite some success with various format modifications improving recall of the information given, recall was still questionable in many studies mainly showing that about two-thirds of information was correctly recalled in patients receiving the intervention. Therefore it is suggested that there is only so much that format modifications may contribute to improving patient knowledge of the information. If recall is still questionable following successful format interventions, then the question of cost effectiveness of researching such complex interventions becomes paramount. Many of the format modifications discussed were highly specific to certain homogenous populations of patients limiting generalisability. Furthermore, the technology involved was sometimes expensive, and the studies were complex highlighting both time and cost issues.

**Implications for future studies**

Given the many limitations of the current literature on format modifications of informed consent tools, much research still needs to be done to (a) decide which of the many alternative interventions deserves further investment, (b) which modifications can be applied to various procedural and treatment areas, (c) are modifications worthwhile if they only produce minimal, clinically questionable improvements in patient recall against usual care, and (d) which modifications are time and cost efficient given some of the investments such as building and implementing computerised systems. Despite numerous studies being conducted, the evidence is still considered in its infancy and needs to be further streamlined to answer these
important questions to be clinically meaningful. However, one important theoretical question remains unanswered before such an investment should be made in this area.

If the patients’ experience of receiving surgical or non-surgical treatment actually enables patients to recall relevant information from their consent process, there seems to be little need to implement such novel tools. As outlined above, there are a number of reasons for this which mainly focus on time and cost savings. Firstly, the time saved on designing and implementing novel interventions is great but also the time and costs associated with replicating studies to make sure interventions prove to be effective is questionable given the lack of clinically meaningful findings.

Given the findings of this review, it is likely that there are limits to how much patient recall of consent information can be improved shortly after treatment. However, if patients eventually recall important consent information over a period of time, then expensive, complicated novel interventions to modify consent procedures may be unnecessary to prevent future legal or other consequences. For instance, patients may naturally recall consent information in the future especially during a lengthy treatment such as chemotherapy where side effects and complication can be important to identify long after treatment ceases or treatment adherence with ongoing medication (like hormonal therapy following breast cancer) is essential. Therefore, given the evidence just reviewed, it seems necessary to further investigate whether patient recall improves with experience in treatment settings. This will be the aim of the next literature review.

More importantly, the heterogeneity in the evidence, and the time and cost of conducting such complicated format modifications in this area supports the notion that research into the effect of experience of treatment on knowledge may be a more acceptable area of research to conduct when attempting to better understand and improve current consent processes, especially in long term treatment settings. As mentioned earlier in this chapter, if there is a significant association between treatment experience and patient knowledge of the information given, further research into effective tools may become redundant.
Chapter 4: Literature Review Two

Introduction

As learnt from the first literature review (Chapter Three), a great deal has been done in order to improve poor patient recall or knowledge of the treatment information given for both informed consent and decision-making purposes. Briefly, this included the evaluation of the use of information booklets, audio and videotapes, interactive multimedia, and decision aids. Many studies also assessed the effect of these interventions on outcomes other than patient knowledge, such as patient satisfaction and anxiety. The literature review examined numerous studies, some from close to four decades ago and although the results showed that some of the tools were effective, recall was still questionable. There were many inconsistencies in the findings, the potentially effective findings from studies were difficult to generalise, and a number of limitations were identified. The implementation of these different formats may also not be cost effective even if they were consistently found to be effective in improving patient knowledge of the treatment information.

To combat this issue, attention was focused on an approach that may be both effective in practice as well as cost effective. As a result, it was deemed necessary to take a step back from implementing a tool, to assess the impact of patient experience with any therapeutic procedure on patient knowledge of necessary medical information. In other words, after patients are given material information of a medical procedure to give informed consent, how much does patient knowledge of this information improve with their experience of treatment? This means that although patient knowledge at the time of consent may be poor, as it may improve with the experience of treatment, then perhaps informed consent before treatment cannot be obtained, but patients may still become equipped with the necessary knowledge.
This question led to this second literature review which aimed to identify and evaluate studies that assessed the impact of patient experience of medical procedures through prospective longitudinal assessment, on improving their knowledge of the information patients had received. Longitudinal assessment not only allows for a capturing of the experience but also allows for measuring patient knowledge of the information given in the long-term. Patient knowledge of the name of chemotherapy drugs will allow patients to inform their physicians and specialists of the drugs they are taking. This may make the consultation process easier and quicker and will allow time for other important factors. In the long term, patient knowledge of the side effects and risks will allow patients to know what to do, such as avoiding certain types of food that are believed to interact with certain drugs. Also, it allows them to seek health care if signs of serious complications occur. After treatment completion, patients visit their physicians or specialists less often and hence the long-term knowledge of information given will benefit them in gaining control of their condition (Mills & Sullivan, 1999), improving compliance with treatment (Fallowfield, 2008), and reducing anxiety (Gaston & Mitchell, 2005), amongst other things.

To my knowledge, no review has assessed the effectiveness of patient experience with any treatment (rather than the use of tools) on their knowledge of the information given which forms the aim of this second literature review in this thesis.
Methods

The inclusion criteria for studies in this review is as follows; any adult population undergoing some form of medical procedure in a health care setting who had consented before commencement of the procedure. Therefore this includes screening or diagnostic procedures, such as colonoscopy, treatment (e.g. chemotherapy), and surgical procedures (e.g. lumpectomy). Health care settings may have included hospitals, hospices, clinics, and/or medical centres. Study designs included in this review were prospective studies, longitudinal where possible. Therefore although studies may only measure outcomes prospectively at one time point, as long as they occurred sometime after the consent process, in order to capture patient experience, they were included. No comparators were required as patient experience of the standard practice was the focus.

Studies in which patients received information by standard practice, such as written forms, were included while studies evaluating some form of novel method of delivering information were excluded. An example of this would be a study that assessed patient knowledge of information given by means of a video or computer that is not standard practice. This prevents confounding variables impacting on the effectiveness of pre-procedural information when combined with experience of patient knowledge of information given. This particular literature was previously reviewed in Chapter Three.

The primary outcome of the review was to identify studies that measured patient knowledge after receiving the necessary information and with procedural experience. Other patient outcomes discussed in the studies were also reported in this review such as patient satisfaction, anxiety, and denial. Studies other than English were not translated for two reasons; firstly, the reduced generalisability of non-English studies to the Australian population and the feasibility of translating numerous studies that may not be relevant to the review was considered too low.
The medical and health literature was searched to identify relevant studies and reviews with no restrictions on when the study was conducted, within the limitations of the electronic database coverage of articles. The reference lists of all included studies were searched for additional sources. The search terms that were used to search the databases are as follows. MeSH terms: Informed consent, disclosure, consent forms, comprehension, mental competency, memory, longitudinal studies, follow-up studies, prospective studies. Text words included longitudinal stud*, longitudinal survey*, follow-up stud*, follow-up survey*, prospective stud*, prospective survey*. Upon retrieval of the studies that met the inclusion criteria for this review, data was extracted by a single researcher. A profile was developed for each study, outlining the study characteristics, study design, study authors, year and setting, target population, and outcomes assessed in the follow-up period (Table 5).
Table 5 Study profiles of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Setting</th>
<th>Population</th>
<th>Outcome(s) assessed</th>
<th>Length of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Byrne, Napier, &amp; Cuschieri, 1988)</td>
<td>Prospective study</td>
<td>Department of Surgery, Dundee</td>
<td>Surgical patients (n=100)</td>
<td>• Knowledge of organ operated on, basic details of operation</td>
<td>2 – 5 days post-operation</td>
</tr>
<tr>
<td>(Cassileth et al., 1980)</td>
<td>Prospective study</td>
<td>University of Pennsylvania Cancer Center, Philadelphia, USA</td>
<td>Cancer patients (n=200) receiving chemotherapy, radiotherapy or surgery</td>
<td>• Knowledge of content of consent form</td>
<td>1 day post-operation</td>
</tr>
<tr>
<td>(Craft et al., 2005)</td>
<td>Prospective, longitudinal study</td>
<td>Canberra Hospital, Woden, ACT Australia</td>
<td>Patients with a diagnosis of incurable malignant disease (n=181)</td>
<td>• Knowledge of purpose of treatment</td>
<td>One and twelve weeks after study entry</td>
</tr>
<tr>
<td>(Dodd &amp; Mood, 1981)</td>
<td>Prospective study</td>
<td>University of California, San Francisco, USA</td>
<td>Patients who had received chemotherapy for cancer (n=30)</td>
<td>• Recall of drug names, potential side effects, reasoning for chemotherapy</td>
<td>Up to 6 months post-chemo-therapy</td>
</tr>
<tr>
<td>(Fleischman &amp; Garcia, 2003)</td>
<td>Prospective study</td>
<td>Dept. of Dermatology, Oklahoma City USA</td>
<td>Skin cancer patients undergoing Mohs micrographic surgery (n=85)</td>
<td>• Recall of potential complications</td>
<td>1 week post-surgery</td>
</tr>
</tbody>
</table>
| (Gattellari, Butow, Tattersall, Dunn, & MacLeod, 1999) | Prospective study                   |                                              | Cancer patients receiving radio or chemotherapy (n=242) | • Information understanding  
• Denial of information                                                               | Median of 28 days (range 1 -148 days) |
Table 5 continued…

<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Setting</th>
<th>Population</th>
<th>Outcome (s) assessed</th>
<th>Length of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Godwin, 2000)</td>
<td>Prospective study</td>
<td>Dept. of Plastic Surgery, City Hospital Nottingham, UK</td>
<td>Patients undertaking reduction mammoplasty (n=38) Patients undergoing routine thyroidectomy, parathyroidectomy or parotidectomy (n=54)</td>
<td>• Surgical complications</td>
<td>Six days post-procedure</td>
</tr>
<tr>
<td>(Hekkenberg, Irish, Rotstein, Brown, &amp; Gullane, 1997)</td>
<td>Prospective study</td>
<td></td>
<td>Patients undergoing routine thyroidectomy, parathyroidectomy or parotidectomy (n=54)</td>
<td>• Risk recall</td>
<td>One – eight weeks post surgery</td>
</tr>
<tr>
<td>(Kriwanek et al., 1998)</td>
<td>Prospective study</td>
<td>Rudolfstiftung Hospital, Vienna, Austria</td>
<td>Patients undertaking elective cholecystectomies (n=200)</td>
<td>• Main indications of surgery, principles of operative procedure, major operative risks</td>
<td>5 days post-surgery</td>
</tr>
<tr>
<td>(Madan, Kulkarni, Friedrichs, &amp; Barrett, 2001)</td>
<td>Prospective study</td>
<td>Southampton University Hospital UK</td>
<td>Patients undertaking day case knee arthroscopy (n=103)</td>
<td>• Patient satisfaction</td>
<td></td>
</tr>
<tr>
<td>(Muss et al., 1979)</td>
<td>Prospective study</td>
<td>Oncology Research Centre, North Carolina USA</td>
<td>Breast cancer patients undertaking chemotherapy (n=100)</td>
<td>• Comprehension of diagnosis and procedure Recall of purpose, risks and benefits of chemotherapy</td>
<td>3 weeks post-operation Post-treatment (unclear follow-up)</td>
</tr>
<tr>
<td>(Olver, Turrell et al., 1995)</td>
<td>Prospective study</td>
<td>Royal Adelaide Hospital, Australia</td>
<td>Patients receiving chemotherapy treatment (n=100)</td>
<td>• Recall of number &amp; name of drugs, side effects, length and goal of treatment Predictors of information recall</td>
<td>Second chemotherapy cycle</td>
</tr>
<tr>
<td>Study</td>
<td>Study design</td>
<td>Setting</td>
<td>Population</td>
<td>Outcome(s) assessed</td>
<td>Length of follow-up</td>
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<tr>
<td>(Priluck, Robertson, &amp; Buettner, 1979)</td>
<td>Prospective study</td>
<td>Mayo Clinic, Rochester, Minnesota USA</td>
<td>Patients undergoing a primary scleral buckling procedure for rhegmatogenous retinal detachment (n=100)</td>
<td>• Information recall • Patient satisfaction</td>
<td>Two to eleven days post-procedure</td>
</tr>
<tr>
<td>(Ravidn, Siminoff, &amp; Harvey, 1998)</td>
<td>Prospective study</td>
<td>University of Texas Health Science Center, San Antonio, Texas, USA</td>
<td>Breast cancer patients who received adjuvant chemotherapy (n=318)</td>
<td>• Knowledge of Information</td>
<td>Unclear</td>
</tr>
<tr>
<td>(Robinson &amp; Merav, 1976)</td>
<td>Prospective study</td>
<td>Montefiore Hospital and Medical Center, Bronx, NY, USA</td>
<td>Patients undergoing cardiac procedures (n=20)</td>
<td>• Recall of informed consent information</td>
<td>Four to six months post-operation</td>
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</tbody>
</table>
Results

Findings of the literature review are reported in two sections based on the type of treatment: non-surgical or surgical. This is because the two groups of patients are believed to be exposed to different types of experience so are therefore discussed separately. Specifically, surgical patients often experience surgery once and side effects may be transient however non-surgical treatment commonly occurs over a period of time and side effects may occur at different stages and may be prolonged due to the nature of receiving several courses of treatment.

Enhancing knowledge of non-surgical treatment

The first study identified to be conducted in an oncology setting was by Muss et al. (1979) in 100 female breast cancer patients, both adjuvant cases (n = 35) and advanced cancer patients (n = 65). This study aimed to evaluate patients’ knowledge and perceptions of the purpose, risks, and benefits of chemotherapy. While the majority (86%) of the population were between 41 and 70 years old, the mean age was not clear. Over half of the patient population (58%) were blue collar workers or housewives and more than two-thirds (68%) had at most completed high school. This study measured patient knowledge of treatment using free recall and recognition and the main variables measured included drug names, potential side effects, and reasoning for chemotherapy. Patient assessment was conducted after initiation of chemotherapy at one time point but this varied amongst patients as it was unclear at what cycle they were asked to fill in the questionnaire.

Results showed that adjuvant therapy patients correctly recalled all drug names more often than metastatic patients (57% vs. 22%). Complete recall of drug names was found to be 34% overall. The authors also calculated percentage recognition for each side effect, which ranged from 42% to 90% and a mean of 3.44 (SD = 2.07) total errors in naming possible side effects (where 0 = completely correct, 11 = completely wrong). This study found that the risk of infection and bleeding to be the least recognised with overall rates of 42% and 43%, respectively. Lastly, results for recall of the purpose of chemotherapy were concerning.
Muss and colleagues (1979) found that only 10 out of 35 (28.6%) of the adjuvant patients knew the purpose of their treatment. Metastatic cancer patients were found to have a lack of knowledge regarding their purpose of their treatment with the study identifying less than 50% of patients knowing that their chemotherapy was not to cure the disease. This may not necessarily be due to a lack of knowledge but rather denial, unrealistic expectations, and/or positive thinking.

Finally, this study assessed the impact of their educational level on patients’ knowledge of their drug names however it was not clear how this was carried out. The main limitations of this study was the time patients were interviewed to assess knowledge was unclear and potentially ranged between 0-24 months. Clearly, there is likely to be a big difference in patient knowledge measured immediately after treatment compared with two years, post-treatment, and there may be a difference in knowledge before early stage and late stage disease. Also, early adjuvant treatment is more standard whereas palliative treatments change according to the patient’s response. Obviously, knowledge appeared higher in this study for knowledge of side effects as this particular aspect was assessed using recognition rather than free recall.

Two years later, Dodd and Mood (1981) carried out a very similar study to Muss et al. (1979) without limiting the population to breast cancer patients but instead the sample consisted of 30 patients receiving chemotherapy with either curative (n = 5) or palliative (n = 25) intent for a variety of malignancies. This included the following diagnostic groups: gastrointestinal (n = 13), breast (n = 7), head and neck (n = 5), lung (n = 3), and ovarian cancer patients (n = 2). The population in Dodd and Mood’s study consisted of 60% females and the age range was 41 to 80 years with a mean of 57 years (SD = 8.6).

Dodd and colleagues (1981) also measured patient knowledge of treatment using a 20-item questionnaire that measured recognition, like Muss et al.’s (1979) study and also measured the same variables. Similar findings were seen in this study with patient recognition of the drugs received (30%). This is believed to be low especially as recognition of drug names would be significantly easier than free recall. Reported recognition rates for the potential side effects in
this study were different to that of Muss and colleagues (1979). Dodd and Mood (1981) calculated a mean of 3.56 (SD = 2.31) for correctly identified side effects from an average of 11.86 (SD = 5.23) possible side effects. It was expected that at a minimum, the potentially lethal side effects would be recognised, and in this situation potential lethal side effects included infection and bleeding. It was reported that 10 patients (33.3%) identified risk of infection as a potential side effect and no one identified bleeding as a potential complication, which is an even lower recognition than that found in Muss et al. (1979). Patients were also asked if one of the purposes of their chemotherapy was to cure disease. In the study, four out of the five (80%) adjuvant patients remembered the purpose correctly.

Dodd and Mood (1981) also assessed the impact of educational level on patients’ knowledge of their drug names. They dichotomised the patient sample into two groups: less than or more than nine years of schooling. The categories were chosen based on nine years representing the median number of schooling years amongst the patients. It was found that patients with more schooling were better able to recognise the names of their drugs (p < .05). Muss et al. (1979) also found a statistically significant difference in patients with some form of college education versus patients with a formal education of nine years or greater (p < .001). Association of information recognition with gender, age, and marital status were also measured in these studies, however no significant differences were seen. Dodd and Mood’s (1981) study, was more generalisable than Muss et al.’s (1979) but only included a small sample of 30 heterogeneous patients.

Early in the next decade, Cassileth, Zupkis, Sutton-Smith, and March (1980) conducted a study to assess recall of the information regarding consent, and to determine patients’ perceptions of the purpose, content, and implications of the material in the consent form. Two hundred cancer patients consenting for chemotherapy, radiotherapy, or surgery were included and had a median age of 59 (age range 20 – 82 years). The sample consisted of 55% males, 63% Caucasians, and 69% blue collar workers or lower. One day after patients consented, questionnaires were given which implies that their experience contributed little to patients’ knowledge.
Patient knowledge of having signed a consent form and the points covered in the consent process were assessed by means of multiple choice questions hence measuring recognition. If recognised correctly, a score of one was given while incorrect responses were given zero and a maximum of six could be obtained. The remaining questions were open-ended, measuring free recall and covered topics such as diagnosis or illness, proposed procedure, purpose of the proposed procedure, possible risks or complications, and appropriate alternatives to the proposed procedure. This section had a maximum score of six for correct responses giving a total of 12 for the whole questionnaire.

Overall, patients had a mean recall score of 8.26 (SD = 2.56) out of 12. Other figures showed that 60% of patients correctly described what their treatment would involve, 59% described the purpose of the treatment, only about half (55%) were able to list a single major risk or complication. The only area which had a good response was that 82% of patients correctly identified their diagnoses although this was expected to be nearer 100%. The authors conducted analyses of variance to identify any differences based on age, education, race, hospital, and treatment and found education to be the only significant factor. Patients with less than a high-school education had significantly poorer recall of information than those with at least a high-school education (M = 6.72, no SD vs. M = 9.1, no SD), p < .001). A non-demographic variable that was found to be related to recall scores was the extent with which patients read the information given. For patients who reported reading the entire form carefully or curiously (n = 177), a mean of 8.81 (no SD) was obtained while those who read only parts of the form or did not read it at all scored 7.19 (no SD; p < .001).

It was further identified that age (p < .05), race (p < .01), and education (p < .001) were factors in differentiating patients who read the consent form or not. Also, patients who had a strong opinion such as those stating consent forms don’t matter one way or another reported lower scores on the recall test (p < .01). Most patients (76%) believed they had received the right amount of information and these people had higher scores on the recall test than those who believed that the information was inadequate or too much (p < .001).
The findings of this study support findings of earlier studies in that patients remain unable to recall major portions of information on the consent form. Better recall in more highly educated patients suggests that the information given may have been too complex to comprehend, the patients with lower levels of education did not read all of the information, or patients have a strong negative opinion regarding the forms purpose.

The decade of the 1990s saw an increase of longitudinal studies assessing knowledge of information given regarding consent to a treatment. These studies were conducted on patients receiving various treatments. One study conducted on oncology patients receiving treatment for chemotherapy by Olver, Turrell, Olszewski, and Willson (1995) was based in Australia. In this study, 100 patients undergoing chemotherapy were assessed on recall of the information at their second chemotherapy cycle. The median age of patients was 61 years (range 19-86 years) and 62% were males. Two thirds (68%) had achieved a secondary level education and 61% were blue collar workers or lower. Three quarters of patients consented on the day of treatment initiation and recall was mostly assessed between 22-28 days after consenting (48%), with a further 24% conducting the survey less than 22 days after consenting. Open-ended questions were used in the questionnaire implying that free recall was assessed. It was identified that 37% knew the number of drugs they had received and 25% were able to name one or more of the drugs they were receiving. Higher recall rates were achieved for knowledge of the length of treatment (46%) and the goal of treatment (65%). More importantly, recall of side effects was low amongst the patients with 17% not remembering any and only 15% remembering all four of the listed adverse events, despite their obvious experience of some side effects by the second cycle of chemotherapy.

This study, like the one conducted by Cassileth and colleagues (1980), also measured the association between the extent of reading the consent form and information recall. It appeared to be a significant factor in being able to name the drugs (p < .0001), knowing the number of drugs (p = .02), remembering the duration of treatment (p = .03), remembering the common side effects (p = .03), and recalling the goal of treatment (p = .005). In addition, educational level was a significant factor in remembering aspects of the chemotherapy information.
This study pointed out that transient side effects such as hair loss were commonly recalled while complications such as infertility were less commonly stated. Common recall of the transient side effects may be due to the patients experiencing them. The main limitation of this study was the unclear timing at which recall of the information was being asked.

Another study conducted in the oncology setting, this time only on breast cancer patients, was conducted a few years later in the USA. Ravdin, Siminoff, and Harvey (1998) reported on a survey given to 318 newly diagnosed breast cancer patients who had received adjuvant chemotherapy. The eight page questionnaire included sections asking about demographics, tumour-related information, and what they had been informed about in regards to treatment, prognosis, benefits, and additional information preferred by the patient. The mean age of the women was 49 years, and they were predominately white (94%), college-educated (65%), and married (74%).

Findings showed that 46% of women recalled being given quantitative estimates of their prognostic outcome if they were to receive chemotherapy, that is, a numerical estimate. More patients were given qualitative estimates of their outcome if they were to receive adjuvant chemotherapy (68%). It is unclear what these qualitative estimates were. The study found that women less than 50 years old (p = .01), and having a college education (p = .003) were predictors of being given quantitative estimates of prognosis both with and without adjuvant therapy. This study, while it measured information recall, did not provide a scoring system so that the extent of knowledge could be assessed. Also, it was unclear how recall was measured so there was no indication whether open-ended questions, multiple choice questions, or any other form of questions were used. In addition, the study did not report the timing of the questionnaire in relation to when chemotherapy was received. Data was provided on year of diagnosis ranging from 1980 to 1996 but this does not reflect when the patients had chemotherapy. Other limitations included questionnaires being mailed making it unclear how much patients recalled freely and how much patients took from information given to them. Like several of the other studies, the patient population were also all female limiting the generalisability. This does, however, highlight the limited number of studies assessing knowledge of procedural information in the oncology setting.
Gattellari, Butow, Tattersall, Dunn, and MacLeod (1999) conducted a study to assess the understanding of information given regarding treatment to be received. Cancer patients receiving radiotherapy or chemotherapy were recruited (n = 242) and interviewed before they received their second treatment dose. The reasoning for this was that by this stage patients should have received all the relevant medical information about their disease and may have overcome the initial anxiety. The median age of patients was 59 years (range 22-90 years) and there were slightly more females in the study (58%). The majority of patients had a school certificate (73%) and were married or in a de facto relationship (71%). Nearly three quarters were either in a professional role, in sales, or were a tradesperson (71%). The interview aimed to measure understanding and denial of information given. Denial was measured using a reliable and validated eight-item Cardiac Denial of Impact Scale which was partly adapted to suit the study. The total score ranged from eight (minimal denial) to 40 (maximum denial) and was measured by identifying the extent that patients minimise the emotional impact of having cancer and deny feeling worried or afraid.

After denial was assessed, understanding was assessed using a seven-item scale that asked about patients’ diagnosis, extent of their disease, goal and types of treatment they were receiving as well as the probability that the treatment would result in cure, prolongation of life, and if relevant, palliation. Probabilities were estimated as 0%, 1%-25%, 26-50%, 51-75%, or 76%-100%. While it was unclear whether some of the items of the scale were being measured using free recall, the probabilities were definitely measured using recognition. Patients also rated the clarity of information received from the oncologist. The oncologists were also asked to provide the facts that matched the seven items of the scale as well as indicate if patients were informed of the facts. Patient understanding and denial were assessed at a median of 28 days (range 1 – 148 days) after treatment decisions were made. All patients correctly reported the type of treatment they were receiving but 8% misunderstood what they had been diagnosed with. A large proportion of patients (71%) correctly stated the extent of their cancer and 60% of patients correctly stated the goal of treatment. Of these, 17% of palliative patients thought their treatment was to cure the disease or prevent recurrence and on the other hand, 32% with advanced disease, receiving curative therapies, believed their treatment was palliative.
There was a significant association between an increase in understanding of treatment intent with an increased chance of treatment curing the disease (p < .01). Those with more than a 50% chance of cure were almost 7.8 times more likely to understand the intent of treatment (95% CI 2.44 - 24.73) or alternatively more likely to state that they will be cured.

Factors that predicted the extent that patients agreed with doctors’ estimates of the likelihood of cure included low levels of denial (OR 2.20, 95%CI: 0.99 - 4.88, p = .05), English as their first language (OR 4.33, 95%CI: 0.93 - 20.13, p = .03), and if they rated the information received as very clear (OR 2.18, 95%CI: 1.00 - 4.77, p = .05). Doctors were also assessed on their ability to detect patient understanding and it was found that physicians over-estimated patient understanding by stating that almost all patients understood their diagnosis (96%) and treatment type (100%).

The main limitation of this study was that the authors believed they were measuring understanding although it was clear that this was not being measured. While part of the questionnaire included recognition it was unclear whether the other questions were measuring free or prompted recall. Other limitations included the reliance on doctor reports of the information communicated to patients, and there was also a large range of time during which recall was measured. Otherwise it is the first study identified in this literature review to assess the effect of denial on patient understanding of information received. Indeed the results showed that denial did play a role in patient misunderstanding although they also showed that the doctor’s ability to communicate effectively also played a role.

Craft, Burns, Smith, and Broom (2005) conducted a longitudinal study on advanced cancer patients’ knowledge of the medical purpose of treatment. A sample of 181 patients with a diagnosis of incurable malignant disease who were receiving palliative therapies such as supportive care, hormonal manipulation, chemotherapy, and/or radiotherapy were recruited to the study. Two surveys were conducted at one and 12 weeks later. The questionnaires included questions about whether they understood that their illness was life-threatening and to identify their sources of information.
There were a similar number of males and females in the study (47% males) although the males taking part were slightly older with 74% compared to 54% females being 60 years and older. Nearly three quarters of the population (71%) were married and more than half (57%) had educational achievements of completing secondary school and/or having a university degree. There were some significant gender differences including more males having radiotherapy only (46%) compared to females (15%). Also nearly half of males (47%) were less than six months from death compared with one quarter of females (23%, p < .002). After one week, all patients were aware that their diagnosis was cancer however one fifth (22%) were not aware that it was life-threatening and this was not found to change over time. Overall, less than half (47%) correctly understood that their treatment was not curative. Also, it was found that the proportion of patients with accurate knowledge remained the same over time.

To measure changes over time from week one to week 12, a matched sample who had responded to both questions was used (n = 119). The questions asked regarding the aim of the treatment could have more than one response and findings showed that about two-fifths (41%) of patients correctly thought the aim of treatment was not to cure their illness at week one which increased slightly to 48% by week 12 but was not a significant difference. Just over half (59%) thought that the aim of treatment was to monitor their illness and again this was not found to increase significantly over time. The majority of patients thought that the treatment aim was to improve quality of life and control the illness, although there were no significant differences found.

After one week associations between socio-demographic characteristics and knowledge of treatment intent were associated. Being married was associated with knowing the treatment goal was not to cure the illness (p = .02) and these patients also had a clearer understanding of the treatment aim (p < .01). Similar results were found for residence in metropolitan areas (p < .02), patients who were non-ambulatory (p =.01), and those closer to their death (p < .02). Patients receiving supportive care as their treatment were also more aware that the treatment goal was not curative compared to patients receiving other treatment modalities (p = .04).
The main limitation of this study was that no details of the questionnaire were given such as whether patients were given the questionnaire to complete themselves or had assistance and whether their knowledge was prompted. Also, it was unclear whether the questionnaire was designed for the study and/or whether it had been validated and was reliable. It would be interesting to know the time since patients were informed of their palliative condition as this could influence their acceptance of the information which would reflect on their knowledge. The authors only reported that the majority of patients received some form of therapy within one month of enrolling in the study so it is assumed that they had not been aware of their condition for too long.

Summary of studies in non-surgical settings

Seven studies were conducted on patients receiving non-surgical treatment all of which were based in the oncology setting, with patients receiving chemotherapy, radiotherapy and in one study, palliative therapy. The main measures of patient knowledge in these studies included the number of drugs received, drug names, potential side effects, length of treatment, and goal of treatment.

Muss et al.’s (1979) study and the replication study of this carried out by Dodd and Mood (1981) measured free recall and recognition while the other studies reported to measure free recall suggesting most studies used a superior measure of patient knowledge. As explained throughout the thesis, our ability to freely recall what we know is far superior to our ability to recognise information we have seen previously and hence recall rates from the latter studies are predicted to be lower, but more accurate. Indeed this appeared to be the case, with drug names found to be recalled by 30-34%, in the two earlier studies but by less (25%) in Olver et al.’s study (1995). However the timing of recall measurement was unclear in the first two studies and therefore may not be comparable to Olver and colleagues’ study which assessed recall at the second chemotherapy cycle (usually 3 to 4 weeks after starting treatment). There may be speculation that at this time point it was still early on in the treatment course for patients to be completely aware of factors such as drug names. Measurement of recall with
more experience of the treatment may help improve recall. No other studies assessed knowledge of drug names.

Results of patient knowledge of side effects were found to be inconsistent and this could be due to a number of differences between studies, apart from the way in which recall was assessed. Three of the four studies were conducted between 1979 and 1981 while the fourth study by Olver et al. (1995) was conducted around 15 years afterwards in which time informed consent procedures may have changed. An example of such a change may be an increased emphasis on the risks, complications, and side effects in Olver et al.’s study due to an increase in the rigour required by Ethics Committees, increasing litigation, improving hospital procedures, or even more complicated treatments. Additionally, patients have become more active participants in their treatment process over the years therefore they may take greater notice of what information is given or are more likely to seek information. It was difficult to assess this using the studies identified as the measurement of recall of side effects varied. Regardless, the most recent study showed that only 15% were able to recall the four side effects listed and a further 17% did not remember any of these side effects (Olver et al. 1995).

Another factor of patient knowledge measured was the goal of treatment. Six of the studies were found to assess this but again inconsistent results were seen across the studies, ranging from 29% to 80% correct recall. The only study conducted in a treatment setting that measured knowledge more than once found no significant differences over time between one week and 12 weeks after treatment (Craft et al., 2005), suggesting that experience did not improve patient knowledge, unless a Type II error was made. This study did not report effect sizes so it was difficult to ascertain whether this was a possibility.

The small population of advanced cancer patients researched in the study by Muss et al. (1979) recognised the purpose of the treatment less than adjuvant cancer patients. This is of major concern as the patients may agree to a toxic treatment only because they have the belief that it will be curative, and thus may compromise their quality of life. One explanation for this may be that advanced cancer patients are more in denial than adjuvant cancer patients.
Denial was found in one study to be a predictor of patients agreeing with estimates given on their likelihood of cure, in other words, a low level of denial was associated with patients agreeing to the information given (Gattelari et al., 1999). Gattellari and colleagues (1999) also showed similar findings to that of Muss et al. (1979) regarding the stage of cancer and recall of the goal of treatment. An increase in the chance of treatment curing the disease was associated with an increase in understanding of the treatment goal ($p < .01$). More specifically, those with more than a 50% chance of cure were almost eight times more likely to understand treatment intent (95% CI 2.44 – 24.73).

Two studies assessed patient knowledge of diagnosis and found the majority (>82%) of patients were aware of their diagnosis (Cassileth et al., 1980; Craft et al., 2005). However this indicates that around 20% of the patients do not have knowledge of their diagnosis which is believed to be poor as it is expected to be one aspect of the information that patients would have knowledge about. It would be interesting to know whether it is because they don’t know they have cancer or because they don’t remember the name of the cancer they were diagnosed with. However this finding was not found to be assessed with the experience of treatment and only at baseline in the study by Craft and colleagues, and after day one in Cassileth and colleagues’ study. There were no other factors assessed that were comparable across studies.

Amongst studies measuring knowledge of patients with experience of non-surgical treatment, Craft and colleagues (2005) conducted the longest follow-up at 12 weeks after treatment consent. Also it was the only study comparing changes over time while all other studies measured knowledge following some experience at one time point. The authors of this study did not find any significant changes in knowledge of the information given with experience over 12 weeks. Therefore more longitudinal research needs to be conducted in the treatment setting to assess the impact of experience on the knowledge of the information given.


**Enhancing knowledge of surgical information**

The earliest study identified to measure recall of the information given for informed consent to a surgical procedure was conducted by Robinson and Merav (1976). Twenty patients who had undergone cardiac procedures (n = 9 atherosclerotic heart disease, n = 11 acquired valvular heart disease) and had convalesced uneventfully after a satisfactory postoperative course were randomly selected to be interviewed. The mean age of the patients was 52 years (range 35 – 66 years) however patient gender was unclear. Recall of the information was assessed between four and six months after the operation. At the interview, the tape of the original informed consent interview was replayed to patients, and a chart of the points discussed was provided. It was unclear why the tape was replayed but it is assumed that it was for patients to recall aspects of the interview. Recall was measured at two levels: primary and secondary.

Primary recall was based on responses to questions in each of six categories of informed consent (diagnosis, proposed operation, risk, potential complications, benefits, alternative methods of management) which is measuring free recall. Secondary recall was measured based on the material of the conversation relating to each of the categories. The authors reported that it was unavoidable to suggest the correct responses to patients, thereby making it cued recall of the information given. Overall, there was poor recall of information in all of the categories with an average of 29% primary recall and 42% secondary recall. Interestingly, there was only 10% primary recall of potential complications and with suggestions of responses, hence being prompted, the patients achieved a secondary recall of 23%. Each of the 20 patients failed to recall major parts of the interview. The highest score was 57% primary recall and 87% secondary recall. Of the 20 patients, 16 denied that certain major items were discussed with them.

This study concludes that it is essential to document the details of the informed consent process as memory of the event is unreliable. The authors of the study place a high level of importance in compiling permanent records for legal purposes however authors do not highlight the concern that patients can only recall one tenth of potential complications.
This may make them ill-prepared for nine other potential complications when they may only know about if they experience the complication. It is also worth noting that all the patients had been educated by their previous experience with their disease; all had attended many times for diagnostic and therapeutic procedures. The study, does, however, have some limitations including a very small sample size from which to obtain meaningful results. Also, recall was measured at one time point four to six months after the operation so there is no awareness of their recall ability straight after, or a short time following the procedure. The questions used had not been validated and questions measuring secondary recall varied among patients, making it hard to obtain an overall judgement. Finally, patients in this study were included based on the fact that they had recovered well from the surgery therefore biasing the sample.

Also, in the same decade, another prospective study was conducted in a surgical population in Rochester, Minnesota by Priluck, Robertson, and Buettner (1979). One-hundred patients undergoing a primary scleral buckling procedure for rhegmatogenous retinal detachment made up the population. The population consisted of 63% males and 80% were over 50 years of age. Patients were asked 12 questions about their eye disorder between two and 11 days after surgery which measured free recall (M = 4.2 days, no SD). The questions were subjectively assessed to determine if the patient response was adequate. Results indicated that the overall mean accuracy for retention was 57%. However, fewer patients retained knowledge of surgical risks (23%) and patients’ who inadequately answered a question most of the time denied that the particular information was discussed with them. Regardless, 97% of the patients said that they had a satisfactory preoperative discussion and had all of their questions adequately answered.

There were a few limitations to this study including the subjective assessment of recall, and the lack of validity and reliability of the questionnaire, or at least the lack of reporting of such. Also there was a difference in the timing that post operative recall was measured amongst patients which may have had an impact on the results. There is the potential that two days after surgery patients may remember a different amount of detail of their surgery compared to 11 days.
This is a particular concern in surgical patients as they experience the procedure at one time point compared with several time points with non-surgical treatment. Another limitation is regarding the population, as the majority of patients were older than 50 years and therefore this may have an impacted on the patients’ recall ability. This study did not, however, analyse the association between age and recall.

Byrne, Napier, and Cuschieri (1988) also conducted a study on a surgical population, however did not have the limitations of the study by Priluck and colleagues (1979). The study had the same sample size (N = 100) but patients recruited had varying types of surgery. Patients included 59 women and 41 men with a mean age of 55 years (age range 16-84 years). Patients were interviewed regarding their knowledge of the information provided between two and five days post surgery however it was unclear how recall was measured. Results from this study better represent knowledge of the information given than in Priluck and colleagues’ study which had a greater time range (2-11 days). Byrne and colleagues asked patients about the organ that was operated on, and basic details of the operation performed.

Findings revealed that 27% did not know which organ was being operated on and 44% were unaware of the basic facts relating to the operation. Unlike Priluck and colleagues’ (1979) study, this study conducted analysis by age and found that patients unaware of basic information relating to their recent operation were significantly older than patients who were aware of this information. Patients who were aware of the procedure on the organ had a mean age of 41.6 years (SD = 15.6) while patients unaware had a mean age of 61.9 years (SD = 10.0). This study was reported to be a pilot study and although results regarding the two questions that were asked, were considerably alarming, there was not sufficient data collected on knowledge of surgical information given to confidently say that patients were not informed.

In 1997, a prospective study measuring recall in a surgical population was conducted by Hekkenberg, Irish, Rotstein, Brown, and Gullane (1997) which assessed risk recall in a sample of 54 patients (74% females) undergoing routine thyroidectomy (n = 32), parathyroidectomy (n = 15), and parotidectomy (n = 7). The population had a mean age of 46.9 years (no SD given) and follow up was between one to eight weeks with an average of 33 days.
A parotidectomy had four risks associated with it (facial scar, facial nerve weakness/paralysis, greater auricular nerve paraesthesia, Frey’s syndrome) with half of the patients recalling two of the four, one-quarter recalling three, and another quarter recalling four risks. Thyroidectomy and parathyroidectomy only had three risks (neck scar, recurrent laryngeal nerve weakness/paralysis, hypocalcemia) which were explained to the patient by the surgeon. Of the patients, 18% couldn’t recall any risks and only 8% could recall all three. Overall, recall of all complications for all procedures was 48%.

In order to determine whether gender, educational level, age, and time from the consent interview had an impact on risk recall, the sample was categorised into two groups: Group A included those who recalled greater than 50% of the surgical complications and Group B were those who recalled less than 50% of the risks. There were statistically significant differences for patient age and educational level.

Group A patients were on average 7.6 years younger than those in Group B (p = .04) and those patients with university level education recalled more operative risks than those with postsecondary non-university education and grade school education (p = .04). It was believed that females would be more concerned about the surgical risks as they included facial scars from the parotid surgery and neck scars from the thyroid/parathyroid surgery. Nevertheless, gender was not found to significantly influence risk recall yet no effect sizes were reported. There were also no statistically significant differences between the two groups for the length of time from the consent interview to the recall interview. Similarly, no significant differences were found for recall success rate of the four different surgeons.

One limitation of this study was that no details of the questionnaire used to measure recall were given therefore it was unclear from the study whether patients were being assessed on free or cued recall or recognition. Also, there was the possibility of Type II error given the compromised power due to the small sample size and no effect size calculations were reported.
A larger study assessing information recall of surgical patients was conducted by Kriwanek, Armbruster, Beckerhinn, Blauensteier, and Gschwantler (1998). They assessed information recall of 200 consecutive patients, with a mean age of 51 years (no SD given; range 16-88yrs; 119 females; 81 males) undergoing elective cholecystectomy. The information assessed incorporated the main indications for surgery, principles of operative procedure, and major operative risks. Assessment was conducted on the fifth day after the operation and was in the form of answers to open-ended questions rather than responses to multiple choice questions thus assessing free recall. The results indicated that the risks of the operation were only recalled adequately (i.e. between one and three major risks were recalled) by less than a third of the patients. This could be because patients tend to neglect the risk information from such a minimally invasive procedure, especially considering that the conversion to open surgery is itself associated with low complication and mortality rates. Half of the patients were able to name between one and three of the four steps in the operative procedure which was considered ‘acceptable or good’. However, the majority of patients had ‘good or acceptable’ recall of the indications for surgery (85%) which was based on the patient being able to name between one and two indications. The impact of demographic or other variables were not assessed. Patients were also asked about their satisfaction with the information given in the preoperative consultation to which 84% indicated a high level of satisfaction with the oral and written information. The majority of the remaining patients said that they were given too much information (12%) but a small group also felt under informed (4%). This was a well conducted study that clearly defined the criteria for evaluation of recall and measured the free recall of patients. The study also had a large sample size reducing the possibility of Type II errors. Although regardless it would have been beneficial to report effect size.

Two years later, a prospective study was performed in the UK by Godwin (2000) on patients receiving reduction mammoplasty. The 38 patients participating in the study were followed up exactly six days post-surgery to measure patient recall of the factors specified by the surgeon at the time of consent. This follow-up time was chosen as patients would no longer require analgesics that could impair cognition. The seven questions asked of the patients were a mix of open-ended and multiple choice questions measuring free and cued recall although there was no mention of whether it was a valid and reliable questionnaire. Although an overall recall
rate was not given, it was reasonably low. Specifically, two of the 12 complications were not recalled by any of the thirty eight females (M = 31yrs, no SD). From the remaining 10 complications, eight were each remembered by less than 50% of the sample. The most commonly recalled complication was nipple sensation (71%) and nipple necrosis (50%).

The mean number of complications remembered was three from a possible 12 (25%) with only three patients recalling six complications (50%), which was the highest number recalled. Not surprisingly, two of these three patients were nursing staff, but one would expect that nursing staff would remember more than 50% of the complications, if not all. This study also measured patient satisfaction with the information supplied by the surgical team and found that 66% were completely satisfied (10/10) and the lowest score given was (7/10) by 5% of the participants. Like several of the other studies identified, this had an all female population due to the type of cancer patients recruited which is commonly not generalisable to the whole population, although studies have shown that there is no association between gender and recall, therefore this may not be such a limitation.

Madan, Kulkarni, Friedrichs, and Barrett (2002) evaluated patient comprehension and recollection of information given for informed consent of day case knee arthroscopy. This study, unlike others in the surgical setting, measured recall at more than one time point. One-hundred and three patients formed the study which consisted of mainly males (67%) and patients had a mean age of 38.6 years (range 14.4-74.9 yrs, no SD given). Recall was measured at two time points post-operatively, one on the same day of discharge and three weeks later at their follow-up consultation. The questionnaire consisted of multiple choice questions about details of the patients’ diagnoses and the procedure suggesting recognition of information was measured. The results for this study were presented poorly with limited data. The authors have reported that 38.8% of patients had no recollection but no comparison was made with time point one measurements at discharge.

Another study in the field of oncology was conducted by Fleischman and Garcia (2003), and carried out less than five years ago in the US. It was designed to determine the recall rates of patients undergoing a surgical procedure, namely Mohs micrographic surgery, for skin cancer
patients. The mean age, amongst the 85 patients, was 67 years (SD = 10.9) with a range of 54-82 years, and 74% were males. The authors were solely interested in recall of the potential complications of the surgery 20 minutes and then one week after the informed consent process. Patients were informed on 10 potential complications and at one week the overall recall rate was 24.4% (M = 2.44, SD = 1.73). The most frequently remembered complications included death (45.9%), blood loss (41.2%), scar (37.7%), and infection (36.5%). The least remembered complications were failure (6%) and loss of functioning (4%). Evidently, no changes in the most and least frequently remembered complications were found at 20 minutes and one week but the overall retention rate of patients at 20 minutes after the discussion was slightly higher (M = 2.65, SD = 1.67). No significant differences were found with recall rates and gender, age, and educational level.

These results indicate that the experience of surgery had no impact on information recall in this population. In the case where patients did not experience side effects post surgery, the findings makes sense as the patients did not have prolonged treatment. The authors do not provide any information on what side effects patients had experienced between the two measurements to identify if they had experienced them and still could not recall them. Also, it was unclear how recall was measured and the study does not state how patients were asked to recall the potential complications. Also, there was no reporting on whether there were statistically significant differences between recall at the two time points.

**Summary of studies in the surgical setting**

The experience of surgery or convalescence after surgery may still improve knowledge once the effects of anesthesia or the impact of analgesic medications on cognition fade away, and patients know what actually happened, including the side effects of the procedure. A total of nine studies conducted in the surgical setting were reported ranging from studies conducted in the 1970s to early 2000s. It is difficult and of no benefit to compile findings from these studies as knowledge is measured in numerous ways and is also reported differently hence no meta-analytic analyses are provided.
Six of these studies assessed recall of potential complications (Godwin, 2000; Fleischman & Garcia, 2003; Hekkenberg et al., 1997; Kriwanek et al., 1998; Priluck et al., 1979, Robinson & Merav, 1976). The two oldest studies found patients retained knowledge of the same proportion of risks and complications (23%). Both studies used free recall as a measure of knowledge and Robinson and Merav (1976) used cued recall however there was no indication from the studies whether these were valid and reliable questionnaires. There were differences between the studies including assessment of recall at very different time points with Robinson and Merav (1976) assessing knowledge four to six months after the operation while Priluck and colleagues (1979) assessed this between two and 11 days post-operation. Also the studies had different sample sizes and surgical procedures making the studies not comparable on this measurement. However, latter studies conducted by Fleischman and Garcia (2003) and Godwin (2000) also found on average between 24-25% of all complications were recalled by patients. It was unclear how recall was measured in Fleischman and Garcia’s study and although Godwin measured free and cued recall, there was no indication of whether the questionnaire was valid or reliable. Regardless, these studies were, like Priluck and colleagues’ (1979) study, measured a short time after the operation (six to seven days).

In the study by Kriwanek et al. (1998), whilst an overall rate for free recall of complications was not given, as they measured patient recall of the surgery indications, purpose of procedure, and major risks of the surgery, 30% were able to recall at least one major risk. However, 4.5% of these (n = 9) patients had experienced complications and therefore could easily name these operative risks. Hekkenberg and colleagues (1997), on the other hand, found an overall rate of 48% for recall of all specific operation risks. This was, in comparison, almost double the complication recall rates in the other studies however the study did not state how recall was measured. Clearly, findings in this study were of interest, as they were remarkably higher than the other studies, despite their differences. A number of reasons may have led to this result. If recognition was being measured, this may give higher rates than if it was based on free recall. However, other reasons may be that the Parotidectomy and Thyroidectomy procedures were only associated with a small number of risks (i.e. four and three risks, respectively). It would seem much easier to remember a small number of risks such as these, rather than a long list of risks. Also, the type of risks may have led to greater
knowledge as these procedures are associated with serious risks that could impact on the patients’ physical appearance such as scars and facial nerve paralysis. In addition, patients may become more anxious if they are exposed to a long list of risks and/or side effects rather than a few, hence impacting on their recall abilities.

Another factor impacting on the high level of recall found in the study by Hekkenberg et al. (1997), was the follow up of patients being between one to eight weeks, the longest in the more recent studies assessing recall of complications. Therefore, the experience of the patient with the surgical procedure, and post-surgery matters over a long period of time, may have allowed the patients to remember the risks. This is especially significant if patients received anesthesia or analgesic medications which may have impaired cognition, in the early stages post surgery.

Potential complications relevant to these surgery based studies include scars, infection, blood loss, loss of function, and death, amongst others. These are not all transient consequences hence it is very concerning if half to three quarters of such complications are not retained, as the studies suggest. One reason such complications are not retained post surgery is because they may no longer be relevant. In other words, the potential for immediate blood loss or death during surgery won’t be of concern after surgery (if bleeding did not occur) hence easily forgotten.

Nevertheless, other complications such as scars and loss of function may occur after surgery and thus are pertinent to remember. This may lead to increased legal pressures for the physician if valid informed consent was not obtained or may be life-changing if the physician clearly highlighted the complications and at the time the patient was happy to proceed. Clearly, this is the condition unless the scars or loss of function were due to negligence rather than just the expected outcome. Longitudinal assessment, as in the study by Hekkenberg and colleagues (1979), demonstrates improved knowledge of the information and this is particularly important from a medico legal standpoint as the knowledge of the side effects by the prompting of experience may prevent litigation. This is because litigation often arises when patients don’t know of side effects and claim that they have not been communicated to
them. It is however unknown from this literature whether patients retain the information for longer than two months post surgery or non-surgical treatment.

Three studies measured the recall rate of all informed consent information including diagnosis, alternatives, surgical technique, and complications. Parallel findings were found in two of the three studies with 57% and 62% reported in the study by Priluck et al. and Madan et al., respectively. Madan and colleagues used recognition as a means of measuring understanding and as stated earlier, this does not require patient memory to the extent of free recall which may explain the slightly higher recognition rate. On the other hand, two studies, both unclear in their form of measuring recall, provided patients’ overall recall rates of surgical complications which was found to be one-quarter to one-half of the information (24%, Fleischman & Garcia, 2003; 48%, Hekkenberg et al. 1997). Other studies did not provide overall recall rates of factors. These findings may suggest that patients remember other aspects of their surgery to a greater extent than the surgical risks.

One proposed explanation for this is if patients trust their physician they may believe that once they have consented everything will happen satisfactorily. Alternatively, the diagnosis of the disease or condition may hold greater importance for the patient, when compared with potential risks. This may especially occur when only a few risks are listed and the surgery is itself minimally invasive. Patients, once consented, may focus on undertaking the procedure and the expected result rather than what risks they may encounter, which may be a form of denial or avoidance of the threatening aspects of their illness and recall of the less anxiety causing aspects of consent. The theory of attentional narrowing, possible in situations perceived as stressful such as undertaking non-surgical or surgical procedures, may also explain this. This, discussed by (Kessels, 2003), occurs once the patient is told that they have been diagnosed with a certain condition, whereby the diagnosis becomes their focus and therefore does not allow for peripheral information, such as surgical risks, to be properly processed or stored into memory. In turn, this reduces the patient’s knowledge of such information. Nevertheless, the idea of longitudinal assessment, primarily effective in treatment settings, is to allow for experience with the repeating of information to remove the primary focus of the diagnosis and hence maximise attentional resources.
The idea for longitudinal assessment is to gain insight into the impact that experience has on patient knowledge of the informed consent process. One study (Madan et al., 2001) measured patient recall at more than one time point post-surgery. However results were poorly reported as no comparison was made between the two time points. The only deduction made from the results from Madan and colleagues who measured cued recall was that 57.3% had complete recollection at three weeks and this was assumed from the available data as it was reported that 38.8% had no recollection and 3.9% had partial recollection. Even so, findings from one study are clearly not sufficient from which to make strong recommendations.
**Discussion**

There are many decades of research conducted on informed consent, and yet there is scarce data on the effects of surgical or non-surgical experience on patient knowledge of information given. More so, there were a limited number of longitudinal studies identified by this review that assessed the impact of experience on patient knowledge of the information given at the time of consent. Therefore this study also reported on prospective studies that assessed the impact of experience but which were not longitudinal in nature. No pooled analysis, such as a meta-analysis, could be carried out in this review as the studies varied extensively with regards to the way recall was measured and aspects of the consent process that were questioned.

The findings of this review were divided into two sections based on the setting: non surgical versus surgical. The review reports on a similar number of studies conducted in each of the settings. Experience for patients receiving surgery is often short-term due to the nature of surgery occurring once. On the other hand, studies conducted on patients receiving non-surgical treatments measure experience with treatments often occurring over time or on a number of separate occasions hence taking a longer time to complete than surgery. Findings of these particular studies are believed to be more relevant to this research thesis. However studies conducted in the non-surgical setting most often measured patient knowledge at one time point only despite treatment occurring over a period of time, therefore the studies did not often capture the actual changes in patient knowledge with treatment experience.

Overall, it is evident that a high percentage of patients did not recall or recognise aspects of the procedure they undertook, more so in the immediate post-operative period but also in the long term. As discussed previously, a major reason for this, more significant to the surgical setting, is the relevance of the complication post procedure. In the case of surgery, some of the risks patients are informed about include peri-operative complications thus if the patient recovers from surgery acceptably, these risks are likely to be forgotten.
In addition, factors such as attentional narrowing, denial, and anxiety may explain the deficiencies in the immediate post-operative recall. The patients immediately after surgery may be focusing on their current condition, the success or failure of the surgery, and their recovery process. Therefore this does not allow for peripheral information such as the risks associated with the surgery to be at the forefront of their memory. Also, if patients were in denial when they gave informed consent, it would have impacted the way they encoded the information. Therefore, when they were asked about it after surgery, the patients may not be able to retrieve the information. On the other hand, patients experiencing long-term chemotherapy are exposed to transient and potentially long-lasting complications and/or side effects, over that period of their treatment and beyond. Therefore we would hope that treatment experience should help in recall of this vital information once the shock of diagnosis has calmed and new information can be remembered.

This limitation in patients’ knowledge of their health care has implications for a valid consent process to be obtained as well as for treatment compliance of patients and their help-seeking behaviour in the case where they are unaware of symptoms to be cautious of. Overall the findings from this review do not convincingly answer the question of whether experience will increase the information recall abilities of patients. Therefore, this indicates a gap in the literature where further research needs to be executed before experience is deemed effective or ineffective. If experience is deemed effective, it may impact the way we view informed consent. Clearly, recall of the informed consent information prior to receiving treatment is not possible, therefore additional layering of information over time may need to be continued and expected to ensure patients have as much knowledge as possible. This is both to benefit the patient but also so it allows physicians to feel comfortable that the patients do have knowledge of the information.

Although, this literature review was primarily interested in the measurement of patient knowledge in longitudinal studies, it was apparent that researchers were interested in measuring other factors as well. As discussed by Kessels (2003), there are associations between certain demographic and psycho-social factors and recall of the information given.
This review identified a number of factors that were found to impact on patient recall of medical information including educational level, age, extent of information read and potentially gender, although this was not found to be significant. Nevertheless, there is inconclusive evidence on predictors of patient knowledge of information given but the findings of such research will be further elaborated in the next chapter (Chapter 5).
Chapter 5: Predictors of patient knowledge of the information given

The aim of this chapter is twofold. Firstly, this chapter aims to summarize findings from research outlined in the literature reviews on factors that were measured for their association with patient knowledge of medical information given. Secondly, this chapter aims to highlight other factors that may be associated with patient knowledge of medical information given at the time of consent but which were barely evaluated or not examined at all in the reviews. More specifically, this chapter aims to outline what factors, both previously researched and novel factors, that may predict knowledge of information given that will be considered in this research thesis and why.

The research presented in the second literature review of this thesis (Chapter Four) aimed to identify studies assessing the impact of patient experience of any therapeutic procedure on patient knowledge of necessary medical information. In other words, after patients are informed of a therapeutic procedure to give informed consent, how much does patient knowledge of this important information improve with their experience of treatment, if at all? Limited research was available, particularly in the oncology setting which is the interest of this thesis, and the studies that were reviewed appeared inconclusive with respect to patient knowledge of information given and sometimes studies were methodologically flawed. However, some of the identified studies also assessed whether several demographic factors predicted patient knowledge of information given.

Only a limited number of studies measured the association between demographic factors and patient knowledge of information given. For the most part age, educational level, and gender were assessed in relation to how much medical procedure (consent) information patients successfully recalled. Specifically, younger patients with better education were sometimes found to be better at recalling such information. For instance, Hekkenberg and colleagues (1997) who assessed patient recall of risks associated with routine thyroidectomy, parathyroidectomy, and parotidectomy found age to be a significant predictor (p = .04) of
patient recall. Those that were significantly better at recall were on average 7.6 years younger. The risks of the procedures included facial and neck scars, facial nerve weakness/paralysis, greater auricular nerve paraesthesia, amongst others. These risks may impact on physical appearance which may be more concerning in younger patients. An alternative theory may be that as Kessels (2003) suggested, defects in encoding and storage rather than retrieval are the key factors in why older patients forget information conveyed about treatment (Kessels, 2003).

Better educational level was found to be positively, significantly associated with patient knowledge in a few of the studies reviewed earlier in the thesis (Dodd & Mood, 1981; Hekkenberg et al., 1997; Muss et al., 1979) one of which was conducted in the surgical setting (Hekkenberg et al., 1997). Several studies measured the association between gender and recall of the information given but none of the studies found this to be a significant factor (Dodd & Mood, 1981; Fleischman & Garcia, 2003; Hekkenberg et al., 1997). These scant findings on the impact of these factors on recall of the information given during the informed consent process indicate a need for further research, especially given some of the positive associations found. Although gender was not found to be a significant predictor of knowledge, it was not measured very often as many of the studies concentrated on all female populations (or biased toward being female due to the types of illness assessed).

Another factor found to be associated with knowledge included being married in one recent study by Craft and colleagues (2005). This may be because patients in the study were palliative and therefore social support would probably be really high for this group of patients. In this study, patients had knowledge that the treatment goal was not to cure the illness and these patients also had a clearer understanding of the treatment aim. Being married may improve knowledge because the partner also has knowledge of the information and by discussing this information it is understood and retained by the patient. Alternatively, just having some form of social support may help patients improve their knowledge, however this is not based on any evidence and would need to be explored further.

Additionally, one factor measured in two studies, was the extent that reading the consent information predicted recall of the same information (Cassileth et al., 1980; Olver, et al.,
1995). As would be expected, the evidence supported the notion that the more patients read the information, the more they recalled. These were the only studies that measured this factor and indeed found it to be highly significant, however stronger support for this finding is needed. It appears to be such common sense to measure this factor, but previous studies appear to have not considered that patients were not even reading the information hence impacting recall. The earlier of the two studies conducted by Cassileth and colleagues (1980) also examined factors that differentiated people who read the consent form or not and found that age, race, and education were all significantly associated with who carefully read the information. In other words, younger, white, better educated patients tend to read the consent forms more carefully. Hence, these other demographic factors may indirectly impact recall through this factor.

The predictors of knowledge of information covered in the literature presented in Chapter Four were mostly demographic factors but also included patient satisfaction with information which was assessed in several studies. Patient satisfaction with information was reported more so in the studies included in the first literature review (Chapter Three). The first literature review found that about half of the studies that were included evaluated the effects of the format modifications on patient satisfaction. Patient satisfaction was found to be similar in patients who received an intervention or usual care, in both cases, patients showing a high level of satisfaction. The literature highlighted that satisfaction levels of patients were commonly found to exceed 75%. The main problem with measuring satisfaction, established from the studies, was that most were study-specific questionnaires and not many standardised questionnaires were used. This may in some cases be unavoidable because authors may need to measure satisfaction with a specific factor, therefore have to develop their own study specific satisfaction questionnaire. These studies appeared to find that although patient knowledge of the information given was low, patient satisfaction remained high, so perhaps they are inversely related. However one study identified in Chapter Three measured the association between these two factors found them to be positively correlated (Hack et al., 1999). The study which assessed the impact of offering breast and prostate cancer patients with an audiotape of their primary oncology treatment consultation, found this to be significant for males only. Due to the small sample this was tested on and the lack of findings
compared with other studies, this needs to be further assessed before the association can be confirmed.

Other measured factors included patient anxiety however this was mainly found in studies included in the first literature review. Anxiety was measured as it was thought to impact on recall or knowledge of information but also to determine whether the format modifications had any impact on the patient’s anxiety. Findings from the majority of studies showed no differences between experimental and control groups at baseline and/or after interventions were given. Only a few studies found an improvement in the level of anxiety of patients who received format modifications compared with patients receiving usual care (Luck et al., 1999; North et al., 1992; Olver et al., 2009). North and colleagues (1992) found advanced cancer patients had improvements in anxiety levels more so when they received an audiotape than usual care. Luck and colleagues (1999) found an information video for severely anxious patients undergoing a colonoscopy was of greater benefit compared with usual care.

Based on previous studies reported here, there still remains a lack and sometimes an inconsistency in findings regarding demographic factors predicting knowledge of information given. Therefore, in the current research’s longitudinal study, demographic predictor variables including age, gender, and education level will be assessed to validate or counter findings from previous research. As mentioned above, although patient satisfaction appeared to be commonly high in patients, it is unclear how this is associated with patient knowledge of the information. In other words, limited research evaluated the actual associations between patient satisfaction and knowledge of the information given, so further research on this factor is needed. Patient levels of anxiety was believed to be adequately covered in Chapter Three and as findings were consistent, and based on validated questionnaires, this was not researched further thus allowing space to research new, more novel factors.
Satisfaction and novel predictors in the current research

Measures that were found to be lacking in the literature included, but were not limited to, patient trust for health care professionals including the physician and nurses, social support given to patients, patient expectations of the treatment outcome, quality of the information provision, and patient quality of life. Therefore, these factors should attempt to be measured in future research in this area. However, for the purpose of this research only a few additional novel variables will be added to the research design in addition to the obvious measure of patient satisfaction. These include trust for the physician and social support as explained in detail below. These were believed to be novel and important predictor variables of patient knowledge of the information, for which there is limited research available. In the remainder of this chapter, an overview of the three psycho-social variables that will be measured in the longitudinal study of this thesis is given.

Patient satisfaction with information

Patient satisfaction is a widely recognised and measured outcome in the design of interventions aimed at improving the informed consent process. Clearly this is an important indicator of effectiveness as dissatisfaction may have negative consequences such as low recall and perhaps poor understanding of information, poor compliance, lengthier recovery periods, and increased complication rates (Fallowfield, 1992). Research into satisfaction includes satisfaction of overall care, treatment, physician behaviours, and information given, just to name a few. Patient satisfaction with the information given and treatment received is important because it appears to be an indicator of the quality of care (Idvall, Rooke, & Hamrin, 1997; Sitzia & Woo, 1998). There is evidence that suggests increasing involvement of patients in decision-making promotes the satisfaction of patients (Gattellari, Butow, & Tattersall, 2001).

Although a common conceptual definition of patient satisfaction is lacking, it has been defined as a merging of expectations and perceptions of the patient (Risser, 1975). In relation to information given, patient satisfaction can be said to be the expectations patients have about ideal information and their perception of the information that they really get.
While this definition may appear to be simple, patient satisfaction is a complex phenomenon as it is potentially influenced by a range of factors. For example, patient expectations and perceptions are each shaped by many factors including prior experiences, cultural standards, and level of knowledge, among others. Three longitudinal studies on patient satisfaction of information given were reported in the second literature review (Godwin, 2000; Kriwanek et al., 1998; Priluck et al., 1979). Godwin (2000) assessed patient satisfaction with the information supplied by a surgical team and found that 66% were completely satisfied (10/10) and the lowest score given was 7/10 by only 5% of the participants.

Priluck and colleagues (1979) and Kriwanek and colleagues (1998) found patients to be highly satisfied with the information with 97% of the patients saying they had had a satisfactory preoperative discussion and had all of their questions adequately answered. Kriwanek et al., asked several questions and reported that 84% of patients found that they received a high level of information, 12% had too much information, and 4% were under informed. One implication of these findings is the need for more extensive data collection on patient satisfaction with different aspects of the information provided. This may indicate areas where patients are less satisfied and hence need improving. Also, these three longitudinal studies measured patient satisfaction with information in a surgical setting. These studies, being conducted on surgical patients measured changes in patient satisfaction with information between two and 11 days post operation, that is, in the short-term. The short-term assessment of satisfaction may perhaps be because the side effects of surgical treatments are more likely transient and once off, compared with non-surgical treatments which may be ongoing. However longitudinal assessment of patient satisfaction with information given for non-surgical procedures is unclear from the findings of this second literature review and would be interesting and novel.

As mentioned in the introduction of this chapter, patient satisfaction with the information was measured more in the first literature review mainly to compare the effectiveness of interventions on patient outcomes, including satisfaction. The interesting finding from studies from both reviews was that although recall was often low, satisfaction remained high raising the question, are these two factors related? If a patient is satisfied from the outset of treatment, then are they likely to take in the consent information to recall at a later stage?
As previously stated, satisfaction is a complex factor – it could be related to many other factors. If satisfaction is negatively related to recall, then when a patient is satisfied, for whatever reason, they may not be paying attention to the consent information enough to warrant remembering this information at a later date.

One of many reasons patients may stop taking in information is because they trust their physician. Like satisfaction, trust is a complex factor dependent on various aspects in different situations. A patient may trust their physician because of good communication, because they like the way the physician looks, because they were recommended to them, etc. However, once a patient trusts their doctor and they may appear satisfied, they may not worry about the details of having the treatment, which may be of minor importance to them. In fact, there is evidence that a patient’s trust for the physician improves their satisfaction with care. Thom, Kravitz, Bell, Krupat, and Azari’s (2002) observational study of 732 patients found that patients with a low level of trust were less satisfied with their care (p < .001) (Thom, Kravitz, Bell, Krupat, & Azari, 2002). Similar results were found in a study by Safran, Taira, Rogers, Kosinski, Ware, and Tarlov (1998) in which patients with trust scores on the 95th percentile were about five times more likely than those with median levels of trust to express complete satisfaction with their physicians (87.5% vs. 18.4%, p < .001) (Safran, Taira, Rogers, Kosinski, Ware, Tarlov, 1998).

In a cross-sectional study, Raupach and Hiller (2002) found that breast cancer patients were satisfied with the information they received from their physician and other health professionals, despite receiving decreasing amounts of information over time. Based on the studies by Thom and colleagues (2002) and Safran et al. (1998), the question arises, ‘is patient satisfaction high because they trusted the physicians?’ Raupach and Hiller (2002) found that patients were not as satisfied with the information they received from other sources including the television, newspapers, magazines, and radio. The lack of satisfaction with such sources, namely the media, may be because these are not believed to be trusted sources of information (Raupach. J. & Hiller, 2002).
At the micro level, different patient characteristics can also impact on the association between information and satisfaction. Davidson and Mills (2005), in a recent study, suggested that satisfaction with information varies with age and cancer site; patients with common solid tumours such as breast and colorectal cancer reported significantly higher satisfaction with information than patients with ‘other cancers’ such as gynaecological cancers (Davidson & Mills, 2005). This may be because these two common cancers have seen the most research both in terms of treatment options but also the quality issues in cancer care. These factors have allowed health care professionals to provide these cancer patients with more accurate information in a way that is preferred and this may lead to higher satisfaction. Additionally, this study found younger patients (< 45 years old) to be less satisfied with the communication of their diagnosis than older patients (p < .05). It may be that cancer diagnoses included in this study were less frequently expected in younger patients and therefore the provision of information may not be as efficient, or other factors may be involved such as the difference in age between young patients and older physicians.

One complexity regarding patient satisfaction that needs to be mentioned is the method of measurement. Patients may have a tendency to give socially desirable responses, so that criticism of their physicians or the information they gave would not adversely affect their care (Fallowfield, 1992). One approach to measure this would be to add a social desirability scale to the research however there is possibly no best solution in resolving this issue and only efforts can be made to build rapport with patients to reduce this occurring. Also, as the studies have shown, often patient satisfaction is found to rate highly which may introduce the possibility of a ceiling effect with the patient satisfaction surveys used. The ceiling effect may not allow differences among patients to be determined, particularly in longitudinal studies. This is because if patient satisfaction is high at baseline, and there are large improvements in their satisfaction over time, this can not be identified.

The studies reported here show some links between patient satisfaction and trust which may directly or indirectly impact on patient knowledge of the information given. The next section will review research on patient trust for the physician to obtain more of an understanding on its relationship with patient knowledge of information given at the time of consent.
Patient trust in their physician

The Australian Oxford dictionary defines trust as ‘a firm belief based on experience, qualities such as honesty and veracity, and actions such as justice and strength of a person or thing’ (pg. 872, Hawkins, 1989). This definition covers the three main, related domains of trust: technical competency, interpersonal competency, and loyalty. Trust has been found to be a defining characteristic of the patient-physician relationship, a highly important interaction due to its personal and life-altering nature (Mechanic & Meyer, 2000; Thom & Campbell, 1997). Trust in a patient-physician relationship has been shown to increase acceptance of medical advice and treatment adherence (Gray, 1997; Thom, Ribisl, Stewart, & Luke, 1999). Thom and colleagues reported that about two-thirds of patients (62%) in the highest quartile of trust ratings stated that they always took prescribed medication compared with 14% of patients in the lowest trust quartile (Thom et al., 1999). Previous studies have also shown that patient dissatisfaction with the information may reduce compliance to treatment (Fallowfield, 1992) which again indicates that patient satisfaction and patient trust for the physician may be linked.

An international online survey of 600 post-menopausal women diagnosed with early stage breast cancer, who had undergone surgery, found that 81% indicated that trust in their physician was a vital component of their care (Lansdown, Martin, & Fallowfield, 2008). In a questionnaire survey of 1006 elective or emergency obstetrics and gynaecology patients post-surgery, patient explanations of why they may have not read the consent form were measured. The two leading reasons for not reading the consent form included ‘had a verbal explanation’ (46%) and ‘trusted the doctor’ (31%; (Akkad, Jackson, Kenyon, Dixon-Woods, Taub, Habiba, 2004).

In a study by Keating, Green, Kao, Gazmararian, Wu, and Cleary (2002), trust was strongly related to the communication of health information (Keating, Green, Kao, Gazmararian, Wu, and Cleary, 2002). In other words, physicians not always providing as much medical information as patients wanted, not taking enough time to answer questions, or not giving answers to questions that were understandable were each independently associated with lower
trust (p < .001). However both of these latter studies focused on women who may differ to men with regards to their trusting nature. Two years later, Keating, Gandhi, Orav, Bates, and Ayanian (2004) conducted a similar survey, this time on a broad range of cardiology, neurology, nephrology, gastroenterology, and rheumatology patients and included males (Keating, Gandhi, Orav, Bates, & Ayanian, 2004). Similar findings were found in this study and additional results showed that trust was also higher among patients who reported that they spent as much time as they wanted with the specialist.

Just as trust in a physician has been found to increase compliance and satisfaction, distrust has been found to lead to patients changing physicians and fracturing continuity of care (Keating et al., 2002) (Mechanic & Meyer, 2000), as well as withholding information such as non-compliance with medication regimens (Mechanic & Meyer, 2000). This further supports the link between trust and satisfaction. In 2002, Keating and colleagues conducted a telephone survey of 2,052 patients about experiences with their primary care physician. The authors found that the number of patients who had considered changing physicians increased substantially as the number of problems experienced increased. Half of the patients (53%) who had experienced six problems with their physicians had considered changing physicians compared to only 10% of patients who had experienced three or less problems.

Such research highlights that trust between the patient and their physician is of great importance. If trust also shows to be predictive of patient knowledge of information given, mechanisms to increase trust between patients and physicians may be a strategy to be implemented to improve knowledge of the informed consent process. There is no known research that attempts to answer this question hence the rationale for this factor being included in this study.
**Social support of patients**

Social support can be described as all forms of encouragement and assistance that help a person to cope with particular situations, in this case, the commencement of cancer treatment. Social support may be sought by the patient or provided by others. Different types of support may include emotional support, informational support, and instrumental support. Emotional support may include providing company to the patient, showing concern over the patient’s well-being, and providing encouragement. Informational support generally refers to information provided by health care professionals either in the hospital or through friends or community groups who are qualified or who have been through similar circumstances. Instrumental support may include helping with household chores or transportation to and from treatment sessions. Common resources of support include physicians, nurses, family, friends, community groups, and fellow patients.

The provision of social support and individual medical and psychological well-being has been well recognised (Silliman, Dukes, Sullivan, & Kaplan, 1998). Seeking social support may have both beneficial and detrimental effects, the latter caused by a risk of rejection. A large proportion of the studies assessing the impact of social support both physically and psychologically do not specify whether it was provided or sought but rather the overall support received.

A qualitative study was conducted on issues faced by patients in deciding whether or not to disclose their diagnosis of cancer to others (Williams & Kent, 1996). Most patients, both males and females disclosed the nature of their diagnosis and treatment to others however concerns about the treatment, their own or the family’s future were disclosed by fewer patients. This implies emotional information is less likely to be disclosed than factual information. Males were significantly less likely than females to disclose concerns about treatment (p < .001) and about their own future (p < .01), however there were no gender differences regarding disclosure of concerns about the family’s future. Of interest, males were likely to disclose to other males, and females were more likely to disclose to other females (p < .001).
Reasons for disclosing information to others included their right to know, to seek personal support, and just to inform everybody. Reasons for non-disclosure included patients believing that the information would be abused by others, either by telling others or not respecting their privacy, and also to avoid worrying others. Silliman, Dukes, Sullivan, and Kaplan (1998) assessed the association between social support and older women’s general and breast cancer specific emotional health outcomes. Social support was based on marital status, attendance at religious services, and physician-patient communication associated with treatment decision making. All three factors were found to be significantly associated with both general and breast cancer specific emotional health outcomes (p < .05).

There is also some evidence that social support is positively associated with breast cancer progression measured as time to the next stage of disease and survival (Carlsson & Hamrin, 1994; Falagas, Zarkadoulia, Ioannidou, Peppas Chritodoulou, & Rafailidis, 2007; Nausheen, Gidron, Peveler, & Moss-Morris, 2009; Spiegel, 1997). The latest systematic review by Nausheen and colleagues published in 2009 identified 26 longitudinal studies of which 13 were methodologically sound. Of seven methodologically sound studies with a population of breast cancer patients, five found higher social support to play a significant role in less breast cancer progression (no p value). Studies assessing social support of patients with cancer types other than breast cancer did not find any significant findings. However the authors suggest that the results should be considered with caution due to the limitations of the studies, such as social support being measured heterogeneously and lack of control for potential confounders. The authors of this study state that further conclusive research on the influence of social support on cancer outcomes is warranted.

Other research shows that structural (e.g. marital status and living arrangements) or functional (e.g. instrumental, emotional, family cohesion) social support was associated with patient adherence to medical treatment (DiMatteo, 2004). DiMatteo conducted a review of the literature from 1948 to 2001 identifying 122 studies. Meta-analyses showed significant average effect sizes between adherence and practical, emotional, and unidimensional social support; family cohesiveness and conflict; marital status; and the living arrangements of adults. Practical support such as instrumental support, assistance, reminders, and organization
showed the greatest correlation with adherence ($r = .31, p < .001$). Adherence was 1.74 times higher in patients from cohesive families and 1.53 times lower in patients from families in conflict.

As mentioned above, patient trust in a physician, and their satisfaction have also shown to be correlated with an increase acceptance of medical advice and treatment adherence (Fallowfield, 1992; Gray, 1997; Thom et al., 1999). Similarly, knowledge of the information given has been associated with improving compliance with treatment (Fallowfield, 2008). Clearly, these factors are somehow associated, however it is unclear what these associations are? They could be direct or indirect, small or large.

Information disclosure to others may also aid the individuals cognitive processing of a particular event and may reduce psychological stress (Pennebaker, 1989). If psychological stress or anxiety is lower, then patients may have more knowledge based on previous studies (Jepson & Chaiken, 1990; Ley, 1979). This may include physicians disclosing information, with the patients consent, to family or friends of patients or the patients themselves disclosing the information to family and friends. The study by Williams and Kent (1996), discussed above, identified that patients often disclose information to seek personal support; therefore does social support impact on cognitive processing and psychological stress? Subsequently, if social support reduces psychological stress or anxiety, then as mentioned above, patients have more knowledge, therefore does this suggest an association between social support and knowledge of the information given at consent?

Chen, Diamant, Thind, and Maly (2008) conducted a study on newly diagnosed, low income, breast cancer patients living in medically underserved areas, that is, areas where health care resources are deficient. The aim was to identify modifiable determinants associated with knowledge of information given (Chen, Diamant, Thind, & Maly, 2008). Amongst other determinants physician emotional support, office visit support by relatives/friends, and self-efficacy in interacting with physicians was measured. The latter of these was assessed as evidence that greater self-efficacy is associated with significantly higher cancer screening knowledge (Carpenter & Colwell, 1995).
On the other hand, physician emotional support and office visit support by relatives/friends were measured to explore the hypothesis that patients would be more likely to elicit, register, and retain information necessary to their medical care in a more nurturing environment. A sample of 921 patients was eligible and participated in a telephone survey. This included 10 true-false knowledge questions, three questions on physician emotional support using a 4-point scale (Cronbach $\alpha = .91$) and the previously validated five item measure called ‘Perceived Efficacy in Patient-Physician Interactions Questionnaire’ (PEPPI; Maly, Frank, Marshall, DiMatteo, & Reuben, 1998). The PEPPI asks about patients’ confidence in their ability to communicate with their physicians and obtain attention to their medical concerns.

The average screening knowledge score was 6.9 (SD = 2.3, range 0 - 10) and a multivariate linear regression analysis revealed that self-efficacy and physician emotional support were the only individually significant determinants of patient knowledge ($p < .000$). A significant interaction between these two determinants was also found. Having more physician emotional support was of greatest benefit to women in the lowest self-efficacy quartile (predicted knowledge score: 6.3 for women with physician emotional support vs. 5.4 for women without physician emotional support). The main limitation of this study was the use of multiple choice questions which indicated the measuring of recognition rather than free recall but also there was no indication whether the questionnaire used had been validated and was reliable. Despite the study being conducted on a large sample, the participants were all low income patients therefore this reduces the external validity of the findings. There is a paucity of research, such as that of Chen and colleagues (2008), in which the association of social support and patient knowledge of information given is directly assessed. While Chen’s study had positive findings, it also had its limitations and therefore this is an area in which further research is needed.

Summary
A review of the literature regarding three psycho-social variables, namely, patient satisfaction, trust in their physician, and their level of social support, has highlighted several important factors.
Previous studies have shown that these three factors have been associated with an increase in compliance with treatment (DiMatteo, 2004; Fallowfield, 1992; Thom et al., 1999). Similarly, patient knowledge of the information given at consent has been associated with improving compliance with treatment (Fallowfield, 2008). Therefore the association between the psychosocial factors and knowledge of the treatment information given is of interest.

Clearly, the association between patient satisfaction and knowledge of the treatment information given has been researched to some extent but some differences in results have been found. On the other hand, limited evidence regarding the association between social support and patient knowledge of the information given showed a positive correlation between the factors. This one study measured recognition as a means of patient knowledge therefore a replication of this study using a superior form of knowledge assessment such as free recall would be beneficial (Chen et al., 2008). Lastly, there were no known studies that assessed the association between trust for the physician and patient knowledge of the information given. For a number of reasons, this area is believed to need more focus. Firstly, one study found that most patients believed that trust in their physician forms a crucial component of their care (Lansdown et al., 2008). There is also evidence that patient’s trust for the physician improves their satisfaction with care hence patients with a low level of trust were less satisfied with their care (Thom et al., 2002). It is not known, however, whether these factors work together in improving patient knowledge of the information.

As a result, this study aims to determine the level of patient satisfaction, trust in their physician, and social support longitudinally. This is together with the demographic factors mentioned above, including age, gender, and education. Following this, the longitudinal study endeavors to determine whether any or all of these demographic and psychosocial factors are predictors of patient knowledge of the information given. While there is a complex array of factors that may predict patient knowledge of information given at the time of consent, it is beyond the scope of this thesis to cover them all. Other potential predictors will be highlighted in the Discussion (Chapter Nine). In the next chapter, the design of the longitudinal quantitative and qualitative study will be outlined.
Chapter 6:  Rationale for the Research Design

At the time of commencing the present series of studies there was little published data on the impact of patient experience of medical procedures on improving patient knowledge of information considered important to ensure informed consent could be obtained. In other words, after patients are informed of a medical procedure to give informed consent, how much does patient knowledge of this important information improve with their experience of treatment, if at all? Evidence of this lack of data is highlighted in the literature review in Chapter Four. To address this gap in the literature, various scientific methods were employed in light of their ability to address the proposed research question. This chapter aims to explain and justify the design and method underpinning the current research which addresses this gap in the literature. In doing so, an integration of the literature reviewed in Chapters Three and Four will be provided and links to the empirical component of the current research will be made.
**Phase one of the research**

The first phase of the research included conducting a literature review to identify tools implemented to improve patient knowledge of information given for informed consent and outline their success. The importance of this was to determine whether the tools were effective in improving the patients’ ability to give truly informed consent. One explanation for the lack of patient knowledge identified by Kessels (2003) includes information related factors which comprise the mode in which the information is given to the patient. This formed the basis for the first literature review reported in Chapter Three. As expected, the results of this review showed that the multitude of tools assessed were not always effective, difficult to generalise, and not necessarily cost effective, although no specific costs analyses were provided in any of the studies reviewed.

Interventions that were identified from the first literature review included additional written consent information or modifications of written information, prompt sheets, audiotapes of the consultation, videotapes, interactive multimedia, and decision aids (DAs). While each of these formats were shown by some studies to be somehow effective, most studies measured knowledge by assessing patient recognition of information, making this a less stringent method compared to assessing free recall. This meant that findings from the studies were overestimating the correct knowledge of patients. Despite this, recall of the information was identified to be as low as 26% in a study of cancer patients that measured the effectiveness of the consultation audiotape (Dunn et al., 1993). It is difficult to provide an overall level of patient recall of the information given that is accurate, from the studies showing effectiveness, due to the heterogeneity in the way recall was measured and reported. Nonetheless, it was roughly estimated that among studies showing effectiveness, less than two-thirds of the information given was recalled or more commonly, recognised, when the intervention was implemented compared to about half of the information recognised by usual care groups. Therefore, more accurate assessment of free recall of this information by intervention groups is likely to be much less. This highlights that even the success of interventions did not increase patient knowledge to near 100% which implies that maybe there is only so much that can be
done to improve the knowledge of patients. Therefore to be able to further test this multitude of complex interventions in various populations with various treatments/procedures, and to be able to generalize results, much time, money, and effort is needed. Thus the inconsistency of evidence for improving recall or knowledge, the inability to generalize, and the difficulty of conducting such complicated format modifications suggests that further investment should not be considered prior to addressing one critical theoretical question. If the patients’ experience of receiving treatment or undertaking surgery eventually improves patients’ knowledge of relevant information given at the time of consent, then the implementation of such novel tools seems redundant (particularly if this cannot improve knowledge over that currently achieved).

It is clear that in the majority of cases, even when novel format changes to consent procedures do improve patient knowledge, that recall remains less than perfect, and in some instances, this is not adequate. Therefore informed consent is not being successfully achieved, especially in the area of chemotherapy treatment as is the focus of this thesis.

Therefore research into the effect of the treatment experience on patient knowledge of the information should be conducted in an attempt to better understand and perhaps improve current consent processes, especially in long-term treatment settings and to reassure clinicians that even if all of the information considered ideal cannot be imparted pre-treatment, the situation will correct itself as the patient experiences treatment.

It is the main aim of this dissertation to explore whether patient experience of receiving treatment together with the standard pre-treatment consent information given increases patient knowledge. This is derived from an important concept that is being overlooked, this being that simply ‘recognising’ consent information in order to avoid negative consequences and legal setbacks is not adequate for patients. They must have complete knowledge of the information because patients experience the real impact of treatment after its initiation. If experience is necessary for patients to eventually understand the complex information given at consent then perhaps full informed consent (especially before chemotherapy treatment) is unattainable and repeated layering of information over treatment periods is necessary. Essentially, what happens during and after treatment is equally important as what happens at the time of giving informed consent, hence patients need to have knowledge and continue to recall this
information and at best, understand it. Therefore, even if they didn’t remember it at first, as long as they eventually take this information in it will be a superior result compared with not recalling anything (recall plus experience = knowledge). Cancer patients are surviving for longer periods of time, suggesting that more patients are experiencing a complete chemotherapy course, which also means that patient satisfaction post-treatment is more significant. This form of assessment is also supported by psychological theories like ‘attentional narrowing’ as mentioned above. Attentional narrowing, as first mentioned in Chapter Four, refers to the limiting of attention to only one factor or a class of factors which implies possible neglect of valuable information. The element of experience may improve attentional narrowing and allow for peripheral information to be remembered or indeed taken in for the first time. This may be achieved through several mechanisms. Simply experiencing the treatment in real time may make the process more salient and more understandable than just a written form given before any treatment commences.

Furthermore, patients may need experience with the actual process to gradually take on the information originally given to them at a time of great stress, where some patients would have experienced extreme anxiety, and confusion. Consequentially, a literature review was essential to determine whether prospective, longitudinal studies that assessed knowledge of information given for the consent process were available. This literature review was presented in Chapter Four. However scarce data was found and the studies assessed appeared inconclusive and sometimes methodologically flawed.

In the second literature review, a total of seven studies were reviewed on patients receiving non-surgical treatment and nine studies were reviewed in the surgical setting. The research spanned 30 years from the 1970s to early 2000s. Studies in the non-surgical treatment setting measured patients’ recall of the various factors outlined in the consent process, such as number of drugs received, drug names, potential side effects, etc. All of the studies assessing patients undertaking non-surgical treatment were oncology based, with patients receiving chemotherapy, radiotherapy, and in one study, palliative therapy.
Varied results were obtained regarding patient recall (or recognition) abilities using different methods and different samples therefore no distinct conclusions could be made. However, a number of gaps in the literature were identified. Firstly, only one study was identified to measure recall at more than one time point in a non-surgical setting (Craft et al., 2005). This was also the only study that had a long follow up period, (12 weeks after entry) with most studies conducting measurements soon after the information was given, or after limited experience. However the authors of this particular study found that the proportions of accurate knowledge remained the same over time, that is, patient knowledge did not improve with the experience of treatment. The patients in this study were advanced cancer patients who may have different experiences than patients receiving adjuvant chemotherapy. The authors suggested that excessive optimism may lead to impaired decision-making, as less than one third of patients understood that the treatment was not curative. This highlights one reason that more longitudinal research needs to be conducted in the non-surgical setting, to assess the impact of experience in other settings where patients are expected to live with the outcomes of their treatment for long periods of time.

Similar findings on patient recall of information were found in studies conducted in the surgical setting in that a high percentage of patients did not recall or recognise aspects of the procedure they undertook. Most of the studies identified, measured recall of potential complications and very few measured overall knowledge of all information provided. In the case of surgery, some of the risks patients are informed about include peri-operative complications, thus if the patient recovers from surgery without incident, these risks are likely to be forgotten. Most of the studies measured patient knowledge in the short-term (after surgery) and therefore it was not clear whether patients had knowledge of the late side effects or complications and whether experience of these would have improved their knowledge.

The second explanation for the lack of patient knowledge identified, as suggested by Kessels (2003), is patient-related with factors including demographic measures such as age, gender, educational level, and also psycho-social variables such as anxiety, depression, trust for the physician, and social support for the patient, among others. Research on these factors have been found in studies, with some more commonly measured than others.
These factors were also measured in the studies identified in Chapter Four. All of the studies that measured education established that the level of education significantly predicted recall of information. However other demographic factors such as age and gender were inconsistent across studies so this requires further research. Cassileth and colleagues (1980) and Olver et al. (1995), measured a novel factor as a predictor of recall, this being the extent of how much of the treatment information was actually read by patients. Both studies found this to be highly significant and hence this predictor needs to be further tested to clarify its significance. It appears to be such common sense to measure this factor, but previous studies appear to have not considered that patients were not even reading the information.

Other factors were identified to have been scarcely or not at all mentioned in the literature, as predictors of knowledge of the information given. For the specific purpose of this study, as outlined in Chapter Five, this thesis is particularly interested in the factors of patient satisfaction, trust for the physician, and social support of patients, although many other factors could contribute to this area of research. Chapter Five highlighted these three factors to be important factors for adherence to treatment, as is, patient knowledge of the information given (DiMatteo, 2004; Fallowfield, 1992) (Fallowfield, 2008; Thom et al., 1999). Patient satisfaction and social support of patients have been shown to be associated with patient knowledge of the information given however methodological flaws and heterogeneity of the studies make these findings questionable. On the other hand, there is no evidence on patient trust for the physician, which could be considered a crucial part of patient care, and possibly a good predictor of patient knowledge of the information given. Trust in the physician has been shown to be associated with patient satisfaction in that a low level of trust leads to dissatisfaction (Thom et al., 2002). Therefore, to address the gaps identified in the first phase of the research, the current study was designed forming the second phase (empirical phase) of the research which is discussed in this next section.
**Phase two of the research**

The main purpose of the current dissertation was to explore whether patient experience of chemotherapy treatment, when added to the standard pre-treatment information given for consent, improves patient knowledge. In other words, do patients need the actual experience of chemotherapy to gain a more adequate amount of knowledge expected for undergoing such treatment? Assessment of this was conducted on cancer patients who were followed prospectively over the course of their adjuvant chemotherapy cycles.

Quantitative and qualitative methods were employed to address the aims of the research. Mixed methodology use in this research involved initially undertaking a quantitative study (Study 1) primarily to investigate the effects of treatment experience on information knowledge and to further assess predictors of knowledge such as satisfaction, demographics, and psycho-social variables. Qualitative methods were used to strengthen the evidence through exploration of significant facets discovered from the primary quantitative study as well as triangulation of the findings. The purpose of triangulation in qualitative research is to increase the credibility and validity of the results but to also add richness by assessing constructs from more than one standpoint (Cohen & Manion, 2000). Qualitative methods allow participants to express themselves in a naturalistic manner allowing for greater understanding of their views. Subsequently, qualitative data collection (Study 2) can be seen as complementary to the quantitative methods rather than exclusive of them. The second study aimed to provide a richness and depth to the research findings. In the remaining part of this chapter a description of the research design is presented.

**Quantitative research design**

In the first layer of this empirical investigation a longitudinal sample of patients undergoing adjuvant chemotherapy treatment for breast or colorectal cancer was chosen to primarily assess the impact of the treatment experience on the knowledge of the information given at consent.
Adjuvant chemotherapy was the chosen form of treatment because it is common practice in a population where there has been early diagnosis of breast or colorectal cancer. Therefore the widespread use of this treatment means that a greater number of patients can be studied compared with patients with other cancer types or patients with advanced cancer. Furthermore, the patients were deemed able to take part in the study in terms of the physical condition, although psychologically they are still faced with a life-threatening illness that may interfere with their ability to receive and understand the information given. Also, this group usually has a good prognosis and therefore the effects of treatment (or information about prolonged effects of treatment) are important for them. Additionally, a great deal of research in the area of informed consent has been conducted with breast and colorectal cancer patients, as they form some of the most highly diagnosed types of cancer, hence making some aspects of the current research comparable to previous work. By not just concentrating on one homogenous group (such as breast cancer) this study was able to include both men and women allowing an assessment of gender.

Each patient partook in the standard informed consent process at the attending clinic and then voluntarily participated in the research study. Patients were prospectively followed with repeated assessments at three time points. The idea was to determine whether the experiences of chemotherapy treatment over the course of several cycles improved patient knowledge of their chemotherapy. It was also an intention of this study to establish whether knowledge remained stable and if so, highlight this important finding. Put simply, the rationale behind conducting a longitudinal study was to prospectively capture experience driven changes that may have occurred.

This involved three separate interview schedules during patients’ chemotherapy period which was made up of five main assessment sections: demographic and general questions (such as where patients received most of their information from), knowledge assessment, information satisfaction scales, trust, and social support scales.
Qualitative research design

Stratified purposive random sampling was used to select a subgroup of patients from the larger quantitative sample to participate in in-depth qualitative interviews. This hybrid approach involves the selection of a group of patients who are reasonably homogeneous but nevertheless show variation on a particular phenomenon (Pope & Mays, 1999). The aim was to conduct qualitative interviews on 10% of patients who completed three data collection points for the quantitative study in order to establish themes in an attempt to explain why cancer patients may have not taken in the information given at the time of consent.

The in-depth interviews were semi-structured to allow for both fixed questions to be asked as well as open-ended questions whereby patients were given the opportunity to discuss their thoughts and opinions. These interviews took place upon completion of the patients’ chemotherapy cycles in order to capture the patients’ experience from initiation to the completion of chemotherapy treatment. All qualitative interviews were audio-taped and transcribed.

The current qualitative study employed a framework approach. This is a common form of analysis used with individual interview data whereby the interest is to identify themes. Effectively, the framework approach is a systematic form of thematic analysis as this process starts deductively from pre-defined aims and objectives and continues as an inductive process once data is generated. This was considered the most suitable approach for conducting the current study as it allowed for the development of themes and triangulation of the data with the quantitative study (Pope & Mays, 1999). Data analysis was carried out with the assistance of a computer program, NVIVO Version 7.1.

In summary, the literature reviews facilitated development of the design for the empirical component of the research. The research flow diagram below is a visual diagram of the various aspects of this research and the gaps in the literature to date that are attempting to be addressed. The following two chapters will report on the quantitative and qualitative findings of the empirical part of this study.
THE INFORMED CONSENT PROCESS IS IMPORTANT FOR CANCER PATIENTS TO GAIN MAXIMUM KNOWLEDGE BEFORE TREATMENT INITIATION

HOWEVER
TO DATE, NO INTERVENTION HAS SHOWN CONVINCING CONCLUSIONS REGARDING IMPROVEMENT IN INFORMATION KNOWLEDGE OF CANCER PATIENTS

FURTHERMORE
THERE IS A LACK OF UNDERSTANDING OF PATIENT KNOWLEDGE OF INFORMATION WITH EXPERIENCE OF TREATMENT

THEREFORE

DOES PATIENT KNOWLEDGE IMPROVE WITH EXPERIENCE?

IMPROVE WORSEN SAME NON-LINEAR

ARE THERE PREDICTORS OF PATIENT KNOWLEDGE?

AGE SEX TRUST SOCIAL SUPPORT

BASED ON THIS EXPERIENCE, WHAT DO PATIENTS SUGGEST COULD BE IMPROVED, IF ANYTHING?

READING CONSENT FORM EDUCATION SATISFACTION
ARE PATIENTS SATISFIED WITH THE INFORMATION THEY RECEIVE?

QUANTITATIVE

QUALITATIVE

TRIANGULATION

WHAT IS THE LEVEL OF PATIENT TRUST/SOCIAL SUPPORT FOR THEIR DOCTOR?

QUANTITATIVE

QUALITATIVE

TRIANGULATION
Chapter 7: Quantitative Longitudinal Study: Enhancing knowledge of patients: the impact of experience and information

Studies reported in both literature reviews presented in Chapters Three and Four have clearly shown a lack of patients’ knowledge with regards to details of surgical and non-surgical treatments. Most studies measured recall or some other surrogate of knowledge immediately following or shortly after patients consented to treatment. There was limited literature available on the long-term impact of treatment experience on patient knowledge of necessary information supplied at the time of consent. In the surgical setting, some aspects of consent information that are not recalled following the procedure may not be of great concern as any complications specified to the patient that were related to the actual surgery itself have passed and are no longer relevant. However, in the non-surgical setting, treatment such as chemotherapy is often given over several cycles and can impact the patient for many years to come. Therefore patients undergoing such treatment need to continue to be able to recall and often understand a complex amount of information given at the time of consent. Hence the role of experience during treatment and how it impacts patients’ knowledge is in need of further investigation especially as most patient samples in the literature show poor recall even after successful improvements in consent formats. Patients are now living longer after cancer and therefore their experience of treatment and life after treatment is highly significant. This means it is now, more than ever, essential to improve the informed consent process and patient knowledge of medical treatment information.

To do this, the present study has primarily aimed to measure patient knowledge defined as the patient’s recall of necessary medical information given at the time of consent together with their experience of the treatment. Specifically, this study aims to determine any change in early stage cancer patients’ knowledge of their chemotherapy treatment information over the period of treatment.
A longitudinal, prospective method was employed to explore whether treatment experience improves patient knowledge of the necessary information given prior to treatment. This study was also interested in measuring other factors, some of which were novel measures, while others were factors found to be important in other studies that were assessed in order to confirm previous findings. Therefore, the study questions are stated below:

**Study Research Questions**

1. Does patient knowledge of chemotherapy improve when the experience of chemotherapy is added to the pre-treatment information given to obtain informed consent?
2. Are patients satisfied with the information provided pre-treatment and does patient satisfaction change over the chemotherapy treatment period?
3. Do patients have trust in the physician and does this change over the chemotherapy treatment period?
4. Do patients receive social support and does this change over the chemotherapy treatment period?
5. Are there particular demographic (age, gender, level of education) or psycho-social variables (patient satisfaction, trust, social support) that predict knowledge of information?
Methods

Participants

Consecutive patients receiving adjuvant chemotherapy treatment for breast or colorectal cancer at the Royal Adelaide Hospital Medical Oncology Unit, Ashford Cancer Centre, and The Brian Fricker Oncology Centre were approached. Inclusion criteria for the study were that participants were (a) aged 18 years or older; (b) had the ability to understand and speak English well, and (c) had given informed, written consent to participate. Patients were excluded from this study if they (a) had concurrent psychiatric or medical co-morbidities, (b) were participating in the trial Improving informed consent to chemotherapy: written information versus an interactive CD-ROM, and/or (c) were participating in ongoing clinical trials assessing knowledge and/or satisfaction. Ethical approval for this study was obtained from the participating hospital and University of Adelaide human ethics review committees.

Seventy one men and women agreed to participate in the study (males = 17, females = 54) between September 2003 and March 2007. This was from a pool of 84 patients who were eligible and available to approach for participation in the study, giving a participation rate of 85% based on initial eligible, consenting participants. Those who declined participation did so because they were not interested in being involved, they said they were too busy, or they were not in a good condition on the day of recruitment.

While there may have been a larger number of patients eligible for the study during this period, certain constraints did not allow for the patients to be approached. This included patients who had already been enrolled in other studies, as preferred by the nurse and/or doctor. Nurses also advised against approaching patients who were not in a good emotional condition. In addition, patients who were having some chemotherapy cycles at a country hospital were not approached as it was not feasible to collect data.

Out of the 71, all patients provided completed Time 1 data (100% response rate), 65 patients provided completed Time 2 data (92%), and 57 patients completed Time 3 follow-up data (80%).
Therefore a total of 193 interviews were conducted and completed over the longitudinal period of the study. Of the 57 patients who completed Time 3 follow up data, there were 45 female and 12 male patients. Fourteen patients did not complete Time 3 data of whom six also did not complete Time 2 data because they were too ill from the side effects of chemotherapy. Other reasons why the remaining patients did not complete Time 3 data included that the patient refused further participation; the patient stopped attending chemotherapy or were lost to follow-up in the clinic; or at the investigator’s discretion, withdrawal was in the best interests of the patient.

**Procedure**

Patients diagnosed with breast or colorectal cancer who were referred to the cancer centres for adjuvant chemotherapy were considered for participation in the study. Consecutive patients due to receive their first chemotherapy treatment were approached and eligible patients were given an information sheet detailing the study purpose and what was involved. This was done at the first chemotherapy treatment to build rapport with patients. However, where possible, patients were initially approached while they were waiting to attend scheduled appointments with clinicians in medical oncology, prior to receiving their first chemotherapy. This was often difficult to do as some patients came in late for their appointment so there was limited time to approach them beforehand and immediately afterwards they were being consulted by the nurse prior to chemotherapy. Also some patients preferred not to be interrupted as they were already anxious about starting chemotherapy and with these cases, patients were asked if they could be seen prior to their second chemotherapy cycle. In other cases, patients wanted more time to read the information sheet and decide whether to consent to the study and these patients were followed up in the waiting room prior to their second chemotherapy treatment to determine whether they wanted to take part in the study or not. Other patients consented immediately.

With all patients, as soon as written consent was obtained, they were asked for demographic information. Following this, regardless of when patients consented, either previously or on the day of their second chemotherapy cycle, they were asked to complete the first questionnaire in the form of a structured interview, prior to attendance for their second cycle of adjuvant
chemotherapy (Time 1). Similarly, patients were again visited prior to their fourth cycle of chemotherapy (Time 2), and a third time at one month post-chemotherapy to complete a similar questionnaire (Time 3).

The three time points were chosen to be able to identify trends over time. Baseline data prior to chemotherapy commencement was not obtained as this was not considered feasible for several reasons. Often patients started consultation with the chemotherapy nurses before treatment which often occurred straight after their consultation with the physician. Following this, there was no time to approach patients about the study, or obtain their consent. Collecting Time 1 data at such a difficult time in the treatment process would have probably resulted in a low participation rate as patients were already overwhelmed with the treatment initiation process and to burden them with more information was not considered appropriate. For this reason patients were approached during their first treatment for consent to the study. This timing allowed for building rapport with the patients which was considered of prime importance for participation in a longitudinal study. This also allowed the researcher (me) to adequately inform patients about the study and allow them to make a careful decision whether to participate or not at their subsequent chemotherapy cycle.

In addition, previous studies have shown that patients have poor recall or knowledge immediately after consenting therefore this was considered well established. However, there was a lack of literature measuring recall or knowledge in the long-term, as most measured it in the short-term, often up to a couple weeks after treatment initiation. One aim of this thesis was to overcome this by measuring the impact of chemotherapy experience throughout the whole process.

Also, it was of prime importance in this study not to lead the patients by asking them about their knowledge at the exact time they were looking over their consent form. This is because it may have impacted the degree to which they tried to retain or understand the information given on the consent form and information sheet adding the confounding factor of experimenter effects. Even if a baseline measure of knowledge would have been beneficial, it was not viable in the time frame of this thesis, to add a fourth time point as it would mean
recruiting more patients. This is part of the constraints of doing research and it was a compromise that was made. So, to reiterate:

_Time 1:_ Patients were seen at the beginning of their second chemotherapy treatment, often while in the waiting room, to complete the first questionnaire.

_Time 2:_ The second questionnaire was given at their fourth chemotherapy cycle to allow patients some time to experience the treatment.

_Time 3:_ The third questionnaire was given one month after their chemotherapy course was complete. As the length of chemotherapy courses can vary between four to six months, asking patients at the four or six month time point was expected to result in inconsistent results across patients. Therefore asking them one month post-chemotherapy meant that patients should be in a similar frame of mind.

The three questionnaires that were given were identical in content and focused on questions about knowledge of treatment-related information given, satisfaction with this information, trust with the physician, and social support of patients. As previously mentioned, knowledge was defined as the patient’s ability to freely recall the necessary medical information given at the time of consent together with their experience of the treatment. Specific details of the sections that formed the questionnaires are detailed in the next section with the heading ‘Instrumentation.’

The questionnaires aimed to identify the extent of patient knowledge over the course and at completion of their chemotherapy treatment. Despite attempts to interview all patients at the hospital, in some cases questionnaires had to be sent by post as not all patients were able to attend the hospital one month post chemotherapy treatment. This was not considered ideal as patients could have referred to their information sheet and consent form – a limitation pointed out in other studies reviewed. Although not ideal, without attempting to collect data this way, more patients would have been lost to follow up. These particular questionnaires were checked to make sure no one provided perfect information (a crude measure of whether they referred to the consent forms). However, this data collection flaw should be considered with caution as this is a limitation of the study.
Instrumentation

**Demographic questionnaire:** Demographic data were collected using an investigator-designed demographic data form (Appendix B). Data collected included the participant’s age, level of education, marital status, profession/occupation, and current employment status as well as the presence of family or friends at chemotherapy treatment. This was based on other studies conducted by the psycho-oncology team at the Royal Adelaide Hospital (Olver, Turrell et al., 1995; Olver et al., 2009).

**Structured Interview:** The questionnaire used for the structured interview conducted at the three time points was made up of five main parts: general questions, knowledge assessment, questions on patient satisfaction, trust of the physician, and social support. For assessment of patient knowledge, a modified version of the informed consent questionnaire used in a previous study carried out by Olver and colleagues (Olver, Turrell et al., 1995) was utilised. All questions related to the information given to patients on the standard hospital information sheet and consent form prior to chemotherapy treatment. Patients were interviewed by the researcher (me) rather than being given self-report questionnaires to ensure they clearly understood that their knowledge of the information provided on the Information Sheet and Consent Form was being assessed.

**Assessment of knowledge:** The questions assessing knowledge aimed to be consistent with previous research in order to increase external validity. Therefore such questions included recall of how many chemotherapy drugs patients were given during treatment and the drug names, and potential side effects of the drugs. Additional questions related to information included how much information patients read, and what other sources of information they had accessed (Appendix C).

Reliability testing could not be carried out on questions assessing patient knowledge of the information as they consisted of single items, rather than several items in a scale. Although not ideal to assess single items, previous research including that by Olver and colleagues (1995) measured knowledge using single items, therefore this study aimed to replicate these findings.
Thus, items were considered complex and in need of investigation as single knowledge components.

**Patient satisfaction with information questions:** The patient satisfaction with information scale was made up of 13 questions specifically designed for the current study in the form of a six-point scale ranging from zero (strongly agree) to five (strongly disagree). All negative worded questions (questions 1, 4, 5, 6, 7, 9, 12, and 13) were recoded in a positive direction for the purposes of summed scoring. In addition, the small percentage of randomly missing values were replaced by the mean of each question before adding items to gain a total score in cases where less than 50% of data were missing. Only one patient had almost 50% of the satisfaction scale questions missing for Time 2 and Time 3 thus this patient was removed from any analyses including the satisfaction scale (Appendix C). Scale reliability was calculated for the current study as the satisfaction questionnaire used was not previously validated. This, as mentioned previously, is because there are no known validated satisfaction scales relevant to this research. Internal reliability of the satisfaction questionnaire including all 13 items was found to range from .70 at Time 1 to .85 at Time 3 suggesting good reliability. The possible range of scores on this scale was between zero and 65.

**Patient trust in the physician:** In order to measure patient trust in their physician, a subset of the validated *Functional Assessment of Chronic Illness Therapy - Treatment Satisfaction - Patient Satisfaction (FACIT-TS-PS)* questionnaire was used. This questionnaire is a chronic illness specific measure of patient satisfaction which comprises nine areas that assess quality of health care services (Hahn, Cella, Chang, Lent, Webster, Eremenco, et al., 2000). One of the areas in this questionnaire is ‘trust’ which is made up of four questions that are answered on a four-point scale ranging from zero (No, not at all) to three (Yes, completely). Therefore a minimum of zero and a maximum of 12 could be obtained. Only the trust subscale was used in this study. The scoring key from the FACIT manual was used to calculate a total score for patients on the trust scale. There were no items in this scale that needed reverse scoring. Therefore, first, a total score was obtained by summing the scores for each of the four items on the trust scale. This total score was multiplied by the number of items in the scale, which in this case was four. This number was then further divided by the number of items answered by
the individual to obtain a final score on trust of the patient for the physician. This method therefore takes into account missing data by adding such a division. This method can only be utilized when the individual has less than 50% of their data missing. Missing data for this scale was only seen in patients who were not followed up at Time 2 and 3. At Time 2, six patients did not have any data for this scale and at Time 3, 14 patients did not have data for this scale. Internal reliability of the trust questionnaire including all four questions was found to range from .79 at Time 1 to .92 at Time 3 suggesting good reliability.

Social support of patients: Similarly, a subset of the validated Functional Assessment of Cancer Therapy - General population (FACT-GP) was used to assess the social well-being of the patients. This questionnaire is a general measure of well-being designed for patients with a chronic illness and is made up of four subscales, one of which is social well-being (Cella, Zagari, Vandoros, Gagnon, Hurtz, & Nortier, 2002). This particular subscale is made up of five questions assessed on five-point scales ranging from zero (Not at all) to four (Very much). Therefore a minimum score of zero and a maximum of 20 were achievable. As mentioned above, the scoring key for the social well-being scale from the FACIT manual was used. There were no reverse coding necessary for this scale either. Therefore, first, a total score was obtained by summatating the scores from each of the five items on the social well-being scale. This total score was multiplied by the number of items in the scale, which in this case was five. This number was then further divided by the number of items answered by the individual to obtain a final score on social well-being of the patient. As mentioned above, this method therefore takes into account missing data by adding such a division. This method can only be utilized when the individual has less than 50% of their data missing. There were some missing data for some of the social well-being items, at most two of the five questions were missing hence no one had more than 50% missing data for the subscale, which is the maximum amount allowed by the FACIT scoring manual.

The missing data were mainly from question five (‘I am satisfied with my sex life’) for which the FACT-GP give people the option of answering this item or using a specific checkbox to show they chose not to answer this question. Internal reliability of the social well-being
subscale including the five questions was found to range from .83 at Time 1 (n = 53) to .80 at Time 3 (n = 42) suggesting very good reliability.

**Statistical analysis**

Data were analysed using the Statistical Package for Social Sciences (SPSS) version 15.0. Non-parametric K Related Samples analyses (Cochrane’s Q Test) were used to determine if knowledge of treatment information changed across the three time periods. Patient knowledge was assessed using three separate dependent variables including the number of chemotherapy drugs received and the name of the drugs. The third knowledge variable was parametric (the number of side effects correctly recalled) so was analysed using a repeated measures ANOVA.

Parametric repeated measures analyses of variance (ANOVAs) were used to determine if satisfaction with initial treatment information, trust with the physician, and social support changed over time. Separate ANOVAs were used to assess each of the changes over time in patient knowledge, satisfaction, trust, and social support, as the mixture of parametric and non-parametric data did not allow variables to be added to one single analysis. Therefore, as interaction effects could not be assessed, binary logistic regression and standard multiple regression analyses were used to further determine whether specific demographic and psychosocial variables (i.e. age, sex, education, trust, social support, and satisfaction, and extent of reading information) significantly predicted patient knowledge.

It was anticipated that approximately 30 patients with completed data (three repeated assessments, within subjects) was needed to achieve 80% power in an attempt to detect medium differences over time with an alpha = .05 (Stevens, 2002). However, to perform the regression analyses with a minimum ratio of 1:10 of independent variables: cases (Hair, Anderson, Tatham, & Black, 1998), data was to be collected for at least 70 patients (to analyse seven predictors). Analyses of effect size (partial $\eta^2$) were also conducted to determine the magnitude of associations without sole reliance on null hypothesis significance testing (Cohen, 1998). To interpret the magnitude of effects (partial $\eta^2$), the following guidelines were used: .01 = small effect, .06 = medium effect, and .14 = large effect (J. Cohen, 1998).
Alternatively for the effect sizes of $r$ (used in Wilcoxon Signed Rank tests) values were equivalent to .10 = small effect, .30 = moderate effect, and .50 = large effect (Cohen, 1998).

For the main parametric variables (patient satisfaction, patient trust in their physician, and social support), reliable change indices (RCIs) were calculated across the three time points. Specifically, positive, negative, and no reliable change was calculated for individual patients at Time 1, 2, and 3. The first time period included change from the second cycle of chemotherapy (Time 1) to the fourth cycle of chemotherapy (Time 2). The second period included change from the fourth cycle of chemotherapy (Time 2) to one month post chemotherapy (Time 3), and the third period included change from the second cycle of chemotherapy (Time 1) to one month post chemotherapy (Time 3). Analyses were based on those described by Evans, Margison, and Barkham (1998) using the following formula (Evans, Margison, & Barkham, 1998):

$$\text{RC} = \frac{X_2 - X_1}{SE_{\text{diff}}}$$

In the above formula, $X_2$ is the post-test or second time point score and $X_1$ is the pre-test or baseline score. The $SE_{\text{diff}}$ refers to the standard error of the difference between the two test scores and is calculated using the formula below where $SD_1$ refers to the pre-test or baseline standard deviation and the $r$ refers to the internal consistency (Cronbach’s alpha) of the measurement tool.

$$SE_{\text{diff}} = SD_1 \sqrt{2 \sqrt{1-r}}$$

Although RCIs are often used to determine change in clinical situations, such as following a therapeutic intervention, they are still considered useful in research as they show the extent of change evidenced by an individual outside of that which could be attributed to measurement error or variability of the assessment tool being used. Reliable change suggests that actual change was likely to occur 95% of the time.
Results

Data screening

Before analyses, the data were screened for outliers and missing values. While no outliers were found, missing values were identified with some of the measures and these are reported here. Overall, there were no missing values for any patient at Time 1. There was a loss of six patients to follow up at Time 2 and a loss of 14 patients at Time 3 therefore these patients had missing values for all of the variables measured at these two time points.

With regards to the patient satisfaction scale, as mentioned in the Methods section above, the small percentage of randomly missing values were replaced by the mean of each question before adding items to gain a total score in cases where less than 50% of data were missing. Only one patient had almost 50% of the satisfaction scale questions missing for Time 2 and Time 3 thus this patient was removed from any analyses on patient satisfaction.

Missing data for the trust scale was only seen in patients who were not followed up at Time 2 and 3. At Time 2, six patients did not have any data for this scale and at Time 3, 14 patients did not have data for this scale. Similarly, a final score for the social support scale was missing for six patients at Time 2 and 14 patients at Time 3. However, in addition to the data being missing for patients lost to follow up, there was some random missing data for the items in the scale. As mentioned in the Methods section, at most two of the five questions were missing hence no one had more than 50% missing data for the subscale, which is the maximum amount allowed by the FACT-GP scoring manual. The missing data were mainly from question five (‘I am satisfied with my sex life’) for which the FACT-GP give people the option of answering or not, by offering a specific checkbox that they can check to opt out. Among the patients who were followed up, missing data at each time point across the five items of the subscales was as follows; at Time 1 (n = 71), there were 18 missing values, at Time 2 (n = 65), there were 27 missing values, and at Time 3 there were 29 missing values.
Also prior to analyses, data were screened to ensure that statistical assumptions were not violated. Non-parametric Cochran’s Q tests were conducted for two of the three measures of knowledge (number and name of drugs) as these were categorical variables. Although one assumption for non-parametric techniques includes the test of independence, whereby each case is to be considered an independent observation, in the case of Cochran’s Q test, where the same subjects are retested at different time points, an exception is made. Therefore the assumptions were met to conduct non-parametric Cochran’s Q test (Pallant, 2005). Each analysis included a total of 57 patients as this was the total number of patients followed up at all three time points.

Where continuous variables were used, such as patient knowledge of potential side effects and patient satisfaction, the parametric one-way repeated measures ANOVA was the statistical test of choice. The assumptions include the following: the dependent variable has to use a continuous scale, the samples should be normally distributed, and there should be homogeneity of variance. Normality and homogeneity of variance were determined by Kolmogorov-Smirnov tests and Levene tests, respectively, showing significance or not (Pallant, 2005; Tabachnick & Fidell, 2001). The assumption of normality was violated for the parametric variables percentage of knowledge on side effects and total patient satisfaction of information according to the Kolmogorov-Smirnov tests. Nevertheless repeated measures ANOVAs are reasonably robust and therefore tolerant to some degree of violation of this assumption. This has been reported widely, by several statisticians, and is especially robust with sample sizes >30, such as in this study (Pallant, 2005; Stevens, 2002). Nevertheless the results obtained should be considered with caution.

Binary logistic regressions and a standard multiple regression were used to identify predictors of information knowledge. Predictor variables that were correlated $r \geq 0.1$ were included in each regression model as, according to Cohen (1988) they represent associations of small or greater magnitude. The regression analyses were done for Time 1 knowledge questions only as hardly any significant changes in knowledge were seen over time. Logistic regression allows for prediction of a discrete outcome from a set of variables which may be continuous or categorical or a mix of both.
In addition, predictors do not have to be normally distributed hence making it a flexible form of analysis. One requirement for binary logistic regression is that the dependent variable be dichotomous. Also, there are three assumptions to conducting logistic regressions, which include sample size, multicollinearity, and outliers. As mentioned in the Statistical Analysis section, to perform the regression analyses with a minimum ratio of 1:10 of independent variables: cases (Hair et al., 1998), data was to be collected for at least 70 patients (to analyse seven predictors). As this was achieved, the sample size assumption was met.

Multicollinearity, the presence of high inter-correlations amongst the predictor variables, also needs to be low. Collinearity diagnostic statistics determines this and where tolerance values are very low (less than .1) this indicates that the variable has high correlations with other variables in the model. Where multicollinearity does occur, the set of variables to be included in the model may need to be re-considered (like removing one of the highly inter-correlating variables). This was not found to be of concern in this study (Pallant, 2005; Tabachnick & Fidell, 2001).

**Descriptive statistics**

Demographic and clinical characteristics of the sample are summarised in the table below. The mean age of the sample was 55 years with a larger proportion being breast cancer patients and therefore more females participated. Most patients were Australian and almost three quarters were married or in a de facto relationship. Almost two-fifths of patients had a high level of education (tertiary) and half were professionals or white collar workers. Half of the patients were employed and the majority of patients were capable of normal activity or had symptoms but were still active at the time of their second chemotherapy cycle (Table 6 and Table 7).
Table 6: Demographic characteristics of the study sample

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (M, SD)</td>
<td>55.4 (10.9) range 25-76 yrs</td>
</tr>
<tr>
<td>Gender (% female)</td>
<td>54 (76.1%)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Never married/single</td>
<td>4 (5.6%)</td>
</tr>
<tr>
<td>Married/De facto</td>
<td>51 (71.8%)</td>
</tr>
<tr>
<td>Separated/Divorced</td>
<td>11 (15.5%)</td>
</tr>
<tr>
<td>Widowed</td>
<td>5 (7.0%)</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>7 (9.9%)</td>
</tr>
<tr>
<td>Secondary</td>
<td>38 (53.5%)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>26 (36.6%)</td>
</tr>
<tr>
<td>Nationality</td>
<td></td>
</tr>
<tr>
<td>Australian/New Zealand</td>
<td>57 (80.3%)</td>
</tr>
<tr>
<td>European</td>
<td>13 (18.3%)</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>English as first language (% Yes)</td>
<td>64 (90.1%)</td>
</tr>
<tr>
<td>Live alone (% Yes)</td>
<td>7 (9.9%)</td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
</tr>
<tr>
<td>Blue collar/Trades person</td>
<td>6 (8.5%)</td>
</tr>
<tr>
<td>White collar worker</td>
<td>15 (21.1%)</td>
</tr>
<tr>
<td>Professional</td>
<td>23 (32.4%)</td>
</tr>
<tr>
<td>Home duties</td>
<td>21 (29.6%)</td>
</tr>
<tr>
<td>Other</td>
<td>6 (8.5%)</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>36 (50.7%)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>7 (9.9%)</td>
</tr>
<tr>
<td>Retired</td>
<td>12 (16.9%)</td>
</tr>
<tr>
<td>Other</td>
<td>16 (22.5%)</td>
</tr>
</tbody>
</table>

Table 7: Clinical characteristics of the study sample

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of cancer</td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>60 (84.5%)</td>
</tr>
<tr>
<td>Colorectal</td>
<td>11 (15.5%)</td>
</tr>
<tr>
<td>Hospitals</td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>43 (60.6%)</td>
</tr>
<tr>
<td>Private</td>
<td>28 (39.4%)</td>
</tr>
<tr>
<td>ECOG* status at second cycle</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>35 (49.3%)</td>
</tr>
<tr>
<td>1</td>
<td>30 (42.3%)</td>
</tr>
<tr>
<td>2</td>
<td>5 (7.0%)</td>
</tr>
<tr>
<td>3</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>4</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

*The Eastern Cooperative Oncology Group (ECOG) performance status is the criteria are used by doctors and researchers to assess how a patient's disease is progressing, assess how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis. Scores can range from (0) 'normal activity' to (5) 'death' (Oken, Creech, Tormey, Horton, Davis, McFadden, et al., 1982)
Table 8 shows the chemotherapy regimens undertaken at the hospitals of patients in this study. Treatment plans of some patients included a combination of these different types of chemotherapy (for e.g. AC plus CMF, AC plus Paclitaxel) but no patients had monotherapy. Patients received between two and five chemotherapy drugs and patient recall of the number of drugs given was found to be similar over the three time points ranging between 60% to 68% of patients with correct recall (as discussed in more detail below).

Table 8: Chemotherapy taken by patients in the study

<table>
<thead>
<tr>
<th>Chemotherapy Composition</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-Fluorouracil, Epirubicin, Cyclophosphamide</td>
<td>FEC</td>
</tr>
<tr>
<td>Doxorubicin, Cyclophosphamide</td>
<td>AC</td>
</tr>
<tr>
<td>Oxaliplatin, Folinic Acid, 5-Fluorouracil</td>
<td>Folfox</td>
</tr>
<tr>
<td>5-Fluorouracil, Folinic Acid</td>
<td>5-FU/FA</td>
</tr>
<tr>
<td>Cyclophosphamide, Methotrexate, 5-Fluorouracil</td>
<td>CMF</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>-</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>-</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>-</td>
</tr>
</tbody>
</table>

Descriptive statistics on patient sources of information, as well as patients’ perceived extent of reading and understanding the information given are reported in Table 9 and Table 10. This was asked of the patients in order to repeat methods from Olver and colleague’s study (1995) in an attempt to see whether similar findings would be achieved. Doctors, followed by books/magazines/pamphlets/newspapers, and then nurses appeared to be the most commonly perceived information sources by patients for gaining treatment information prior to consenting (Table 9).

The majority of patients thought that the information they received was enough, almost two-thirds (63%) read all of it (Table 10). Over half of the patients perceived to understand all of the information that was given with another third suggesting they understood most of the information.
Table 9: Patient sources of information

<table>
<thead>
<tr>
<th>Source of information</th>
<th>Time 1 (N = 71)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors</td>
<td>57 (80.3%)</td>
</tr>
<tr>
<td>Books/Magazine/Pamphlets/Newspapers</td>
<td>28 (39.4%)</td>
</tr>
<tr>
<td>Nurses</td>
<td>24 (33.8%)</td>
</tr>
<tr>
<td>The Internet</td>
<td>8 (11.3%)</td>
</tr>
<tr>
<td>Information and consent form</td>
<td>7 (9.9%)</td>
</tr>
<tr>
<td>Television</td>
<td>3 (4.2%)</td>
</tr>
<tr>
<td>Videos</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Understanding Cancer CD-ROM</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Other</td>
<td>9 (12.7%)</td>
</tr>
</tbody>
</table>

Table 10: Perceived patient reading and understanding of information content

<table>
<thead>
<tr>
<th>Information related aspects</th>
<th>Time 1 (N = 71)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount of information*</td>
<td></td>
</tr>
<tr>
<td>Too little</td>
<td>6 (8.5%)</td>
</tr>
<tr>
<td>Just right</td>
<td>57 (80.3%)</td>
</tr>
<tr>
<td>Too much</td>
<td>6 (8.5%)</td>
</tr>
<tr>
<td>Can’t remember</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Amount understood*</td>
<td></td>
</tr>
<tr>
<td>All of it</td>
<td>39 (54.9%)</td>
</tr>
<tr>
<td>Most of it</td>
<td>24 (33.8%)</td>
</tr>
<tr>
<td>Some of it</td>
<td>5 (7.0%)</td>
</tr>
<tr>
<td>None of it</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Can’t remember</td>
<td>1(1.4%)</td>
</tr>
<tr>
<td>Amount patient read</td>
<td></td>
</tr>
<tr>
<td>All of it</td>
<td>45 (63.4%)</td>
</tr>
<tr>
<td>Part of it</td>
<td>18 (25.4%)</td>
</tr>
<tr>
<td>Quick skim through it</td>
<td>6 (8.5%)</td>
</tr>
<tr>
<td>Did not read it</td>
<td>1 (1.4%)</td>
</tr>
<tr>
<td>Can’t remember</td>
<td>1 (1.4%)</td>
</tr>
</tbody>
</table>

*One person failed to answer this question.

Several other information related questions were asked of the patients including whether they received help with reading the informed consent information and/or making a decision to consent to chemotherapy (Table 11). It appeared that the majority of patients did not receive help with either reading the information sheet and consent form or making a decision. However amongst those that did receive help, this was mainly from their family. Patients
looked at the information a maximum of 10 times with 14% not looking at it at all. In addition, 34% of the patients stated that they had less than one day to look at it (i.e. consented on the day).

**Table 11: Help with reading information and decision making**

<table>
<thead>
<tr>
<th>Help with reading information*</th>
<th>Time 1 (N = 71)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>23 (32.4%)</td>
</tr>
<tr>
<td>Family</td>
<td>12 (16.9%)</td>
</tr>
<tr>
<td>Nurse</td>
<td>5 (7.0%)</td>
</tr>
<tr>
<td>Friend</td>
<td>3 (4.2%)</td>
</tr>
<tr>
<td>Doctor</td>
<td>2 (2.8%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Help with making a decision*</th>
<th>Time 1 (N = 71)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>29 (40.8%)</td>
</tr>
<tr>
<td>Family</td>
<td>18 (25.4%)</td>
</tr>
<tr>
<td>Doctor</td>
<td>6 (8.5%)</td>
</tr>
<tr>
<td>Family &amp; doctor</td>
<td>2 (2.8%)</td>
</tr>
<tr>
<td>Nurse</td>
<td>2 (2.8%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (1.4%)</td>
</tr>
</tbody>
</table>

*One person failed to answer this question

Descriptive statistics on the measures of the psycho-social variables are presented in Table 12. This table shows that the mean values for all three psycho-social variables at all three time points were high suggesting patient satisfaction with the information given, trust in the physician, and social support were good throughout the entire chemotherapy process and one month after treatment was complete.
### Table 12: Descriptive statistics on psycho-social variables measured

<table>
<thead>
<tr>
<th>Psycho-social measures</th>
<th>Possible range</th>
<th>Time 1 (N = 71)</th>
<th>Time 2 (n = 65)</th>
<th>Time 3 (n = 57)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient satisfaction</td>
<td>M (SD)</td>
<td>0 - 65</td>
<td>52.9 (8.13)</td>
<td>52.1 (9.11)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient trust</td>
<td>M (SD)</td>
<td>0 - 12</td>
<td>11.4 (1.26)</td>
<td>11.2 (1.65)</td>
</tr>
<tr>
<td>Patient social support</td>
<td>M (SD)</td>
<td>0 - 20</td>
<td>17.7 (3.14)</td>
<td>17.3 (3.59)</td>
</tr>
</tbody>
</table>

*Patient satisfaction was based on 56 patients at Time 3 due to one patient having more than 50% missing values for this scale.*
Research question 1

Does patient knowledge of chemotherapy improve when the experience of chemotherapy is added to the pre-treatment information given to obtain informed consent?

Patient knowledge of information was measured by asking the patients three main questions at each of the three time points and these were as follows:

1. Do you know how many drugs are/were in your chemotherapy regimen?
2. Do you know the name of the chemotherapy drug(s) that you are/were receiving?
3. Do you know the potential side effects listed on the information sheet and consent form?

Knowledge measure one: number of chemotherapy drugs received

A K Related Samples test (Cochran’s Q) showed that there were no significant differences over the chemotherapy course with regards to recall of number of drugs received (Table 13).

Table 13: Patient knowledge of the number of chemotherapy drugs from Time 1 to Time 3

<table>
<thead>
<tr>
<th>Knowledge question</th>
<th>N</th>
<th>Time 1</th>
<th>Time 2</th>
<th>Time 3</th>
<th>Cochran’s Q</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct knowledge of number of drugs</td>
<td>57</td>
<td>34 (59.6%)</td>
<td>39 (68.4%)</td>
<td>36 (63.2%)</td>
<td>2.24</td>
<td>.33</td>
</tr>
</tbody>
</table>

* Number and percentage of patients correctly recalling number of drugs

A line graph was drawn, regardless of statistical significance, to determine the trend of knowledge of the information over time with regards to number of drugs received. This suggests that the peak of correct knowledge of the chemotherapy drug numbers occurred at the fourth chemotherapy cycle and although patients were less likely to have knowledge of this information after chemotherapy had finished, there was only a slight reduction in recall between these time points. In fact patients knew their correct number of drugs post chemotherapy more so than at the second chemotherapy cycle. Therefore this graph indicates a trend toward an increase over time, despite not reaching significance (Figure 6).
Knowledge measure two: name of chemotherapy drugs received

Patients were asked about the name of drugs they received and they were considered correct if they had the complete name given correctly. Patient knowledge of the name of drugs was found to significantly increase over time as presented in Table 14. As mentioned previously, the range of the number of chemotherapy drugs received by patients as part of their regimen was between one and five which was an average of three drugs per patient. Between 11% and 26% of the patients were able to completely name one or more of the chemotherapy drugs depending on the time they were approached during or after treatment. In order to measure changes over time, a K Related Samples test (Cochran’s Q) was used.
Table 14: Patient knowledge of the chemotherapy drug names from Time 1 to Time 3

<table>
<thead>
<tr>
<th>Knowledge question</th>
<th>N</th>
<th>Time 1 n(%)*</th>
<th>Time 2 n(%)*</th>
<th>Time 3 n(%)*</th>
<th>Cochran’s Q</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct knowledge of drug names</td>
<td>57</td>
<td>6 (10.5%)</td>
<td>8 (14.0%)</td>
<td>15 (26.3%)</td>
<td>8.93</td>
<td>.01</td>
</tr>
</tbody>
</table>

Three Wilcoxon Signed Ranks tests were carried out to determine where the significant change occurred. These results are shown below in Table 15. While no significant difference in patient knowledge of the drug names was evident from the second to the fourth chemotherapy cycle, there was a small effect according to the r value calculated. Similarly, there was a small trend towards significance in recall between the fourth chemotherapy cycle and one month after completion of chemotherapy treatment (Figure 7).

Figure 7: Proportion of patients who had complete knowledge of the name of chemotherapy drugs given over the three time points
Clearly, the statistically significant difference occurred across the whole time period, specifically from the patients’ second chemotherapy cycle to one month after chemotherapy treatment completion. This effect was small-to-moderate as shown in Table 15.

Table 15: Changes in the knowledge of drug names between two time points

<table>
<thead>
<tr>
<th>Correct recall of drug names (n = 57)</th>
<th>Z value</th>
<th>p</th>
<th>r</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time 1-Time 2</td>
<td>-1.34</td>
<td>.18</td>
<td>.11</td>
</tr>
<tr>
<td>Time 2-Time 3</td>
<td>-1.94</td>
<td>.05</td>
<td>.17</td>
</tr>
<tr>
<td>Time 1-Time 3</td>
<td>-2.50</td>
<td>.01</td>
<td>.22</td>
</tr>
</tbody>
</table>

r = effect size, .10 = small, .30 = moderate, and .50 = large effect

This still indicates that a large proportion of patients did not have knowledge of the names of drugs they received. It seems logical that they have greater knowledge of the number of chemotherapy drugs compared with the chemotherapy drug names as these are often too complex and difficult to comprehend.

Knowledge measure three: potential side effects of chemotherapy

The third measure of patient knowledge and probably the most vital is that of chemotherapy side effects. Each chemotherapy treatment had a specific number of side effects associated with it and these were listed in the information sheet and consent form given to patients at the time of consent. Scores were calculated by dividing the number of correct knowledge of the side effects by the number of side effects listed on the information sheet and consent form supplied to the individual patient.

A one-way repeated measures ANOVA was carried out to determine whether patients remembered a greater number of side effects with treatment experience. Results obtained from this analysis suggest that participants’ knowledge of potential side effects did not significantly increase over time [Wilks’ Lambda = .98, F(2, 55) = 0.65, p = .52, partial η² = .02].
This result, although not significant, shows a small magnitude of change suggesting that perhaps with increased power this result may have been significant if this result is reliable in a larger sample.

The line graph below demonstrates the pattern of patient knowledge of side effects (Figure 8). It indicates, although not significant, that the peak of side effect knowledge of patients was at the fourth chemotherapy treatment, perhaps due to this being a time where they experienced the most toxicities of the treatment. Nevertheless this increase was only a matter of 1%.

![Line graph showing patient knowledge of side effects over time.]

**Figure 8**: Percentage of knowledge of the proportion of chemotherapy side effects

Common side effects remembered by patients were all transient side effects. Those frequently recalled by patients, in order of frequency, were nausea, hair loss, fatigue, mouth ulcers, vomiting, diarrhoea, and constipation. However, most patients did not have knowledge of the major side effects such as fertility and chest pain. The following table outlines all side effects recalled (Table 16).
Table 16: List of side effects that patients had knowledge about at each time point

<table>
<thead>
<tr>
<th>Side effects</th>
<th>Time 1</th>
<th>Time 2</th>
<th>Time 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N (%)</td>
<td>n/N (%)</td>
<td>n/N (%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>39/71 (55%)</td>
<td>38/65 (58%)</td>
<td>25/57 (44%)</td>
</tr>
<tr>
<td>Hair Loss</td>
<td>38/71 (54%)</td>
<td>30/65 (46%)</td>
<td>23/57 (40%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>25/71 (35%)</td>
<td>24/65 (37%)</td>
<td>23/57 (40%)</td>
</tr>
<tr>
<td>Sore mouth</td>
<td>22/71 (31%)</td>
<td>24/65 (37%)</td>
<td>19/57 (33%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>15/71 (21%)</td>
<td>10/65 (15%)</td>
<td>10/57 (18%)</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>14/71 (20%)</td>
<td>12/65 (18%)</td>
<td>13/57 (23%)</td>
</tr>
<tr>
<td>Constipation</td>
<td>12/71 (17%)</td>
<td>12/65 (18%)</td>
<td>9/57 (16%)</td>
</tr>
<tr>
<td>Heart damage</td>
<td>4/53 (8%)</td>
<td>0/51 (0%)</td>
<td>3/47 (6%)</td>
</tr>
<tr>
<td>Sensitive Skin</td>
<td>5/71 (7%)</td>
<td>9/65 (14%)</td>
<td>5/57 (9%)</td>
</tr>
<tr>
<td>Bone marrow suppression</td>
<td>3/71 (4%)</td>
<td>0/65 (0%)</td>
<td>3/57 (5%)</td>
</tr>
<tr>
<td>Bowel/bladder bleeding</td>
<td>2/55 (4%)</td>
<td>1/52 (3%)</td>
<td>3/43 (7%)</td>
</tr>
<tr>
<td>Nail changes</td>
<td>2/71 (3%)</td>
<td>0/65 (0%)</td>
<td>1/57 (2%)</td>
</tr>
<tr>
<td>Taste changes</td>
<td>1/71 (1%)</td>
<td>4/65 (6%)</td>
<td>3/57 (5%)</td>
</tr>
<tr>
<td>Fertility</td>
<td>0/71 (0%)</td>
<td>1/65 (2%)</td>
<td>2/57 (2%)</td>
</tr>
<tr>
<td>Chest pain</td>
<td>0/51 (0%)</td>
<td>0/46 (0%)</td>
<td>0/42 (0%)</td>
</tr>
<tr>
<td>Tissue Injury</td>
<td>0/71 (0%)</td>
<td>1/65 (2%)</td>
<td>0/57 (0%)</td>
</tr>
<tr>
<td>Muscle and bone pain</td>
<td>0/19 (0%)</td>
<td>3/18 (17%)</td>
<td>3/15 (20%)</td>
</tr>
</tbody>
</table>
**Research question 2**

Are patients satisfied with the information provided pre-treatment and does this change over the chemotherapy treatment period?

A parametric repeated measures ANOVA was conducted to measure the level of satisfaction of patients at the three time points, with the information given. Results indicated a significant, moderate effect for time [Wilks’ Lambda = .89, F(2, 54) = 3.47, p = .04, partial $\eta^2 = .11$]. This suggests that there was a change in satisfaction scores across the three different time periods, as shown in Figure 9.

![Mean level of patient satisfaction](image)

**Figure 9** Mean level of patient satisfaction with information over the three time points

The maximum actual range of scores for patient satisfaction with the information given was between 15 and 65 at Time 3 (of a possible range of 0 - 65). Patients were most satisfied with the information at the second chemotherapy cycle and over time their satisfaction decreased. Of a total of 65 points, the highest mean patient satisfaction score was 52.64 (SD = 8.16) at the second chemotherapy cycle which reduced to a mean of 49.45 (SD = 10.97) one month post chemotherapy.
Therefore post hoc analyses were conducted to compare each pair of time points and determine where the difference in satisfaction was significant. Table 17 shows the pairwise comparisons (post hoc analyses) between two time points. It is clear that the significant difference was between Time 1 and Time 3. In other words, patients were significantly more satisfied at the beginning stages of treatment compared with post-treatment and this negative change over time was considered moderate in magnitude.

**Table 17**: Pairwise comparison of patient satisfaction at two time points

<table>
<thead>
<tr>
<th>Time Comparisons</th>
<th>Mean difference</th>
<th>SE</th>
<th>p</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2</td>
<td>1.42</td>
<td>1.26</td>
<td>.79</td>
<td>-1.69</td>
<td>4.54</td>
</tr>
<tr>
<td>2 3</td>
<td>1.76</td>
<td>1.12</td>
<td>.36</td>
<td>-0.99</td>
<td>4.51</td>
</tr>
<tr>
<td>1 3</td>
<td>3.18</td>
<td>1.24</td>
<td>.04</td>
<td>0.13</td>
<td>6.24</td>
</tr>
</tbody>
</table>

As specified in the Statistical Analyses section in the Methods, for all parametric variables that evidenced significant change across the three time points, reliable change indices (RCIs) were calculated to determine how meaningful the change was for each individual patient.

Table 18 shows the number of patients with positive, negative, or no reliable change in their total satisfaction scores for three different time periods. Specifically, RCIs have been calculated from the second chemotherapy cycle (Time 1) to the fourth chemotherapy cycle (Time 2), from the fourth chemotherapy cycle (Time 2) to one month post chemotherapy (Time 3), and then again from the second chemotherapy cycle (Time 1) to one month post chemotherapy (Time 3).
Table 18: Reliable change indices (RCIs) for total patient satisfaction with the information given

<table>
<thead>
<tr>
<th>Period</th>
<th>Time 1 to Time 2</th>
<th>Time 2 to Time 3</th>
<th>Time 1 to Time 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive reliable change</td>
<td>6</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Negative reliable change</td>
<td>8</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>No reliable change</td>
<td>51</td>
<td>45</td>
<td>43</td>
</tr>
</tbody>
</table>

Positive reliable change refers to satisfaction scores improving during the time period; negative reliable change refers to satisfaction scores worsening.

These results indicate that for the majority of patients there was no reliable change in patient satisfaction with the information across the three time points. There were only a small number of patients who had a positive reliable change in satisfaction scores (n = 9) and in most cases this was seen between Time 1 and Time 2 (n = 6). The highest number of patients for which satisfaction scores worsened were seen between the Time 1 and Time 3 period (n = 11).

Research question 3

Do patients have trust in the physician and does this change over the chemotherapy treatment period?

A parametric repeated measures ANOVA was conducted to determine the level of patient trust in their physician over the three time points and whether it significantly changed. Mean patient trust remained high at all three time points as highlighted in Figure 10. The maximum range of actual scores was between four and 12 of a possible range of 0 to 12 with mean trust often being around a mean of 11. There were no statistically significant changes found over time [Wilks’ Lambda = .98, F(2, 55) = .50, p = .61, partial \( \eta^2 = .02 \)], although the effect size indicated a small magnitude of change. Therefore, throughout the chemotherapy treatment patients had a high level of trust for their physician that did not significantly vary. Therefore, no further analyses were conducted as results were not significant.
Research question 4

**Do patients receive social support and does this change over the chemotherapy treatment period?**

A one-way repeated measures ANOVA was conducted to assess the level of social support of patients at the three time points and to determine whether it changed significantly. Mean social support was also high, as in patient trust, and similarly indicated a trend of decreasing over time (Figure 11). Unlike the patients’ level of trust, the change seen in social support showed statistical significance \([\text{Wilks’ Lambda} = .87, F(2, 55) = 4.10, p = .02, \text{partial } \eta^2 = .13]\), with the magnitude of change verging on a large effect.
Therefore post hoc analyses were conducted to compare each pair of the time points to determine where the difference in social support was significant. The table below shows the pairwise comparisons (post hoc analyses) between two time points (Table 19). The results show that a significant change in social support was seen between Time 1 and 3, as well as Time 2 and Time 3. This indicates that the mean difference in social support of patients after completion of chemotherapy had dropped significantly compared to their social support at the early stages of and during treatment.
Table 19: Pairwise comparison of social support of patients at two time points

<table>
<thead>
<tr>
<th>Time Comparisons</th>
<th>Mean difference</th>
<th>SE</th>
<th>p</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>0.08</td>
<td>0.38</td>
<td>1.00</td>
<td>-0.86</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>0.91</td>
<td>0.33</td>
<td>.03</td>
<td>0.09</td>
</tr>
</tbody>
</table>

As previously reported for patient satisfaction, as significant change occurred across the three time points for social support, RCIs were calculated to determine how meaningful the change was for each individual patient. Table 20 shows the number of patients with positive, negative, or no reliable change for social support scores for the three time periods (Time 1 to Time 2; Time 2 to Time 3; and Time 1 to Time 3).

Table 20: Reliable change indices (RCIs) for social support

<table>
<thead>
<tr>
<th></th>
<th>Time 1 to Time 2</th>
<th>Time 2 to Time 3</th>
<th>Time 1 to Time 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Period</td>
<td>Period</td>
<td>Period</td>
</tr>
<tr>
<td>Positive reliable change</td>
<td>4</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Negative reliable change</td>
<td>6</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>No reliable change</td>
<td>55</td>
<td>53</td>
<td>48</td>
</tr>
</tbody>
</table>

Positive reliable change refers to social support scores improving during the time period; negative reliable change refers to social support scores worsening

These results indicate that for the majority of patients there was no reliable change in patient social support scores across the three time points. There were only a small number of patients who had a positive reliable change in social support scores (n = 5) and similar to patient satisfaction, this was mainly seen between Time 1 and Time 2 (n = 4). Again, the highest number of patients for which social support scores worsened were seen between the Time 1 and Time 3 period (n = 8).
Research question 5

Are there particular demographic (age, gender, level of education) or psycho-social variables (patient satisfaction, trust, social support) that predict knowledge of information?

Firstly, in order to determine associations, if any, of patient knowledge of the consent information and demographic or psychosocial factors, univariate correlations were performed. Table 21 highlights variables that were correlated with the three measures of knowledge of the information given. Knowledge of the number of drugs correlated significantly with five demographic (age, gender, marital status, living alone, and public vs. private hospital) and two psycho-social variables (total satisfaction and total trust). Age, level of education, living alone, and social support were correlated with patient knowledge of the drug names while correct patient knowledge of the side effect information given was correlated with four demographic variables (age, gender, education, and public vs. private hospital) and one psycho-social variable (total trust).

Table 21: Demographic and psycho-social correlates of knowledge of information

<table>
<thead>
<tr>
<th>Variable</th>
<th>Knowledge of number of drugs r (p)</th>
<th>Knowledge of drug names r (p)</th>
<th>Knowledge of side effects r(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-.18 (.13)</td>
<td>-.20 (.01)</td>
<td>-.12 (.31)</td>
</tr>
<tr>
<td>Gender</td>
<td>.41 (.00)</td>
<td>.04 (.74)</td>
<td>.19 (.12)</td>
</tr>
<tr>
<td>Education</td>
<td>.04 (.76)</td>
<td>.22 (.06)</td>
<td>.24 (.04)</td>
</tr>
<tr>
<td>Marital status</td>
<td>.18 (.13)</td>
<td>.08 (.52)</td>
<td>.02 (.86)</td>
</tr>
<tr>
<td>English speaking</td>
<td>-.01 (.91)</td>
<td>.02 (.99)</td>
<td>.01 (.95)</td>
</tr>
<tr>
<td>Live alone</td>
<td>.11 (.36)</td>
<td>.14 (.24)</td>
<td>.01 (.93)</td>
</tr>
<tr>
<td>Attending hospital</td>
<td>.50 (.00)</td>
<td>.06 (.60)</td>
<td>.16 (.20)</td>
</tr>
<tr>
<td>Extent of information read</td>
<td>.10 (.41)</td>
<td>.28 (.02)</td>
<td>.21 (.08)</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>.29 (.02)</td>
<td>-.05 (.66)</td>
<td>.05 (.71)</td>
</tr>
<tr>
<td>Trust</td>
<td>.26 (.03)</td>
<td>.02 (.87)</td>
<td>.19 (.11)</td>
</tr>
<tr>
<td>Social Support</td>
<td>.03 (.98)</td>
<td>-.15 (.21)</td>
<td>-.04 (.75)</td>
</tr>
</tbody>
</table>

Bold numbers indicate those variables that correlated $r \geq .10$ to be added to regression models.
Before deciding whether to add all the variables specified to regression models, the inter-correlations between dependent variables were further assessed to see whether they met the assumptions of multicollinearity. For example, it was expected that measures of social support, being married, and living alone may share a large amount of variance, possibly making some of the dependent variables in models redundant. While the assumption of multicollinearity was met in that no dependent variables were correlated at $r = .80$ or above (Pallant, 2005), the results did show some interesting associations related to previous research.

Patient satisfaction, patient trust for the physician, and social support of patients were all positively and significantly correlated with each other. Patient satisfaction with the information given and trust in the physician were highly correlated ($r = .53$, $p = .000$). Satisfaction and social support were moderately correlated ($r = .34$, $p = .003$), as were social support and trust in the physician ($r = .35$, $p = .003$). Also, age was found to be significantly correlated with education in a negative direction, indicating that patients who were younger had a higher level of education ($r = -.31$, $p = .008$). Another interesting correlation identified was gender and trust for the physician. Being female was moderately associated with a higher level of trust for the physician ($r = .37$, $p = .002$). Living alone was only weakly associated with social support (and not significantly) with lower social support occurring in patients who lived alone ($r = -.12$, $p = .31$). Similarly, being married and level of social support were not significantly associated ($r = .07$, $p = .55$). The correlation matrix showing all associations between dependent variables is in Appendix E.

**Predictors of correct knowledge of number of chemotherapy drugs**

Once univariate correlates were determined, the variables were added to regression models. The findings from the first logistic regression in determining demographic and/or psycho-social predictors of patient knowledge of the number of drugs received are shown below. There was a significant model $[\chi^2(8, 70) = 30.72, p = .000]$ including two individually significant predictor variables: gender and private or public hospital attendance (Table 22). This model explained 47.8% of the variance (Nagelkerke R) which indicated that all the
dependent variables combined explained almost half of the variance on knowledge of patients on the number of drugs, and this model correctly classified 78.6% of patients.

**Table 22:** Logistic regression model describing predictors of knowledge of the number of drugs received

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>Wald</th>
<th>p</th>
<th>Odds Ratios</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-0.02</td>
<td>0.64</td>
<td>.42</td>
<td>0.98</td>
<td>0.92</td>
<td>1.03</td>
</tr>
<tr>
<td>Gender</td>
<td>-1.98</td>
<td>6.04</td>
<td>.01</td>
<td>0.14</td>
<td>0.03</td>
<td>0.67</td>
</tr>
<tr>
<td>Marital status</td>
<td>0.07</td>
<td>0.01</td>
<td>.93</td>
<td>1.07</td>
<td>0.24</td>
<td>4.88</td>
</tr>
<tr>
<td>Live alone</td>
<td>-1.04</td>
<td>0.64</td>
<td>.42</td>
<td>0.35</td>
<td>0.03</td>
<td>4.52</td>
</tr>
<tr>
<td>Attending hospital</td>
<td>-2.43</td>
<td>9.64</td>
<td>.00</td>
<td>0.09</td>
<td>0.02</td>
<td>0.41</td>
</tr>
<tr>
<td>Extent of information read</td>
<td>0.08</td>
<td>0.01</td>
<td>.91</td>
<td>1.08</td>
<td>0.27</td>
<td>4.33</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>0.07</td>
<td>2.16</td>
<td>.14</td>
<td>1.07</td>
<td>0.98</td>
<td>1.17</td>
</tr>
<tr>
<td>Trust</td>
<td>-0.22</td>
<td>0.60</td>
<td>.44</td>
<td>0.80</td>
<td>0.46</td>
<td>1.40</td>
</tr>
</tbody>
</table>

This means that together, the variables that formed the model significantly predicted knowledge of the information. Of particular note, being female and being a private hospital attendee individually predicted patient knowledge of the number of drugs in their chemotherapy regimen making them the strongest, unique predictors. Although not statistically significant, other variables contributed small amounts to this model including being younger, married, not living alone, having read a greater extent of the information, a high level of satisfaction, and a low level of trust.

**Predictors of correct knowledge of chemotherapy drug names**

Five predictor variables were identified for knowledge of chemotherapy drug names. The model was found to be significant \( \chi^2 (5, 70) = 12.61, p = .03 \) suggesting a combination of the variables predicted knowledge. However no individual independent variable was strong enough to be a unique predictor above and beyond the others (Table 23). This could have been
due to compromised power. The model was found to explain 32.4% of the variance (Nagelkerke R) and correctly classified 90.0% of patients.

**Table 23:** Logistic regression model describing predictors of knowledge of the name of drugs received

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>Wald</th>
<th>p</th>
<th>Odds Ratios</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-0.03</td>
<td>0.49</td>
<td>.48</td>
<td>0.97</td>
<td>0.89</td>
<td>1.06</td>
</tr>
<tr>
<td>Education</td>
<td>-1.17</td>
<td>1.96</td>
<td>.16</td>
<td>0.31</td>
<td>0.06</td>
<td>1.60</td>
</tr>
<tr>
<td>Live alone</td>
<td>-17.24</td>
<td>0.00</td>
<td>1.00</td>
<td>0.00</td>
<td>0.00</td>
<td>-</td>
</tr>
<tr>
<td>Extent of information read</td>
<td>-19.61</td>
<td>0.00</td>
<td>1.00</td>
<td>0.00</td>
<td>0.00</td>
<td>-</td>
</tr>
<tr>
<td>Social support</td>
<td>-0.12</td>
<td>0.98</td>
<td>.32</td>
<td>0.89</td>
<td>0.71</td>
<td>1.12</td>
</tr>
</tbody>
</table>

Although no individually significant predictors were found, the variables contributing small amounts to this model appeared to be younger patients, having a lower level of education, not living alone, not reading the information given and a low level of social support.

**Predictors of correct knowledge of chemotherapy drug side effects**

A standard multiple regression was conducted to determine whether any demographic or psycho-social variables predicted patient knowledge of chemotherapy side effects because the dependent variable was continuous. This model was not found to be significant (n = 70, Adjusted R Square = .058, F = 1.71, p = .13), explaining only 6% of the variance and hence the variables, although correlated to some degree, when combined, were not significantly predictive of patient knowledge of chemotherapy side effects (Table 24).
Table 24: Standard multiple regression model of predictors of recall of chemotherapy side effects

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unstandardised Coefficients</th>
<th>Standardised Coefficients</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>SE</td>
<td>β</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>-0.05</td>
<td>0.14</td>
<td>-0.04</td>
<td>-0.34</td>
</tr>
<tr>
<td>Gender</td>
<td>4.25</td>
<td>3.64</td>
<td>0.15</td>
<td>1.17</td>
</tr>
<tr>
<td>Education</td>
<td>5.70</td>
<td>3.19</td>
<td>0.23</td>
<td>1.79</td>
</tr>
<tr>
<td>Attending hospital</td>
<td>0.18</td>
<td>3.13</td>
<td>0.01</td>
<td>0.06</td>
</tr>
<tr>
<td>Extent of information read</td>
<td>4.52</td>
<td>2.96</td>
<td>0.18</td>
<td>1.53</td>
</tr>
<tr>
<td>Trust</td>
<td>0.76</td>
<td>1.17</td>
<td>0.08</td>
<td>0.65</td>
</tr>
</tbody>
</table>
Discussion

Several key findings were identified from this longitudinal investigation. Patient knowledge of the number of drugs was found to be reasonably high at all three time points assessed in this study. Chemotherapy experience did not improve patient knowledge with regards to the number of chemotherapy drugs received over three time points. At the second chemotherapy cycle, almost two thirds (60%) of patients knew the number of drugs they were receiving as part of their chemotherapy regimen and this showed an increased trend by the fourth chemotherapy cycle (68%, ns). However, the trend dropped slightly to 63% by one month post-chemotherapy. One possible reason for this trend in knowledge is that often patients receive two different chemotherapy regimens. In the one course, for example, a breast cancer patient may have three cycles of FEC (Fluorouracil, Epirubicin, and Cyclophosphamide) followed by three sets of Paclitaxel. This change may lead to confusion towards the precise number of drugs received and hence may have been the cause of the small drop in patient recall between patients’ fourth chemotherapy and one month post chemotherapy assessments. Another factor that may have altered patient knowledge is the fact that some patients were receiving anti-emetic drugs, and they may have counted this to be one of the number of chemotherapy medications, hence making their score incorrect. Based on the data collected, it is not possible to identify this but this result should only impact on percentage of knowledge at each time point, rather than knowledge changes over time as this is believed to be a consistent problem throughout their treatment experience. Nevertheless, this can be considered for improving future research on patient knowledge of the information given. An alternative reason may be that patients may not remember the number of drugs they are receiving as they do not believe this to be an important factor.

On the other hand, patient knowledge of the name of drugs was very low among the patients however it was found to significantly improve across the three time points, suggesting more patients picked up this knowledge with experience. Patients had the least knowledge regarding the name of the drugs at their second chemotherapy cycle (Time 1).
The study found 11% of patients to have knowledge of the drugs names at the second chemotherapy cycle compared with 25% at the same time point in the study by Olver and colleagues (1995). This may be because the patients were receiving different types of chemotherapy and therefore different regimens however it was not clear from Olver et al.’s study what types of cancer patients were included other than they were receiving cytotoxic chemotherapy. The demographic characteristics of patients in this study compared with that of Olver and colleagues was reasonably similar with the only difference being the proportion of females was much greater in this longitudinal study. Olver and colleagues’ study also had a larger sample size (N = 100).

Nonetheless, this study found the biggest improvement to be from the second chemotherapy treatment to one month after completion of treatment, at which time, 26% of patients knew their drug names. This significant change may be due to the poor knowledge of many patients at the second chemotherapy cycle, and with the experience of treatment, such as watching the drugs being administered, improvements in knowledge were seen. Although there was about a 15% improvement in knowledge, a large proportion of patients still were not aware of the names of drugs they were receiving.

Chemotherapy experience did not improve patient knowledge of the side effects of chemotherapy when assessed over three time points, however the findings showed a small effect size which may suggest that with increased power, this change may be significant. Patients only knew 20% of the potential side effects of their treatment. Despite patients having knowledge of only one-fifth of side effects, this appeared to be similar to findings from Olver et al.’s (1995) study that found two-fifths of patients (42%) recall zero to 25% of the side effects, at their second chemotherapy cycle. The common side effects that patients knew about were mainly transient side effects such as nausea, hair loss, fatigue, mouth ulcers, vomiting, diarrhoea, and constipation. The side effects information sheet of the chemotherapy drugs which were received by all patients included these transient side effects on the first page. This was consistent across all of the different regimens of patients in this study as it was believed the short-term side effects were commonly reported in the first page. The short-term side effects such as nausea and fatigue were widespread side effects across many chemotherapy
drugs. This may form some explanation for the greater level of knowledge of these side effects. In addition, the high likelihood of patients experiencing these transient side effects repeatedly throughout their chemotherapy treatment may also justify higher knowledge of these. It was easy for patients to recall the side effects they were currently experiencing at the time knowledge was assessed.

From the three measures of patient knowledge of the information given, knowledge of the number of drugs was found to be the greatest. It seems logical that patients have greater knowledge of the number of chemotherapy drugs compared with the chemotherapy drug names as these are often too complex and difficult to remember. However the most important factor for patients to have knowledge on is the side effect information given. This is because if patients are not aware of the side effects they may not be aware of what to avoid, what to take, or what to do if some event occurs. For example, some chemotherapy drugs make the skin sensitive to the sun, however if patients do not have knowledge of this, they will not know to avoid the sun or at least apply sun block and wear protective clothing.

The psycho-social variables measured, that is, patient satisfaction, trust for their physician, and social support were found to be high at all three time points. Satisfaction of patients with the information given was found to significantly decrease across the three time points and this was found to have a moderate magnitude of change. The biggest change was seen between the second chemotherapy cycle and one month post chemotherapy treatment which was found to be significant. However for the majority of patients, there was no reliable change in patient satisfaction scores across the three time points with only a few patients experiencing positive reliable change and only a few more experiencing negative reliable change.

Regardless, patients seemed to be very satisfied with the information at all time points despite patients showing small improvements in knowledge of the consent information with their treatment experience. A Canadian study found the opposite of this, that satisfaction was positively correlated with recall of the information, such that an increase in recall was associated with an increase in patient satisfaction (Hack et al., 1999).
Trust for the physician was also high at all three time points however this was not found to significantly change across the time points although a small effect size was identified. There was however a small downward change over the chemotherapy cycles which may be suggestive of patients showing a great deal of trust at the beginning of treatment when they believe they need it most and by the end of treatment trust may slightly drop off because the patients experience side effects or problems with their treatment. This may also be indicative of low test re-test reliability of this subscale. However, what this reliability is for the subscale is currently unknown.

The level of social support of the patients was also high at all three time points but was found to decrease over time. Like patient satisfaction, this change was found to be significant and the magnitude of the change was verging on large. This suggests that social support of patients was highest at the early stages of the treatment, when patients most probably needed it the most but diminished over time. By one month after chemotherapy, patients’ friends and relatives may not have felt that patients needed the high level of support that they needed at the initiation stages of treatment. Alternatively this could have also been an artifact of low test re-test reliability, although this is not known about this subscale. Regardless of this reduction, patients continued to receive a high level of support even during the late stages and completion of treatment. Between Time 2 and Time 3, and Time 1 and Time 3, where significant differences were seen, there were not many individual cases of reliable change. Also, with regards to all three psycho-social variables, as they were all rated highly by patients, they may have shown ceiling effects and therefore differences may not be seen across the three time points.

Social support was moderately associated with patient satisfaction and trust for the physician in that patients were satisfied and had a high level of trust therefore did not appear to need or did not themselves seek social support. Patients continued to trust their physician throughout their chemotherapy treatment and this was also highly, positively associated with patient. This is also consistent with findings from previous studies reported in Chapter Five (Safran et al., 1998; Thom et al., 2002)
Several factors were found to be associated and in turn predictive of patient knowledge of information based on univariate correlations and more complex regression models. Univariate analyses showed that age and the extent of reading the information were the two variables that were correlated (≥ .01) with all three measures of information knowledge in this study. In other words, younger patients and a greater extent of reading the information were associated with improved knowledge of the information given. However, only patient knowledge of the chemotherapy drug names was found to significantly correlate with these two variables. It may be that as the names are complicated and often long, older patients are unable to understand them as well as younger patients. Alternatively it may be that by visualization through reading the information on the chemotherapy drugs, they become aware of the names. This finding confirms findings of previous research regarding the significance of these two factors in predicting patient knowledge of information (Cassileth et al., 1980; Olver, Turrell et al., 1995).

Univariate analyses also showed that, of the psycho-social variables measured, only trust for the physician was found to correlate, weakly to moderately, with two of the three measures of knowledge of the information given. It appeared that knowledge of the number of drugs and potential side effects was positively impacted by the level of patient trust of which the former measure showed significance. While it is assumed that if patients trust their physician, they are less likely to recall the information given to them, as they may, in a sense, ‘take their word for it’ the opposite of this was found. This means that patients who had a high level of trust for their physician were more likely to have knowledge of the information that is given to them.

Two regression models of patient knowledge were found to be significant, specifically, significant models were found for explaining knowledge of the number of chemotherapy drugs and the name of chemotherapy drugs. Common factors in both models were age, living alone, and extent of information read although none of these were individual predictors of patient knowledge of the number or name of drugs. Gender and attending hospital, in other words, females and patients being treated in private hospitals were found to be significant individual predictors of the knowledge of the number of drugs received. This finding may be related to the higher socio economic status of private patients which in turn may imply a greater concern
for their health. Socio-economic status is commonly accepted to be positively associated with education, however the patients’ level of education did not form part of this significant model.

The two significant models for knowledge of the name and number of chemotherapy drugs explained one third to half of the variance, respectively which indicates that there are other predictors that explain the remaining variance. Therefore future research should focus on identifying other novel or under-researched factors that may be predictors of knowledge of the information given.

There were two main limitations of this study and these were the small sample size, particularly at Time 3, which included 57 patients. Also, at one month post chemotherapy treatment some patients had to be sent the questionnaire which may impact on their knowledge of the information given. In this way, patients may use the information sheet and consent form to fill in the questionnaire. Every attempt was made for patients to complete these questionnaire while at the hospital, however, in some cases, they would not attend the hospital around one month after their treatment therefore they were sent the questionnaires.

The next chapter (Chapter Eight) shows the findings of an in-depth analysis of the research questions which may be able to better explain what has been found quantitatively here.
Chapter 8: Qualitative study

Introduction

A qualitative thematic analysis forms the second component of the mixed methods approach of this thesis. This additional empirical investigation aims to further explore the effects of treatment experience on patient knowledge of the information given as well as expand on significant facets identified in the quantitative study provided in Chapter Seven. The mixed methods design is an emerging research approach which has seen much debate over the years, but has many advantages, one of which is triangulation. Methodological triangulation is the process of using more than one method to investigate the same phenomenon (Denzin, 2006). Doing this strengthens the validity of results and credibility of qualitative analyses (Cohen & Manion, 2000). The purpose of this qualitative study is not only to test the consistency of findings found against the longitudinal study through triangulation, but it aims to further explore aspects for which objective evaluation, achieved quantitatively, does not suffice.

The basis for this study was also the primary interests of the longitudinal study however, further exploration outside of these aims were not dismissed. The aims were as follows:

1) To determine patients’ knowledge of the necessary treatment information that was given at the time of consent;

2) To identify whether patients are satisfied and the degree of satisfaction about the provision and quality of treatment-related information; and

3) To explore particular psycho-social factors that may impact on patient knowledge.
Method

The study sample consisted of purposely selected patients from the larger sample of patients who participated in the longitudinal quantitative study provided in Chapter Seven. Purposive random sampling was used to select a subgroup of patients. This hybrid approach involves the selection of a group of patients at random from amongst the large sample collected. A random sampling approach was used to allow for minimization of bias. The sample size was based on achievement of data saturation for the prominent qualitative theme of interest, an approach common in qualitative methodology. The prominent themes were trust for the physician and social support of patients as there is limited literature available on these, as discussed in Chapter Five. Trust was also a predictor variable of knowledge of the information given measured in the quantitative longitudinal study, discussed in Chapter Seven. Briefly, trust for the physician formed was the only psycho-social variable that formed part of two regression models. Of these, one was a significant model, that of, the knowledge of the number of chemotherapy drugs received. In this model, trust for the physician was not an individually significant predictor. Recruitment ceased when no additional information concerning patient trust for the physician and social support was forthcoming. Therefore the sample obtained was 10% of patients who completed Time 3 data for the quantitative study (n = 6).

An in-depth semi-structured interview was used to collect data. It was purposefully semi-structured to allow for both fixed questions to be asked as well as open-ended questions whereby patients are given the opportunity to discuss their thoughts and opinion. These interviews took place upon completion of the patients’ final chemotherapy cycle after the final data collection for the longitudinal quantitative study. The semi-structured interviews were conducted using an interview schedule which began with a preamble of the study and then the main interview consisting of 12 main questions, as seen in Appendix D. Prompts, also shown in Appendix D, were given if necessary but avoided when possible to allow for the expression of issues that are of salience to the patients and which may constitute a novel theme. The interview took place at a time and place chosen by the participant, which in some cases was in their home and in other cases, at the Royal Adelaide Hospital Cancer Centre.
Face-to-face interviews were conducted instead of telephone interviews to gain maximum benefit from patients expressing responses and allowing patients to feel more comfortable answering questions regarding their experience of chemotherapy treatment. It also meant that the interviews were able to be audio-taped after gaining permission from the patient and assuring them that anything they said would remain confidential.

**Qualitative analysis**

*Theoretical background and procedure*

In qualitative research there are numerous paradigms and theoretical frameworks that guide researchers in their investigation. The principle of informed consent was developed in biomedical ethics as a way for physicians to promote autonomous decision-making on the part of their patients. This has been described in Chapter One to consist of five fundamental elements of which information disclosure and patient comprehension constitute two of these (Beauchamp & Childress, 2001; Milton, 2000). Clearly, patient knowledge of the medical information given will benefit many aspects of the treatment process including good adherence to treatment, satisfaction, anxiety, creating realistic expectations, and coping mechanisms. Physicians may also feel more comfortable knowing that patients have knowledge of the information given to them.

Furthermore, as discussed in Chapter Five, while psychosocial and demographic factors such as anxiety have received widespread recognition with respect to their impact on patient knowledge of treatment information, to date, limited data is available on the impact of two important factors; patient trust for their physician and patients’ social support. In order to investigate these concepts, a thematic analysis was undertaken. A framework analysis approach was found to be an appropriate method, as it aims to describe phenomena about which little or a lot is known, while ensuring the research stays focused and deductive as *a priori* determination of themes can be made. This approach involves four main stages

- **Familiarisation** - this is where one becomes familiar with the data as it is being transcribed and read. It may involve writing any developing ideas and arising concepts that need to be further explored.
• Identification of thematic framework - at this stage, all of the key issues, concepts, and themes are identified and categorised into groups which can be refined or expanded as the analysis develops. This involves inductive and deductive methods.
• Coding - this involves compiling the data for each of the codes that have been developed.
• Mapping and interpretation – this is the last step of relating the themes developed to the research questions.

Audio-taped interview discussions were initially transcribed and then the data were organised and structured in order to code the prominent themes using NVIVO 7.0 computer package. Following this, the items that fell under each code (or node) were combined or expanded into themes. Themes, in this situation, refer to recurring opinions or perceptions about certain treatment related events. These themes were interpreted using direct quotes from the interview to illustrate the line of reasoning. Conclusions were drawn and these were based on the research questions.
Results

Participants

Participants were recruited from three cancer centres in Adelaide, namely the Royal Adelaide Hospital Cancer Centre, Ashford Cancer Centre, and The Brian Fricker Oncology Centre. The first is a public hospital while the latter two are private cancer centres. Of the 71 men and women who took part in the longitudinal study described in Chapter Seven, six women with breast cancer (10% of the Time 3 sample of 57 patients) agreed to participate in the in-depth qualitative interview. Although purposive sampling was used to achieve this 10%, two things impacted on this (1) some people who were randomly selected actually declined, therefore a certain degree of the patients had to be randomly re-selected, and (2) more women comprised the original sample due to inclusion of breast cancer patients, a higher proportion of females agreed to participate in the longitudinal quantitative research, and more women completed Time 3 data, therefore at Time 3, the sample comprised of 79% females, so all participants in this section ended up being female. This interviewing continued until data saturation of the prominent themes were achieved and no further patients were approached beyond this.

The six women who provided interview data all had breast cancer, were all married with children and had secondary or higher education, and more than 50% were white collar or professional workers (n = 4). Even numbers of women constituted private and public patients. The participants’ ages ranged from 47 to 63 years, with a mean age of 52.3 years (SD = 6.2). Interviews with patients lasted between 20 and 90 minutes.

Emergent themes

Defining informed consent

Patients were initially asked about what they understood the term ‘informed consent process’ to mean. The idea behind this question was to establish at the forefront whether they knew what informed consent meant. If patients were not familiar with the meaning, it would have needed to be explained so that the remaining questions were answered with consistent understanding of the term rather than phenomenological interpretation.
The informed consent process was defined in Chapter One as being a process made up of five elements: (1) disclosure, (2) competence, (3) comprehension, (4) voluntariness, and (5) consent (Beauchamp & Childress, 2001; Milton, 2000). None of the patients made reference to all of these factors however informed consent to treatment was recognised by patients to be a process which is three-fold; being given treatment information (disclosure) and agreeing to have the treatment (consent), as shown by direct patient quotes below. Also, patient accounts overall showed that they recognised the process to be voluntary. When specifically asked about what the process of informed consent meant to them, four patients suggested the following:

**Process**

Having been given information, the relevant information, me having had the opportunity to read it and ask other questions about that and then after doing that to agree to going ahead with. 

P1

Have I been informed about what my treatment will do to me, what side effects I will have and am I consenting to it. Do I agree to have the treatment, um? P2

**Treatment information**

What actually is happening and the risks, I suppose the benefits and risks and [sic] of the treatment. 

P3

The good and the bad, the pros and the cons, and all the side effects and outcomes that are expected. 

P4

Patient knowledge of the meaning of informed consent and what it entails, exemplifies the transition from the passive to the active role of treatment decision-making, as patients in previous decades may have only believed it to be a legal doctrine. Patients acknowledged that the information sheet and consent form consisted of treatment benefits and risks, and potential side effects. If patients had not read this information, they would not have known that it was made up of such components and therefore this was an indicator that patients had read at least part of the information given to them.
This is consistent with the findings from the longitudinal study which indicated that the majority of patients read all or part of the information given. Patients did not, however, mention why it was important for them to have knowledge of the information given on the information sheet and consent form. Although not a running theme amongst patients, one interesting finding was the notion that the patient felt as if *they* had to make the decision, not because of self-determination, but simply to avoid blaming others, if something went wrong: “If my husband had said, ‘look you should definitely have it’ and I got very sick, you know, you can imagine the emotional problems surrounding that so I knew it was a decision that I had to make myself” (P1). This particular account refers to a woman who does not want to blame her husband, which is a novel thought, as much research has focused on the relationship between the patients’ informed consent and avoiding blaming the physician. Indeed, this thesis, in part, stems from the notion that patient consent should be valid to avoid future litigation. In other words, patients should have knowledge of the material information regarding their treatment so that they can create realistic expectations.

Nevertheless, further exploration of patient knowledge of the information given, revealed a theme, that is, the perceived importance of the information given on the information sheet and consent form. At the time of discussing the meaning of informed consent, patients were also asked about the information sheet and consent form which they were given but they did not discuss either of these documents. Rather patients appeared to focus the conversation on three main factors that they perceived to be important determinants of treatment decision-making; physician trust, family values, and optimism/trust in the treatment. An exploration of the three identified factors is given below:

**Physician trust**

Indeed, the most prominent theme that arose from the qualitative interviews regarding the consent process was patient trust for the physician. All six women raised the topic prior to being prompted. Specifically, trust of their physician was found to be a strong determinant to their informed decision-making as stated by the following patients:

This is the recommended treatment for you and you put your trust in your doctor  P2
It started with the doctor, with the surgeon who said, who suggested that I should have it in my interests and from there on I followed her advice. Whatever she suggested I did, whatever she thought was the right thing to do, so when I went to see oncologist basically I already consented even prior to seeing him.  

They gave me a copy to take home with me but I never took it out again um she read it all through for me, so what was the point. I was quite happy with the way they did that.

No doubt, when patients were, later in the interview, specifically asked about the physician’s role and their trust for their physician, they all had very strong positive opinions towards it.

I thought about it a lot and as I say my surgeon, I had a hell of a lot of trust in him.

I think your attitude is different when you are trusting your doctor and I personally feel if you if you trust your doctor, if you thinking positive, ah, if you calm, not stressed, I think you go through the whole thing a lot better than when your stressed or you’re not sure or if you doubting your surgeon.

The key concept here, though, was to find an explanation for this association of informed consent to adjuvant chemotherapy and physician trust. In other words, what attributes of the physician build trust in the patients? The emerging dominant feature was the physicians’ expertise, as shown below:

I pretty much trust them and their judgment, that’s what their expertise is.

You just have to, you have to with especially some things that you are not expert yourself in you have to just have faith or trust in those who are.

One woman pointed out that her trust was built on … “her [physician’s] attitude, her manner” (P5). Another patient alluded to the fact that trust in their physician came with being acquainted with the physician. This was a novel finding that suggests the length of the relationship between the patient and the physician may impact on their trust levels. This may have come about due to the patient’s experience in a busy oncology setting where patients may not always see the same physician.
There is a number of doctors that you had and nobody sort of had you following through sort of thing. I think if we’d had the same doctor all the time as you were going through, you would have had a bit more faith in them’….you’ve got the doctor that actually tells you what treatment you are going to go through. He has given you confidence in him…. couple of times, the different doctors that I have had said oh I can’t see your pathology report here. I’m like it’s in there somewhere…and then their sitting there going through it. It’s like nobody has done any homework at all on it sort of thing.

Evidently there may be more than being a doctor with expertise to build trust in patients. While some patients may find physician characteristics give them confidence, others need to build an ongoing relationship with the physician before having trust in them. On the other hand, the interviews revealed that several patients believe they just have to trust the doctor, which signifies patients may still believe in the physician having decisional authority. However all patients at some stage in the interview pointed out that they were aware of their right to refuse treatment, therefore it cannot be that they lack of awareness of patient autonomy. One suggestion may be the complexity of medical knowledge from which patients need to base their decision, however this did not surface throughout any interviews. What did become known, though, is the thought process of certain patients towards their treatment options and decision-making. There was the opinion that regardless of what the informed consent process involved, only a limited number of options were available: “what are your choices, you either have it or you don’t have it.” (P6). What patients did not appear to realise was that the information given to them by the physician, including the survival rates with and without treatment, indirectly impacted on their decision to go ahead with treatment as pointed out by the same patient: “the odds, the factoring of you know your survival rates with the extra treatments and stuff like that. It sort of goes like from 19 % to 75 or something like that” (P6).

Overall, all of the interviewed women appeared to have high trust in their physician which supports the findings of the longitudinal study as everyone showed high level of trust across all three time points (Time 1: M = 11.4, SD 1.26, possible scores 0 – 12). Although trust appeared to reduce slightly over the three time points, this was not a significant reduction.
Family values

The second important contributor, from the patients’ perspective, to the decision of receiving chemotherapy treatment was based on family values. Some women believed that, regardless of the information given and the potential side effects to be experienced, they were obliged to consent to treatment to improve their chance of survival for the sake of their children. It is unclear whether this is an important factor for men as well, as men were not interviewed.

I knew I was going to do the chemotherapy to me there was no question about it. I kept thinking I got two young kids, I got to throw everything I got at it. P4

You really want to give yourself the best chance to sort of come out of it and be there for your kids. P6

Similar to the discussion in the above section on patient trust, patients did not appear to recognise that their decision to have treatment because of their family values was indirectly impacted by the information given by the physician regarding survival rates. Once they appeared to build trust in their physician about the information they were given, patients may feel that any treatment which may help them stay alive to be around for their family was worth having. The potential risks and side effects of chemotherapy treatment seemed insignificant in comparison with the motivation to extend life for family, such as seeing your children grow up. Therefore the information was not perceived by patients to be important in comparison to these factors, yet the basis for these thoughts may have arisen from the information they were given prior to consenting such as being given rate of survival if treatment is received.

Optimism

The last identified factor that was believed to impact on the decision-making process for the women sampled, was the optimism of the patient towards treatment success. This optimism reflected a will to live, both for themselves and the people around them and stemmed from experience observed in others.

I’d seen it working on other people P6

Working in medicine, I’m a believer in western medicine and it works so that’s why I had it and to me there has never been a question of not doing it P4
a thousand people have gone through it, so..

Of more concern, however, is the noticeable use of the word ‘told’ at some point in the patients’ interviews. This implies a one way arrow in the physician→patient decision making process which questions whether these patients believe the concept of informed consent is a mere formality. This is shown in the patient accounts below:

I got told I would be having chemotherapy with the surgeon

She just told me that I will have to have chemotherapy

The literature suggests a potential shift from a passive to an active role on the patient’s part. However, these findings appear different from that portrayed in the literature with regards to shared decision-making. The literature highlights that in the ever increasing shift to shared decision-making, patients exchange information and treatment preferences with their physician to come up with a mutually acceptable decision regarding treatment. This is contrasted by interview data from this qualitative study, as explained by the emerging themes previously discussed. Here the evidence relates back to the belief that they had a limited choice and also accepted the authority of their physician. This may be because the study investigates patients who are given the choice to have, or not have, chemotherapy treatment as opposed to other settings in which there may be more of a choice, such as, choosing between having a lumpectomy or mastectomy. Also, the sample consisted of women who are committed to their families, particularly living for children, which may differ to patients who have no children. This may indicate that no matter how much they understand the process or read the information, their mind frame has not changed from the passive role patients had several decades ago. While current patients may understand the importance of the informed consent process to a greater extent than patients did decades ago, their thoughts towards having treatment may be similar as suggested by these results.

The women did believe the information sheet and consent form to be an important part of their treatment process, however it did not receive the importance that ethical or legal theories
believe it has in consenting to treatment. Consent forms are useful for the physicians in helping ensure uniformity of information and providing prima facie evidence that the appropriate information was given. So the question is: what do patients believe the treatment information is used for? and, why do so many people continue to read it? The discovery from this study regarding the use of the written information was seen by the patients as a reinforcement tool which could be referred to at any stage during their course of treatment. This ties in with the limited importance of the information perceived by patients, the theme discussed previously.

I could go and ask or try and find out myself about the drug or ask the doctors P1

I’ll skip that for now because maybe it’s not relevant at the moment P3

There are times that I may have forgotten something so I would go and re-read and go yes that’s right P4

Aspects associated with the method of information provision were not discussed with the women nor were their preferences for mode of information as this has been covered exhaustively in the literature.

**Sources of information**

Apart from the physician being a source of information, patients identified three other main sources and these were the Internet, nurses, and friends or family who had experienced cancer. Patients, however, discussed these sources of information when referring to consent information as a reinforcement tool rather than for treatment decision making. Essentially, no one referred to use of other forms of information to facilitate their decision to consent.

Although mentioned as a main source of information, the Internet raised conflicting feelings with some patients pointing out that they purposely avoided the use of the Internet because of the overwhelming effect that it may have on them, as a result of information that may be incorrect, and it not being individualised and hence may not apply to them. Patients who did search the Internet for further information after consenting did so to glean more information
but indeed found it to also be overwhelming and overall did not provide them with any additional information that they were not already informed about.

Overall, all of these findings point towards women feeling satisfied with the information that was given to them, especially from their physician, as well as trying to avoid any additional stress that information seeking may cause. This verification that all relevant information had been perceived by patients as being provided may improve patient satisfaction but this does not impact on the informed consent process.

I felt that the information that really was most important to me is what the doctors told me. I mean I knew I could get on the computer. I could be reading for 8 hours straight because there is a lot of websites and a lot of pages but the point is how do I know what applies to me. P5

I just didn’t want to be overwhelmed with information that may not apply to me P1

I had a look on the net but there’s something like 110 references for breast cancer P2

I didn’t go to the Internet...I thought I had seeked plenty of information  P3

Nurses were specifically mentioned as a good source of information, as was pointed out:

the nurses are obviously highly trained and highly capable, you certainly have to trust the nurses P1

nurses were pretty good in chemotherapy because they answered a lot of those questions because sort of a[sic] you sitting there, this is happening to you, and that’s when the question comes to mind P5

They had prosperity, very knowledgeable, they knew what they were doing and just seeing it in action too, just seeing they knew what they were doing.  P2

Nurses may be considered to be an information source for the same reason as the physician, that is, trust in the expertise. Once again, this may be a sign that either the medical information is complex and for that reason, patients turn to nurses or doctors as they do not trust their own judgment of the information given. One other alternative idea, arising from the second quote above, is the convenience of asking the nurses while receiving treatment and building rapport with someone who you have to trust to treat you.
The role of family and friends who have experienced cancer was also a priority source of information, as stated by one participant: “I think the best tool in that situation is somebody else who has gone through it” (P1). An interesting discovery, mentioned by one woman was the impact of physician gender on information seeking behaviours of patients. This, although did not emerge as a theme, it was a unique finding that was noteworthy.

I mean a male doctor, now I wouldn’t have asked Dr Male ‘Could I colour my hair when it comes back’ but I don’t mind asking Dr Female because I knew she would understand...so there are some things like that that[sic] you just not comfortable asking your doctor

For some patients, it may be uncomfortable or embarrassing to seek the more personal information from the physician who is of the opposite sex as described by a patient. This could also explain the important role that family or friends who have experienced cancer have in providing information to information seeking patients.

Having trust in their physician’s ability to recommend the best treatment and provide the relevant information precluded treatment information seeking prior to consenting. Acknowledgement of physicians being the experts links trust with the view that medical knowledge may be complex but also that the physician had the ability to individualise this information for each patient, this being reflected by patient accounts. This is an important topic because it differentiates the information given by the physician to that on the Internet. Fortunately, the women saw the Internet only as a means of trying to find further information that they did not receive rather than to confirm the recommended treatment. As mentioned previously, it was pointed out that the Internet did not give them anything beyond what they had already been provided by their physician. This may however point to a lack of trust or at least not knowing whether they were satisfied with the physicians information until they looked at another source that confirmed that they were ok with it.

**Patient satisfaction with the information**

Patient satisfaction has been defined as a merging of expectations and perceptions of the patient (Risser, 1975). Therefore in relation to information given, patient satisfaction can be
said to be the expectations patients have about ideal information and their perception of the information that they really get. As a result of this, patients were asked about their expectations of the information given to them as part of the consent process, to see if this fit within the definition. The findings from this analysis show that patients had no expectations about the treatment information given. There may be several explanations for this, firstly, patients may build expectations from the treatment to be received, stemming from the importance they place on the physician’s recommendations and treatment outcomes, and these factors make the treatment information and consent form given appear to be less significant. Another reason for the common lack of expectations amongst the patients regarding the information given was discovered to be patient attempts to deny or avoid the whole process and this can be regarded as an emerging theme. Patient quotes in the following section suggest a conscious decision to avoid the information with the hope that it will go away. This may be a strategy used by patients to avoid or relieve anxiety, as one patient stated: “don’t worry about something until it happens because worrying about something was a waste of time and effort on my behalf” (P4). If this is the case, it may also serve as an explanation for the poor knowledge of the information given, in that patients specifically try to avoid thinking about it. Another patient stated:

you just don’t want to think about, you really don’t want really want to know about

fairly fast track you go on and you don’t think

The findings highlight a distinct link between patient expectations and satisfaction. If patients do not have any prior experiences of a similar situation they do not know what to foresee, as one woman stated: ‘if you don’t know any different it’s really hard to compare things’ (P3). This implies that patients with no expectations have nothing to weigh their satisfaction against and hence patients are found to be satisfied with the information. The results of this study suggest this to be accurate in that all women who were interviewed were satisfied with the information. Quantitative findings also statistically indicate that patients were highly satisfied with the information. This is based on a designed satisfaction scale of 13 items that was found to be reliable with a Cronbach’s alpha score that ranged from 0.70 at Time 1 to 0.85 at Time 3.
The mean level of patient satisfaction at Time 1 was 52.9 (SD 8.13) from a possible score of between zero and 65. This did, however, decrease slightly over time, perhaps due to expectations beginning to change with a gain in the experience of treatment.

**Social support**

Social support can be described as all forms of support that assist a person to cope with particular situations, in this case, the commencement of treatment. Often this is provided by close individuals such as family or friends. There is a prediction that information disclosure to others aids the individuals cognitive processing of a particular event and may reduce psychological stress (Pennebaker, 1989). If this stands true, it may impact on the patient knowledge of the information given and therefore this was investigated both quantitatively and qualitatively. Patients were asked about receiving support from others and whether it was helpful and there was a consistency with positive responses such as:

- Yeah I think that it would be very hard if you didn’t have support of family P3
- When you are having treatment obviously someone has got to support you P6

Also, patients indicated in their interviews that they felt most supported when others were physically present and just being able to share the experience with them.

- Well you can never be prepared for that, but I think so long as you got somebody with you, I think it’s really important to have somebody with you when you go to the oncologist P5

While some appear to believe social support is essential, others believed family support, in particular, may be more problematic and more damaging rather than beneficial, by the additional stress it may cause as one particular woman describes:

- My husband becomes a very doughty man, always treating you like a puppy dog, trying to over care for you. Your family seems to come across as pitying you….so just too overwhelming P2
He was there if I wanted it, that’s the best way of putting it, he was there, I had friends who were there if I needed them, my neighbours were there, but I didn’t feel the need to

None of the women discussed having to seek social support. This may signify the patients’ recognition that support was available if needed. This is important because, seeking social support may be harmful as there is the risk of rejection. Although anecdotal evidence, while completing the quantitative questionnaires, patients mentioned that they were surprised at the number of friends who would withdraw themselves from them (the patients) when learning about their cancer diagnosis. This is an example of the possibility of rejection from certain support groups. Nevertheless, nothing can be concluded from this until evidence based research is conducted.

Support with the informed consent process may be appreciated by patients and in fact result in a reduction in anxiety, therefore improving their knowledge of the consent information. However there is the possibility that the support of another may reduce the patients knowledge of the information as they become reliant on the support provider for reiteration of the information. Regardless, patients did not associate availability of social support with their knowledge of the information, and it was not found to be associated with two of the three measures of information knowledge. Quantitatively, it was only discovered that an increase in knowledge of the name of drugs was gained when patients had less social support. This implies that patients refer to the given information sheet for this and hence understand it better as opposed to believing that their support network would know, if ever they needed to know.

**Time**

Often patients referred to the informed consent process as being ‘quick’ or ‘fast track’ but no further ideas were mentioned. While the lack of evidence indicated this to be an area to be further explored, upon investigation, patients were satisfied with the time given to understand the information before treatment commenced. Treatment commencement ranged from one to three weeks after being given the information and patients believed this to be sufficient time. There are a number of confounding factors to this outcome: firstly, patients may be satisfied because they have no standard to compare it against; secondly, patients may be eager to start
treatment sooner and therefore prefer less time given, however this assumes that the decision is made independent of the information given. As a whole, time given to patients to read and absorb the information for treatment decision-making may be a challenging notion to improve on, as often patients are benefited by starting treatment at the earliest time possible.

**Treatment experience**

In hindsight it is often easier to be satisfied, especially in the case of these women who were feeling healthy and were moving onto the next phase in their life: life after cancer. Interview findings may be different if patients were confronted with many complications. In other words, such patients may be less trusting, and have lower satisfaction levels. This is a difficult case because there is the possibility that patients who have complications, or a bad experience, may not agree to participate in such a study. This study only measured satisfaction with the information received however future studies may measure satisfaction with the treatment received and its association with patient knowledge of the information given. Nevertheless, one patient said that she believed her satisfaction towards the information would be the same had she experienced complications.

Oh yes it would’ve, it would’ve, Im sure if I had a shit, no actually no, maybe not, um I think if my experience had been worse, the information I had received was still the same  
P4

If an increase in expectations with treatment experience led to a drop in satisfaction, having complications may have also impacted on patient satisfaction. This is not an accurate indicator of the true experience of the patient. Consequently, credible research by means of a comparative analysis of people with good versus bad experiences of treatment needs to be done.
Discussion

Informed consent process and perceived importance of information

Patients, although not clear about all of the five elements that comprise the informed consent process, understood three main components. Informed consent was recognised by most patients to be a process that involves information disclosure by an expert and the patient agreeing to the treatment. This level of knowledge regarding informed consent, although potentially considered by the patient as ample, is not adequate but still demonstrates improvement when compared with patients’ knowledge decades ago. Nevertheless, comprehension was not specifically identified by patients as an element of the informed consent process. With the knowledge gained about patient priorities in decision-making from this thematic analysis, it is not unexpected that ‘comprehension’ was ignored. In other words, patients perceive that knowledge or the comprehension of the information sheet and consent form may be irrelevant when other factors, such as family values is a higher priority. Also, when asked to provide their thoughts on the information sheet and consent form, patients discussed factors other than the information sheet and consent form. They stated that having optimism for the treatment was important, as was putting trust in their physician. Patients stated that they ‘have to do it for their children’ and that ‘it was the recommended treatment’. When a patient refers to the treatment information as ‘what my treatment will do to me and what side effects I will have’, their words suggest they have already, in a sense, made up their mind to have treatment. This ties in with identification that the value of the information given as part of the consent process was not recognised to a great extent. This is also consistent with findings from the quantitative study, suggesting a poor level of knowledge of the information given at consent, overall. Together, this means that the amount of information known is closely related to the level of importance of the consent information. Importance of information may be related to the extent of information read, which was identified to be a predictor of patient knowledge of all three aspects of knowledge of the consent process measured. The issue of importance is also evident in a recent qualitative study by Davey and Butow (2006) of breast cancer patients receiving diagnostic information (Davey & Butow, 2006).
In the study, an emerging theme was that patients perceived information to be more than just understanding but rather a form of support and control as well as promotion of patient trust in their physician (Davey & Butow, 2006). The similarity of this with our findings is that while perceived importance of the information prior to consenting has not been found to be high, patients repeatedly mentioned its importance as a reinforcement tool which can be considered a form of support and control of their treatment.

Consistent with previous literature, the present study found that women with breast cancer found information to be an important aspect of their treatment process. The difference found in this study, though, is the inadequate level of importance given to the information by the patient in relation to the informed consent process. Patients in this study emphasised the significance of the information provided at times where they had forgotten or wanted to confirm the potential of a side effect while receiving treatment. Instead three factors rated higher in their consent process: physician trust, family values, and optimism in the treatment.

**Physician trust, family values and optimism**

Clearly, physician trust has been established, from this mixed methods research, to be prominent yet complicated. Trust for the physician was found to be weakly associated with patient knowledge of the number of drugs and their potential side effects. Regardless of this, the level of patient trust for their physician was found to be high at all three time points and this finding comes from a validated questionnaire that is highly reliable as well as interviews with patients, who were not prompted about their level of trust. While trust in the physician is itself a potential factor in building optimism in patients towards the treatment, there was mention of the positive experience of other cancer patients increasing the hope of the patients. In addition, patients who had children or a partner were more eager to receive the recommended treatment and in such populations, the importance of the information given for decision-making is not of great relevance, other than the improvement of survival.
**Patient satisfaction versus expectation**

There is a lack of research on patient expectations with the information provided. Although much research has been conducted on patient information needs and preferences, no data on expectations has been identified, to date. This qualitative analysis has discovered that patients do not have any expectations about the consent information given unlike expectations with treatment outcomes. Indeed one important aspect of giving the information is to increase patient knowledge to avoid unrealistic patient expectations which may have a detrimental effect post treatment. Further exploration of this is recommended to confirm these findings are accurate in larger populations and if accurate and reliable, the effect that the lack of patient expectations may be having on the informed consent process. It is believed, from the findings that the lack of expectations may be linked to the high degree of patient satisfaction that has been found. However, perhaps as expectations were formed, satisfaction of the patients declined.

**The Internet**

The increasing exposure to the Internet has amongst other things, triggered a rapid growth in information exposure to lay people and this is exemplified by results from the thematic analysis conducted. One concern arising from this overwhelming coverage of information is the quality of the information and the impact it may have on doctor-patient relationships. No doubt there is the potential for medical information on the Internet to be incomplete, misleading, and inaccurate and hence could lead to harmful effects for both patients and healthcare professionals who fail to use the Internet properly. Certainly many researchers (Silberg, Lundberg, & Musacchio, 1997; Winker, Flanagin, Chi-Lum, White, Andrews, Kennett, et al., 2000) have shown that health information on the Internet is of variable quality but considering most women in this sub sample were highly educated and working in a high level position, would probably be aware of the differences in good and poor health-related web sites. The Internet, according to the longitudinal study, was only used by about one tenth of the population for the purposes of decision-making. Women interviewed did explore the Internet for information, however, their main aim was to identify additional information which they may have not been informed about. Women did not find this to be a successful exercise.
No suggestions were made about the information having an impact on their relationship with the physician and evidently, the high level of trust reported, both quantitatively and qualitatively, also confirms this. Additionally, there was also discussion that the Internet sites were not able to individualise the information for the reader and the exposure to numerous websites made patients feel overwhelmed. It may also mean that the use of the Internet increased their satisfaction with the information given and potentially confirmed their trust for their physician.

**Limitations of the study**

Limitations relating to the interview content include the potential for participants not to feel comfortable talking about their trust for the physician as well as talking about satisfaction when they may not entirely trust the researcher (me). The researcher (me) may have been perceived as being closely linked to the medical care providers and hence may have led to reluctance by the patient to criticise medical staff or the treatment-related care. There has been an attempt to overcome this bias through building rapport and trust during the patient sessions as part of the quantitative study. It would be reasonable to say that after five visits, which includes the first time that the study is explained to patients when consent was obtained, the participants would feel relatively comfortable discussing issues brought up in the qualitative interview.

Although this study reached the data saturation that was anticipated, a further limitation of the study includes, the sample size being small, with only six women which may not be enough to make large assumptions, and with more interviews new themes may have arisen. However this is a common limitation of a lot of qualitative studies. The sample was limited to capturing experiences of women, and therefore this was not generalisable to the whole population. Men, people undergoing treatment for diseases other than cancer, and those with other health problems may have a different perspective on the issues explored in this study. In addition, the participants were being consulted by different oncologists and nursing staff making experiences not entirely comparable, although the heterogeneity of this experience may have added some richness.
Lastly due to the retrospective nature of the study, patients may not have been able to correctly remember the treatment information, or the attitudes they felt at the time of consent and hence this could have led to inaccuracies. Nevertheless, this cannot be avoided as a prospective study is not viable in answering the research questions. Opinions of young women with breast cancer were also not captured here and they may be different to the findings of this study.
Conclusion

The findings of this study suggest that women with breast cancer are reasonably aware of the process of informed consent. Of concern though is the fact that they do not see the importance of recalling or understanding this information prior to consenting. The information was seen as a reinforcement tool which could be referred to when needed and hence may be a form of support for patients. The importance of other factors that formed greater importance in their treatment decision-making process included trust in their physician, family values, and optimism. The way that these factors impact on knowledge of consent information varies according to the quantitative findings from Chapter Seven. While trust was associated with improved knowledge of the patients for two measures of knowledge, social support was not and family values and optimism for the treatment were not objectively measured in this study. Thus future research may explore these and other factors in order to better the informed consent process.

Often satisfaction was associated with the whole process rather than the information given for informed consent purposes and this lack of sensitivity to differentiate between the two can be a result of the perceived importance of other aspects of their treatment process. Research on satisfaction often suggests that patients are highly satisfied. This may be due to several reasons. Firstly, patients may believe they will be treated differently if they do not say they have been satisfied although this is not likely as most research is clearly indicated to be confidential. Secondly, patients may be trying to stay positive about their treatment and therefore see the care or information, in this case, in a positive light as well. Lastly, patient expectations appear low therefore satisfaction is easily achieved. Indeed this is what was seen in this sample of women.

This study has shown that while patients may have a good idea of what the informed consent process involves, the purpose of the information given throughout the consent process is viewed as supplementary support material rather than integral, important information. While it serves a purpose for the patient, it does not follow the intent and level of importance of health care professionals.
Chapter 9: General discussion

In this final chapter, the longitudinal assessment of the impact of experience on patient knowledge of important treatment information given at consent and the thematic analysis are examined in detail. An attempt was made to triangulate these findings and to incorporate findings from previous research. This concluding chapter has three aims (1) to outline the key conclusions which have been made on the basis of this psycho-oncology based research, (2) to recognise and articulate the limitations of the studies, and (3) to discuss the implications of the research and its ability to contribute to the wider body of knowledge regarding informed consent, and to suggest directions for future research.

The core significance of this research derives from a plethora of earlier research highlighting a lack of patient knowledge or poor recall of necessary treatment information given at the time of consent. In turn, this poor knowledge or recall of information may result in negative consequences for the patient, the physician, or others such as the patient’s family. With regards to physicians, they need to know that if there are limitations to how much information can be usefully given pre-treatment, does a patient make up for this eventually because of the information gained through experience. At the patient level, they must be aware of the consequences of agreeing to such treatment as chemotherapy, as it will impact on them during treatment and for many years after treatment. For instance, they may not understand that they shouldn’t consume foods that negatively interact with their chemotherapy drugs, patients may become pregnant during chemotherapy treatment because they didn’t realise that this is advised against, or patients may not be aware that heart problems are a complication of treatment and may not know the course of action to take if such signs occur. Patient knowledge of the information given regarding treatment for making an informed decision to consent is crucial for a number of other significant reasons. These include allowing patients to gain control of their condition (Gaston & Mitchell, 2005; Mills & Sullivan, 1999), improving compliance with treatment (Fallowfield, 2008), reducing anxiety (Gaston & Mitchell, 2005), enabling patients to create realistic expectations (Gaston & Mitchell, 2005; Mills & Sullivan, 1999), reducing uncertainty and decision delay (O’Connor, 1995; O’Connor et al, 1997), and increasing patient satisfaction (Hinds et al., 1995; Mills & Sullivan, 1999).
The five key elements necessary for an autonomous decision to be made, as discussed in Chapter One, include (1) disclosure, (2) competence, (3) comprehension, (4) voluntariness, and (5) consent (Beauchamp & Childress, 2001; Milton, 2000). Of these, voluntariness and consent are dependent on the patient, competence is unable to be changed which leaves the two multi-faceted elements, disclosure and comprehension. Physicians need to disclose all of the material information regarding the procedure to the patient prior to them providing consent. In order to provide informed consent, patients need to comprehend the information that has been disclosed. In the absence of these informed consent processes that lead to increased recall and knowledge of the information given, patient autonomy may be compromised. These factors, which have been shown to be questionable, need to be researched and improved. As a result extensive research has attempted to improve disclosure of information and patient comprehension for an autonomous decision to be made and for a stress-free, satisfying, successful treatment process.

However, findings concerning these elements have been relatively inconsistent. While successful efforts have been made in determining the material information that needs to be given to patients, it is difficult to identify the best process by which to provide patients with this information in practice and attain adequate comprehension by patients of all the important details of treatment prior to consenting. Even though patients may believe that they understand the information and portray this to their physicians, efforts have been made to improve this process through different formats of information delivery as objective assessments suggest patients cannot recall adequate amounts of consent information. This extensive research of effective formats has identified several promising novel interventions for improving patient knowledge or recall of information. However these interventions are not without limitations.

In some cases the intervention cannot be generalisable to greater populations, they are complex and not likely to be cost effective, research testing these interventions is methodologically flawed therefore questioning findings, and hence such interventions require more research to confirm their usefulness.
One fundamental concept that has been raised by this research, is that the patients’ experience of receiving treatment (surgical or non-surgical) may actually enable patients to naturally gain superior knowledge of the relevant information given at consent. If this was found to be effective, it would obviate the need for further research into how to improve the format of information. The process of assessing the impact of patient experience on consent information is novel and may negate the need for further costly research into modifications of consent information. This can be evaluated by prospectively and longitudinally measuring patient knowledge of the information given at consent as it changes with their experience of the treatment. This thesis explored whether the patients’ experiences of the treatment process will improve their knowledge after the pre-chemotherapy information has been given. Therefore the remainder of this chapter delves into the findings and discussion of the longitudinal quantitative and qualitative research conducted and how this fits within findings from previous research.

**Summary of findings**

**Patient sources of information**

The longitudinal study examined the most used sources of information for patients. Despite, the increasing availability of a range of cancer information resources for patients, aimed at improving accessibility to information so that more people will educate themselves and become knowledgeable, the study found that four fifths referred to doctors as their most used source of information. Two-fifths of patients considered books, pamphlets, magazines and newspapers to be the source where they get most of their information from. A similar proportion of patients also identified nurses to be a good information source. However a lot less patients utilised the Internet and the information sheet and consent form – the latter being the information source of interest in this research. Results obtained from the qualitative study indicated that patients trusted their doctors greatly in providing sufficient, balanced, and accurate information about a treatment and treatment alternatives. The speculation from these findings is that either patients do not trust the other sources of information that are available to them, or as they trust their doctors, they see less of a need to refer to other sources of information. Alternatively, they may trust and make use of other information sources but as
their doctor was their original and earliest source of information, that is, the one that patients believe to be the most significant. This fits in with research from a recent systematic review conducted by Ankem (2006) that concluded health care professionals were the most used and the second most helpful sources of information, followed by books (Ankem, 2006). The study by Olver and colleagues had similar findings with patients believing doctors and nurses provided the most sufficient information (Olver, Turrell et al., 1995).

An abundance of books and magazines given to patients as well as freely available resources may explain why this was the second most used source of information. Qualitatively, it was identified that one reason for sourcing information from nurses was the convenience of being readily available during the treatment process. Video, on the other hand, was not used by anyone and this could be because there may be limited videos that help explain chemotherapy treatment and if available, they may not be adequately marketed. Also, videos are difficult to navigate and select information unlike DVDs. Furthermore, chemotherapy treatment is rapidly changing so that videos, which can only be updated by re-recording, may not be able to stay current for long.

Also with the technological advances in recent years, the use of the Internet has increased and is relevant to patients seeking information regarding treatment to be received. The number of health-related websites continues to expand, with an estimated 20,000 reported on the Internet in 2000 (Pastore, 2000). This would have increased considerably in the last decade. Common diseases for which the Internet is used to seek information include allergies, cancer, heart disease, diabetes, and digestive disorders (Levy & Strombeck, 2002).

Nevertheless, the abundance of sites does not always equate to additional information that is accurate, as no formal regulations apply to the content of websites, a factor which patients may not be aware of, especially older patients. The longitudinal study reported in this thesis, found approximately one tenth of patients considered the Internet as a high priority information source at the beginning of treatment, ranking fourth out of seven sources of information, before the information and consent form, TV, and videos. The mean age of the population being 55 years may explain this. Older patients may have potentially limited
familiarity, access, or awareness of the Internet, or are simply not interested in making use of the Internet for such a matter. When discussed in the qualitative interviews, it appeared that women were aware that the plentiful information was not always accurate and not all of it was relevant to them. This also ties in with evidence from the systematic review by Ankem (2006), on the use of information sources by cancer patients, which found the Internet to be the least used and least helpful as a source of information. Qualitative interviews also identified that the Internet may be a cause of stress as some information may be conflicting. Newnham, Burns, Snyder, Dowling, Ranieri, Gray, et al. (2006) conducted a survey and found that use of the Internet, in cases where it was used, was believed to be linked to its convenience and breadth of information (Newnham, Burns, Snyder, Dowling, Ranieri, Gray, et al., 2006). Another explanation for these patients using the Internet may be due to a potential lack or low level of trust for the physician (Newnham et al., 2006). However, as the current study found a high level of physician trust, it makes sense that Internet use was relatively low, although no correlations were carried out.

The information sheet and consent form, was hardly used by patients as an information source. Qualitatively this was perceived by patients as not being an important part of their treatment process but rather as a reinforcement tool. Qualitatively, patients only spoke of the information given on the information sheet and consent form when they were prompted to know something regarding their treatment rather than to form part of their decision-making or consent process. The impact of this, if it stands true, across the whole population, is immense. Trying to increase patients’ knowledge of treatment information will be difficult if patient’s don’t value being given the information. This theme is suggestive of a couple of factors. The first is that the written information provided throughout the consent process alone may not be sufficient in improving patient knowledge. One study identified in the first literature review reported in Chapter Three (Langdon et al., 2002) compared verbal explanation and written information with verbal explanation alone. Of the ten questions assessing prompted recall of postoperative complications only one complication was significantly better with the addition of written information. Another study assessed information preferences pre-treatment and found that the consent form was infrequently cited as a source of side effect information chosen by less than a third of the patients (Nair, Hickok, Roscoe, & Morrow, 2000).
The second speculation for the information sheet and consent form not being perceived as an important part of the treatment process but rather as a reinforcement tool is that patient trust in the physician may take precedence over the information given. Findings from the quantitative study showed that patients had a high level of trust for the physician which remained that way throughout and post chemotherapy treatment. There was also evidence that the doctor was the most used source of information and the information sheet and consent form was one of the least used sources of information. Almost two fifths of patients did not read all of the information that was given to them which was supported by previous research. Lavelle-Jones and colleagues (1993) highlighted that 69% of patients admitted to not reading the consent form before signing it and Cassileth and colleagues (1980) reported that 60% of patients had not read the consent form ‘carefully’ (Lavelle Jones et al., 1993). A recent study found that the two leading reasons for not reading the consent form were ‘having had a verbal explanation’ and ‘trust in their doctor’ (Akkad et al., 2004). Previous studies have also shown that desire for a passive role was significantly associated with higher levels of trust (Kraetschmer, Sharpe, Urowitz, & Deber, 2004). The qualitative study of this thesis also supports this notion, as patients appeared to take on a passive role and they had a high level of trust for their physician.

Qualitatively this thesis also identified that patients perceive the information to be less useful at the time of consent compared with after initiation of treatment as patients indicated that they have limited choice in the range of treatments available. Therefore repetitive layering of the consent information would be useful after treatment commences. This is of course true for adjuvant chemotherapy however this is unique to some treatments and does not necessarily apply to treatments where more options are available and survival is not directly impacted. Therefore regardless of what information is given, patients will be consenting to either having the treatment or not, but there are not a range of other choices. However previous studies have also found that information is valued with or without an active role in decision-making (Charles, Gafni, & Whelan, 1997; Ende, Kazis, Ash, & Moskowitz, 1989).

Family was regarded as the patient’s first point of call in obtaining help to read the consent information and/or to make a decision to have chemotherapy. One explanation for this is that
people may be more comfortable discussing issues with their family if they value their opinions and trust them. Also, the chemotherapy treatment may impact highly on significant others in the patients life, such as family and friends, especially those with children.

**The role of treatment experience on patient knowledge of the information given**

As described in Chapter One, knowledge can be gained by different means: incidental, accidental, and purposeful. This thesis was interested in patient knowledge defined by the experience of the chemotherapy itself, and whether this enhanced knowledge of the original consent information given. Therefore the knowledge captured in this study covered all three means; incidental, accidental, and purposeful.

Study results found that patients had poor knowledge of aspects that formed the detailed information given prior to receiving treatment. Of the three measures of knowledge used in this study, only one of them (i.e., knowledge of drug names) was found to have significantly increased with the experience of chemotherapy treatment. Only a small number of patients had correct knowledge of the name of the drugs received at Time 1 (11%) but by Time 3 this had increased to 26%, and the size of the effect was small-to-moderate for knowledge from the second chemotherapy cycle to one month post chemotherapy. Nonetheless, this indicates that a large proportion of patients still did not have knowledge of the name of drugs. The complexity of the drug names may have meant that more exposure to them in the chemotherapy centre, or saying it repeatedly to people who asked, allowed patients to learn and remember them. Another explanation for this finding is the unavoidable limitation that at one month post chemotherapy treatment, some patients had to be sent the questionnaire for completion and it is unknown whether, in doing this, they referred to the information sheets given to do so. Although these results should therefore be cautioned, the change over time was highly significant and only a handful of patients had to be sent questionnaires, and thus it may not have largely affected the results. Knowledge of the names of drugs received at the three time points also did not follow Olver et al.’s (1995) findings, this time in the opposing direction.
Essentially, this study found only 11% of patients remembered the drug names at the second chemotherapy cycle, while Olver et al. found a rate of 25%. Once again, it is unclear from the study, how this measure of knowledge was collected. In this longitudinal study, patients were only given credit if they remembered the actual name of the drug not the acronym, such as AC instead of doxorubicin and cyclophosphamide. While many patients remembered the acronyms or parts of the drug names (often long drug names), it was not feasible to score patients based on how well they remembered part of the name, so only patients who remembered the whole name were given credit. Thus very conservative estimates used to score correct responses in the current study may explain inconsistencies between studies.

From the patient point of view, remembering the names of drugs may not be considered important, with the belief that the doctor should know or they can simply refer to the information they are given. However, it may be helpful for patients to be aware of the names of their chemotherapy drugs if they wish to look up further details of the drug or to discuss their treatment with other people. Also, in the case where patients may need to take medications for other conditions, other specialists need to be consulted and it is beneficial if the patient knows the names of drugs they received or are currently receiving. In addition, this information can also help determine and differentiate the side effects that result from the different drugs, hence giving rise to a synergistic effect of remembering potential side effects of the chemotherapy drugs as well.

Knowledge of the number of chemotherapy drugs received, which was attained by giving patients a score of one if the correct number of chemotherapy drugs was stated and zero if it was incorrect, was not found to increase significantly with experience. Patients’ knowledge of the number of drugs ranged between 60% and 68% correct among patients who had completed all of the assessment data. This suggests that knowledge was reasonable over the three time points assessed, despite a conservative scoring system for correct responses. When compared to the findings from the literature on format modifications, this proportion of patients freely recalling this information seems very similar. Results indicated that there was a slight increase in knowledge from the second chemotherapy cycle to one month after completion of chemotherapy treatment, peaking at the fourth chemotherapy cycle (Time 2). Lack of
statistical significance may have been due to a number of reasons, as discussed in Chapter Seven.

This includes, the size of the study sample, particularly as findings of patient knowledge were based on patients with completed questionnaires for all three time points. As there was a small loss to follow up by Time 3, only 57 patients were included in these analyses conducted over time. Also, there may have been some confusion of the precise number of chemotherapy drugs they received as there may have been new drugs added to the regimen at some stage during treatment. Specifically, some patients’ drugs are changed, or entire regimens are updated, during the course of treatment, so it can be more difficult for patients to remember the exact combination. Some patients may have received other drugs such as anti-emetics that they counted as chemotherapy. All of these factors can be controlled for in future research on patient knowledge. Alternatively, as evidenced by the lack of importance patients placed on the information sheet and consent form in the qualitative interview, it may be that some patients do not remember the number of drugs they are receiving as they do not believe this to be a fact that matters and can always be questioned in the future.

The results found here were not consistent with other literature, such as the study by Olver et al. (1995), which reported that only 37% of patients knew the number of drugs at their second chemotherapy cycle. This previous study was conducted in the same Australian State and one of the same cancer centres as the current research, although did not include patients from private hospitals. In this study, private versus public patients were found to be part of two regression models explaining knowledge of the number of drugs and potential side effects and in fact the type of attending hospital (private) was a significant predictor of the knowledge of the number of drugs received. This, together with the likelihood of knowledge being scored differently in the other study as this information was not provided in the literature, may explain the difference in the findings.

Another explanation for this difference in knowledge seen between the studies may be due to the transition from a passive to an active role of patients in their treatment decisions and care now as compared with 12 years ago when Olver et al.’s study was conducted. Also physicians
may have improved their communication skills towards patients, as a result of the greater emphasis on communication skills in medical training or because of providing more complete information from fear of litigation, which indirectly impacted on the patients’ knowledge gained. These two predictions may have worked independently or collectively in achieving improved patient knowledge. On the other hand, differences may be due to the type of cancer patients included in the studies. This prediction arises from the moderate association between cancer type and knowledge of the number of drugs found in the longitudinal study, which favoured colorectal cancer patients, the group that also included mixed genders. Olver and colleagues (1995) did not specify cancer type, only indicating that consecutive patients due to receive conventional cytotoxic chemotherapy were included indicating a variety of cancer types.

The third and last measure of patient knowledge of information in this study, was that of potential side effects, however no significant improvement of this knowledge was observed with treatment experience. There was, however, a small effect size indicating that a larger sample size with increased power may show a significant finding. Patient knowledge of side effects appeared to remain consistent throughout the treatment course with patients having knowledge of 20% of the potential side effects at Time 1, 21% at Time 2 and again 20% at Time 3. The number of side effects to be remembered by patients in the current study ranged from 12 to 18 depending on the combination of chemotherapy treatments received. This was higher than any number of side effects reported in other studies found. Patients in this study appear to have less knowledge of the proportion of side effects as a result of the greater amount of side effects presented. As reported in the results (Chapter Seven), the most frequently remembered side effects across all the time points were all transient, such as nausea (55% at Time 2) and fatigue (35% at Time 1) or they were very memorable side effects due to common knowledge of what happens during chemotherapy such as hair loss (54% at Time 1). There is a possibility that these particular side effects were known as a result of the patients experiencing the side effects. The effect of transient side effects such as nausea, vomiting, and fatigue often decrease over time with additional treatments. On the other hand, patients did not have knowledge of the important complications such as heart damage (8% at Time 1), and fertility (0% at Time 1). Occurrence of these complications is often life-altering and needs to
be understood at all times during and after the chemotherapy treatment. One reason explaining why patients may have not have knowledge of the possibility of infertility may be related to the mean age of patients being 55 years reflecting older men and women who may no longer be considering having children. Indeed, the couple of patients that did report infertility and pregnancy issues were younger which justifies that if highly important and relevant, it will be remembered by the patient. Similarly, women of this age may have already been through (or were going through) menopause. However, heart problems should have been of prime concern to this age group. To understand and accept these potential risks and side effects beforehand is very important, but to continue to remember them throughout and after chemotherapy treatment is vital for some side effects but unfortunately results are not reflective of this.

Overall, this study found that on average patients had knowledge of one fifth of the side effect information given to them on the information sheet and consent form, which fell below the results reported by other authors. Other literature on this measure of knowledge shows inconsistent findings, ranging from 24% to 48% recalled. While one reason for this inconsistency in findings may be the differences in the way information was measured, that is, most studies assessed recognition, another is dependent on whether the treatment is surgical or non-surgical, as each of these treatment types has different side effects in their timing, duration, nature, and seriousness. Therefore it was very difficult, when conducting the literature review of longitudinal studies (Chapter Four) to compile the findings. Again, when comparing results from a very similar study conducted at one of the same cancer centres, at the second chemotherapy cycle, 17% did not remember any of the side effects in Olver et al.’s (1995) study compared with a rate of 13% found in this study. These results are quite similar, especially when compared to the differences for the previous two measures of knowledge discussed above. As suggested above, it is unknown how Olver and colleagues calculated this recall score.

On the whole, findings from this study are not suggestive that knowledge of consent information improves very well with experience of treatment. Apart from the specific reasons discussed above in reference to the individual knowledge questions, there may be other broad reasons for poor knowledge during and immediately after chemotherapy. For instance,
cognitive dysfunction may explain part of this poor knowledge as chemotherapy treatment may negatively impact cognitive abilities of the patient.

A recent literature review and meta-analysis found that although there appeared to be some cognitive effects of systemic cancer therapies, no clear conclusions could be drawn (Anderson-Hanley, Sherman, Riggs, Agochan, & Compas, 2003). Another recent systematic review found that cognitive impairment occurs in breast cancer patients who have undergone adjuvant chemotherapy but the magnitude of this impairment was dependent on the type of design that was used (i.e., cross-sectional or prospective). For the prospective study, the effect sizes ranged from small to large but indicated improvements in cognitive function from the beginning of chemotherapy treatment to three weeks and even one year following treatment (Falleti, Sanfilippo, Maruff, Weih, & Phillips, 2005). It may be that the symptoms are attributed to underlying depression or anxiety, especially if it is assumed that a blood brain barrier prevents cytotoxic agents crossing into the brain (Silberfarb, Holland, Anbar, Bahna, Maurer, Chahinian et al., 1983). Regardless of whether such cognitive dysfunction is real or perceived, patients having chemotherapy commonly report ‘chemobrain’ or ‘chemofog’ suggesting they feel their cognition, such as memory, is impacted by treatment. Further research of this was beyond the scope of this research.

Other reasons for poor patient knowledge of the information include demographic factors such as age, level of education, marital status, and psycho-social factors such as patient satisfaction, trust for the physician, and social support. The next section will discuss the findings from assessing these factors as predictors of patient knowledge of the information.
Patient Satisfaction, Trust and Social Support

Besides achieving optimum patient knowledge of the information given, it is important that patients be satisfied with the information because it has been shown to be an indicator of quality of care (Sitzia & Woo, 1998). Trust in a patient-physician relationship is also vital as it has been shown to increase acceptance of medical advice and treatment adherence (Gray, 1997; Thom et al., 1999). Additionally, the provision of social support and its link to physical and psychological well-being has been well recognised (Silliman et al., 1998). There is limited literature available on these factors so they were measured in this study in determining whether they changed with experience of treatment.

Patient satisfaction with information has mainly been measured in studies comparing different methods of information delivery, as presented in Chapter Three with less longitudinal research studies being published as was seen in Chapter Four. The longitudinal study (Chapter Seven) found that patient satisfaction remained high despite poor knowledge of the information which was consistent with findings from several studies reported in Chapters Three and Four. It is no doubt beneficial that patients are highly satisfied during the beginning of chemotherapy treatment, suggesting that they may have been pleased with information given at the time of consent or that patient satisfaction has little to do with the impact of the information on patient knowledge. However there needs to be a good reason why this change in satisfaction with the information diminished with the treatment experience. This is important for several reasons both patient- and physician-related. In terms of the patient, if the experience of chemotherapy has led them to believe that the information was not good, this means that the information may have been inadequate. The longitudinal study looked at the association between patient satisfaction and patient knowledge of the information given, and found a weak correlation between the knowledge of the number of drugs and patient satisfaction. It did not, however, examine whether patient satisfaction and knowledge of the information interacted over time. Secondly, as previously mentioned, patients need to be satisfied in order to hold good memories from the care they received (such as for coping), which, with increasing survival rates, may be many years.
Consequences that are both patient and physician-related include the commonly reported litigation issues. These legal setbacks may happen months to years after treatment is complete therefore it is important that patients are just as highly satisfied post-treatment as they were at the beginning when they consented.

On the other hand, while there have been a handful of studies on the importance of trust in the patient-physician relationship and associations of trust with other factors such as satisfaction, there has been a lack of research on the longitudinal effect of trust and its relationship with patient knowledge of information given. None of the studies identified for the literature reviews in Chapter Three and Four measured trust for the physician. Trust for the physician was found to be high at all three time points of the longitudinal study and no significant change in the level of trust for the physician was observed over time although there was a small effect size suggesting a small downward trend with experience. Qualitatively patients discussed trust for their physician without being prompted to and all of the women indicated that they trusted the doctor and their recommendations for treatment. Patients found the expertise of the physician to be a dominant characteristic that impacted on their trust for the physician but other features impacting on their trust included their manner, attitude, and the length of their relationship with the physician.

Again, there was limited knowledge on social support measures over time and as a predictor of patient knowledge of treatment information. Thus, the measure of social support was a novel one for this thesis. In the longitudinal study, social support was also found to be high at all three time points but there was significant moderate decline at Time 2 and again at Time 3. One possible reason for this change is that family and friends were more inclined to be supportive at the beginning of the treatment when they felt that patients needed it the most. Qualitative findings revealed that social support can become problematic when the support such as the family appears to pity them or if they want to be exceedingly supportive which may become overwhelming. Therefore the decline in social support may be that patients would seek the support more so at the beginning of the treatment when they do not know what to expect of the treatment and have not experienced it. However, when they experience the treatment, they do not seek as much support.
In the quantitative study, satisfaction was measured at three time points using a 13-item questionnaire, using a 6-point scale designed for the study with good internal reliability. On the other hand, trust for the physician and social support of patients were measured using validated questionnaires, also with good internal reliability. Similar patterns were seen for the three factors longitudinally. Overall, the study found patients were moderately to strongly satisfied with the information throughout the treatment process, highly trusting of their physician and received ‘quite to very much’ social support. Alternatively, the decline in social support (and also satisfaction and trust in the physician) could have been due to the measures utilized. It was unknown what the test re-test reliability was for any of the measures as satisfaction was study-specific and therefore untested, and trust and social support were unknown. Changes in scores over time could therefore have been an artifact of the psychometric properties.

Patient satisfaction was found to be significantly correlated, in a positive direction, with patient trust for the physician and social support that patients received. In other words, a high level of satisfaction was associated with a high level of trust for the physician and a high level of social support. As a correlation does not determine causality, it is not clear which of these factors is impacting on the other factors. However previous studies, as described in Chapter Five, show evidence that a patient’s trust for the physician improves their satisfaction with care (Thom et al., 2002; Safran et al., 1998). Also, as mentioned above, in a recent study Kraetschmer and colleagues (2004) results have shown that desire for a passive role was significantly associated with higher levels of trust. Based on this evidence, one potential theory may be that a high level of trust leads to a high level of patient satisfaction which leads to a less active role, potentially lowering the knowledge of patients. Another speculation is that a decrease in patient satisfaction with information with experience is simply a reflection of patients having negative experiences with their chemotherapy (such as enduring side effects) or that the patients have some expectations with experience but they are not as highly met as when they had no expectations at the beginning of the treatment.

If, as identified, there is an association between patient satisfaction and patients’ trust in the doctor, it makes the physician’s role immensely significant in the patient’s experience of
treatment. No doubt, it is difficult to pinpoint exactly what the doctor needs to do and avoid doing in gaining the patient’s trust, as trust is a complex construct and is very much individualised. Patients in this study were asked to suggest how to improve the information given in order to maximise satisfaction, however this did not yield useful information. Patients stated that they did not have any expectations regarding the information and therefore felt that they did not know how it could be improved. Nevertheless a plethora of research has aimed at improving physician’s communication skills (Fallowfield et al., 2002; Fellowes, Wilkinson, & Moore, 2004).

Other theories may be that patients’ overall satisfaction with the consent form information may have decreased over time as a consequence of patients’ internal conflict, perhaps best explained by Festinger’s (1957) Cognitive Dissonance Theory. This theory contends that dissonance, or an uncomfortable feeling, ensues when two conflicting thoughts occur at the same time or a specific behaviour contradicts a previous behaviour (Festinger, 1957). People are compelled to lessen or to extinguish the dissonance and will usually do this in the simplest way they can. In the case of patients’ satisfaction, although a patient may remember filling in the same questionnaire at previous time points and reporting that they were very satisfied with the consent information, as they progress through their chemotherapy and feel very ill, they may experience conflict when asked to continue reporting that they felt satisfied with the information they were given pre-chemotherapy.

For instance, conflict may stem from the idea that one can understand they will probably experience nausea and vomiting, but when they actually experience the sensations, they feel much more intense, and the patient feels ill-informed. Essentially, this highlights the difference between expectations and experiences. This notion is supported by research by Olver, Taylor, and Whitford (2003) which aimed to identify whether patients’ expectations were associated with post-chemotherapy experiences (Olver, Taylor, & Whitford, 2003). Therefore one of the simplest ways patients can decrease this conflict is to say that at the current time, they feel less satisfied, hence scores decrease over the chemotherapy experience. This theory may also apply to changes which were seen for trust in the physician over time.
A recent qualitative study on decision-making in cancer found that even when patients report a desire for collaborative decision-making, they rely heavily on their doctor’s opinion and seek more information to understand the rationale behind the doctor’s recommendation than to make the decision themselves (Henman, Butow, Brown, Boyle, & Tattersall, 2002). This implies that patients desire an active role in the process but not necessarily in the final decision. Therefore it was anticipated that, similar to Henman et al.’s (2002) study, findings from this research would show significance with regards to trust. This can be explained by the high level of patient trust for their physician found.

Each of the factors also had a weak correlation with one of the measures of knowledge. Patient satisfaction and trust showed significant associations with knowledge of the number of drugs. Trust also showed a weak but not a significant association with patient knowledge of side effects. Thirdly, social support showed a weak, negative association with knowledge of the names of drugs which was also not significant. Their role as a predictor of information knowledge is discussed in the next section.

**Predictors of patient knowledge of the information given**

A number of factors have been found to be associated with patient knowledge of the information given. Based on univariate correlations, these include age, gender, education, marital status, living alone, attending hospital, extent of information read, patient satisfaction, trust in the physician, and social support of patients. The only factor that was not found to be associated with any of the measures of knowledge was ‘English as a first language.’ Of these variables, only age and extent of information read weakly correlated (r ≥ .10) with all three measures of knowledge however both factors were only significantly associated with the knowledge of the drug names. This means, that younger patients, and those who read the information to a greater extent had a higher level of knowledge on all three measures (number and name of drugs, and potential side effects). The weak associations may not have been significant due to the small sample size compromising power. Results regarding the association of knowledge and extent of reading the consent form was consistent with findings from Olver et al. (1995) who also found the extent of reading the consent form to be a
significant factor in being able to name the drugs, know the number of drugs, remember the
duration of treatment, remember the common side effects, and recall the goal of treatment. It is
unclear whether these are the results of univariate analyses such as correlations or multivariate
analyses such as regressions. Indeed this longitudinal study was aimed at replicating the
findings from this study (Olver, Turrell et al., 1995). Therefore, the extent of reading the
information and age formed part of three models of knowledge of the information given, two
of which were found to be significant: knowledge of the number and name of drugs. However
neither of the factors were found to be individually significant predictors in the regression
models. While both models showed younger patients to have greater knowledge of the name
and number of chemotherapy drugs, the extent of reading the information showed varying
results. While the regression model showed that a greater extent of reading the information
was found to be a predictor of the knowledge of the number of drugs, the model for the
knowledge of the name of chemotherapy drugs was predicted by patients reading less of the
information given. This may be because their knowledge of the name of drugs was not through
the information given but through their experience of treatment, such as by sitting in the clinic
and acquiring this knowledge through reading the drug labels.

Knowledge of the number of drugs was predicted by a number of factors including younger,
female, private patients who did not live alone or were married, who had read most or all of
the information and were satisfied with it, and who had less trust in their physician. This may
be explained by the fact that younger patients may be more concerned about aspects of cancer
treatment and as they had less trust in their physician regarding this measure, they read the
information to a greater extent. Also, living alone was found to be negatively yet weakly
associated with social support indicating an increase in social support when not living alone.
Therefore, evidence from this research that suggests that, when not living alone, patients were
more likely to be supported, and in turn patients were more likely to be have knowledge of
their treatment process Being female and being a private patient were individually significant
predictors of knowledge of the number of drugs suggesting they made the strongest impact of
all three models. This may be partially explained by a moderate correlation seen between
private patients and level of education. In other words, private patients may be more educated
leading to their improved knowledge of the number of drugs. It may also be speculated that
privately insured patients may pay more attention to the details of their treatment process ultimately increasing their knowledge of the information given. There is no supporting evidence of this found in the current study and would therefore need to be explored further. Potential research should consider determining what attributes and behaviors patients have regarding their health care, their treatment, and consent process. This may help in researching and improving knowledge gained by public patients. Also, variables not being strong enough to be individually significant may be related to the power of the study.

A significant model for the knowledge of the names of drugs was found to be predicted by age, education, living alone, extent of information read, and social support. Younger, less educated patients, who were not living alone, and who had read the information to a lesser extent and had a low level of social support had greater knowledge of chemotherapy drug names. None of these factors was able to individually significantly predict knowledge of drug names suggesting their strength alone was not high, but in combination they provided a significant model of prediction. This is a complex model and the combination of predictors cannot be easily explained. Younger patients may be able remember the complex names much easier than older patients. Also it appears that having the knowledge of the drug names does not require a high level of education. As mentioned previously, this knowledge may have been gained while the patient was in the clinic receiving treatment, at which time they may have read the drug labels or were informed by the nurse of the name of the drugs they were receiving.

Of concern, though, is that the model explaining knowledge of side effects was not found to be significant. Although this factor was univariately associated with several demographic and psycho-social factors, in combination, the dependent variables there were not strong enough predictors to make this model count. Remembering the potential side effects is crucial for informed consent and to control one’s own treatment and health, more research is necessary to establish how we can improve this knowledge.

It is clear that for the three measures of knowledge, the predictors identified in the longitudinal study only account for, at most, 48% of the variance. Therefore there are other factors that
explain the remaining variance and while we are unsure what these are, potential predictors not measured in this study may include the impact of anxiety and coping abilities. Patients diagnosed with cancer and receiving treatment may suffer severe distress, including anxiety and depression (Hyodo et al., 1999). As mentioned earlier (Chapter Three), there has been a good deal of research on anxiety and the informed consent process. Two different scenarios exists for such research; firstly, a patient’s anxiety may interfere with their ability to understand hence anxious patients may be less likely to take in information (Keinan, 1987), or the information given to patients may generate anxiety (Faden, Becker, Lewis, Freeman, & Faden, 1981) and either way may be more likely to report dissatisfaction as a consequence of their experience.

Wallace (1986) reported that surgical patients with more knowledge are less worried and potentially recover faster and this is likely to reflect the treatment setting (Wallace, 1986). Much of the research on anxiety measures its changes associated with format modifications to the informed consent process (Mason et al., 2003). However several studies assess the relationship between anxiety and knowledge of information or decision-making capacity. A study by Peterson, Schwartz, Sherman-Slate, Frost, Straub, and Damjanov (2003) showed that the patients’ decisional style did not vary with depression and anxiety suggesting how a person makes decisions is a stable personality trait (Petersen, Schwartz, Sherman-Slate, Frost, Straub, and Damjanov, 2003).

Different patients have different coping strategies towards the pressures of a cancer diagnosis and treatment. The ability to cope with one’s condition will no doubt allow them to focus on the important factors at the time, while those in denial may not be able to accept the series of events that occurs and hence will not take in a lot of the information given. While coping strategies are believed to act in concert with social support, individual differences will also play a role. Indeed research by Roy, Symonds, Kumar, Ibrahim, Mitchell, and Fallowfield (2005) found significant differences amongst Asian compared with Caucasian patients regarding coping and in particular denial (Roy et al., 2005). Caucasian patients appeared to adapt to the psychological pressures of cancer more successfully than Asian patients.
Nonetheless coping styles and the effect of ethnic diversity needs to be considered in future longitudinal research.

In the qualitative study, one theme that arose regarding patients’ consent to treatment was ‘limited choice’. This was not covered in the quantitative analyses but follows other literature that suggests weighing up the risks and benefits is seen as two categories: having treatment or risking one’s survival. Any inconvenience or side effect that may result from treatment is meaningless when compared with the possibility of death if treatment is rejected. This was consistent with research by Charles, Redko, Whelan, Gafni, and Reyno (1998) in a sample of women with early breast cancer (Charles, Redko, Whelan, Gafni, & Reyno, 1998).

Many women interviewed in this study reported that they had to do everything to avoid death, and some participants thought that they would ‘beat the odds’ regardless of their level of risk (Charles et al., 1998). This is a classic example of ‘fighting spirit’, a form of mental adjustment to cancer for the patient. Fujimori et al. (2007) conducted a recent study on Japanese cancer patients aimed at exploring the associations between the dimensions of patients’ communication style preferences and demographic, medical, and psychological adjustment variables (Fujimori, Akechi, Morita, Inagakim Akizukim Sakano, et al., 2007). The study found that ‘fighting spirit’ was positively associated with five factors on the Japanese version of the validated measures of patient preferences (MPP). One of these five factors was medical information which indicates that fighting spirit was positively associated with the information given regarding treatment options. Together with evidence supporting the efficacy of fighting spirit as a coping style (Hassainen, Musgrove, & Bradbury, 2001) this emphasises that if the medical information impacts positively on patients’ ‘fighting spirit’, the patients are more capable of coping with cancer and its side effects. Fighting spirit has also been identified as a psychological factor experienced by patients that may influence cancer outcomes such as survival (Greer, Morris, & Pettingale, 1979; Watson, Homewood, Haviland, & Bliss, 2005). While there is scarce good evidence to confidently support this, as identified by a systematic review of studies measuring coping styles, many patients continue to feel that positive thinking will lead to better outcomes (Peticrew, Bell, & Hunter, 2002). However, when a
patient has a terminal illness, then fighting spirit can be seen as denial which may explain why many studies have found the patient cannot correctly recall the correct goal of treatment.

One other factor to explain the remaining variance in knowledge in the study is that patient knowledge is very much dependent on the patient’s ability to recall at a particular time, however when given a short time to complete the questionnaire, under sometimes demanding conditions, or when the patient has more important matters to resolve in their minds, it is difficult for them to answer optimally.

In summary, while we are now aware of some factors that are predictive of aspects of knowledge of the information such as age, attending hospital, and gender, amongst others, there are many other known variables that have not been measured and possibly unknown factors as well. Therefore, research needs to focus on identifying such factors and also trying to identify how these predictors will help in improving patient knowledge of the information and the consent process. From this study, it has been identified that age, and the extent of information read were the common variables across both of the significant models.
**Conclusion**

Although the experience of chemotherapy treatment alone does not appear to be sufficient at improving patient knowledge of chemotherapy information, more sizeable and extensive research is necessary before disregarding this concept based on the limitations suggested above and the lack of replication. Although not all outcomes were successful, such as improving patient knowledge with experience, other interesting findings were found and some elements of this research improved on previous efforts. For instance, this study was superior to other studies in the area of informed consent as it measured free recall rather than prompted recall or recognition. However, this did make comparison to other studies in the area more difficult as this measurement type along with the stringent scoring methods made knowledge estimates very conservative.

In terms of some of the interesting findings of this study, different combinations of specific demographic and/or psycho-social factors were found to be predictive of certain aspects of knowledge. The strongest results showed that younger patients and patients who read a greater extent of the consent information had better knowledge of some of the treatment information. Findings were consistent with previous literature in that younger patients may recall consent information better than older patients. Results from Olver et al.’s (1995) study and Cassileth and colleagues’ (1980) study, regarding the extent of information read were also supported. How much of the information the patients read, together with other factors, aids in predicting knowledge of the consent information (Olver, Turrell et al., 1995). These factors, in combination with other variables, provided significant models accounting for significant levels of variance for knowledge of the number of chemotherapy drugs received and the names of those drugs. Predictors of both significant models included being younger, female, less educated, not living alone, being married, being a private patient, being satisfied with the information given, had low trust in the physician, and social support of patients. The extent of reading the information given was also found to be a predictor of both models but the results varied depending on the measure of knowledge. That is, knowledge of the number of drugs received was predicted by a greater level of reading the information given, while the
chemotherapy drug names were predicted by reading the information given to a less degree. Therefore, the results point to multiple patient-based as well as physician-based components that influence and hence may predict some aspects of knowledge of medical treatment information. However due to the complexity of the relationships of the predictor variables and each aspect of knowledge of the information given, it makes improving patient knowledge at the time of consent very difficult to achieve.

**Limitations of the studies**

There are several limitations of the studies that need to be noted. Firstly, the sample size compromised power in some of the analyses. Specifically, due to drop outs across the three time points of the longitudinal study, the sample went from 71 to 57 patients. This could have contributed to Type II errors – specifically, overlooking significant effects when they truly existed. However, the sample size was unable to be improved due to the longitudinal nature of the study, the sensitive population being studied, and time constraints. The longitudinal study still had a reasonably high follow-up rate and instead of purely relying on null hypothesis significance testing, where possible, effect sizes were reported to determine the magnitude of change or associations. Furthermore, reliable change indices were reported for significant changes over time to determine clinically meaningful change, something not reported in any other studies reviewed in the two literature reviews.

Although an attempt was made to study a generalisable population of cancer patients, that of colorectal and breast cancer, two common types of cancer, covering both males and females, there is limited external validity in that the study focused solely on adjuvant chemotherapy treatment. Nonetheless, any study with a specific focus such as this would not be generalisable to other treatments, and this is a limitation of much informed consent research including research presented in Chapter Three on format modifications to improve the informed consent process. Consecutive recruitment of patients led to more females in the sample population, a limitation which was unavoidable. Specifically, as breast cancer patients were included it was expected that the female ratio would be higher than the male ratio, also females are commonly known to participate in more psycho-social research than men. Similarly, despite randomised
selection, no men formed part of the qualitative sample, as more women completed time three assessments, and men approached showed a lack of interest, hence potentially limiting the themes to emerge.

The lack of validated scales for assessing knowledge of information given and patient satisfaction with the treatment information meant that these assessments had to be specifically designed for the purposes of this study. This is a particularly common problem in informed consent research as outlined in the literature reviews of this thesis. Reliability testing could not be carried out on questions assessing patient knowledge of the information given as they consisted of single items, rather than several items in a scale. For patient satisfaction, a scale was designed and reliability of the scale was assessed (and was good), however other psychometric properties like test-retest reliability, was untested and therefore could have impacted the results seen.

Knowledge scores obtained based on patient responses were also compromised. This is because the consent interview was not recorded to determine the content of the consultation and hence assess patients on the actual information that was presented by the physician but rather the information specifically provided on the information sheet and consent form. Similarly, patients were not asked what side effects they were experiencing to be able to determine whether knowledge of the information given at the time of consent was improving with experience, or whether, by chance, patients were just experiencing more actual side effects, so they were able to list them.

Despite attempts to interview all participating patients on site at the hospital, in some cases questionnaires had to be sent by post as not all patients were able to attend the hospital one month post chemotherapy treatment. This was not considered ideal and should be considered with caution as patients could have looked up the answers in their information sheet. However, every attempt was made to avoid using this method and those that did return a questionnaire
by post were carefully checked to make sure no one was reporting very high or perfect responses, a crude assessment of referring to the form at home. Also, this study was limited in that it covered three measures of patient knowledge however there are several other measures that could have been considered. Such things include the goal and length of treatment which may be considered by some as more important than the knowledge of the names and numbers of drugs. It was not feasible to include all of the factors and those chosen for the study were based on the measures commonly found in previous research and therefore aimed to be replicated for comparability.

Furthermore, assessment of other variables believed to be associated with knowledge of the information given prior to obtaining consent, such as patient anxiety and patient-physician communication, was not carried out. Both of these factors have seen considerable research some of which was presented in Chapters One, Three and Four, and therefore the focus was turned to researching novel variables that had received limited or no attention, such as level of social support and patient trust for the physician. Other variables of interest such as quality of life, locus of control, (i.e. the extent to which individuals believe that they can control events that affect them) were not measured as it was not feasible to recruit more patients in the limited time frame and achieve the same power. This research did however set the foundation for longitudinal research measuring the experience of treatment in improving the informed consent process and covered assessment of a considerable number of variables and establishment of fundamental themes regarding information given prior to obtaining consent. Some confounding variables directly related to patient knowledge of the information given were not assessed in the longitudinal study. In particular, previous research suggests that cognitive function may be affected by chemotherapy treatment which may confound patient knowledge of the information. Although long-term follow up of patients up to one month after completion of chemotherapy was used to overcome this as far as possible, it is not clear from previous research whether cognitive function returns to normal by this stage, if it was affected. However it needs to be considered that longer term follow-up than was conducted may lead to the risk of patients forgetting consent information due to the passage of time and its impact on memory.
Another limitation of the study was that patient knowledge of the information given was not measured after providing informed consent but before receiving treatment. This would obtain a baseline measure of patient knowledge and would allow to control for the effect of time when measuring the impact of treatment experience. As mentioned in Chapter Seven, in this setting it was not feasible to obtain such data prior to treatment initiation however this could be evaluated in future research. Although as suggested in Chapter Seven there is always the risk of leading patients to better recall their consent information by asking them to be involved in research that assesses this component. This is a difficult area to assess without such impact.
Implications for future studies

Incorporation of these findings in clinical practice is possible at different levels. People differ in their ability to understand information, and have different circumstances and priorities that can influence their interpretations. The longitudinal study found that many different factors may influence knowledge of the different aspects of the consent information given. This leads to recognition of the complexity in enhancing the understanding of the consent process and suggests that an individualised or multi-faceted approach may be necessary. Also, an important finding from the study was that reading the information had positive effects on patient knowledge. It would be straightforward to educate both doctors and patients about the importance of this, as it is likely this simple problem is not foreseen.

Another simple approach would be to focus on layering the information over time, that is, repeating valuable information at more acceptable time points for patients, and when the information becomes more significant. However this was not examined in this thesis and could be considered in future studies. It should be recognised that informed consent cannot be taken over time or post-treatment and therefore it would not be possible to change the consent process to reflect this. However information presented to patients in this novel way may help in improving patient knowledge of the information given.

With the awareness that older patients are less likely to have knowledge of the information compared with younger patients, interventions need to focus heavily on this population. This may include increasing consultation times for older patients or developing the information to best suit their needs. The important factor is to determine what characteristics of older patients lead to the lack of knowledge. It may vary from their anxiety levels to other more significant cognitive impairment compared with younger patients.

While these are implications for pre-treatment consent improvements, this research has also identified factors post-treatment which may also be incorporated into clinical practice once they are further evaluated. This includes an intervention to reinforce the information during the chemotherapy treatment experience. This process is vital so patients are not faced with
detrimental or life-threatening situations. Such an intervention may be the nurse spending a few minutes with the patient at each chemotherapy cycle to re-iterate the potential complications of treatment and to answer any arising questions. This may already be happening however this has not been assessed nor made practice.

Regardless of the method of improving consent, it is not possible to give complete information to patients. One consequence of this is that there may be the possibility that a patient experiences a side effect that was unexpected. Another consequence is that the possibility of litigation may not be completely eliminated. Current requirements of informed consent are framed at whether the clinician took steps to ensure that the patient understood the information rather than what information was given. Therefore even recording every consultation as evidence of information disclosure by the physician will not suffice.

There is a complex array of factors that may predict patient knowledge of information given and some of these were raised in the qualitative study. Although beyond the scope of this thesis, future research may consider investigating the association of patient expectations with knowledge. Although this was measured qualitatively in this thesis, and found that patients had no expectations early in the treatment process, it would be worth measuring this in a larger sample and do so quantitatively. If patients have certain unrealistic expectations regarding the goals of treatment, they may not be likely to try to understand the information. Patient expectations may itself be related to other factors such as satisfaction, which may have a combined effect on patient knowledge. Unfulfilled expectations may or may not lead to less satisfaction, which in turn, may or may not lead to less knowledge of the information. Qualitatively, patients also placed a great deal of importance on some factors not quantitatively assessed that deserve further attention, including family values. There may also be other factors, yet unknown, that may also aid in explaining the deficiency in patient knowledge of the treatment information given.

While the factors mentioned above are all patient factors that may predict their knowledge, there are also physician factors that may do so. Recent studies have found that physicians who
perceived that patients had difficulties comprehending health information, physicians who did not feel it is important to deliver health information, and physicians who rated themselves as effective health information communicators were all significant predictors of lack of knowledge (Lukoschek, Fazzari, & Marantz, 2003)

Another physician related factor includes the quality of the information provision. Effective communication between doctors and patients to improve all aspects of health care is extremely important and receiving increasing attention. The initiation of medical treatment can be a distressing time for patients and the complex and toxic nature of cancer treatments, in particular, means that it is vital for patients to feel comfortable with the way the information has been communicated with them.

Further prospective research exploring patient knowledge of information given should possibly concentrate on other factors such as treatment goals, length of treatment, and prognosis. This stems from the qualitative finding that patients do not remember the number of drugs they are receiving as they do not believe this to be a fact that matters and can always be questioned in the future.

Delivering treatment information in an appropriately and timely manner can be difficult with time pressures and patient numbers leading to short consultations in which there may be an information overload. Physicians may also overestimate the level of patient understanding of treatment information resulting in dissatisfied or confused patients which can create problems, as patients need to be clear about the benefits and risks before consenting to a medical treatment.

In conclusion, there is a limit to the amount of information about treatments that can be assimilated by patients pre-treatment. This study has shown that the experience of the treatment does not add to the patients’ knowledge of their treatment so other strategies such as parceling out information over time will need to be evaluated.
References


Appendix A  The Nuremberg Code (Nuremberg Code, 1949)

THE NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.
Appendix B  Demographic data form
# INFORMED CONSENT: RECALL & SATISFACTION

**STUDY ENTRY FORM**

<table>
<thead>
<tr>
<th>Hospital UR number:</th>
</tr>
</thead>
</table>

**PATIENT STICKER**

<table>
<thead>
<tr>
<th>Cancer type:</th>
<th>□ Breast</th>
<th>□ Colorectal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative/friend present:</td>
<td>□ Yes</td>
<td>□ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INCLUSION CRITERIA:</th>
<th>EXCLUSION CRITERIA:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Aged 18 yrs or above:</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>2. Ability to speak &amp; read English well</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>3. Performance status ≤ 2:</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>4. Consent form signed:</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>1. Concurrent psychiatric or medical morbidities</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>2. Current participation on a trial assessing recall or satisfaction</td>
<td>□ Yes □ No</td>
</tr>
</tbody>
</table>

**DEMOGRAPHIC INFORMATION**

1. What is your marital status?
   - □ Never married/Single
   - □ Married/Defacto
   - □ Separated/Divorced
   - □ Widowed

2. What is your highest level of education?
   - □ Primary
   - □ Secondary
   - □ Tertiary

3. What is your nationality?
   - .............................................

4. Is English your first language?
   - □ Yes □ No

5. What was/is your usual occupation?
   - □ Unskilled
   - □ Blue collar worker or tradesperson
   - □ White collar worker
   - □ Professional
   - □ Home duties
   - □ Student
   - □ Other (please specify) .................

6. What is your employment status at present?
   - □ Employed/Self employed
   - □ Employed but on sick leave
   - □ Unemployed as a result of cancer
   - □ Unemployed, unrelated to illness
   - □ Retired
   - □ Student
   - □ Other (please specify) .................
Appendix C    Quantitative patient questionnaire used
INFORMED CONSENT: RECALL & SATISFACTION

<table>
<thead>
<tr>
<th>Hospital UR number:</th>
<th>Date:</th>
<th>Surname:</th>
<th>First name:</th>
</tr>
</thead>
</table>

**GENERAL**

1. Where did you obtain most of the information about your cancer?
   - Doctors
   - Nurses
   - Books/Magazines/Pamphlets/Newspapers
   - Television
   - Information and Consent form
   - The Internet
   - Videos
   - The Understanding Cancer CD-ROM
   - Other, please describe...

2. What is your current level of activity?
   - Capable of normal activity
   - Have symptoms but still active
   - More than 50% waking hours out of bed
   - Less than 50% waking hours out of bed
   - In bed all the time

3. Did you find the information on the information sheet & consent form...
   - too little?
   - just right?
   - too much?

4. How much of the information sheet & consent form did you understand?
   - All of it
   - Most of it
   - Some of it
   - None of it

**KNOWLEDGE**

1. How much of the information sheet & consent form did you read?
   - All of it
   - Part of it
   - Quick skim through it
   - Did not read it

2. Did anyone help you to read the information on the information sheet & consent form?
   - Yes
   - No

3. Did you get help in making a decision about consenting to the treatment?
   - Yes
   - No

4. Did you look at the information sheet & consent form outside of the hospital?
   - Yes
   - No

5. How many times do you think you looked at the information sheet & consent form?
   - times

6. How long did you have to read the information sheet and consent form?
   - days

7. Can you remember how many drugs in your chemotherapy regimen?
   - Yes
   - No

8. Can you name the chemotherapy drugs that you are receiving?
   - Yes
   - No

9. Can you remember the side effects listed on the information sheet & consent form?
   - Yes
   - No

10. Did you experience side effects that you don’t remember being listed on the information sheet & consent form?
    - Yes
    - No
## SATISFACTION

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Moderately agree</th>
<th>Slightly agree</th>
<th>Slightly disagree</th>
<th>Moderately disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I am satisfied with the information received</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. There was too much detail on the information sheet &amp; consent form</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. More attention should have been paid to the type of language used</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. In general, I felt that I understood the information sheet &amp; consent form</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. I felt the information sheet helped me to be involved in the decision-making process</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. The information given to me answered my questions</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7. I am satisfied with the treatment I have received</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8. I feel unclear about some of the details on the information sheet &amp; consent form</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9. The information sheet &amp; consent form highlighted the most important points</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>10. There was not enough time between receiving the information &amp; making a decision</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11. Reading the information given made me feel more anxious about my treatment</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12. The information given was easy to read</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13. There was plenty of time to read the information before making a decision</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

## TRUST

<table>
<thead>
<tr>
<th></th>
<th>No, not at all</th>
<th>Yes, to some extent</th>
<th>Yes, for the most part</th>
<th>Yes, completely</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did you feel that the doctor(s) answered your questions honestly?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Did the doctor(s) respect your privacy?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Did you have confidence in your doctor(s)?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Did you trust your doctor(s)’ suggestions for treatment?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

## SOCIAL SUPPORT

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel close to my friends</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. I get emotional support from my family</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. I get support from my friends</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. I feel close to my partner (or the person who is my main support)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Regardless of your current sexual activity, please answer the following question. If you prefer not to answer it, please check this box □

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. I am satisfied with my sex life</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix D  Template of questionnaire used for semi-structured interviews
### Questions:

<table>
<thead>
<tr>
<th>General:</th>
<th>Satisfaction: (triangulation with quantitative)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I would like you to think back to when you agreed to have chemotherapy treatment: What do you remember about the information sheet and consent form that you received?</td>
<td></td>
</tr>
<tr>
<td>2. What do you understand by the words ‘informed consent process’?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Satisfaction: (triangulation with quantitative)

3. Lets now focus on one aspect of the informed consent process, which is regarding the information (on the information sheet) you were given:
   a. What did you think about the information that you received at the time of consenting to chemotherapy treatment?
   b. What did you expect to receive in terms of information given on chemotherapy treatment, if anything?

4. What did you think about the information that was presented on the information sheet?
   a. Do you think it could have been better, if so, in what way?

### Prompts:

- Separate the 2 sheets
- Content (Type, length, user friendly)
- Info given – quantity, quality
- Legal/ethical process
- Understanding
- Health care (doc/pat)

- Satisfaction level –quantity, quality
- language used
- layout
- type of info
- mode of info
- length
### Questions:

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| 5. | What can you tell me about the amount of time you were given to understand the given information and make a decision about agreeing to have treatment or not? What made it so quick to decide?  
  a. Was this enough time? If yes, how did you know? If not, why not?  
  b. Would you have liked more time? Why is this so? |
| 6. | Was there anything as part of the informed consent process that didn’t work for you (i.e. could have been done differently)? |
| 7. | Is there anything else that you would like to add regarding the process of consenting to treatment? |
| 8. | Did you make use of other forms of information (internet etc)? If so, what prompted you to do that? (Was it as a result of hospital service?) |
| 9. | Did you talk to others when you were trying to decide whether or not to receive chemotherapy?  
  a. May I ask who?  
  b. Did that help?  
  c. How did that help?  
  d. What made you decide to talk to others? |

### Prompts:

- Clearer understanding
- Time, info, doctor-related, explanations
- improvements
- dissatisfied with info given (lack of)
- confirm what has been given (trust)
- hope/paranoia
- spare time
- support
### Questions:

10. Did the doctor play a part in your decision to consent? If yes, what was that role? If not, was there a reason for this?

11. Some people have said that trust is important, I wondered if you had any thoughts on trust?

12. Is there anything else that you would like to add?

Thank you very much for your time.

### Prompts:

- support
- trust
## Appendix E  Bi-variate correlations of longitudinal study variables

|                           | Hospital (n=71) | Gender (n=71) | Age (n=71) | Marital status (n=71) | Education level (n=71) | English speaking (n=71) | Live alone (n=71) | Total satisfaction (n=71) | Total trust (n=71) | Total support (n=71) | Number of drugs correctly recalled (n=71) | Drug names correctly recalled (n=71) | Proportion of side effects correctly recalled (n=71) |
|---------------------------|----------------|---------------|------------|-----------------------|------------------------|-------------------------|------------------|---------------------------|------------------|------------------|--------------------------------|----------------|--------------------------------|}
| Attending Hospital        | Correlation    | 1             | 0.250(*)   | -0.067                | 0.249(*)               | 0.224                   | -0.170           | 0.074                     | 0.180            | 0.317(**)        | 0.156                        | 0.495(**)          | 0.077                        | .155 |
|                           | p              | 0.035         | 0.577      | 0.036                 | 0.060                  | 0.156                   | 0.542            | 0.132                     | 0.007            | 0.195            | 0.000                        | 0.523            | 0.962                        | .196 |
| Gender                    | Correlation    | 0.250(*)      | 1          | -0.054                | 0.016                  | -0.122                  | 0.075            | -0.186                    | 0.204            | 0.368(**)        | 0.135                        | 0.407(**)          | -0.009                       | .188 |
|                           | p              | 0.035         | 0.656      | 0.898                 | 0.312                  | 0.535                   | 0.121            | 0.087                     | 0.002            | 0.262            | 0.000                        | 0.942            | 0.916                        | .116 |
| Age                       | Correlation    | -0.067        | -0.054     | 1                      | -0.056                 | -0.312(**)              | -0.043           | 0.973                     | -0.104           | 0.389            | 0.999                        | 0.130            | 0.402                        | .306 |
|                           | p              | 0.577         | 0.656      | 0.644                  | 0.008                  | 0.973                   | 0.100            | 0.389                     | 0.072            | 0.180            | 0.124                        | 0.124            | 0.912                        | .222 |
| Marital status            | Correlation    | 0.249(*)      | 0.016      | -0.056                | 1                      | -0.044                  | -0.003           | 0.528(**)                 | 0.229            | 0.089            | -0.008                       | 0.037            | 0.191                        | .243(*) |
|                           | p              | 0.036         | 0.898      | 0.644                  | 0.716                  | 0.980                   | 0.000            | 0.055                     | 0.460            | 0.550            | 0.132                        | 0.302            | 0.855                        | .855 |
| Education level           | Correlation    | 0.224         | -0.122     | -0.312(**)            | -0.044                 | 1                      | 0.141            | 0.153                     | 0.034            | 0.071            | -0.008                       | 0.037            | 0.191                        | .243(*) |
|                           | p              | 0.060         | 0.312      | 0.008                 | 0.716                  | 0.241                   | 0.202            | 0.781                     | 0.556            | 0.949            | 0.760                        | 0.110            | 0.041                        | .041 |
| English speaking          | Correlation    | -0.170        | 0.075      | 0.004                 | -0.003                 | 0.141                   | 1                | 0.109                     | 0.089            | 0.023            | -0.089                       | -0.118           | -0.008                      | .008 |
|                           | p              | 0.156         | 0.535      | 0.973                 | 0.980                  | 0.241                   | 0.364            | 0.461                     | 0.851            | 0.462            | 0.911                        | 0.328            | 0.949                        | .949 |
| Live alone                | Correlation    | 0.074         | -0.186     | -0.197                | 0.528(**)              | 0.153                   | 0.109            | 1                         | 0.151            | 0.085            | -0.123                       | 0.110            | 0.118                        | .010 |
|                           | p              | 0.542         | 0.121      | 0.100                 | 0.000                  | 0.202                   | 0.364            | 0.208                     | 0.483            | 0.306            | 0.363                        | 0.328            | 0.935                        | .935 |

* Correlation is significant at the 0.05 level (2-tailed)  ** Correlation is significant at the 0.01 level (2-tailed).
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* Correlation is significant at the 0.05 level (2-tailed) ** Correlation is significant at the 0.01 level (2-tailed).
Appendix F  Informed consent form template

INFORMED CONSENT

INVESTIGATORS:  Ms Hedyeh Hedayati, BBiotech (Hons), GDPH
Professor Ian N. Olver, MD,PhD,CMIn,FRACP,FACHPM,MRACMA
Dr. Hayley Whitford, PhD Psych
Dr. Dusan Kotasek, MBBS, (Hons), FRACP

STUDY NAME:
Patient satisfaction and recall of treatment information in oncology settings: a longitudinal study

THE NATURE AND PURPOSE OF THE RESEARCH PROJECT HAS BEEN EXPLAINED TO ME. I UNDERSTAND IT, AND AGREE TO TAKE PART.

1. I understand that I may not directly benefit from taking part in the study.

2. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.

3. I understand that I can withdraw from the study at any stage and that this will not affect my medical care, now or in the future.

4. I have had the opportunity to discuss taking part in this investigation with a family member or friend.

5. I understand that my medical records may be accessed to collect demographic information.

6. I am aware that I should retain a copy of this Consent Form, when completed, and the attached Information Sheet.

Name of Participant (printed)  Signature of Participant  Date

I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved.

Name of Investigator (printed)  Signature of Investigator  Date
Appendix G  Patient information sheet

PATIENT INFORMATION SHEET

STUDY NAME: Enhancing knowledge: the impact of treatment and information

INVESTIGATORS: Ms Hedyeh Hedayati BBiotech (Hons), GDPH
Professor Ian Olver D,PhD,CMin,FRACP,FACHPM,MRACMA
Dr Hayley Whitford PhD Psych
Dr Dusan Kotasek MBBS, (Hons), FRACP

Introduction:
This project aims to study patients who are due to receive adjuvant chemotherapy for breast or colorectal cancer and who would therefore receive the standard Royal Adelaide Hospital information sheet prior to chemotherapy. This study is being conducted in order to improve the informed consent process prior to chemotherapy treatment so that patients will be able to better recall this information and in turn be more satisfied with the information they are given.

What is involved in this study?
If you agree to participate in this study you will be asked to complete three different questionnaires in the form of structured interviews. These structured interviews should take no longer than 10-15 minutes to complete. The interviews will occur at three different time points; one prior to attendance to the second cycle of chemotherapy, the second questionnaire will be given prior to the fourth cycle of chemotherapy and the last questionnaire will be given one month after the chemotherapy cycle has been completed. These questionnaires aim to collect data on age and educational level, recall of information about the chemotherapy, and satisfaction with the extent of information given. In addition, after the last questionnaire, given at one month after completion of the chemotherapy cycle, you will be invited to take part in a longer in-depth discussion about your satisfaction with the information provided and any other views or preferences that you may have. This discussion will take between 30-60 minutes and conducted at a time that suits you. All interviews will be audiotaped and transcribed by an investigator who will protect confidentiality.

Permission for review of records, confidentiality and access to records
One of the investigators conducting the study will collect demographic information about you from your medical records, however all of the collected data during the course of the research will be kept confidential. In addition, this research will form part of Hedyeh Hedayati’s doctor of philosophy degree and the data may also be used in publications about the study; however, your name will not appear in any publications.

What are my rights as a participant?
Your participation in this study is entirely voluntary. You may choose not to take part, or you may withdraw from the study at any time. Refusing to participate or leaving the study will not affect your current or future medical care.

Whom do I call if I have any questions or problems?
If you have any questions regarding the study, please refer to the attached ‘Independent Complaints Procedure’ form.
Appendix H  Complaints form

THE UNIVERSITY OF ADELAIDE
HUMAN RESEARCH ETHICS COMMITTEE

Document for people who are subjects in a research project

CONTACTS FOR INFORMATION ON PROJECT AND INDEPENDENT COMPLAINTS PROCEDURE

The Human Research Ethics Committee is obliged to monitor approved research projects. In conjunction with other forms of monitoring it is necessary to provide an independent and confidential reporting mechanism to assure quality assurance of the institutional ethics committee system. This is done by providing research subjects with an additional avenue for raising concerns regarding the conduct of any research in which they are involved.

The following study has been reviewed and approved by the University of Adelaide Human Research Ethics Committee:

Project title: “Assessing patient satisfaction and recall of treatment information in oncology settings: a longitudinal study”

1. If you have questions or problems associated with the practical aspects of your participation in the project, or wish to raise a concern or complaint about the project, then you should consult the project co-ordinator:

   **Contact 1:**
   
   **Name:** Professor Ian Olver
   
   **Telephone:** (08) 8222 5577

   **Contact 2:**
   
   **Name:** Ms. Hedyeh Hedayati
   
   **Telephone:** (08) 8222 2482

2. If you wish to discuss with an independent person matters related to
   
   • making a complaint, or
   • raising concerns on the conduct of the project, or
   • the University policy on research involving human subjects, or
   • your rights as a participant

   contact the University of Adelaide Human Research Ethics Committee’s Secretary on telephone number (08) 8303 6028

   **OR**

   the chairperson of the Royal Adelaide Hospital Human Research Ethics Committee on telephone number (08) 8222 4139.