

HAEMATOPOIETIC STEM CELL TRANSPLANTATION:
EVALUATION OF A PATIENT AND CARER
PSYCHOEDUCATION PROGRAMME

KATHLEEN L WALLBANK

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ABSTRACT

Haematopoietic stem cell transplantation (HSCT) is a complicated and high-risk procedure used to cure disease or stop the spread of disease in a range of cancers. HSCT carries a high incidence of mortality and is associated with distressing short and long-term side effects. In addition, patients remain at risk of recurrence or mortality years after transplantation. Therefore, patients undergoing HSCT have been found to experience significant emotional and psychosocial distress because of the trauma associated with treatment. The literature suggests that about 50% of HSCT patients will experience clinical levels of distress. Carers and family members play an important role in caring for these ill patients in the short and long-term. Major role changes and financial stressors are experienced in many families, adding to the burden of care. However, very little is known about the rates of psychopathology in carers of HSCT patients.

Due to the arduous nature of HSCT, psycho-educational programmes have been developed by major transplant centres and hospitals in order to provide HSCT patients and their families with information on the treatment process, side effects, risks, and long-term outcomes. Research on patient education in oncology has shown that providing patients and carers with information about their illness and treatment reduces anxiety and distress. To date, there have been no empirical evaluations to support the use of education programmes for HSCT patients. While it could be assumed that information would be helpful in reducing anxiety and depression in HSCT as it is in oncology generally, the information provided to these patients is usually more confronting and therefore, may be less reassuring. Thus, it is not known whether providing patients with education about HSCT reduces patient and carer distress or whether it might actually increase adverse outcomes.

The aim of the present study was to evaluate the rates and correlates of distress in carers and patients and examine the effect of a psychoeducation programme for patients undergoing HSCT and their carers on knowledge, distress, information satisfaction, social support and caregiver burden. A randomised control trial was conducted to provide empirical data in relation to the latter aim. The following hypotheses were proposed. Firstly, it was hypothesised that patients and carers who received the education programme would have higher levels of knowledge, not evidenced in a group waiting to receive the programme. Secondly, it was hypothesised that the education program would not lead to increased anxiety and depressive symptoms. Thirdly, patients who know more about their condition would be the least distressed. As predicted, this study found high levels of distress, particularly in carers. Higher patient distress was related to having more concern about one's illness and experiencing more symptoms. Education was effective in increasing patient and carer knowledge. Importantly there were no adverse effects of knowledge and greater patient knowledge following the education program was associated with less distress, although there was no direct effect of education on distress. Future research should aim to identify what aspects of the education program are helpful to patients. Finally, support interventions such as CBT are needed to help patients and carers, in particular, cope with the high levels of distress inherent in the HSCT experience.

OVERVIEW

This thesis is structured into two separate studies with four chapters. Chapter 1 reviews the current literature on Haematopoietic Stem Cell Transplantation, patient and carer psychopathology, informed consent and patient and carer education. It also provides a rationale for the thesis. Chapter 2 reports the rates and correlates of distress in patients and carers from the baseline assessment of the main study (reported in Chapter 3). The results of this study demonstrated high rates of distress, particularly for carers of HSCT patients. The randomised controlled trial of the education programme is presented in Chapter 3. This demonstrates that the education program was effective in improving knowledge and that there were no adverse effects associated with the intervention. Chapter 4 provides a general discussion of the results of both studies with reference to the literature review.

CHAPTER 1: LITERATURE REVIEW

1.1 INTRODUCTION

Haematopoietic Stem Cell Transplantation (HSCT) is a medical treatment that involves the transplantation of blood stem cells. This treatment is more commonly referred to as bone marrow transplantation because in the history of this procedure, the stem cells used for transplantation were only obtained from the bone marrow (Pavletic & Armitage, 1996). However, today haematopoietic stem cells are more commonly collected from peripheral (circulating) blood and umbilical cord blood and, as a result, HSCT is now seen to be a more appropriate and inclusive term for explaining the procedure.

The purpose of the transplantation is to replace bone marrow stem cells in patients whose immune system has been destroyed by lethal levels of chemotherapy and/or radiotherapy that has been used to either cure or control the spread of disease (Bone Marrow Transplant Network NSW, 2006). The bone marrow, the soft matter found in the hollow bones of the hips, legs and arms, produces most of the body's circulating blood cells, including red and white blood cells and platelets. Without HSCT the patient would not be able to endure the toxic doses of chemotherapy and/or radiotherapy that is required to kill the cancer or suppress the immune system (Bone Marrow Transplant Network NSW, 2006). Healthy stem cells are intravenously inserted into the body and they find their way to the bones and become bone marrow. For diseases such as lymphoma and leukaemia, HSCT aims to increase the chance of cure. However, for illnesses where cure is not possible, such as multiple myeloma, the use of HSCT can help to control the spread of disease (Bone Marrow Transplant Network NSW, 2006).

Since its first controversial use in 1968, HSCT has recently become a standard treatment for people with cancer (Prieto, Blanch, Atala, Carreras, Rovira, Cirera et al., 2002). For people who have a critical blood or immune system disease, HSCT can be a life-saving treatment option (Bone Marrow Transplant Network NSW, 2006). Yet traditionally, HSCT was a last resort

treatment for incurable diseases used only when all other treatment options had been implemented because of the high risk of mortality associated with this procedure (Andrykowski & McQuellon, 1999). Advances in tissue typing procedures, improved understanding of the immune system, the biological response modifiers, and better supportive care have led to a dramatic change in the way HSCT is perceived and used (Lesko, 1994). For instance, it is now used earlier in more illnesses with curative intent. HSCT has been used in the treatment of leukemia, lymphoma, multiple myeloma, immune system diseases and, less frequently, solid tumours (Bone Marrow Transplant Network NSW, 2006; Pavletic & Armitage, 1996). HSCT is now being utilised as a “first-line” treatment for some conditions such as multiple myelomas, myelodysplastic syndromes, and acquired aplastic anaemia (Andrykowski & McQuellon, 1999). Approximately 1000 children and adults undergo HSCT each year in Australia, with about 300 being performed in New South Wales alone (Bone Marrow Transplant Network NSW, 2006).

1.2. TYPES OF TRANSPLANTS

There are two types of transplant: autologous and allogeneic (Bone Marrow Transplant Network NSW, 2006). Autologous HSCT, or reinfusion, involves the transplantation of the patient’s own stem cells. Allogeneic HSCT involves transplantation of stem cells from a closely matched donor (who can be either related or unrelated). A number of factors determine which type of transplant a patient will receive. Furthermore, the type of transplant utilised has significant implications for prognosis and quality of life following transplantation.

1.2.1. AUTOLOGOUS TRANSPLANTS

Autologous transplants are the preferred method of treatment and can be done when the disease is responsive to chemotherapy or in remission (Bone Marrow Transplant Network NSW, 2006). However, an autologous transplant is not possible if the illness involves the bone marrow, such as in Hodgkin’s or non-Hodgkin’s lymphoma, multiple myeloma or acute myeloid leukaemia. For autologous transplants, stem cells from the blood or bone marrow of the patient are

harvested and frozen prior to the transplant. The stem cells are then reinfused after high-dose chemotherapy or radiotherapy.

1.2.2. ALLOGENEIC TRANSPLANTS

Allogeneic transplants involve the process of finding a closely matched donor who can be either related or unrelated to the patient (Bone Marrow Transplant Network NSW, 2006). Human leukocyte antigen (HLA) markers help the body differentiate its own cells from foreign cells (e.g. bacteria). People are born with two sets of HLA markers, one from each parent. Since each parent has two sets of HLA markers, this means that their children have a one in four chance of having the same markers as each other (Bone Marrow Transplant Network NSW, 2006). As a result, the patient's immediate family are the ideal source of donor stem cells, and most commonly, the donor will be the patient's brother or sister. Approximately a third of people will have a fully matched donor in their immediate family. When a related donor cannot be secured, the transplant doctor will apply to the Australian Bone Marrow Donor Registry to begin a search for a donor who has a tissue type that closely matches that of the patient. The process of finding an appropriately matched donor can take from weeks to months. Closeness in match between donor and patient HLA has a considerable impact on the success of the transplant. Rejection of the graft does occur and has serious consequences for the patient's prognosis. This is why allogeneic transplants are riskier than autologous transplants. In Canada, allogeneic transplants made up 40% of transplants performed each year (Leger & Nevill, 2004).

1.3. RISKS ASSOCIATED WITH HSCT

HSCT is a complex high risk procedure that can involve lengthy and recurring hospitalisation and prolonged recovery (Heinonen, Volin, Zevon, Uutela, Barrick, & Ruutu, 2005). Generally the average length of hospital stay for patients having HSCT is five weeks; although this can increase when there are complications (Leger & Nevill, 2004). For autologous transplants the length of hospital stay is usually shorter with twenty-five days found to be the median length of

hospital stay per admission (Moya, Espigado, Parody, Carmona, MÃ¡rquez, & Blas, 2006). In the first three months after HSCT about 25% of patients will require at least one readmission (Leger & Nevill, 2004). Hospital visits can be necessary for many years following transplantation for monitoring patient recovery and blood work.

Short-term side effects of HSCT include nausea, vomiting, diarrhoea, fatigue, mouth and throat problems, weight loss, hair loss, and skin reactions (Bone Marrow Transplant Network NSW, 2006). Some patients, particularly those undergoing allogeneic transplants, may experience long-term problems with their liver, kidneys, lungs, heart, cataracts and fertility. The risk of developing another cancer is also increased with the use of radiation and chemotherapy required for HSCT (Bone Marrow Transplant Network NSW, 2006).

Patients who are free of their primary disease two years following the transplantation are referred to as long-term survivors (Socie, Veum-Stone, Wingard, Weisdorf, Henslee-Downey, Bredeson et al., 1999). Only about 50% of patients with leukaemia who undergo HSCT are expected to have long-term survival (Kulkarni, Powles, Treleaven, Riley, Singhal, Horton et al., 2000). However, even those who survive HSCT are at risk of other complications, such as graft versus host disease (GvHD), bleeding, infections and relapse (Downs, 1994; Kulkarni et al., 2000).

GvHD is the most common complication affecting allogeneic HSCT patients. In GvHD the white blood cells from the donor marrow (the graft) attack the patient's body (the host) because the patient's cells are identified as foreign (Bone Marrow Transplant Network NSW, 2006). GvHD is called acute if it occurs within 100 days of HSCT (Leger & Nevill, 2004). If it occurs after 100 days, it is referred to as chronic GvHD. Acute GvHD occurs in about 30-50% of matched-sibling and 60-80% of unrelated-donor transplant recipients and is characterized by a rash, hepatic dysfunction, diarrhea and vomiting (Leger & Nevill, 2004; Weisdorf, 2007). The

probability of getting chronic GvHD is 25% (Zittoun, Mandelli, Willemze, de Witte, Labar, Resegotti et al., 1995). Chronic GVHD most commonly occurs as a transition from acute GVHD, but it can occur also occur without prior acute symptoms in 20-30% of patients. Chronic GvHD has been observed in 33% of genetically HLA-identical sibling recipients who survived more than 150 days after transplantation, in 49% of recipients of phenotypically HLA matched related transplants and in 64% of recipients of HLA-matched unrelated transplants. HLA disparity is the major risk factor for GvHD. Other factors that have been found to increase risk of GvHD include female donor to male patient, certain HLA alleles and the host environment. GvHD can have serious and fatal consequences for patients, depending on the severity of the symptoms, which can range from mild to severe. Some of the more common symptoms include skin rashes on the hands and feet, problems with the mouth and throat, infections, and complications with the liver, gut and lung function. If GvHD occurs it is initially treated with high-dose corticosteroid therapy, which has a satisfactory response in 50% to 75% of affected patients.

A mortality rate of 80% has been reported for patients with grade III and IV acute GvHD, although this figure is likely to be inflated by deaths caused by superimposed infection (Przepioraka, Weisdorf, Martin, Klingemann, Beatty, Hows et al., 1995). More recently, the incidence and severity of, and mortality associated with acute GvHD have significantly decreased through the introduction of newer immunosuppressive drug regimens. As a result, the most recent survival rates after acute GvHD has been close to 90% (Goerner, Gooley, Flowers, Sullivan, Kiem, Sanders et al., 2002). Chronic GvHD is a direct cause of death in about 15% of patients.

Compared to Allogeneic HSCT, Autologous HSCT has a lower mortality rate (5-10%) but higher rate of relapse of disease (Fefer, 1999; Kulkarni et al., 2000). In a randomised study of

patients with Acute Myelogenous Leukemia in first remission, the risk of relapse was 66% for autologous patients and 43% for allogeneic patients (Zittoun et al., 1995). Relapse is thought to occur primarily because the conditioning treatments have not been effective in destroying all of the remaining host cancer cells (Fefer, 1999). Although relapse can also occur when the transplanted autologous cells contain tumour cells (Johns, 1998). Despite having a lower mortality rate, autologous transplants can still have a significantly detrimental effect on quality of life due to the physical and emotional consequences of the treatment (Stephens, 2005).

Allogeneic transplants have a greater (around 50%) mortality rate due to the risk of infection and GvHD (Kulkarni et al., 2000). For allogeneic transplants, the chance of early non-relapse mortality is high (Tichelli, 2007) and there is a greater possibility of death within two years post transplantation (Socie et al., 1999). After two years, the chance of survival is higher, although the risk of mortality is still greater than in the general population. GvHD can be a 'double-edged sword' in that because it can reduce the chance of relapse for patients undergoing allogeneic HSCT. This is because a graft-versus tumour effect can occur in which the donor's stem cells engraft and attack the cancer cells (Fefer, 1999). Allogeneic patients in first remission from acute leukaemia or first chronic phase of Chronic Myeloid Leukemia have a relapse risk ranging from 20–30% (Aschan, 2006). Risk of relapse increases to 40–60% if transplanted in later remission or second chronic phase (Appelbaum, 1997; Horowitz, 1999). Patients not in remission or with chemorefractory disease may have a relapse risk exceeding 70% (Aschan, 2006). Long-term survival is more likely if patients experience a form of mild acute and/or limited chronic GvHD.

1.4. LONG-TERM SURVIVAL

The outcome of HSCT is affected by numerous disease and demographic variables including diagnosis, the original disease, the stage of disease, time between diagnosis and transplantation, the general health of the patient at the time of the treatment, how well they respond to treatment,

type of transplant, HLA matching, source of stem cells, T-cell depletion, age, ethnicity, and the sex of donor and recipient (Bone Marrow Transplant Network NSW, 2006; Hoodin, Kalbfleisch, Thornton, & Ratanatharathorn, 2004). There has been growth in the number of long-term survivors due to the increased use of HSCT and better treatment outcomes (Horowitz, 1999; Tichelli, 2007). Today more than 20,000 people have survived for five or more years post-transplantation. Long term survival is usually accompanied by the decline of the physical side-effects of treatment, reduced symptoms of disease, a return to pre-illness levels of psychological adjustment, and the return to necessary and valued life roles and responsibilities (Andrykowski & McQuellon, 1999). Most HSCT patients that are well after five years are no longer taking immune suppression and are enjoy a good quality of life (Horowitz, 1999). However, these patients remain at risk of late complications. These include infections, cataracts, abnormalities of growth and development, thyroid disorders, chronic lung disease, and avascular necrosis. Complications are more likely for those patients with chronic GvHD. Furthermore, HSCT patients have a greater risk of leukemias, myelodysplasias, and solid tumours than the general population. As a result, long term surveillance and awareness of late complications is important for these patients (Horowitz, 1999).

Long-term survival and mortality has been investigated in a study involving 6691 patients who had remained free of their primary disease for 2 years after an allogeneic transplant (Socie et al., 1999). As a group, the chance of these patients surviving for another 7 years was high (89%). Of these patients, 25% had developed acute GvHD (<100 days) and 43% had developed chronic GvHD (100 days +) following transplantation. For 27% of patients, chronic GvHD continued to be active 2 years following transplantation. Recurrent leukaemia and chronic GvHD were identified as the two main causes of late death in HSCT recipients (Socie et al., 1999). Chronic GvHD resulted in late death either directly through complication, such as bronchiloitis obliterans, or indirectly by increasing susceptibility to infections due to immunodeficiency.

A study which examined treatment-related mortality in 1000 consecutive patients who had undergone autologous transplantation for leukemia, non-Hodgkin's lymphoma, Hodgkin's disease, multiple myeloma, sarcoma, ovarian cancer and breast cancer found 5.9% of patients died within 100 days of treatment (Weaver, Schwartzberg, Hainsworth, Greco, Li, Buckner et al., 1997). Approximately 3.4% died because of treatment-related side effects, half due to infection and half to regimen-related toxicity. Progression of the disease accounted for the other 2.5% of deaths. The patients who died were more likely to have advanced and more refractory types of disease. Age was also shown to be a predictor of higher mortality (Weaver et al., 1997).

In a study examining 27 patients with high risk or relapsing leukaemia, 27 (15%) patients died from relapse, and nine (33%) from transplantation-related complications. Fourteen patients (52%) were still alive and in ongoing complete clinical remission when the study was published (Reske, Bunjes, Buchmann, Seitz, Glatting, Neumaier et al., 2001). A more recent study reported a survival rate of 43% for 21 patients with high-risk acute myeloid leukaemia, myelodysplastic syndrome or advanced myelodysplastic syndrome at follow up of 23–60 months. The treatment-related mortality was 28.6% and an equal number of patients died of relapsing disease within 30–385 days after transplantation (Koenecke, Hofmann, Bolte, Gielow, Dammann, Stadler et al., 2008).

1.5. PSYCHOSOCIAL SEQUELAE AND HSCT

Due to the arduous nature of HSCT, patients and families are often put under considerable stress. Some of the psychological sequelae that patients undergoing HSCT experience are psychological distress, anxiety over loss of control, physical complaints, sexual dysfunction, problems with social relationships, occupational disability and financial consequences (Baker, 1994). People who undergo HSCT can be affected physically, psychologically, socially and spiritually due to

the high level of trauma associated with the procedure (Krasuska, Dmoszynska, Daniluk, & Stanislawek, 2002). Poor social support, a history or current symptoms of depression or substance abuse, and rigid or inflexible coping styles are factors that have been identified as being associated with poor coping with the HSCT process (Andrykowski & McQuellon, 1999). A qualitative study, using multidimensional scaling and hierarchical cluster analyses to rank primary stress clusters, found HSCT patients were most to least distressed by: change of life and long-lasting treatment, side-effects, treatment outcome and health status, family-related distress, death and depressive thoughts, other concerns, negative social support and lack of information and medical staff (Heinonen et al., 2005). It has been suggested that patients undergoing HSCT benefit from being informed about the possible psychosocial effects of treatment as it can help patients with decision-making and provide realistic ideas about what to expect after HSCT (Broers, Kaptein, Le Cessie, Fibbe, & Hengeveld, 2000).

1.5.1. PSYCHOSOCIAL SEQUELAE OVER DIFFERENT STAGES OF HSCT

Researchers have identified physical and psychological factors that are likely to be present during the major stages of the HSCT process (Andrykowski & McQuellon, 1999; Brown & Kelly, 1976; Haberman, 1988). Although the number of stages discussed in the literature varies, there appears to be six major stages involved in the HSCT process including: (1) making the decision to undergo HSCT, (2) preadmission, (3) the conditioning regimen, (4) immunosuppression and isolation, (5) transplantation and engraftment and (6) hospital discharge and follow-up (Brown & Kelly, 1976; Haberman, 1988).

Because the chance of disease cure or long-term disease-free survival is uncertain, the decision to undergo HSCT is a stressful stage for most patients and their families (Andrykowski & McQuellon, 1999). Common issues that may be present in the decision making stage include: facing the chance of death, coping with the uncertainty of the treatment outcome, dealing with

financial and insurance restrictions and consenting to treatment (Andrykowski & McQuellon, 1999). Patients need to prepare themselves for a range of highly distressing short-term and long-term side effects even in the 'best case' scenario. Patients may even be faced with an earlier death if they undergo HSCT than they would have if they had continued with other more conventional treatments or even palliative care (Andrykowski & McQuellon, 1999). However, even though the treatment outcome is uncertain, patients appear to be prepared to endure considerable toxicity and face greater risk of mortality for an increased chance of survival. Patients are likely to experience a range of emotions during this time including shock, anger, anxiety, disbelief and confusion (Haberman, 1988). There is a paucity of research about the process prospective HSCT patients go through in deciding whether to undergo HSCT. Andrykowski and McQuellon (1999) have argued that the patient may already be psychologically committed to HSCT once the referring physician has suggested it to them as a treatment option; particularly when it is presented as a last resort. This may mean that patients make the decision to undergo HSCT prior to receiving information about the risks and benefits from the transplant centre. However, for many patients HSCT will be the only viable treatment option.

During the second stage, preadmission to hospital, patients often experience anxiety in anticipation of the transplantation (Haberman, 1988; Lesko, 1994). Some authors have argued that anxiety is exacerbated by a lack of knowledge about the treatment (Lesko, 1994). Surprisingly, the pre-treatment stage of HSCT may provoke higher levels of distress in patients than the actual day of transplant, possibly due to a lack of knowledge about the treatment process and the uncertainty associated with treatment (Brown & Kelly, 1976). This finding is not limited to HSCT patients. In breast cancer, for example, the time between diagnosis and treatment has been shown to be the most distressing stage for patients (Moyer & Salovey, 1996). Feelings of uncertainty about what to expect from treatment is seen to be an important factor contributing to

patients' anxiety and distress (McQuellon, Wells, Hoffman, Craven, Russell, Cruz et al., 1998). Patients need to organise their personal affairs and say goodbye to family and friends so that they can focus on coping with the treatment ahead. Some patients try to prepare family and friends for the possibility of their death and as a result may decide to make funeral arrangements and organise wills (Haberman, 1988). Patients may want to deal with these matters while they are capable of doing so and to make sure that their loved ones are not burdened by these arrangements at a later time. Families may need to relocate for treatment and make arrangements for leave of absence from work or educational commitments. Patients can also be required to wait for the results of medical tests and for a hospital bed to become available (Haberman, 1988). Prior to being admitted to hospital, HSCT patients undergo what is called 'the work up', which involves routine medical tests to ascertain that the patient's body will be well enough to withstand the physical demands of HSCT (Bone Marrow Transplant Network NSW, 2006). The work up may involve investigations of the heart, the kidney, lung function, sinus infection, blood tests, assessment of dental health and nutrition, and discussions about options for preserving the possibility of having children after HSCT in younger patients. Patients may experience frustration, anger and anxiety during this stage because it can feel as if they are stuck in limbo due to the protracted waiting period (Haberman, 1988). A retrospective study found that 28% of patients described symptoms during the pre-treatment stage that would have met criteria for a major depressive episode according to the Diagnostic and Statistical Manual of Mental Disorders III (DSM-III) (Jenkins, Linnington, & Whittaker, 1991). The same authors conducted a prospective study with patients about to undergo HSCT and found that 16% met criteria for major depressive disorder (Jenkins, Lester, Alexander, & Whittaker, 1994).

The conditioning regimen is the third major stage of the HSCT process (Haberman, 1988). In the days leading up to the transplant, patients undergo a conditioning or preparative therapy over 1 to 10 days (Andrykowski & McQuellon, 1999; Bone Marrow Transplant Network NSW, 2006). Usually this phase involves extremely high doses of chemotherapy drugs. Occasionally, a

conditioning regimen called Total Body Irradiation Therapy is also used to suppress the recipient's immune system for acceptance of the graft and to eradicate the recipient's underlying disease and bone marrow (Thomas & Storb, 1999). Thus the aim of this stage of the treatment is to destroy the cancer cells, to a greater extent than is normally possible, and/or to suppress the immune system so that the donors stem cells are not rejected (Bone Marrow Transplant Network NSW, 2006). Patients frequently experience symptoms of nausea and vomiting, hair loss, diarrhoea, fatigue, and painful mouth ulceration (mucositis) which continue even after the treatment has been completed. Total body irradiation has been recognised as a significant cause of distress during this stage (Brown & Kelly, 1976). Patients may have doubts about the need for such toxic levels of radiation. The symptoms associated with the conditioning regimen may bring to the forefront of patients' minds doubts and fears which they have previously been able to manage.

The fourth major stage involves immunosuppression and germ-free isolation (Haberman, 1988). Patients are often severely immunoincompetent for weeks or months; and this period is longer for allogeneic transplants (Thomas & Storb, 1999). As a result, the patient is at extremely high risk of infection and needs to be kept isolated from sources of contamination (Bone Marrow Transplant Network NSW, 2006). Otherwise, it is possible for patients to become inundated by a range of infections that are rare in healthy people. After the conditioning phase, patients are left with no option but to have the transplantation since without it they will certainly die. The period of isolation, when patients are at risk of infection, has been identified as a stage in which HSCT patients may be more psychologically vulnerable. This appears to be more likely for individuals who are inclined to be active (Brown & Kelly, 1976). It has been suggested that minimal physical contact with others and intensive nursing care are extremely detrimental to patients' psychological functioning. Because young children have an increased risk of infection they are typically prevented from entering the isolated unit. This can be an additional stressor for HSCT

patients who have young children as both the parent and children must endure the distress of separation. In a sample of leukaemia patients, 41% met criteria for a mental disorder during the period of isolation (Sasaki, Akaho, Sakamaki, Akiyama, Yoshino, Hagiya et al., 2000). The most frequent diagnosis given was adjustment disorder with anxiety and/or depression.

The actual transplantation and the period of waiting for the engraftment to occur is the fifth major stage of treatment (Haberman, 1988). The day of HSCT is often experienced as anti-climatic because the infusion of the stem cells is more often than not a short and straightforward procedure. However, the day of transplantation may have emotional significance similar to a new beginning for some patients and families (Lesko, 1994). A period of waiting then occurs after transplantation, when the patient is monitored for symptoms and signs that the graft has been successful and the immune system has returned to normal functioning. This occurs until the patient's white blood cell count rises above 0.5, indicating that the bone marrow is producing new cells (Bone Marrow Transplant Network NSW, 2006). This waiting period can produce high levels of distress due to feelings of vulnerability and loss of control (Andrykowski & McQuellon, 1999). The threat of death or serious side effects is often more present at this time (Haberman, 1988). Patients often experience the effects of prolonged and confined hospitalisation including boredom, regimentation, loss of control and diminished sense of personal identity (Andrykowski & McQuellon, 1999).

The final stage of transplantation involves discharge from hospital and prolonged recovery as an outpatient (Andrykowski & McQuellon, 1999; Haberman, 1988). Some anxiety about separating from the care of hospital staff may be present at this time. Patients may be worried about whether they and their family will be able to cope with emergencies or serious side effects. In addition, patients may develop close bonds with particular nursing staff. Studies have indicated that some HSCT patients identify particular nurses as key support persons rather than their spouses or partners. Molassiotis, van den Akker, and Boughton (1997) looked at perceptions of

social support in long-term survivors of HSCT. Twenty-three percent of HSCT patients named at least one nurse who was a primary source of support for them; suggesting the important role that nurses can have in patient care and recovery as well as in relation to quality of life. Once patients return home, readjusting to normal life can be difficult due to ongoing concerns and risks about health (Haberman, 1988). Patients are still likely to feel physically compromised and easily exhausted (Andrykowski & McQuellon, 1999). Patients are also required to wear a protective mask in public which can be a source of embarrassment and difference (Haberman, 1988). Patient's expectations of life after HSCT can have implications for how well they adapt to this phase (Andrykowski & McQuellon, 1999). For instance, if patients expect that their life will return to normal following transplantation, then it will be much harder for them to adjust; at least in the short term. The threat of marrow failure, graft rejection, chronic GvHD, relapse and death continue to be present at this stage and therefore anxiety and depression may occur in response to fear of these negative outcomes (Haberman, 1988). A subgroup of about 25% of transplant survivors have been found to have moderate to severe psychological symptoms following HSCT (Hjermstad & Kaasa, 1995). The distressing reality for many survivors, particularly those who have had allogeneic transplants, is that they are never likely to be "non-patients" again because of the continuing need for monitoring and the possibility of late complications (Tichelli, 2007).

1.5.2. PSYCHOSOCIAL DISTRESS AND RATES OF DISORDER

Rates of psychopathology in oncology have been found to vary depending on type of cancer, prognosis and burden of illness. Generally, a third of cancer patients are likely to experience clinical levels of distress (Zabora, BrintzenhofeSzoc, Curbow, Hooker, & Piantadosi, 2001). Lung cancer patients (43.4%) were found to have higher rates of distress than patients with gynaecological cancers (29.6%) (Zabora et al., 2001). HSCT patients have been shown to have even higher rates of clinical distress than other cancer patients (Trask, Paterson, Riba, Brines,

Griffith, Parker et al., 2002). This finding is not surprising considering the fact that HSCT has much higher risk of mortality and more stressful side effects (Andrykowski & McQuellon, 1999; Langer, Abrams, & Syrjala, 2003; Lesko, 1994). Fifty percent of patients undergoing HSCT are likely to experience clinical levels of distress prior to receiving information about their treatment (Trask et al., 2002). This rate has also been found at other time points such as immediately following HSCT and follow-up (Neitzert, Ritvo, Dancey, Weiser, Murray, & Avery, 1998). For instance, Leigh, Wilson, Burns and Clark (1995) found rates of clinical psychopathology in 54% of patients before and after treatment with HSCT. Six to nine months later, patients still rated highly on psychological distress. Fife et al. (2000) investigated emotional distress after admission to hospital and before HSCT infusion. These authors found that patients were most vulnerable to psychosocial distress during hospitalisation prior to HSCT. Three months and 1 year after transplantation were the time points that were associated with the least distress. Similarly, Broers et al (2000) found higher levels of anxiety prior to treatment compared to post HSCT. Degree of emotional distress at baseline, personal control, cognitive response, and symptomatology (physical and emotional symptoms) were the factors most likely to affect patients' emotional distress and adaptation.

One study compared the National Comprehensive Cancer Network Distress Thermometer (DT) with a cut-off score of 5, with the Anxiety and Depression Scales of the Hospital Anxiety and Depression Scale (HADS) in a sample of 50 candidates for HSCT (Trask et al., 2002). These researchers found that 50% of the patients met the cutoff of 5 on the DT, 51% of patients met cutoff of 8 for the HADS anxiety subscale, and less than 20% (the authors did not specify how much less) met the cut-off of 8 for the depression subscale. There was no investigation of the concordance of the measures in this study. Keogh and colleagues (1998) conducted a prospective repeated measures study pre and post HSCT in a sample of 28 patients. They found moderate to high levels of anxiety and depression in 61% and 14% of patients respectively pre-treatment

using the HADS. Three months later, rates of clinical anxiety had reduced to 20%. However, clinically significant cases of depression had increased to 40%. At 12 month follow-up 33% and 14% remained as clinically significant cases of anxiety and depression. Jenks Kettmann & Altmaier (2008) found higher rates of clinically significant depression, with 29.1% of patients meeting the cut-off point before HSCT and 27.6% one year post-HSCT. These studies support the view that a significant proportion of HSCT patients experience elevated levels of distress throughout the treatment process.

Although not all distressed patients fulfil criteria for some form of psychiatric diagnosis, some patients do. One study of patients admitted to hospital for HSCT investigated rates of psychiatric disorders based on clinical interviews (Prieto et al., 2002). Using the Diagnostic and Statistical Manual of Mental Disorders IV (DSM-IV), the prevalence of a mood disorder was 14.1%. However, the authors found overall psychiatric disorder prevalence to be 44.1%. Another study reported 28% of patients who had undergone HSCT described symptoms from pre-treatment that would have met criteria for clinical depression (Jenkins et al., 1991). These results were confirmed in a prospective study that found that 16% of patients met criteria for major depressive disorder pre-HSCT (Jenkins et al., 1994). In addition to elevated levels of distress, severe symptoms sufficient to warrant diagnosis are more common than in the general population. The poor prognosis, demanding treatment, and wealth of physical complaints likely contribute to these elevated rates of psychological disorder and distress.

1.5.3. EFFECTS OF DISTRESS AND DISORDER IN HSCT PATIENTS

Examining the rates of distress and disorder in HSCT is important because apart from the obvious burden of psychological distress, high levels of distress have been associated with adverse outcomes for quality of life, physical condition, adaptation to illness and adherence to care regimens and survival (Colon, Callies, Popkin, & McGlave, 1991; Goetzmann, Klaghofer,

Wagner-Huber, Halter, Boehler, Muellhaupt et al., 2007; Hann, Jacobson, Martin, Kronish, Azzarello, & Fields, 1997; Sutherland, Fyles, Adams, Hao, Lipton, Minden et al., 1997).

There have been few methodologically sound investigations of the effect of psychological variables on survival in HSCT (Hoodin et al., 2004). Nevertheless, the limited research in this area suggests that depression can have a negative effect on survival in HSCT patients. Specifically, negative emotional profiles before HSCT are associated with worse survival in the long term whereas optimism about the treatment appears to positively affect survival in the short term (Hoodin, Uberti, Lynch, Steele, & Ratanatharathorn, 2006). Major depression has been found to be associated with higher risk of death in patients who have been treated with HSCT at 1 and 3 years post transplant (Prieto, Atala, Blanch, Carreras, Rovira, Cirera et al., 2005). However, this association was not found for patients 5 years after HSCT. The authors concluded that these findings emphasise the need for efficient and thorough diagnosis and treatment of major depression in patients undergoing HSCT. Hoodin and colleagues (2004) also found that patients with lower levels of depression prior to undergoing HSCT survived longer than those with higher levels of depression. However, no differences in survival were found for patients with or without anxiety.

1.5.4. DIFFERENTIATING PATIENTS SUSCEPTIBLE TO DISTRESS

Although there are high rates of distress, not all patients facing these grave outcomes experience clinical levels of psychopathology. It is of interest to understand what factors might differentiate those who show clinical levels of distress from those who do not. Despite there being little research that helps to identify what factors differ in patients undergoing HSCT, there are theories supported by evidence in other areas that may be relevant.

Self-Regulation Theory (SRT) asserts that individuals use information from concrete and abstract sources to construct schematic representations of illness and health-threats (Leventhal, Meyer, & Nerenz, 1980). According to SRT a coping response will be activated if information is perceived as threatening. While a health professional may provide advice, how patients respond to that advice is determined by their illness schema. SRT is a dynamic process that is also influenced by lived experience of the illness (Leventhal, Nerenz, & Steele, 1984). Patients' knowledge of others' experiences may affect their illness representations. For example, if a HSCT patient has a friend who had a good recovery from transplantation they may be more likely to attribute less danger to the treatment. Thus, schemas are constantly modified and updated based on new information. Illness representations have been found to be multidimensional and apply to a range of illnesses (Weinman, Petrie, Moss-Morris, & Horne, 1996). Although, aspects such as the structure and levels of the representations may vary across illnesses (Heijmans & De Ridder, 1998).

Based on SRT, the development of the Illness Perception Questionnaire-Revised enabled measurement of the constructs related to SRT (Hagger & Orbell, 2005). Petrie, Jago and Devcich (2007) define illness perceptions as the beliefs or cognitive structures that patients use to describe their illness. Illness perceptions can include patients' beliefs about illness identity (symptoms attributed to the illness), cause of illness, personal consequences, personal control and treatment control. Patients with the same illness can have very different illness perceptions depending on the information they have and their experiences (Petrie et al., 2007).

Illness representations have been found to be relevant to emotional adjustment and recovery in a range of illnesses including gastroenteritis, MS, Huntington's disease, rheumatoid arthritis and diabetes (Helder, Kaptein, van Kempen, Weinman, van Houwelingen, & Roos, 2002; Parry, Corbett, James, Barton, & Welfare, 2003; Skinner, Hampson, & Fife-Schaw, 2002; Vaughan, Morrison, & Miller, 2003). Illness perceptions have also been found to be significantly

correlated with quality of life in patients diagnosed with head and neck cancer (Scharloo, Baatenburg de Jong, Langeveld, van Velzen-Verkaik, Doorn-op den Akker, & Kaptein, 2005). A new line of research has started to look at the effectiveness of changing illness perceptions when they are detrimental to behaviour and treatment responsiveness. One study on patients having myocardial infarction found reduced disability and faster return to work following an intervention to change patient illness beliefs (Petrie, Cameron, Ellis, Buick, & Weinman, 2002).

Tham and Gibbon (1996) conducted an exploratory qualitative study of the perceptions of patients who had undergone HSCT. Using unstructured interviews, these authors found five broad categories emerged as important: mortality and death, luck, protective isolation ('prison'), relationships and physical effects. This study was based on a small sample of six patients and focus upon broad concerns rather than illness perceptions. Nevertheless, it highlighted patients' greater concerns for mortality and death over physical effects following transplantation. Another study investigated health beliefs and coping styles in patients scheduled to have autologous HSCT (Frick, Fegg, Tyroller, Fischer, & Bumedder, 2006). They found that patients were most likely to attribute causal attribution to chance. A causal attribution of self-blame was associated with a depressive coping style and a relation was found between fate or destiny causal attributions and a religious coping style. Most patients in this study had a control style that was externally oriented. That is, they were more likely to attribute control to their physicians and nurses. To date there have been no studies specifically examining the illness perceptions of HSCT patients.

1.6. PSYCHOSOCIAL IMPACT ON CARERS AND FAMILY

Due to the long-term care required by the HSCT patient, support from family and carers is critical to their management (Franco, Warren, Menke, Craft, Cushing, Gould et al., 1996). The existing literature highlights the crucial function of the family in providing optimum adaptation

and recovery from HSCT (Boyle, Blodgett, Gnesdiloff, White, Bamford, Sheridan et al., 2000). In the field of oncology generally, perception of social support has been acknowledged as having an important influence on coping, health behaviours, illness outcomes, and survival (Boyle et al., 2000). Families are involved in both the acute and long-term care of the patient, once they have been discharged from hospital. There has been limited research, however, on the support needs and experiences of HSCT carers and families (Boyle et al., 2000; Foxall & Gaston-Johansson, 1996). Understanding the experience of carers in HSCT is likely to have important implications for the long-term functioning and quality of life of HSCT carers and patients (Boyle et al., 2000); allowing for the development of effective and timely interventions that facilitate coping and adaptation to the HSCT process (Foxall & Gaston-Johansson, 1996).

1.7. CAREGIVER BURDEN

While the caregiving experience has been looked at to a small extent in the cancer literature, these studies have been largely descriptive (Langer et al., 2003). Caregiver burden has primarily been examined for carers of patients with neurological disorders (e.g. stroke, Alzheimer's, and traumatic brain injury). The term 'caregiver burden' has been used to describe a range of difficulties experienced by carers, such as physical, psychological, emotional, social and financial problems (Given, Given, Stommel, Collins, King, & Franklin, 1992). In essence, caregiver burden conceptualises the caregiver's response to caring responsibilities that may have negative consequences for their physical and psychological health (Boyle et al., 2000).

A longitudinal study of family caregiver burden in carers of advanced breast cancer patients found carers had similar levels of depression but significantly greater anxiety compared to patients at the start of the palliative period (Grunfeld, Coyle, Whelan, Clinch, Reyno, Earle et al., 2004). Burden was the biggest predictor of caregiver anxiety and depressive symptomatology. Decline in patients' functional status was associated with increases in caregivers' depressive symptoms and burden. Another study investigating the effects of caregiving on spouses of

advanced cancer patients demonstrated that they have a high-risk of developing depression (Braun, Mikulincer, Rydall, Walsh, & Rodin, 2007). Higher rates of depression were demonstrated for spousal caregivers compared to patients (38.9% vs. 23%). Subjective caregiving burden, caregiver's anxious attachment, caregiver's avoidant attachment, and caregiver's marital satisfaction were found to make significant contributions to carer depression. Therefore, caregiver burden is an important issue in cancer settings.

1.7.1. CAREGIVER BURDEN IN HSCT

A few studies have examined caregiver burden in HSCT. Caregivers of HSCT patients experience substantial burden and responsibility caring for these extremely ill patients (Foxall & Gaston-Johansson, 1996). Stressors that are thought to impact on caregiver burden in HSCT include unexpected and rapid changes in the patient's prognosis, numerous invasive medical procedures, recurring infections, risk of death, prolonged hospitalisation, separation from other family members, and disruptions to home life and work commitments (Foxall & Gaston-Johansson, 1996; Lesko, 1994). The limited research in this area suggests that families often feel unprepared for the intense and continual demands of the transplant process (Boyle et al., 2000). Misunderstanding about the ongoing care required by HSCT patients can result in families feeling ill-equipped to continue in the caregiving role. Spouses and partners are often the primary carers and as such may be required to juggle the care demands of the patient, other family members (e.g. children, elderly parents), career and other responsibilities. In families in which the patient was a primary bread-winner prior to becoming sick, role changes are often required, adding further burden to family members. Furthermore, patients and families often have to travel long distances for treatment which may require families or carers to obtain temporary housing near the transplant centre (Blume & Amylon, 1999).

Most of the information on carer burden in HSCT patients is based upon qualitative designs. However, Foxall and Gaston-Johansson (1996) conducted a descriptive correlational study with repeated measures to investigate caregiver burden in 24 family caregivers one week prior to patient admission and five and 20 days after transplantation. These authors consider caregiver burden to be a multidimensional concept made up of objective and subjective burden. Objective burden refers to tangible events, financial difficulties, personal activity restrictions, family disruptions, and family tension. Subjective burden is defined as feelings, attitudes and affects experienced by the caregiver (Foxall & Gaston-Johansson, 1996). For carers of HSCT patients, objective burden was found to be a larger issue than subjective burden across all of the stages measured. Fatigue, disruption to everyday life and financial strain were the most frequently endorsed items of objective burden. Greater burden post HSCT was related to poorer health outcomes (including distress) for carers in the short-term.

Krususka et al. (2002) contend that family and carers of HSCT patients experience significant interpersonal and personal distress throughout the transplantation process. Interestingly, Foxall and Gaston-Johansson (1996) found that caregivers as well as patients experienced higher levels of anxiety in the lead up to HSCT compared to days five or 20 post HSCT. One week prior to HSCT, caregivers were found to have moderate levels of anxiety on the State Trait Anxiety Inventory (STAI). Yet there was no indication that the different stages of HSCT were likely to lead to depression in caregivers in this study.

Langer et al. (2003) examined affect and marital satisfaction in patients undergoing HSCT and their carers at three time points: prior to transplantation, six months post transplantation, and one year post transplantation. Compared to non-medical controls, caregivers reported higher levels of anxiety and depression. There was also a significant decline in relationship satisfaction for couples at both six months and one year following HSCT. Although couples were matched in

relationship satisfaction prior to HSCT, caregivers appeared to feel increasingly dissatisfied compared to their partners. Interestingly, this mismatch in relationship satisfaction was not related to patient physical or psychological characteristics but was related to the gender of the caregiver. Female caregivers were more likely to become dissatisfied with their relationship over the course of treatment than male caregivers were.

As has been described, HSCT is a potentially dangerous and highly demanding procedure. The patients for whom HSCT is the treatment of choice usually have serious conditions that without transplantation are likely to be life-limiting. This reality needs to be balanced against the risks of the procedure itself, which can result in premature death in a small but significant proportion of patients. Therefore, it is essential that patients are properly informed about the pros and cons of treatment prior to deciding whether or not to have the procedure.

1.8. INFORMED CONSENT

As the conditions that are treated with HSCT were previously associated with extremely high rates of mortality, the advent of HSCT has given hope to a group of patients for whom there were previously no effective treatment options. However, as has been described, the procedure is not without a range of risks and possible complications that patients and their families need to take into account when deciding about treatment. The values which patients place on both the possible positive and negative outcomes of treatment are likely to have an impact on decision making (Gattelari, Butow, & Tattersall, 2001). Current models of medical care are increasingly embracing the concept of shared-decision making, where patients are becoming more involved in their care than has previously been the case and are thereby taking more responsibility for the health and medical treatment decisions that affect them.

1.8.1 MODELS OF INFORMED CONSENT

In the history of medical care prior to the 1980s, patients invariably took a subsidiary role in terms of decision making about their medical treatment and doctors were seen to be omnipotent and beyond reproach (Charles, Gafni, & Whelan, 1999). This type of patient-doctor relationship has been characterised as the paternalism model, otherwise known as the physician as agent model, in which decisional authority is vested solely in the hands of the doctor who is viewed by the patient as the expert advisor (Gattelari et al., 2001). The major assumptions of this model are that there is a gold standard treatment for every illness, that all doctors are up to date with the latest treatment practises, that doctors apply this information about best treatments without fail, that doctors are in the best position to weigh up trade-offs between different treatments and make the best decision, and that doctors have a genuine investment in every treatment decision due to their professional concern for the rights, welfare and personal interests of patients (Charles et al., 1999). In the paternalism model, while the patients' values may be elicited and considered, the doctor is seen to have the final say over the decision making process. One of the primary dangers of this model is that the patient's autonomy may be undermined (O'Conner, 1989). This is especially a concern when the information given by the doctor, or to doctor by the patient, is biased or incomplete or when the choice between two treatment options is finely balanced. The paternalism model also places the doctor in a position of overall and almost exclusive responsibility for any error in the decision-making process resulting in a wrong decision being made concerning treatment.

Beginning in the 1980s, there has been a growing dissatisfaction with this imbalanced relationship between doctors and patients (Charles et al., 1999). Improvement in patient education, access to information, medical negligence/liability litigation and changing societal ideas about the role of doctors, has contributed to the emerging attitude that the medical profession should be held responsible for its conduct and decisions (Gattelari et al., 2001). Furthermore, it became apparent that there were a number of illnesses that did not have clear

treatment options, making treatment decisions more complex due to the reality of a trade-off between risks and benefits (Charles et al., 1999). These changes have had implications for the law and policy-making. In the United States, the Patient Bill of Rights states that patients must be given written information prior to undergoing a medical procedure (Climent, 1999). Although there is no law to this effect in Australia, landmark cases have highlighted the need for doctors to provide patients with adequate information about the adverse effects of medical treatment (Gattelari et al., 2001).

These changes have led to a change in the dominant model of medical decision-making. The informed choice model, or patient-led decision making, was developed in response to the rejection of the paternalistic model and is at the opposite of the spectrum in terms of physician and patient involvement in medical decisions (Charles et al., 1999). In the informed choice model, the knowledge and expertise of the doctor is acknowledged but the patient is seen to be capable of coming to a thoroughly informed decision (Gattelari et al., 2001). Like the paternalistic model, the informed choice model is largely one-way in terms of information exchange (Charles et al., 1999). However, in this model the patient takes the responsibility for accessing information from the physician. The informed choice model also assumes that patients have the skills necessary to obtain information that they need from the doctor and other sources, make sense of the information about treatment alternatives, express their preferences and values and are able to formulate all of these factors in order to come to a well thought out decision. In the informed choice model, the doctor's role is to openly disclose information but they are not expected to advocate for one treatment choice or another. Research examining patient preferences for participation in decision making indicates that although the majority of patients want to be involved in medical decisions, they also want their physician to help them in deciding which approach to take with their treatment (Freedman, 2002). It has been found that patients sometimes misunderstand information about their treatment, such as the likelihood that treatment

would cure their disease. This was also shown to be predicted by patient denial and anxiety and doctors' ability to communicate effectively (Gattelari, Butow, Tattersall, Dunn, & MacLeod, 1999; Ley, Bradshaw, & Kinsey, 1973).

The literature shows that the majority of patients and physicians no longer support the extreme positions advocated by the paternalistic or informed choice models. Rather, most authors now support a shared-decision making paradigm which is seen to be a compromise between paternalism and informed choice (Makoul & Clayman, 2006). In the shared decision making model, doctors and patients are viewed as equal in status and are both expected to share responsibility, information and preferences with the aim of arriving at a negotiated and mutually acceptable treatment decision (Gattelari et al., 2001). Charles, Gafni and Whelan (1999) have outlined four characteristics that they see as essential for shared decision making: (1) both the physician and the patient are involved in the decision making process, (2) both share information with each other, (3) both take steps to participate in the process by sharing preferences, and (4) the treatment decision is made jointly and both agree on the best treatment to perform.

1.8.2. RESEARCH ON INFORMED CONSENT

Involving patients in the decision making process is generally looked upon favourably by both physicians and patients (O'Conner, Llewellyn-Thomas, Sawka, Pinfold, To, & Harrison, 1997). Overall, the increased importance placed on informing and educating patients has evolved due to a number of factors including the focus on shared decision making, technological advances in health care and the resulting complex treatment regimens, more rigorous guidelines for consent procedures, litigation, reimbursement policies, and consumer demands (Fernsler & Cannon, 1991; Gurrud, Wood, & Stainsby, 2001). When the risks of a particular treatment are high and the outcomes uncertain, patient-involved decision making is seen to be especially important (Gattelari et al., 2001). The literature suggests that most cancer patients want detailed

information about diagnosis, treatment, side effects, symptoms and self-care needs (Hagerty, Butow, Ellis, Lobb, Pendlebury, Leighl et al., 2004; Treacy & Mayer, 2000). Cancer patients have reported feeling dissatisfied with the quality and quantity of information that they have been given about their illness and treatment. Indeed, in a study conducted by Blanchard, Labrecque, Ruckdeschel and Blanchard (1988) adult patients with cancer reported that they preferred to receive all the information about their disease and treatment regardless of whether it was good or bad. Perceived lack of information about treatment and related risks has been found to be associated with increased anxiety, uncertainty, dissatisfaction, distress and poor treatment decisions in patients with cancer (Fallowfield, Ford, & Lewis, 1995; Gamble, 1998).

Information-seeking has been shown to be a coping strategy for some patients with cancer which helps them to gain a sense of control and mastery over their illness (Derdiarian, 1987; Treacy & Mayer, 2000). Lazarus (1966) has suggested that seeking information helps to alleviate fear and concerns of harm in potentially dangerous situations. However, shared decision-making is not without its own consequences in situations where prognostic information may be considerably uncertain and frightening, since informed decision-making requires patients to be knowledgeable about their illness and the treatment that they undergo. This is a particular issue in HSCT because the treatment is very complicated and the prognosis is worse than for many cancers and other treatment procedures. When HSCT was largely utilised as a treatment of last resort, the decision to undergo transplantation was easier because candidates had very few alternative options. Now that it is being used as a “first line” treatment for some conditions, such as breast cancer, the decision to undergo HSCT is likely to be more difficult and distressing (Andrykowski & McQuellon, 1999; Hann et al., 1997). In a sample of HSCT patients who attended an appointment where a doctor discussed the risks and benefits of treatment, patients had higher levels of psychological distress 48 hours later (Dermatis & Lesko, 1991). Whether it was the information, the imminent need for the procedure or the natural course of adjustment that was

responsible for the increase in distress is unknown. Nonetheless, elevated levels of distress can affect how well patients understand the information provided. However, in the area of oncology generally, educational programmes have been encouraged so that patients have the opportunity to gain a good understanding of their illness and hence can be more involved in its management. This is particularly true for chronic illnesses that require the patient to adhere to medical regimens in order to improve their outcome (as is the case with HSCT).

1.9. PATIENT EDUCATION

Patient education has been defined as a method of shaping behaviour in order to produce change in knowledge, attitudes, and skills required to sustain and improve health (Phillips, 1999). Patient education has generally been found to have a number of positive benefits for the patient (Fernsler & Cannon, 1991) in a range of illnesses, including cancer, rheumatoid arthritis, and chronic obstructive pulmonary disease (COPD). Positive outcomes of patient education have included improved knowledge about treatment and recall of information, increased patient participation in decision-making, better commitment to treatment, improved symptom management, greater satisfaction, increased ability to cope with illness, decreased length of hospital stay, reduced health care utilisation, less post-operative opioid use, reductions in anxiety and depression, improvement of symptoms (e.g. nausea, vomiting, pain), and enhanced quality of life (Fernsler & Cannon, 1991; McPherson, Higginson, & Hearn, 2001; Treacy & Mayer, 2000; Yoon, Conway, & McMillan, 2006). Patient education has been seen as an effective method of facilitating coping and encouraging patients to take more responsibility for their care following discharge from hospital. For cancer patients generally, education has been used with the aim of increasing knowledge as a way of alleviating helplessness and inadequacy (Fawzy, Fawzy, Arndt, & Pasnau, 1995). Furthermore, patient education can provide patients and their families with a sense of care and support (Yoon et al., 2006).

1.9.1. THE EFFECT OF EDUCATION FOR OTHER ILLNESSES

Patient education has also been effective in improving outcomes with a range of illnesses and procedures such as rheumatoid arthritis, chronic obstructive pulmonary disease (COPD) and patients waiting to undergo cardiac catheterisation (Brus, Taal, van de Laar, Rasker, & Wiegman, 1997; Gurrud et al., 2001; Harkness, Morrow, Smith, Kiczula, & Arthur, 2003; Johnson, 1982). Patients with a chronic illness who took part in a 4 week patient education course reported less anxiety and a greater sense of meaning in their lives compared to those who did not participate in the course (Johnson, 1982). Similar to the waiting period for transplantation, waiting for elective cardiac catheterisation has been found to produce increased levels of anxiety and reduce perceived quality of life (Harkness et al., 2003). Harkness and colleagues (2003) found that an early education session provided by nursing staff during the waiting period was effective in reducing anxiety levels compared to controls. Gurrud, Wood, and Stainsby (2001) compared the effects of two patient education leaflets for women undergoing an elective laparoscopy. One leaflet contained detailed information about potential adverse consequences of the treatment. Women who received the leaflet that contained more risk information reported greater knowledge of all aspects of the treatment, higher satisfaction with information and no difference in anxiety compared to women in the control group. Furthermore, there was no evidence that patients that read the detailed education leaflet were less likely to proceed with the treatment. Thus, the authors concluded that providing detailed information about the risks of treatment does not appear to be detrimental in terms of anxiety but rather it may be beneficial in terms of increasing knowledge and satisfaction. Notwithstanding, the authors maintain that it is not known whether these results would generalise to providing detailed risk information for more life-threatening and risky procedures and treatments (Gurrud et al., 2001).

1.9.2. THE EFFECT OF EDUCATION ON ONCOLOGY PATIENTS

In an attempt to address the information needs of patients with cancer, a number of methods have been used to educate patients including the provision of written material, telephone help lines, teaching and audiovisual aids, interactive media, and patient education programmes (McPherson et al., 2001). A prospective study of an interdisciplinary psychoeducational intervention in a German acute cancer clinic randomly assigned cancer patients with various illnesses to an intervention or control group (Gundel, Lordick, Brandl, Wurschmidt, Schussler, Leps et al., 2003). The intervention focussed on health education and coping skills. The results showed significant differences for the intervention group compared to the control group in terms of increased knowledge and better emotional functioning two months after the intervention. Four months after the psychoeducational program, patients in the intervention group continued to show an increase in knowledge, were more emotionally stable and were less inclined to engage in rumination compared to controls. Gundel and colleagues (2003) concluded that short-term interdisciplinary interventions can be helpful for improving knowledge and emotional functioning in cancer patients.

A study that looked at the effect of an information booklet on patients with Hodgkin's disease found that patients who received the information booklet demonstrated greater knowledge, less treatment problems and lower anxiety compared to the control group (Jacobs, Ross, Walker, & Stockdale, 1983; Treacy & Mayer, 2000). Anxiety is frequently examined as an outcome measure of patient education in cancer patients because (like HSCT) cancer and its treatments have been found to be associated with increased anxiety for patients and families (Fernsler & Cannon, 1991). Similarly, a study that examined the effect of an orientation program for patients who had just received a cancer diagnosis (McQuellon et al., 1998) found that patients who were assigned to the orientation program were more satisfied with their care, were more knowledgeable about the clinic and reported reduced anxiety, depression and overall distress one

week later. The orientation involved a tour of the clinic, information, and participation in a question and answer session with the oncology counsellor.

Using a quasi-experimental time series design, Poroch (1995) compared two groups of cancer patients who were about to undergo radiation therapy. The intervention group received two structured teaching sessions that involved sensory and procedural education about the treatment, whereas the control group received the standard information. The intervention group were found to be less anxious and more satisfied during treatment than the control group and this result was maintained for up to seven weeks. Similarly, patients undergoing chemotherapy who received education about self care also experienced decreased anxiety six weeks later (Dodd, 1988). A comparable study examined the effects of an education/orientation program for radiation treatment on patients and families (Cartledge & Haaga, 2005). The education program involved verbal and written information. The authors found no differences between the intervention and control group in terms of state anxiety, general distress, treatment adherence, or knowledge. However, the intervention group reported greater satisfaction with their care and they were more likely to make use of psychological services at the clinic or elsewhere.

1.9.3. NEGATIVE OUTCOMES OF EDUCATION

Although the vast majority of studies looking at variety of illnesses have reported reductions or no differences in patient anxiety levels as a result of information and education, there have been some findings that have shown that information and education can have a negative impact on patients. Brus, Taal, van de Laar, Rasker, and Wiegman (1997) carried out an evaluation of a patient education program for rheumatoid arthritis patients, comparing the effect of education on high disease activity patients versus low disease activity patients. Four months after participating in the education program, patients with high disease activity showed greater levels of anxiety and

depression compared to controls. On the other hand, patients with low disease activity had lower levels of anxiety following education.

In the field of oncology generally, there are still many aspects about the illnesses and related treatment that are not completely understood (Freedman, 2002). Thus, it could be confronting for patients to front up against the relative uncertainty and limitation of their prognosis. There is evidence to suggest that some patients do not want to be fully informed about their treatment and prognosis (Hagerty et al., 2004). Patients with lower education, patients from ethnic minorities, highly anxious patients and patients with a worse prognosis are more likely to want only positive information about their illness and prognosis and may prefer to leave treatment decisions to their doctor (de Haes, 2006; Hagerty et al., 2004). The degree of desire for information, level of education, cultural background and socio economic status are factors which have also been found to influence the degree to which patients seek out information (Harris, 1998). Hagerty and colleagues (2004) looked at information needs among 126 patients with metastatic cancer. Although the majority of patients (95%) wanted to be fully informed about their prognosis, less than half of the patients wanted to know their survival estimate in quantitative terms. Patients who had a poorer prognosis were less likely to want to know how long they were expected to live. Likewise, a large survey of cancer patients revealed that patients who reported higher levels of anxiety and those with a worse prognosis had less desire for information (Kaplowitz, Campo, & Chiu, 2002). On the other hand, cancer patients have been shown to be more satisfied when shared decision-making is achieved even when they did not want it to begin with (Gattelari et al., 2001). The research suggests that in some circumstances information may be detrimental to psychological functioning when prognosis is less positive, which may have implications for HSCT patients.

1.9.4 PATIENT EDUCATION AND HSCT

From the moment that the patient is considered as a potential candidate for transplantation, education becomes an important issue. Patients are likely to have questions about the transplant procedure, the possible effects or consequences of the treatment, the course of treatment and their expected quality of life post treatment (Franco et al., 1996). Some patients may have already sought out information themselves via the internet and as a result may be either well informed or misinformed depending on the source of the information (Blume & Amylon, 1999). However, it has been noted that HSCT patients often have an inadequate understanding of their disease and are inclined to overestimate their prognosis which impacts on communication about life-threatening transplant options (Stiff, Miller, Mumby, Kiley, Batiste, Porter et al., 2006). A qualitative study of HSCT patients who had undergone treatment reflected that they would have liked to have more information about what to expect, such as information about others' experiences, as this would have helped to reduce uncertainty and distress (Rini, Lawsin, Austin, DuHamel, Markarian, Burkhalter et al., 2007).

HSCT is likely to be one of the most physically and psychologically traumatic events of a person's life (Blume & Amylon, 1999). Therefore, education may be useful in preparing patients and families for a process that is likely to be prolonged and difficult (Franco et al., 1996). It has been argued that education that prepares patients and families for what to expect at the different stages of the HSCT process can be useful in relieving anxiety and fear of the unknown (Baker, 1994). Furthermore, it is thought that the medical team would be more able to assist the patient through the HSCT experience if patients know what to expect from the different stages of treatment, understand the rationale for diagnosis and treatment, are aware of the significance of adverse events, and realise the overall risk (Blume & Amylon, 1999).

Traditionally, patient education about HSCT was provided by the patient's primary physician. Since then various methods have been used for educating patients, families and donors about

HSCT including scripts, booklets, videotapes, and computerised materials (Whedon & Fliedner, 1999). More recently, group education programs supported by visual aids have been designed by transplant centres and hospitals which perform high volumes of HSCT in order to educate transplant candidates, families and carers about the transplant procedure, possible benefits, risks, and side effects, the course of treatment and the long term outcomes (Franco et al., 1996; Johns, 1998; Whedon & Fliedner, 1999). Because of the complexity of HSCT, these educational programs are typically provided by a multidisciplinary team involving physicians, nurses, specialists, and nurse coordinators (Downs, 1994; Johns, 1998). Patients, families and carers are also given information about technical aspects such as care and maintenance and medication (Franco et al., 1996). Immuno-suppressive regimens, central venous line care and maintenance, dressing changes, and medications are some examples of the technical skills that patients and carers need to be taught (Franco et al., 1996). Baker (1994) argues that for education to be effective in HSCT it needs to be provided by a multidisciplinary team and be provided throughout the treatment process. Therefore, although major authors all endorse such programmes, and they have developed in many major centres, no form of education in education in HSCT has been tested. Despite the assumption that multidisciplinary patient education programs are effective in HSCT, to date there have been no empirical evaluations to support or refute this assumption.

Informing patients about the possible adverse side effects of a treatment is a primary aim of providing patients with information (Gurrud et al., 2001). Due to the high level of risk associated with HSCT, education of the patient and family is considered to be an essential component of patient care (Downs, 1994; Franco et al., 1996). Stewart (1999) maintains that transplant treatment centres need to be absolutely honest about the risks of HSCT. HSCT requires that patients are cooperative, knowledgeable and aware (Blume & Amylon, 1999). Regret, complaints and legal recourse are potential outcomes for patients who are not adequately

informed about the risks associated with the proposed treatment. However, professionals can be hesitant to divulge all the possible adverse consequences of a treatment on the basis that they believe that patients are not interested in knowing about every possible outcome and/or that risk information could result in increased anxiety or rejection of necessary treatment (Gurrud et al., 2001). It has been suggested that the educational process can have a negative effect on the patient's emotional state (Stewart, 1999). However, Lesko (1994) noted that adult HSCT patients were not satisfied with only learning about the positive aspects of treatment. The needs of individual patient and family and the patients' ability to use the information should be considered when deciding what to communicate (Baker, 1994).

It has been argued that it may be unrealistic to expect patients to take on board the full range of potential consequences and risks of undergoing HSCT (Thomas, 1983). Haberman (1988) has also highlighted the fact that HSCT patients tend to have a poor understanding of the HSCT process and what to expect of themselves despite receiving an extensive amount of information from the multidisciplinary team. A study examining informed consent in adult bone marrow transplant patients, parents of paediatric bone marrow transplant patients, and the physicians, found that the majority of adults remembered less than half of the possible treatment complications (Lesko, Dermatis, Penman, & Holland, 1989). Interestingly, despite the fact that physicians believed that the information provided was too technical, the majority of the adults reported being satisfied with the information they received and that they did not find the information to be too technical. Another study of adult HSCT candidates examined 99 patients understanding of their disease through a survey before and after a 3 hour consultation (Stiff et al., 2006). Prior to the consultation, 23% of patients felt they had enough information to make an informed decision about HSCT, whereas post-consultation this had risen to 67%. Fifty four percent of these patients reported a significant reduction in the need for more information after the consultation. Stiff et al. (2006) concluded that, although investigating methods of increasing

patient understanding of disease and prognosis was justified, a 3 hour consultation visit is sufficient for making an informed decision about HSCT for the majority of patients. Despite the positive results of a three hour consultation, it is interesting that 33% still did not feel that they had enough information to make an informed decision and that nearly half of the patients felt that they needed more information. This makes a strong argument for longer multi-disciplinary education programmes.

1.9.5. CARER AND FAMILY INFORMATION NEEDS

Changes in doctor patient communication in recent times has resulted in the patient no longer being viewed as the passive recipient of information but rather one element of the patient-caregiver partnership (Adams, 1991). Despite this emerging attitude, the lack of effective communication with members of the healthcare system has been reported to be a major contributor to caregiver stress (Krasuska, 2002). In particular, caregivers have pointed out that they need more information about the complex skills needed to care for the patient post-transplant. In line with this, it has been argued that the primary carer needs to be central to the decision-making process as they play such an important role in the patient's care after transplantation (Franco et al., 1996). Rehabilitation and cooperation with self-care has been shown to be poorer when the family is left out of the education process; particularly for acutely and chronically ill patients (Phillips, 1999). Thus, there is a strong argument for the inclusion of families in patient education, regardless of whether the education is given in the hospital setting or the home. To date, there had been no studies that have looked at the effects of educational methods on the HSCT patient's family or caregiver. Not surprisingly then, there is a considerable need for empirical evidence evaluating interventions for carers of HSCT patients.

1.10. SIGNIFICANCE OF CURRENT STUDY

As a result of the evidence supporting patient education in oncology, education programs are considered best practice and as such have proliferated. However, because HSCT is a relatively

rare procedure, and has a considerably poorer prognosis than other cancer treatments (particularly allogeneic HSCT), we cannot assume that these programs are helpful and to date they remain untested. Indeed, the results of education programs in other settings may not generalize to these patients and may even be harmful for some patients. For example, because HSCT is so rare, in practice education programs typically combine patients receiving allogeneic and autologous HSCT. It is possible that having a combined information day for autologous and allogeneic HSCT patients will result in decreased anxiety for the low risk group (autologous) but increased anxiety for the high-risk group (allogeneic). As discussed, in a small number of studies, patients with poorer prognosis have been found to experience greater distress as a result of educational programs. On the other hand, it is equally possible that patients awaiting autologous transplants will not distinguish between the information that is relevant to them and the information relevant to patients awaiting allogeneic HSCT. This may inadvertently increase anxiety in the low risk (autologous) group. Additional information has been suggested to increase anxiety, especially when it is confusing or misunderstood (de Haes, 2006). Targeting information to the individual patient can help reduce the amount of information that needs to be taken in and ensures that the patient only receives information that is relevant to them (McPherson et al., 2001). This has been found to have positive effects on recall, patient and carer satisfaction, anxiety and sense of meaning and purpose in life. At this stage, the effect of educational programs on HSCT patients is not known. Intuitively, having a multidisciplinary team discuss all aspects of HSCT may help to reduce patient distress because patients may feel more supported in their illness. However, without research into the efficacy of education programs, the effect of education in the area of HSCT will remain an empirical question.

This study aims to provide the first evaluation of a group patient education programme for patients undergoing HSCT and their carers. The questions that will be examined by this research are: (1) What are the rates and correlates of distress in HSCT patients and carers, (2) What effect

does education have on patients and carers and (3) Is there a relationship between knowledge following the education programme and distress?

The primary goal of the education intervention is to increase knowledge. Based on the existing literature it was hypothesised that patients and carers who received the education programme would have higher levels of knowledge not evidenced in a group waiting to receive the programme. The secondary objective of the intervention was to ensure that the education programme did not result in any adverse effects for patients and carers. Based on the literature review, it was hypothesised that the education program would not lead to increased anxiety and depressive symptoms. Furthermore, we predicted that patients who knew more about their condition would be less distressed. It was also of interest to investigate other outcomes likely to be effected by the intervention such as support, information satisfaction, patient illness perceptions and caregiver burden. Thus, this thesis has two empirical studies. Chapter 1 investigates the psychosocial sequelae and correlates of HSCT for patients and carers and Chapter 2 examines the effectiveness of the intervention using a randomised control trial of the HSCT education programme.

CHAPTER 2: RATES AND CORRELATES OF DISTRESS

2.1. INTRODUCTION

Psychopathology and Cancer

A diagnosis of cancer is a frightening experience; associated with uncertainty and a range of understandable psychological sequelae. The National Comprehensive Cancer Network (NCCN) guidelines define distress as affect experienced by people as a result of their experience of cancer and its treatment (NCCN, 1999). According to this definition, distress can range from sadness through to more severe and clinically significant symptoms characteristic of psychiatric diagnoses. It is known that a significant proportion of cancer patients experience high levels of psychopathology. Research examining patient distress in oncology has revealed clinical levels of distress in approximately a third of patients (Zabora et al., 2001). Rates of psychopathology vary according to type of cancer, prognosis and burden of illness. For instance, a higher prevalence of distress was found in lung cancer patients (43.4%) compared to those with gynaecological cancers (29.6%) (Zabora et al., 2001). However, patients experiencing distress do not necessarily come to the attention of hospital staff as there is considerable evidence that distress is under-detected in clinical settings (Lee, Loberiza, Antin, Kirkpatrick, Prokop, Alyea et al., 2004). Therefore, assessing patients for clinical levels of distress early on is important. Psychopathology or distress associated with cancer treatment has been found to negatively impact on patients' quality of life, symptom related-distress, adherence to care regimens, and disease-free survival (Colon et al., 1991; Goetzmann et al., 2007; Hann et al., 1997; Sutherland et al., 1997).

Psychopathology in HSCT

In high-risk groups, such as patients having HSCT, rates of distress appear to be higher than in other cancer patients (Trask et al., 2002). This is not surprising given the higher risk of mortality and the stressful side effects associated with this treatment which include: GvHD (acute and chronic), infection, cataract formation, pulmonary and neurological complications, gonadal failure, infertility, relapse and secondary malignancy (Andrykowski & McQuellon, 1999; Langer

et al., 2003; Lesko, 1994). Research on psychological distress experienced by HSCT patients has indicated that approximately 50% of patients experience clinical levels of distress prior to receiving information about their treatment (Trask et al., 2002). This rate is also consistent with distress levels assessed at other time points during the HSCT process (Neitzert et al., 1998). For instance, Leigh, Wilson, Burns and Clark (1995) found rates of clinical psychopathology in 54% of patients before and after treatment with HSCT. Six to nine months later, patients still rated highly on psychological distress. Fife et al. (2000) investigated emotional distress after admission to hospital and before HSCT infusion. These authors found that patients were most vulnerable to psychosocial distress during hospitalisation prior to HSCT. Three months and 1 year after transplantation were the time points that were associated with the least distress. The factors most likely to affect patients' emotional distress and adaptation were degree of emotional distress at baseline, personal control, cognitive response, and symptomatology (physical and emotional symptoms). Keogh and colleagues (1998) found moderate to high levels of anxiety and depression in 61% and 14% of patients respectively pre-treatment. Similarly, Jenks Kettmann & Altmaier (2008) found clinical levels of depression in 29.1% before HSCT and 27.6% one year post-HSCT. These studies support the view that elevated levels of distress are common in HSCT patients throughout the treatment process.

Rates of Disorder

Although not all distressed patients fulfil criteria for some form of psychiatric diagnosis, a significant proportion of patients do. Twenty-eight percent of patients who had undergone HSCT described symptoms from pre-treatment that would have met criteria for clinical depression (Jenkins et al., 1991). These results were confirmed in a prospective study that found that 16% of patients met criteria for major depressive disorder pre-HSCT (Jenkins et al., 1994). This suggests that not only is general distress heightened in HSCT patients, but also severe symptoms sufficient to warrant diagnosis are also more common than in the general population. The poor

prognosis, demanding treatment, and wealth of physical complaints likely contribute to these elevated rates of psychological disorder and distress.

Factors Associated With Distress

Although rates of distress and disorder are higher in HSCT patients than controls, the majority of patients do not experience clinical levels of psychopathology. Hence, it is of interest to determine what factors may be associated with levels of distress as this may help to identify effective interventions. The way patients perceive their illness has been found to influence patient behaviour and emotional reactions in other illnesses (Weinman & Petrie, 1997). In relation to cancer patients, illness perceptions have been found to have important effects on quality of life in patients diagnosed with head and neck cancer (Scharloo, Baatenburg de Jong, Langeveld, van Velzen-Verkaik, Doorn-op den Akker, & Kaptein, 2005). HSCT patients appear to be most likely to attribute causal attribution of their illness to chance rather than themselves or others (Frick et al., 2006). However, those that did attribute the cause of their illness to themselves were more distressed. More research is needed regarding the illness perceptions of HSCT patients and their relationship to patient distress.

Satisfaction with information and social support are factors that have been identified as being associated with less distress in cancer patients. Perceived lack of information about treatment has been found to be associated with increased anxiety, uncertainty, dissatisfaction, distress and poor treatment decisions (Fallowfield et al., 1995; Gamble, 1998). Social support has been highlighted as a potentially significant factor for patients undergoing HSCT (Jenks Kettmann & Altmaier, 2008). Jenks Kettmann & Altmaier (2008) found perceived social support pre-transplant significantly predicted levels of depression one year post-HSCT over and above pre-transplant depression. Another study of HSCT patients found an association between stable social support, increased survival and better quality of life post-transplant (Rodrigue, Pearman, & Moreb, 1999).

Patients generally see their partner and friends as their primary sources of social support. However, hospital staff can also come to play an important role. Frick, Motzke, Fischer, Busch, and Bumeder (2005) found significant increases in perceived social support from health care professionals from pre-HSCT to the period directly before transplant when patients were receiving large doses of chemotherapy.

Carer Distress

The illness and its treatment are demanding not only for the patient but also for members of their immediate family. Family and carers of HSCT patients have been found to experience significant interpersonal and personal distress throughout the transplantation process (Krasuska et al., 2002). There have been relatively few studies that have looked at the psychosocial effects of HSCT on caregivers. One study that assessed relatives of HSCT patients using the General Health Questionnaire (GHQ) found 88% scored above the stress threshold at pre-treatment (Keogh et al., 1998). Family members' distress reduced over time with 62% at three months, 40% at six months, and 18% at twelve months scoring above the clinical threshold. However, the GHQ is a measure of overall health and therefore while this indicates carer distress, the nature of that distress is unclear. Foxall and Gaston-Johansson (1996) also investigated HSCT caregivers levels of anxiety. One week prior to HSCT, caregivers were found to have, on average, moderate levels of anxiety on the State Trait Anxiety Inventory (STAI). These heightened levels of anxiety did reduce over time. Notably, these authors did not find elevated rates of depression in carers. Carers of HSCT patients have identified fatigue, disruption to everyday life and financial strain as the major sources of burden (Foxall & Gaston-Johansson, 1996). In HSCT and cancer generally, greater burden has been found to be associated with worse health outcomes for carers, including increased levels of distress (Foxall & Gaston-Johansson, 1996; Grunfeld et al., 2004).

Aims and Hypotheses

While it is well documented that patients have higher levels of distress than controls, carer's distress is less well understood. The primary purpose of this chapter was to examine the baseline rates of psychopathology in HSCT patients and their primary carers prior to undergoing treatment and to investigate correlates of heightened levels of distress. Knowledge of factors associated with elevated distress may be useful in understanding what elements of an education programme will be most helpful to patients and carers. It was hypothesised that both patients and carers would experience elevated levels of distress.

2.2. METHOD

2.2.1. PARTICIPANTS

The participants were a consecutive sample of patients awaiting HSCT and planning to attend an education program at Westmead Hospital, a major transplant centre. Patients nominated a primary carer who was also planning to attend the HSCT education program. Details of recruitment are specified in Chapter 3. Seventy-five patients were sent out a research information statement or were informed about the study by the Transplant Coordinator. Patients who were non-English speaking were excluded. Thirty-six patients gave permission to be contacted by a researcher, which was followed up by telephone. Of those contacted, thirty-two agreed to take part. Twenty-nine of these patients had carers who participated. One carer of a patient who was non-English speaking participated without the patient. Written consent was obtained at the education day.

2.2.2. PROCEDURE

Patients were sent information about the study with their invitation to attend the education program or were asked by the Transplant Coordinator over the telephone if they would agree to be contacted about the research. Those who agreed were contacted by the researcher who sought

verbal consent to take part. Patients and carers were administered a battery of questionnaires via telephone, which took approximately 20 minutes for patients and 10 minutes for carers. All patients and carers completed these assessments before receiving the education program.

2.2.3. MEASURES

The assessment measures were chosen due to their psychometric properties, length of time to complete and ease of administering via telephone. See Table 1 for a list of assessment measures.

Table 1. Assessment Measures

List of Measures	Completed By
Hospital Anxiety and Depression Scale	Patients and Carers
Distress Thermometer	Patients and Carers
Brief Illness Perception Questionnaire	Patients
Information Satisfaction Questionnaire	Patients
DUKE Functional Social Support Questionnaire	Patients
Caregiver Reaction Assessment	Carers

Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983)

The HADS is a 14-item self-report screening measure designed to detect depressive and anxiety-related symptomatology in medical patients. The scale may be used to assess change in a patient's emotional state as well as for assessing presence or absence of clinically significant degrees of anxiety and depression (Zigmond & Snaith, 1983). Patients are asked to assess each item in the context of how they have felt over the past week. Each item is rated on a four-point scale, with a higher score indicating greater state depression and/or anxiety. There are two subscales, anxiety and depression, consisting of 7-items each. Combined raw scores for each scale range from 0 to 21. Scores can be categorised as normal (0-7), possible clinical disorder (8+), or probable clinical disorder (10+) (Zigmond & Snaith, 1983). The items on the depression subscale tap into anhedonic symptoms whereas the items on the anxiety subscale measure affective and cognitive symptoms more than somatic symptoms (Campbell & Martin, 1994). In a study of 568 cancer patients, the reliability of each subscale was found to be high: depression (r

= 0.90) and anxiety ($r = 0.93$) (Moorey, et al., 1991). Moorey and colleagues (1991) found two distinct, but correlated, factors corresponding to anxiety and depression. The internal consistency of the two subscales was also high. For the purposes of the analyses, the depression and anxiety subscales were used to examine patient and carer distress.

National Comprehensive Cancer Network Distress Thermometer (DT;1999)

The DT is a one-item screening tool for assessing distress in cancer patients. Patients are asked to rate their level of distress over the past week based on a rating scale used to measure pain: 0 (no distress) to 10 (extreme distress). Originally, a cut-off score of 5 or above (moderate distress) was suggested for identifying a need for intervention. Although, more recent studies, including a study validating the DT for patients about to undergo HSCT, have used a cut-off score of 4 or above (Ransom, Jacobsen, & Booth-Jones, 2006). Psychometric studies have shown good reliability (0.81) and validity of the DT as a rapid screening measure for distress associated with cancer treatment. It compares well with longer psychological measures of distress. It is well correlated with the HADS total score and the anxiety subscale; the depression subscale is not as well correlated (Trask et al., 2002). For the purposes of this study, a cut-off score of 5 or above was used.

2.2.4. PATIENT MEASURES

Brief Illness Perception Questionnaire (BIPQ) (Broadbent, Petrie, Main, & Weinman, 2006)

The BIPQ is a short nine-item scale designed for taking a quick assessment of cognitive and emotional perceptions of illness. The BIPQ is a brief version of the well-validated Illness Perception Questionnaire (Weinman et al., 1996). The IPQ examines the cognitive representations patients make of their illness and focuses on five major themes that research has identified as pertinent: Identity, Cause, Time-line, Consequences, and Cure/control. The revised

version (IPQ-R) incorporated more items including understanding, emotional impact, cyclical time line and also distinguished between personal and treatment control (Moss-Morris, Weinman, Petrie, Horne, Cameron, & Buick, 2002). The BIPQ taps into the original five constructs plus the additional four from the IPQ-R. It is recommended for very ill patients because it usually takes only a couple of minutes to complete (Petrie et al., 2007). Patients are asked to rate how much each item applies to them on a 10-point scale. It has demonstrated good test-retest reliability (ranging from .48 to .70 for the 9 scales) and concurrent validity (Broadbent et al., 2006). Cause of illness was not considered appropriate for this study so only the first 8 items were used. In order to make the questionnaire specific to the sample population under investigation, the word “illness” was replaced with “transplant” or “condition” accordingly.

Information Satisfaction Questionnaire (ISQ) (Thomas, Kaminski, Stanton, & Williams, 2004)

The ISQ is a brief scale designed to assess the general information satisfaction of cancer patients. The questionnaire includes one item assessing information needs on a 3-point scale, a yes/no item asking if information could have been improved and 6 items examining satisfaction with specific categories of information. These 6 items ask about satisfaction with information provided about the illness, possible side effects, treatment options and relative benefits, lifestyle issues (e.g. support groups), practical issues (e.g. parking and follow-up plans) and overall satisfaction. Patients rate each item on a 5-point Likert scale from 0 = not satisfied to 4 = very satisfied. For this study, a total satisfaction score was created by taking the mean of the first five items. No studies have been conducted to validate this measure. However, given the focus of this research on education, it has considerable face validity.

**Duke-University of North Carolina Functional Social Support Questionnaire (FSSQ)
(Broadhead, Gehlbach, de Gruy, & Kaplan, 1988)**

The Duke-UNC Functional Social Support Questionnaire is a brief 8-item self-report measure designed to assess a person's satisfaction with functional and affective social support. It consists of two scales, Confidant Support (i.e., general emotional support from family and friends) and Affective Support (i.e., support from those identified as a confidant with whom [s]he feels free to discuss any problems). Responses to all questions were rated on a 5-point scale ranging from 1 = "much less than I would like" to 5 = "as much as I would like." Internal consistency ranged from .50 for useful advice to .85 for help around the house (Broadhead, Gehlbach, de Gruy, & Kaplan, 1989). This test has been shown to have good reliability (.66) but low convergent validity (McDowell, 2006).

2.2.5. CARER MEASURES

Caregiver Reaction Assessment (CRA) (Given et al., 1992)

Consisting of 24-items, the CRA aims to assess caregiver experiences in five domains: daily schedule, financial situation, relationships with others, physical health and self-esteem. Each subscale is added to a sum score, which is divided with the number of items, reflects the unweighted mean-item score with a range from 1.0 to 5.0. A total CRA score was created by taking the mean of the five scales. The self-esteem dimension was recoded because the original score meant a high score indicated positive reactions to caregiving. After this recoding, the CRA total score could be interpreted as a dimensional scale of the caregiver situation where higher scores reflect higher burden. The CRA has been found to have sound psychometric properties when applied to carers of cancer patients (Nijboer, Triemstra, Tempelaar, Sanderman, & van den Bos, 1999). The original paper examined caregivers looking after late palliative stage cancer patients (Grosv, Fossa, Tønnessen, & Dahl, 2006). In their sample the total CRA score was 11.37 (SD = 2.1). The internal consistency of the subscales of the CRA have been demonstrated to

range between 0.57 (finances) and 0.85 (self-esteem) and the coefficient of the CRA total scale has been shown to be high at 0.74 (Groves et al., 2006).

2.2.6. DATA ANALYSIS

Scores were created to differentiate clinical and non-clinical levels of anxiety and depression for patients and carers' anxiety and depression subscales on the HADS pre transplantation. The scores were created based on clinical and non-clinical levels of depression and anxiety, with scores of 0 to 7 on both scales recoded as 0 and scores 8 to 12 recoded as 1. A similar score was created using the DT for patients and carers, with a score of five or more indicating clinical levels. Frequencies were conducted to obtain percentages of clinical levels of depression, anxiety and distress (see Appendix D for statistical analyses). Correlations were also conducted to look at the relationships between distress and the other patient measures (BIPQ, ISQ and DUKE-UNC) using Pearson's Correlation Coefficient. Patient and carer comparisons for the distress measures will be conducted using paired t-tests.

2.3. RESULTS

2.3.1. DEMOGRAPHICS

Thirty-two patients with various illnesses (see Table 3) and thirty carers completed the measures pre treatment. Of the patients, 21 (65.6%) were male and 11 (34.4%) were female. There were 10 (32.3%) male carers and 21 (67.7%) female carers. The mean age for patients was 46.84 (SD = 11.64) (range = 22 – 71) and 46.32 (SD = 11.45) (range = 24 – 74) for carers. Illness length ranged from one to 66 months, with a mean length of 11.56 (14.81) months. Most patients (93.8%) had children, and 59.4% had children who were under 18 years. Similarly, 93.5% of carers had children, with 58.1% under 18 years of age. Most carers were spouses (87.9%). 12.2% were the patients' sibling or child. See Table 2 for other demographic information on the sample.

Table 2. Patient and carer demographic and medical characteristics

		Patient (n = 32)		Carer (n = 31)		
		No.	%	No.	%	
<i>Marital Status</i>	Married/living with partner	30	93.8	26	86.7	
	Single/separated/divorced/widowed	2	6.3	4	13.3	
<i>Ethnicity</i>	Caucasian	26	81.3	26	83.9	
	Asian	3	9.4	2	6.5	
	Hispanic	2	6.3	2	6.5	
	Other	1	3.1	1	3.2	
<i>Occupation</i>	Managers/Administrators	1	3.1	0	0	
	Professionals	9	28.1	10	32.3	
	Associate Professionals	3	9.4	4	12.9	
	Tradespersons	8	25	0	0	
	Advanced clerical/service	3	9.4	2	6.5	
	Intermediate clerical/sales/service	6	18.8	5	16.1	
	Intermediate production/transport	2	6.3	3	9.7	
	Elementary clerical/sales/service	0	0	1	3.2	
	Labourers	0	0	1	3.2	
	Unemployed/Pension	0	0	5	16.1	
	Working	Yes	9	28.1	21	67.7
		No	21	65.6	9	29
		Retired	2	6.3	1	3.2

Table 3: Patient illness diagnosis characteristics

<i>Diagnosis</i>		
Leukemia (AML, ALL, CML)	19	59.4
Lymphoma (Hodgkin's, non-Hodgkin's)	6	18.8
Multiple Myeloma	4	12.5
Myelodysplastic Syndrome	3	9.4

2.3.2. DEPRESSION

The means and standard deviations for depression, anxiety and distress are presented in Table 4. The mean for patients on the HADS depression subscale was 6.42 (SD = 4.05). Based on a cut-off point of 8 on the HADS, 61.3% of patients had non-clinical levels of depression and 38.7% had levels indicative of clinical depression (see Table 5). The mean HADS depression score was 6.67 (SD = 4.13) for carers. Sixty percent of carers scored in the non-clinical range for depression and 40% had clinical levels of depression.

Table 4: Means (and standard deviations) of patient and carer psychopathology

<i>HADS & DT Means & SDs</i>	Patient		Carer	
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>
Depression (HADS)	6.44	3.98	6.79	4.14
Anxiety (HADS)	7.35	4.44	10.21	4.19
Distress Thermometer (DT)	4.03	2.54	5.24	2.20

2.3.3. ANXIETY

The mean HADS anxiety score for patients was 7.35 (SD = 4.44). Based on a cut-off point of 8, 51.6% of patients scored in the non-clinical range for anxiety and 48.4% scored in the clinical range. The mean HADS anxiety score was 10.03 (SD = 4.22) for carers. Using the same cut-off point, 70% of carers had clinical levels of anxiety and 30% were in the non-clinical range.

Table 5: HADS & DT cases

<i>HADS & DT Cases</i>	Patient		Carer	
	<i>No.</i>	<i>%</i>	<i>No.</i>	<i>%</i>
Depression (HADS)	12	38.7	12	40
Anxiety (HADS)	15	48.4	21	70
Distress Thermometer (DT)	11	34.4	21	70

Note: A case is defined as a score >7 in either the anxiety or depression HADS subscales and >5 on DT.

2.3.4. DISTRESS

The mean DT score for patients was 4.03 (SD = 2.54). Based on a cut-off point of 5, 64.5% of patients were in the non-clinical range for distress and 35.5% were in the clinical range. For carers, the mean DT score was 5.24 (SD = 2.20). Seventy percent of carers were in the clinical range for distress and 30% were in the non-clinical range.

2.3.5. PATIENT ILLNESS PERCEPTIONS

Patients were assessed on the eight illness perception items. Means and standard deviations of each scale are reported in Table 6. Each of the eight items was examined to see whether they were related to any of the other patient measures (see Table 7 for significant correlations). Interestingly, patient depression was positively associated with consequences, illness identity (degree and severity of symptoms), and emotional response. Patient anxiety was positively related to timeline, concern and emotion. Distress was correlated with identity, concern, and

emotion. Data on the illness perceptions of myocardial infarction (MI) patients from Broadbent and et al's (2006) study are included in Table 6 in order to see how HSCT patients compared to other patient groups. In comparison to MI patients, HSCT patients appear to report greater consequences, concern and emotional response in relation to their illness. They also perceive their illness will continue for less time and feel that they have less personal control.

Table 6: Brief IPQ mean scores in HSCT and MI patients

	HSCT	MI	T-Score	Sig. (2-tailed)
Consequences*	7.55 (2.08)	4.1 (2.8)	9.235	.000
Timeline*	4.20 (2.82)	7.2 (3.1)	-5.825	.000
Personal Control*	3.10 (3.22)	7.7 (1.7)	-7.964	.000
Treatment Control	8.84 (1.67)	8.8 (1.2)	.148	.883
Identity*	4.28 (3.06)	3.1 (2.6)	2.442	.021
Concern*	8.44 (2.08)	6.2 (3.4)	6.491	.000
Understanding	7.81 (2.09)	8.0 (2.2)	-.509	.615
Emotional Response*	6.28 (2.28)	4.2 (3.1)	5.175	.000

MI data from Broadbent et al. (2006)

Table 7: Correlations between distress, BIPQ, ISC and DUKE-UNC

<i>Correlations</i>				
	Subscales	Depression	Anxiety	Distress
BIPQ	Consequences	.506**	-.227	.205
	Timeline	.255	.394*	.297
	Personal Control	-.123	-.110	.138
	Treatment Control	-.290	-.195	-.093
	Identity	.513**	-.226	.348
	Concern	.182	-.273	.416*
	Understanding	.197	.046	.032
	Emotional Response	.342	-.121	.589**
ISC	Information Satisfaction	-.285	-.257	-.202
DUKE-UNC	Confidant Support	.171	.084	.147
	Affective Support	.078	.107	.076

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

2.3.6. PATIENT INFORMATION SATISFACTION

A total score for information satisfaction was created by taking the mean of the five scales.

Patients had a mean score of 2.82 (SD = 0.55). According to the means (see Table 8), patients

were most satisfied with treatment information (e.g. options available and relative benefits) and least satisfied with practical information (e.g. parking, transport and follow up plans). Overall, mean responses for all of the scales indicated that patient satisfaction ranged from two (not sure) to three (satisfied). The only significant correlation for the information satisfaction scales with the distress measures was for explanation of illness (i.e. diagnosis, outcome, and aggressiveness). Greater patient satisfaction with the explanation of their illness was associated with less distress ($r(32) = -.37, p = .04$).

Table 8: Patient information satisfaction means & standard deviations (N=32)

Information Satisfaction Means & SDs	Mean	SD
Explanation of Illness	2.91	.89
Information on Side Effects	3.06	.91
Treatment Information	3.13	.75
Lifestyle Information	2.53	.84
Practical Information	2.47	.88
Overall Satisfaction	2.78	.61

2.3.7. PATIENT SOCIAL SUPPORT

For confidant support, patients had a mean of 21.17 (SD = 3.76) and for affective support they had a mean of 14.53 (SD = 0.88). Based on the means, patients appeared to have more confidant support (e.g. opportunities to talk about problems and attend social activities) than emotional support (e.g. love, affection and care from others). These means were similar to those reported in a study of patients with early stage (0-II) breast cancer (Trunzo & Pinto, 2003). Baseline means from Trunzo and Pinto's paper were 20.5 (SD = 4.5) for confidant support and 13.1 (SD = 2.4) for affective support. Neither confidant nor affective support were significantly correlated with the HADS or DT (see Table 7).

2.3.8. CAREGIVER BURDEN

The individual means and standard deviations for the five scales on the CRA are reported in Table 9. For the total score, carers had a mean of 15.29 (SD = 1.96) burden. This sample had significantly higher total burden ($t(29) = 10.97, p < .000$) compared to palliative cancer patients

(Groves et al., 2006). Comparisons of the means of the HSCT and palliative cancer (PC) patients for the subscales are listed in Table 9. Significant differences were found for all the scales except family support. Greater burden on carer health was associated with higher levels of carer depression ($r(30) = .56, p = .001$) and distress ($r(30) = .42, p = .022$).

Table 9: Carer CRA HSCT & PC Means & SDs

<i>CRA Means & SDs</i>	HSCT Patients	Palliative Patients	T-Score	Sig. (2-tailed)
Self Esteem*	4.38 (.41)	2.1 (.6)	30.28	.000
Family Support	1.99 (.76)	2.1 (.7)	-8.22	.418
Finances*	2.96 (1.07)	2.2 (.8)	3.86	.001
Schedule*	3.50 (.77)	2.8 (1.0)	5.01	.000
Health*	2.48 (.56)	2.2 (.6)	2.68	.012

Palliative cancer patient data from Groves et al (2006)

2.3.9. COMPARISON OF CARERS AND PATIENTS

Although rates of distress were expected to be high in both carer and patient samples, the levels in the carer sample were particularly high. In order to determine whether carers were more distressed than patients, three paired t-tests were conducted. There was no difference between patient and carer levels of depression, $t(28) = -.470, p = .642$. However, a significant difference was found between patient and carer anxiety, with carers having greater anxiety than patients, $t(28) = -2.967, p < .01$. Carers were also significantly more distressed than patients, $t(28) = -2.398, p < .05$. Correlations were conducted between patient and carer distress measures (see Table 10). The DT was positively related to both HADS scales for carers, but only the depression subscale was positively correlated with the DT for patients. Patient depression was also associated with higher carer distress on the DT.

Table 10: Patient & carer correlations on HADS & DT

<i>Correlations</i>	Carer DT	Carer Anxiety	Carer Depression	Patient DT	Patient Anxiety
Patient Depression	.382*	.191	-.353	.534**	.283
Patient Anxiety	.002	.180	-.089	.624**	
Patient DT	.220	.198	.032		
Carer Depression	.724**	.699**			
Carer Anxiety	.697**				

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

2.4. DISCUSSION AND CONCLUSION

2.4.1. DISCUSSION

The purpose of this chapter was to examine rates and correlates of distress in patients undergoing HSCT and their carers. It was hypothesised that levels of anxiety and depression would be elevated in both patients and carers and it was expected that clinically significant levels of distress would be common. These hypotheses were supported. Patient distress was shown to be elevated and of a level consistent with other studies on HSCT. Carer distress was also elevated. Furthermore, carers were found to be significantly more anxious than patients.

The results indicated that there is significant emotional distress among patients prior to receiving HSCT. Almost half of the patients in our sample reported clinical levels of anxiety. Rates of depression were also substantial, with approximately 40% of patient reporting clinically significant depressive symptomatology. About 35% of patients had a cut of score in the clinical range on the DT, indicating a need for intervention. These findings correspond with the research on rates of distress in HSCT patients suggesting that patients undergoing HSCT experience greater distress than other cancer patients.

The DT score was highly correlated with patient anxiety and depression, supporting its use as a brief screening measure in HSCT. However, there was surprisingly no correlation between anxiety and depression on the HADS. This finding is difficult to explain because normally anxiety and depression are significantly related. Although this result may be due to the small sample size and resulting lack of power, in most samples a correlation of between 0.5 and 0.8 is found between depression and anxiety. Whereas in this sample the correlation is only 0.28. It may be that anxiety is elevated for most patients due to the understandably anxiety-provoking nature of HSCT (even if for some these elevated symptoms fall below the cut-off point for

clinical distress). As such, the elevated anxiety scores across the sample may have obscured the usual relationship between depression and anxiety. The fact that the average anxiety score fell within the clinical range supports this view.

In terms of the effect of HSCT on caregiver psychopathology, the results were surprising. The majority of carers (70%) had levels of anxiety in the clinical range prior to treatment. Carer distress, as assessed on the DT, revealed the same number of cases as the anxiety subscale of the HADS, with 70% indicating substantial distress. Again, the DT was highly correlated with carer anxiety and depression. Although it was expected that carers would have elevated levels of distress, the levels were even higher than anticipated. Post-hoc analyses comparing carers with patients showed that carers were significantly more anxious than patients. However, there was no difference in carers' levels of depression, with around 40% of carers reporting clinically significant levels of depression. Although there is limited research on caregiver psychopathology in HSCT, Foxall & Gaston-Johansson (1996) also found that a high proportion of HSCT carers developed elevated levels of anxiety but not depression. Interestingly, carer distress was related to patient depression but there were no other significant correlations between patient and carer psychopathology variables. Since the primary carers are predominantly spouses of the patients, it is not surprising that if the carer is distressed that this will also affect the patients' ability to cope emotionally. Patients are likely to rely heavily on their spouses for both emotional and practical support.

Illness perceptions were found to be significantly higher in our sample compared to MI patients in Broadbent et al's study (2006). HSCT patients perceived more consequences of their illness and symptoms, less personal control and had greater concern and emotional response in relation to their illness. They also perceived a shorter time frame for their illness compared to MI patients. These differences make sense because the impact of HSCT is greater and the patients

are more ill than in MI. Patients having HSCT are less likely to be able to have as much potential to improve their health as MI patients. For example, once someone has had an MI, the risk of future problems can be ameliorated through changes in lifestyle. This is not the case in HSCT. Therefore, although patients see less control, increased consequences, symptoms and emotional impact, this likely reflects the fact that HSCT is more serious. Furthermore, the fact that HSCT patients perceive a shorter illness length is consistent with the expectation that the transplant will cure them of the disease, or at least control the spread of disease.

Interesting relationships were found between patient illness perceptions and distress. Patient depression was positively correlated with consequences and identity. This result indicates that patients are more likely to experience higher levels of depression if they perceive their illness as being more serious and they experience more symptoms. It makes intuitive sense that patients would feel more depressed the more they perceive their illness as have a negative impact not only physically but also generally. Conversely, if patients are more depressed, they are more likely to focus on the consequences of the illness and symptoms. Not surprisingly, depression was also associated with emotional impact of the illness, as were anxiety and distress. Patients who were more anxious were more likely to perceive their illness continuing for longer and have greater concern about their illness. More research is needed to understand the meaning of these findings. However, these results suggest areas that may be targeted by treatment interventions to reduce patient distress levels. Understanding patient perceptions may also have the potential to improve adherence to treatment regimes, recovery and quality of life as has been found in other illnesses (Petrie et al., 2007; Scharloo et al., 2005).

Patients appeared to be moderately satisfied with information as a whole prior to treatment. They were most satisfied with information about their treatment and least satisfied with practical information relating to parking, transport and follow-up plans. This is probably because they had

not received this information prior to the education program. Patients who reported greater satisfaction with the explanation of their illness were least distressed. Although this finding is correlational it appears to be consistent with previous research on the effect of information on distress (Fallowfield et al., 1995; Gamble, 1998).

Patients reported higher levels of confidant support than affective support. That is, they felt they received more opportunities to talk to others about problems than love or affection. These findings are consistent with social support rated by early stage breast cancer patients (Trunzo & Pinto, 2003). It may be that patients have more access to confidant support because it can be provided by extended family and friends easily via telephone communication. However, affective support may be primarily provided by close family members who are likely to be occupied by many competing demands and perhaps their reaction to the patient's illness and treatment and the life changes thereby imposed upon their own lives. In contrast to previous studies, we did not find a relationship between patient social support and psychopathology. The lack of association may be because the majority of patients appeared to have high levels of social support.

Levels of caregiver burden were high in our sample. Compared to carers of late palliative cancer patients, HSCT caregiver burden was significantly greater. Aside from family support (how easy it is to get support from family), significant differences were observed for the total score and the remainder of the subscales. Thus, caregivers perceived more burdens on self-esteem, finances, daily schedule and health. These results are consistent with Foxall & Gaston-Johansson's study (1996) in which carers of HSCT patients reported fatigue, disruption to everyday life and financial strain as the major causes of burden. Although total burden was not related to any of the distress measures, greater burden on carer health was associated with higher levels of carer depression. Poorer carer health due to caregiving is likely to be one of the most important

indications of carers who are struggling to cope. Thus, this may explain the association between health and depression, particularly since carers may include mental health in their responses to this factor. It is surprising that overall burden was not correlated with carer distress, as this has been observed in other caregiver samples (Groven et al., 2006). Research using different measures of burden may be useful in order to explore the relationship between burden and distress in HSCT carers more thoroughly.

This study had a number of limitations. Firstly, the participants were a small sample of those who were invited to (and intended to) attend a HSCT education program. This study had a low recruitment rate and a limited number of constructs could be measured. Because of the small sample, we could not justify multivariate statistics, such as investigating predictors of distress through regression analysis due to power. Despite these limitations, this study is one of the first to investigate illness perceptions in HSCT and the relationships between illness perceptions and distress; and predictable relationships were observed. Furthermore, this is also one of the first studies to investigate carers' distress and caregiver burden in HSCT and the results suggest these are important areas for future research.

2.4.2. CONCLUSION

This evaluation supports previous studies that have demonstrated that HSCT patients experience higher rates of anxiety and depression than do other oncology patients. A surprising and important finding is that most carers are experiencing even greater anxiety and distress than the patients. In line with this finding, levels of caregiver burden were found to be high and burden on health was related to higher levels of depression. More support is needed to facilitate coping and reduce rates of psychopathology in patients and carers early on in the process of HSCT. Because patient and carer psychopathology are associated with one another it is important to provide support for both patients and carers. Furthermore, patient distress is associated with a number of

illness perceptions that have been shown to affect recovery and quality of life post-HSCT. Therefore, it may be beneficial to provide patients with interventions that would influence helpful illness perceptions.

CHAPTER 3: RANDOMISED CONTROLLED TRIAL OF A
PSYCHOEDUCATION PROGRAMME

3.1. INTRODUCTION

Haematopoietic Stem Cell Transplantation (HSCT) is a medical treatment involving the transplantation of blood stem cells. Although previously considered a last resort procedure it is increasingly being used to treat patients with a range of diagnoses (Bone Marrow Transplant Network NSW, 2006). Some significant advances have been made in the use of HSCT. However, it is still considered to be a complex procedure that is arduous and associated with high-risk (Heinonen et al., 2005). Only 50% of patients with leukaemia who undergo HSCT are expected to be free of their primary disease 2 years after transplantation (Kulkarni et al., 2000).

Patients and families are often under considerable stress due to the arduous nature of HSCT. Some of the psychological sequelae that patients undergoing HSCT experience include psychological distress, anxiety over loss of control, physical complaints, sexual dysfunction, problems with social relationships, occupational disability and financial consequences (Baker, 1994). It has been suggested that patients undergoing HSCT would benefit from being informed about the side effects of treatment as it can help patients with decision-making and provide realistic ideas about what to expect after HSCT (Broers et al., 2000). To date however, there are no studies that have specifically addressed this issue in relation to HSCT. Similarly, there has been limited research on the educational needs and experiences of HSCT carers and families. The results in Chapter 2 have highlighted the fact that carers can be even more distressed than patients. Thus, there is a considerable need for empirical evidence evaluating education interventions for carers of HSCT patients.

Patient education has generally been found to have a number of positive benefits for the patient in a range of illnesses, including cancer, rheumatoid arthritis and chronic obstructive pulmonary disease (Fernsler & Cannon, 1991). Education had been associated with improvements in

knowledge and recall, quality of life, decision-making, commitment to treatment, symptoms, symptom management, satisfaction, adaptation to illness, length of hospital stay, health care utilisation, post-operative opioid use and anxiety and depression (Fernsler & Cannon, 1991; McPherson et al., 2001; Treacy & Mayer, 2000; Yoon et al., 2006). In oncology specifically, patient education has been shown to increase knowledge and emotional functioning and satisfaction and reduce treatment problems, anxiety, depression and overall distress (Dodd, 1988; Gundel et al., 2003; McQuellon et al., 1998; Poroch, 1995; Treacy & Mayer, 2000). Retrospectively, HSCT patients have reported that having more information about HSCT before treatment would have helped to reduce distress and uncertainty (Rini et al., 2007).

Not all education programs are associated with positive results. Cartledge and Haaga (2005) found no differences between the intervention and control group in anxiety, distress, treatment adherence or knowledge following an education program for radiation treatment. However, the intervention group were more satisfied with their care and were more likely to utilise psychological services. Hagerty and colleagues (2004) investigated the informational needs of 126 patients with metastatic cancer. Patients who had a poorer prognosis were less likely to want to know how long they were expected to live. Likewise, a large survey of cancer patients revealed that patients who reported higher levels of anxiety and those with a worse prognosis had less desire for information (Kaplowitz et al., 2002). These results provide evidence that some people prefer not to be given information, particularly if they are anxious and/or have a poor prognosis. HSCT is associated with a poor prognosis compared to many other cancer treatments and, as the results of chapter two indicate, HSCT patients have high levels of anxiety. As such, it is not entirely clear whether the benefits of education found in other settings will generalise to HSCT.

Westmead Hospital in Sydney provides an intensive four-hour seminar for all patients and their families. The education program is held every two months and all patients who are listed to receive a transplant are invited. Generally the size of the groups are around 15-30 people including family members. The programme involves a series of presentations provided by members of the multidisciplinary team including a haematologist, transplant coordinator, clinical nurse consultant, transplant nurse, dentist, dietician, social worker and clinical psychologist (see Appendix A for presentation slides). A presentation is also given by a patient who survived HSCT about their experience before and after treatment. The intervention includes introductions of the primary staff members, background on HSCT, procedures required prior to admission and important contacts. Patients are also provided with information about pre-treatment and follow-up procedures, important recovery time points, serious complications and side effects, hospital stay and infection control procedures. Other components of the education programme include psychosocial effects, oral hygiene, nutrition, and social and practical support. Many of the slides are accompanied by pictures, which aid comprehension, and some 'hands on' demonstrations are included to familiarise patients with central lines and masks/gowns. Patients and families are provided with slides to accompany the presentation. The seminar is interspersed with morning tea, lunch and afternoon tea, provided by the Cancer Council. During these breaks, patients and families have the opportunity to talk with staff. Following the programme, patients can visit and inspect the ward where they will be treated.

Despite the support for education programmes in oncology, HSCT is a relatively rare procedure and has a considerably poorer prognosis than other cancer treatments. Thus, we cannot assume that education interventions are helpful in HSCT. The aim of this study is to provide the first evaluation of a patient education programme for patients undergoing HSCT and their carers. The questions that will be examined by this research are: (1) How effective is education for patients and carers? and (2) Is there a relationship between knowledge following the education

programme day and distress? It was hypothesised that education would lead to an overall increase in knowledge not evidenced in a group waiting to receive the education programme. It was also hypothesised that education would not increase patients' anxiety and depressive symptoms, but rather that patients who knew more about their condition and its treatment would be the least distressed.

3.2. METHOD

3.2.1. PARTICIPANTS

The participants were a consecutive sample of patients enrolled to have allogeneic or autologous HSCT at Westmead Hospital who were invited to attend the education program. Patients whose transplants were scheduled between education days or at the time of the education program were not able to attend. This was also true for patients who were sick at the time the program was held because it was unsafe for them to be around other people. Patients who were non-English speaking were excluded from the study.

At the outset of the study, it was advised that at least 12 patients attended each education day. With 6 days held per year, it was estimated that we could expect a sample of 72 patients plus carers. Most patients who were invited to attend the education day over the course of the study were also asked to consent to be contacted about the research (see Appendix B for contact and consent forms). Some patients were not given the opportunity to consent to be contacted about the study because they were invited to attend the education program just prior to the day and hence too late to participate due to randomisation.

Data was collected over a fifteen-month period between December 2006 and February 2008, which included eight education days. One hundred and two patients were invited to attend the education program over this period. Of these, 75 patients were invited to be contacted about this

research study. Forty-one patients replied to the transplant coordinator that they would not be able to attend the education program. Reasons for not attending were being too sick, in hospital, distance to travel, financial difficulties, being invited too late, and no longer being on the transplant list. Thirty-six agreed to be contacted about the research study. Only 51 patients actually attended the education program and 33 participated in the study. One patient who had agreed to be contacted had decided not to attend due to distance, one was excluded as they were non-English speaking, and the third was participating in another research project and felt it would be too much to do both. Attrition rates for three time points were 65% at pre, 59% at post and 39% at follow-up.

3.2.2. PROCEDURE

Patients were enrolled in the research up to 10 days prior to the next education day and stratified according to whether they are awaiting allogeneic or autologous HSCT. Randomisation to education or control group was conducted using SPSS Bernoulli function, which was concealed until after each consecutive patient had consented to participate. Patients nominated a primary carer and carers were allocated to groups by patient. Patients and carers were contacted by telephone to answer a battery of questionnaires, which took approximately 20 and 10 minutes respectively to complete. Those in the control group completed the questionnaires twice (one week apart) while waiting for the educational day. Those in the intervention group completed the same measures one week prior to the education day and immediately after. Both groups received the education program and were followed up at 100 days post-transplant. 100 days post transplantation is a commonly used time point that is used to assess the success of the transplantation. Therefore, it was expected that we would see the most changes at this stage. However, because education is already offered as part of routine care, the waitlist needed to have the opportunity to attend the education programme in the meantime.

3.2.3. MEASURES

Detailed information on all the measures and psychometrics are included in Chapter 2. See Appendix C for patient and carer questionnaires.

Demographics Questionnaire

A demographic questionnaire was used to obtain information on the participants' age, marital status, number of children and ages, cultural background, illness, diagnosis, transplant type that was collected by patient report prior to treatment.

Knowledge Questionnaire

A knowledge questionnaire was developed based on the information in the education programme. Six experts in the field were consulted on what should be included. The final version of the questionnaire consisted of 20 items. Participants were asked to respond to each item on a 5-point Likert scale using true or false, probably true or probably false, or not sure. Chronbach's alpha was used to examine internal consistency of the scale, which was 0.67 for patients and 0.50 for carers. A total knowledge score was created by reverse scoring items so that a higher score indicated greater knowledge. To be able to determine the level of improvement in knowledge a total mean score was used. The total knowledge score ranged from 1-5.

Hospital Anxiety and Depression Scale (HADS) (*Zigmond & Snaith, 1983*)

The HADS is a 14-item self-report screening measure designed to detect depressive and anxiety-related symptomatology in medical patients. The depression and anxiety subscales were used to assess changes in patients and carers over time.

Distress National Comprehensive Cancer Network Distress Thermometer (NCCN, 1999)

The Distress Thermometer (DT) is a one-item screening tool for assessing distress in cancer patients. It asks patients to rate their level of distress over the past week based on the rating scale used to measure pain: 0 (no distress) to 10 (extreme distress).

3.2.4. PATIENT MEASURES

Brief Illness Perception Questionnaire (BIPQ) (Broadbent et al., 2006)

The BIPQ is a short nine-item scale designed for taking a quick assessment of cognitive and emotional perceptions of illness. Patients are asked to rate how much each item applies to them on a 10-point scale. The cause of illness item was left out of this study.

Information Satisfaction Questionnaire (ISQ) (Thomas, Kaminski, Stanton, & Williams, 2004)

The ISQ was designed as an auditing tool for assessing the specific information concerns of cancer patients. The questionnaire includes one item assessing information needs on a 3-point scale, a yes/no item asking if information could have been improved and 6-items examining satisfaction with specific categories of information. For the purpose of the study, we only used the six items as they can be combined to create a total score.

Duke-University of North Carolina Functional Social Support Questionnaire (FSSQ) (Broadhead et al., 1988)

The Duke-UNC Functional Social Support Questionnaire is a brief 8-item self-report measure designed to assess a person's satisfaction with functional and affective social support. It consists of two scales, Confidant Support (5 items) and Affective Support (3 items). This test has been shown to have good reliability but low convergent validity (McDowell, 2006).

3.2.5. CARER MEASURES

Caregiver Reaction Assessment (CRA) (Given et al., 1992)

Consisting of 24-items, the CRA aims to assess caregiver experiences in five domains: daily schedule, the financial situation, relationships with others, physical health and self-esteem. The

CRA has been found to have sound psychometric properties when applied to carers of cancer patients (Nijboer et al., 1999).

3.2.6. DATA ANALYSIS

Baseline differences between the intervention and control group were assessed using parametric (for continuous variables) and non-parametric (for dichotomous variables) tests to identify covariates. A series of 2 (group: education; control) X 2 (time: pre; post) mixed model ANCOVAs were performed, using SPSS 15.0 for Windows, to determine the effectiveness of the intervention. Controlling for transplant type was considered because of the differences in risk between autologous and allogeneic transplants. However, we decided not to control for it because there were equal numbers of each transplant type in both groups and no significant relationships were found between transplant type and any of the other variables. Correlations were conducted to look at the relationship between knowledge following the education day and distress. Since all patients had received the intervention at follow-up it was only possible to assess what happened over time. Data was assessed using paired t-tests for baseline and follow-up results. We also thought it would be worthwhile to see whether there were any significant relationships between survival and other measures. Spearman Rho correlations were used to analyse this data.

3.3. RESULTS

See Appendix D for data analyses.

3.3.1. DEMOGRAPHICS

Thirty-two patients and 30 carers consented to participate in the study. Two patients' chose not to ask their carers to participate due to perceived burden on them and one carer participated without the patient due to the patient being non-English speaking. All sixty-two participants (100%) completed pre-treatment questionnaires. At post-treatment 30 patients and 30 carers

completed post-treatment measures (97%). One patient was hospitalized and was unable to complete the second telephone survey and another patient withdrew due to problems with the psychological aspect of the study. Twenty patients and 20 carers completed questionnaires at 100 days post-transplant (65%). Five patients had passed away, three declined to participate, one had a brain infection and was unable to participate, and one was unable to be contacted. Attempts were made to contact the carers of the deceased patients. Only one of these carers was contactable and participated at follow up. Of the remaining six carers, three carers declined to participate and three were unable to be contacted. One patient and carer had separated following the transplantation but they both agreed to participate at follow-up.

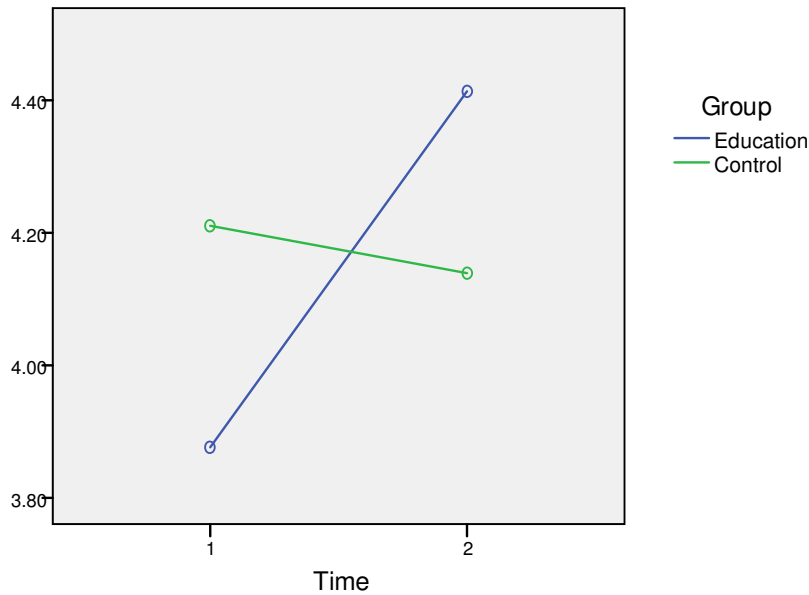
The mean age for the intervention group was 45.50 (S.D. = 12.25) and 48.19 (S.D. = 11.23) in the control group. In the education group, there were 9 male and 7 female patients and 7 male and 10 female carers. In the control group, there were 12 male and 4 female patients, and 4 male and 1 female carer. There were no significant differences between the intervention and control groups for patient age ($t(1, 30) = -.65, p = .523$) or gender ($\chi^2 = 1.25, p = .264$). This was also the case for carer age ($t(1, 29) = .46, p = .649$) and gender ($\chi^2 = .42, p = .519$). Nor were there any significant differences for any other demographic or disease measures (see Appendix C). Refer to Chapter two for more demographic details for the sample.

3.3.2. KNOWLEDGE

At post-treatment both patients and carers in the education groups showed improvement in knowledge compared to controls (see Table 10 for means and standard deviations). For patient knowledge, there was a main effect for time indicating that all patients, regardless of education became more knowledgeable over time ($F(1,27) = 17.13; p < 0.000; \eta^2 = 0.39$). Importantly the group by time interaction was also significant indicating that those in the intervention group had

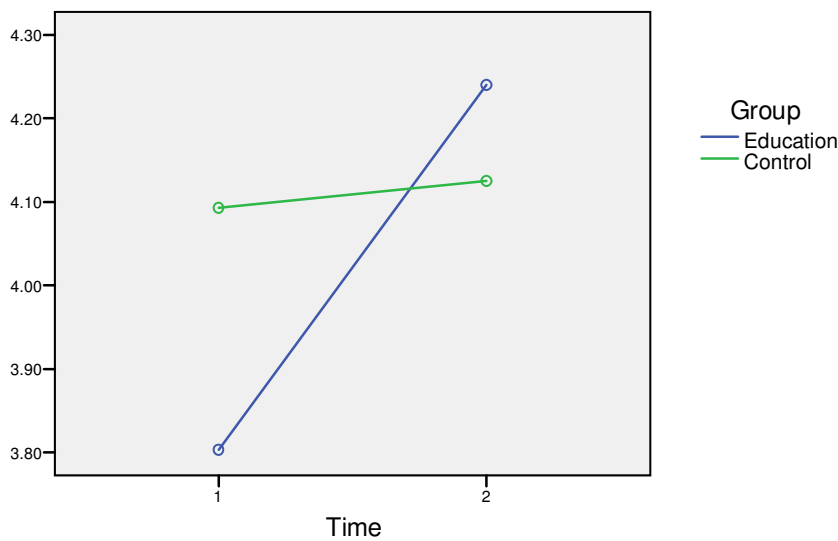
greater improvement in knowledgeable compared to the controls ($F(2,27) = 29.26; p < 0.000; \eta^2 = .31$).

Figure 1: Interaction of patient knowledge by group



A time effect was also found for carer knowledge ($F(1,27) = 12.31, p < 0.01, \eta^2 = .25$) with carers becoming more knowledgeable with time (see Table 11). As with patients, an interaction effect was found for carer knowledge such that carers in the education group became more knowledgeable than controls following education ($F(2,27) = 9.17, p < 0.01, \eta^2 = .25$).

Figure 2. Interaction of carer knowledge by group



3.3.3. PSYCHOPATHOLOGY

There were no significant main or interaction effects of group on any of the psychopathology measures. Specifically the time by group interaction for depression was not significant for patients ($F(2,28) = .592, p = .448, \eta^2 = .21$) or carers ($F(2,27) = .239, p = .629, \eta^2 = .008$). This was also the case for anxiety, with no significant time by group interaction for patients ($F(2,28) = .035, p = .852, \eta^2 = .01$) or carers ($F(2,28) = .974; p = .332; \eta^2 = .34$). There was also no group by time effect for patient ($F(2,28) = .159; p = .693, \eta^2 = .124$) or carer ($F(2,28) = .133, p = .718, \eta^2 = 0.005$) distress.

Table 11: Patient group means and standard deviations

Group Means & (SDs)	Education		Control	
	Pre	Post	Pre	Post
Knowledge	3.88 (.46)	4.41 (.44)	4.21(.42)	4.14 (.45)
Depression (HADS)	6.00 (4.69)	6.00 (5.36)	6.53 (3.38)	5.60(4.31)
Anxiety (HADS)	6.80 (4.16)	6.80 (4.49)	7.60 (4.79)	7.73 (4.80)
Distress (DT)	3.33 (2.44)	4.13 (3.18)	4.47 (2.45)	5.00 (1.77)
Consequences	7.47 (2.10)	7.33 (2.35)	7.47 (2.10)	7.80 (1.61)
Timeline	4.20 (2.60)	4.80 (2.04)	4.21 (3.24)	5.71 (2.61)
Personal Control	2.73 (2.69)	3.47 (2.03)	3.00 (3.38)	3.93 (3.26)
Treatment Control	8.73 (1.75)	8.00 (1.77)	9.00 (1.65)	9.20 (1.15)
Identity	3.67 (3.09)	4.13 (2.85)	4.86 (2.93)	4.71 (3.22)
Concern	8.20 (1.93)	7.33 (2.13)	9.00 (1.46)	8.33 (1.88)
Understanding	7.27 (2.43)	7.73 (1.62)	8.27 (1.75)	7.73 (1.87)
Emotion	6.13 (2.13)	5.87 (2.50)	6.80 (2.27)	6.07 (2.28)
Information Satisfaction	2.69 (.56)	2.89 (.50)	2.96 (.56)	2.97 (.71)
Confidant Support	20.17 (4.34)	11.36 (2.59)	22.07 (3.03)	12.44 (3.17)
Affective Support	14.47 (.92)	13.33 (2.89)	14.53 (.92)	14.73 (.70)

Table 12: Carer group means and standard deviations

Group Means & (SDs)	Education		Control	
	Pre	Post	Pre	Post
Knowledge	3.80 (.34)	4.24 (.45)	4.09 (.50)	4.13 (.52)
Depression (HADS)	6.50 (3.60)	6.63 (3.84)	6.86 (4.80)	7.36 (5.05)
Anxiety (HADS)	10.00 (4.15)	10.00 (4.27)	10.07 (4.46)	10.93 (4.39)
Distress (DT)	5.31 (1.89)	5.50 (2.73)	5.21 (2.52)	5.14 (2.44)
Caregiver Burden	15.13 (2.30)	14.71 (1.76)	15.48 (1.55)	15.18 (1.71)

3.3.4. OTHER MEASURES

No significant interaction effects were found for group by time on any of the illness perceptions items (see Table 12). A significant time effect was found for Timeline ($F(1,27) = 7.624, p = .010, \eta^2 = .22$) such that patients' perception of how long their illness would continue increased with time regardless of intervention. There was no difference for patient information satisfaction with education ($F(2,28) = 1.02, p = .321, \eta^2 = .04$). On the social support measure, there was a significant time effect for confident support ($F(1,28) = 194.05, p < 0.000, \eta^2 = 0.87$). All patients reported less confident support over time. There were no significant main or interaction effects for either confident support ($F(2,28) = .38, p = .540, \eta^2 = 0.14$), affective support ($F(2,28) = 2.66; p = .114; \eta^2 = .09$) or caregiver burden ($F(2,28) = .14, p = .715, \eta^2 = .01$).

Table 13: Group by time effects for illness perceptions

	<i>df</i>	<i>T-Score</i>	<i>Sig. (2-tailed)</i>	η^2
Consequences	28	.39	.537	.01
Timeline	27	1.40	.247	.05
Personal Control	28	.03	.861	.00
Treatment Control	28	2.50	.125	.82
Identity	27	.38	.545	.01
Concern	28	.05	.824	.00
Understanding	28	2.25	.145	.07
Emotional Response	28	.66	.425	.023

3.3.5. CORRELATIONS

Correlations between patient and carer knowledge post-education and distress measures are shown in Table 13.

Table 14: Correlations between knowledge and distress measures

<i>Correlations</i>	Patient DT	Patient Anxiety	Patient Depression	Carer DT	Carer Anxiety	Carer Depression
Patient Knowledge	-.378*	-.011	-.243	.135	.310	.056
Carer Knowledge	-.306	.044	-.266	-.329	-.167	-.302

* Correlation is significant at the 0.05 level (2-tailed).

The only significant correlation was between patient knowledge at post-education and patient distress. Greater knowledge post-education was associated with less distress on the DT.

3.3.6. FOLLOW UP

Significant differences were found at 100-day follow-up for patient and carer knowledge and carer anxiety (see Table 14). Patients and carers had higher knowledge scores at follow-up compared to baseline. Carer anxiety had reduced significantly at follow-up, with the mean score close to the normal range. Differences were also found for consequences and concern on the BIPQ. Patients perceived the illness as have less effect on their life (Consequences) and were less concerned about their illness at follow-up. Affective and confidant support also showed significant change at follow-up. Patients reported having more affective support but less confidant support at follow-up versus baseline.

Table 15: Significant differences at follow-up

	<i>Baseline</i>	<i>Follow-up</i>	<i>T-Score</i>	<i>Sig. (2-tailed)</i>
Patient Knowledge	81.25 (9.27)	86.00 (8.32)	-2.767	.012
Carer Knowledge	80.70 (7.87)	87.85 (5.31)	-5.244	.000
Carer anxiety	9.80 (4.47)	7.65 (3.59)	2.772	.012
Consequences	7.58 (2.19)	6.11 (2.51)	2.220	.040
Concern	8.79 (1.36)	6.42 (2.39)	4.415	.000
Affective	14.50 (.52)	14.83 (.71)	-2.062	.055
Confidant	20.75 (3.89)	11.83 (3.23)	9.230	.000

3.3.7. SURVIVAL

At 100-day follow-up, 15% (N = 5) of patients had died. All of the patients who had died had received allogeneic transplants. Infection (N= 4) and acute GvHD (N = 1) were the causes of early death in this sample. There were no significant relationships between survival and illness or demographic variables. There was a correlation between personal control and survival post-education ($r(30) = -.48, p = .007$). Lower perception of personal control post-education was associated with mortality.

3.4. DISCUSSION AND CONCLUSION

3.4.1. DISCUSSION

The aim of the present study was to evaluate the effectiveness of an education intervention for HSCT patients and carers. We were also interested in examining the effect of education on distress and whether there was a relationship between knowledge following the education programme and distress. It was hypothesised that education would lead to increased patient and carer knowledge compared to waitlist controls. In addition, we predicted that the education programme would not have adverse effects on anxiety and depressive symptoms and that those who knew more about HSCT would be the least distressed.

The intervention was successful in achieving its primary goal of increasing knowledge. Patients in the education group showed increased knowledge about HSCT compared to patients in the control group. This was also true for their carers. Looking at the means on the knowledge scale, on average both patients and carers appeared to have a reasonable understanding to begin with but they became more certain following the education programme. Importantly, the education programme did not have any adverse psychological effects for either patients or carers. There were no differences between the groups in terms of depression, anxiety, or distress. We expected that the education programme might result in decreases in distress. However, this was not the case. There was, however, a significant correlation between patient knowledge following the education programme and distress. Consistent with the hypothesis, greater knowledge was associated with less distress.

There were also no differences between the groups in terms of patient illness perceptions, patient information, patient social support or caregiver burden. However, changes over time were found for the BIPQ timeline scale and confidant social support. Patients' perception of how long their

illness would continue increased with time and they reported decreased confident support with time. As time progresses, it is not unusual that patients would have a better understanding of their illness and the fact that it will take a long period of time to be well again. This is particularly true for HSCT patients because in some cases they will never be considered completely 'cured'. The finding that perceived confident support decreased with time may be a result of important support people in the patients' life simply being less available or having less capacity to be as personally accessible. Alternatively, patients may perceive their need to confide in others as a burden to their support people. Further research is needed to explain this finding.

Patients and carers were followed up at 100 days post transplant in an attempt to evaluate the long-term impact of the education programme. At 100-day follow-up, patients and carers' knowledge was still significantly greater than baseline. Patients perceived fewer consequences from, and had less concern about, their illness. They also felt they had more affective, but less confident, support compared to baseline. There were no changes in patient anxiety or depression, but carer anxiety decreased over time; with the mean score at 100 days post-transplant falling within the normal range. It is heartening that carer anxiety improves with time and indicates that, even without support, carers will be able to cope despite high levels of anxiety. Unfortunately, due to the importance of all patients and carers receiving education it was not possible to randomize this aspect of the study. Hence, it is unclear whether changes can be attributed to the education programme. Although this study is unable to conclude any long-term benefits in relation to the education programme, it is possible that there are positive long-term effects on carer anxiety. It is a concern that there were no reductions in patient distress. The findings that patients' perception of the impact of their illness and concern for their illness decreased over time is, however, positive. This finding highlights the significance of the 100-day time point as a marker of hope for patients. This may also indicate the possibility that reductions in psychological symptomatology would be observed in patients over the longer-term, such as six

months to one year. An interesting association was found for perceived personal control and survival post-education. Lower perceived control over one's illness was significantly correlated with mortality. Perhaps this finding relates to helplessness or patients who are less well accurately perceive that they have less personal control over the outcome.

Although steps were taken to minimize limitations with the methodology, there are nevertheless areas for improvement in this study. Despite a long period of recruitment, there was a significantly lower recruitment rate than was anticipated. Recruitment was affected in part due to the attendance of the education programme itself. Approximately 50% of patients declined the offer to receive education. Many patients lived a long distance from the transplant hospital and they may have found it difficult to attend. Other patients may have decided they did not want more knowledge. Attempts were made to minimize burden from the study on participants, however some patients may have still decided not to participate due to the perception of the study creating even greater burden. Other patients were unable to participate because they were only invited to the education programme just prior to the day of its occurrence; making it impossible to randomize and assess them in time. The psychological aspect of the study as well as the invitation to carers could have also discouraged some patients from participating. The fact that such a large proportion of patients declined to attend the education programme also raises questions about the generalisability of the results. Finally, the small sample size is problematic because it affects power, reducing the number of constructs that could be examined and preventing the use of multivariate statistics.

It would have been interesting to look at the effect of the two types of transplant on participants' experience of the education programme. Because HSCT is so rare, in practice education programmes typically combine patients receiving allogeneic and autologous HSCT. Having a combined information day for autologous and allogeneic HSCT patients may result in decreased

anxiety for the low risk group (autologous) but increased anxiety for the high-risk group (allogeneic). On the other hand, it is equally possible that patients awaiting autologous transplants will not distinguish between the information that is relevant to them and the information relevant to patients awaiting allogeneic HSCT. This may inadvertently increase anxiety in the low risk (autologous) group. Additional information has been suggested to increase anxiety, especially when it is confusing or misunderstood (de Haes, 2006). Unfortunately, this study did not have the power to explore this aspect of the education programme but it would be useful for future studies to evaluate. There was no indication of these affects in the small sample in this study.

These limitations notwithstanding, this study also has a number of strengths. It was the first evaluation of the effects of a patient education programme for HSCT patients and carers and one of the few to include both allogeneic and autologous transplant types. The evaluation demonstrated that the educational intervention was effective in increasing knowledge and importantly, greater knowledge did not increase patient or carer distress.

3.4.2. CONCLUSION

This was the first randomized study evaluating a patient education programme for patients undergoing HSCT and their carers. Patients and carers experienced an increase in their knowledge of HSCT as a result of the education programme. This knowledge did not adversely affect patients or carers in terms of anxiety or depression. Rather patients with more knowledge were found to be least distressed. The education programme did not have any effect on information satisfaction, illness perceptions, social support or caregiver burden. Patients and carers knowledge was still significantly greater than baseline at 100-day follow-up. Patients also perceived fewer consequences from, and had less concern about, their illness. They also felt they had more affective but less confident support compared to baseline. Carer anxiety returned to

within normal levels for anxiety, but depression did not change. Furthermore, there were no changes in patient symptomatology. These findings support the use of an education programme for increasing knowledge without affecting patient and carer distress. There is also a need demonstrated, however, for greater psychosocial supports for both carers and patients.

CHAPTER 4: GENERAL DISCUSSION

4.1. MAJOR FINDINGS

This primary purpose of this investigation was to run the first randomised controlled trial of a patient education programme for patients undergoing HSCT and their carers. This objective raised the following questions: (1) what are the rates and correlates of distress in HSCT patients and carers, (2) what effect does education have on patients and carers and (3) is there a relationship between knowledge following the education programme and distress? Based on the existing literature evaluating the effect of education on patients with cancer and other serious illnesses, it was hypothesised that education would lead to an overall increase in knowledge, not evidenced in a group waiting to receive the educational programme. It was also predicted that increasing knowledge would not increase patient or carer anxiety or depressive symptoms. Furthermore, it was hypothesised that patients who knew more about their condition would be the least distressed.

High rates of psychopathology were found for patients and carers. Approximately forty percent of the patient sample had depressive symptomatology in the clinical range. This was also supported by patient ratings of distress, with 40% reporting clinical levels. The presence of clinically significant anxiety was even greater with about half the patient sample indicating high levels of anxious symptomatology. There were no differences between patients and carers in terms of depression, with a similar number of carers reporting clinically depressive symptomatology. However, there was a significant difference between patient and carer rates of anxiety and distress. On both measures, 70% of carers reported symptoms of anxiety and distress indicative of a need for clinical support. This is an important finding because rates of clinically significant symptoms in carers of HSCT patients have not received as much attention as the patients. Thus, it has not necessarily been assumed that carers could require more psychosocial support than patients.

The primary goal of the intervention programme is to provide patients with more information. The results provide support for the effectiveness of the psychoeducation programme, as there was a robust increase in both patient and carer knowledge. Patients in the education group had significantly greater knowledge compared to controls. This was also true for carers in the education group. Thus, the education programme is an effective intervention for providing patients and carers with greater knowledge and new information. At follow-up, there were also significant differences in patient and carer knowledge compared to baseline. Although, this cannot be attributed to the education programme, it is indicative that patients have maintained a higher degree of knowledge than they had prior to treatment. You would also expect that knowledge would increase by experiencing the procedure first hand.

The hypothesis that would not be adversely affected by the education programme was support. Increasing knowledge did not lead to increases in anxiety and depressive symptomatology. The fact that the intervention does not appear to have any adverse effects whilst still providing patients and carers with more information lends further support to the effectiveness of the intervention. Interestingly, education did not lead to any reductions in patient or carer distress. This finding is contrary to research looking at the effect of education in other illnesses, including cancer, where patient education programmes have been useful in increasing knowledge and decreasing patient distress. Nonetheless, those who knew most about their illness following education were the least distressed. Hence, it is possible to exclude the possibility that information increases distress in any way.

4.2. LIMITATIONS

4.2.1. SAMPLE SIZE

There were a few obvious limitations to this study. Firstly, the size of the sample was much smaller than anticipated. Originally, we aimed to get a sample of seventy-five patients in order to

have enough power to look at the differences between autologous and allogeneic transplant types with education. Over the sixteen months of data collection, which included eight education programmes, 102 patients were invited to attend education. Seventy-five of these patients were invited to be contacted about the study. Only 36 out of these 75 patients consented to be contacted by the researcher about the study. While this might give an indication of a very low recruitment rate, only 51 (50%) of the original one hundred and two patients actually took up the offer to receive education. Those who did not attend would have been ineligible to take part in any case. Thus only 51 patients were potential participants for this study. Of these, we were able to recruit 32 patients (63%) of those who actually attended the education programme. Further, out of the 36 who elected to be contacted, a very high proportion agreed to take part in the study (32/36). Of those who declined, one was excluded due to being non-English speaking, two had decided not to attend the education programme due to travel distance and the fourth was participating in another research study already and did not want to be over burdened.

Therefore, although the education programme was helpful for those patients who did attend, a high proportion of patients chose not to receive education. This raises issues about whether those who attend the education programme have different information needs compared to those who do not attend. A considerable number of patients came from regional NSW and faced difficulties with travel costs and accommodation in order to attend the education programme. For example, one of the patients who declined to attend due to travel lived close to the Queensland border. He said that they could not afford to travel for the education programme because they would need to travel for the transplant itself and the cost physically and financially would be too great to do both. Therefore, it possible that rural patients are under-represented in the sample, although many of the participants were from regional areas. It is also possible that the people who chose not to attend differed systematically from those who attended. For example, it is possible that some people prefer not to receive information. The low take-up rate for the education program

raises a dilemma. While it is not possible to force patients to attend or even to devise an education programme for those who do not want to be educated, it is quite concerning that such a large number of patients may be agreeing to HSCT in the absence of a proper understanding of the risks. The fact that this programme has been created in the first place indicates that it is important for patients to be educated about HSCT. Yet, almost half of all patients are not utilising this service.

This is surprising given the research suggests that cancer patients generally want to receive substantial information about their illness and treatment. However, this finding concurs with some research that has found that cancer patients with higher levels of anxiety and worse prognosis have less desire for information (Kaplowitz et al., 2002). Certainly, there are individual differences when it comes to how much people want to know about conditions that may be threatening and confronting. While some people want to have all the information available, others are content to know the minimum required. A lot of research has been conducted on differences in patient information preferences. Although it is not within the scope of this thesis to explore this topic, it would be interesting for future research to investigate information preferences and associated behaviour in relation to HSCT. It may be necessary to encourage and better facilitate more comprehensive participation in the education programme, for example by providing an interactive Internet based education programme for remote patients, if the program is considered to be important for informed consent. This will at least provide the opportunity for all patients who are willing to be educated to receive the intervention.

The psychological aspect of the study may have also discouraged patients from participating. One couple (patient and carer) withdrew from the study after time one because they were uncomfortable with the questions on the HADS. They felt that an investigation of their psychological functioning was unnecessary and unhelpful. Although only one patient and carer

in the sample reported feeling this way, there may have been others who chose not to participate in the first place in order to protect themselves from thinking about these aspects. Two patients did not take up the offer for the researcher to speak to their carer because they thought that their carers would not cope with being a part of the study on top of coping with the illness and treatment. Thus, patients and carers who chose not to be contacted may also have been protecting each other in this way. The fact that carers were asked to participate may have been enough to discourage some patients from participating themselves as they may have thought that they could not participate alone. Although these issues are speculative, it is possible that the people who chose to attend the education programme are different from those who declined to attend. This may limit the generalisability of the results.

A major challenge to recruitment was the ethical requirement that the researchers were not able to contact patients directly. The Transplant Coordinator for the Bone Marrow Transplant ward at Westmead Hospital was initially only allowed to send out a 'Permission to Be Contacted about Research' form with a reply paid envelope along with the invitation to receive education. Following low recruitment to the study, the ethics committee allowed the Transplant Coordinator to also ask patients directly if they would be willing to be contacted (either in person or over the phone) because many people were missing out on taking part because they were being invited to the education day too late. Alternatively, it seemed that consenting to be contacted by the researcher over the phone to the Transplant Coordinator was much less a burden to patients compared to considering, completing and sending back a form. This change did improve recruitment to some degree because it at least meant that there were less patients missing out due to the late scheduling of the education programme. Some patients, however, were still not asked in time due to the need for randomisation in the study that required that the researcher contact participants a week prior to the education programme. Further, being contacted by the researcher who can explain the commitments of the study and the right to withdraw, is a different

experience for the potential participant than to have someone outside the study seek to explain what is involved. More patients may have taken part in the study if a different method of recruitment had been acceptable to the ethics committee.

The small sample size presents a limitation in respect of power in the study. The effect of the sample size on power may have meant that some findings did not reach significance, but differences actually existed. However, an examination of the effect sizes (η^2) suggests that the only two variables where power was likely to be an issue were (a) affective support; and (b) understanding. Both of these large effect sizes suggest that a difference would have been observed if 26 patients had been included in the sample. In addition to the issues of power, it is of note that there was no attempt to control for multiple comparisons by using a more stringent criteria. If we had adjusted for the 15 outcome variables, we should have adopted a stringent alpha value of 0.003. It was decided not to do so because this would have compounded the problem of power. Nonetheless, had a more stringent alpha level been adopted, the results would have remained largely unchanged as the major finding on knowledge was $p < 0.003$.

4.2.2. LACK OF LONG-TERM CONTROLS

While patients and carers were followed up, it was not possible to assess the effect of the education over time. In the unit at Westmead, the education programme was offered as part of routine treatment. There is no evidence that education is beneficial and therefore at one level there should not be any ethical objection to randomising patients. On the other hand, it is not considered ethical to withhold something considered part of routine treatment. This ethical constraint means, however, that the long-term outcome of education cannot be assessed. If it were possible to survey the patients who did not take up the offer to attend the education programme, it would be possible to compare them to the patients in our sample at follow-up. If the samples are systematically different, however, the comparison may not be valid. In hindsight,

given the large percentage of those who failed to attend, a more natural design of following up attendees versus non-attendees may have been preferred. Although one could have been less confident that differences were solely attributed to the education, such a design would have allowed other questions to be answered more clearly. Specifically, the differences between those who attended versus those who did not and the long-term effect of education would have been easier to gauge. This approach would also have allowed a larger sample for the analyses in second study.

4.2.3. MEASURES

Another shortcoming of the study was the limit to the type and number of measures that could be used. In designing the study, we were conscious of overburdening these very ill patients and we did not want the study to impact greatly on their time and effort. We also expected this would increase recruitment. Some measures were selected in preference to others because they were brief. In doing this, it is possible that we missed out on using measures which have stronger reliability and validity. For example, the Brief Illness Perception Questionnaire was selected over the more widely used and validated Illness Perception Questionnaire Revised (IPQ-R). The IPQ-R has been used to assess illness perceptions in breast cancer patients (Fotios & Efrosyni, 2005). It is possible that we would have found more information if we had been able to use this longer measure. This was also the case for the measure of information satisfaction, social support and caregiver burden.

4.2.4. TRANSPLANT TYPE

This study also differed from other research on this patient population in that it looked at people having both autologous and allogeneic transplants. Most studies tend to look at just one type of transplant. Since initially we intended to examine the differences between these two groups with education, patients were equally randomised by transplant type. Unfortunately, due to limited numbers, there was not the power to evaluate this possible difference. Because there were equal

numbers of each transplant type in both groups and no indication of transplant type being correlated with any significant variables, we decided not to control for transplant type. However, it is still possible that transplant type could have an effect on the results. For example, we initially wondered whether those autologous patients with a better prognosis may be confronted by reference to complications, such as GvHD, which are not relevant to them. If autologous patients failed to distinguish between the information relevant to them versus that relevant to allogeneic patients, they may believe that their prognosis is worse than they thought. This would lead to increases in patient beliefs and possibly indices of distress. The opposite could be true of allogeneic patients. That is, they might think their prognosis is better as a result of taking on board information relevant to autologous patients, resulting in a decrease in distress and perceived seriousness of the condition. The fact that the education had different effects on the two groups may obscure any effects of the education. Although one would expect a correlation between transplant type and outcomes if this were the case, this possibility cannot be excluded. Therefore, it is a limitation of the study. On the other hand, because other studies have generally not included both autologous and allogeneic, there may be some benefit in looking at both groups together.

4.2.5. INTERVENTION

A further downside of the study was that it is not clear what it was about the particular education that was effective in improving knowledge. Patients are provided with written, verbal and visual information in the course of the education programme. The impact of having the multidisciplinary team invest time may have been important for patients. In addition, for each programme, a past patient is present to discuss their experiences and this experienced-patient to novice-patient may be very effective. There was no scale that measured participants' response to the education programme. Qualitative research is needed to assess patients' reflections following the education programme in more detail. For instance, patients and carers commented

on the helpfulness of being able to meet the Transplant Coordinator at the education programme as they had only spoken to her on the phone previously. Also anecdotally, the presentation by the experienced-patient who had survived HSCT appeared to have a substantial and positive impact on the outlook of patients and carers alike.

4.3. STRENGTHS

Despite the aforementioned limitations of the study, this research has a number of strengths. Firstly, we were able to support the existing literature in terms of the higher proportion of clinically significant psychopathology in HSCT patients. More importantly, this study has brought to attention the substantial level of distress experienced by HSCT carers. Some preliminary investigation of illness perceptions were also conducted which showed relationships with distress. Finally, this was the first empirical evaluation of an education programme for HSCT patients and their carers and it found support for the intervention in increasing the primary outcome variable of knowledge without leading to detrimental effects on psychopathology.

4.4. DISCUSSION OF RESULTS

4.4.1. PATIENT AND CARER DISTRESS

The rates of clinically significant distress were high in our patient sample with approximately 50% of patients meeting the cut-off point of eight or above on the anxiety subscale of the HADS and almost 40% on the depression subscale. On the DT, approximately 35% met the cut-off score of five or above. In cancer generally, about a third of patients have been found to have significant distress (Zabora et al., 2001). Our results appear to correspond with the research on HSCT patients which have found the rates of distress to be higher than in other oncology settings. Trask et al (2002), examined rates of distress, anxiety and depression on the DT and the HADS in a sample of 50 candidates for HSCT. They found that 50% of the patients reported clinical levels of distress and 51% of patients reported clinical levels of anxiety. Less than 20% of the patients

reported clinically significant depressive symptomatology. We found a similar level of anxiety in our patient sample (48.4%). Levels of depression, however, were higher (38.7%) and less patients reported clinical levels of distress (34.4%). Leigh, Wilson, Burns and Clark (1995) found rates of abnormal psychopathology in 54% of patients before and after treatment with HSCT. Six to nine months later, patients still rated highly on psychological distress. Furthermore, Keogh and colleagues (1998) found moderate to high levels of anxiety and depression in 61% and 14% of patients respectively pre-treatment. Sixteen percent of prospective HSCT patients met criteria for major depressive disorder (Jenkins et al., 1994) and 28% of patients who had received HSCT described symptoms from the pre-treatment indicative of a major depressive episode (Jenkins et al., 1991). The results of this research are generally consistent with the literature. That is, HSCT patients have a high level of distress, anxiety and depression indicating a need for psychosocial support.

The rates of distress in carers of HSCT patients have not received as much attention by researchers. In our sample, 70% of carers reported rates of anxiety and distress that were indicative of a need for clinical intervention and 40% reported clinical levels of depression. Keogh et al (1998) found 88% of HSCT relatives scored above the stress threshold on the GHQ pre-transplant. Sixty-two percent were still distressed at three months, 40% at six months, and 18% at twelve months. Another study found carers of HSCT patients had moderate levels of anxiety on the State Trait Anxiety Inventory (STAI) but normal levels of depression (Foxall & Gaston-Johansson, 1996). Foxall and Gaston-Johansson (1996) also found reductions in caregiver anxiety over time, with the lead up to HSCT being a time of increased anxiety compared to days 5 or 20 post HSCT. The results confirmed the very high rates of psychopathology in carers. Surprisingly, even higher levels of distress than those previously described for patients. This is an important finding because it means that carers are clearly

strongly affected by their role and the patient's illness. Therefore, there is a vital need for psychosocial support for carers themselves.

It is known that carers of HSCT patients experience major role changes and high levels of stress caring for these sick patients, with whom they are most often in close domestic relationships, over the long-term. Most of the carers in our sample were spouses, who also had children to care for, some of whom were dependents under eighteen years of age. Some carers in the sample were continuing to work as well as care or had recently taken up employment due to the patients' loss of income. Some carers also mentioned the stress of not being able to talk to anyone about their fears for the future and the uncertainty about what would happen to their family. Some carers retrospectively spoke about the times when patients were very sick and they could not be near them for fear of spreading infection. There is the rule that children are not able to be on the ward and so they may only talk to their parent on the phone. One carer reported that at one stage her husband had such significant GvHD that he was not able to eat or talk due to severe mucitis, so their children would just speak to him on the phone and he would listen.

Carer levels of anxiety did appear to decrease over time in our study; which is positive. Nevertheless, the mean level of anxiety in carers was still high at follow-up; indicating moderate levels of anxiety. The fact that the education programme is not sufficient to reduce anxiety in the short-term lends further support for the introduction of more targeted carer support intervention.

4.4.2. CORRELATES OF PATIENT DISTRESS

Correlates of patient distress were investigated in order to identify factors that may help differentiate patients who are likely to experience more significant psychopathology. A number of interesting relationships were found between patient distress and illness perceptions. The impact of illness and symptoms was associated with higher levels of depression. Not

surprisingly, depression, anxiety and distress were associated with perceiving greater emotional impact of the illness. Patients who were more anxious were more likely to perceive their illness continuing for longer and to have greater concern about their illness. Patients who reported greater satisfaction with the explanation of their illness were least distressed. Although this finding is correlational, it appears to be consistent with previous research on the effect of information on distress (Fallowfield et al., 1995; Gamble, 1998). No significant relationships were found for patient social support and psychopathology. More research is needed to understand the meaning of these findings since they are correlational.

4.4.3. EFFECTS OF EDUCATION

The results for knowledge showed that education did increase patient and carer knowledge about HSCT. This occurred despite the fact that many patients and carers had a reasonable level of knowledge prior to attending. A high proportion of patients and carers mentioned reading the book provided by the hospital, with some reporting too little information and others too much information. Many patients had received personal information from their specialist, the transplant coordinator or had acquired it from their own Internet research (e.g. The Cancer Counsel website). The data shows that patient and carer knowledge was high prior to treatment and that they became more accurate with the education. For patients, the degree of improvement was 3.88 to 4.41 out of 5. For carers it improved from 3.80 to 4.24 out of 5. This indicates that patients and carers were fairly correct and knowledgeable before education but became more certain afterwards. Patients who received the intervention had still greater knowledge post education. Knowledge was greater at follow up compared to baseline for patients and carers; indicating some level of retention over time. The primary aim of the education intervention was to provide information and therefore the programme is successful in fulfilling its primary purpose; and even in a previously well-informed patient group.

Our results concur with research on education programmes for oncology and other illnesses in terms of increasing knowledge (Fernsler & Cannon, 1991; McPherson et al., 2001; Treacy & Mayer, 2000; Yoon et al., 2006). However, education programmes have generally been found to provide other benefits apart from improving knowledge. Research on the positive effects of education have demonstrated reductions in psychopathology, increased participation in decision-making, better commitment to treatment, improved symptom management, greater satisfaction, increased ability to cope, decreased hospital stay, greater health care utilisation, less post-operative opioid use, better symptom improvement and increased quality of life (Fernsler & Cannon, 1991; McPherson et al., 2001; Treacy & Mayer, 2000; Yoon et al., 2006). It was hypothesised that education would lead to similar changes in HSCT patients, but this was not the case. Despite the small sample size, it does not appear that this education programme would produce changes in many of our outcome measures in a larger sample based on the effect sizes. Hence, it seems these broader benefits were not forthcoming.

Aside from knowledge, patient and carer distress was the most important outcome variable examined in this study because lack of information has been associated with increased anxiety and distress in cancer patients (Fallowfield et al., 1995). Indeed, that relationship was replicated in this study. That is, those patients with more knowledge had less distress. Furthermore, one of the main aims of education is often to alleviate helplessness and improve adaption to illness (Fawzy et al., 1995). Although there have been no randomised control trials examining the effect of education in HSCT, it has been reported by some of these patients that they would have liked to have more information about what to expect prior to treatment as this would have helped to reduce anxiety (Rini et al., 2007). Yet, because of the greater risks associated with HSCT it was also considered that education could have the opposite impact and increase distress.

The fact that patients and carers' levels of distress did not change despite attending the education intervention is interesting to consider. Reflecting on the literature, a comparable randomised controlled trial of patients having radiation therapy also found no differences between the control and intervention groups for anxiety and distress (Cartledge & Haaga, 2005). While this is the case, it should be noted that these authors did not find any improvement in patient knowledge; which may explain their results. This was not the case in the present study. However, it is worth mentioning that levels of knowledge were high to begin with in our patient sample. The measure that we used to assess knowledge combined certainty and knowledge. The majority of patients knew most facts about HSCT prior to education but what increased was certainty. It may be because patients were well-informed at the outset that the increases in knowledge, while statistically significant, were not sufficient to change views or impact distress.

Most studies of cancer patients have indicated that patients prefer to receive as much information as possible. The research suggests oncology patients want detailed information about diagnosis, treatment, side effects, symptoms and self-care needs (Hagerty et al., 2004; Treacy & Mayer, 2000). Cancer patients have reported feeling dissatisfied with the quality and quantity of information that they have been given about their illness and treatment. Patients with cancer have also reported that they preferred to receive all the information possible about their disease and treatment regardless of whether it was good or bad (Blanchard et al., 1988). Furthermore, dissatisfaction with information provision about treatment and related risks has been found to be associated with increased anxiety, uncertainty, dissatisfaction, distress and poor treatment decisions in oncology patients (Fallowfield et al., 1995; Gamble, 1998).

One of the reasons that the education intervention programme did not affect other outcome measures may be due in part to differences in individual reactions to the education programme day. Some people may have been reassured by hearing how the staff will look after them. For

many participants, where the patient had been previously treated in a hospital outside of Sydney, the education programme day was the first time they had met key staff (the transplant coordinator, nurses, the social worker, clinical psychologist, dentist and dietician). Some patients may have assumed that they were likely to die and meeting the team and hearing from the experienced patient who survived may have provided hope of survival and been otherwise reassuring. For others, the enormity and significance of the treatment could be made real by attending an education programme with their family. Prior to this, they may have been able to deny the reality of their predicament and avoided receiving more information. The impact of having the multidisciplinary team present an education programme of this type could be very comforting. On the other hand, patients could interpret the provision of the education as a need to cover the hospital and doctors in terms of informed consent, raising their awareness of the riskiness of the procedure. Another factor is that specialists will have given patients a lot of information about their prognosis already. Having attended a number of the education programmes it was observed that patients commonly enquired about the risk of mortality when the specialist presenting asked for questions. A standard reply was that prognosis varied considerably depending on individual factors such as disease and age and that it was important that they talk to their specialist to receive a personal answer to that question. Finally, the education programme may not be providing all that patients and carers really need to help them cope. For instance, many patients particularly appreciated hearing from the experienced patient who had survived. However, this patient was not able to attend all the education programmes evaluated in the study and perhaps this affected the results. Reports of the positive impact of this example of peer support and the sharing of information and knowledge by those who have 'walked the walk' is consistent with the results of a qualitative study on peer mentoring in HSCT (Rini et al., 2007). Patients in this study reflected that experiential information from patients who had survived helped them to feel more prepared for treatment, improved decision-making, reduced uncertainty and increased hope. Based on these preliminary findings, there may be value

in expanding this additional aspect of patient carer support in HSCT. Likewise, peer mentoring provided by experienced carers may be expected to be as valuable as that provided by experienced patients. Further research is needed, however, to ascertain the potential positive and negative effects of experiential information on patients and carers.

Information satisfaction is an outcome that has been used in previous evaluations of education interventions (Gurrud et al., 2001; McQuellon et al., 1998). In our study, satisfaction with information was good to begin with and there was no difference in satisfaction levels after receiving the intervention. This may be because patients were already satisfied and the increase in information did not make patients any more satisfied. Anecdotally, most patients appeared to be satisfied with the education provided. In Gurrud et al.'s study (2001) compared the effects of providing detailed risk information pamphlets versus a standard information pamphlet to patients who were deciding to undergo elective laparoscopy. Patients who received the pamphlet containing the information on adverse side effects had higher satisfaction with information. It is likely that patients undergoing HSCT are already very aware of the risks associated with treatment compared to other illnesses. It is likely that the patient's specialist has informed the patient about their individual prognosis prior to attending the education programme. In addition, many participants reported obtaining information from the Internet. It may have been more informative if we had measured satisfaction with the education programme generally, instead of specific to information. This may have told us more about satisfaction with the education programme per se', as other studies have found increased satisfaction with education in oncology (Cartledge & Haaga, 2005; McQuellon et al., 1998; Poroch, 1995). A measurement of what patients liked about the education programme day and what they disliked may have been informative. Further it would significantly enhance understanding of the role such an education programme can play in improving patient and carer experience of critical medical treatment if

they could be assessed for whether they felt they had been given too much, too little or the right amount of information about specific aspects of that medical treatment.

A fundamental caution that should be noted in interpreting the findings of this research, in respect of information satisfaction at least, is the lack of participation of that cohort of patients and careers who could have participate in the education programme, more or less conveniently, but chose not to. Hypothetically, those patients who did not have major obstacles preventing them from attending but who still did not attend may have shown the most benefit from the education programme. This is based on an assumption that patients who attend are more likely to be 'information-seeking' people who already know a lot about HSCT. Whereas those who did not take up the offer of education, may not be as well informed. Therefore, non-attending patients may have shown the greatest changes on measures such as information satisfaction and perhaps even distress and illness perceptions after attending the education programme. At the same time, the refusal of this group of people to participate in both the education programme and this research may indicate an adaptive coping strategy based upon avoidance of information. On the other hand, perhaps this satisfaction with the information they already have or reluctance to participate in formally organised and professionally supervised events. Of course, these issues are speculative but they suggest interesting avenues for future research.

Illness perceptions have been found to have an important impact on patients' behaviour and emotional reactions in a variety of illness (Weinman & Petrie, 1997). There was no effect of education on illness perceptions in our study, although there were changes in some illness beliefs over time. For instance, in the short-term patients' estimation of how long their illness would continue became greater with time. Nevertheless, this effect was not seen at 100-day follow-up. At this time, patients perceived greater emotional support but felt they had less confident support. The cause of the perceived decrease in confident support during this time is not clear.

Perhaps it is because of the restrictions in contact with other people that can occur during recovery in order to control the risk of developing infection. Patients may be secluded from family and friends while they are in the acute phase of recovery. One hypothesis is that perception of emotional support is less affected by regular contact.

Some studies have found relationships between illness perceptions and adherence to treatment regimes and recovery (Weinman & Petrie, 1997). In this study, there was a relationship between perception of personal control and survival. Early death from HSCT was associated with lower perception of personal control over the illness. Because this is a correlation, this result should be interpreted with caution. More research is needed to understand the implications of this result. If the result is true there are two potential meanings: (1) people realise the prognosis is worse and believe that they have less control accurately or (2) people who believe they have less control are less compliant, make poorer lifestyle choices and this impacts their health. Hoodin and colleagues (2006) found patients who had optimistic cognitive styles prior to HSCT were more likely to have longer survival and better quality of life post HSCT. Again, this finding is relational but suggests an issue worth exploring further.

Changing illness perceptions may be useful, particularly if illness beliefs are detrimental to emotional functioning and resulting in unhelpful behaviour. However, if illness perceptions are realistic (e.g. if patients appreciate the seriousness of their illness) it may not be useful to change these perceptions. This may explain why illness perceptions were not affected by the education programme. As discussed, patients and carers who participated in this research had most likely received a large amount of information prior to the education programme. The information provided by the intervention may have corresponded with what patients already knew and thus did not result in changed perceptions. For example, most patients believed their treatment could

help their illness. This is a positive belief and helpful because it is likely to encourage behaviours that support compliance with treatment regimens.

Another outcome of interest in this project was social support. The support of family and carers was predicted to be important for HSCT patients because they play such a vital role in the recovery of the patients; physically and emotionally. Indeed, consistent social support prior to HSCT has been associated with increased survival and better quality of life post-transplant (Rodrigue et al., 1999). It was also thought that patients might feel more support with the education programme or that there would be indirect benefits to the patients through the caregivers receiving the intervention. Surprisingly, there were no changes in patient support as a result of education. Perhaps this finding makes sense in light of the lack of influence of the education programme on patient or carer psychopathology. If the intervention is increasing knowledge but not helping to relieve anxiety or depression, there is unlikely to be changes in perception of social support either. Some patients mentioned the benefit of meeting with the transplant coordinator and other members of the multidisciplinary team, however, other stressful information provided on the day may have cancelled out the impact of this support. In addition, the measure of social support specifies family and friends and thus patients may have excluded the support provided by the hospital staff. Nevertheless, it would be expected that there would be an impact on support provided by the carer who is the primary support person.

Again, since carers of HSCT patients play such an important role and are likely to be significantly impacted by the illness, caregiver burden was included as an outcome measure. Notwithstanding, there was no impact of education on carers' burden. Although carer levels of distress and anxiety were certainly high in our sample, there was no impact of education on distress either. This may reflect the lack of change in caregiver burden also. One would expect

that burden would be related to levels of psychopathology and if education is not affecting distress, then it is not surprising that perception of burden is also not affected.

4.5. FUTURE RESEARCH

4.5.1. STUDY DESIGN

Suggestions for future directions for research would be to consider including a larger sample size to be able to investigate the differences between autologous and allogeneic transplant patients. If patients could be contacted directly, it is possible that recruitment would be improved. Conducting a multicentre trial would be useful if you could coordinate with the hospitals to have the same education programme. It would also be beneficial to assess the long-term outcome of the education programme. Adding the intervention to a hospital that does not offer an education programme is another way of obtaining a long-term control.

Qualitative follow-up is important to discover what patients and carers understood and valued from the education programme. Having attended the education programme it was clear that difficult topics were not addressed in detail. When patients asked about their individual risk of mortality, the specialist would advise them to speak to their doctor about those sorts of questions. The presentation by the clinical psychologist was very superficial in information about distress. It did not provide any indication of the levels of distress that patients and/or carers may experience. Nor did it suggest strategies to cope or identify important people to speak to in case of significant anxiety or depression.

Future research should also consider whether providing the education programme is more effective than not providing education or using other models of presentation. The intervention is an enormous expense in terms of money and time and only 50% of patients are taking up the opportunity. Perhaps there are better and cheaper ways to inform people. Every patient is

provided with a book about the transplant. Anecdotally, there appeared to be differences in the way this information was received. Some patients and carers found it to be helpful, others found it lacking in detail and still others reported that it had too much detail. There were also patients and carers who chose not to read it at all. It would be informative to evaluate patients and carer use of, and response to, the written information booklet provided. In addition, research should investigate preferences for information and other methods of education. Perhaps a combination of information delivery methods should be trialled, such as an interactive Internet educational programme with staged levels of complexity combined with a subsequent in-person education programme. Providing alternate ways of accessing information may be helpful for patients who want more information but do not want to read a booklet or attend a public seminar. Incorporating the opportunity to meet both health professionals and experienced patients and carers for peer support could be another way to support individual patient needs.

An important question yet to be addressed is how to manage those patients and carers who do not take up the offer of education. Qualitative information regarding what patients received from the education programme day will be useful in this regard and in adjusting the education programme so that there is a balance between the need for hospitals and medical professionals to gain informed consent and for patients to hear about what is useful and important to them. Further, as discussed above, studies of the information receptive needs and biases of those who could have, but did not, attend would be useful.

It is well established in the research that there are patients who do not want more information (Harris, 1998). If the education programme is provided as a means for the hospital to obtain informed consent, are these patients then not giving informed consent? It raises the ongoing dilemma of who is responsible for establishing informed consent. If the hospital and treating medical professionals carry the burden of responsibility for providing informed consent, or at

least should assume that burden in their own self-interest, then there may well be a need to make the education more accessible to patients. All patients are sent out a thorough information book particular to their transplant type. Yet it is not known which patients and carers are capable of, or care to, both read and comprehend the information contained in these books. It is arguable that if hospitals and treating medical professionals provide adequate opportunities for patients to receive detailed information, it is the patients' and carer's responsibility and right to choose how much information they would like to receive. It is equally arguable that, while it is the responsibility of hospitals and treating medical professionals to provide a readily accessible, flexible and adequate treatment education programme, the patient (and even critical caregivers) should undertake to participate in education and acknowledge that they have as a condition of treatment. This argument maintains that, if a medical treatment should only be administered if the patient's consent is properly informed, then the treatment provider is entitled to make the receipt of that treatment, where reasonably practical and possible, conditional upon the patient genuinely seeking, and acknowledging, the acquisition of the knowledge.

4.5.2. PSYCHOSOCIAL SUPPORT

The fact that patients and carers still had high levels of distress at follow-up indicates that information alone is not sufficiently meeting patient and carer needs beyond informed consent. Thus, evaluating what psychosocial support is currently available and its effectiveness is another avenue for future research in this area. Unfortunately, psychological support was not easily available for patients or carers at the hospital. Evaluating the benefits of different treatments at different stages of transplantation is another avenue for future research in HSCT. A trial of Cognitive Behaviour Therapy (CBT) is recommended based on the results of this study. Illness perceptions were found to be associated with increased distress and CBT is effective in moderating unhelpful cognitions and behaviour. In other cancer settings CBT has been shown to have positive effects on psychosocial and medical outcome measures (Hopko, Bell, Armento,

Robertson, Mullane, Wolf et al., 2008). Providing CBT prior to transplantation may help patients to reduce their distress and improve their experience of treatment.

4.5.3. DISTRESS

In order to better target treatment interventions, studies that investigate why patients and carers are distressed are needed. Providing carers only with emotional support would not be effective if lack of practical and financial support is what is causing them the most concern. Similarly, if patients are distressed due to their carers not coping, providing carers with support and treatment is likely to be helpful in reducing patient distress more so than only providing patient support.

4.5.4. DONORS

Finally, donors information and psychosocial needs seem to have received little attention at least in terms of hospital interventions. More information is needed about their experience because the strain of the donation of stem cells in HSCT can be substantial. One patient reported that his brother felt he was not being given enough information or preparation for his role as a donor. It is important to know how donors are coping and what their needs are. A qualitative study would be most useful initially in order to assess their experience and concerns.

4.6. CLINICAL IMPLICATIONS

One of the main clinical implications of the study is that there seems to be a need for greater psychological support for patients and carers. The literature suggests that psychological function pre-transplant has a direct effect on post-transplant distress (Broers et al., 2000). In one study, psychological distress, sense of personal control and physical health accounted for 50 percent of the variance in psychological distress at one-year post-HSCT (Fife et al., 2000). Therefore, it would appear that making therapeutic and support services easily accessible to patients and carers prior to transplantation would be one of the best ways to improve health and wellbeing. At Westmead Hospital, the clinical psychologist's caseload was stretched between two departments

and the waiting list was too long to be functional for HSCT patients who need to be able to receive assistance in a timely and effective way. Psychoeducation, supportive therapy, cognitive therapy, relaxation training, problem-solving and social skills training, biofeedback, and hypnosis are some of the psychological interventions that have been used with cancer patients (Hopko et al., 2008). No one intervention has been thoroughly established as the treatment of choice for cancer patients to date. A review of evidence-based interventions in the literature indicate group therapy, education, structured counselling, cognitive-behavioural therapy, communication skills training, and self-esteem training are efficacious in improving patient psychological outcomes (Newell, Sanson-Fisher, & Savolainen, 2002). Generally, behaviourally based therapies appear to be more effective than supportive therapies. Research studies on effective psychological interventions for HSCT patients are few and far between (Hoodin et al., 2006). There is preliminary support for mindfulness interventions with HSCT patients (Bauer-Wu, Sullivan, Rosenbaum, Ott, Powell, McLoughlin et al., 2008). One pilot study has found significant decreases in heart and respiratory rates and improvements in symptoms immediately before and after each meditation session (Bauer-Wu et al., 2008). However, whether these interventions have long-term and broader application is unclear. Due to the medical demands placed on HSCT patients, brief and frequent behavioural interventions have been advocated.

A randomized study compared two brief support interventions for 53 cancer patients of varying diagnoses (Cunningham & Tocco, 1989). The first group was a psycho-educational or coping skills training programme, which included some supportive discussion and the second group was a control intervention comprising supportive discussion alone. While patients in both groups benefited, the coping skills training group had greater improvements in affect. CBT may be the most practical psychological treatment for medical settings and cancer patients because it is time-limited and focuses on changing unhelpful behaviours. It can also be effective in increasing self-efficacy and sense of “control” over one’s life. This could be helpful for patients who are

feeling helpless about their treatment. Hopko et al (2008) found CBT led to significant improvements in depression, anxiety, quality of life, and medical outcome measures in depressed cancer patients.

In the wider population, CBT and antidepressant medication (ADM) are frequently used in the treatment of depression. In medical patients, there may also be a tendency to rely more heavily on ADM due to its ease of delivery and cost-effectiveness. Unfortunately, psychologists may not be as accessible in hospitals where there may be understaffing. A number of trials have shown that ADM is superior to placebo in the treatment of depression (Hollen et al., 2006). ADM tends to suppress symptoms for as long as it is maintained but there is no evidence that it helps to reduce the underlying cause of symptoms or reduces their risk of recurrence once it is terminated. CBT has been shown to be very effective in treating symptoms of anxiety and depression. The research on treatment for depression suggests that CBT is at least as effective as ADM in reducing acute distress (Hollen, Stewart, & Strunk, 2006). Furthermore, the effect of CBT appears to be more enduring than that of ADM. CBT has been shown to be particularly effective with individuals who have higher initial levels of depressive symptoms (Cuijpers, van Lier, van Straten, & Donker, 2005). Further, since the efficacy of ADM is based on the hypothesis that there are biochemical correlates of depression and depression in HSCT may be reactive to stressors rather than chemicals, the efficacy of ADM cannot be assumed.

CBT for depression and/or anxiety is a structured therapy that involves collaborative formulation that links past experiences with current stressors and draws attention to the relationships between thoughts, feelings and behaviours (Beck, Rush, Shaw, & Emery, 1979). Symptom reduction and problem solving are argued to be the primary targets of a CBT intervention (Scott, 1996). Clients are taught to collect evidence in a systematic fashion in order to offset the influence of maladaptive information-processing strategies and to conduct behavioural experiments to test the

accuracy of negative beliefs (Hollen et al., 2006). The independent use of strategies taught in session is an important aspect of this treatment in recognition of the chronic recurrent nature of depression and anxiety. A meta-analysis of studies investigating psychotherapy and pharmacotherapy separately and in combination found that the combination of both treatments was slightly more effective than either treatment separately (Conte, Plutchik, Wild, & Toksoz, 1986).

For some patients who were identified as suffering from depression, it was asked whether they had any access to treatment. Many replied that they had not received any care. This is not surprising given that research indicates hospital nursing staff are not adept at identifying patients in need of psychological support. Some patients were on anti-depressant medication prescribed by their general practitioner. There are limitations to the effectiveness of medication in providing long-term relief from distress. Naturally, there are significant situational causes that explain why patients could suffer from anxiety and depression, which makes them good candidates for CBT interventions. A major difficulty is that there is little support available in the hospital for assessment and intervention. Despite the fact that a clinical psychologist presents in the education programme, the reality of the situation is that there are not enough clinicians on staff to meet patient needs. Waiting lists are substantial because one psychologist is responsible for multiple wards and works part-time. Therefore, the availability of psychological support is low. In a perfect system, patients should be regularly and routinely screened for depressive and anxiety symptoms. Patients who are identified as needing support should be given the opportunity to speak to a psychologist or social worker. This is also necessary for carers, and although it may be more difficult to assess carers, it is imperative that they receive attention as well given their significant anxiety and distress levels. Regular support groups should be run for carers so that they can meet other carers in similar situations. This would provide the opportunity for carers without good support networks to discuss their fears, readily acquire coping and

performance skills and find ongoing resources which may cumulatively lessen their anxiety and increase their effectiveness and role satisfaction.

4.7. CONCLUSIONS

Despite the limitations addressed, this study also has a number of strengths. The high proportion of clinically significant psychopathology in our patient sample is consistent with the existing literature. More importantly, this research adds to the limited knowledge on carer psychopathology and burden and highlights their need for support. Preliminary investigation of illness perceptions were conducted, identifying important relationships between illness perceptions and distress. Finally, this was the first empirical evaluation of an education program for HSCT patients and their carers and it found support for the education intervention in increasing the primary outcome variable of knowledge. Notably the intervention was successful in increasing knowledge without increasing patient or carer distress or care burden. At the same time, simply increasing knowledge is not enough to reduce patient and carer distress and thus further research is needed to identify what aspects of the education program are helpful for patients and what are unhelpful and how such programmes may be further developed so as to enhance their reception by patients and carers. This study seeks to consider and contribute some suggestions in that regard. Exploring illness perceptions further may identify patients who are more likely to experience significant distress. Finally, treatment interventions, such as individual or group CBT, are needed to help patients and carers cope with the significant stress of HSCT.