THE UNIVERSITY OF CALGARY

The Effect of Outpatient Management of Cancer Patients After Autologous Blood Stem Cell Transplantation on Psychological, Social and Physical Well-Being and Quality of Life

by

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A THESIS

SUBMITTED TO THE FACULTY OF GRADUATE STUDIES

IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE

DEGREE OF MASTER OF SCIENCE

DEPARTMENT OF COMMUNITY HEALTH SCIENCES

CALGARY, ALBERTA

SEPTEMBER, 1998

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ABSTRACT

Because of restraints to the cost of health care, an increasing number of patients are receiving ABSCT as outpatients. This pilot study provides a comprehensive description comparing inpatients and outpatients physical status, psychological well-being, caregiver burden, quality of life and impact on personal finances immediate post transplantation. Questionnaires (FACT-BMT, POMS, CES-D, Caregiver Reaction Assessment and Perception of Control) were administered at baseline, days 4 to 6, 12 to 16 and 30. Individuals were assigned to care as an inpatient (n=20) or outpatient (n=21) based on preference and eligibility criteria for outpatient care. Overall, outpatient ABSCT is feasible as outpatients did no worse psychologically, physically, socially or financially and number of nights in hospital was reduced significantly. At day 4 to 6, some outpatients experienced greater anxiety and the majority of hospital admissions was at this time. Implementation of outpatient mode of care utilizes health care services efficiently and effectively.

ACKNOWLEDGEMENTS

This study was financially supported by the Foothills Hospital, Research & Development Committee through the Gary Owen Memorial Fund.

There are a number of people whom I feel I must thank:

Dr. Douglas Stewart, a member of my committee, for encouraging me to pursue the subject area, for allowing me access to the clinic patients, and for advise to provide greater understanding of the population being studied;

Dr. J.M. Nabholtz for allowing me access to his patients at the Cross Cancer Institute in Edmonton and Evelyn Sansergret for accrual of these patients;

the staff of the Bone Marrow Transplant Unit at the Tom Baker Cancer Centre, and Unit 57 at the Foothills Hospital for helping me locate patients;

Cindy Railton for data collection, providing insight into the patient population and continual encouragement;

all of the patients who responded to the lengthy questionnaire, without whom the study would not have been possible;

Dr. E. A. Henderson, a member of my committee, for her advice and support;

and especially, Dr. U. Dawe, my supervisor, for her direction, positive encouragement and commitment to the study.

DEDICATION

This thesis is dedicated to my husband Kirk, and my children Alex and Jamie for their continual support, understanding and encouragement.

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CHAPTER 1

THE RESEARCH PROBLEM

I. Introduction

High-dose chemotherapy followed by autologous blood stem cell transplantation (ABSCT) is having a significant impact on the survival of cancer patients with a poor prognosis. The number of patients treated with ABSCT is increasing at a time when the delivery of care is changing due to the following pressures: i) a need to control the cost of institutional care, ii) a shift from hospital to community and home based care, iii) a trend towards more efficient utilization of services and iv) the influence of new technology. The increased number of ABSCT procedures being performed is adding to the strain on the health care system. Until recently, patients treated with ABSCT were provided inpatient care in an acute care hospital setting for approximately twenty-one days in order to monitor and treat toxicities, complications and side-effects caused by the high-dose chemotherapy. At present, a shift is beginning to occur in how ABSCT care is provided; increasingly patients are receiving their course of care as outpatients.

The establishment of an outpatient approach to caring for ABSCT patients raises concerns about the impact of this method of care on patients'

overall health and well-being. Knowing that the physical and psychological impact of ABSCT is great, how are patients and families able to cope with the added demands of outpatient care? This study describes the effects of this shift in care on patients and families. The results of the study will be useful for service providers in planning programs to meet the needs of patients and families who receive care as outpatients.

The goal of this study was to compare inpatient and outpatient care after transplantation of blood stem cells, by measuring patient and family outcomes in terms of treatment related complications, quality of life, anxiety, depression, perception of control, satisfaction with care, burden to the caregiver, and direct/indirect costs to the patient.

II. Rationale and Relevance

ABSCT involves treatment with high-dose chemotherapy followed by the infusion of bone marrow or blood derived stem cells which have been previously collected from the patient. These stem cells 'rescue' the patient's bone marrow which would otherwise be irreversibly damaged by the intensive chemotherapy. This technology permits five to ten fold escalation of chemotherapy doses which results in a substantial increase in tumour cell killing. Compared with conventional dose therapy, high-dose chemotherapy improves the survival of patients with lymphoma, Hodgkin's Disease, myeloma, leukemia, breast cancer, testicular cancer and several pediatric tumours.

For a number of reasons, requirements for intensive inpatient supportive care following high-dose chemotherapy have diminished in recent years. First, there has been a move away from collecting stem cells from the bone marrow towards collecting stem cells from the blood stream. These blood stem cells cause a more rapid recovery of blood counts and therefore reduce the risk of

severe infection or need for transfusion. Second, more potent and less toxic antibiotics are available for prevention and treatment of infection. (Gilbert, Meisenberg, Vredenburgh, Ross, Hussein, Perfect and Peters, 1994). The convenience of providing some antibiotic regimens has also improved whereby, these drugs can be given orally or used intravenously once daily. Third, growth factors are now available to stimulate blood count recovery even faster (Bociek, Stewart, and Armitage, 1995). Fourth, patient selection has improved so that most patients currently undergoing ABSCT are less heavily pretreated and are provided treatment earlier in their disease course. These patients are better able to tolerate the side effects of high-dose chemotherapy. Finally, readmission to the hospital inpatient unit that cares for patients treated with ABSCT is readily accessible for outpatients requiring immediate access to medical care. All of the above factors suggest that an outpatient approach to managing the care of patients during the period after transplantation of blood stem cells is potentially feasible.

Treatment complications of high-dose chemotherapy include nausea, vomiting, diarrhoea, mouth sores, anorexia, dehydration and infections. These complications require the use of oral or parenteral hydration, nutritional supplements, anti-emetics, antibiotics, and transfusion of blood products. In order to prevent and provide care for these complications outpatients are required to make commitments to daily procedures and schedules. These procedures include teaching sessions, laboratory investigations, clinical evaluations to determine vital signs and physical examinations, monitoring of compliance, and adjustment of medications. Patients who are cared for in the hospital inpatient setting experience these interventions as part of their daily routine. There is an added inconvenience of travel and organizing schedules

for patients in the ambulatory group. With such demands placed on the outpatient and their family or caregiver to comply with a rigorous daily routine, consideration must be given to issues of physical, psychological and social well-being as well as the economic impact of outpatient care.

III. Research Questions

For patients undergoing care in the period after ABSCT:

1. How does physical status of the outpatient group compare to the inpatient group? Physical status is indicated by the occurrence of toxicities and complications, by morbidity, patient's perception of side-effects and by physical and functional aspects of quality of life.
2. How does psychological well-being of the outpatient group compare to the inpatient group? Psychological well-being is indicated by emotional aspects of quality of life, anxiety, depression, perception of satisfaction with care and perception of control.
3. How does social interaction in the outpatient group compare to the inpatient group? Social interaction is indicated by caregiver burden, and social/family and relational aspects of quality of life.
4. How does global measure of quality of life of the outpatient group compare to the inpatient group?
5. How does the personal financial impact of treatment in the outpatient group compare to the inpatient group? Personal financial impact is indicated by direct and indirect cost to the patient and family.

IV. Conceptual Framework

This study investigates the influence of the mode of delivery of care on patients undergoing ABSCT. The theory of outcomes research was utilized to guide the selection of factors that are examined in order to evaluate the impact of both inpatient and outpatient methods of care delivery on patients and family.

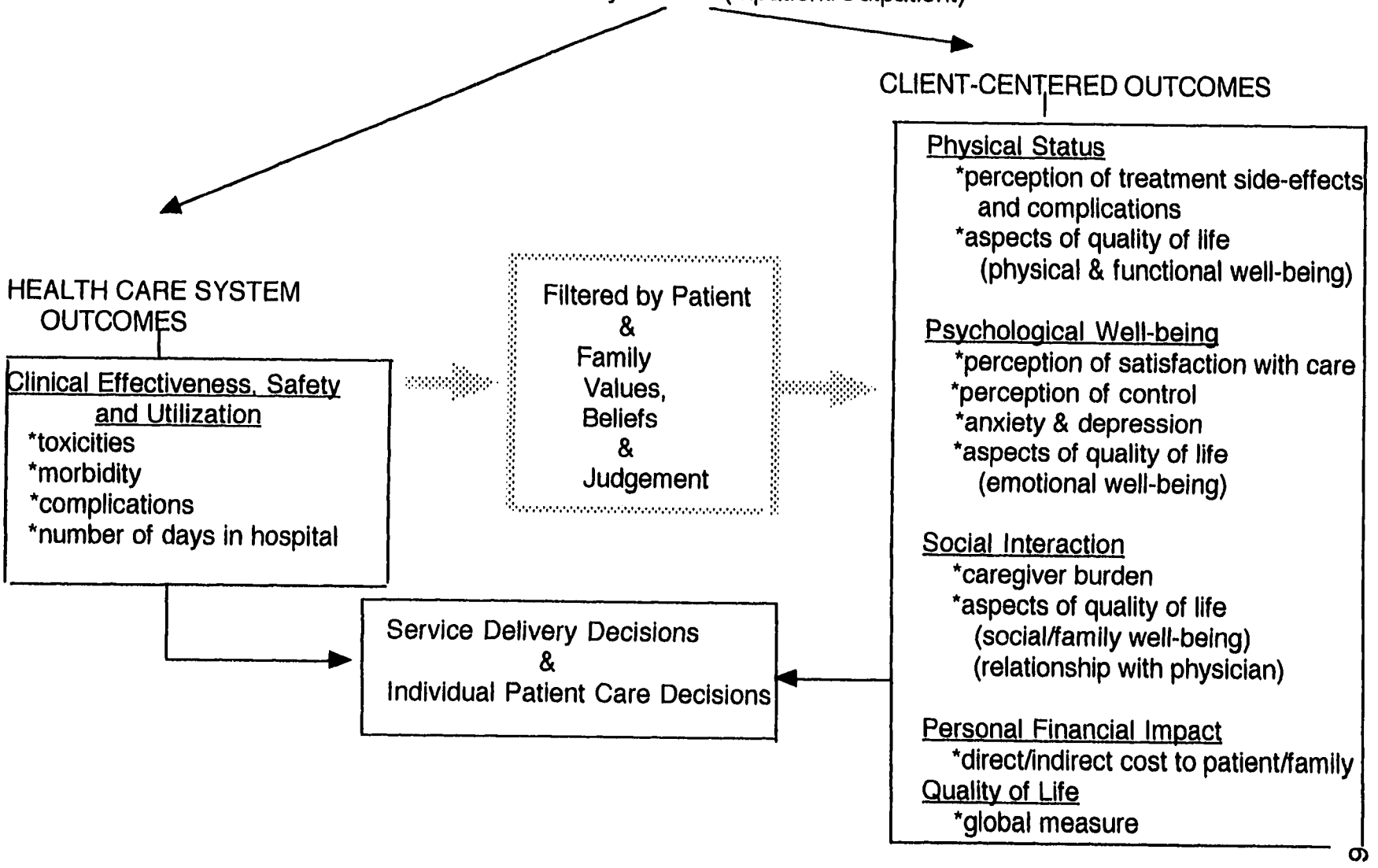
As judged from the health care provider's perspective, desired outcomes of health interventions are clinical effectiveness, safety and efficient utilization. In contrast, client-centered outcomes are related to the impact of interventions or the method of health delivery, as perceived by the patient and family. These outcomes consider the client's values, beliefs and judgements in relation to their health. Such health outcomes are multidimensional and include evaluation of the patient's physical status, psychological well-being, social interaction and economic status (Barr, 1995). In describing outcomes research, Lohr (1988) emphasizes the need for measuring patient outcomes in light of the growing concerns about the effects of cost containment on patients' well-being.

Outcomes method of research encourages a comprehensive approach to the assessment of the effects of the delivery of care. Such an approach necessitates studies that explore a broad range of outcomes in the domains identified above (Brook, Davies-Avery, Greenfield, Harris, LeLah, Solomon and Ware, 1977; Benjamin, 1995).

With this in mind, the following conceptual framework provides the direction for this study. The conceptual framework is illustrated in Figure 1. This framework ensures that the outcomes that are measured are sensitive to the impact of the care delivery method being assessed. The outcomes identified in Figure 1 have been chosen because they are directly affected by a change in the care delivery method, that is, a change from inpatient to outpatient care.

Figure 1. Conceptual Framework

Impact of Service Delivery Method on System and Patient-Centered Outcomes



Other outcomes are not considered as they are less impacted by such a shift in care setting.

Outcomes of Interest to the Study

For patients receiving care during the period after transplantation of stem cells, the outcomes of interest identified directly from the health care provider's perspective include morbidity, toxicities as a result of the high-dose chemotherapy and number of days in hospital. Such outcomes occur frequently and are easy to measure.

Client-centered outcomes are identified under the domains of physical status, psychological well-being, social interaction and economic status. Within the domain of physical status the outcome variables of patient's perception of side-effects and toxicities as a result of the treatment were assessed. The patient's perception of their physical status may be different from the medical grading of complications and toxicities and therefore, their perspective of physical status must be considered.

The concept of psychological well-being includes the patient's anxiety, depression, quality of life, satisfaction with care and perception of control.

A patient's perception of control over their illness is an important measure. It is hypothesized that by providing patients with outpatient care, the perception of control over their daily environment is increased, thereby reducing anxiety and depression. This prediction is based on the relationship between control and adjustment as described by Reid's (1984) Multidimensional Compensation Model. This model suggests that patients experiencing chronic illness will decrease their health related beliefs of internal control and shift their beliefs of control to an external source, usually the qualified caregivers. Reid suggests that patients manage to regain an acceptable sense of control through

adopting participatory control. That is, patients will respond in ways that ensure they have input into treatment decisions by taking on a cooperative role. As a result of this shift in control, patients develop some needs: i) input into medical decisions, ii) assurance that information concerning their illness is available, iii) open communication, and iv) control over everyday activities other than their health care (Reid, 1984). It is proposed that this last need can be met by providing care in the outpatient setting.

Anxiety and depression were measured because of their association with perception of control, as described above, and also because of the concern for psychological disturbance during the early period after transplantation (Gaston-Johansson, Franco and Zimmerman, 1992). It is proposed that anxiety, depression and quality of life are influenced by the patient's physical status, satisfaction with the care, feelings of being a burden to the family, and the financial impact of their illness.

Patient satisfaction is one method of assessing patient experiences from the perspective of those utilizing the health services (Fleming Courts, 1995). Lohr, in describing outcomes research, states that the "growing attention given to consumers' views about quality makes satisfaction an increasingly important element in evaluating the end results of care. A high level of satisfaction is seen as a desirable outcome in its own right" (1988, p. 43). Patient satisfaction will specifically assess patient's perception about whether their needs are being met.

Within the domain of social interaction, it is proposed that caregiver burden will be altered as a result of outpatient care. The increased demand on the caregiver is evident by the patient's need for 24 hour continuous assistance with care and the highly technical and emotional support required. Other

factors may also have an effect on caregiver burden, such as the caregiver's age, gender, level of education and number of other family members in their care.

There is potential for the personal financial cost to the patient and family to be altered with the shift in care away from the in-hospital environment. An increase in direct expenses to the patient and family in the outpatient environment may be related to child care costs, fees for required health related services, medications, medical supplies and equipment, transportation and parking. Indirect costs may also be incurred by outpatients as a result of the caregivers loss of salary because of the need to provide care to the family member.

The theoretical framework for this study also incorporates the conceptual framework by Ferrell, Grant, Schmidt, Rhiner, Whitehead, Fonduena and Forman (1992), which illustrates the impact of bone marrow transplantation on quality of life (see Appendix A). Ferrell suggests that although many of the factors influencing quality of life are consistent across health problems, this model illustrates that there are also many factors specific to transplantation that influence quality of life. This model was used to identify outcomes that are comprehensive and appropriate when assessing quality of life. The domains of physical well-being, psychological well-being, and social well-being reflect the same domains of the client-centered outcomes as described earlier and therefore were the three domains of quality of life that were assessed. Quality of life was assessed in order to provide a more comprehensive description of the impact of the shift to outpatient delivery of care.

Ferrell (1995) suggests that when a person experiences pain all domains of quality of life are affected. For this reason, the patient's perception of pain

was determined in the present study.

In using the conceptual framework as shown in Figure 1, decisions about the method of caring for patients experiencing ABSCT will be comprehensive and based on appropriate determinants of effective practice. Application of the framework at an individual level may be useful for screening patients to ensure that the most appropriate patients are selected for outpatient care.

V. Litrature Review

A. Clinical Effectiveness, Safety and Efficient Utilization

In a review of the research, Stewart (1996) provides evidence that much has been published supporting the value of high-dose chemotherapy and autologous blood stem cell transplantation for malignant diseases such as Hodgkin's Disease, acute myeloid leukemia, multiple myeloma, breast cancer, ovarian cancer, germ cell cancer and Ewing's Sarcoma. For example, a randomized trial by Bezwoda, Seymour and Dansey (1995) compared high-dose chemotherapy (n=45) to conventional-dose chemotherapy (n=45) for the treatment of metastatic breast cancer. It was found that high-dose chemotherapy results in a twofold increase in the overall survival as well as the duration of time that patients remained in remission. It was also found that a substantially higher proportion (51%) of patients experienced a complete response (i.e. no evidence of disease) following high-dose chemotherapy compared to a complete response of 4% for patients treated with conventional-dose chemotherapy. However, a complete response can be difficult to determine as there may be residual or microscopic disease that goes undetected. Therefore, the number of patients experiencing a disease free response may have been overestimated. In this study there was a significant

difference (p=.01) in the duration of a positive response to chemotherapy in those whose response was complete (100 weeks) compared to patients with only a partial response (40 weeks). The achievement of a complete response appears to be necessary for prolonged disease control. This evidence supports the use of high-dose chemotherapy in reducing mortality and prolonging life. The results, however, are specific to breast patients being treated with a specific high-dose chemotherapy regimen. This study was based on two physiological outcome measures (i.e. the number of survivors and the duration of remission). Other dimensions of health such as morbidity, functional ability and quality of life after treatment were not assessed.

Another study concerning the safety of high-dose chemotherapy was undertaken to determine the maximum chemotherapy dose tolerated with regard to toxicities (Fields, Elfenfein, Lazarus, Copper, Perkins, Creger, Ballester, Hiemenz, Janssen and Zorsky, 1995). Using the World Health Organization (WHO) scales for toxicity, 154 patients were given chemotherapy in escalating doses. Cancers treated in the study included breast, intermediate to high grade non-Hodgkins lymphoma, ovarian and sarcomas. According to the WHO toxicity scales, safe doses of chemotherapy were determined by the highest dose that could be given before the toxicity was graded as life threatening for a predetermined number of patients. The study was successful in determining the highest tolerated dose of a specific chemotherapy regimen and was able to identify the specific types of toxicities experienced by patients treated with such a regimen. Of particular interest is that grade 3-4 (high level) mucositis/enteritis was experienced by all the patients involved in the study. This side-effect was not considered life threatening and did not prohibit escalation of the chemotherapy dose. Such a physiological outcome does not

consider the perception of the patient experiencing such a side-effect. It is possible that if the patient's perception of their sore mouth was sought, it would be a dose limiting factor.

Another aspect of concern found in the literature deals with the intensity of the supportive care required by the patient during the period immediately after the stem cell transplantation. Miyahara, Dix, Devine, Holland, Connagham, Fleming, Geller, Heffner, Hillyer, Walker, Winton and Wingard (1995) conducted a descriptive study to evaluate the use of supportive services by bone marrow transplantation among 43 individuals in the outpatient setting. Eighty-eight percent of the patients required IV antibiotics for neutropenic fever, 21% were treated for persistent fever, 93% were received care for sores in their mouths, 29% were treated for nephrotoxicity and 48% received hyperalimentation. All of the above required invasive treatment (i.e. intravenous therapy), and daily assessment and monitoring. This study suggests that supportive care to meet the physical needs of transplant patients is intensive and necessary.

A study from the United States (Peters, Ross, Vredenburgh, Hussein, Rubin, Dukelow, Cavanaugh, Beauvais and Kasprzak, 1994) provides a description of the clinical support required during the period after transplantation by patients treated with ABSCT in an outpatient setting. Seventy percent of this outpatient group (n=110) required either no readmission or brief readmission (1 to 4 days) to the hospital. Reasons for readmission were elevated temperature, viral pneumonia, dehydration, persistent nausea, and decreased platelet count. In looking at hospital billings for the patients in the study, the traditional inpatient approach compared to the outpatient approach showed a reduction by 50% over the last 2 to 5 years. Peters et al. stated that

"patients generally favour this [outpatient] treatment approach, and the movement to even earlier discharges and fewer readmissions was prompted by patient preference"(1994, p. 29). The issue of patient preference for outpatient care may be based on economic realities of the patient and not only their personal choice as the study is from the United States. A more comprehensive study may provide further insight into the patient's preference.

The study by Peters et al. incorporates a small component of outcomes research, i.e. length of stay and physiologic information such as complications experienced by patients. The issues of patient satisfaction, quality of life or sense of control were not considered in this study.

In Canada in 1993, $68 billion was spent on direct costs of all illness, with $3.5 billion spent on the care of cancer patients (Canadian Cancer Statistics 1996). Direct costs are the financial resources actually expended that could have been allocated elsewhere in the absence of diseases. According to National Cancer Institute of Canada (1996), cancer ranks fourth for cost behind cardiovascular, respiratory, and digestive diseases. Hospital care, the most expensive component of cancer care, costs $2.7 billion or 79% of the overall cost of cancer care.

Cost is recognized as an important factor in the evaluation of the care delivery system. A Canadian study that is beyond the realm of cancer care, yet worth noting, compares inpatient and outpatient (n=182) post-operative care after three specific surgical procedures (Pineault, Contandriopoulos, Valois, Bastian and Lance, 1985). This randomized clinical trial was undertaken to compare one-day stay (outpatient) verses the inpatient method of care, in terms of patient satisfaction, clinical outcomes and cost. This study found no significant difference in physician costs and personal costs between the

inpatient and outpatient delivery of care. Hospital costs were significantly more for two of the inpatient groups and were attributed to the number of hours of nursing care required. Within the third surgical group, where no significant difference was found, the outpatient group required daily physiotherapy which offset any potential savings of the hospital costs. This study may not be generalizable to other medical procedures such as ABSCT because of the variation and complexity of care and support services required. However, the study is informative as the investigators considered a variety of outcomes for the evaluation of inpatient verses outpatient care delivery. Conclusions and recommendations were based on all outcome variables measured. For example, as well as the assessment of cost, it was also found that there was no significant difference in clinical outcomes of discomfort and the occurrence of complications and symptoms between the two modes of care delivery. In considering only cost to the health care system and clinical outcomes, outpatient delivery of care for certain surgical procedures was justified. However, when patient satisfaction with care was considered, then justification for outpatient care was diminished. That is, patients were dissatisfied with physician availability, appropriateness of length of stay and would have preferred inpatient care.

In a study considering the financial impact of outpatient care for patients treated with ABSCT, the length of stay in hospital of the outpatient program was compared to the length of stay of patients who refused outpatient care (Meisenberg, Miller, McMilland, Callaghan, Sloan, Brehm, Kosty, Kroener, Longmire, Saven and Piro, 1997). The outpatient group was subdivided into two groups. The first group of 97 patients were treated as outpatients upon receiving high-dose chemotherapy. The second outpatient group of 48 patients

received all high-dose chemotherapy as an outpatient and remained as outpatients during the recovery phase. The average length of hospital stay for patients who refused outpatient care was 18.33 (+/- 5.06) days. The average length of stay in hospital for patients treated as outpatients after the high-dose chemotherapy was 8.22 (+/- 5.76) days. The group that was treated as outpatients for the total treatment process experienced an average length of hospital stay of 2.81 (+/- 7.66) days. It was further identified that the inpatient group used increased antiemetics, intravenous fluids and miscellaneous medications.

Of the 113 patients, 85% agreed to participate in the outpatient program. The reasons for refusing the outpatient approach were that a caregiver was not available and that patients were not comfortable with the idea of being cared for as an outpatient. The study also found that 70% of the patients were never readmitted to the hospital.

Selection bias is of concern in this study. The group of patients that refused outpatient care may have been sicker and required more supportive services, thereby increasing the cost of inpatient care. This study provides evidence that outpatient approach to care is safely accomplished. As well, there is a decrease in cost for patients cared for out of hospital compared to those receiving inpatient care. However, the study fails to provide a comprehensive evaluation of the effect of outpatient care. The length of stay indicating cost and physical complications are only two aspects in an evaluation of care within a delivery system.

A feasibility evaluation of outpatients treated with ABSCT was conducted to determine the requirement for therapeutic interventions and to assess side-effects (Gluck and Des Rochers, in press). Forty-three percent of all the patients

(n=51) in the study were readmitted for low white blood cell counts. Overall, compared to the expected number of days of hospitalization, each patient had an average of 10 days less hospitalization. There was no significant difference in the neutropenic recovery (white blood cells and absolute neutrophil count) of the patients that remained as outpatients compared to the patients who were readmitted to the hospital. Blood counts (as noted above) are often used to grade the severity of neutropenia caused by chemotherapy. However, the results from this study suggest that physiological measurement of blood cell counts may not be sufficient for evaluating the impact of outpatient versus inpatient care. Other important indicators or variables may provide a more comprehensive evaluation of the outcomes of care.

B. Psychological Well-being

Recent outcome evaluations report quality of life and survivorship of patients within one year of bone marrow transplantation (BMT) (Chao, Tierney, Bloom, Long, Barr, Stallbaum, Wong, Negrin, Horning and Blume, 1992); one year post bone marrow transplantation (Whedon, Stearns and Mills, 1995); 2 to 5 years post bone marrow transplantation (Andrykowski, Greiner, Altmaier, Burish, Antin, Gingrich, McGarigle and Henslee-Downey, 1995) and long-term survival of BMT (Haberman, Bush, Young and Sullivan (1993). This body of literature highlights the importance of defining the success of BMT not only by the length of survival but also by the quality of survival.

Chao et al. (1992), Haberman et al. (1993) and Whedon et al. (1995) concluded that the majority of patients reported good to excellent quality of life after BMT. Andrykowski et al.(1995) (n=200) and Whedon et al. (1995) (n=29) both reported fatigue (78% and 50%), sexual dysfunction (63% and 30%) and occupational disability (33% and 44%) to be of concern to patients. A variety of

instruments (City of Hope QOL-BMT, Qualitative QOL instrument and Quality of Life Follow-up Questionnaire) were used for measuring quality of life, therefore comparison between studies is difficult. Selection bias may also be an issue in the studies by Whedon et al. (1995) and Andrykowski et al. (1995) as mailed surveys were used. Patients with good quality of life may be more motivated to respond. The occurrence of death in the study populations from which the study samples were drawn may have resulted in an overestimation of the quality of life after transplantation. As well, the number of years post BMT increases the chance for selective recall and distortion of distant memories.

McQuellon, Graven, Russell, Hoffman, Cruz, Perry and Hurd (1996) used the Functional Assessment of Cancer Therapy instrument to assess the quality of life in 52 breast cancer patients before and after ABMT. Data were collected by a telephone interview initiated by the researcher in order to reduce the selection bias as described in the above survey studies. To evaluate the representativeness of the data, a comparison of baseline data of subjects with pre-transplant data available to subjects with both pre and post-transplant data showed no significant difference in baseline measures. This indicated that the scores of the post-transplantation group were representative of the sampling population. A significant improvement was found in quality of life and mood after transplantation. Mood disturbance and depression were highest prior to transplantation, at the time of hospital admission.

As evident from the foregoing studies, quality of life has been assessed for long-term survivors of bone marrow transplantation but there is little known about the quality of life of patients who are in the process of undergoing bone marrow transplantation. The proposed study will focus on this period of time.

Two studies of significance to this topic provide a description of

psychological distress and quality of life in patients undergoing autologous bone marrow transplantation in the hospital setting (Gaston-Johansson, Franco and Zimmerman, 1992; Gaston-Johansson & Foxall, 1996). In the study by Gaston-Johansson et al.(1992) 17 cancer patients provided information about pain, anxiety, depression, health locus of control, quality of life, and coping strategies. These factors were measured in a hospital setting at 2 days prior to ABMT, and then 5, 10 and 20 days following ABMT. It was found that patients experienced moderate to severe levels of anxiety and mild to moderate depression throughout the 15-20 days of hospitalization. The highest average scores for both anxiety and depression occurred 5 days after transplantation and were significantly higher than day 20. Gaston-Johansson et al. (1992) also identified that patients enduring inpatient ABMT were less likely to believe that a positive relationship existed between their own behaviour and health outcomes compared to normal values of health locus of control.

Gaston-Johansson et al. (1996) evaluated quality of life, anxiety and depression of 24 patients at baseline (2 weeks prior to admission), 2 days before being treated with ABMT and at days 5, 10, and 20 after ABMT. Quality of life was measured using the Quality of Life Index instrument. Quality of life, anxiety and depression scores were all lowest on the baseline measures. Patients reported moderate anxiety at baseline and 2 days before ABMT and mild anxiety was reported on day 5 and day 20. There was a significant improvement in depression scores over time. Patients were less depressed on day 20 compared to baseline, day 2 before ABMT and 5 days after ABMT. It was noted that quality of life was rated highest at 5 days even though patients reported to be the sickest at this time. Health and functioning aspects of quality of life had the lowest scores at all time intervals. These two factors had the

greatest negative impact on the overall quality of life score.

Although the samples for both studies by Gaston-Johansson et al. (1992) and Gaston-Johnasson et al.(1996) were small, the results of these studies provide valuable information about psychological distress and quality of life during the transplantation process.

The Functional Assessment of Cancer Therapy-Bone Marrow Transplantation (FACT-BMT) was chosen as the standardized instrument to measure quality of life as it is specific to cancer patients and in particular to patients undergoing BMT. As well, all the questions within the FACT-BMT are relevant to the period immediately after the transplantation when patients are the sickest.

One study has shown that perception of control plays a significant role in the maintenance of emotional well-being and in dealing with stressful life situations like cancer. It suggested that feelings of lack of control correlate with depression and that feelings of control result in better adjustment (Taylor, Helgeson, Reed and Skokan, 1991).

Cancer patients' perception of control was studied by Thompson, Shubin, Galbraith, Schwankovsky and Cruzen (1993). Seventy-one paired interviews with patients and their spouses were done to obtain information concerning psychological maladjustment and perception of control. In evaluating psychological maladjustment (as measured by depression and anxiety) it was found that perception of control over a life stressor such as cancer ($r=-.25$) was not as important as perception of control over the consequences associated with the stressor, such as emotional and physical symptoms ($r=-.64$). These results support the Compensation Model of Control, as discussed earlier in relation to the conceptual framework. Thompson et al.

also reported that a greater sense of control was associated with lower levels of anxiety and depression. Cancer patients were recruited into the study by mailed invitation. Only 32% of the patients who were invited agreed to participate in the study. Possible selection bias due to this accrual method may have implications for the extent to which the results are representative of the sampling population. However, the study is useful in understanding relationships between perception of control and maladjustment. Because the design of the study was cross-sectional and the results correlational, a causal relationship between perception of control and positive adjustment cannot be concluded.

C. Social Interaction

A body of literature reviewed for further understanding of the impact of an outpatient approach to care on patients and their family or caregivers, relates to caregiver burden. In a study assessing quality of life of survivors of ABMT, 93% of the patients (n=29) expressed moderate to severe psychological distress about family burden resulting from the illness and transplant (Whedon, et al., 1995). Christ and Siegel (1990) conducted a study of cancer patient's needs. It was recognized that sicker patients with more complex needs are being cared for outside the hospital. Family and friends are overwhelmed by the increasingly complex and demanding requirements of caring for a seriously ill patient. Christ and Siegel (1990) identified that cancer patients have unmet needs as a result of this increase burden on the caregiver.

A longitudinal study by McCorkle, Shegda Yost, Jepson, Malone, Baird and Lusk (1993) was designed to explore caregiver burden of families caring for cancer patients. This study looked at 17 patients and their caregivers to evaluate the impact of the changes in health-care delivery, such as shortened

hospital stays and earlier discharge of patients with complex problems. The Caregiver Reaction Assessment tool was used to measure the reaction of family members to the burden of caregiving. Measures were taken at the time of discharge and at 3 and 6 months after discharge. Likert scales were used to measure i) caregiver's esteem, ii) amount of family support, iii) impact on schedule, iv) impact on finances and v) impact on physical health. As well, a tool was used to measure the caregiver's physical responsibility of caring for the cancer patient. Physical and psychological patient variables that were measured included the presence of distressing symptoms, level of social dependency on the caregiver, mental health status and depression.

Results showed that patients, who at the time of discharge required help from other people in order to perform activities of daily living and had high symptom distress, had a significant impact on caregivers' self esteem, schedule, finances and physical health. Amount of family support available to the caregiver showed no correlation with patient variables. It was also found that during this early period out of hospital, caregiver burden was positively correlated with the symptom distress and dependence of the patient. These results indicate that the caregiver's stress levels may be highest following the patient's hospital discharge. At 3 months after discharge there was a positive association between caregiver burden and psychological well-being of the patient as measured by mental health status (mental distress) and depression. Significant associations were found between patient status and impact on finances ($r=.62$, $p<0.01$), schedule ($r=.45$, $p<0.05$), and physical health ($r=.46$, $p<0.05$), all aspects of caregiver burden.

The associations found in this study are worth considering particularly because the results may be conservative. The study sample did not include

patients who had died or were too sick to participate in the 3 and 6 month follow-up. Thus, there may be an underestimation of the strength of the associations between burden and patient factors.

D. Patient Satisfaction

Patient satisfaction as an indicator of quality of care is not without problems with regard to measurement variability, response bias, ability to operationalize and methodological weaknesses such as social desirability (Health Services Research Group, 1992; Ross, Steward and Sinacore, 1995; Williams 1994). There are few studies relevant to ABMT or cancer care generally that have included patient satisfaction as an outcome measure.

Because patient satisfaction evaluation is measured to determine differences in patient acceptability between the outpatient and inpatient delivery of care, the measure of patient satisfaction used will be specific to whether patients needs were or were not met and not the technical quality (e.g., diagnosis and management) of the care received. The Health Services Research Group (1992) states that rating of technical aspects of care when complex services are received is difficult to obtain. The patient's legitimate concerns and unmet needs will provide specific feedback necessary to assess the delivery of outpatient care to ABSCT patients. A standardized score is felt to provide inadequate information with regards to specific issues of the program. Avis, Bond and Arthur (1995) and Williams (1994) support a qualitative approach to obtaining patients' views about their care as it is "essential in order to maintain a critical perspective, utilizing the full range of patients' values and experiences" (Avis, et al., 1994, p. 320). However, a qualitative approach to measuring patient satisfaction is beyond the scope of this study. As no specific instruments exist to assess satisfaction for patients undergoing ABMT or

ABSCT, specific questions about their experience were asked.

The previously noted study by Pineault et al., (1985), compared the impact of inpatient to outpatient method of care after surgical procedures. Patient satisfaction was evaluated. Clinical outcomes (discomfort, complications and symptoms) showed no significant differences between the two groups. However, patients in the one-day stay (outpatient) group were not satisfied with physician availability or the appropriateness of length of stay and would have preferred the alternate method of in-hospital care. Although there was no difference in the clinical outcomes between the two modes of care, the patient's perception of care may have a strong influence over the acceptance and success of outpatient programs of care.

E. Financial Impact of Care

A New Zealand study by Bowie, Tobias and Williams (1996) considered the effect of shifting in the cost of illness from the state onto the sick individual and their family or caregiver. This study identified and measured the outside hospital costs, or private costs, incurred by people with HIV/AIDS. Twenty-five patients were asked to keep a daily diary of direct and indirect costs related to their disease over a one month period. Direct costs were defined as 'out-of-pocket' expenses for extra resources consumed such as medical services, prescriptions, counselling, allied health services and travel. Indirect costs were foregone employment income as a result of the illness. Although this study does not compare the 'out-of-pocket' costs of inpatient verses outpatient delivery of care, the study concludes that private costs of HIV/AIDS were considerable, ranging from $100 to $400 per month. Travel costs accounted for one-third of the total direct costs. Further breakdown of costs for other medically related services were not reported. The study did not determine the extent to

which the extra costs were covered by third party insurance plans. Depending on the extent to which individuals have insurance plans to cover costs of services and supplies, direct non-reimbursable costs may vary widely with the individual patient. The sample size was small and the health needs of HIV/AIDS patients may be different from cancer patients. However, the study is helpful in highlighting the significance of 'out-of-pocket' costs to the patient and family.

F. Summary

The review of the literature suggests that high-dose chemotherapy is clinically effective and safe. The supportive care of patients experiencing numerous side-effects during the period after the transplantation of autologous blood stem cells is intensive and often invasive. However, the majority of the patient's physical needs can be managed in the outpatient setting. Studies have concluded that length of hospital stay is shortened by the implementation of an outpatient approach to care and as a result the cost to the health care system is reduced.

Psychological factors such as quality of life, anxiety and depression were found to be of concern during the period after stem cell transplantation and therefore must be considered in evaluating methods of delivery of care. A positive relationship between perception of control over day-to-day activities and psychological well-being has been documented in past research. For the purpose of this study, this evidence allows for the prediction that outpatient care will enhance the patient's sense of control and will therefore have a positive effect on their psychological well-being. A high perception of control was considered a positive outcome when comparing the two methods of care delivery. Past research also indicates that with outpatient care the burden on

the caregiver and costs to the family are important variables to assess. The direct costs for patients and family will vary depending upon the types and amount of related health services required and the extent to which supplemental insurance plans cover these costs.

Although satisfaction with care is difficult to measure, patient's perception of the quality of the care they received may have a strong bearing on the overall acceptance of new programs. The success of programs may be limited if patient's expectations are not met. This aspect of care has not been studied in a systematic way in previous research.

In summary, there is research to support the feasibility of an outpatient approach to the care of patients treated with ABSCT, when system costs and physical outcomes are used as criteria for feasibility. However, there is no comprehensive evidence to suggest that an outpatient method of delivery of care is appropriate in terms of quality of life, perception of control, satisfaction with care, cost to the patient and family and caregiver burden. An understanding of these variables may ensure appropriate care of this unique group of individuals through provision of outpatient support and may be useful for screening patients who may not cope well in the outpatient environment.

CHAPTER 2

METHODS

I. Study Design

A quasi-experimental design, as shown in Figure 2, was used to address the research problem. Therefore, a non-equivalent control group pre-test and post-test design was chosen for this study, meaning that the responses from the experimental group and the control group were measured before and after a treatment. Randomization of participants into two comparison groups was not possible for two reasons. First, eligibility criteria necessary for outpatient care would be too restrictive, limiting patients' entry into the study. Second, a number of patients were not comfortable with being assigned to outpatient care and it would be unethical to assign patients unwillingly into this mode of care. Because randomization was not possible, it could not be assumed that the experimental and control groups were equal prior to implementation of outpatient care and therefore causal inference can be difficult and less strong. In particular, threats to internal validity such as selection bias must be acknowledged and if possible controlled for in the process of analysis.

Figure 2. Quasi-experimental Design with a Control group and Experimental Group.

t =	day -7 to -3 (baseline)	day 0 (ABSCT)	day 4 to 6	day 12 to 16	day 30 (post tx)
A)	O_1	X	$O_{1,2}$	$O_{1,2}$	O_3
B)	O_1		$O_{1,2}$	$O_{1,2}$	O_3

where t = time, day 0 is the time of autologous blood stem cell transplantation

A = outpatients
B = inpatients
X = outpatient care initiated
O = completion of measurement tools, data collection
1 = personal data, illness related data, quality of life, anxiety, depression, perception of control, pain, caregiver burden, morbidity
2 = toxicities, complications, perception of side-effects, satisfaction with care
3 = direct and indirect cost to family, number of days in hospital, satisfaction with care, quality of life, and caregiver burden.

By designing the study to include a pre-test collection of data, similarities, in terms of a number of variables, could be determined between the groups. These variables consisted of personal characteristics, illness related variables and measures of aspects of quality of life, physical status, psychological well-being and social interaction.

The independent variable was the method of care (either inpatient or outpatient care after ABSCT). Outpatient care was defined as "not planning on staying in hospital over night". Care method was determined after informal discussion between the patient and the transplant program staff. Although

eligibility criteria for outpatient care was established by the program, patients had a significant amount of say as to which method of care they would receive. The experimental group were patients who were treated as outpatients during the period after the transplant, while the control group were patients cared for as inpatients during the period after the transplant. The dependent or outcome variables were quality of life, anxiety, depression, perception of control, caregiver burden, satisfaction with care, number of days in hospital, complications and toxicities of the treatment regimens and financial expenses for patients and families.

In the original conceptualization of the study design, it was hoped that the method of care (inpatient or outpatient) would be determined according to geographic location. That is, the control group (inpatients) would be patients treated with ABSCT at the Cross Cancer Institute in Edmonton. The experimental group (outpatients) were to be selected from patients in Southern Alberta who were treated with ABSCT at the Tom Baker Cancer Centre (TBCC) in Calgary. This method of assignment to the different study groups was not possible and is discussed further in Chapter 4. In the end, each Cancer Centre contributed inpatients and outpatients to the study sample.

This pilot study was designed to gain an initial understanding of how patients manage when cared for in the outpatient setting. The research questions and study design enabled a systematic and controlled exploration of the effects of outpatient management of patients undergoing ABSCT, that has not been well documented in the literature. The value of this initial work is to provide an opportunity to refine the design, methods and tools for a future study. This study was undertaken as an exploratory pilot study in order to assess the appropriateness of the outcome variables and the feasibility of using the

instruments identified to measure quality of life, satisfaction with care and caregiver burden. Since the study used a large number of questionnaires and tools, the pilot phase also confirmed that patients were able to complete the battery of questionnaires without excessive burden. The pilot also allowed for hypothesis setting for further assessment of the research problem.

The following research questions were explored:

1. How does physical status of the outpatient group compare with the inpatient group?
2. How does psychological well-being of the outpatient group compare with the inpatient group?
3. How does social interaction in the outpatient group compare with the inpatient group?
4. How does a global measure of quality of life of the outpatient group compare with the inpatient group?
5. How does personal financial impact of treatment in the outpatient group compare with the inpatient group?

II. Sample

The study collected data starting March 1997 and continued for a seven month period of time. Of the 43 individuals approached to participate in the study, 20 were treated as outpatients at the TBCC, 1 was treated as an outpatient at the CCI. Sixteen subjects were treated as inpatients at the TBCC and 4 were treated as inpatients at the CCI. Participation in the study was declined by 2 patients.

Because this was an exploratory, observational pilot study, eligibility for the study included all patients being treated with ABSCT. A convenience

sample was used for this study and consisted of patients being treated for malignant disease using high-dose chemotherapy and ABSCT at the TBCC and CCI. This included patients residing outside of Alberta who received their treatment at either of the two cancer centres. In order to be eligible for the study, individuals were required to meet the following inclusion criteria:

i) the ability to perform self care activities;

ii) a Karnofsky score equal to or greater than 70%;

iii) the ability to communicate in English in verbal and written forms.

In order to be eligible for outpatient care, individuals were required to meet the foregoing eligibility criteria and in addition were required to have: i) a caregiver available 24 hours per day; ii) accommodation within 45 minutes driving time from the TBCC; iii) access to transportation.

III. Measurement

Data were collected on a number of personal and illness related variables. Personal data included age, birth date, address, gender, education level, changes in employment status due to illness, marital status, changes in living arrangements due to illness and availability of medical insurance coverage. This information was obtained from the patients. Illness related variables included tumor site and type of chemotherapy given. As well, information concerning previous failures of chemotherapy to control the disease process and the number of times a relapse from disease remission was experienced was obtained from the chart. The National Cancer Institute of Canada Common Toxicity Criteria and Regimen-Related Toxicity Grading System (Scott, Bearman, Applebaum, Buckner, Petersen, Fisher, Clift and

Thomas, 1988) was used to grade complications and toxicities as a result of the high-dose chemotherapy. The Karnofsky Performance Scale was used to quantify the patient's physical health status, which is referred to in this study as morbidity. Information about the reason for readmission to hospital was collected for outpatients who required in-hospital care. As well, it was noted whether the readmission was initiated by the physician, patient or caregiver. Total number of days in hospital was also determined. The above variables were collected from the patient's chart.

Quality of life was measured by the Functional Assessment of Cancer Therapy-BMT Scale (FACT-BMTS). This tool provided a global measure of health-related quality of life, including issues specific to BMT (bone marrow transplant). The tool's subscales provided measures of physical status, psychological well-being and social interaction.

Physical well-being was measured by a variety of instruments. Patient perception of the side-effects and toxicities experienced was measured. This was done by asking patients to prioritize the top three most difficult physical problems related to treatment that they had experienced and to rate the severity of the physical problem. A subscale of the FACT-BMTS also provided measures of physical health and function. A visual analogue scale was used to measure the amount of pain experienced by patients.

Psychological well-being was measured using the following standard instruments. A subscale of the FACT-BMT provided a measure of emotional well-being; the Shortened Profile of Mood States (POMS) Measure of Distress provided a measure of anxiety and depression; the Centre of Epidemiological Studies - Depression Scale (CES-D) was used to measure depression. Perception of control was measured by using a tool designed specifically to

measure patient's sense of control over physical, emotional, relationships, medical care and course of the disease. Questions constructed for the purpose of this study were used to assess patient's perception of satisfaction with care.

Social interaction was measured by the FACT-BMTS subscales concerning social and family well-being and relationship with the physician. As well, the Caregiver Reaction Assessment tool is a standard instrument that was used to evaluate burden on the caregiver. The following personal data were collected about the caregiver: age, sex, level of education, marital status, relationship to the patient, number of dependent family members living with the caregiver and where the patient and caregiver lived during the period after transplantation. Depression and level of anxiety of the caregiver were also measured using the CES-D and POMS respectively.

Personal financial impact of care was determined by measures of direct and indirect expenses to the patient and family. Participants were asked to keep a diary of expenses incurred related to their disease and treatment. Insurance coverage was documented to determine the extent of support from third party payers.

A detailed description of the standardized instruments identified in the foregoing section is given below.

A. Toxicities

The Regimen-Related Toxicity system allows for the grading of toxicities due to high-dose chemotherapy. It is a grading system designed to assess the impact of chemotherapy on morbidity of the heart, bladder, kidney, lungs, liver, mucosa, central nervous system and gut (Scott, Bearman, Applebaum, Buckner, Petersen, Fisher, Clift and Thomas, 1988).

The National Cancer Institute of Canada Clinical Trial Group (NCIC CTG)

Common Toxicity Criteria grading scale was used for monitoring and classifying toxicities as a result of the chemotherapy. A grade of 0 (meaning no toxicity) to 4 (indicating the toxicity is life threatening) was assigned to the following biological categories: blood/bone marrow, cardiovascular, coagulation, flu-like symptoms, gastrointestinal, genito urinary, hepatic, infection, metabolic, neurologic, pulmonary, skin, weight, other. Toxicity grades were determined by physicians or nurses treating the patient and are a part of the routine assessment for all ABSCT patients.

B. Morbidity

The Karnofsky Performance Scale is a measure of physical performance and dependency. It is commonly used in the clinical setting and in clinical trials. A category ranging from 100% meaning 'no evidence of disease' to 0 meaning 'death' was assigned to the patient by a health care professional. Inter-rater reliability at 4 months retest is 0.97 (Bowling, 1991).

C. Health-Related Quality of Life

The study measured quality of life using a tool specific to cancer patients and their treatment. The Functional Assessment of Cancer Therapy (FACT) scale is a self-administered instrument that provides a subjective measure of three domains (Cella, Tulsky, Gray, Sarafian, Linn, Bonomi, Siberman, Yellen, Winicour, Brannon, Eckberg, Lloyd, Purl, Blendowski, Goodman, Barnicle, Stewart, McHale, Bonomi, Kaplan, Taylor, Thomas and Harris, 1993). The physical domain includes physical and functional status. The social interaction domain includes social and family well-being as well as relationship with the physician. The domain of psychological well-being refers to the emotional well-being of the patient. The general version of the FACT instrument has been used previously in a study to assess quality of life of cancer patients after

autologous bone marrow transplantation (McQuellon, et al., 1996).

The 38 items in the tool are linked to 5 subscales. Internal consistency of each subscale and the total FACT score ranges from 0.65 to 0.89, with high measures of association for the total score and physical, functional and emotional well-being. Test-retest reliability 3 to 7 days after initial testing has been reported to be high (ranging from .82 to .92) in all three domains. The FACT has been shown to be sensitive to the stages of disease, as well as sensitive to changes in disease over time.

Developers of the tool have validated the FACT by comparing it with a variety of other quality of life instruments (Cella, et al., 1993). As well, convergent validity has been estimated by comparing the FACT to the FLIC (general quality of life tool) (r= .79) indicating that the FACT actually measures quality of life.

The Functional Assessment of Cancer Therapy - Bone Marrow Transplant (FACT-BMT) Scale consists of the general version of the FACT, as described above, and a Bone Marrow Transplantation Subscale (BMT). The BMT is used to assess health related, quality of life aspects specific to bone marrow transplantation. The FACT-BMT is only to be used in combination with the general FACT instrument where the internal consistency is .84 to .92. The FACT-BMT has been found to be sensitive to change in patient's performance status. The BMT questions correlate highly with the general version of the FACT (.72) and with the subscales within the general version that measure physical (.60) and functional (.60) well-being. (McQuellon, Russell, Cella, Craven, Brady, Bonomi and Hurd, (in press).

D. Anxiety

The Shortened Version of the Profile of Mood States (POMS) Measure of

Distress was derived from a large 58-item scale (Total Mood Disturbance Score) which contained six subscales measuring specific dimensions of distress (Cella, Jacobsen, Orav, Holland, Silberfarb and Rafla, 1987). The Shortened Version of the POMS scale measures general psychological distress for cancer patients. Internal consistency of the Shortened Version of the POMS has been found to be the same as the original version of the POMS with alpha coefficients ranging from .80 to .90 (Shacham, 1983). Validation of the Shortened Version of the POMS was accomplished by comparing the scores of cancer patients using the original 58 item scale with the results of the Shortened Version of the POMS. The results were found to be highly correlated (r=0.95). The POMS is sensitive to change over a short period of time with rating specific to the past week (McQuellon, Craven, et al., 1996).

E. Depression

Depression (depressed symptomatology) was measured using a screening instrument derived from the U.S. National Institute of Mental Health. The Centre of Epidemiological Studies - Depression Scale (CES-D) is a 20-item self-administered screening tool used for the general non-psychiatric population. The CES-D provides an assessment of the frequency of cognitive, affective, behavioural and somatic symptoms associated with depression in the preceding week. The CES-D has been used for numerous research projects including epidemiological studies of psychiatric disorders by Radloff and Locke (1986) and quality of life for cancer patients (McQuellon, et al., 1996). The scoring of this instrument is done by weighting symptoms according to the frequency by which they occur. Scores can range from 0 to 60 with higher scores reflecting greater distress (Devines and Orme, 1985). Because the distribution of scores tends to be positively skewed (i.e., low scores are more

common in the general population) a cutoff score of 16 is used to identify depression (Comstock and Helsing, 1976).

Reliability of the CES-D has been determined in a number of ways. Test-retest reliability at 2 weeks through to 8 weeks ranges from r = .52 to r =.67. Internal consistency as determined by Cronbach's alpha is 0.84 to 0.90. (Devines and Orme, 1985).

Validity of the CES-D was determined by a number of methods. The CES-D was able to distinguish between individuals diagnosed with depression from those who were not depressed. However, the CES-D could not distinguish between different levels of depression (major, minor or depressive personality). (Devines and Orme, 1985).

Convergent validity was determined by comparing the results of the CES-D to the widely used Hamilton rating scale and the Raskin scale with Pearson Correlations of r=.50 to .80 and r=.30 to .80 respectively. Studies to determine discriminant validity were less successful. The CES-D reflects psychological distress in general and not only depressive symptomatology. The CES-D scale has been evaluated by its ability to demonstrate the known association between the construct of depression with other variables associated with depression (Devins and Orme, 1985).

F. Satisfaction with Care

Questions were developed for this study to determine patient's preference and satisfaction with the mode of post transplant care received. These questions focused on access to care, adequacy of educational information provided, adequacy of emotional and instrumental support provided by family and overall satisfaction with care. Open-ended questions were also asked of the outpatient group concerning what patients liked and did not like

about being cared for in the outpatient setting.

G. Caregiver Burden

The Caregiver Reaction Assessment (CRA) is a multidimension instrument used to measure physical, psychological, emotional, social and financial problems experienced by family members or significant others caring for persons with chronic physical and mental impairment (Given, Given, Stommel, Collins, King and Franklin, 1992). Strong homogeneity was found among the items in each subscale (caregiver esteem, amount of family support, impact on finances, impact on schedule and impact on health). This was accomplished by principal component analysis. The 24 items account for 65.1% of the variance and the interscale correlations indicated fairly independent dimensions (ranging from r=-0.02 to 0.358, with the exception of impact on health and impact on schedule, r=0.45).

Cronbach's alpha of .80 to .90 indicates high internal consistency. The CRA subscales were found to remain stable across diverse groups of caregivers and the tool is suited for measuring changes in caregiver's reaction. Construct validity has been estimated by correlating patient dependencies in activities of daily living with caregiver depression, (alpha coefficient of .83 and .90 respectively).

H. Perception of Control

The Perception of Control instrument used in this study was constructed by Thompson et al. (1993) in order to evaluate how cancer patients maintain a sense of control in low control circumstances. The tool was administered in a face-to-face interview with the patient. Patient's perceived control was measured using 9 items to reflect the following 4 subgroups. Two of the items ask about emotions and physical symptoms, 3 items refer to relationships, 2

items inquire about medical care, 1 item asks about the progression of disease, and the final item evaluates general perceptions of control. Responses to items are given on a 4-point Likert-type scale ranging from 1 (indicating no control at all) to 4 (indicating a great deal of control). Open-ended questions are also included and these identify techniques used to exercise control over the four subgroups listed above. Patients are then asked how effective they feel their control efforts are on a 3-point scale ranging from 1 (not at all effective) to 3 (very effective).

The internal consistency has been determined for each subgroup using both the amount and effectiveness of each item. The Cronbachs' alpha values for each subgroup are a follows: emotion and symptom control = 0.70; relationship control = 0.70; medical care control = 0.69; and course of disease control = 0.88. The overall scale measuring perceived control was created by summing up the scores in all four subgroups. Overall internal consistency is adequate with a Cronbach's alpha of 0.79.

I. Pain

The most practical tool for the assessment of pain is the visual analogue scale because it is simple, reliable and valid. The descriptor "little or no pain" is at one end of the visual scale, and "the most severe pain imaginable" at the other end. Patients quantify their pain intensity on a 10 point scale. (Librach, 1993) The results are interpreted as the amount of pain experienced by the patient.

Test-retest reliability for a literate group of patients is .94 (MacDowell & Newell, 1996). The validity of the Visual Analogue Scale has been assessed by comparing results to a 4-point descriptive scale and the McGill Pain Questionnaire with correlations of .78 and .63 respectively (MacDowell &

Newell, 1996). The MacGill Pain Questionnaire is a more complex measure of pain and considered the leading measure of pain. For the purpose of this study, the Visual Analogue Scale provides a sufficient measure of pain.

J. Out-of-Pocket Expenses

The financial burden imposed on the patient and family or caregiver during the period of observation in this study was obtained through an expense diary. Expenses included housing, transportation, domestic help, baby sitting, medication, supplies, special equipment and cost of services related to the illness and treatment. Expenses that were eligible for reimbursement by third party payers were included in the direct costs to the patient. Data concerning third party insurance coverage were collected. Indirect costs were also estimated and include loss of salary for caregivers, and premiums required to maintain insurance coverage and pension plans.

IV. Procedure

The student researcher collected data from the Calgary subjects. As well, a research nurse involved with patients being treated with autologous blood stem cell transplantation in Edmonton was volunteered to collect data from subjects at the Cross Cancer Institute. The research nurse was orientated to the study protocol and measurement instruments prior to the beginning of the study. The research nurse in Edmonton was part of the BMT team and therefore it was assumed that she would know of all patients entering the ABSCT program. Because she was employed by the CCI in the BMT program it was appropriate for her to recruit patients.

Members of the BMT team at the TBCC discussed the study and reviewed the consent form with the patient. With the patient's permission, their

name was given to the student researcher for further contact. The student researcher, who is also a Registered Nurse, and the research nurse in Edmonton are referred to as research nurses for the purpose of describing the procedure.

During a scheduled visit to the bone marrow transplant unit at both Edmonton and Calgary Cancer Centres, the research nurses met with each new patient to explain the study, invite participation, obtain informed consent (see Appendix B) and answer any questions. Data collection began at this time or arrangements were made for a time that was convenient for the patient, before treatment started. These initial (baseline) data were collected 1 to 7 days prior to the administration of high-dose chemotherapy. Collection of baseline data required approximately an hour and a half and included information about personal characteristics, morbidity, pain, perception of control, anxiety, depression, and quality of life. The baseline assessment was not always done before the patient's eligibility for the outpatient mode of care had been determined. It is possible that knowing which mode of care would be received may have influenced patients' initial responses to the instruments. The research nurses reviewed with the caregiver and the patient the reason for the 'Expense Diary' and the method for recording expenses.

At the time of the baseline assessment, caregiver information was also collected including personal data, caregiver burden, anxiety and depression. Caregiver data collection took place away from the patient to avoid bias as a result of the patient's presence. It was recognized that not all inpatients undergoing ABSCT would have caregiver support. Therefore, information concerning caregiver burden was missing for these patients.

The research nurses collected data concerning illness related variables

from the patient chart. The patient's level of morbidity (Karnofsky Score) was determined by the physician or nurse and recorded in the chart. The Karnofsky Score was obtained at each of the four data collection points.

Day 0 was identified as the day the patient was infused with the blood stem cells. Because day 5 after transplantation has been identified as the day when depression and anxiety are rated to be the highest (Gaston-Johansson, et al., 1992), the second set of interviews and tools were completed by the patient and caregiver on day 4, 5 or 6 in order to provide the best measures of the variables for the purpose of analysis. A third period of measurement of the study variables was obtained between day 12 and 16. The second and third period of data collection occurred when outpatients and caregivers were scheduled to return to the Cancer Centre for routine treatment. For the inpatient group, the research nurse arranged an interview session to take place in the patient's hospital room when the caregiver was present.

Information collected at the second and third interviews included morbidity, pain, perception of side-effects, satisfaction with care, perception of control, anxiety, depression and quality of life. The caregiver completed instruments measuring caregiver burden, anxiety and depression. The research nurses conducted the interview and ensured completion of the paper and pencil instruments.

The fourth period of data collection occurred around day 30. The supportive phase of care after ABSCT had been completed at this point in time and both groups of patients were residing in their home environment. It was desirable to compare variables of well-being in both the inpatient and outpatient groups to determine physical and psychological well-being upon completion of treatment. In Calgary and Edmonton, routine follow-up for medical treatment

varied, however patients were seen at least once a week at this point in their care. The fourth session of data collection coincided with appointments so that the research nurses saw the patients and their caregiver in person. The research nurses coordinated this visit with the primary nurse of the Bone Marrow Clinic and ensured that the 'Expense Diary' was returned. The patient variables that were measured were perception of satisfaction with care and quality of life. The caregiver provided information concerning caregiver burden. The 'Expense Diary' was reviewed with the patient and caregiver at this time. Completion of these study instruments required one half hour from each of the patient and caregiver. The number of days in hospital was obtained from the patient's chart.

V. Data Management

All of the questionnaires were collected from participants in or returned by mail. Each one of the questionnaires that was to provide quantitative results were scored manually. These included the FACT-BMT, CES-D, POMs, Caregiver Reaction Assessment and Perception of Control. Instructions for scoring of all these instruments was established by the specific developers of the questionnaire.

The personal and illness related information, as well as the results from the questionnaires was entered into a computer according to patient study number. Because some information was collected repeatedly over four time intervals, it was entered on to the same spread sheet, under the same variable, according to time of collection. Once the information and scores were entered, the data were reviewed for unusual entries. These entries were checked with the original questionnaires and corrections were made as necessary.

Responses to the few open ended questions were manually organized into common themes. The proportion of responses and the confidence interval for each theme was reported.

The data from the expense diaries were divided into categories of expenses. Total expenses within each category was calculated for each subject, as well as each subjects' total expenses.

VI. Analysis

The data were first analysed to provide a description of the participants in the two study groups with respect to personal characteristics and illness related variables. Description of personal characteristics included age, gender, education, relation of caregiver and living arrangements during treatment. Illness related variables provided a description of disease type, morbidity, chemotherapy protocol and experience with treatment failure. Tables and graphs were used to summarize and illustrate the data. Confidence intervals were used where appropriate.

Comparisons were made between the study groups (Inpatients vs Outpatients) at baseline to determine similarities and differences between the two study groups. Specifically, the groups were compared with respect to age, type of disease, morbidity, chemotherapy protocol, failure to respond to chemotherapy regimens in the past and relapses.

The comparative analysis of the data from day 4-6, day 12-16 and day 30 was specific to the research questions. Box plots were used to illustrate the distribution of the variable of interest and to make comparisons between the study groups. A box plot (Figure 3) contains 50% of the data, showing the upper (75^{th}) quartile and the lower (25^{th}) quartile of the data by horizontal lines

or "hinges". The difference between the upper and lower quartiles is called the interquartile range. The line through the box plot represents the median or 50th quartile, indicating that 50% of the data lie above this line and 50% of the data lie below this line. The values beyond the hinges are represented by lines (called "whiskers") extending in both directions and terminating at the inner fences. Each whisker represent the data that are distributed 1.5 times the interquartile range. Ninety-nine percent of the data are contained within the box plot and whiskers. The values outside the "inner fence" are considered outliers or extreme values in the data.

A confidence interval provides a range of values that is calculated in the hope that the interval will include the parameter of interest. Ninety-five percent confidence interval are interpreted to mean that in repeated sampling, 95 times out of 100, the true value of the variable of interest is contained within the interval. In comparing the medians of two groups, if the confidence intervals for each of the median scores do not overlap, one can conclude that the medians are different, hence the two groups are different. Interpretation of confidence intervals that do overlap is more difficult, since the width of a confidence interval is determined to some extent by the size of the sample from which the data are drawn. That is, if the sample is small, the two confidence intervals for the median scores may be broad and overlap despite an apparent difference in the value of the median scores. Thus, to conclude that the median scores are similar may be erroneous even though the confidence intervals overlap. A larger sample provides narrower confidence intervals, thereby giving more precise estimate as to whether a difference in median scores actually exists.

VII. Analysis of Research Questions

Question 1: How does physical status of the outpatient group compare with the inpatient group?

Physical status was measured in a number ways. Client-centred outcomes included perception of treatment side-effects and toxicities and aspects of quality of life (physical and functional well-being). Health care system outcomes included grading of toxicities, morbidity and number of days in hospital.

Perception of treatment side-effects that (identified by the patients as very bothersome or somewhat bothersome) were summarized to determine the proportion of patients with similar complaints. The proportion of bothersome side-effects were compared between inpatients and outpatients. Ninety-five percent confidence intervals of the proportion for each group were used to determine between groups differences.

The FACT-BMT instrument measuring quality of life, provided the scores for the continuous variables of physical well-being and functional well-being. Median, range and 95% confidence intervals were used to describe the distribution of scores between the two study groups. Side by side box-plots of inpatients and outpatients describe the distributions of the two groups for comparison. If a visual difference between the groups was identified and believed to be clinically significant, further statistical tests for comparison of the means were done.

Question 2: How does psychological well-being of the outpatient group compare with the inpatient group?

The scores of emotional well-being (as measured from the FACT-BMT), anxiety, depression and perception of control are continuous variables. Median

scores, the range and 95% confidence intervals were used to describe the sample. Side by side box plots of the inpatient and outpatient groups were used to observe for differences in the variables of interest.

Patient satisfaction with care was not evaluated as a total score. Rather, the information from each question was analysed separately to provide specific information about the satisfaction of the two methods of care. The proportion of patients indicating their satisfaction as excellent, very good, good were combined into one category indicating "good" satisfaction. The categories fair and poor were combined into another category indicating "poor" satisfaction. Proportions in each category were used to compare inpatients and outpatients.

The open-ended responses to questions concerning patients' likes and dislikes with the care they received were listed. The lists were reviewed separately by the researcher. Categories were developed according to the responses given by patients. The proportion of patients in each category was then compared between inpatients and outpatients.

Question 3: How does social interaction in the outpatient group compare with the inpatient group?

The variables that define social interaction are caregiver burden, social/family and relationship aspects of quality of life, caregiver anxiety and caregiver depression. All of these variables provided scores that were analysed as continuous variables. Caregiver personal data were analysed by describing the two groups with respect to age, gender, level of education, number of dependents in the family, marital status, living arrangements during the patient's treatment, anxiety and depression.

The Caregiver Reaction Assessment was used to measure caregiver burden and provided scores for i) impact on schedule; ii) caregiver esteem; iii)

family support; and iv) impact on health. Each of these factors was scored separately. Side by side box plots of the inpatient and outpatient groups were used to illustrate the median scores and the distributions of the variables of interest. Ninety-five percent confidence limits for each group were examined for overlap.

Question 4: How does a global measure of quality of life of the outpatient group compare with the inpatient group?

The FACT-BMT instrument was used to measure quality of life. A total score was provided and analysed as a continuous variable. Again, the median scores, range and 95% confidence interval were used to describe the distribution of the total sample. Side by side box plots were used to compare the study groups. Gender, level of morbidity, pain and previous treatment failures were believed to influence quality of life, therefore separate analyses were done to control for a potential confounding effect.

Question 5: How does the personal financial impact of treatment in the outpatient group compare with the inpatient group?

Direct and indirect expenses for the patient and family were recorded over the thirty day period of observation. This data collection allowed description of what constitutes direct and indirect expense to this group of patients. As well as total expense, expense was divided into categories of travel, medicine, and conveniences (television and telephone). Estimates of the mean and median, range and 95% confidence intervals of direct and indirect expenses were calculated for inpatients and outpatients. The distribution of expenses for the inpatient and outpatient groups were illustrated by using side by side box plots. The Caregiver Reaction Assessment instrument was used to measure the impact on finances for families. This continuous variable was

compared between study groups using side by side box plots.

VIII. Ethical Considerations

Informed written consent was obtained from each patient and caregiver. The purpose of the study, expected involvement and type of information requested was explained. Participants were assured that involvement in the study was entirely voluntary. Confidentiality of information was maintained by numeric identification of the subjects.

Ethical approval was obtained from the Conjoint Health Research Ethics Board at The University of Calgary, Faculty of Medicine prior to initiation of the study. Once ethical approval was obtained in Calgary, notification of approval and the protocol was sent to the Research Ethics Committee, CCI in Edmonton for reciprocal approval.

CHAPTER 3

RESULTS

This chapter begins with a brief summary of the participation rate and describes how the comparison groups were constituted. The majority of this chapter presents the results of the analysis of data according to the research questions that were asked.

I. Participation Rate

Over a seven month period beginning in March 1997, 41 subjects were enrolled in this pilot study. During this period of time, the total number of patients undergoing Autologous Blood Stem Cell Transplant (ABSCT) in Calgary and Edmonton was 39 and 17 respectively. In Calgary, at the Tom Baker Cancer Centre and Foothills Hospital, 36 patients and their caregivers agreed to participate in the study. This represents 92% of the patients undergoing ABSCT in the seven month time period. Of the three patients who did not participate in the study, one was not approached because of his inability to understand and complete the study instruments. Two individuals were provided with detailed information about the study but declined participation. They did not wish to complete the various measures required of participants. Of the 17 patients from Edmonton, 5 were approached for the study, all of who

agreed to participate. The other 12 patients were not referred to the research nurse in Edmonton.

With respect to caregiver participation, four patients enrolled in the study did not have a caregiver who could provide information. Two of these individuals were single and lived alone and did not have a designated caregiver. One patient's spouse who was the caregiver, lived out of town and declined participation in the study. A fourth caregiver was actually willing to participate, but was advised by his employer to decline participation because of the assessment of depression that was part of the study.

II. Establishing Experimental and Control Groups

The original design included two control groups (i.e., one inpatient group from Edmonton and one inpatient group from Calgary) and one experimental group (i.e., an outpatient group in Calgary). By the end of the seven month period of data collection, 16 inpatients and 20 outpatients had been enrolled in Calgary. A total of 5 patients had been enrolled in Edmonton, of whom 4 were treated as inpatients and 1 outpatient. Because of the poor accurral rate in Edmonton, the design of the original proposed study was altered.

True to the original design, the experimental group was comprised of the twenty participants who were treated in Calgary as outpatients. However, due to the low accrual of participants in Edmonton, a control group from that centre could not be assembled. Personal and illness related variables and baseline scores of the Edmonton participants were compared with Calgary participants to determine if the two groups were similar enough to be combined to form one inpatient and one outpatient group. The results of this assessment follows.

A. The Inpatient or Control Group

A comparison was done of personal and illness related information of the 16 inpatients in Calgary with the 4 inpatients in Edmonton. In Calgary, 81% (13) of the inpatient participants were female. Of these, 10 (63%) had breast cancer, 2 were diagnosed with multiple myeloma, 2 with Hodgkin's Disease, 1 with lymphoma and 1 with a malignant brain tumour (oligodendroglioma). All of the 4 Edmonton inpatients were diagnosed with breast cancer and all were treated with the high dose chemotherapy protocol of Mitoxantrone, Vinblastine and Cyclophosphamide. This was the same protocol used for 80% of the breast patients in the Calgary inpatient group. It was concluded that with regard to the type of cancer diagnosis and the treatment protocol used, the Edmonton and Calgary inpatient groups were similar.

The age of inpatients in Calgary was normally distributed. Age ranged from 36 years to 64 years with a mean of 48 (95% Confidence Interval (C.I.)= 44 years to 52 years). Although the sample size in Edmonton was too small (4) to illustrate a normal distribution of age, the age range was from 37 to 57 years, with a mean of 44. These data suggest that Edmonton and Calgary inpatients did not differ remarkably with respect to age.

The Karnofsky score, which is an indicator of morbidity, was compared between the two inpatient groups. The majority of Calgary inpatients (56%) had Karnofsky scores of 90% (i.e. able to carry on normal activity; minor signs or symptoms of disease), with scores ranging from 70% to 100 %. The range of Karnofsky scores for the 4 Edmonton inpatients were from 70% to 80%, with 3 of the 4 patients having scores of 80% (normal activity with effort; some signs or symptoms of disease). These data suggest that all participants were functionally able to care for themselves and very few patients experienced

limitations in normal activity or ability to do active work.

The baseline quality of life scores (FACT,BMT) for Edmonton and Calgary inpatients were also compared. Scores for the Calgary inpatient group were normally distributed, ranging from 71 to 137 with a mean of 105 (95% C.I. = 96 to 114). Scores for the 4 Edmonton inpatients were similar, ranging from 98 to 114 with a mean score of 107.

In the Calgary inpatient group, there was wide variation in the range of scores for physical well-being, functional well-being, emotional well-being, social well-being, depression, control and anxiety. Scores from the patients in Edmonton were similar to scores in Calgary, as shown in Appendix C.

In conclusion, given the similarities between the Edmonton and Calgary inpatients on all the foregoing variables, the 4 inpatients from Edmonton were combined with Calgary inpatients to form one control group of 20 patients.

B. The Outpatient or Experimental Group

The Calgary outpatient group consisted of 20 participants, 15 (75%) of whom were female. Ten of the participants were diagnosed with relapsed or refractory lymphoma, 2 with Hodgkin's Disease, 6 with breast cancer, 1 with multiple myeloma and 1 with Amyloidosis. The high dose chemotherapy protocols used included: 14 patients treated with Melphalan; 5 patients treated with Mitoxantrone, Vinblastine and Cyclophosphamide and 1 patient treated with Melphalan and Total Body Irradiation (TBI). The one Edmonton patient that was treated as an outpatient was diagnosed with neuroblastoma and treated with Melphalan.

The age of outpatients in Calgary was normally distributed with a mean of 45 years (95% C.I.= 40 years to 49 years) and a range from 22 years to 62

years. The one outpatient in Edmonton was younger at 19 years of age.

The majority of Calgary outpatients (n=12; 60%) had a Karnofsky score of 90%. Scores ranged from 70% to 100%. The Karnofsky scores of the Edmonton outpatient was 90%.

Again, in considering the variables that measure quality of life, anxiety, depression and perception of control, the range of scores was broad, indicating wide variation in scores among the individuals in the Calgary outpatient group. Because of these variations in scores and because there was only one person in the Edmonton group, comparison of scores between Calgary and Edmonton patients was not possible. Nevertheless, all scores on measures taken from the one outpatient from Edmonton were within the range of scores of the Calgary outpatients. (See Appendix D.) Although the Edmonton outpatient was younger than Calgary outpatients and had a different diagnosis, the individual was similar to Calgary outpatients with respect to the treatment protocol used and scores on the various study measures. Thus the one Edmonton outpatient was added to the Calgary group. These 21 patients constitute the experimental group.

III. Personal Characteristics and Baseline Measures

The following section provides a description of the control group (n= 20) and the experimental group (n=21) according to socio-demographic and illness related variables. This section also compares baseline measures of the groups in order to describe similarities and differences with respect to physical status, psychological well-being, social interaction and quality of life.

As well, this section describes the caregivers of subjects in the two groups including a comparison of their personal characteristics and baseline

measures of caregiver burden.

A. Personal Characteristics of Inpatients and Outpatients

1. Gender and Age of Subjects

Of the 20 participants in the inpatient group 16 (80%) were female (95% C.I. = 63% to 98%). In the outpatient group 15 of the 21 (71%) participants were female (95% C.I. = 52% to 90%).

Age distribution of the inpatients and outpatients was close to being normally distributed, meaning that there were approximately the same number of participants who were younger and older than the average age. The mean age of the inpatient group was 48 years (95% C.I. = 43 years to 53 years), with the youngest being 36 years of age and the oldest being 64. The mean age of the outpatient group was 42 years (95% C.I. = 37 years to 48 years). The age range was 19 to 60 years of age. In summary, age and gender were similar between the comparison groups.

2. Cancer Diagnosis and High Dose Treatment Protocol

The comparison groups differed with respect to disease. The inpatient group consisted mainly of breast cancer patients and the outpatient group was composed of mainly lymphoma patients. Therefore, the high dose treatment protocols also differed between groups.

Of the 20 inpatients treated with high dose chemotherapy, 15 (71%) (95%C.I. = 51% to 91%) had breast cancer. Of these, 13 (87%) were treated with the high dose chemotherapy consisting of Mitoxantrone, Vinblastine and Cyclophosphamide. The other 2 breast cancer patients were treated with different high dose protocols. One of these patients received high dose Mitoxantrone, Carboplatin and Cyclophosphamide and the other received the

high dose Melphalan protocol. Two patients had multiple myeloma and were treated with high dose Melphalan and total body irradiation. A patient with Hodgkin's Disease and another with a lymphoma were treated with high dose Melphalan alone. One patient had a malignant brain tumour (oligodendroglioma) and was treated with a Throtepa.

Unlike the inpatient group, the majority of outpatients had a diagnosis of lymphoma (10 or 48%, 95% C.I. = 27% to 69%). Of these patients, 9 (90%) were treated with high dose Melphalan and one was treated with Melphalan and total body irradiation. Of the 5 (24%) breast cancer patients, 4 were treated with a protocol consisting of Mitoxantrone, Vinblastine and Cyclophosphamide and one was treated with Melphalan. Three patients with Hodgkin's Disease, 1 with multiple myeloma and 1 with amyloidosis and 1 with neuroblastoma were all treated with Melphalan.

Table 3.1

Summary of Patients' Cancer Diagnoses and Treatment Protocols

DIAGNOSIS	INPATIENTS n=20		OUTPATIENTS n=21	
	n	%	n	%
Breast Cancer	15	71	5	24
Lymphoma	1	5	10	48
Hodgkin's Disease	1	5	3	14
Multiple Myeloma	2	10	1	5
Oligodendroglioma	1	5	0	
Amyloidosis	0		1	5
Neuroblastoma	0		1	5
TREATMENT PROTOCOL				
Mitoxantrone, Vinblastine, Cyclophosphamide	13	65	4	19
Melphalan	3	15	16	76
Melphalan, Total Body Irradiation	2	10	1	5
Mitoxantrone, Carboplatin, Cyclophosphamide	1	5		
Throtepa	1	5		

The proportion of patients whose disease relapsed or whose disease did not respond to previous chemotherapy, also differed between groups. These two conditions, although not mutually exclusive, generally describe patients who are deemed to have experienced 'treatment failure' prior to entering the

ABSCT program. The difference between groups with respect to treatment failure is important since past experience could influence physical, psychological and social well-being of individuals.

In this study, 7 or 35% (95% C.I. =14% to 56%) of the inpatients and 15 or 71% (95% C.I. =52% to 92%) of the outpatients had experienced previous treatment failure (P=.021). The confidence intervals barely overlap suggesting the groups may differ with respect to the proportion of patients who experience treatment failure (Table 3.2). Replication with a larger sample may provide conclusive evidence of the distinctiveness between the study groups.

Table 3.2

Treatment Failure

	INPATIENTS n=20			OUTPATIENTS n=21		
	n	%	95% C.I.	n	%	95% C.I.
Total Patients with Relapse of Disease	5	25	6% to 44%	12	57	35% to 79%
breast cancer	4			2		
hodgson's disease	1			3		
lymphoma				7		
Total Patients with Failure to Respond to Chemotherapy	4	20	3% to 37%	11	52	31% to 73%
breast cancer	3					
hodgkin's disease				2		
lymphoma	1			7		
multiple myeloma				1		
neuroblastoma				1		
Total Patients with Treatment Failure	7	35	14% to 56%	15	71	52% to 92%

3. Education and Employment

Overall, education, occupation and employment status of the inpatient and outpatient groups were similar. Accerding to the Dictionary of Occupational Titles, the majority of subjects in both groups were engaged in occupations classified as Professional, Technical and Managerial (45%; 95% C.I.=23% to 67% and 52%; 95% C.I.=31% to 73%, for inpatients and outpatients respectively). As well, the majority of inpatients (70%) and outpatients (81%) were employed either full-time or part-time.

Detailed comparison of inpatients and outpatients with respect to level of education showed that 60 % (95% C.I.= 39% to 82%) and 52% (95% C.I.=31% to 73%) respectively had completed some or all post secondary education. Of interest was that a relatively large proportion (30%) of inpatients did not complete high school. There were no outpatients who did not complete high school.

4. Family Structure

This section describes a number of family related variables. Table 3.3 describes the family structure of the patients in both groups. The majority of inpatients lived with a partner or lived with a partner and children aged 12 years or older. The same was true for the outpatient group.

Table 3.3

Family Structure

FAMILY STRUCTURE	INPATIENT			OUTPATIENT		
	freq.	%	95% C.I.	freq.	%	95% C.I.
Lives alone or Single & Children =>12	3	15	0% - 30%	3	14	0% - 29%
Single & Children <12	0	0		1	5	0% - 14%
Partner or Partner & Children =>12	14	70	50% - 90%	10	48	27% - 69%
Partner & Children <12	3	15	0% - 30%	7	33	13% - 53%

5. Living Arrangements

This section which describes living arrangements reported participants' place of residence and whether there was a change in living arrangements during the period after ABSCT. As shown in Table 3.4, for both the inpatient and the outpatient groups, the number of subjects who lived in the same city where treatment was obtained (Calgary or Edmonton) appears to be similar.

Table 3.4

Patients' Place of Residence

Place of Residence	INPATIENTS			OUTPATIENTS		
	n	%	95% C.I.	n	%	95% C.I.
City (Calgary or Edmonton)	8	40	19% to 62%	12	57	36% to 78%
Southern Alberta	4	20	2% to 38%	6	29	10% to 48%
Northern Alberta	2	10	0% to 23%	1	5	0% to 14%
Out of Province	6	30	10% to 50%	2	10	0% to 23%

The proportion of subjects and caregivers in both groups who experienced relocation was similar. Among caregivers of inpatients, 13 or 65% (95% C.I.= 44% to 86%) continued living in their home for the period after ABSCT. Two caregivers were able to live with family or friends and 5 were required to live in a hotel or hostel.

To make outpatient care possible, intense monitoring and follow-up during the period after the ABSCT is necessary. Since outpatients were

required to have easy access to the hospital (i.e., reside within 45 minutes driving time of the hospital), alternative living arrangements were necessary in some circumstances. Eleven outpatients with their caregivers (52%; 95% C.I.= 31% to 73%) were able to live at home. Living arrangements for 9 outpatients and caregivers from out of town included 5 who lived in a hotel, hostel or apartment; 4 lived with friends or family.

6. Patients' Preference for Inpatient or Outpatient Care

Of the 41 subjects in this study, 46% preferred inpatient care and 49% preferred the outpatient option. Of those who preferred inpatient care, 90% were actually cared for in the hospital environment following transplant. Of those who preferred outpatient care, 86% were actually cared for in this way. The vast majority of patients received the type of care they preferred. Patients' preference for one mode of care or another was influential in the physician's decision regarding inpatient or outpatient care following transplant. The potential for bias as a result of this form of self selection into the control group or experimental group will be discussed later in Chapter 4. Patients' reasons for their preference will also be presented later in this chapter.

B. Personal Characteristics of Caregivers

Overall, there were 18 participant caregivers in the inpatient group and 19 in the outpatient group. Two outpatients did not have designated caregivers despite this requirement for eligibility for outpatient care.

1. Gender and Age

In the inpatient group 12 (67%; 95%C.I.= 45% to 89%) of the caregivers were male. Similarly, in the outpatient group 11 (58%; 95%C.I.= 36% to 80%) of the caregivers were male. This was expected since the majority of patients in

each comparison group were female and the main caregiver was generally a spouse. This slight difference in proportions may reflect the slight difference in the proportion of female subjects in each comparison group, where there were slightly more women in the inpatient group.

The outpatient caregiver group was generally younger than the inpatient group. This is consistent with the slight age difference between patient groups where outpatients were slightly younger. The age distribution of caregivers of inpatients was close to normally distributed. However, for the outpatient group the age distribution of the caregivers was positively skewed. A large number of the caregivers in the outpatient group were narrowly dispersed at the younger range of age (Q1= 36, Q2= 40, Q3= 53). The median ages of caregivers in the inpatient and outpatient groups were similar at 49 years (95% C.I.= 42 years to 56 years) and 40 years (95% C.I.= 34 years to 46 years) respectively.

2. Relationship of Caregiver

In the inpatient group, 83% of the caregivers were a spouse. The remaining 3 caregivers were a mother, a sibling and a child. In the outpatient group, 79% were spouses. Three outpatients were cared for by a friend and 1 by a mother.

In the inpatient group, a small number (3 or 17%, 95% C.I.= 0% to 34%) of caregivers had previously cared for someone who was seriously ill. All caregivers had provided care in the home setting. More caregivers (7 or 37%, 95% C.I.= 15% to 59%) (P= .057) from the outpatient group had previously cared for someone who was seriously ill. Although the confidence intervals overlap, a larger sample size could add precision to this estimate, allowing for a more definitive conclusion.

Previous experience of caring for someone with a serious illness may

provide a caregiver and patient with the confidence required to participate in outpatient care. Even though more caregivers in the outpatient group had past experience in caring for someone with a serious illness, the reasons given by patients who preferred the outpatient mode of care was not because of the caregivers' past experience.

In this study, the number of caregivers with previous experience was too small to consider the impact of past experience on caregiver esteem, anxiety and preference for outpatient care. In a larger study, the value of past experience as a predictor of successful coping with outpatient care could be examined more precisely.

3. Education and Employment of Caregivers

In summary, educational attainment and employment status for caregivers of both groups were similar. For the inpatient group the majority of caregivers' occupations were classified as 'Professional', whereas in the outpatient group the majority of occupations were classified as 'Clerical/Sales'.

In comparing the level of formal education of the caregivers in each study group, 89% (16) of the caregivers in the inpatient group had completed high school or greater. As well, 38% of these caregivers completed post secondary education. In the outpatient group, 95% of the caregivers completed high school or more; 32% of these caregivers completed post secondary education.

Of the 72% of caregivers in the inpatient group who were employed, most (85%) were employed full-time. Similarly, of the 84% of the caregivers in the outpatient group who were employed, 88% were employed on a full-time basis. Of the caregivers who were not employed, their status was retired, unemployed or student.

C. Baseline Measures

1. Baseline Physical Status

Physical status in this study includes a variety of measures. The following baseline measures of morbidity, pain, physical well-being, functional well-being and additional health concerns were compared between the inpatient and outpatient groups.

a) Level of Morbidity and Pain

Morbidity is indicated by the Karnofsky score. This standard morbidity measure reflects the extent to which illness has disrupted an individuals' normal activity pattern. The majority (45%) of inpatients registered a Karnofsky score of 90%, indicating the ability to carry on normal activity and with minor signs or symptoms of disease (95% C.I. = 23% to 67%). Score ranged from 70% (able to care for self; but unable to carry on normal activity or do active work) to 100% (normal level of activity; no complaints; no evidence of disease).

The Karnofsky score for the majority (57%) of outpatients was 90% (95% C.I. = 36% to 78%). Scores ranged from 70% to 100%. These data are shown in Table 3.5.

Table 3.5

Karnofsky Performance Score by Mode of Care at Baseline

KARNOFSKY PERFORMANCE SCORE	INPATIENTS			OUTPATIENTS		
	n	%	cum. %	n	%	cum.%
70 percent	5	25	25	4	19	19
80 percent	5	25	50	3	14	33
90 percent	9	45	95	12	57	90
100 percent	1	5	100	2	10	100
Total	20	100		21	100	

Participants were asked to rate their pain using a visual analogue scale. For the inpatient group the pain scores were positively skewed, indicating that most patients experienced 'little or no pain'. Therefore, the median and not the mean pain scores are reported. Inpatients' median pain score prior to receiving the high dose chemotherapy was 1 out of 10 (Q1=0, Q3=1, IQR = 1) indicating slight or no pain. Pain scores for outpatients were similar with a median score of 0 (Q1= 0, Q3= 1, IQR = 1).

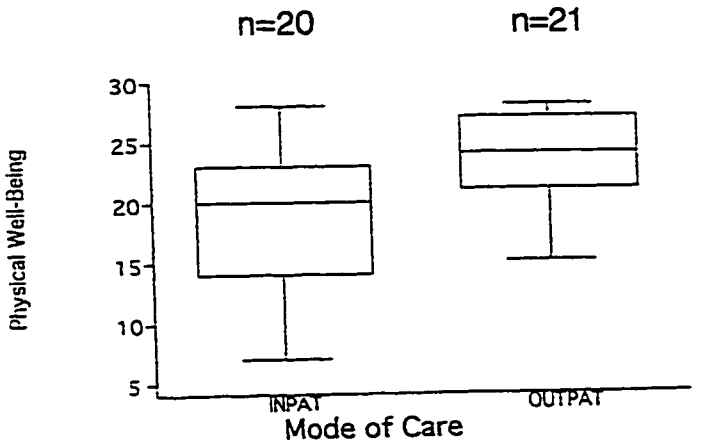
In summary, these results show that the level of morbidity and experience of pain were similarly low for both inpatients and outpatients at the time of the baseline measure.

b) Baseline Physical Well-Being (Quality of Life Measure Subscore)

Physical well-being was measured by a subscale of the overall

quality of life measure, as given by the FACT, BMT tool. A maximum score of 28 is possible, with higher scores indicating an increasingly positive sense of physical well-being. Figure 3 illustrates a large amount of variation in the scores for the inpatient group. The data are slightly negatively skewed because of a number of patients with scores at the upper limit. The median score for the outpatient group was somewhat higher (Outpatient group: median score = 24, 95% C.I. = 22 to 26; Inpatient group: median score = 20, 95% C.I.= 17 to 23). The between group difference of the mean scores was statistically significant (P=.007). Overall, the outpatient group had a more positive sense of physical well-being as indicated by the physical well-being aspect of quality of life.

Figure 3. Physical Well-Being by Mode of Care at Baseline.

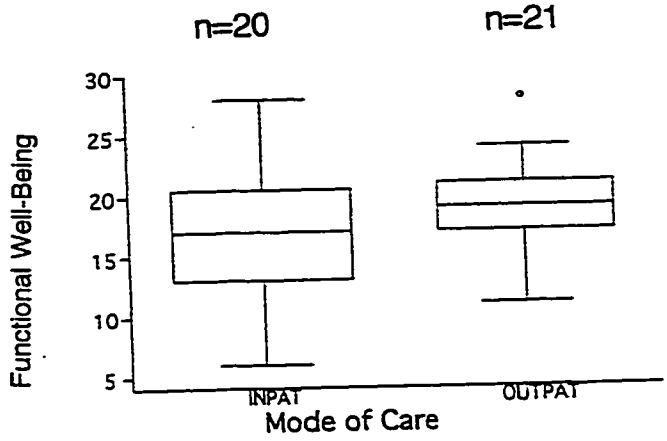


c) Baseline Functional Well-being (Quality of Life Measure Subscore)

Like physical well-being, functional well-being was measured using a subscore of the FACT-BMT. At baseline, scores of functional well-being of both groups were normally distributed. A maximum high score of 28 is

possible. The median scores for the inpatient and outpatient groups were similar at 17 (95%C.I.= 14 to 20) and 19 (95% C.I. = 17 to 21) respectively. The box plots (Figure 4) illustrate the dispersion of scores in the two groups.

Figure 4. Functional Well-Being by Mode of Care at Baseline.

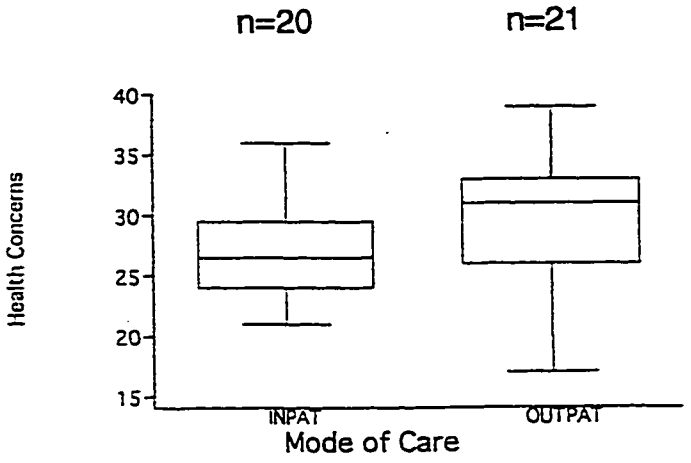


d) Baseline Health Concerns (Quality of Life Measure Subscore)

A subscale of the FACT,BMT poses questions about additional health concerns. Questions about the effects of the transplant included effect on appetite, body appearance, sexual function, fatigue and physical impact of treatment. As well, questions explored patients' concerns about ability to return to normal functioning, ability to maintain personal relationships, worries about the outcome of the transplant and confidence in nursing care. A maximum possible score of 40 indicates minimal concern about additional health issues that could be affected by the transplant. The scores for both groups were normally distributed. Again, box plots shown in Figure 5 illustrate the distribution of the scores of the two groups. Even though there is a slight

overlap in the confidence intervals, the median scores differed between the groups (Inpatient group median = 26.5, 95% C.I. = 24 to 29; Outpatient group median = 31, 95% C.I. = 28 to 34). The mean scores (P= .037) also differed significantly between groups. These results suggest that outpatients had fewer concerns about their health in areas other than problems related to their cancer diagnosis.

Figure 5. Additional Health Concerns by Mode of Care at Baseline.



2. Baseline Psychological Well-being

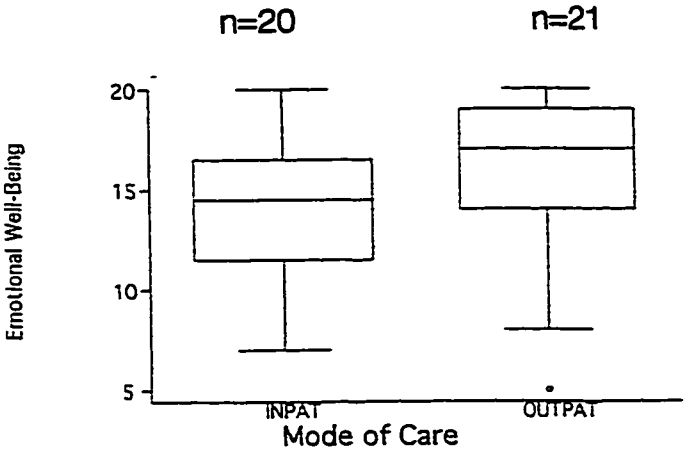
Psychological well-being of the inpatient and outpatient groups at baseline was determined by measuring emotional well-being, anxiety, depression and perception of control.

a) Baseline Emotional Well-Being (Quality of Life Measure Subscore)

Emotional well-being was scored out of 20 using the FACT,BMT instrument. The scores for inpatients was normally distributed. The scores of the

outpatient sample were negatively skewed, indicating that more outpatients had scores in the higher range. In comparing the box plots in Figure 6, the median scores of inpatients' was lower than outpatients' (14.5; 95%C.I.= 12.5 to 16.5 and 17; 95% C.I. = 15 to 19 respectively). The confidence intervals overlap very little suggesting that the groups may differ in this aspect of well-being. Statistical comparison of the mean scores was not undertaken because the outpatients' scores were not normally distributed. Replication with a larger sample would provide definitive data. Outpatients appeared to have slightly better emotional well-being.

Figure 6. Emotional Well-Being by Mode of Care at Baseline.



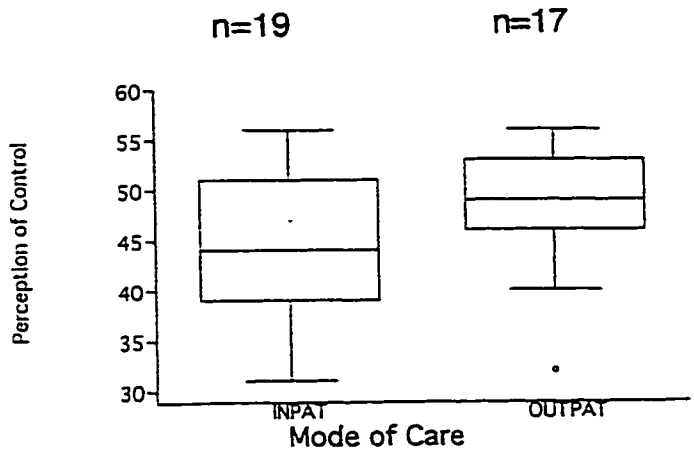
b) Baseline Perception of Control

Perception of control was expressed as a total score with a maximum possible score of 56 indicating a great deal of control and effective ways of maintaining control. Subscores were also obtained in the following areas: control of emotions and symptoms, control of relationships, control of medical care and control over the course of disease. Results for the total score for perception of control and the subscore for perception of control over medical

care are presented.

The distribution of scores for perception of control are shown in Figure 7. The IQR for the inpatient group (Q1=39, Q3=51, IQR=12) was wider than the IQR for the outpatient group (Q1=46, Q3=53, IQR=7), indicating a wider range in scores for perception of control among inpatients. The outpatient scores were negatively skewed as a result of an outlier at the low end of the scale. The difference in median scores of both groups at baseline was similar (Inpatient median score= 44, 95% C.I. = 40 to 48; Outpatient median score= 49, 95% C.I. = 45 to 53).

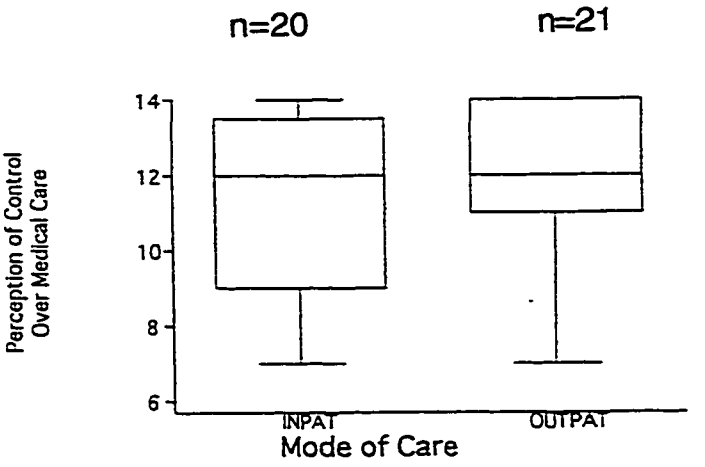
Figure 7. Perception of Control by Mode of Care at Baseline.



Perception of control over medical care is a relevant issue in considering the impact of outpatient management of ABSCT. Therefore, the following is a description of patients' perception of control over their medical care at baseline (Figure 8). A maximum score of 14 indicates that the subject perceives having a great deal of control over their medical care. The distribution of scores in both groups were negatively skewed (more high scores). Both groups had a large number of maximum scores (14). The median scores for both groups were the

same at 12, indicating that generally patients in both groups had a fairly strong sense of control over their medical care .

Figure 8. Perception of Control Over Medical Care by Mode of Care at Baseline.

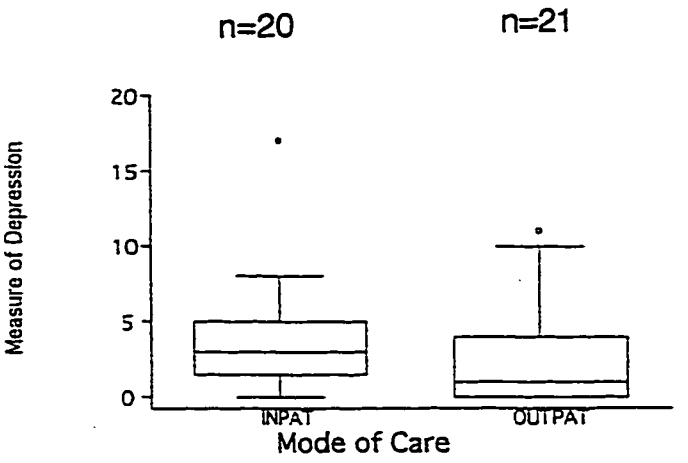


c) Baseline Measure of Depression and Anxiety

Overall, levels of depression and anxiety as indicated by the POMS, were similar for both study groups. As well, the scores indicated that generally few individuals suffered from depression and anxiety.

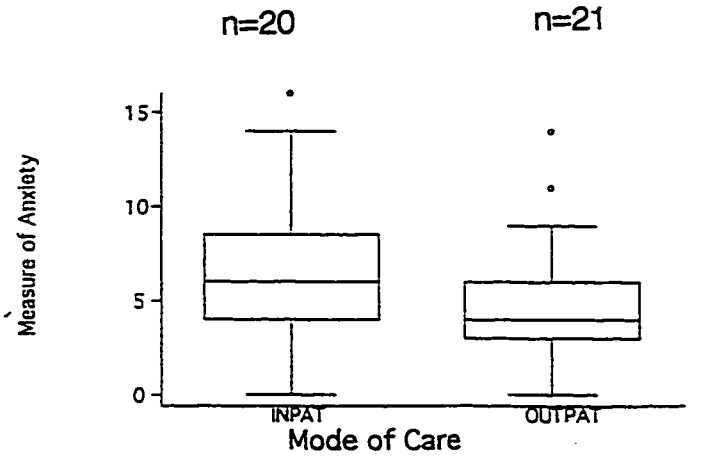
A subscore of the POMS provides a measure of depression, with higher scores (up to a possible score of 20) indicating higher levels of depression. It is evident from the box plots (Figure 9) that the distribution of depression scores for both groups was positively skewed, indicating most patients had little or no depression. The median scores for depression were similar for the comparison groups, with the inpatient median score of 3 (95% C.I. =1 to 5) and the outpatient median score of 1 (95%C.I.= 0 to 3). Each group had one individual with extreme high scores.

Figure 9. Measure of Depression by Mode of Care at Baseline.



The POMS also provides a measure of anxiety, with higher scores indicating higher levels of anxiety. With a maximum possible score of 20, the distribution of scores was positively skewed, indicating that more patients had low levels of anxiety. This was more evident in the outpatient group. The median scores were low and similar for both groups (Inpatient = 6, 95% C.I.=4 to 8; Outpatient = 4, 95% C.I.= 3 to 6).

Figure 10. Measure of Anxiety by Mode of Care at Baseline.



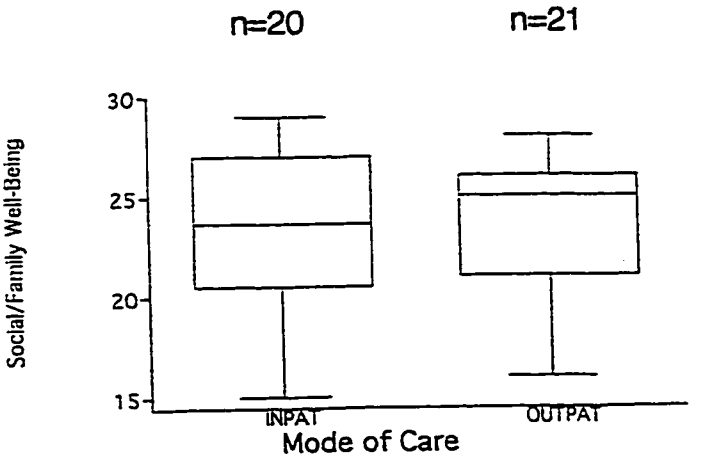
3. Baseline Social Interaction

The aspect of social interaction includes 3 components. The FACT,BMT Quality of Life tool provides measures of patients' social and family well-being and their relationship with their physician. The Caregiver Reaction Assessment tool provides measures of the burden placed on the caregiver.

a) Baseline Social/Family Well-being (Quality of Life Measure Subscore)

Social well-being was indicated by a subscore from the FACT,BMT Quality of Life measure. The maximum possible score, indicating a high level of social well-being, was 28. It is evident, as seen in Figure11 that the scores of the outpatient group are slightly negatively skewed as a result of more patients with high scores. However, the median scores for the inpatients and outpatients was similar (23; 95% C.I. = 21 to 25 and 25; 95% C.I. = 23 to 27 respectively).

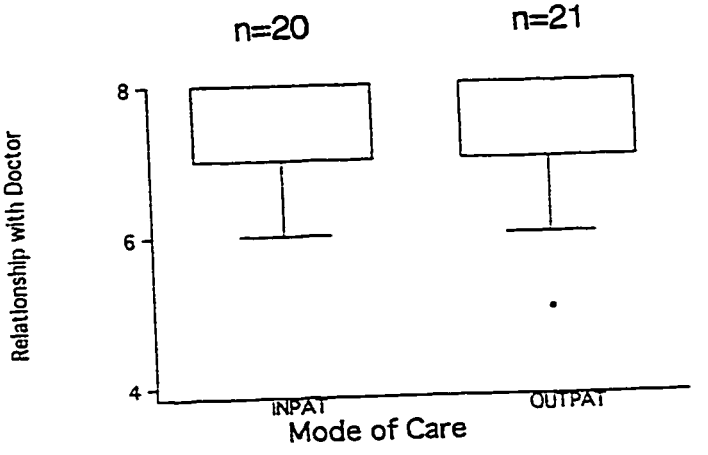
Figure 11. Social/Family Well-Being by Mode of Care at Baseline.



b) Baseline Relationship with Doctor (Quality of Life MeasureSubscore)

This subscale assesses the subject's confidence in and availability of the physician. As evident from the box plots in Figure 12, the scores for both the inpatient and outpatient groups are negatively skewed suggesting that most patients had a positive relationship with their physician. The median score for the inpatient and outpatient groups was 8. The box plots illustrate that the median score and distribution for both groups was similar and the range of scores were very narrow.

Figure 12. Relationship with Doctor by Mode of Care at Baseline.



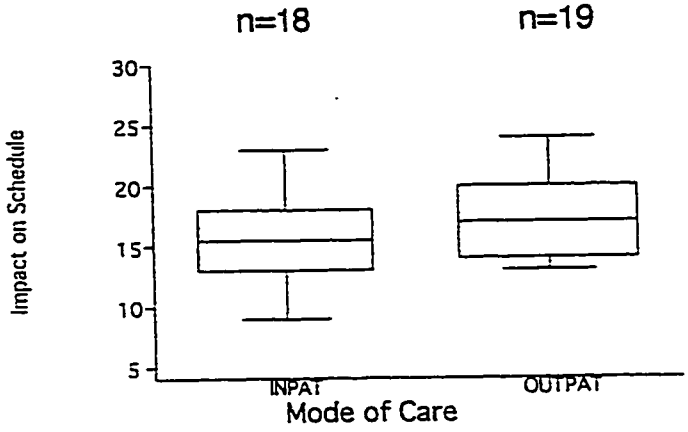
c) Baseline Caregiver Burden

This instrument was used to obtain input from caregivers about the impact of the two methods of care. Five areas were assessed including: impact on schedule, caregiver's esteem, family support, impact on health and impact on finances. Each area is described separately and the caregivers' responses are compared for both the inpatient and the outpatient groups.

Impact on Schedule: The measure of impact on the caregiver's schedule

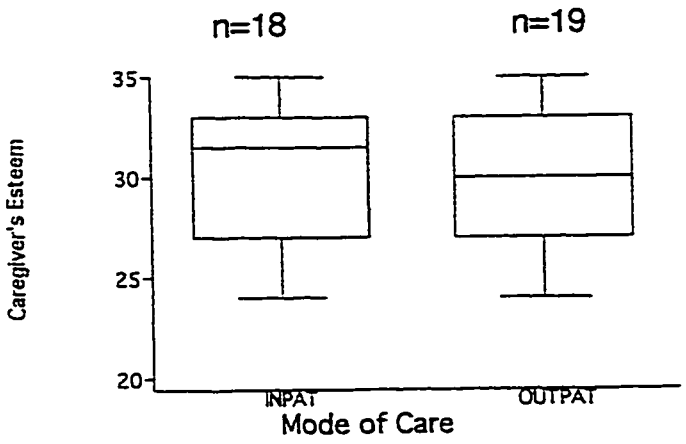
has a maximum possible score of 25, with higher scores indicating a greater impact. The scores for both groups were close to being normally distributed. The range of scores for the inpatient group were somewhat broader, suggesting that some caregivers in this group rated the impact on their schedule as less than the outpatient group. These data suggest that caring for a cancer patient, even at baseline, has a great impact on the caregivers' schedule. However, the median score for the inpatient caregivers was 15.5 (95% C.I.= 13 to 18) which was similar to the outpatient caregivers' score at 17 (95% C.I.= 15 to 19).

Figure 13. Impact on Caregivers' Schedule by Mode of Care at Baseline.



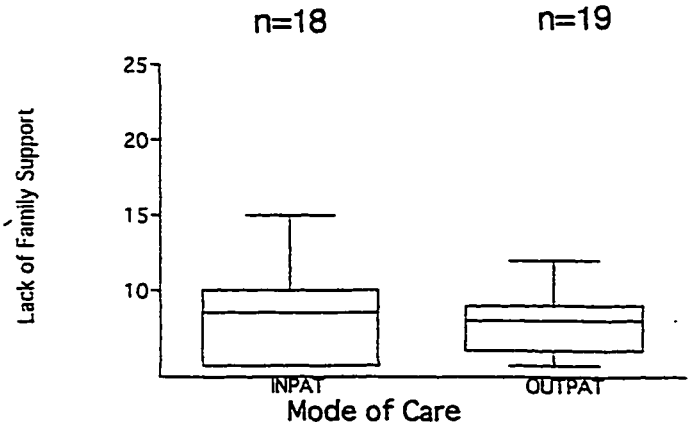
Caregivers' Esteem: Caregiver's esteem reflects the desire, comfort and fulfilment in caring for the patient. A maximum score of 35 is possible. Higher scores indicate a greater desire and comfort with caring for the patient. As shown in Figure 14, although the range of scores was similar for both groups, the distribution of scores of the inpatient group was somewhat negatively skewed, suggesting better esteem. A larger number of caregivers in the inpatient group conveyed higher scores. The median scores for both groups were high and similar (Inpatient median = 31.5, 95% C.I.= 28 to 33; Outpatient median = 30, 95% C.I.= 28 to 33).

Figure 14. Caregivers' Esteem by Mode of Care at Baseline.



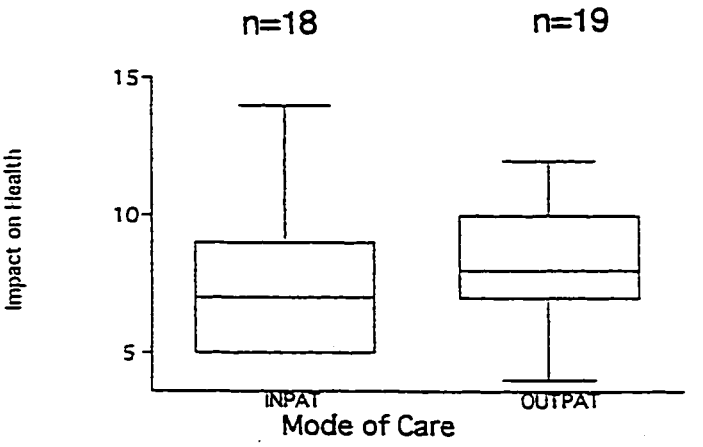
Family Support: Family support can have a great effect on the caregiver's ability to care for the patient. Higher scores on this measure, up to a possible maximum of 25, indicates diminishing family support. The box plot in Figure 15 suggests that in both groups the distribution was slightly positively skewed meaning that caregivers had adequate support (low scores). Generally, both groups indicated adequate family support with the median scores being similar for both the inpatient caregivers (8.5, 95% C.I.= 7 to 10) and outpatient caregivers (8 , 95% C.I.= 7 to 9).

Figure 15. Family Support by Mode of Care at Baseline.



Impact on Health: Out of a possible score of 20, with higher scores indicating a greater impact, caregivers were asked to consider the impact on their own health when caring for the patient. In viewing the box plots in Figure 16, both caregiver groups felt the impact on their health was minimal, as indicated by the positively skewed dispersion of responses. In comparing the median scores for both groups, the inpatient median score was 7 (95% C.I.= 5 to 9) and for the outpatient median score was 8 (95% C.I.= 7 to 9). Both scores were at the low end of the range and similar.

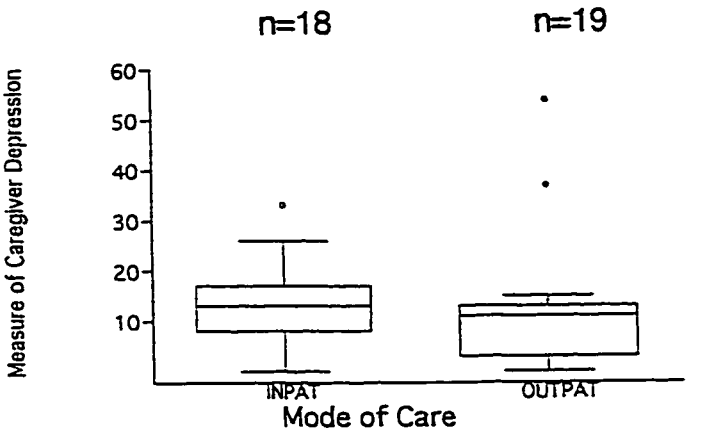
Figure 16. Impact on Caregivers' Health by Mode of Care at Baseline.



Caregivers' Depression: The caregiver's level of depression was measured using the CES-D tool. This tool is able to identify individuals experiencing depression from those who are not. The possible range of scores is from 0 to 60, with higher scores reflecting greater distress. A score of 16 or higher indicates depression. Caregivers' scores in the outpatient group were positively skewed, indicating a lower incidence of depression. Within the outpatient group, two caregivers indicated extreme scores (37 and 54). All other scores in this group were below 16 indicating an absence of depression.

The dispersion of scores for the inpatient group was more normally distributed (see Figure 17). Because of the skewness of the outpatient group, the IQR and the median scores for both groups were similar (inpatient caregiver median score of 13, 95% C.I.= 8 to 18; outpatient caregiver median score of 11, 95% C.I.= 4 to 13).

Figure 17. Measure of Caregivers' Depression by Mode of Care at Baseline.

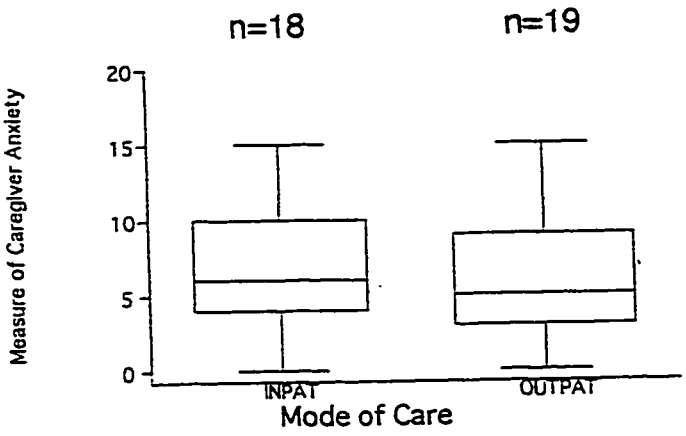


Overall, 39% (95% C.I.= 16.5% to 58.5%) of the caregivers from the inpatient group indicated depression compared with 11% (95% C.I. = 0% to 25%) from the outpatient group. The confidence intervals are wide and do overlap. However, the proportion of caregivers in the inpatient group with depression was significantly greater than those in the outpatient group (P=.038).

Caregivers' Anxiety: Caregivers' level of anxiety was measured using the POMS tool. The highest possible score is 20, indicating a high level of anxiety. The range of scores for both groups was from 0 to 15. The distribution of responses from outpatient caregivers was positively skewed, indicating that more caregivers experienced low levels of anxiety (see Figure 18). The anxiety

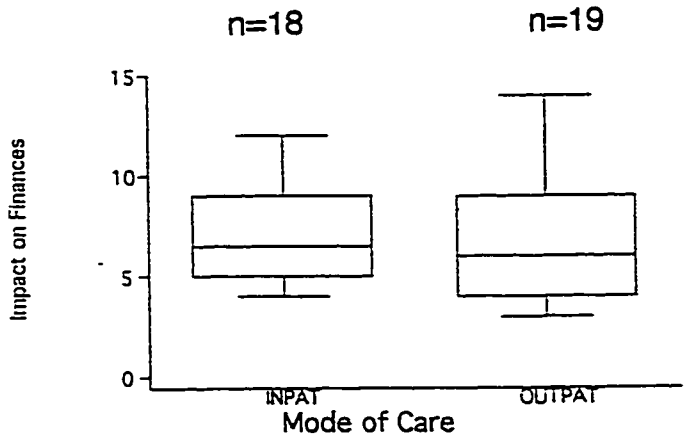
scores of inpatient caregivers was more evenly dispersed throughout the range of scores. Caregivers of both groups indicated low levels of anxiety with the median scores being similar. The median score for the inpatient caregivers was 6 (95% C.I.= 4 to 10) and 5 (95% C.I.= 3 to 8) for the outpatient caregivers.

Figure 18. Measure of Caregivers' Anxiety by Mode of Care at Baseline.



Impact on Finances: In comparing the box plots (Figure 19) that represent the financial impact of caring for patients in both groups prior to the transplant, the range of scores appear to be slightly wider in the outpatient group. Both groups were close to being normally distributed, however, slightly positively skewed suggesting low impact on finances. Out of a possible maximum score of 15 (high financial impact), the median scores for the inpatient and outpatient groups were 6.5 (95% C.I.= 5 to 8) and 6 (95% C.I.= 4 to 8) respectively. Both groups indicated a moderate impact on their finances with consideration to their out-of-pocket expenses of treatment during the time prior to ABSCT.

Figure 19. Impact on Finances by Mode of Care at Baseline.



4. Baseline Global Quality of Life

The following section provides a comparison between groups for overall quality of life (QOL) prior to the ABSCT. Quality of life, as measured by the FACT,BMT consists of the sum of a variety of subscores including physical well-being, social well-being, emotional well-being, functional well-being, relationship with doctor and bone marrow transplant concerns. The higher the score the better the quality of life. The highest possible score for this measure is 152. The scores for both groups were close to normally distributed, therefore all calculations were performed with the assumption of a normal distribution.

A comparison of the distribution of the overall QOL scores for the inpatient and outpatient groups is depicted by Figure 20. The median scores were 104 (95% C.I.=94 to 114) and 122 (95% C.I.= 112 to 132) respectively. The confidence intervals of the median scores of the two groups overlap very little despite the width of the intervals that result from the small sample size. For this reason it can not be reliably concluded that the median scores are similar. Statistical comparison of the mean scores indicates the difference between the

groups was significant (P=.043) and not the result of chance. This result suggests that outpatients were experiencing a better quality of life prior to ABSCT.

Figure 20. Global Quality of Life by Mode of Care at Baseline.

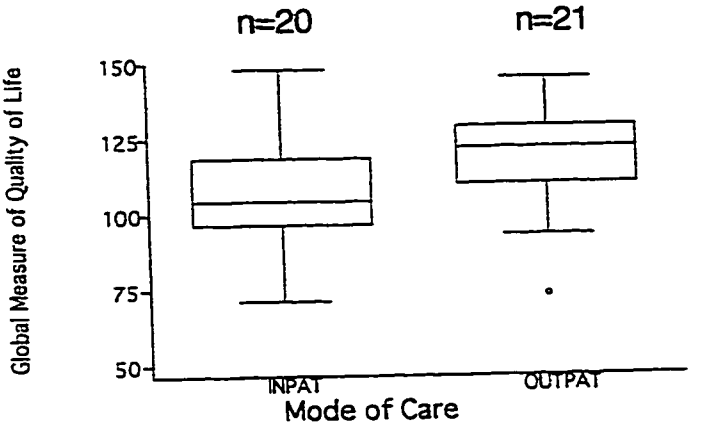


Table 3.6

Summary of Baseline Measures

BASELINE MEASURES	Median Scores	
PHYSICAL STATUS	INPATIENTS	OUTPATIENTS
Physical Well-Being *	20	24
Functional Well-Being	17	19
Additional Health Concerns*	26.5	31
PSYCHOLOGICAL WELL-BEING		
Emotional Well-Being	14.5	17
Perception of Control	44	49
Perception of Control Over Medical Care	12	12
Depression	3	1
Anxiety	6	4
SOCIAL INTERACTION		
Social/Family Well-Being	23	25
Impact on Caregiver Schedule	15.5	17
Caregivers' Esteem	31.5	30
Family Support	8.5	8
Impact on Caregiver Health	7	8
Caregivers' Depression	13	11
Caregivers' Anxiety	6	5
Impact on Finances	6.5	6
GLOBAL QUALITY OF LIFE *	104	122

*P <.05

N. Summary

In summary, the comparison of the inpatient (control) and the outpatient (experimental) groups revealed some important differences at baseline. Firstly, there was a difference in the patients' cancer diagnosis and therefore a difference in the high dose chemotherapy protocols used. The majority of the inpatients (71%) were diagnosed with breast cancer and treated with Mitoxantrone, Vinblastine and Cyclophosphamide. Whereas in the outpatient group, the majority of the patients were diagnosed with lymphoma (48%) and treated with high dose Melphalan. It is also important to note that 24% of outpatients were diagnosed with breast cancer. Perhaps outpatients with breast cancer are similar to inpatients with breast cancer with respect to the measures of interest in this study. If this is the case, inpatients and outpatients will tend to look more similar in their scores. Secondly, there was a difference in educational levels between both groups. All of the patients in the outpatient group had completed high school, compared with only 70% of the inpatient group. Thirdly, more outpatients (71%) experienced treatment failure compared to inpatients (35%). Fourthly, in considering overall quality of life, outpatients expressed a better overall quality of life at the time of the baseline assessment. Finally, physical well-being was rated as higher by the outpatients and outpatients had fewer concerns about health problems.

There were also differences between the caregivers of the inpatient and the outpatient group at baseline. Firstly, caregivers of outpatients (37%) had more experience in providing care for someone who was seriously ill compared to caregivers of inpatients (17%). Secondly, a greater number of caregivers in the inpatient group had experienced depression compared to the outpatient caregivers.

Although not statistically significant, outpatients tended to rate better than inpatients on most other measures: morbidity, functional well-being, emotional well-being, perception of control, depression, anxiety and social and family well-being. Caregivers of outpatients also fared better than their inpatient counterparts as shown by ratings on impact on schedule, family support, impact on health and anxiety.

Finally, it is also important to note that when patients were asked if they preferred to be cared for as an inpatient or outpatient, in almost all cases their preference was consistent with the modality they received.

IV. Physical Status

A description and comparison of patients' physical status in the two modes of care will be undertaken in this section. Physical status is indicated by level of morbidity, occurrence of significant of toxicity, patient's perception of severity of side-effects and three aspects of quality of life: physical well-being, functional well-being and health concerns. All measures were taken at day 4 to 6 and day 12 to 16. At day 30, only the aspects of quality of life were measured. By day 30, patients were feeling better and most were back in their home.

The relationship between physical status and age, cancer diagnosis and type of treatment protocol would have been interesting to consider when comparing the experience of inpatients and outpatients, however these analyses were not possible due to the small sample size in one or both study groups.

In summary, the analysis showed that overall, physical status as indicated by level of morbidity, perception of side-effects, experience of toxicities, and physical and functional well-being of the outpatient group was no worse than the inpatient group and for some specific aspects of physical status (eg. morbidity, physical well-being), in fact had better scores at day 4 to 6 compared to inpatients. It is difficult to draw conclusions about better scores among outpatients at day 4 to 6 since the sample size was small and the groups differed with respect to type of cancer and type of treatment protocol that was used.

Once patients had begun to feel better (by day 12 to 16), there was evidence that physical and functional aspects of quality of life improved earlier for outpatients. The main reason outpatients were admitted to hospital was for intravenous therapy to treat elevated fever, mouth sores and dehydration. Although most (19/21) outpatients were admitted to hospital, overall, they spent significantly less time in the hospital compared to inpatients.

A. Level of Morbidity

Patients' level of morbidity was measured using the Karnofsky Performance Status Scale. A Karnofsky score of less than 70% indicates that a person requires assistance with caring for his/her own needs or requires special medical care and assistance. These patients are considered to be 'sick' and may require hospitalization. Thus for the purpose of this study, a Karnofsky score of less than 70% indicates significant morbidity.

At day 4 to 6, 78% of the inpatients had significant morbidity (95% C.I. 58% to 97%). For the outpatient group, only 37% of the patients had the same level of morbidity (95% C.I.= 15 % to 58%). Although there was a significant difference between groups in the proportion of patients with a high morbidity (P=

.012) the difference is not likely related to whether patients received care as inpatients or outpatients but rather, it is more likely related to the different drug treatment protocols used in each group. Breast cancer patients (who dominated the inpatient group) received Mitoxantrone, Vinblastine and Cyclophosphamide. Side-effects were at their worst around day 2 to 4 after the ABSCT. In comparison the patients who received high-dose Melphalan (the majority of outpatients) experienced side effects at their worst around day 6 or 7. With this in mind, it was not surprising that the inpatient group had a higher level of morbidity at day 4 to 6, as 65% of this group were treated with high-dose Mitoxantrone, Vinblastine and Cyclophosphamide whereas 76% of the outpatient group were treated with high-dose Melphalan.

The level of morbidity at day 12 to 16 presents a very different picture. By this point in time the side-effects from all the high dose protocols were improving. In the inpatient group, 24% of the patients experienced significant morbidity (95% C.I.=4% to 44%), while the proportion in the outpatient group was 53% (95% C.I.= 31% to 75%). The confidence intervals are broad and overlap suggesting that there was no difference between groups in level of morbidity at day 12 to 16. However, this conclusion is tenuous in light of the small sample size.

B. Occurrence of Significant Toxicity

Toxicities from the side-effects of the high-dose chemotherapy were measured using two grading systems: the NCIC Expanded Common Toxicity Criteria and the Regimen-Related Toxicity For High-Dose Chemotherapy. These measures were used to grade toxicities that occur between day 0 and day 7 and again between day 8 and day 14. Thus all toxicities over the 14 day period were accounted for. Because these time intervals do not coincide with

the time intervals used in this study (i.e. measures taken at days 4 to 6, and days 12 to 16) it was not possible to compare the occurrence of toxicities with other measures of physical status such as morbidity. Table 3.7 displays the frequency of side-effects graded as moderate and severe (grade 2 or greater) at days 0 to 7 and days 8 to 14. Moderate and severe side-effects are reported because they are clinically significant, that is, they require medical intervention.

Table 3.7

Occurrence of Significant Toxicities at Day 0 to 7 and Day 8 to 14

SIGNIFICANT TOXICITIES	INPATIENTS N=20			OUTPATIENTS N=21		
	n	%	95% C.I.	n	%	95% C.I.
Fever >38.5 [1]	19	95	86% to 100%	14	67	47% to 87%
Mouth Sores day 0 to 7 [2]	15	75	56% to 94%	15	71	52% to 90%
Mouth Sores day 8 to 14 [2]	3	15	0 to 31%	5	23	5% to 41%
Nausea day 0 to 7	10	50	28% to 72%	15	71	52% to 90%
Nausea day 8 to 14	5	25	6% to 44%	7	35	15% to 55%
Vomiting day 0 to 7	6	30	10% to 50%	9	43	22% to 64%
Vomiting day 8 to 14	0	0		6	29	1% to 48%
Diarrhea day 0 to 7 [2]	2	10	0 to 23%	1	5	0 to 14%
Diarrhea day 8 to 14 [2]	2	10	0 to 23%	1	5	0 to 14%

[1] indicates at least one occurrence of fever >38.5° C during days 0 - 30

[2] measured by Regimen-Related Toxicity for High-dose Chemotherapy

The frequency of side-effects was found to be similar in the inpatient and outpatient groups at both time intervals. However, the sample size is small and the confidence intervals are broad making this conclusion difficult to support. A larger sample size would provide more precise estimates of the prevalence of these side-effects. The side-effects of nausea and vomiting appear to be slightly higher in the outpatient group. Further, 32% of the outpatients were admitted to hospital because of nausea and vomiting. Nausea and vomiting may be more prevalent in the outpatient group because outpatients may be unable to manage these symptoms as well in the home environment.

Fever (temperature greater than 38.5 o C) was found to be more prevalent in the inpatient group (P = .023). Patients and caregivers of the outpatient group were instructed to monitor the patient's temperature every 4 hours, similar to the hospital routine. The difference between groups may be accounted for by the different treatment protocols. Patients treated with Mitoxantrone, Vinblastine and Cyclophosphamide (majority inpatients) experience a longer period of neutropenia (decreased neutrophils in the blood) and are therefore at greater risk of experiencing fever. The most common side-effect for both groups was mouth sores. Up to 75% of patients experienced this problem.

Other side-effects that occurred but were uncommon were rash (5), paralytic ileus (2), pleural effusion (2), severe weight loss (1), cardiac toxicities (2) and an autoimmune response to the stem cells (1). These side-effects were not specific to one mode of care.

The previous section reported a significant difference between groups with respect to morbidity at day 4 to 6. Further, it was expected that most morbidity is caused by treatment related toxicity. Yet, as shown in the foregoing

analysis, the two groups did not appear to differ with respect to toxicities. This discrepancy in the results is due to use of different time intervals for measuring morbidity and toxicity. Also contributing to the discrepancy is the notion that the morbidity measure reflects a single point in time (day 4 to 6 or day 12 to 16) whereas the toxicity measure reflects the cumulative experience over the entire post-transplant period from day 0 to 14.

C. Perception of Side-Effects

Patients were asked to identify which side-effects were most bothersome at day 4 to 6 and day 12 to 16. The two most bothersome side-effects for both groups were nausea and mouth sores. Table 3.8 lists patients' perception of the side-effects that were 'somewhat' and 'extremely' bothersome. In addition to the side-effects listed in Table 3.8, many other side-effects were reported but the frequency of occurrence was very low.

Table 3.8

Bothersome Side-Effects Reported by Patients at Day 4 to 6 and Day 12 to 16

BOTHERSOME SIDE-EFFECTS	INPATIENTS			OUTPATIENTS		
	n	%	95% C.I.	n	%	95% C.I.
Nausea day 4 to 6	9/19	47	25% to 69%	11/20	55	33% to 77%
Nausea day 12 to 16	6/18	33	11% to 55%	6/19	32	11% to 53%
Mouth Sores day 4 to 6	10/19	53	31% to 75%	9/20	45	23% to 67%
Mouth Sores day 12 to 16	10/18	56	33% to 79%	10/18	56	33% to 79%
Fatigue day 4 to 6	6/19	32	11% to 53%	6/20	30	10% to 50%
Fatigue day 12 to 16	7/18	39	17% to 62%	6/19	32	11% to 53%
Vomiting day 4 to 6	3/19	16	0 to 32%	4/20	20	2% to 38%
Vomiting day 12 to 16	1/18	6	0 to 29%	3/19	16	0 to 32%
Diarrhea day 4 to 6	2/19	11	0 to 25%	2/20	10	0 to 23%
Diarrhea day 12 to 16	4/18	22	3% to 41%	2/29	11	0 to 25%

Nausea was reported at both time periods however the impact seems to have diminished by day 12 to 16. Mouth sores were also reported frequently and the impact at both time periods seems to be equally great. As well, fatigue was reported by one-third of patients and the effect of fatigue did not diminish over time.

At day 4 to 6, there was no differences in the frequency and order of the top three bothersome side-effects between the two groups at the two time intervals. The confidence intervals were broad because of the small sample size and therefore not instructive in determining any difference in the subjective experience of side-effects between groups.

Patients' perceptions of their pain experience at day 4 to 6 and day 12 to 16 was measured using a visual analogue scale. Zero indicated 'no pain' and 10 indicated 'the most severe pain imaginable'. For the analysis, perception of pain was divided into two categories. Patients who described their pain as less than 5 were categorized as having 'little or no pain'. Patients who described their pain as 5 or greater were categorized as having a 'great deal of pain'.

At day 4 to 6, 55% (95% C.I.= 33% to 77%) of the inpatient group were experiencing a 'great deal of pain', whereas 33% (95% C.I.=13% to 53%) of the outpatient group indicated they had a 'great deal of pain'. Although the confidence intervals overlap, the data are suggestive of some between group difference. These data suggest that pain management may be more of an issue for inpatients. It is possible that the different treatment protocols used for inpatients and outpatients as described previously accounts for the between group difference. Unlike the inpatient group, who were experiencing side-effects at their worst at day 4 to 6, outpatients experienced side-effects at their worst slightly later at day 6 to 7 when study measures were not being taken.

Too few patients experience a great deal of pain at day 12 to 16 for analysis of this subgroup to occur.

Consistent with the exploratory purpose of this study, results indicate that symptom management appears to be an important aspect of care, especially for outpatients. More detailed study should be done with care taken to ensure that the periods or points of observation occur at times when symptoms are at their worst.

D. Physical and Functional Well-Being

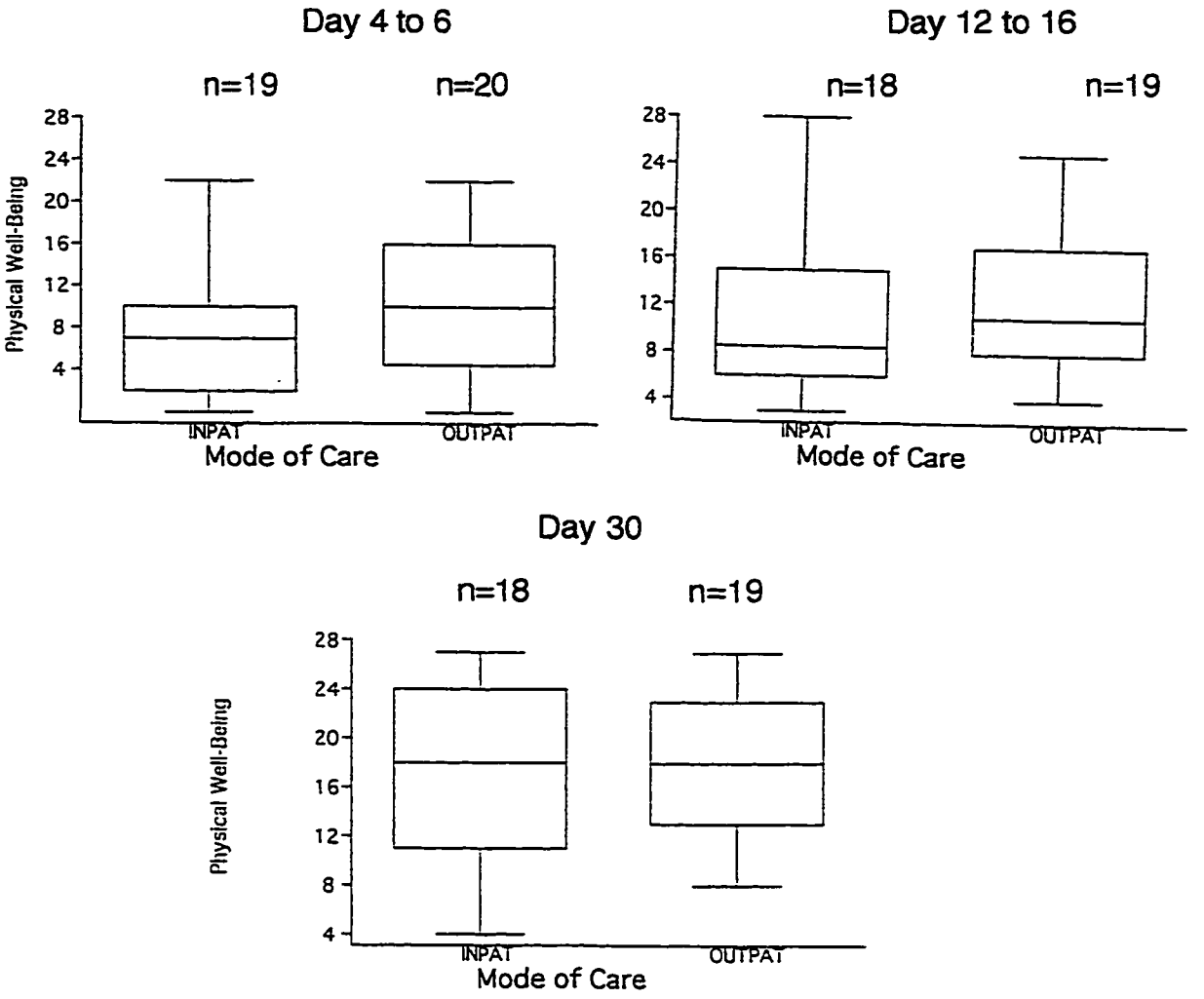
Two other variables that were measured as indicators of physical status were physical and functional well-being. Both of these variables were measured using the FACT,BMT instrument. Physical well-being is a composite measure reflecting the patient's perception of energy level, nausea, pain, discomfort due to side-effects, feeling ill, amount of time spent in bed and ability to meet family needs. A maximum score of 28 indicates good physical well-being. Figure 21 displays the physical well-being scores for the two groups at day 4 to 6, day 12 to 16 and day 30.

Although the range of scores for day 4 to 6 were the same for both groups, the median score (10; 95% C.I.=5 to 16) for the outpatient group was somewhat higher, indicating better physical well-being in comparison to the inpatient group (7; 95% C.I.=3 to 10). This result is consistent with other study variables that measure aspects of physical status, such as morbidity and global quality of life. Again, the observed difference in physical well-being may be the result of different treatment protocols used with the inpatient and outpatient groups.

The measure of physical well-being of the inpatient and outpatient groups at day 12 to 16 and day 30 appeared to be similar with respect to

dispersion of scores and median score.

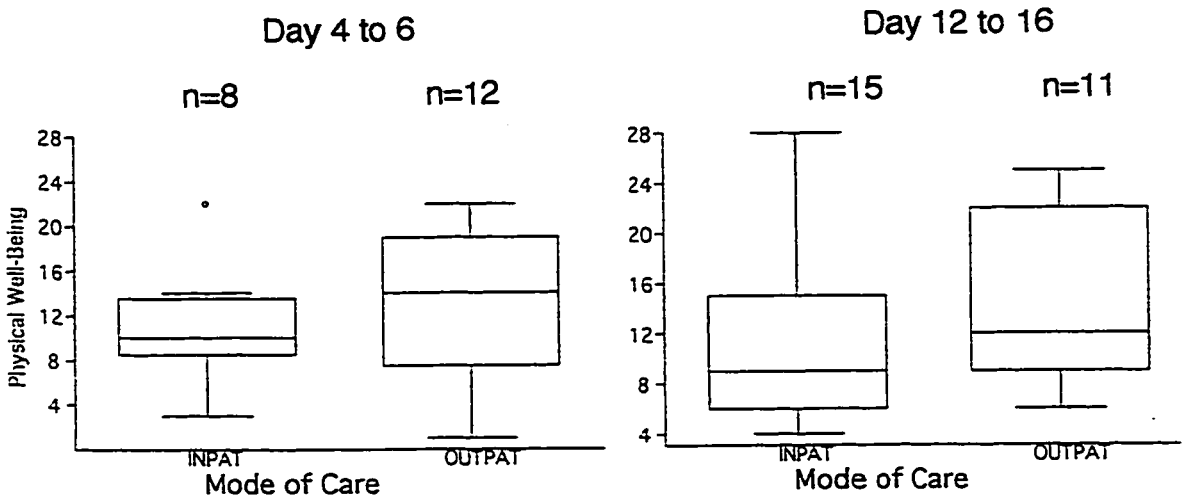
Figure 21. Physical Well-Being by Mode of Care.



For inpatients and outpatients experiencing 'little or no pain' at day 4 to 6, the physical well-being scores were somewhat higher than patients experiencing 'a great deal of pain', as would be expected. Among those patients with 'little or no pain' there was a greater variation in physical well-being scores for the outpatient group, as evident by the interquartile range of 11.5 (Q1=8.5, Q3=13.5) compared to 5 (Q1=7.5, Q3=19) for the inpatient group.

As well, the data suggests that the groups differed in their physical well-being (outpatient median score = 14; 95% C.I.=6 to 20 compared with inpatient group median score = 10; 95% C.I.=6 to 17) (Figure 22). The confidence intervals overlap suggesting no difference, however, the study sample was too small to detect this difference between groups. A similar pattern of scores was seen at day 12 to 16 (Figure 22).

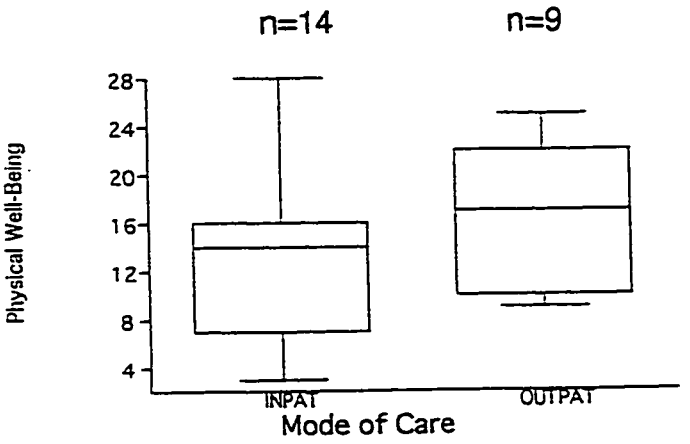
Figure 22. Physical Well-Being of Patients Experiencing 'Little or No Pain' by Mode of Care.



Like pain, outpatients with a low level of morbidity at day 12 to 16 also appeared to have better physical well-being (Figure 23). The outpatients' median score was 17 (95% C.I. = 9 to 23). For inpatients, their median score was lower at 14 (95% C.I.= 7 to 16). Again, the confidence intervals overlap as a result of small sample size. Once morbidity improves, those patients in the outpatient environment appear to experience better physical well-being sooner.

Figure 23. Physical Well-Being of Patients Experiencing Low Morbidity by Mode of Care.

Day 12 to 16



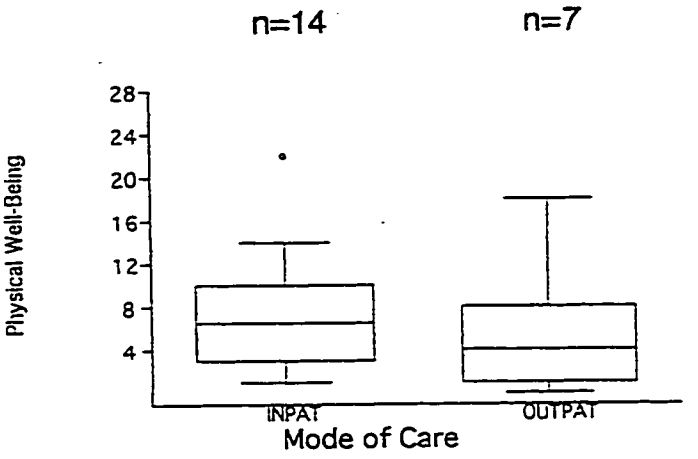
It is possible that morbidity and pain could influence an individual's physical well-being. In this study there was a differential influence of the treatment protocols on physical well-being of inpatients and outpatients, therefore controlling for the effect of the different protocols gives a more precise description of the patients' experience. This analysis is possible by comparing physical well-being among inpatients and outpatients who have similar levels of morbidity or pain. Outpatients with either high morbidity or a 'great deal of pain' may experience poorer physical well-being as a result of inability to manage symptoms at home. Although the study did not directly measure the effectiveness of symptom management, analysis of physical well-being may provide some indication of how the outpatients managed at home.

Whether care was received as an inpatient or an outpatient, patients with a high level of morbidity at day 4 to 6, indicated low physical well-being with similar median scores of 6.5 (95% C.I.=3 to 10) and 4 (95% C.I.= 0 to 14)

respectively (Figure 24). Analysis for day 12 to 16 could not be done because most subjects in the subgroup had attained an improved level of morbidity (Karnofsky < 70%) and there were too few subjects remaining at that time period for meaningful analysis.

Figure 24. Physical Well-Being of Patients Experiencing High Morbidity by Mode of Care.

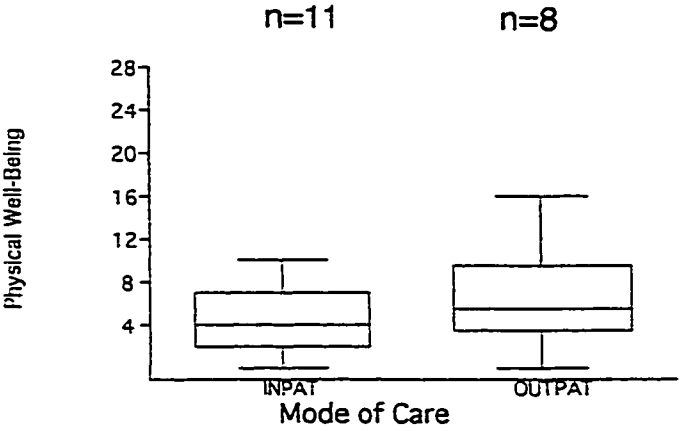
Day 4 to 6



Like morbidity, patients in both subgroups who experienced a 'great deal of pain' at day 4 to 6 also scored low on physical well-being (Figure 25). The median scores for the inpatient and the outpatient groups were 4 (95% C.I.= 2 to 8) and 5.5 (95% C.I.= 2 to 13) respectively. Again, because of small numbers, analysis of this subgroup was not possible at day 12 to 16 because, like morbidity, there were too few patients with pain at this time period.

Figure 25. Physical Well-Being of Patients Experiencing 'A Great Deal of Pain' by Mode of Care.

Day 4 to 6



Thus among patients experiencing higher levels of morbidity or pain, physical well-being appeared to be similar for both inpatients and outpatients at day 4 to 6.

Functional well-being, as measured by the FACT,BMT quality of life instrument, assesses the patient's ability to do the things they usually do and the level of enjoyment they receive from such activities (maximum high score of 28). Figure 26 shows the dispersion of scores for day 4 to 6, day 12 to 16 and day 30. Within each time interval the median scores were similar between inpatients and outpatients. Generally, functional well-being at all time intervals was low suggesting patients were not able to perform usual tasks with a feeling of fulfillment and enjoyment. Surprisingly, even patients who were in their own home (where there may have been more opportunity to do some things that were enjoyable) had low functional well-being.

Figure 26. Functional Well-Being by Mode of Care.

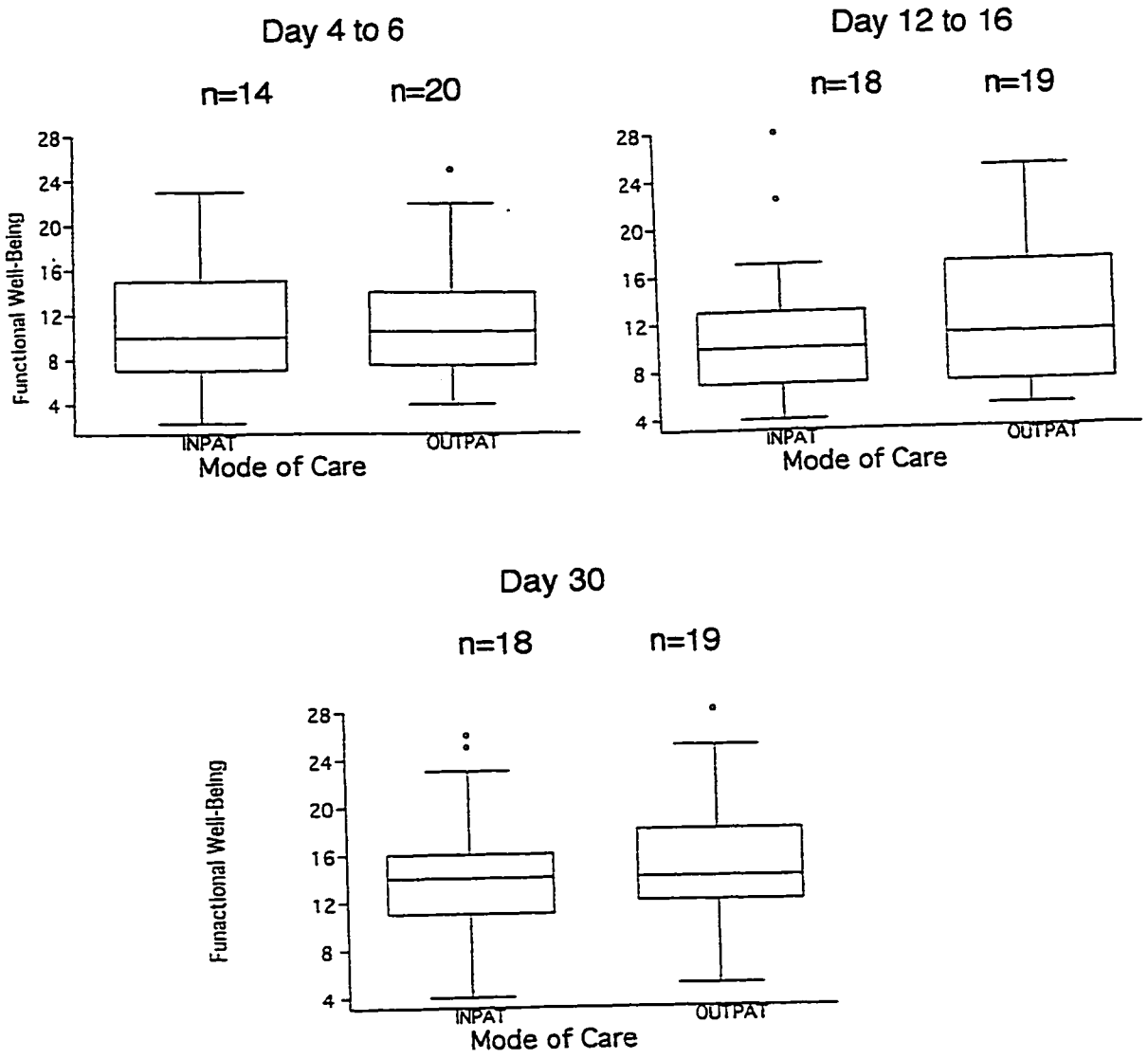


Figure 27 and Figure 28 display the dispersion of functional well-being scores for those patients experiencing a 'great deal of pain' and those experiencing high level of morbidity at day 4 to 6. These two variables of pain and morbidity are shown together since one would expect to see similar patterns for functional well-being scores. Again, because of the influence of the

different treatment protocols used in the inpatient and outpatient groups on other aspects of physical status such as morbidity, pain and physical well-being, it is useful to analyse the functional well-being of patients with similar levels of morbidity and pain.

Inpatients that experienced a 'great deal of pain' at day 4 to 6 (8; 95% C.I.=4 to 11) had a slightly lower level of functional well-being when compared to outpatients (11; 95% C.I.=8 to 13). Further, inpatients with a high level of morbidity at the same time interval showed similar level of functional well-being (9.5; 95% C.I.=7 to 13) as the outpatient group (8; 95% C.I.=5 to 13). By controlling for differences in morbidity between the study groups the results provide further evidence to support the conclusion that functional well-being is no worse for outpatients.

Figure 27. Functional Well-Being of Patients Experiencing 'A Great Deal of Pain'

by Mode of Care.

Day 4 to 6

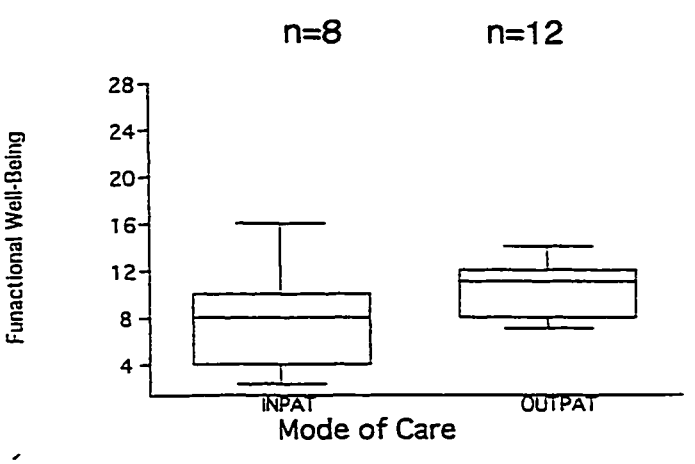
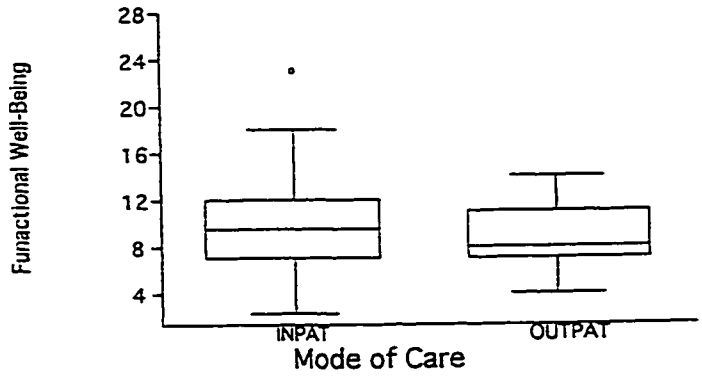


Figure 28. Functional Well-being of Patients Experiencing High Morbidity by Mode of Care.

Day 4 to 6

n=14 n=7

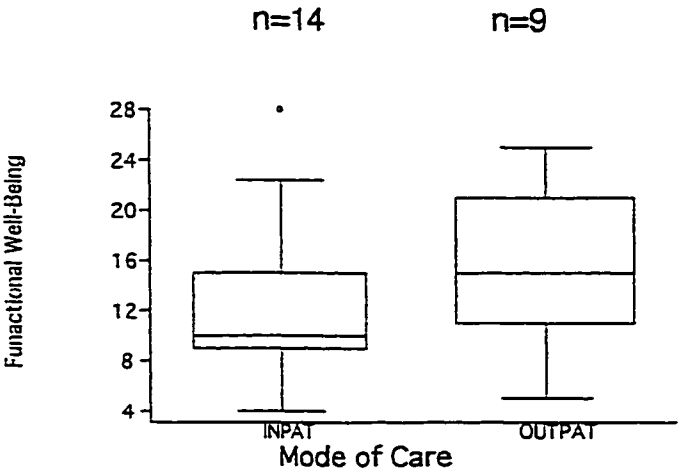


Analysis for day 12 to 16 could not be done because most subjects in the subgroup had attained an improved level of morbidity (Karnofsky < 70%) and pain (pain < 5). Therefore, there were too few subjects remaining at that time period for meaningful analyses.

Once outpatients were beginning to feel better, as indicated by level of morbidity at day 12 to 16, their functional well-being also improved and was better compared to the inpatients (Figure 29). The median score for outpatients was 15 (95% C.I. =8 to 21), while the median score for inpatients was 10 (95%C.I.=9 to 15). When this subgroup of 'well' outpatients was compared to 'well' inpatients, the outpatients scored higher on functional well-being.

Figure 29. Functional Well-Being of Patients Experiencing Low Morbidity by Mode of Care.

Day 12 to 16



These results suggest that perhaps the outpatient environment serves to enhance functional well-being once a certain level of improvement in health has been reached. The outpatient environment may allow patients to participate in usual activities sooner. As noted at day 30 when both groups were generally at home, they both had similar levels of functional well-being. The level of functional well-being among inpatients at day 30 (Figure 26) was the same as the level among outpatients at day 12 to 16 (Figure 29). This same pattern of improvement in physical well-being was noted at day 12 to 16 for the outpatient group as reported previously under 'physical well-being'.

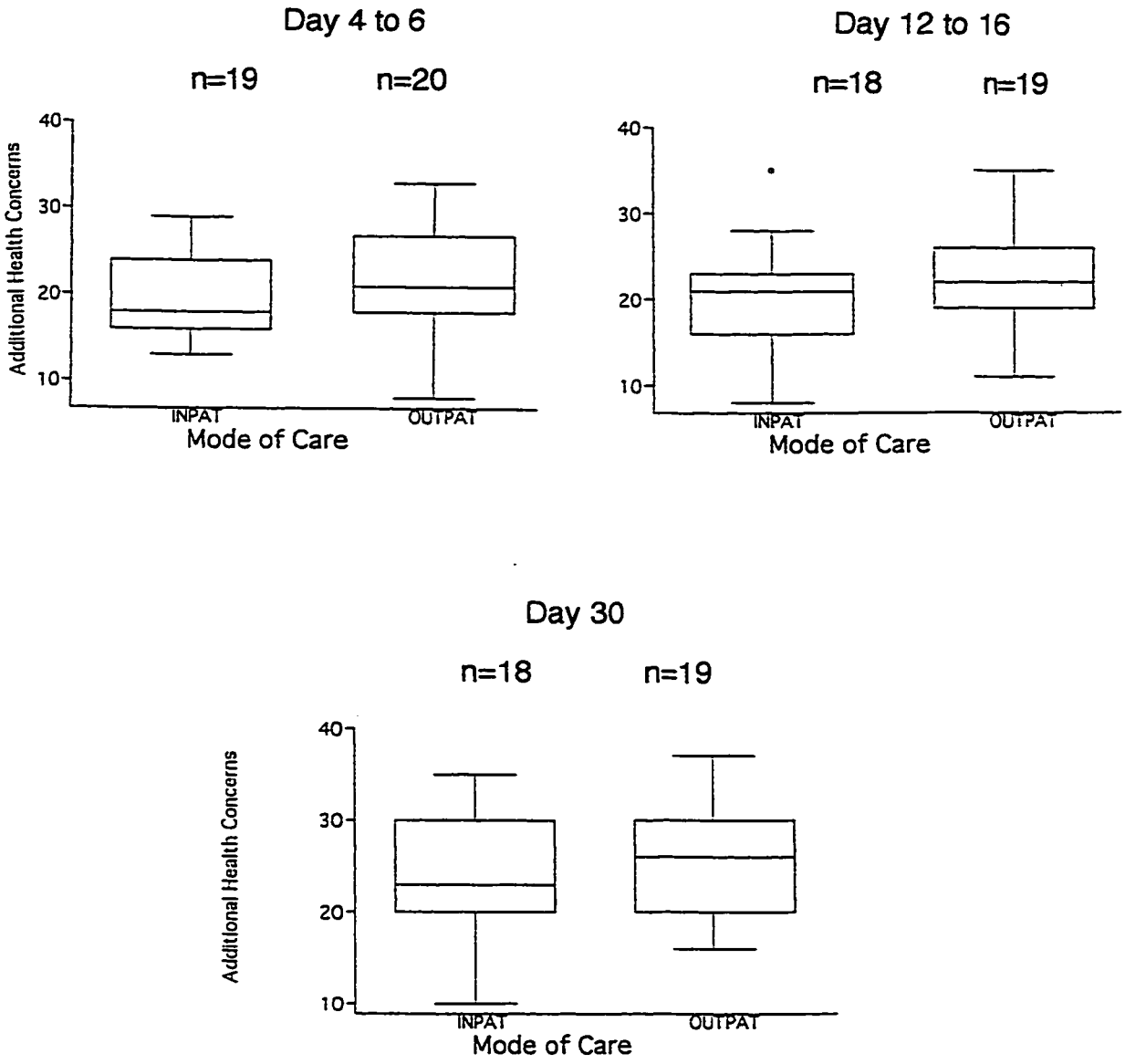
E. Additional Health Concerns (Quality of Life Measure Subscore)

The FACT,BMT also explored patients general health concerns associated with ABSCT. Questions about the physical effects of the transplant included effect on appetite, body appearance, sexual function, fatigue and physical impact of treatment. Emotional aspects that were explored included the ability to return to normal functioning, ability to maintain personal relationships, worries about the outcome of the transplant and confidence in nursing care. A maximum possible score of 40 indicates minimal concern about the transplant.

Overall, patients' concern diminished over the three time periods after the transplant but never returned to the baseline level. At day 4 to 6, patients appeared to have significant concerns about their health compared to prior to the transplant. The median scores for the inpatient and outpatient groups were 18 (95% C.I.=15 to 21) and 21 (95% C.I.=18 to 24) respectively.

At day 12 to 16, the study groups continued to show similar levels of concern about their health. The median scores for inpatients and outpatients was 21 (95% C.I.=16 to 23) and 22 (95% C.I.=20 to 26) respectively. While at day 30, scores had improved slightly to 23 (95% C.I.=20 to 29) and 26 (95% C.I.=21 to 29) respectively.

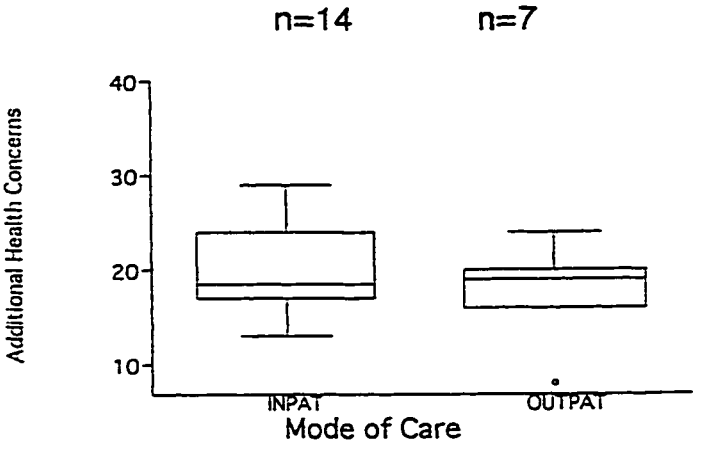
Figure 30. Additional Health Concerns by Mode of Care.



Although the inpatient group reported greater health concerns on the baseline measure, the level of concern was comparable between the groups once the transplant process was underway. Perhaps patients' concerns about their health played a role in determining their preferred mode of care.

In order to control for the effect of the differences in treatment protocols between the groups, patients who were very sick (Karnofsky less than 70%) at day 4 to 6 were analysed as a subgroup (Figure 31). Possibly outpatients who experience a high level of morbidity may report greater concern with their health because of the added responsibility for their own care. However, the median scores for this subgroup were 18.5 (95% C.I.=17 to 24) for the inpatient group and 19 (95% C.I.=11 to 23) for the outpatient group suggesting that patients' concern about health was similar in both groups even when morbidity was high.

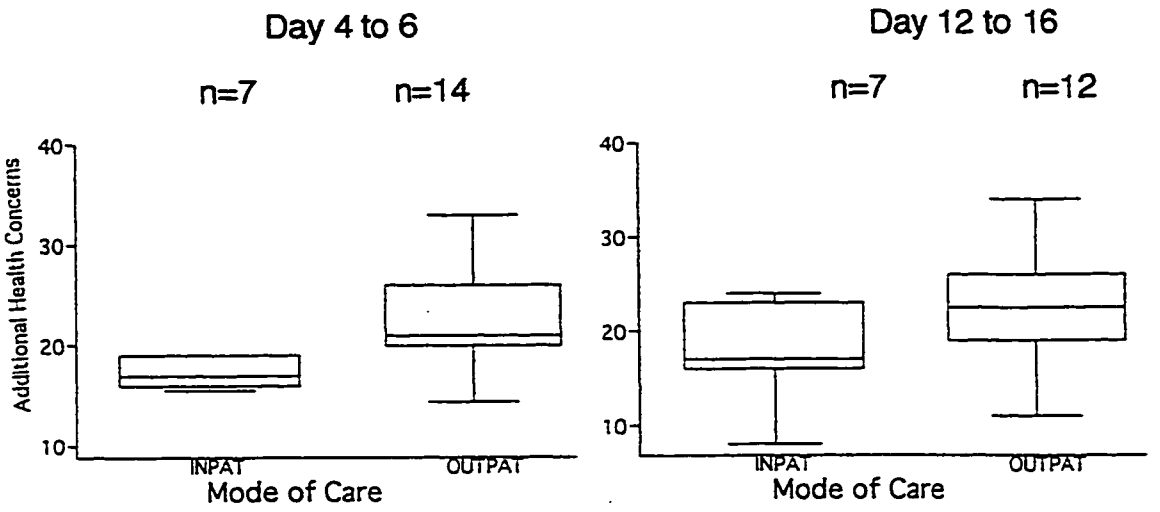
Figure 31. Additional Health Concerns of Patients Experiencing High Morbidity by Mode of Care.



Patients who have experienced previous treatment failure may express less concern about health because they know what to anticipate. In this study more outpatients had experienced treatment failure. Results show that this subgroup of outpatients had significantly less concern about their health (median score=21, 95% C.I.=20 to 26) when compared to the inpatients

(median score=17, 95% C.I.= 16 to 19) (P=.0175). Analysis of the same subgroup at day 12 to 16, shows that inpatients' concerns about the transplant remained high. The median scores for inpatients and outpatients were 17 (95% C.I.=12 to 22) and 22.5 (95% C.I.=18 to 27) respectively.

Figure 32. Additional Health Concerns of Patients who had Previous Treatment Failure by Mode of Care.



F. Hospitalization of Outpatients

Of the 21 participants in the outpatient group, 90% (19) were admitted to the hospital at some point during the 30 days after transplant, with the majority of patients (55%) admitted around day 6 to 7. Of these 19 patients, the reasons for admission to hospital were: 10 (53%) with elevated temperature requiring intravenous antibiotics; 8 (42%) with mouth sores requiring intravenous

narcotics; 6 (32%) with dehydration because of nausea and vomiting; 1 with no caregiver present. Six patients experienced multiple problems: 3 had mouth sores and elevated temperature and 3 suffered from mouth sores and nausea and vomiting.

Table 3.9

MEASURES OF PHYSICAL STATUS	INPATIENTS			OUTPATIENTS		
	Median Score at day 4-6	Median Score at day 12-16	Median Score at day 30	Median Score at day 4-6	Median Score at day 12-16	Median Score at day 30
Physical Well-Being	7	8.5	18	10	11	18
Physical Well-Being with High Morbidity	6.5	N/A	N/A	4	N/A	N/A
Physical Well-Being of Patients with	4	N/A	N/A	5.5	N/A	N/A
Functional Well-Being	10	10	14	10.5	11	14
Functional Well-Being with High Morbidity	8	N/A	N/A	11	N/A	N/A
Functional Well-Being of Patients with	8	N/A	N/A	11	N/A	N/A
Additional Health Concerns	18	21	23	21	22	26
Additional Health Concerns of Patients with Previous Treatment Failure	17*	17*	N/A	21*	22.5*	N/A

*P<.05

G. Length of Hospital Stay

An indicator of health care system costs of ABSCT is inpatient bed utilization (as measured by number of nights of inpatient care). For the twenty inpatients, the median number of nights in hospital was 14 (95% C.I.=13 to 17 nights), with a range from 13 to 25 nights. For outpatients the median number of nights was 7 (95% C.I.=5 to 11 nights), with a range from 0 to 15 nights ($P<.001$).

Two outpatients were not admitted to the hospital at all during the first 30 days after the transplant. In all, 23% of the outpatient group required no hospitalization or only a brief period of hospitalization (4 nights or less in hospital). Although the outpatient group required hospital visits for observation and medical treatment during the 30 day period after the transplant, their bed utilization was significantly less than the inpatient group. These results show that outpatients still require some inpatient care, however the need is comparatively small.

V. Psychological Well-being

This section will address different aspects of psychological well-being including emotional aspects of quality of life, anxiety, depression, perception of control and perception of satisfaction with care. Measures were taken at three different time intervals during the period after the ABSCT: days 4 to 6; days 12 to 16; and day 30. A description and comparison of the scores of inpatients and the outpatients at these time intervals are presented.

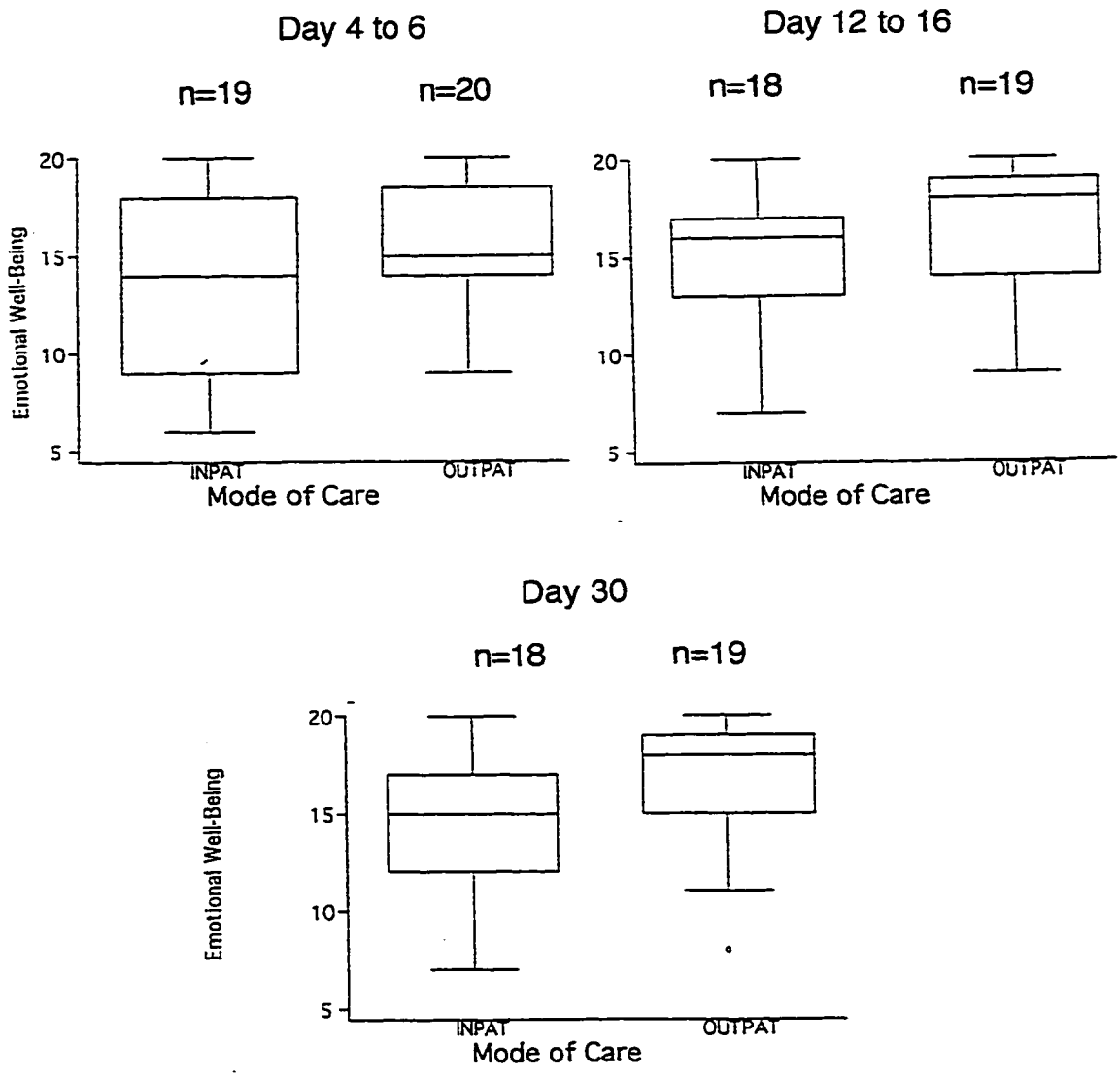
A. Emotional Well-Being (Quality of Life Measure Subscore)

Emotional well-being at day 4 to 6, as measured using one aspect of the FACT,BMT quality of life instrument, is compared in Figure 33 to show the dispersion and median scores of the responses. Scores for both the inpatient and outpatient groups were normally distributed. However, inpatients scores were dispersed more widely, with the IQR equal to 9 (Q1=9, Q3=18) compared to outpatients' IQR of 4.5 (Q1=14,Q3=18.5). As shown in the box plots, both groups tended to have scores in the higher end of a possible range. With a possible range of scores from 0 to 20, the median scores for both the inpatient and the outpatient groups were high at 14 (95% C.I.=11 to 17) and 15 (95% C.I.= 13 to 17) respectively, indicating a good level of emotional well-being.

At day 12 to 16 the range and dispersion of scores for both groups were similar as were the median scores for inpatients and outpatients (16; 95% C.I.=13 to 17 and 18; 95% C.I.= 15 to 18 respectively). Scores for both groups were up slightly from the day 4 to 6 measure.

By day 30, all patients were generally feeling better and inpatients were able to return to their homes. Median scores for emotional well-being were about the same as values obtained for days 12 to 16. The median score for outpatients was 18 (95% C.I.=15 to 19) compared to the inpatient score of 15 (95% C.I.=13 to 17).

Figure 33. Emotional Well-Being by Mode of Care.

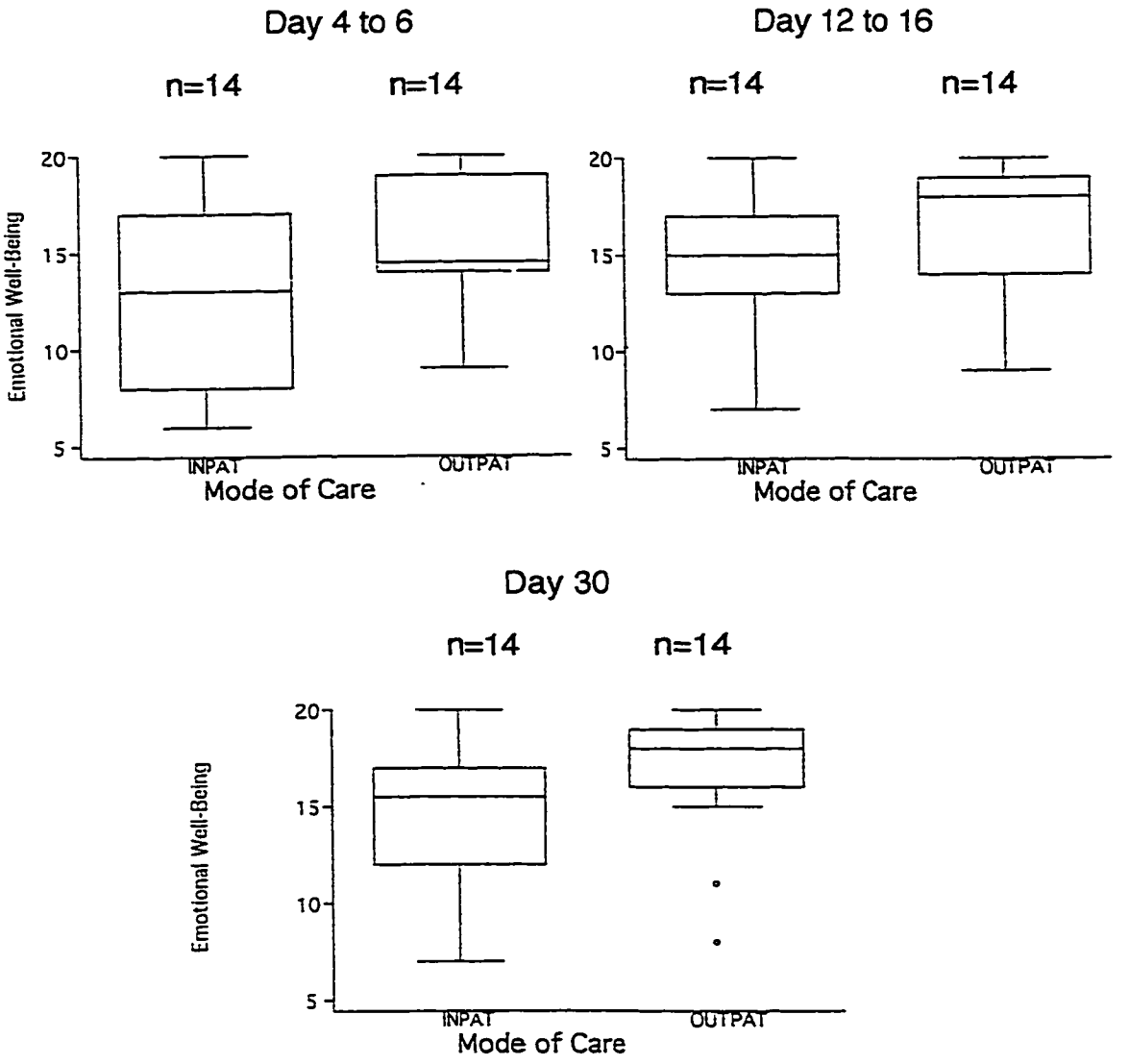


Further description of emotional well-being with respect to the following variables will be presented in this section: gender, morbidity, place of residence, change in living arrangements (in town or out-of-town) and previous experience with chemotherapy treatments. Analyses using the variables age, cancer diagnosis, treatment protocol and family structure were not possible due to the limitations of sample size.

Because of the few men in the sample, analysis for males was not possible. Analysis of emotional well-being of the females in the sample showed that the at day 4 to 6 the median scores for both the inpatient and outpatient groups were similar at 13 (95% C.I.=8 to 17) and 14.5 (95% C.I.=14 to 19) respectively. However, the inpatient group had more scores at the lower end of the range scores.

At day 12 to 16, the emotional well-being of women in the inpatient group appeared to be slightly lower than that of outpatients. Median scores of 15 (95% C.I.=13 to 17) and 18 (95% C.I.=14 to 19) respectively. Results for day 30 were about the same. Although, it is difficult to conclude that outpatients had better emotional-well-being, the data do support a conclusion that emotional well-being of outpatients was no worse as a result of being cared for in an ambulatory setting. The data also suggest that outpatients may regain their sense of well-being faster than in patients.

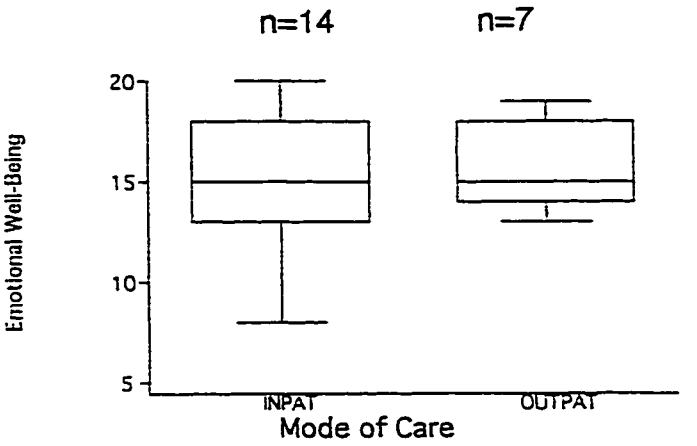
Figure 34. Emotional Well-Being of Females by Mode of Care.



Because of the different protocols used for inpatients and outpatients and the relationship between treatment protocol and level of post ABSCT morbidity, an analysis of emotional well-being adjusted for morbidity was undertaken by comparing inpatients and outpatients with a higher level of morbidity (Karnofsky less than 70%) (Figure 35). At day 4 to 6, the median scores for both study groups were the same at 15, indicating generally good emotional well-being.

However, the range of scores in each group differed, with more inpatients showing low scores on emotional well-being compared to outpatient group.

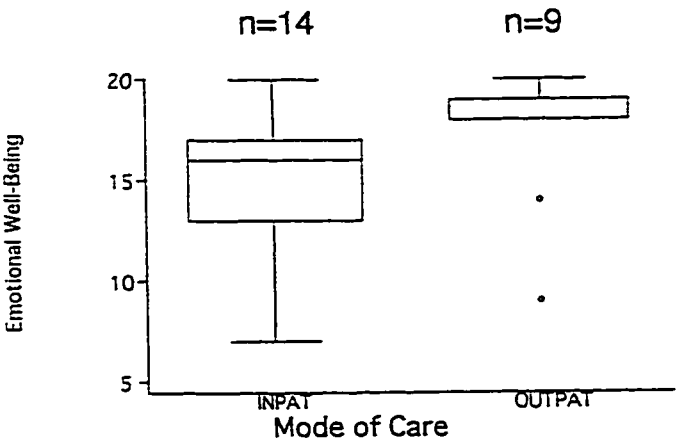
Figure 35. Emotional Well-Being of Patients Experiencing High Morbidity by Mode of Care.



Previous results have shown that by day 12 to 16 there was an overall improvement in morbidity. By this time, the emotional well-being of both groups with Karnofsky scores equal to or greater the 70%, had also improved where inpatients and outpatients had median scores of 16 (95% C.I.=13 to 17) and 18 (95% C.I.= 14 to 20) respectively. Morbidity was not measured at day 30.

Figure 36. Emotional Well-Being of Patients Experiencing Low Morbidity by Mode of Care.

Day 12 to 16

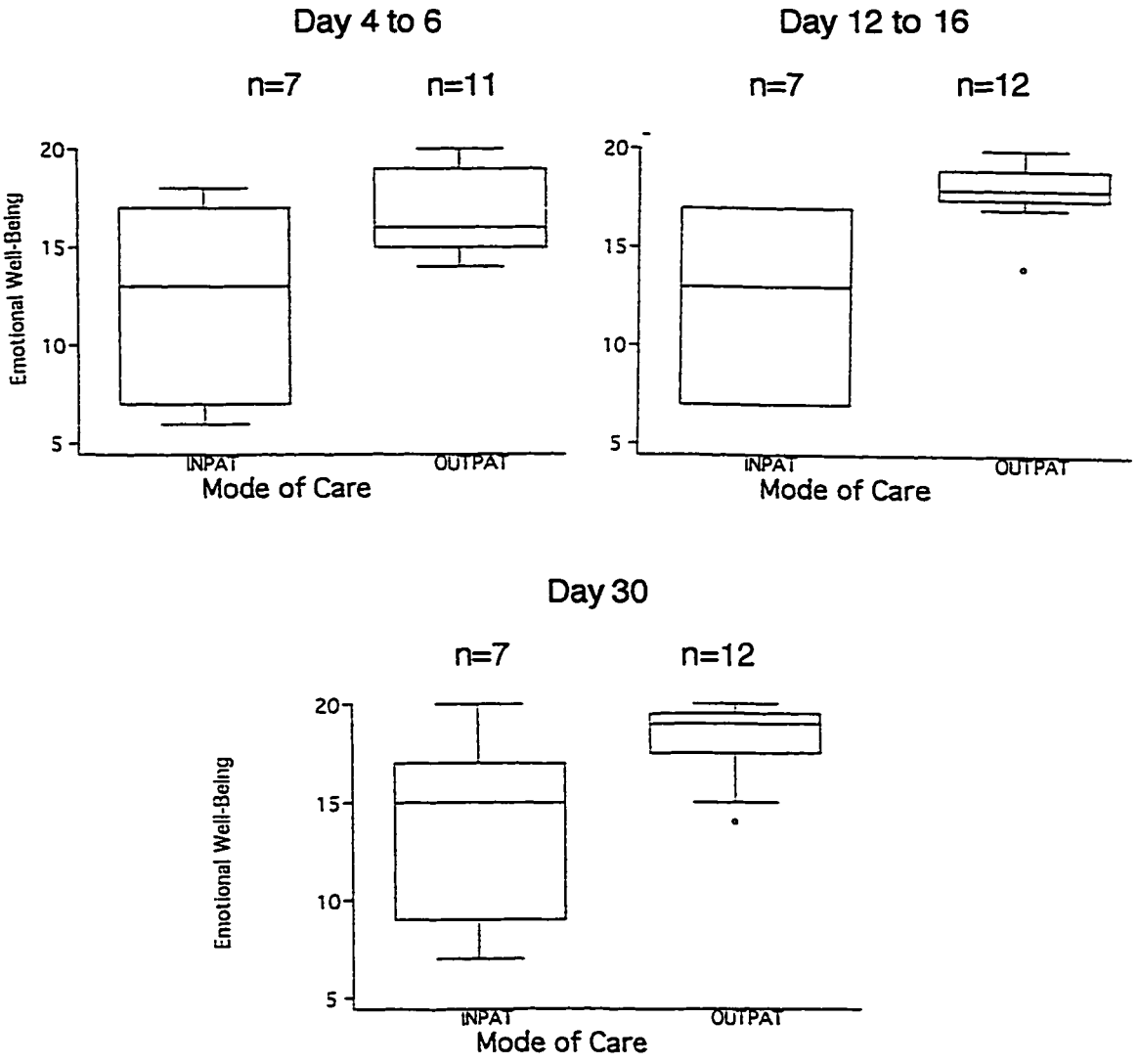


Another important aspect to consider in understanding emotional well-being is the experience of patients whose lives were disrupted because of a change in living arrangements. The hospital provided a quasi-familiar environment that was highly standard for all inpatients. Outpatients were in a variety of settings, some familiar and others not. Thus, the following analysis describes emotional well-being of outpatients who remained in their own home during the 30 day period and the emotional well-being of inpatients whose families were living close to the treatment centre.

Figure 37 displays the scores of emotional well-being of outpatients who lived close enough to the treatment centre to remain in their own home (i.e. those patients living in town). At all three time intervals, this subgroup of outpatients appeared to have better emotional well-being compared to the inpatient group. It is possible that the difference in emotional well-being at day 4 to 6 was the result of the different protocols used for treatment of the two study

groups. However, by day 12 to 16 when the side-effects from both treatments had subsided and were similar, outpatients who were in their own home were still better emotionally (median score 18; 95% C.I.=17 to 19) compared to inpatients (median score 13; 95% C.I.=7 to 17) (P=.0004). Emotional well-being scores remained better for outpatients at 30 days (P=.01) (inpatient median score of 15; 95% C.I.=8 to 19 and outpatient median score of 19; 95% C.I.=17 to 20).

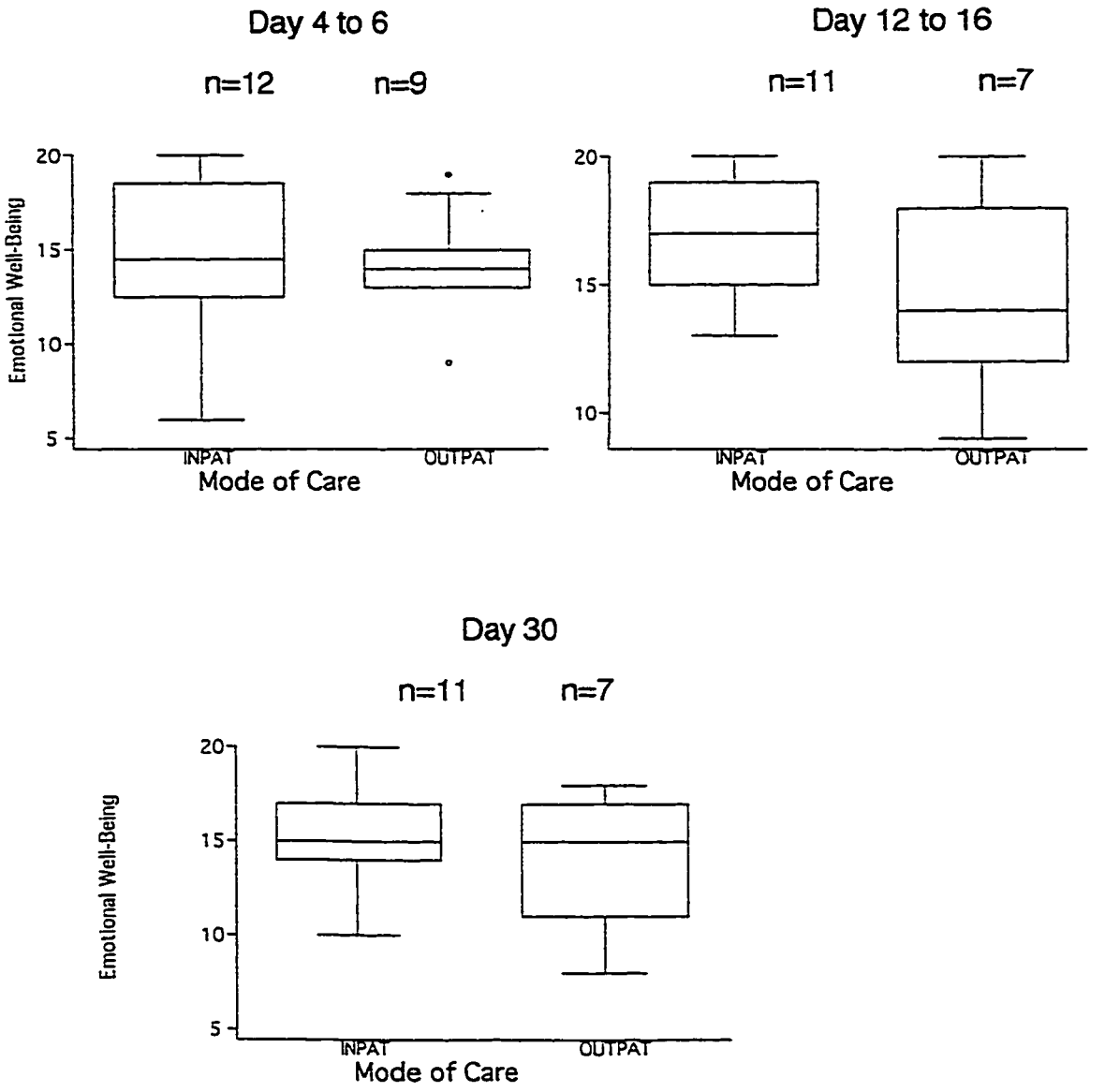
Figure 37. Emotional Well-Being of Patients Living In Town by Mode of Care.



Of the 17 patients who were from out-of-town, 12 were treated as inpatients and 9 were treated as outpatients. This subgroup of 9 outpatients lived in the homes of extended family or in hotels/motels, apartments or hostels. At day 4 to 6 the emotional well-being of both subgroups were similar. However, by day 12 to 16 the outpatient group tended to score lower on emotional well-being with a median score of 14 (95% C.I.=15 to 19) compared to inpatients from out-of-town who scored of 17 (95% C.I.=10 to 19). Although both subgroups had scores of the maximum possible high score, the outpatient group had more subjects with scores in the lower range.

By day 30, most out of town patients from both study groups had returned to their home environment and the median scores for emotional well-being were the same at 15 for both groups.

Figure 38. Emotional Well-Being of Patients Living Out-of-town by Mode of Care.

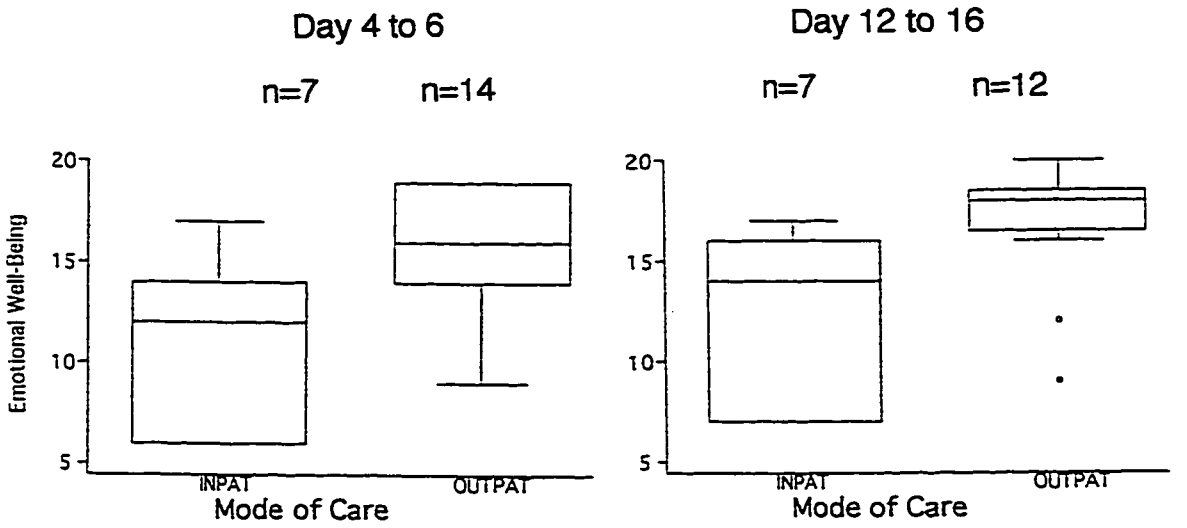


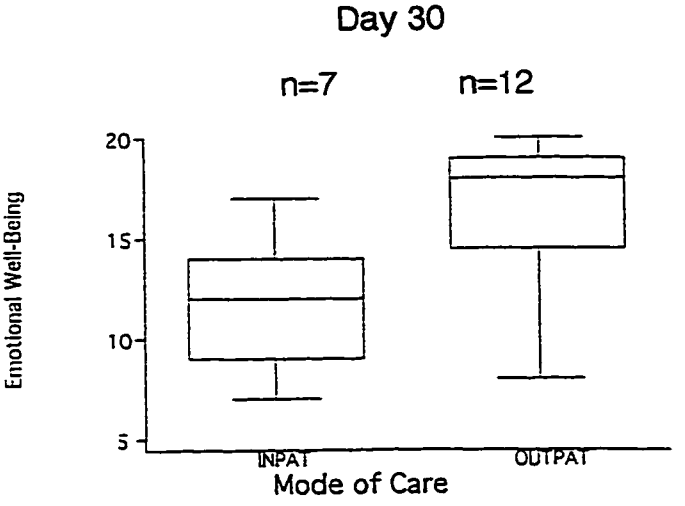
It is possible that the emotional well-being of patients who had experienced treatment failure prior to entering the ABSCT program could be better because of their past experience with treatment and knowing what to anticipate. Treatment failure is defined as relapse or failure to respond to

chemotherapy treatment. More outpatients experienced treatment failure. This may account for the pattern seen thus far of better emotional well-being among outpatients. In light of the possible effect of treatment failure on emotional well-being, inpatients and outpatients who had previous chemotherapy will be compared.

Figure 39 shows that at all three time intervals outpatients with previous treatment failure demonstrated better emotional well-being compared to inpatients. This trend was also evident from the baseline median scores of emotional well-being between inpatients and outpatients (13; 95% C.I.= 8 to 17 and 16; 95% C.I.= 14 to 18 respectively). At day 4 to 6, inpatients who experienced previous treatment failure had a median score of 12 (95% C.I. = 6 to 16) compared to the same subgroup of outpatients with a median score of 16 (95% C.I. = 14 to 19). Statistical comparison of the mean scores suggest there was a difference between emotional well-being between the two subgroups (P=.005). At day 12 to 16, emotional well-being remained better for the outpatient group (median inpatient score was 14; 95% C.I. = 7 to 17 and median outpatient score was 18; 95% C.I. = 16 to 19). Emotional well-being for the outpatients remained better at day 30.

Figure 39. Emotional Well-Being of Patients who had Previous Treatment Failure by Mode of Care.





These results suggest that previous treatment failure does not necessarily prepare everyone to cope better emotionally with the transplant experience, that is, inpatients in this study showed a more negative pattern of well-being. The data do not give any clues as to why outpatients who had previous treatment failure seem to experience better emotional well-being than

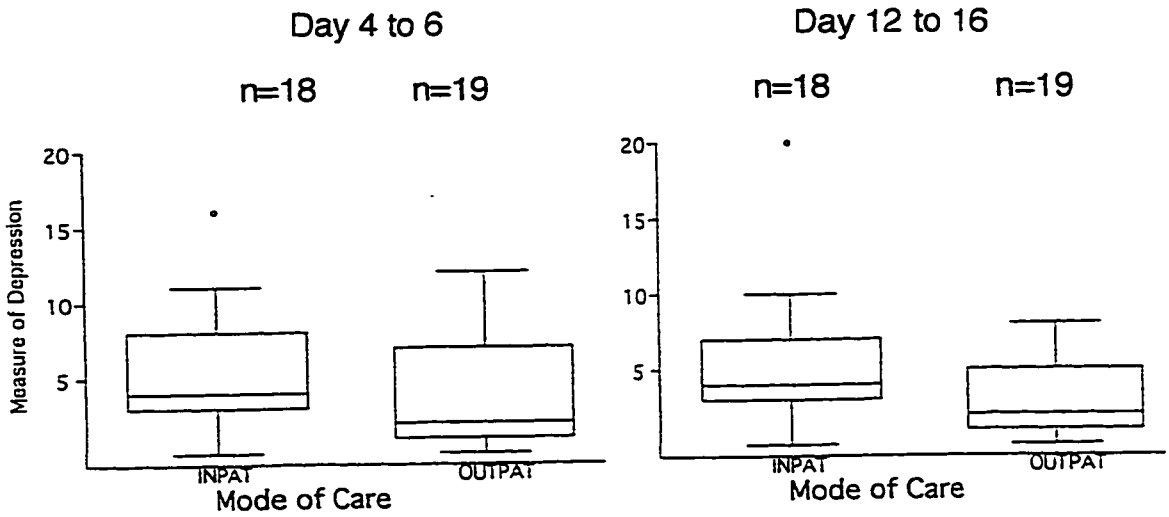
inpatients with previous treatment failure. Perhaps the difference is a result of self selection into the two modes of care. People who chose outpatient care did so because they had good emotional well-being. The combination of previous treatment failure and strong emotional well-being at baseline may be a predictor of patients who will maintain a high level of emotional well-being in the outpatient mode of care throughout the period after the transplant.

B. Patient Depression

Depression is indicated by responses to items on the Profile Of Mood States (POMS) subscale. With a possible range of scores from 0 to 20, higher scores indicate greater depression (feelings of worthlessness, emotional isolation from others, sadness, guilt, and futility in the struggle to adjust). Scores at day 4 to 6 for both inpatients and outpatients were positively skewed, indicating that most patients were not experiencing depression. The range of scores for both groups were similar, with the exception of one high score in the inpatient group that was identified as an extreme score. The median scores for both groups were also similar (4; 95% C.I.= 3 to 8 and 2; 95% C.I.=1 to 6 for inpatients and outpatients respectively).

Depression was also measured at day 12 to 16. Again, most patients in both groups indicated minimal feelings of depression, with median scores of 4 and 2 respectively.

Figure 40. Measure of Depression by Mode of Care

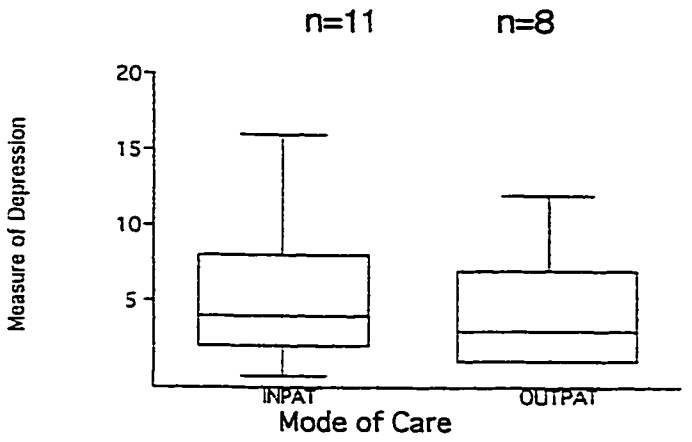


Feelings of depression may differ between the genders. However, because this sample was dominated by females, gender specific analysis could not be done.

Patients with pain may be more vulnerable to feelings of depression. This was explored by comparing depression between inpatients and outpatients who were experiencing a great deal of pain (pain rated as 5 or greater on the visual analogue scale) (Figure 41). At day 4 to 6, the interquartile range and the median scores of depression were very similar in the comparison groups. Inpatients' median score was 4 (95% C.I.=2 to 9) compared to outpatients' score of 3 (95% C.I.=1 to 10). At day 12 to 16, very few patients had indicated they were experiencing a great deal of pain, therefore descriptive analysis was not possible.

Figure 41. Measure of Depression of Patients Experiencing a 'Great Deal of Pain' by Mode of Care.

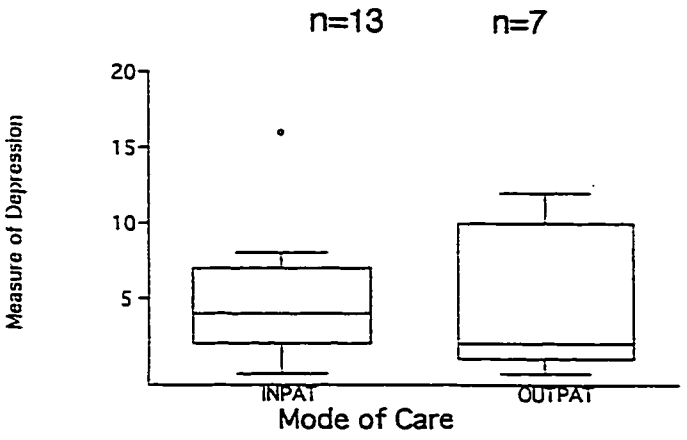
Day 4 to 6



As previously stated, the Karnofsky score provides an indicator of morbidity. A high level of morbidity has been defined previously as Karnofsky score of less than 70%, indicating the patient is unable to care for all of their own needs and requires at least occasional assistance. In order to control for the effect of morbidity on feelings of depression at day 4 to 6, patients' with high morbidity were included in the analysis (Figure 42). Although the outpatient group appeared to have less depression (median score 2; 95% C.I.=0 to 11), when compared to the inpatient group (median score 4; 95% C.I.=2 to 8), the sample size was too small and the confidence intervals too large to permit firm conclusions.

Figure 42. Measure of Depression of Patients Experiencing High Morbidity by Mode of Care.

Day 4 to 6



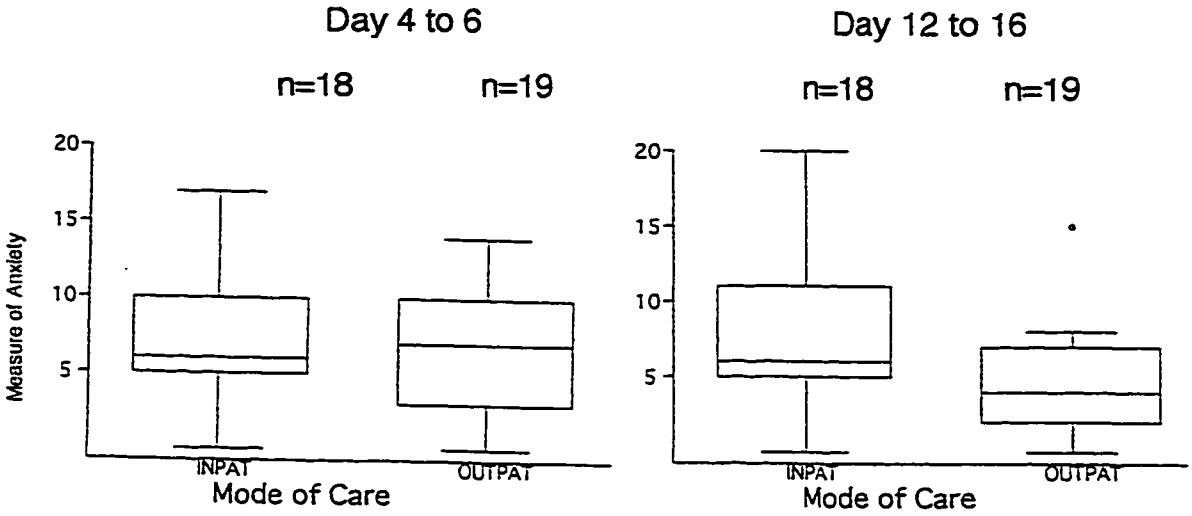
C. Patient Anxiety

Anxiety was also measured using the POMS tool. The possible range of scores for anxiety are 0 to 20. The higher the score the greater the anxiety experienced by the patient. It was predicted that the outpatient group would have more anxiety because of the increased responsibility of managing their own care outside of the hospital. However, early after transplant this did not appear to be the case. Anxiety scores at day 4 to 6, for both the inpatient and the outpatient groups ranged from 0 to 17 and from 0 to 14 respectively (Figure 43). The median scores of anxiety were also similar for inpatients and outpatients (6; 95% C.I.= 5 to 10 and 7; 95% C.I. = 4 to 10) respectively.

At day 12 to 16, anxiety scores in the inpatient group included the entire range of possible scores. In the outpatient group, only one patient indicated a moderately high level of anxiety, with all others in this group scoring low.

Despite wide variation in scores among inpatients, the median scores of both groups were similar. The median anxiety score among inpatients was 6 (95% C.I.=5 to 11) compared to 4 (95% C.I.=2 to 6) among outpatients. These results suggest that although the level of anxiety does not appear to be higher in the outpatient group, further evaluation with a larger sample is necessary in order to draw a more definitive conclusion.

Figure 43. Measure of Anxiety by Mode of Care.

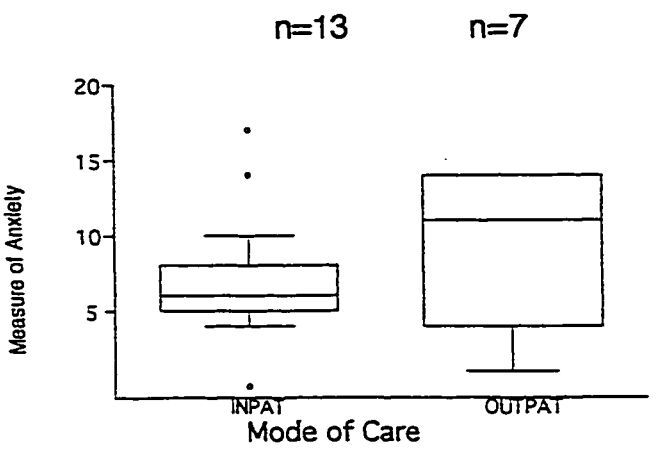


In order to gain further insight about anxiety, variables such as morbidity and previous treatment failure were explored.

Again, anxiety among patients with high morbidity at day 4 to 6 was analysed separately to control for the on-set of treatment related side-effects between the two groups (Figure 44). The median scores for anxiety among inpatients and outpatients were 6 (95% C.I.=4 to 9) and 11 (95% C.I.=2 to 14) respectively thus indicating greater anxiety among outpatients. Because the median scores are not similar to the mean scores, a P value was not calculated. 11 of 21 outpatients were admitted to hospital around day 6 or 7. 7 of the 11

were at the request of the patient or family. Perhaps there was a short period of time around day 4 to 6, when the side-effects were becoming difficult to manage at home and therefore the level of anxiety was elevated. This interpretation is speculative given that the sample size of the outpatient group was very small (n=7).

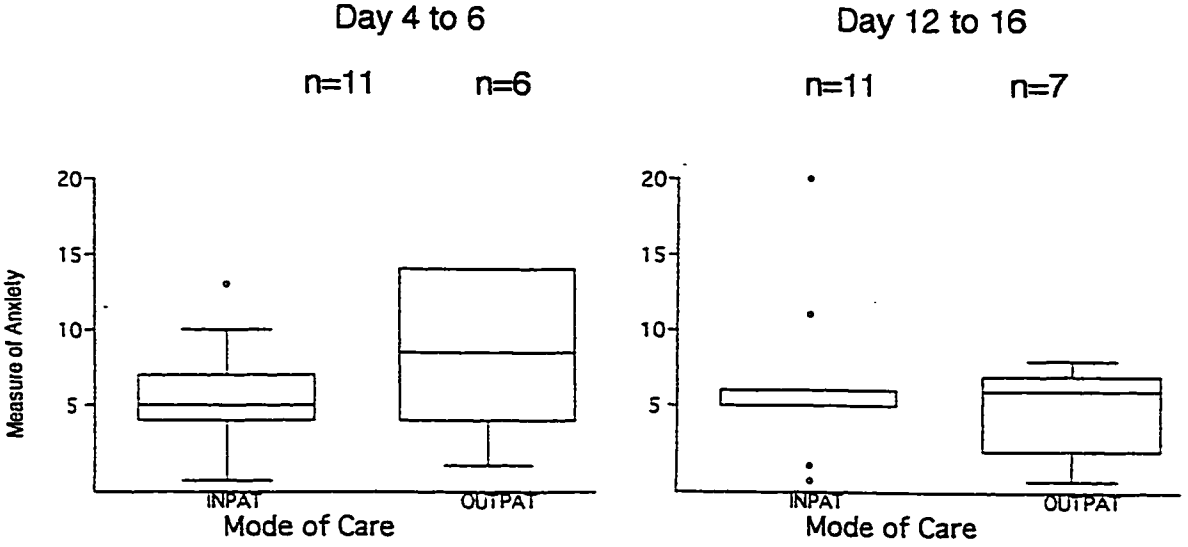
Figure 44. Measure of Anxiety of Patients Experiencing High Morbidity by Mode of Care.



The anxiety levels of patients who had not experienced previous treatment failure prior to entering the ABSCT were compared between inpatients and outpatients (Figure 45). Although there were only 6 subjects in the outpatient group at day 4 to 6 with no previous treatment failure, their median score of anxiety was higher (8.5, 95% C.I.=1 to 14) than that of the inpatient group (5, 95% C.I.=4 to 8). The fear of not knowing what to expect in terms of the side-effects of the high-dose chemotherapy treatment and also being away from the care of a professional may cause patients in the outpatient mode of care to experience higher levels of anxiety. Availability of a

professional caregiver may protect inpatients from experiencing this fear. At day 12 to 16, when the severity of the side-effects had subsided, the level of anxiety for outpatients was the same as inpatients (6 for both groups).

Figure 45. Measure of Anxiety of Patients without Previous Treatment Failure by Mode of Care.



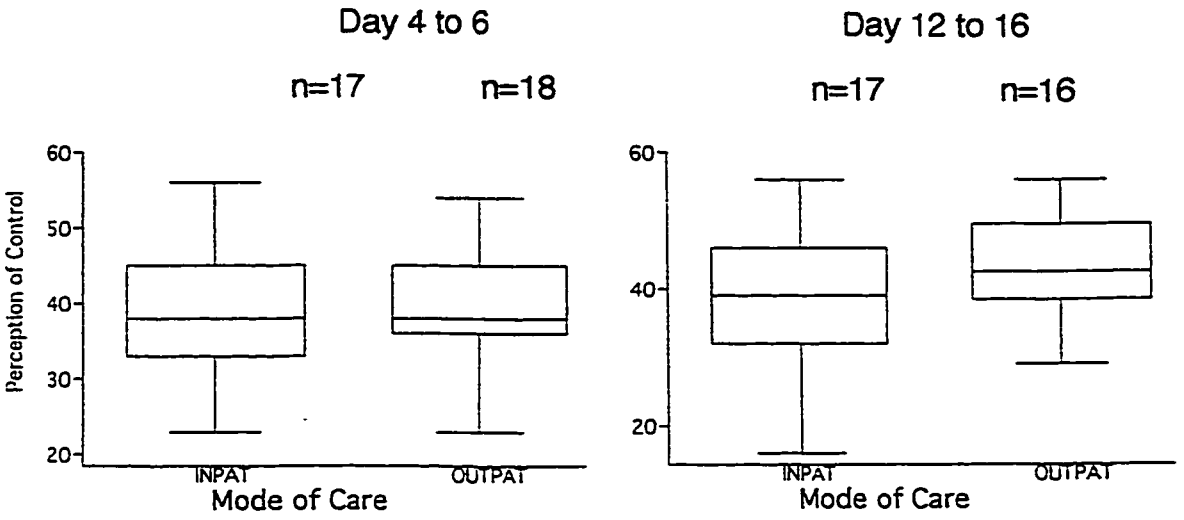
The foregoing analysis of anxiety with respect to morbidity and no previous treatment failure was based on a small sample which in turn reduces the precision of the estimates. Further analysis using a larger sample is necessary in order to draw definite conclusions.

D. Patient Perception of Control

Overall perception of control was indicated by the sum of 5 subscores of perception of control. The possible range of scores for overall perception of control is 16 to 56, with a higher score indicating higher perception of control. As seen in Figure 46, the dispersion and median scores at day 4 to 6 were

similar between inpatients and outpatients. The range of scores for both groups are also very similar with a low score of 23 and high scores of 54 and 56. The median score in both groups was 38. Again, at day 12 to 16, overall perception of control for inpatients and outpatients was seen as similar with median scores of 39 (95% C.I.=32 to 46) and 43 (95% C.I.=39 to 49) respectively. Perception of control was not measured at day 30.

Figure 46. Perception of Control by Mode of Care.



Perception of control over medical treatment was indicated by a subscore of perception of control. This specific aspect of control was analysed because it is relevant to the study question of the impact of outpatient care. With a possible range of scores from 4 to 14 (where higher scores indicate increasing sense of control), many patients in both groups indicated a high level of perceived control over their medical care (Figure 47). At day 4 to 6, the median scores were similar for both inpatients and outpatients with scores of 9 (95% C.I.=6 to 13) and 10 (95% C.I.=9 to 12) respectively.

At day 12 to 16, outpatients indicated slightly higher level of perceived

control over their medical care. The median score for inpatients was 9.5 (95% C.I.=7.5 to 13), whereas the median score for outpatients was 12 (95% C.I.=10 to 14). The small sample contributed to broad and overlapping confidence intervals. The difference between the study groups was close to being statistically significant (P=.068). Analysis using a larger sample would increase the precision of the group specific estimates.

Figure 47. Perception of Control Over Medical Care by Mode of Care.

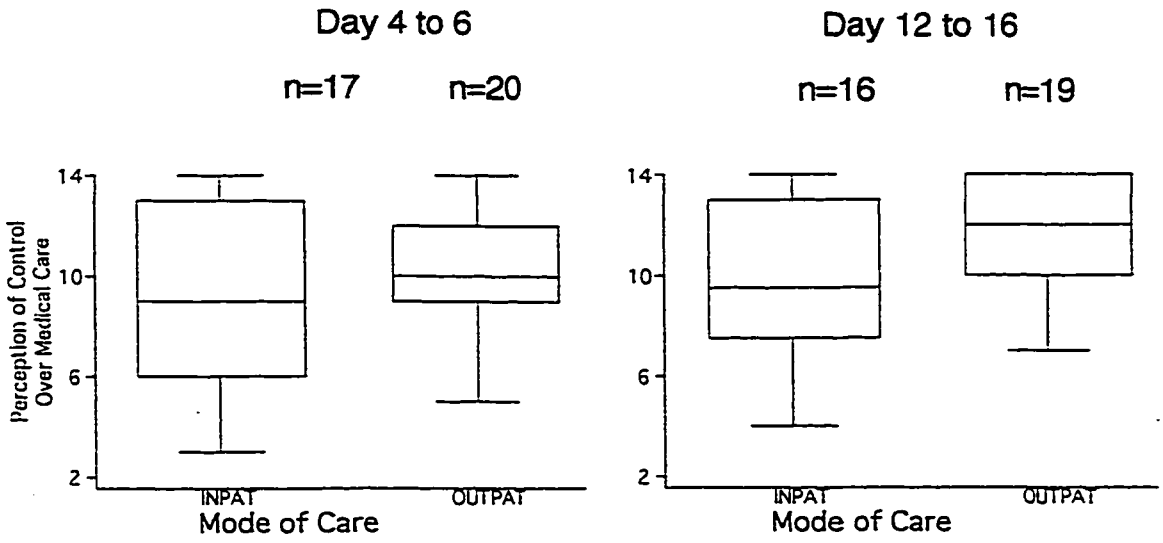


Table 3.10

Summary of Measures of Psychological Well-Being

MEASURES OF PATIENTS' PSYCHOLOGICAL WELL-BEING	INPATIENTS			OUTPATIENTS		
	Median Score at day 4-6	Median Score at day12-16	Median Score at day 30	Median Score at day 4-6	Median Score at day 12 -16	Median Score at day 30
Emotional Well-Being	14	16	15	15	18	18
Emotional Well-Being of Patients Living In Town	13	13 *	15 *	16	18 *	19 *
Emotional Well-Being of Patients Living Out-of-Town	14.5	17	15	14	14	15
Emotional Well-Being of Patients with Previous Treatment Failure	12 *	14	12	16 *	18	18
Depression	4	4	N/A	2	2	N/A
Anxiety	6	6	N/A	7	4	N/A
Anxiety with High Morbidity	6	N/A	N/A	11	N/A	N/A
Anxiety of Patients without Previous Treatment Failure	5	6	N/A	8.5	6	N/A
Perception of Control	38	39	N/A	38	43	N/A
Perception of Control Over Medical Care	9	9.5	N/A	10	12	N/A

*P <.05

E. Satisfaction with Care

Satisfaction with care was assessed by a number of questions. Issues such as the ease of making appointments, accessibility of the medical staff, ease of obtaining information from staff and clarity and completeness of information concerning symptom management. Patients were asked to rate their satisfaction in the above areas according to the following scale: excellent, very good, good, fair, poor or don't know. Table 3.11 displays patients' level of satisfaction in the above areas. Information concerning satisfaction with the care received was missing on 3 patients from the sample who were too sick at day 4 to 6 to complete the questionnaire.

Among inpatients who required medical appointments, all were satisfied with the ease of making an appointment as indicated by rating of very good or excellent. Similarly, all outpatients were satisfied with this aspect of care with the exception of one individual who rated this aspect as "poor".

The accessibility of the medical staff was rated by all inpatients and 94% of outpatients as good, very good or excellent. Again, one subject in the outpatient group rated the accessibility of medical staff as poor at day 12 to 16 and day 30.

At day 4 to 6, satisfaction with the willingness of staff to provide information concerning the treatment or condition was rated positively by all inpatients and all but one subject in the outpatient group. At all time intervals, both groups gave ratings of good, very good or excellent.

For the outpatient group in particular it was important to determine their satisfaction with the clarity and completeness of information received concerning what to do if problems or symptoms continued, got worse or recurred. Ratings given by outpatients were positive with all of the patients at

day 4 to 6, 90% at day 12 to 16, and 94% at day 30 giving satisfaction ratings of good, very good or excellent responses.

Although the majority of patients in both groups expressed a high level of satisfaction in the areas mentioned above, ratings of fair and poor by one participant in the outpatient group are noted and will be further addressed in Chapter 4.

Inpatients and outpatients were asked to provide an overall satisfaction rating for the care received using the following categories: very satisfied, somewhat satisfied, somewhat dissatisfied and very dissatisfied. All inpatients were very satisfied at each of the three time intervals, with the exception of one patient who rated overall satisfaction as somewhat satisfied at day 4 to 6. Overall satisfaction was also high in the outpatient group, with 95% of the participants very satisfied at day 4 to 6 and day 30.

Table 3.11

Satisfaction with Care by Mode of Care.

Areas of satisfaction with Care	INPATIENT			OUTPATIENT		
	Excellent Very Good Good	Fair Poor	Don't Know	Excellent VeryGood Good	Fair Poor	Don't Know
Ease of making appointment						
day 4 to 6	5/18		13/18	17/19		2/19
day 12 to 16	12/17		5/17	19/20	1/20	
day 30	17/18		1/18	18/19	1/19	
Accessibility of Medical Staff						
day 4 to 6	18/18			19/19		
day 12 to16	16/17		1/17	19/20	1/19	
day 30	18/18			19/19		
Willingness to Provide Information						
day 4 to 6	18/18			18/19	1/19	
day 12 to 16	17/17			20/20		
day 30	18/18			19/19		
Clear & Complete						
day 4 to 6	14/18		4/18	19/19		
day 12 to 16	16/17		1/17	18/20	1/20	1/20
day 30	18/18			18/19		1/19
Overall Satisfaction	Satisfied	Not Satisfied		Satisfied	Not Satisfied	
day 4 to 6	18/18			19/19		
day 12 to 16	17/17			19/20	1/20	
day 30	18/18			19/19		

At each of the three time intervals, patients in both groups were asked to report what they liked the most and the least about receiving care as an inpatient or outpatient. Tables 3.12 and 3.13 organizes the comments into categories for the purpose of interpretation. The categories used to organize the data may not be mutually exclusive as patients identified a number of things they liked about the care they received.

In reviewing the narrative comments made by patients in both groups, at all time intervals, they stated that they liked the care that the nursing and medical staff provided. Patients' satisfaction with the professional caregiver had been identified as very important and with similar intensity for both modes of care. Although the outpatient group was not under constant professional care, they indicated that professional care was as important to them as it was to the inpatient group.

Other than the importance of professional care, the themes that the inpatient group identified as liking about the care they received were different from the outpatient group. The inpatient group identified that they liked the feeling of having access to care and help. Some subjects were very specific in identifying that the care was necessary because of the side effects they experienced. Inpatients also commented that they liked the feeling of safety and security that the hospital environment provided.

For the outpatient group, at all three time intervals, being at home in a familiar environment and with their families was identified as a positive aspect of the outpatient mode of care. One patient commented that being at home was less depressing than being in hospital. Outpatients also noted that they liked the feeling of independence, control and flexibility. A few outpatients made reference to receiving adequate attention and information from the medical staff.

Table 3.12

List of What Patients Liked About the Care Received.

INPATIENTS	DAY 4-6 n=19	DAY 12-16 n=17	DAY 30 n=11
Satisfaction with Nurses/Staff	8	8	7
Access to Care/Help	8	9	4
Safety	3	0	0
OUTPATIENTS	n=19	n=17	n=15
Satisfaction with Nurses/Staff	7	7	6
Being Home with Family	5	7	8
Independence	3	3	0
Control and Flexibility	3	0	0
Good Access to Information and Care	5	3	1

Consideration was also given to what patients liked least about the care they received. Many inpatients disliked some aspects of the hospital environment and routines. The comments consisted of: interruption of sleep, quality of food, timing of meals, waiting for nurses to provide care and lack of continuity and consistency of care from professional staff. Inpatients also mentioned being lonely or in an unfamiliar environment. None of these dislikes was expressed by the outpatient group despite spending much time in the clinical setting.

As expected, the aspects of care that outpatients liked least were different from the inpatient group. Whereas only a few inpatients expressed a concern about their physical condition (i.e., lack of control of side-effects), 5 outpatients indicated concerns with regard to their physical condition and ability to care for self. At day 12 to 16, 5 outpatients expressed concerns about their ability to care for self. They did not like being responsible for medication routines, vital signs or coping with side-effects.

Outpatients also disliked the requirement of frequent travel to and from the hospital. This theme was more prevalent at day 30; 5 patients identified this dislike. Travel may have become more of an issue once other problems and concerns were resolved (eg. management of side-effects).

Concerns were also expressed about the physical set-up of the Outpatient Unit. Two patients commented about the lack of patient washrooms within the Unit and no sink in the patients' rooms. One patient did not like the physical set-up of the Outpatient Unit stating that it was "cramped, had uncomfortable beds and overly clinical". At day 30, 2 patients commented that the Unit had problems with heating. It was also interesting to note that one patient expressed concern that there were no emergency call-bells in patient's rooms.

Themes that were infrequently mentioned by patients are also noted in Table 3.13.

Table 3.13

List of What Patients Disliked About the Care Received.

INPATIENTS	DAY 4-6	DAY 12-16	DAY 30
	n=15	n=12	n=4
Hospital Routine/Environment	6	10	4
Lack of Continuity of Care	2	0	0
Being Sick, Side-effects	2	1	0
Lack of Information, Emotional Support	1	1	0
Not with Family, Unfamiliar Environment	5	0	0
OUTPATIENTS			
	n=15	n=13	n=9
Home Environment (boredom)	1	1	0
Travel	2	1	5
Responsibility of Care (medication, vital signs, side-effects)	5	5	1
Set-up of Outpatient Unit	2	2	2
Hostel	0	2	0
Expenses, parking & medication	2	0	0
Lack of Continuity of Staff	1	0	0
Transition from Outpatients to Inpatients	1	2	0
Length of Time for Each Visit	0	0	1
Confined to being Inside	1	0	0

F. Preference

Thirty days after the completion of treatment patients in both groups were asked which mode of care they preferred. At baseline 49% of the patients indicated they preferred to be cared for in the outpatient setting; most (89%) were actually treated as outpatients. Forty-six percent of patients preferred inpatient care, 90% of which actually received inpatient care. At day 30, only 10/37 (27%) of all patients that responded preferred the outpatient environment. Of the 18 inpatients that responded, 16 indicated that they preferred the hospital setting for the period after the transplant (89%, 95% C.I.= 75% to 100%). Two inpatients indicated that they didn't know which mode of care they preferred. Of the 19 participants in the outpatient group, 10 (53%, 95% C.I.= 31% to 75%) stated that they preferred the home setting, 3 preferred the hospital setting and 6 did not know their preference. Fewer outpatients preferred the mode of treatment that they actually received compared to the inpatient group (P=.016).

Out of the total of 37 patients that responded to the question concerning preference, 19 (51%) preferred the hospital setting for four different reasons. First, 9 patients believed that hospital care was necessary. They felt that they could not have managed at home during the period after transplant. Second, 6 patients suggested that the hospital environment provided safety, a sense of security and immediate access to care. Third, one patient felt that the home environment was not appropriate because of the domestic obligations that awaited her at home. Fourth, 2 patients suggested that the set up for outpatient care was not appropriate (i.e., the need for frequent trips to the hospital when feeling sick and the uncomfortable physical set up of the Outpatient Unit).

Patients (n=10) who indicated a preference for outpatient care generally

had two reasons for their preference. First, 6 patients felt that the home setting was a more comfortable environment. The home environment was described as quiet, familiar, not confining and providing privacy and security. Second, 3 patients felt the home setting was a better environment for recovery. Patients felt that they had a greater sense control, there is less focus on sickness and that recovery would progress more quickly. One patient from out-of-town enjoyed the free time away from the hospital but felt the living out-of-town caused stress because no environment was familiar.

VI. Social Interaction

The impact of outpatient care on patients' social interaction will be reported in this section. Social interaction as defined by the conceptual framework includes aspects of patients' perceptions of social and family well-being and relational aspects of quality of life as well as caregiver burden.

In summary, the analysis of all aspects of caregiver burden (impact on schedule, caregiver's esteem, family support and impact on health) suggests that caregivers involved with the outpatient mode of care fared no worse than caregivers of inpatients. Most patients felt that the emotional and instrumental support they received from their caregiver/partner was adequate. The number of patients who had inadequate support was too small for analysis. Yet an understanding of the experience and needs of these patients is important since it could be anticipated that some patients will not have the level of support and care needed to manage in the outpatient setting.

A. Emotional and Instrumental Support from Others

In order to determine if patients were confident and content with the support they received from their caregivers, they were asked to rate the amount of emotional and instrumental support provided by their partner. In most cases this person was also the caregiver, however, this was not true in all cases. In the inpatient group, 94% of the patients indicated that they received 'good', 'very good' or 'excellent' emotional support at day 4 to 6, day 12 to 16 and day 30. For the purpose of description, ratings of 'good', 'very good' or 'excellent' will be referred to as good support.

For the outpatient group at day 4 to 6, 79% of the patients indicated that they received good emotional support. At day 12 to 16 and day 30, 100% and 94% of the outpatients respectively rated their emotional support as good.

Patients were also asked to rate instrumental support or the support received from their partner with regard to physical care and household routines. At day 4 to 6, day 12 to 16 and day 30, more than 80% of the inpatient group indicated a rating of good instrumental support.

For the outpatient group at day 4 to 6, 79% of the patient indicated that they received good support for their physical needs. At day 12 to 16 and day 30, 100% and 95% of the patients respectively, indicated that the instrumental support received was good. These results show that, like emotional support, the instrumental support received from partners was rated highly by both inpatients and outpatients.

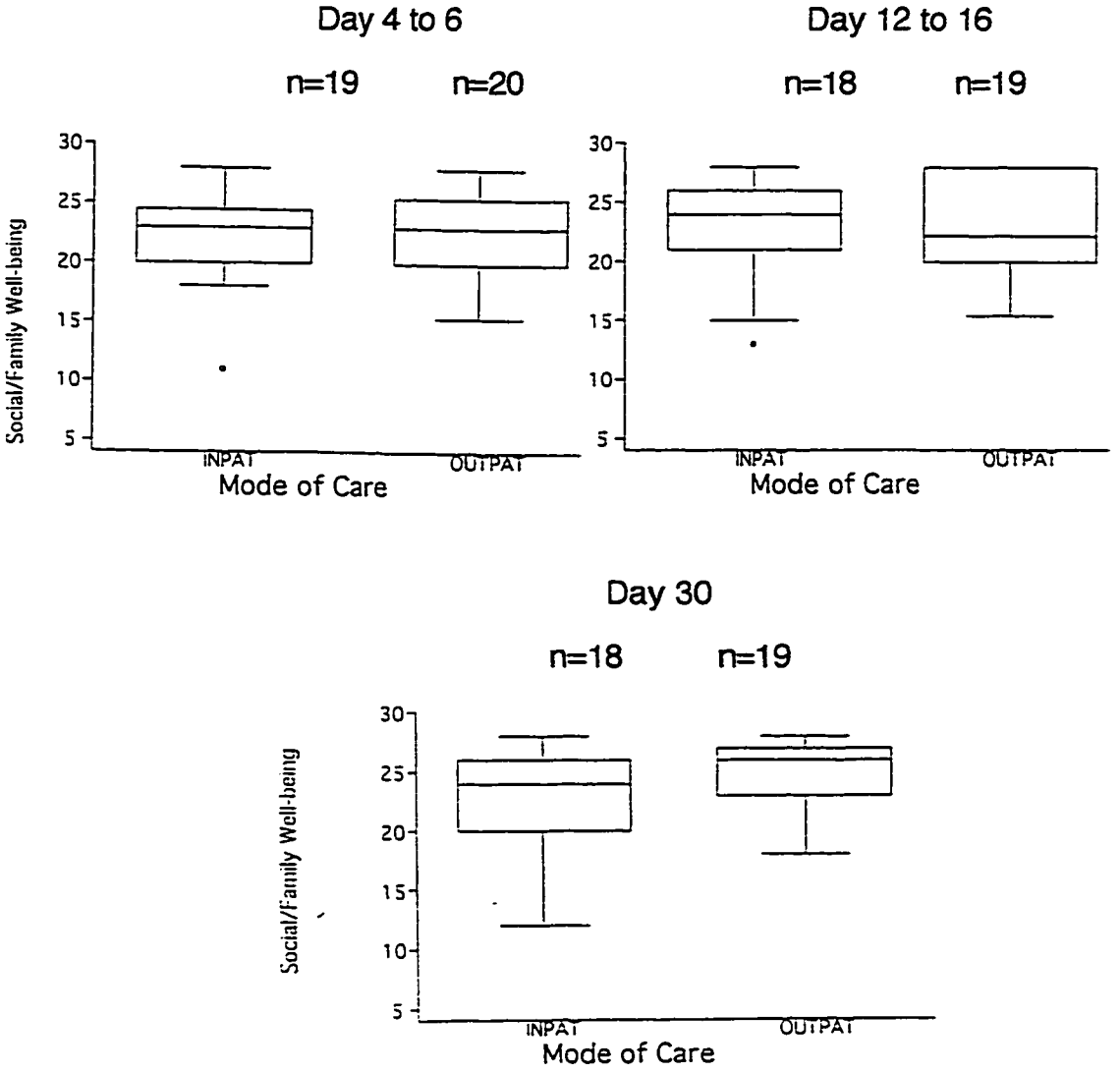
B. Social/Family Well-being (Quality of Life Measure Subscore)

Patients were asked to rate their social and family well-being, as measured by the FACT, BMT quality of life instrument are displayed in Figure 48. It might be expected that patients in the outpatient group would experience

better social and family well-being compared to the inpatient group since they remain in direct contact with their main support system. That is, their family/friends may more involved with their care.

At day 4 to 6, both the inpatient and the outpatient groups had a range of scores from the highest possible score of 28 (indicating good social/family well-being) to a low score of 11 and 15.4 respectively. The data for each group was negatively skewed, with the majority of scores at the high end of the range. The median scores for both groups were the same at 23. The data at day 12 to 16 and day 30 had a similar distribution, with generally high scores. These results indicate that inpatients and outpatients had positive feelings of social and family well-being.

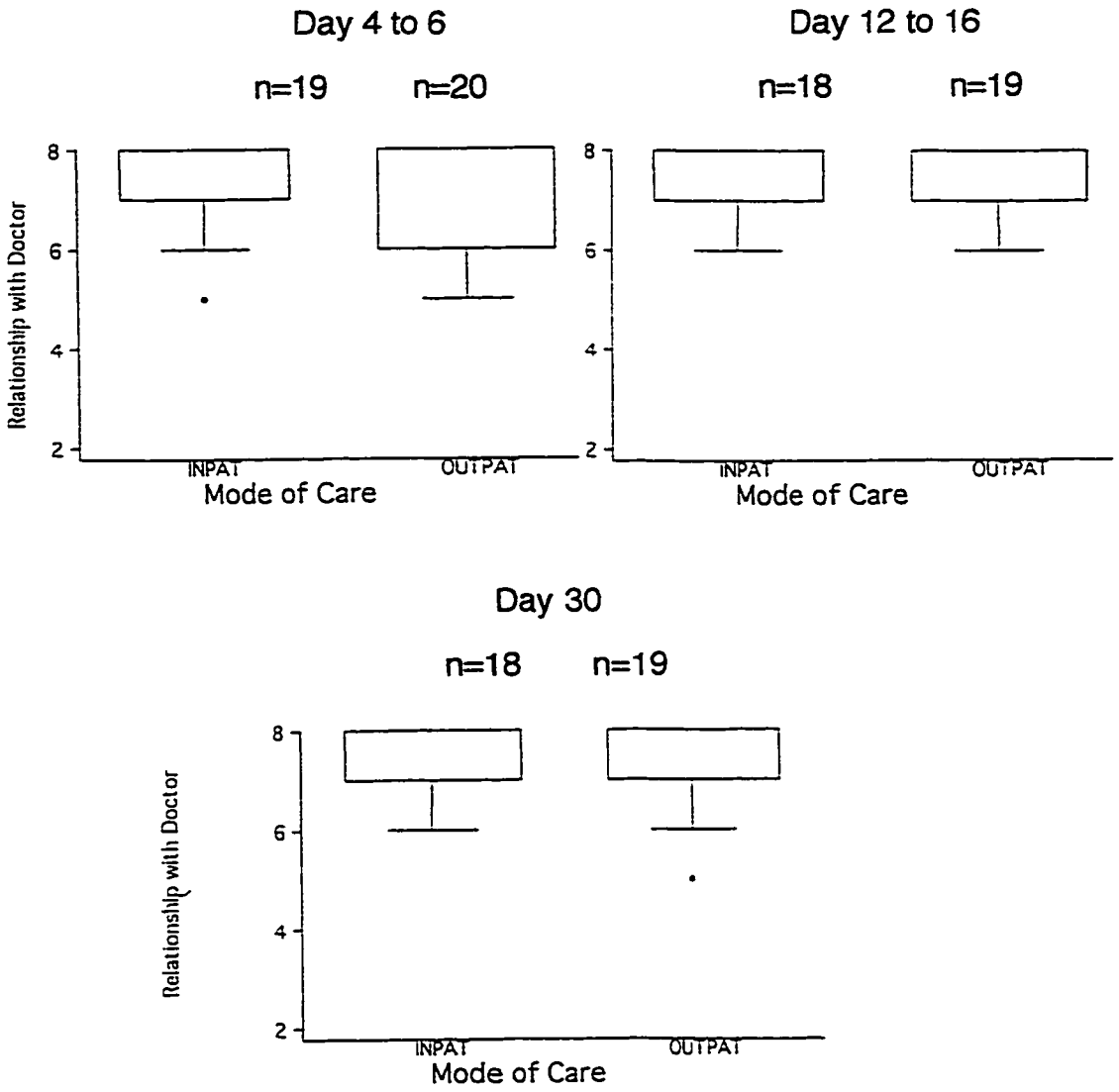
Figure 48. Social/Family Well-Being by Mode of Care.



C. Relationship with Doctor

Patients' confidence in and availability of their doctor was also measured using the FACT, BMT quality of life instrument. Patients indicated a positive relationship (high score) with their doctor throughout the period after the transplant. The median score for the inpatient and outpatient groups at day 4 to 6, day 12 to 16 and day 30 was the maximum possible score of 8.

Figure 49. Relationship with Doctor by Mode of Care.



D. Caregiver Burden

Caregiver burden will be described in detail with consideration to the following areas: impact of providing care on the caregiver's schedule, caregiver's esteem, family support and impact on health (including caregiver's feelings of depression and anxiety).

1. Impact on Schedule

The impact of providing care for patients in the period after the ABSCT on the caregiver's schedule was measured for both inpatients and outpatients at three time intervals. The higher the score (maximum of 35) the greater the perceived impact on the caregiver's schedule which in turn indicates a greater burden on the caregiver. The measurements, as displayed in Figure 50, were taken at day 4 to 6 , day 12 to 16 and day 30 to ensure that the most extreme possible measures of impact on schedule were obtained.

The scores at day 4 to 6 were close to being normally distributed. The dispersion of scores for the inpatient group was slightly positively skewed (more low scores). Whereas for the outpatient group the dispersion of scores were negatively skewed (more high scores). The median scores were similar for both the inpatient and outpatient groups 16.5 (95% C.I.=14 to 19) and 18 (95% C.I.=16 to 20) respectively.

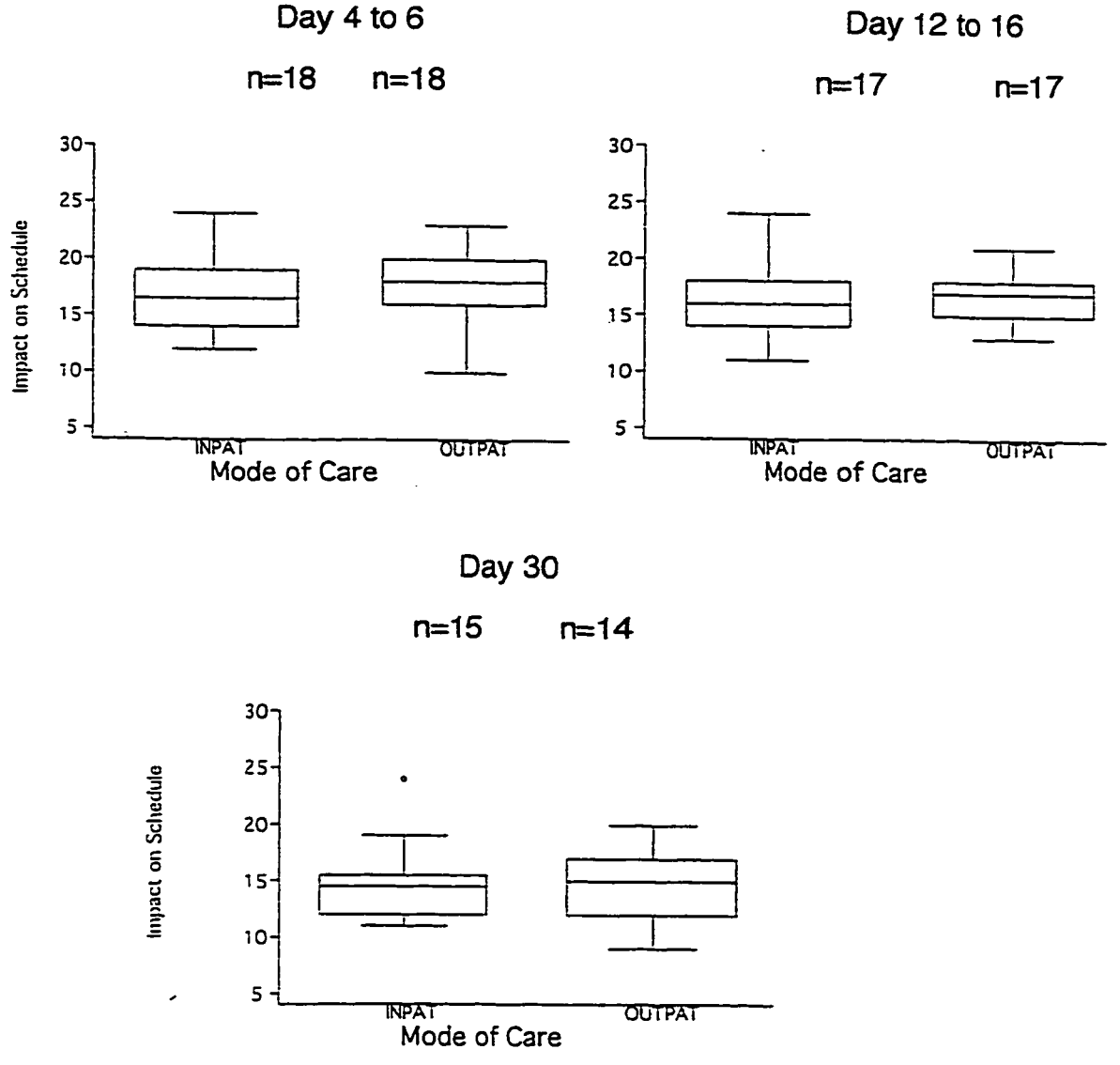
At day 12 to 16, the range of scores showing impact on the caregivers' schedule was wider for the caregivers of inpatients . The median scores appear to be similar. Caregivers in both groups described the impact of providing care similarly.

By day 30 after ABSCT, most patients had been discharged from hospital and therefore the impact of providing care would be expected to be similar in both groups. In comparing the dispersion of data, the upper range (indicating higher impact) of both groups were similar, with the exception of one outlier in the inpatient group. The interquartile range and the median score for day 30 were similar.

In summary, the data suggest that caregivers in both groups and at all three time intervals felt that providing care did have an significant impact on

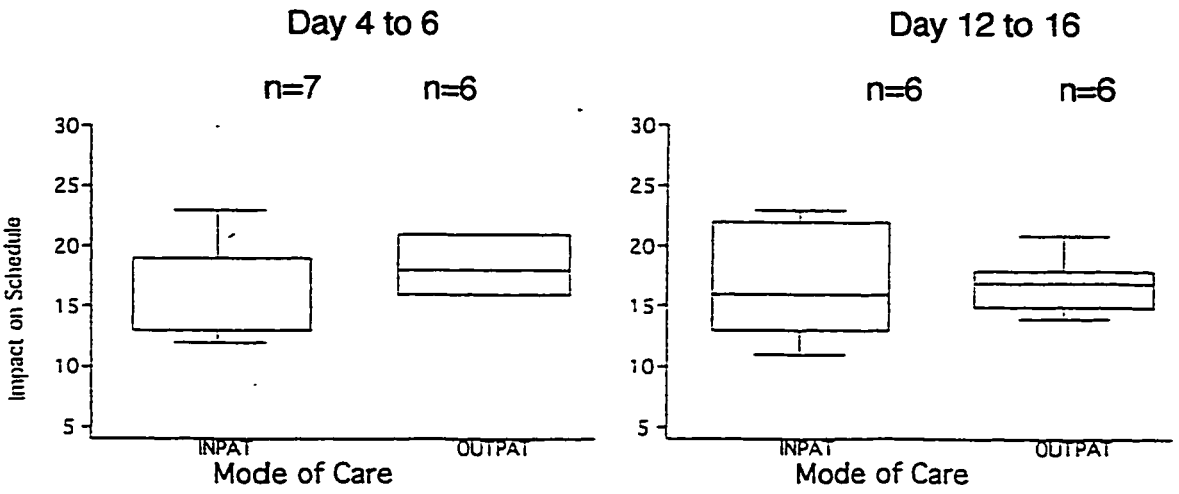
their schedules.

Figure 50. Impact on Schedule of Caregivers by Mode of Care.



Caregivers who had to make alternate living arrangements (hotel, hostel or with extended family) during the period after the transplant may have experienced a greater impact on their schedules. Analysis of this subgroup shown in box plots in Figure 51 demonstrates that outpatient caregivers who were required to make alternate arrangements at day 4 to 6, had a narrower range of scores compared with inpatient caregivers (16 to 21 vs 12 to 23), with median scores of 18 (95% C.I.=16 to 21) and 13 (95% C.I.=12 to 22). Confidence intervals suggest there was no between group difference, however the sample was small. The data suggest that outpatient caregivers may have experienced a greater impact on their schedule. By day 12 to 16, the impact on schedule for caregivers of inpatients was closer to being similar, with a median score of 16 (95% C.I. 11 to 23) compared to outpatient caregivers' median score of 17 (95% C.I.=14 to 21). These results have implications for outpatient care because of the many patients who are from out-of-town and therefore are required to make alternate living arrangements. These results suggest that one aspect of burden of care, that is, impact on the caregivers' schedule, may be greater for outpatient caregivers who are required to make alternate living arrangements.

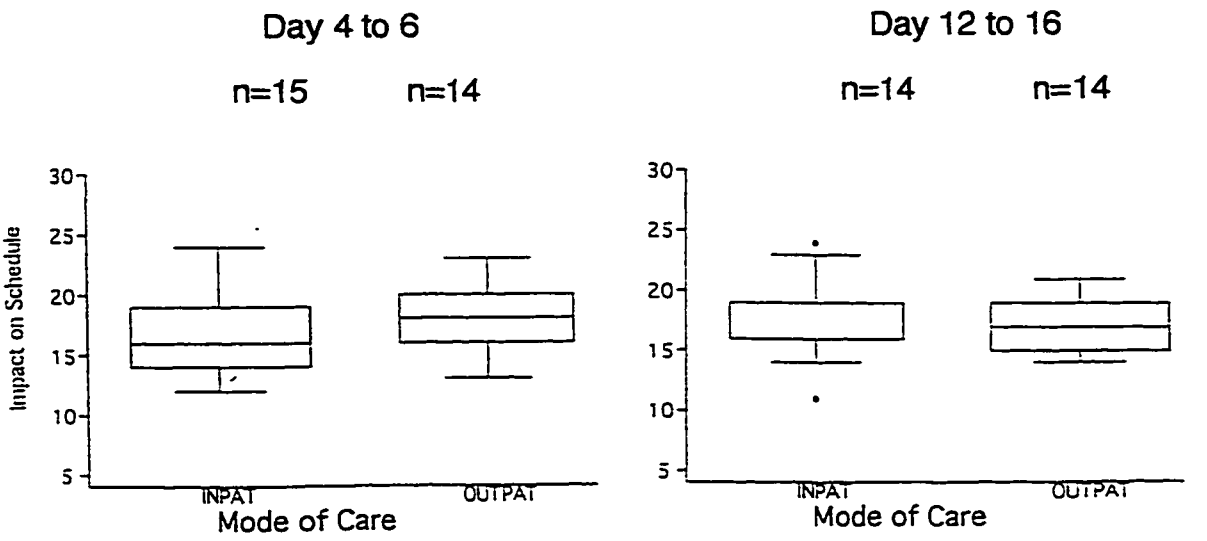
Figure 51. Impact on Schedule of Caregivers Making Alternate Living Arrangements by Mode of Care.



Caregivers were asked about changes in their employment status as a result of their involvement with someone with a serious illness. Thirty-three percent of the caregivers in the inpatient group and 39% in the outpatient group experienced some change in their employment status. Changes included leave of absence, change from full-time to part-time and becoming unemployed. These results show that the employment status of a large proportion of caregivers in both modes of care is affected by their care responsibilities.

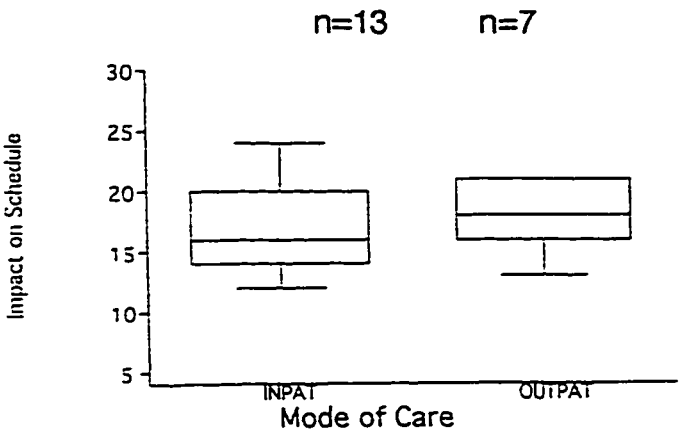
For those caregivers who remained employed either full-time or part-time and were not on a leave of absence, results showed that the median scores for impact on schedule for caregivers' in the inpatient and outpatient groups were 16 (95% C.I.=14 to 19) and 18 (95% C.I.=16 to 20) respectively at day 4 to 6, and 16 (95% C.I.=16 to 20) and 17 (95% C.I.=16 to 18) respectively at day 12 to 16. Thus, impact on schedule appears to be similar between the modes of care for caregivers who remained employed.

Figure 52. Impact on Schedule of Caregivers who were Employed and Working by Mode of Care.



It could be predicted that caregivers of very sick outpatients (Karnofsky<70) at day 4 to 6, experience a greater impact on their schedule because the demand for providing care is more intense. However, the median scores were similar for the inpatient and outpatient groups (16; 95% C.I.=14 to 19 and 18; 95% C.I.=16 to 20 respectively). Even though patients were very sick, the impact on schedule as one aspect of burden of care, did not appear to differ between the study groups.

Figure 53. Impact on Schedule of Caregivers Caring for Patients Experiencing High Morbidity by Mode of Care.



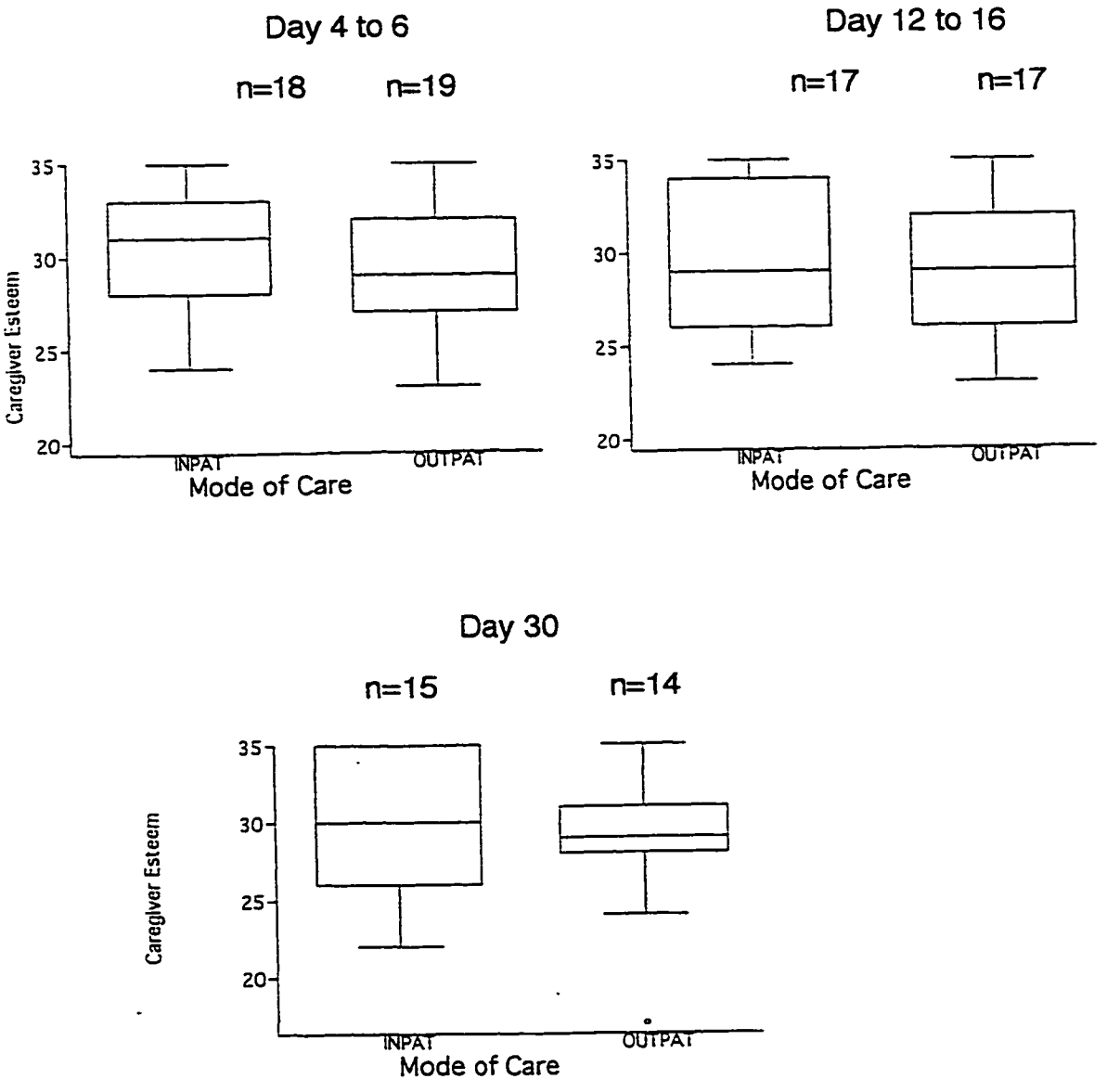
2. Caregivers' Esteem

Caregiver's esteem, as indicated by the Caregiver Reaction Assessment, measured caregivers' desire to be involved and their sense of fulfilment in providing care for their loved one. Caregiver's esteem was measured at day 4 to 6, day 12 to 16 and day 30. With a possible score ranging between 6 and 35, a high score indicates a high level of esteem. At day 4 to 6, the range of scores for caregivers of inpatients and outpatients was 24 to 35 and 23 to 35 respectively (Figure 54). Inpatients had more scores at the higher end of the range as indicated by the negative skew. As well, the median scores for the caregivers of inpatients and outpatients was also similar at 31 (95% C.I.=29 to 33) and 29 (95% C.I.=27 to 31) respectively. At day 12 to 16 and day 30, the range of scores and median scores for both groups were essentially the same as day 4 to 6.

These results suggest that most caregivers in both groups, experience a

high level of fulfilment and desire for providing care. At each time interval, some caregivers actually indicated the highest maximum score. The confidence intervals were fairly narrow and overlapped at all time intervals, indicating that the scores for the inpatient and the outpatient groups were similar.

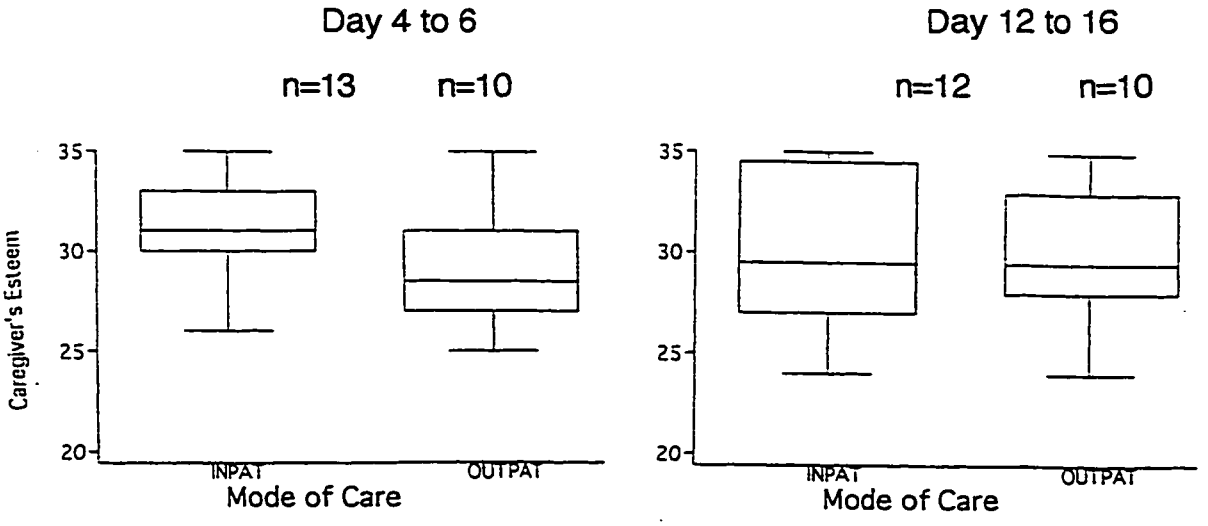
Figure 54. Caregivers' Esteem by Mode of Care.



Traditionally the role of caregiver has been the responsibility of women, with the assumption that women are more comfortable in this role. Therefore if a man is not comfortable in the role of caregiver, the added responsibility of providing care, particularly in the home environment could diminish their esteem. An analysis for the subgroup of male caregivers provided the following results (Figure 55). In considering the esteem of male caregivers at day 4 to 6, results showed a similar range in scores for both groups. The median scores for esteem were 31 (95% C.I.=29 to 33) in the inpatient group and 28.5 (95% C.I.= 26 to 31) in the outpatient group suggesting no difference between groups.

At day 12 to 16, the median scores for male caregivers esteem were equal at 29.5 and similar to median scores at day 4 to 6. Although there is no evidence to suggest a diminished sense of caregiver esteem for males in the outpatient setting, male caregiver's esteem may be an important factor when considering outpatient mode of care. Further investigation with a larger sample may show that the same differential between the study groups at day 4 to 6 to be statistically significant.

Figure 55. Caregivers' Esteem of Males by Mode of Care.

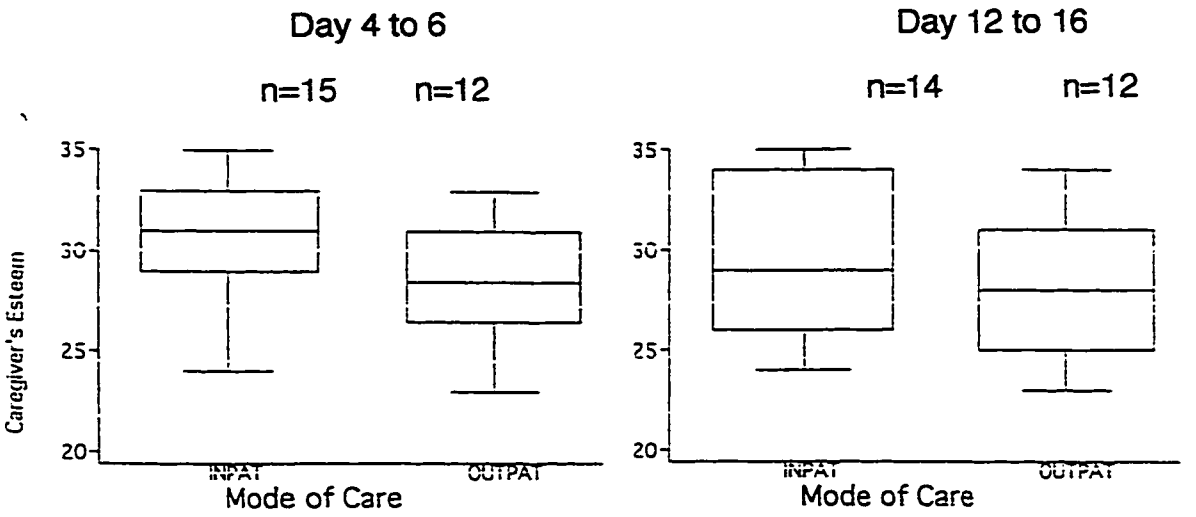


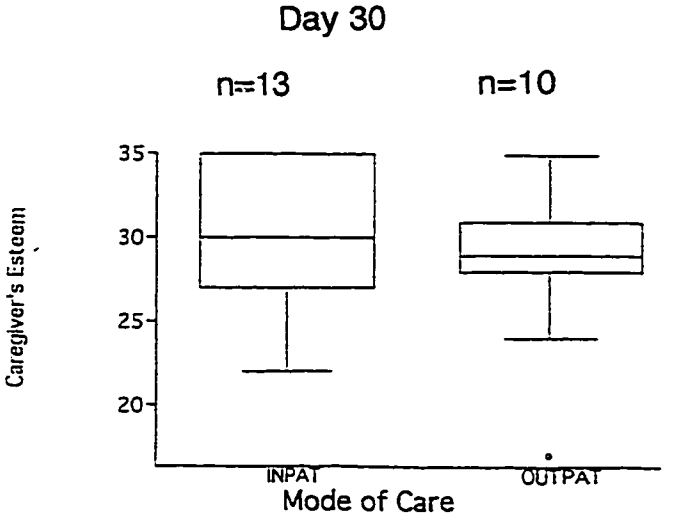
Another factor that may contribute to and enhance caregivers' esteem is their previous experience with someone who has had a serious illness (Figure 56). Inexperienced caregivers may not be comfortable in this role and as a result they may suffer low esteem. The majority of caregivers (inpatient=83% and outpatient=67%) had never had previous experience with someone with a serious illness. Analysis of this subgroup was done to examine the effect of no previous experience on caregiver esteem.

At day 4 to 6, the range of scores for the caregivers of outpatients (23 to 33) was slightly lower than for inpatients (24 to 35). As well, the median score of 28.5 (95% C.I.=26 to 31) for outpatients was slightly lower than for inpatients at 31 (95% C.I.=29 to 33). Because the confidence intervals are narrow and overlap and the data are normally distributed, statistical comparison of the mean scores was possible. The difference in mean scores were close to being significantly different (P= .057). When considering outpatient care for the post transplant patient, caregivers must feel comfortable in their role and experience a sense of fulfilment and desire to be actively involved in providing care. Without such feelings of esteem, the burden of providing care may be onerous.

At day 12 to 16, the median scores for caregivers' esteem for the inpatient and outpatient groups were similar at 29 (95% C.I.=26 to 32) and 28 (95%C.I.=25 to 31). By 30 day, patients' health in most cases had improved significantly enabling patients to be at home. Again the range of scores for both caregiver groups were similar with median scores equal at 30 and 29 respectively.

Figure 56. Esteem of Caregivers with No Experience with Illness by Mode of Care.





There are two possible explanations for the similarities between the groups with respect to caregiver's esteem at these time periods. First, by day 12 to 16, outpatient caregivers may have gained experience with providing care and become comfortable in their caregiving role. Second, the demand for care may be less by day 12 to 16 since many outpatients were admitted to hospital for a brief period of time, which in turn provided respite for the caregiver. As well, by day 12 to 16 patients were feeling better and were less demanding on the caregiver.

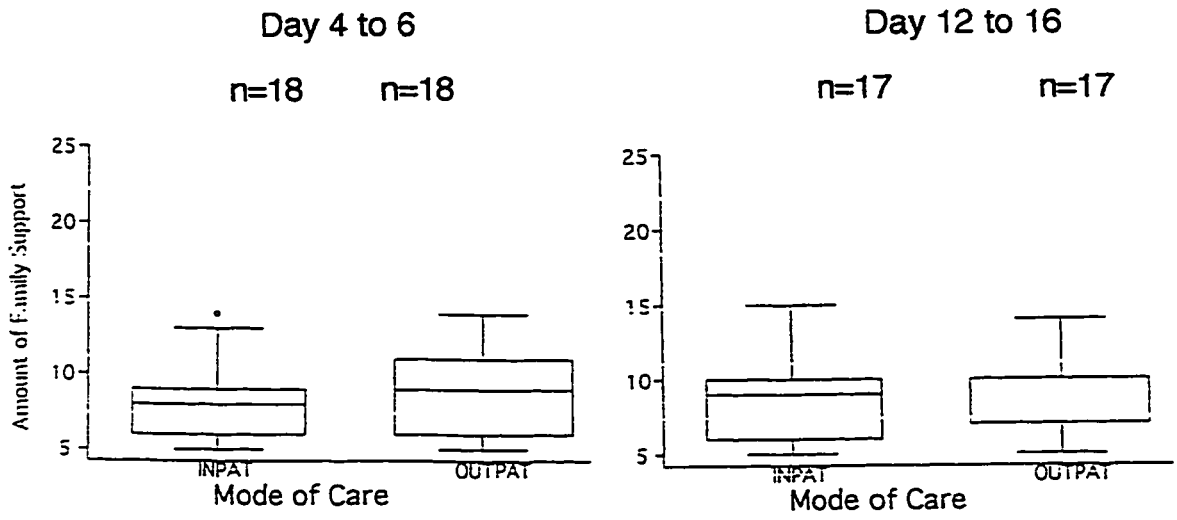
Caregivers are at risk for feeling more anxiety and depression because of their responsibilities of looking after someone with a life threatening illness. These feeling are likely even more intense for individuals who provide care for their loved one if treatment is outpatient based. Heightened anxiety and depression may negatively impact the caregiver's esteem and thereby increase the sense of caregiver burden. Analysis of the subgroup of caregivers with high levels of anxiety and depression was attempted in order to determine how their esteem was affected. However, the number of caregivers with high levels of anxiety and depression was too small for analysis to be meaningful. A larger sample size is necessary to understand this subgroup of caregivers. This analysis would be of interest since there were some caregivers with high scores of depression and anxiety. Their ability to provide care may be reliant upon intense support from the health care team. Caregivers' feelings of anxiety and depression are discussed later in this section.

3. Family Support

The amount of family support available for the caregiver was measured using the Caregiver Reaction Assessment Instrument. This instrument asks caregivers to rate their family's level of involvement in assisting with provision of

care (i.e. ease of getting help, feelings of abandonment and ability of family to work together). Lack of family support may contribute to the caregiver's feeling of burden. The highest possible score, indicating low level of family support is 25. At day 4 to 6, the range of scores for both the inpatient and outpatient groups were 5 to 14, with median scores of 8 (95% C.I.=6 to 9) and 9 (95% C.I.=6 to 11) respectively . Again, at day 12 to 16, the dispersion and median scores were similar to scores at day 4 to 6. Generally, the caregivers in both groups indicated having good family support. However, the scores in the inpatient group were skewed towards the lower range indicating that family support in this group was particularly strong.

Figure 57. Family Support by Mode of Care.



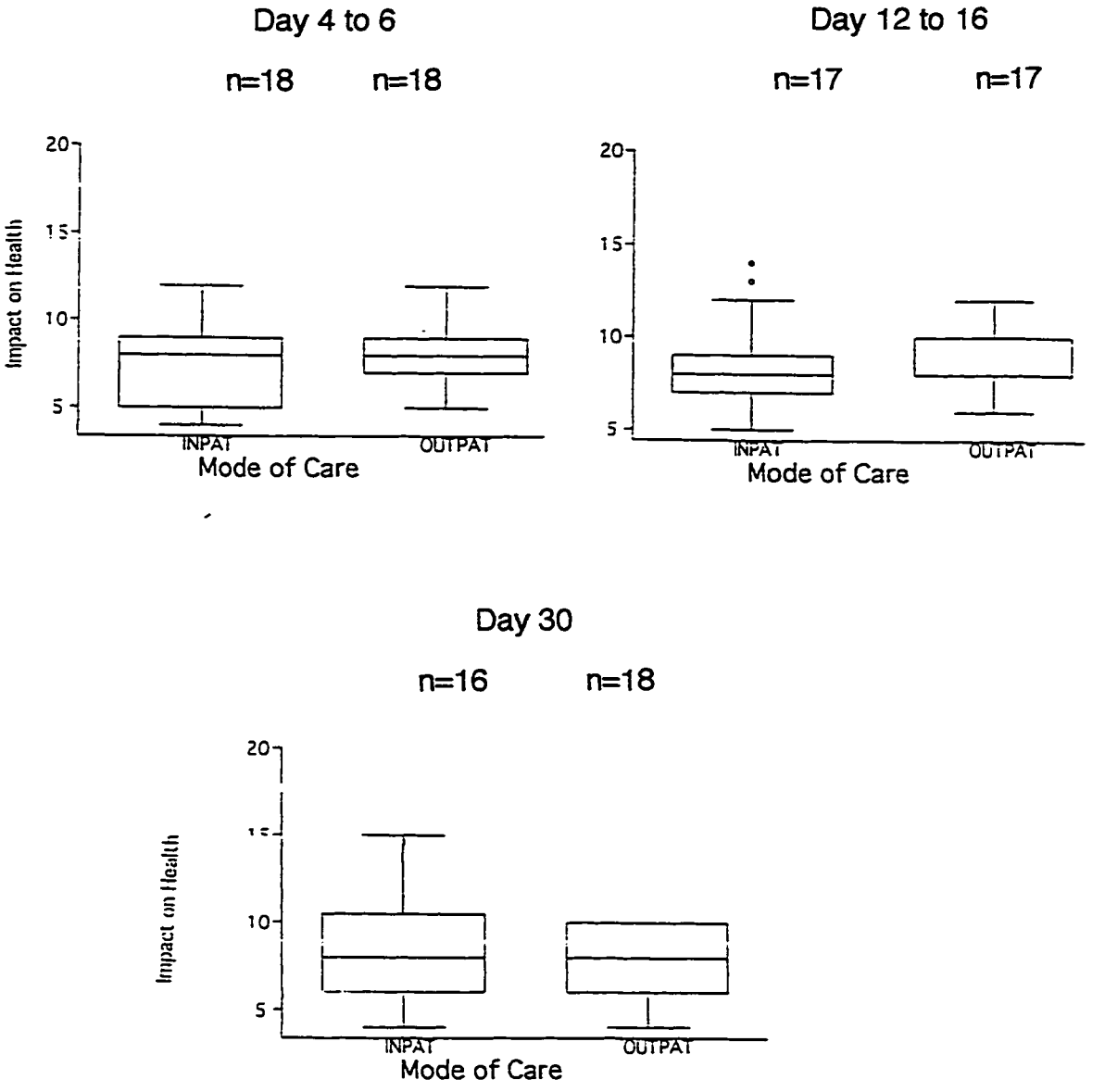
Lack of family support does not appear to be a problem for study participants, however in a larger study there may be more caregivers without adequate family support and this issue may be more pertinent. With a larger sample, more in depth analysis of this issue could consider involvement of extended family in providing care, distance from extended family and relationship with extended family.

4. Impact on Health of Caregivers

The Caregiver Reaction Assessment Instrument was used to assess how the caregiver's physical health was affected as a result of providing care for someone who is seriously ill. The box plot in Figure 58 shows the dispersion of the data. With a possible score of 20 indicating the highest impact on health, the range of scores for both groups, at day 4 to 6 were similar (maximum score of 12 and minimum scores of 4 and 5 for inpatient and outpatient groups respectively). The median score for both groups was 8.

Over time the impact of being a caregiver on physical health remained constant. At day 12 to 16 and day 30, the median score for caregivers of the inpatient group remained at 8 (95% C.I.= 7 to 9), while outpatient caregivers scored slightly higher at 10, indicating a greater impact on health (95% C.I.=8 to 10). The median scores at the other time intervals were the same for both groups. These results suggest that caregivers of outpatients were not adversely affected by their responsibilities.

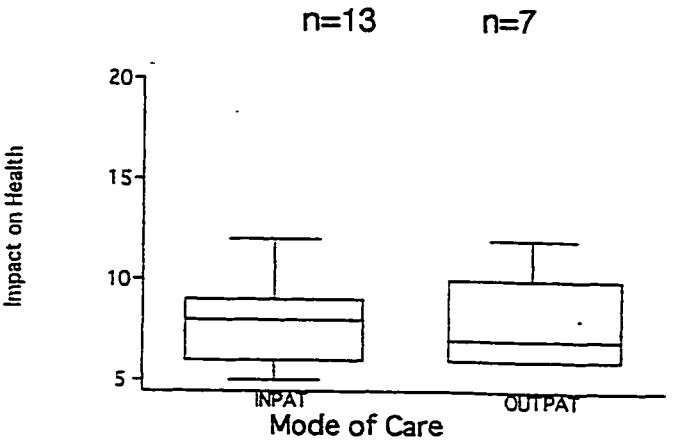
Figure 58. Impact on Health of Caregivers by Mode of Care.



The age of the caregiver could be a factor that influences the health impact of caregiving. The increased demands placed on caregivers of outpatients may have implications for the elderly population. In this study there were too few elderly subjects for this type of analysis.

Patients who experience a higher level of morbidity may place a greater demand on the caregiver, perhaps resulting in a negative impact on caregivers' health. This may be an important influence among the outpatients' caregivers. In considering the impact on caregivers' health, caregivers of inpatients and outpatients who required assistance with some or most of their own needs (as indicated by a Karnofsky score of less the 70%) had similar median scores (8; 95% C.I.=6 to 10 and 7; 95% C.I.=6 to 11 respectively). The data as shown in the box plot in Figure 59 illustrates that the groups did not differ.

Figure 59. Impact on Health of Caregivers Caring for Patients Experiencing High Morbidity by Mode of Care.

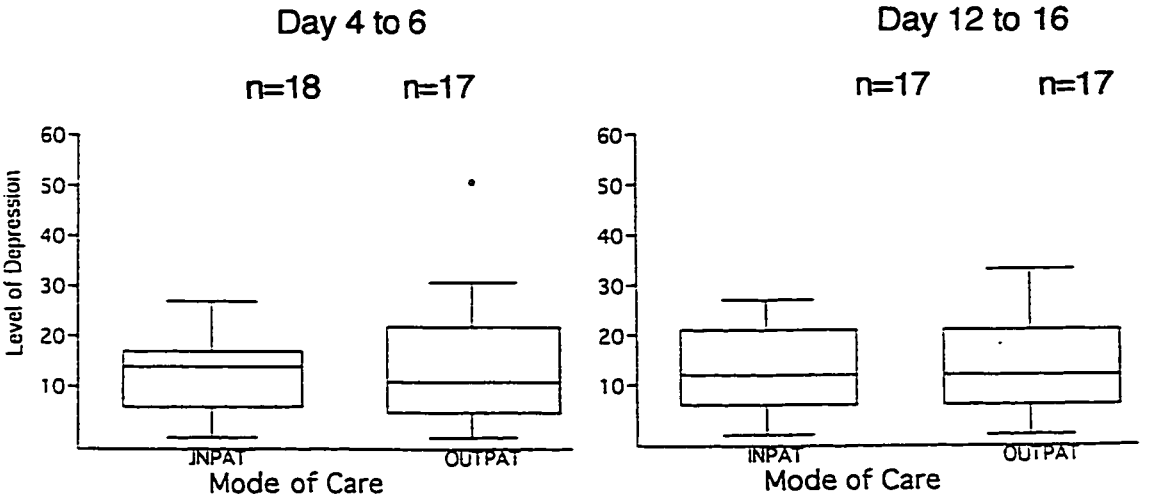


In summary, the physical health of caregivers in this study did not appear to be negatively affected by the demands placed on them for providing care in an outpatient or home environment.

Caregivers' feelings of depression and anxiety could influence their health, especially for caregivers of outpatients. Caregivers are put in a position of great responsibility when the patient is treated as an outpatient. One of the criteria for patient eligibility for outpatient care is that the patient must have a caregiver available on a 24 hour basis. The caregiver is responsible for helping with nutrition, medication, monitoring vital signs and knowing what to do if complications arise. Along with these responsibilities comes the worry about the patient's condition. They may have questions about what to do if something goes wrong and they may be required to make decisions. The added responsibility and worry associated with outpatient care may create stress for the caregiver, which could be expressed as depression or anxiety. Following is a comparison of caregivers' feelings of depression and anxiety at days 4 to 6 and day 12 to 16 (figures 60 and 61).

Caregivers' feelings of depression were measured using the Centre for Epidemiological Study - Depression (CES-D) instrument. Figure 60 displays the data of caregivers' feelings of depression at day 4 to 6. The higher the score (out of a possible maximum score of 60) the higher the level of depression. Overall the comparison groups were very similar. The interquartile range of scores for the outpatient group was wider, indicating more variation in the scores. As well, the distribution of scores in the outpatient group was positively skewed because of more low scores and one extreme high score of 51. The median scores for caregivers' feelings of depression were similar at 14 (95% C.I.=7 to 17) for the inpatient group and 11 (95% C.I.=5 to 21) for the outpatient group. At day 12 to 16, caregivers' feelings of depression were the same (12).

Figure 60. Measure of Depression of Caregivers by Mode of Care.

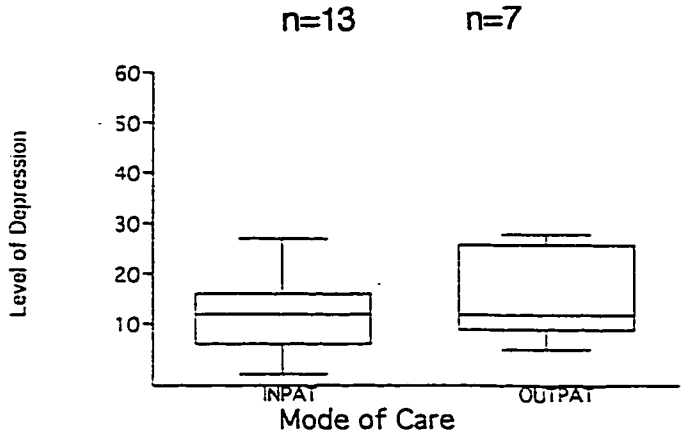


The CES-D allows caregivers to be categorized into those with depression and those without depression. A score of 16 or greater is considered an indicator of depression. According to this interpretation of the scores, 39% (95% C.I.=17% to 62%) of the caregivers in the inpatient group and 28% (95%C.I.=7% to 49%) of the caregivers in the outpatient group would be classified as depressed.

If the patient became sick during the period after the transplant, the caregiver's concern for the patient may increase. This concern could contribute to the caregiver's feelings of depression and anxiety. Feelings of depression were compared at day 4 to 6 for caregivers of patients who were considered to be sick (Figure 61). Patients' level of morbidity was defined as those patients that required assistance with some or most of their own needs, as indicated by a Karnofsky score of less the 70%. Caregivers who cared for patients with a high level of morbidity showed a great difference in the interquartile range of the scores for depression indicating a greater degree of variability even though the median scores were the same at 12. The interquartile range for the caregivers

of the outpatient group is very wide (IQR=17, Q1=9, Q3=26) compared to the inpatient group (IQR=10, Q1=6, Q3=16). However, the total range of scores for the outpatient group was similar to the inpatient group.

Figure 61. Measure of Depression of Caregivers Caring for Patients Experiencing High Morbidity by Mode of Care.

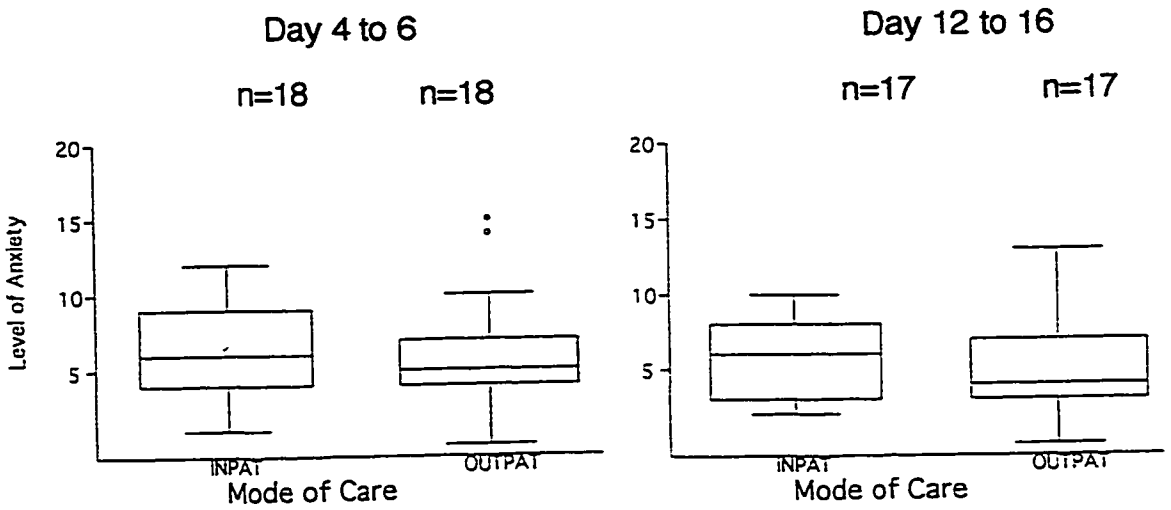


Another way of comparing caregiver's depression would be to consider the number of caregivers who had depression scores 16 or greater. In the inpatient group, 4 of the 13 (31%) caregivers scored in this range compared with 3 of the 7 (43%) in the outpatient group. These proportions suggest the caregivers of both groups experienced depression similarly. By day 12 to 16, there were fewer patients with a high level of morbidity thus the sample of caregivers was too small for further comparison.

Caregivers' feelings of anxiety were measured as a subscore of the Profile for Mood States (POMS). Higher scores indicate more anxiety with a possible maximum score of 20. At day 4 to 6, the scores for anxiety for both groups were low. The scores for the outpatient group were positively skewed

because of more low scores and two outlier (high) scores. Caregivers' feelings of anxiety were the same for both groups as indicated by the median scores of 6 (95%C.I.=4 to 9) for the inpatient group and 5 (95% C.I.=4 to 7) for the outpatient group. The distribution of scores for day 12 to 16 was similar to those scores at day 4 to 6.

Figure 62. Measure of Anxiety of Caregivers by Mode of Care.



Like feelings of depression, the level of morbidity of the patient could be expected to have an impact on caregivers' feelings of anxiety. This was tested by examining the median scores of caregivers' anxiety when caring for patients that required assistance with some or most of their own needs (Karnofsky score of less the 70%). The scores were similar for the caregivers of both inpatient and outpatient groups (median scores of 5; 95% C.I.=3 to 9 and 6; 95% C.I.=4 to 9 respectively).

Figure 63. Measure of Anxiety of Caregivers Caring for Patients Experiencing High Morbidity by Mode of Care.

Day 4 to 6

n=13 n=7

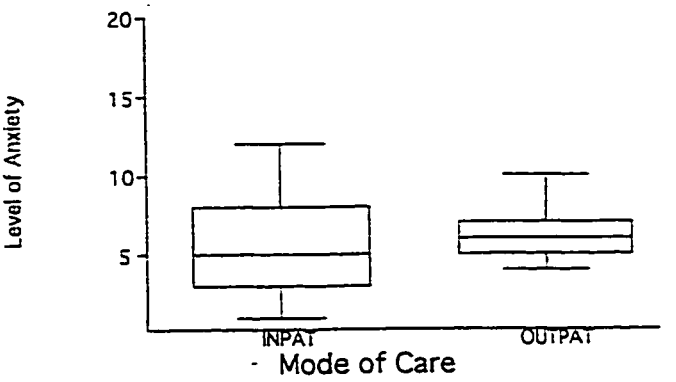


Table 3.14
Summary of Measures of Social Interaction

MEASURES OF SOCIAL INTERACTION	INPATIENTS			OUTPATIENTS		
	Median Score at day 4-6	Median Score at day 12-16	Median Score at day 30	Median Score at day 4-6	Median Score at day 12-16	Median Score at day 30
Social/Family Well-Being	23	24	24	23	23	26
CAREGIVER BURDEN						
Impact on Schedule	16.5	16	14	18	17	15
Impact on Schedule when Alternate Living Arrangements	13	16	N/A	18	17	N/A
Caregivers' Esteem	31	29	30	29	29	29
Esteem of Caregivers with No Experience with Illness	31	29	30	28.5	28	29
Family Support	8	9		9	10	
Impact on Health of Caregiver	8	8	8	8	10	8
Caregiver Depression	14	12	N/A	11	12	N/A
Caregiver Anxiety	6	6	N/A	5	4	N/A

VII. Global Measure of Quality of Life

Global quality of life, as measured by the FACT,BMT, is indicated by the sum of all scores from the subscales of physical well-being, functional well-being, emotional well-being, social and family well-being, relationship with doctor and additional concerns about BMT. The highest possible score for this measure is 152, indicating a good quality of life.

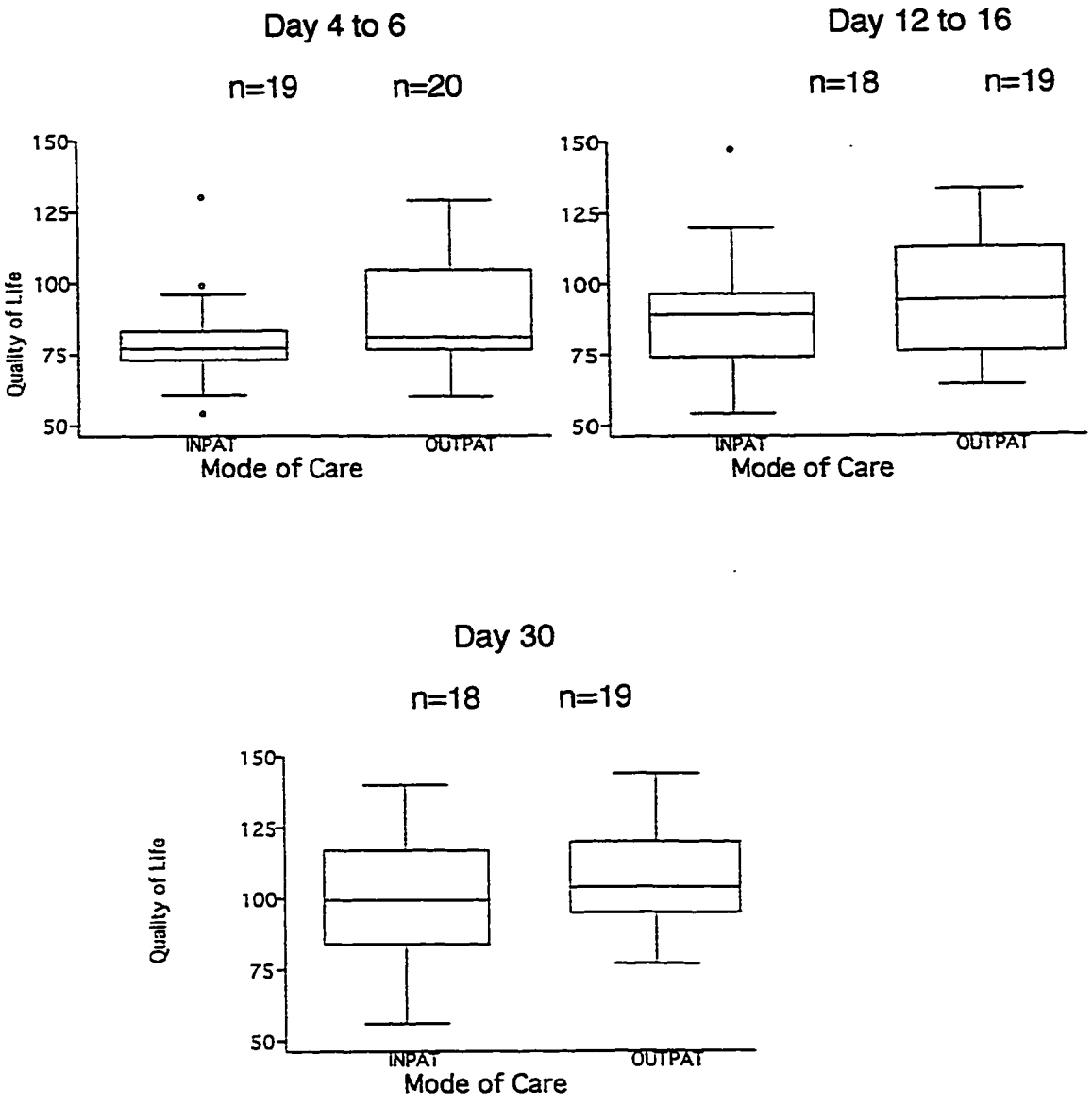
On the baseline measure, the outpatient group appeared to have a better quality of life than the inpatient group, as indicated by a higher total score (see Chapter 3, Baseline Quality of Life). As expected, at day 4 to 6, day 12 to 16, and day 30, the quality of life for both groups was less than the quality of life as measured at baseline. The lower quality of life scores at all three times compared to baseline may be due to the effect of treatment side-effects and emotional stress of undergoing cancer treatment.

Overall, the dispersion of scores at day 4 to 6 and day 12 to 16 was positively skewed with more patients indicating scores at the lower end of the range. Although the range of scores for the inpatient and the outpatient groups were somewhat similar, the interquartile range of the outpatient group was wider, indicating a greater variation in quality of life. The median score for the inpatient group at day 4 to 6 was 77 (95%C.I.=74 to 82) and at day 12 to 16 it was 89 (95% C.I.=75 to 96). The median score, at day 4 to 6 and day 12 to 16, for the outpatient group was 81 (95%C.I.= 77 to 104) and 94 (95% C.I.=77 to 109) respectively. In summary, the global quality of life for both groups was similar at the two time intervals. The confidence intervals overlap suggesting no difference, the study sample was too small to detect a difference between groups.

At day 30, the global quality of life score had increased as side effects

subsided. The median scores for the inpatient and outpatient groups were similar. However, the range of scores for the outpatient group was less variable, with fewer low scores.

Figure 64. Quality of Life by Mode of Care.



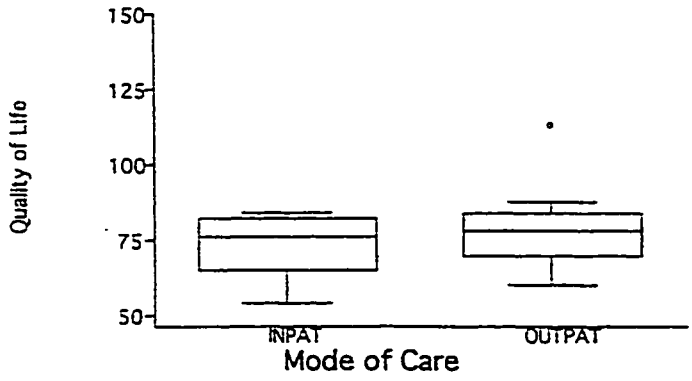
The experience of pain can affect a person's quality of life. Therefore, global quality of life will be reported separately for patients who experienced a great deal of pain and for those who experienced little or no pain.

The quality of life for patients experiencing a great deal of pain at day 4 to 6 (55% of inpatients and 33% of outpatients) was similar for inpatients and outpatients. The median scores were 76 and 78 respectively. By day 12 to 16, the number of patients with a great deal of pain were too few to permit further descriptive analysis.

Figure 65. Quality of Life for Patients Experiencing a 'Great Deal of Pain' by Mode of Care.

Day 4 to 6

n=11 n=8



The global quality of life scores at day 4 to 6 were also compared between inpatients and outpatients who experienced little or no pain. As shown in Figure 66, although the range of scores in both groups was similar, the inpatient median score for quality of life appears to be lower compared with outpatients (median score=82; 95% C.I. =74 to 109 and median score=99; 95%

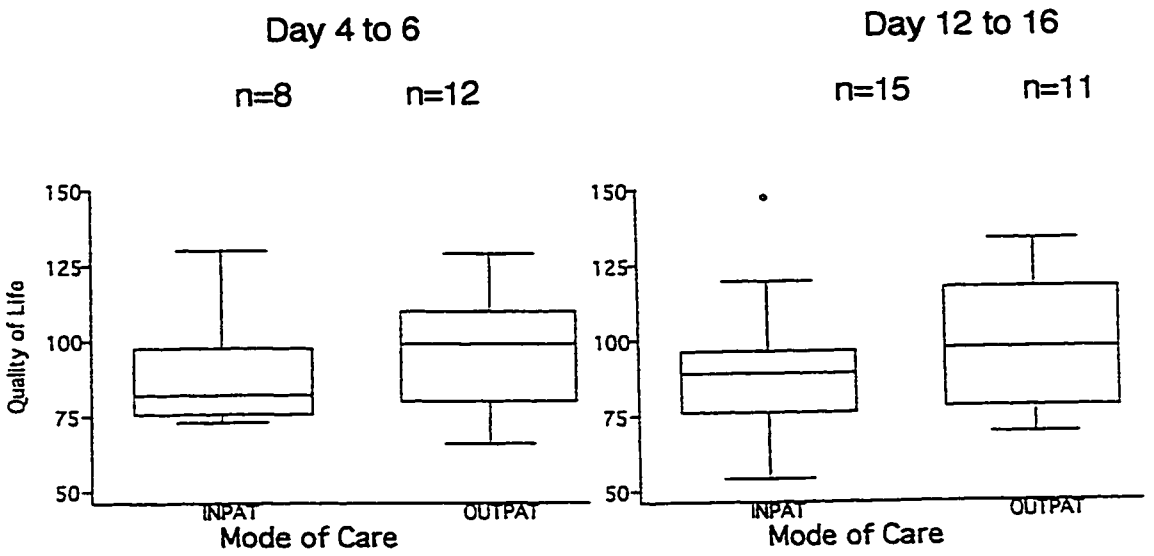
C.I.=80 to 114 respectively). Even though the median scores seem to differ, the confidence intervals are broad and overlap. Therefore conclusions cannot be made about similarities or differences in median scores between the comparison groups.

There are two potential reasons why the outpatient group could have a better overall quality of life compared to the inpatient group. First, the difference between groups could be due to the high dose chemotherapy protocol that the majority of patients in the inpatient group received (Mitoxantrone, Vinblastine and Cyclophosphamide). These patients experienced their worst side-effects around day 2. Most patients in the outpatient group received high-dose Melphalan protocol. The side-effects from this protocol are at their worst around day 6 or 7. With this in mind, the outpatient group would be expected to have a better quality of life at day 4 to 6.

Second, the difference between groups at day 4 to 6 may be related to the baseline quality of life measures. That is, outpatients started with a higher quality of life score and this differential was maintained at day 4 to 6. However, the reason that the outpatient group experienced a better quality of life at baseline remains unexplained.

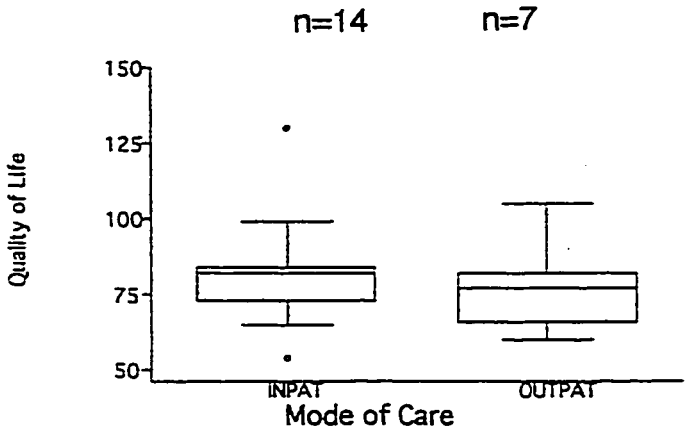
It could be expected that by day 12 to 16, the effects of the high-dose chemotherapy for both treatment groups should be similar and therefore the study samples should not differ on their quality of life scores. Figure 66 confirms this assertion. The median scores for the inpatient and outpatient groups were 89 (95% C.I. = 77 to 96) and 97 (95% C.I.= 77 to 120) respectively. The confidence intervals are broad and overlap suggesting that the median scores for global quality of life at day 12 to 16 for the two modes of care do not differ.

Figure 66. Quality of Life of Patients Experiencing Little or No Pain by Mode of Care.



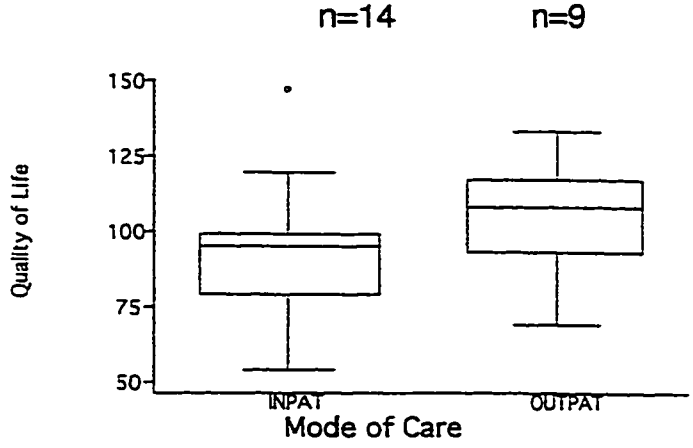
In addition to pain, quality of life can also be negatively influenced by level of morbidity. Patients with a high level of morbidity (Karnofsky less than 70%) at day 4 to 6 had similar quality of life ratings in each comparison group. The median scores for the inpatient and outpatient groups were 82 (95% C.I.=73 to 86) and 77 (95% C.I.=62 to 98) respectively. The quality of life for both subgroups was greatly decreased from baseline. The variation in quality of life scores for the outpatient group was greater as evident by a larger interquartile range. The inpatient group had a greater range in scores only because of extreme outliers on either sides of the 'whiskers'. By day 12 to 16 there were too few subjects in this subgroup to consider further analysis.

Figure 67. Quality of Life for Patients Experiencing High Morbidity by Mode of Care.



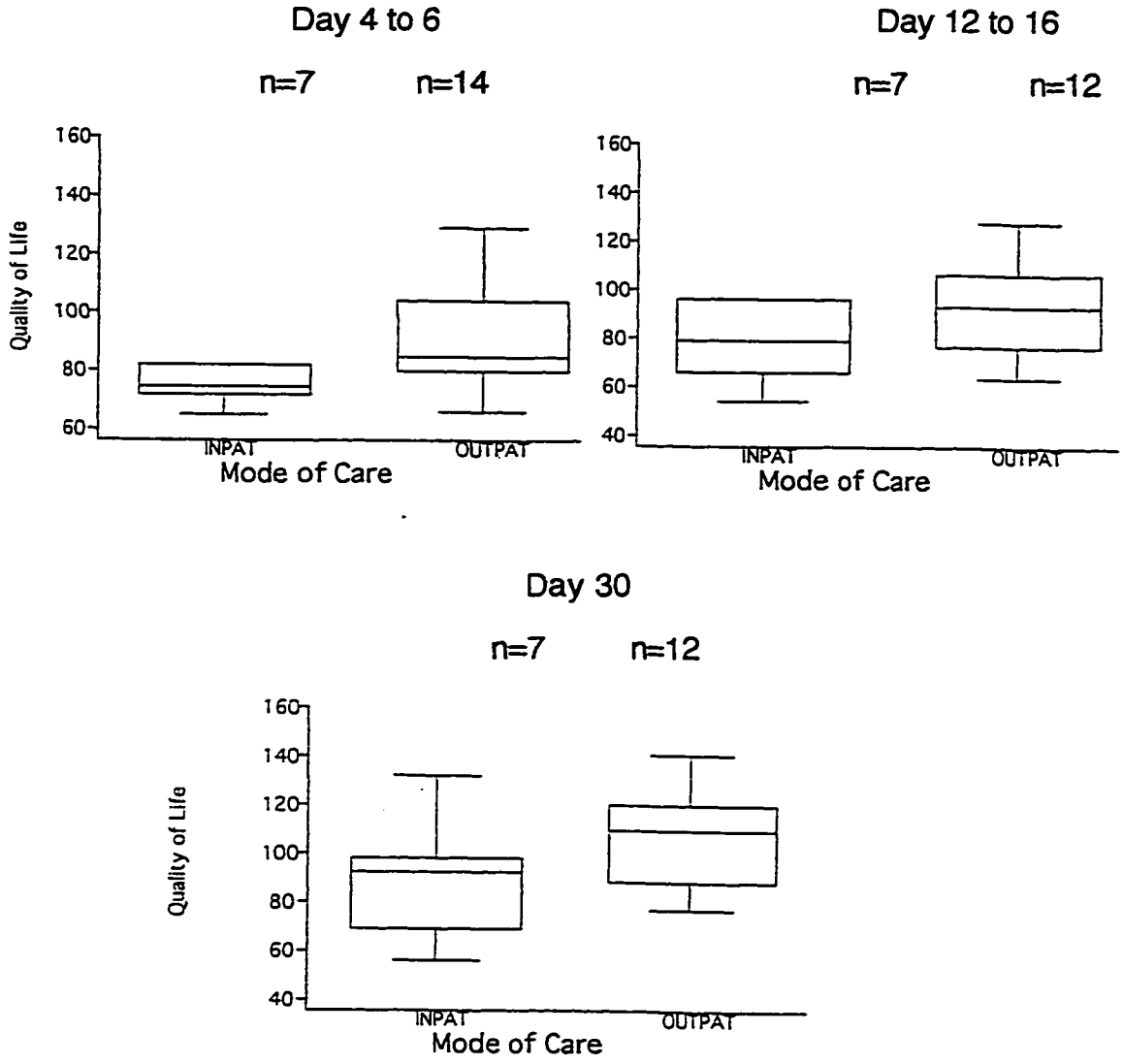
At day 4 to 6, the number of patients with low morbidity were too few (n=5) to justify a comparison with outpatients. By day 12 to 16, the number of patients who were experiencing lower levels of morbidity had increased, thus a larger sample was available for analysis. As shown by the box plot in Figure 68, outpatients appears to have a better quality of life, as indicated by a median score of 108 (95%C.I.=77 to 127) compared to 95 (95% C.I.=78 to 100) for inpatients. Although the confidence intervals do overlap, they are broad as a result of a small sample and therefore precise estimates are not possible.

Figure 68. Quality of Life for Patients Experiencing Low Morbidity by Mode of Care.
Day 12 to 16



Quality of Life scores were analysed for the subgroup of patients who experienced previous treatment failure (Figure 69) . Like emotional well-being, this subgroup of outpatients reported slightly higher quality of life at all three time intervals. At day 4 to 6, inpatient and outpatient median scores were 75 (95% C.I. = 67 to 82) and 85 (95% C.I.= 78 to 104) respectively. Although the scores at day 12 to 16 and day 30 improved somewhat over the time period, the outpatients continued to report slightly better quality of life. Because of this trend, the baseline scores of quality of life for patients who had previous treatment failure was analysed. Outpatients' median score was 122.5 (95% C.I.=105 to 139) compared to inpatients' median score of 101 (95% C.I.= 93 to 124). Thus, outpatients experienced a higher quality of life at the outset of the study.

Figure 69. Quality of Life of Patients who had Previous Treatment Failure.



One reason for this elevation in global quality of life of outpatients who experienced previous treatment failure may be the result of the influence of the elevated score of emotional well-being, as a subscore of quality of life. That is, the higher score for emotional well-being is reflected as a high score in global quality of life.

Another reason for this subgroup of outpatients reporting higher quality of life scores may be explained with similar rationale to the explanation of the between group differences of emotional well-being. Patients whose experience with previous treatment failure was positive reported a high quality of life at baseline and therefore chose outpatient care. They anticipated their experience with high-dose treatment would be positive and thereby believed they could manage well in the outpatient setting.

Table 3.15

Summary of Measures of Global Quality of Life

MEASURES OF GLOBAL QUALITY OF LIFE	INPATIENTS			OUTPATIENTS		
	Median Score at day 4-6	Median Score at day12-16	Median Score at day 30	Median Score at day 4-6	Median Score at day 12-16	Median Score at day 30
Over-all Scores	77	89	99.5	81	94	104
Patients with Low Morbidity	N/A	95	N/A	N/A	108	N/A
Patients with High Morbidity	82	N/A	N/A	77	N/A	N/A

Overall, the global quality of life for outpatients was no worse than the quality of life for the inpatients. It must be remembered that the outpatient group indicated a better quality of life at baseline. The reason for the difference at baseline is unknown, however, something about the outpatient group may have been systematically different from the inpatient group. That being said, although the instrument measuring global quality of life showed a difference in the scores

between the inpatients and outpatients at baseline, measures at other time intervals were not different enough to suggest that patients with high baseline measures will maintain a higher quality of life as outpatients in the immediate post transplant period.

VIII. Personal Financial Impact

Patients and caregivers were asked to record their out-of-pocket expenses during the 30 day study period, starting the day of the transplant. Expenses included travel, parking, lodging, medications, child care, house sitting and telephone and television rental. Caregivers were also asked to report additional insurance coverage other than Alberta Health Insurance.

The following is a summary of the expenses incurred by inpatients and outpatients. The largest expenses for both groups were for travel, medication and parking. The majority of patients had additional insurance coverage that provided reimbursement for the costs of medications. Because ABSCT is provided only in Calgary and Edmonton, patients from out-of-town incurred the added expense of lodging and travel which can added considerably to the cost for these patients and their family.

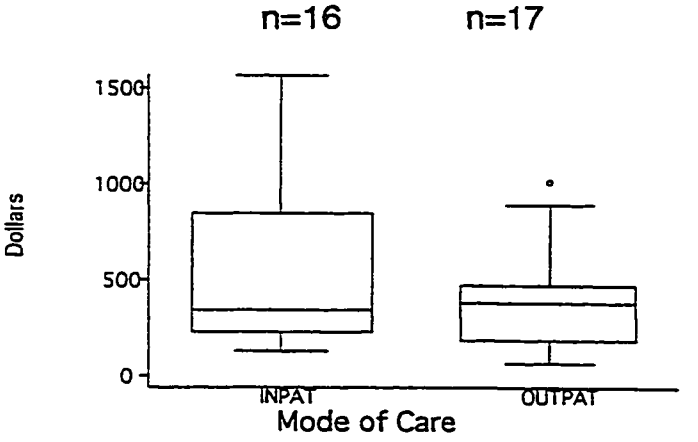
A. Direct Expenses

In this study, outpatients did not appear to carry a greater financial burden compared to inpatients. When caregivers were asked about the impact of the cost of care on their finances, both inpatients and outpatients expressed a moderate amount of concern. Indirect costs such as loss of the caregiver's

salary and loss of health benefits were minimal and found to be similar in the frequency of occurrence in the inpatient and the outpatient groups.

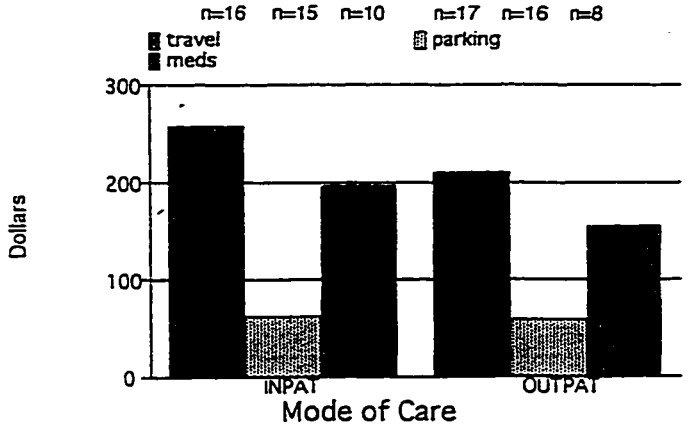
In the following analysis, out-of-pocket expenses are not adjusted for reimbursements from supplementary plans. The median total expenses for inpatients was $340 over the 30 day period (95% C.I.= $230 to $840). The median expenses for the outpatient group for the same time period was $380 (95% C.I.= $190 to $600). The range of expenses were similar for both groups with minimum costs for the inpatient and outpatient groups of $130 and $70 respectively. The maximum out of pocket expenses were $1570 for the inpatient group and $1010 for the outpatient group. Only 3 inpatients and 2 outpatients had total expenses greater than $1 000 but less than $2 000. These 5 individuals were from out-of-town. For 2 of the 3 inpatients the greatest expense was for accommodations for their spouse. For 3 patients the greatest expense was for travel. The amount of these expenses resulted from choices made by patients and their families, (i.e.; choice of hotel or frequency of trips to and from the hospital) as opposed to necessary expenses incurred for medications or medical supplies.

Figure 70. Total 'Out-of-pocket' Expenses by Mode of Care.



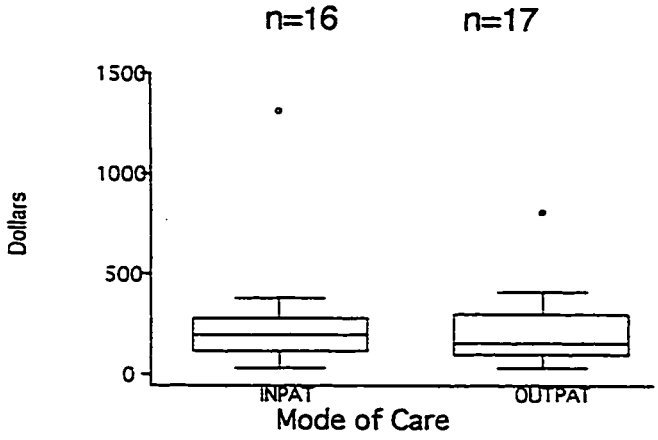
Travel, medication and parking were the three highest expenses for the majority of patients whether they were treated as inpatients or outpatients (Figure 71). Although lodging was a large expense, only 2 inpatients and 4 outpatients paid for accommodations with an average cost of $620 for inpatients and $510 for outpatients.

Figure 71. Mean Expenses by Mode of Care.



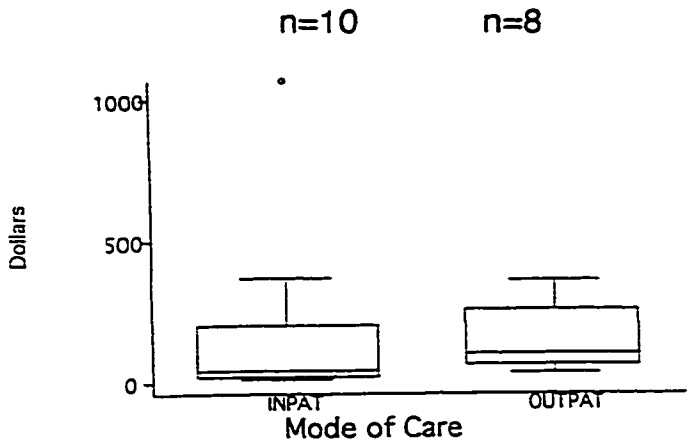
The cost of travel was based on the distance in kilometres from where the patient or caregiver stayed to the hospital, multiplied by the number of trips made by the patient or caregiver over the 30 day period. Expense was calculated based on $.32/kilometre. Both study groups had one extremely high outlier, with the expense for the remaining patients of less than $500. The median expenses for travel for the inpatient group was $200 and for the outpatient group was $150. Even with consideration of those patients that were from out-of-town, the median expenses for travel were similar.

Figure 72. Travel Expenses by Mode of Care.



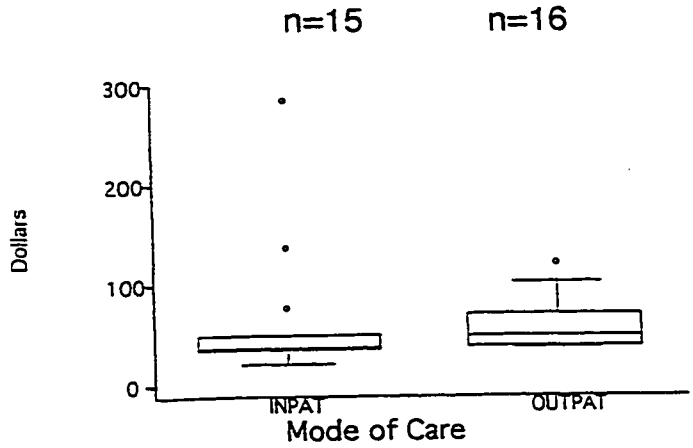
Of the 18 patients that incurred expenses for medications, 14 or 78% had additional insurance that provided 80% to 100% reimbursement of these expenses. The range of expenses within the 'whiskers' were similar. The patient who experienced extreme expense, shown as an outlier in the inpatient group, had additional insurance to cover the total cost. The median expense for medications for inpatients was $43 (95%C.I.=$20 to $320) and the median expense for outpatients was $100 (95% C.I.=$30 to $300). The confidence intervals are wide as a result of small sample and therefore it is difficult to interpret the difference in expenses between groups. Regardless of this limitation in the data, generally a small amount of expense was incurred by patients for medication.

Figure 73. Medication Expenses by Mode of Care.



Parking expenses were incurred by 75% of inpatients and 76% of outpatients. The expenses for parking were similar for both groups, with the median expenses for inpatients and outpatients being $37 and $49 respectively. One caregiver from the inpatient group, who was from out-of-town, had parking expenses that were extreme at $285 because of parking expenses at the place of lodging.

Figure 74. Parking Expenses by Mode of Care.



Other expenses that were incurred during the 30 day period were for child care, house sitting and laundry. Although these expenses were included in the total expense to the patient, the number of patients paying for these services were very few and were not specific to either the inpatient or outpatient group.

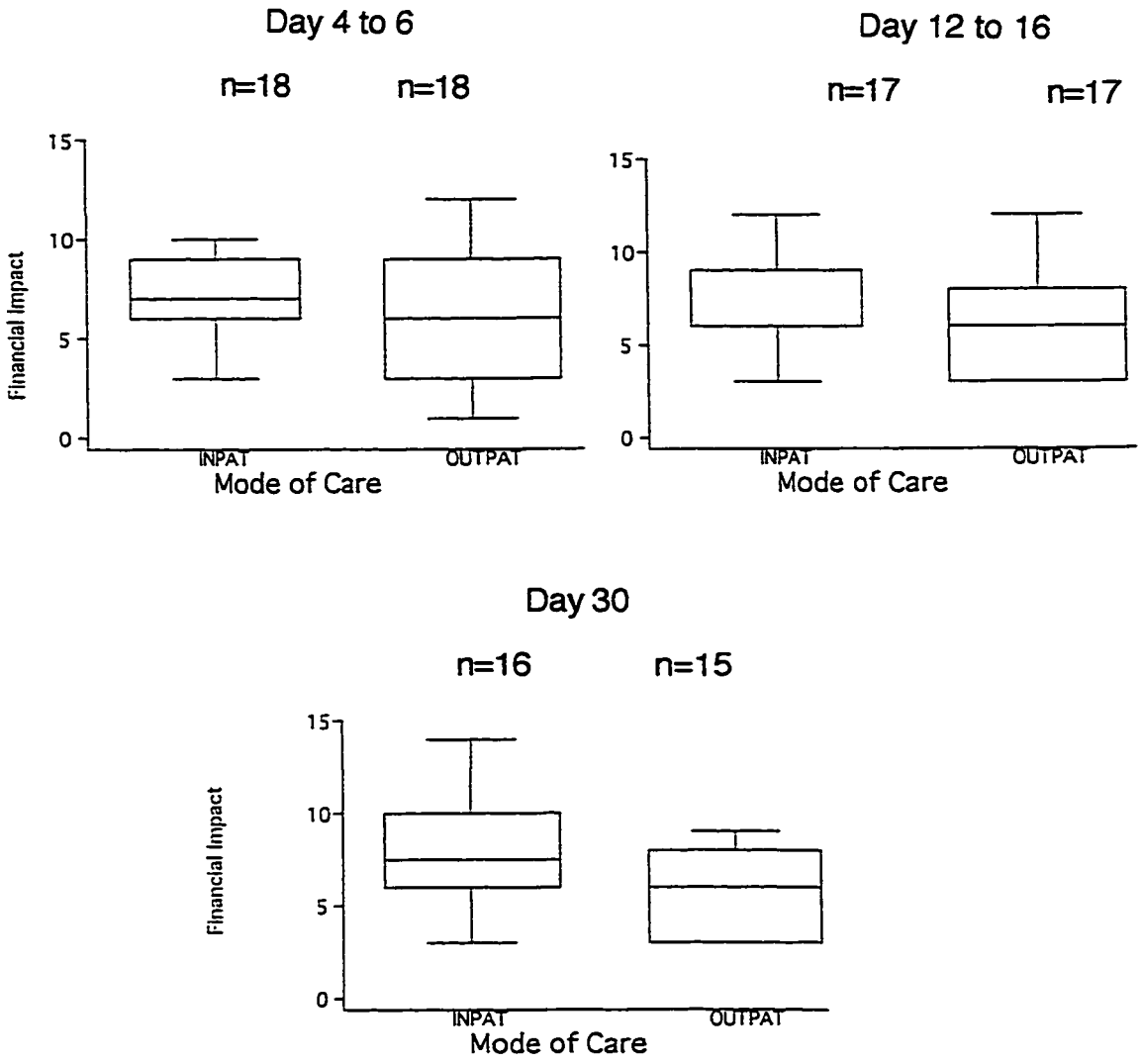
Caregivers were asked about the financial impact of the cost of patients' care during the 30 day period after the transplant. The questions came from the Caregiver Reaction Assessment instrument. The highest possible score of 15 indicated a high impact on finances (Figure 75).

At day 4 to 6, there was more variation in response from caregivers of outpatient regarding the impact on finances. However, the median scores for inpatients and outpatients were similar at 7 (95% C.I.=5.8 to 8.2) and 6 (95% C.I.=4.2 to 7.8) respectively.

At day 12 to 16, although the range of scores was the same for the inpatient and outpatient groups, the median score for inpatients was slightly higher at 9 (95% C.I.=7.1 to 10.8) compared to median outpatient score of 6 (95% C.I.=4.2 to 7.8). The confidence intervals do overlap, but the estimates are not precise enough to draw a final conclusion.

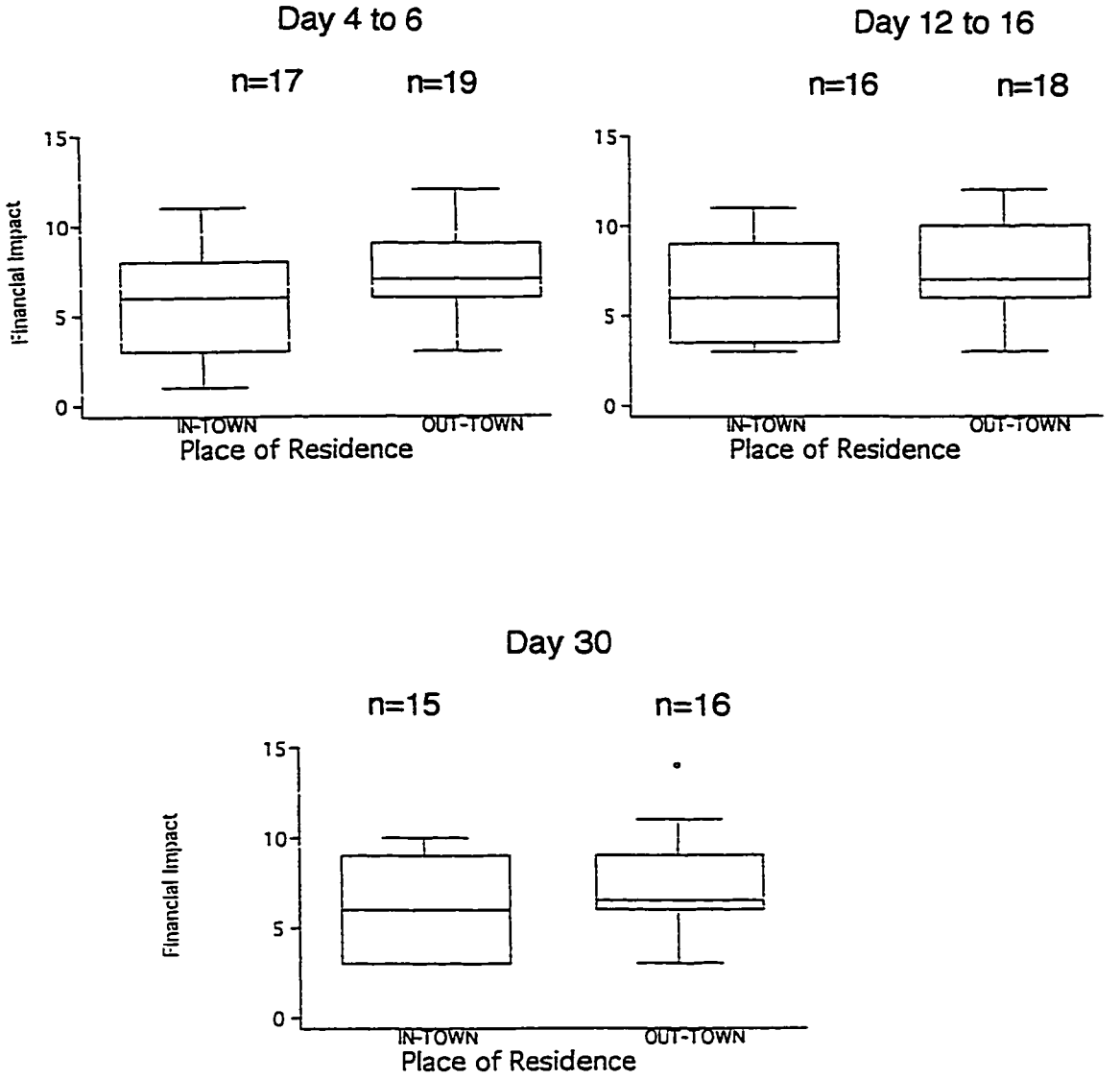
At day 30, caregivers were again asked to indicate the impact of the cost of care on finances. One caregiver from the inpatient group indicated a high level of impact on their finances, as noted by the maximum score at 14. However, median scores were similar for the inpatient and outpatient groups, with moderate scores of 7.5 (95% C.I.=6 to 10) and 6 (95% C.I.=3.4 to 7.8) respectively.

Figure 75. Impact on Finances by Mode of Care.



For those caregivers who lived out-of-town, their concern about the financial impact was the same as caregivers who lived in-town at all time intervals (Figure 76). These data suggest that the potential for additional travel and lodging expenses did not add to the financial concerns of patients from out-of-town.

Figure 76. Impact on Finances of Patients In-Town Compared to Out-of-Town.



Overall, in considering all three time intervals, there appears to be no difference between inpatients and outpatients with respect to the estimated out-of-pocket expenses. There was wide variation in expenses depending on the needs of the patient and their family. Although the total direct out-of-pocket expenses did not appear to be excessive, concern about personal finances was an issue for both study groups as was evident by the moderate scores obtained

from the Caregiver Reaction Assessment instruments.

B. Indirect Expenses

As well as direct 'out-of-pocket' expenses incurred by the patient and their family, indirect expenses during the 30 day period after the transplant were also experienced. Indirect expenses such as the caregiver's loss of salary and loss of employer payments to a health plan and pension were identified during this time period. Indirect costs were assessed for the caregiver and not the patient as it was felt that it was the caregiver who was most likely to be impacted by the outpatient mode of care. Two caregivers from the inpatient group and 1 from the outpatient group experienced loss of the employer's contribution to the cost of health care benefits.

Loss of salary was experienced by 4 caregivers in the inpatient group. One caregiver took a leave of absence without pay for one day and another took a leave of absence without pay for one month. Loss of income was also experienced by two caregivers who were self employed.

Among the outpatient group, 2 caregivers experienced a salary loss. Again, one caregiver was self employed and other caregiver took a leave of absence without pay during the 30 day period after the transplant.

Of the 16 caregivers in the inpatient group and 18 caregivers in the outpatient group, 7 from each group were able to continue to work during the 30 day period. Indirect expenses were experienced by a small number of the caregivers and were found to be similar in frequency between the two study groups. Since the amount of money attributable to indirect expenses was so variable because of differences in employment situations and pay, specific comparisons between the two study groups were not meaningful and therefore not pursued.

CHAPTER 4

DISCUSSION

This chapter will further discuss the results presented in Chapter 3, summarizing the effects of inpatient and outpatient care on client-centered outcomes defined in the study. Also presented are the strengths and limitations of the study, the appropriateness of the instruments used and implications of the findings for care of bone marrow transplant patients.

I. Differences in the Study Groups

It is important to highlight the differences between the two study groups and to discuss the implications of the differences for the results. The comparison groups differed with respect to cancer diagnosis, treatment protocol and the experience of treatment failure.

With respect to cancer diagnosis and treatment, the majority of inpatients had breast cancer and received the high-dose protocol of Mitoxantrone, Vinblastine and Cyclophosphamide. The majority of outpatients were diagnosed with hematological malignancies (lymphoma and Hodgkin's

Disease) and were treated with the high-dose protocol of Melphalan. As well, more outpatients had experienced previous treatment failure prior to entering the ABSCT program.

Differences between the inpatient and outpatient groups have important implications for the study results. The effect of differences in cancer diagnosis and treatment protocol likely had the most impact on measures taken at day 4 to 6 for the following reason. Chemotherapy side-effects for patients treated with Mitoxantrone, Vinblastine and Cyclophosphamide (predominately inpatients) were most severe at day 2 to 4, whereas side-effects for patients treated with Melphalan (predominately outpatients) were most severe around day 6 to 7. Therefore, the day 4 to 6 measures reflect the 'recovery' period for inpatients, where side-effects are beginning to resolve, while the measures reflect a 'pre-morbid' state for outpatients. Not surprisingly, outpatients appeared to be in better health compared with inpatients at day 4 to 6.

For example, psychological well-being, (in particular emotional well-being, depression, anxiety and perception of control) were similar and often better for the outpatient group at day 4 to 6. The same was true for physical status. At this time, outpatients also experienced lower morbidity and less pain.

The outpatient group was also characterized as having a greater proportion of individuals who had experienced previous treatment failure. That is, patients diagnosed with hematological malignancies (predominately outpatients) were treated with ABSCT as the second line of treatment after lower-dose chemotherapy. On the other hand, the majority of breast cancer patients (predominately inpatients) received ABSCT as a first treatment option and therefore this group had fewer cases who experienced failure of treatment or relapse.

The effects of previous treatment failure on patients is not fully understood in this study. It is possible that patients who had experienced treatment failure (relapse or progressive disease) prior to entering the ABSCT program may have greater acceptance of their disease because they have been living with a diagnosis of cancer over a period of time. Regardless, it is felt that having more patients who had previous treatment failures in the outpatient group may bias the results. If having experienced previous treatment failure or having a hematological malignancy as opposed to breast cancer influences patients' emotional well-being, these patients may be at an advantage when receiving outpatient care during the period after the transplant.

II. The Definition of Outpatient Care

For the purpose of this study, outpatient care was defined as "not planning on staying in hospital over night", however classification as an inpatient or outpatient was violated at times. Firstly, outpatients remained part of the outpatient program of care even if they were admitted to the hospital at any point and for any length of time during the period after the transplant. These patients continued to complete the study tools while they were in hospital and this data was analyzed as a component of the outpatient group. Although it was recognized that data collected while an outpatient was actually in hospital might underestimate between group differences, it was believed that this approach would more accurately describe outpatients' experiences.

Secondly, there were a few inpatients who went on day-passes and returned to the hospital at night. They usually went home during their time on pass. For these patients, their in-hospital experience may have been altered either negatively or positively by their time away from the hospital and therefore

may have influenced their responses to the study tools. Again, the inpatient and outpatient experience may appear to be more similar as a result of inpatients going on day-passes.

Thirdly, outpatients who were from out-of-town were required to live in alternative housing during the period after the transplant. One of the benefits of outpatient care was that the patient would be at home in his or her own environment. For patients from out-of-town, their outpatient experience may not be as positive because they were not in their own environment, similar to patients in hospital. Again, the inpatient and outpatient experience may appear more similar because of the experience of outpatients who were from out-of-town.

Fourthly, by day 30, patients in both study groups were generally feeling better and at home. During this period of time only a few study tools were completed by patients and caregivers to specifically assess whether study groups were similar in psychological well-being at the end of their experience. The study groups were no longer actively involved in either the outpatient or inpatient mode of care. Because the two groups were considered similar in the care they received by day 30, the responses of the battery of tools were expected to be similar.

Despite the overlap in the concepts of inpatient and outpatient care, the data collected in this study were worthwhile as it provided a true description of the experience of the outpatients. As well, because the majority of outpatients were admitted to hospital around day 6 or 7, assessments at day 4 to 6 are felt to be the most meaningful as most patients were still in the outpatient environment.

III. Summary of Outcomes

A. Physical Status

Generally, the physical status of inpatients and outpatients was similar at all 3 time intervals. Some differences in morbidity and physical well-being were observed at day 4 to 6 however these differences were likely the result of differences in treatment protocols between the study groups.

Although the number of days in hospital were less for the outpatient group compared to the inpatient group, hospital admission for clinical support was required for the majority of outpatients (90%). In contrast, other recent studies reported that a smaller proportion of outpatients require hospital admission (54%, Peters et al., 1994 and 21%, Jagannath, Vesole, Zhang, Desikan, Copeland, Jagannath, Bracy, Jones, Crowley, Tricot and Barlogie, 1997). The reasons for admissions to the hospital were similar in all three studies (fever, dehydration, nausea and mouth sores). However, in the study by Peters et al. (1994) patients did not suffer mouth sores that required narcotics by intravenous. The authors recognized the level of morbidity that can result from mouth sores in the comment: "the presence of severe mucositis [mouth sores] ... might severely limit the potential of this [outpatient] approach" (pg 29). However, the study by Jagannath et al. (1997) included patients suffering from mouth sores and yet the number of hospital admissions was lower than the present study.

Perhaps one reason for the difference in the proportion of hospital admissions between the present study and the American studies may relate to fundamental differences between the two health care systems. The motivation to reduce admissions to hospitals in the United States may be greater because of the stronger influence of the financial cost of hospital care to the health care

system, insurance companies and particularly patients. In Canada, the concern for the cost of hospital care to the health care system is less obvious and not motivated by costs to insurance companies and patients to the same extent. For this reason, perhaps there was less hesitation to admit patients to hospital in the present study.

Further, the outpatient approach of providing care for ABSCT patients in Southern Alberta was initiated early 1997, just prior to data collection for the present study. As discussed later in this Chapter, selection into the comparison groups was based primarily on patient preference, as opposed to patient eligibility for outpatient care. The newness of the program and hence this conservative approach for assignment to study groups may also be evident with regard to admission to hospital. To ensure that the new outpatient program would be successful, conservative management of patients, including hospital admissions for just about any reason, was adopted to avoid patients having a negative experience.

Jagannath et al. (1997) described their method of management of side-effects in order to support multiple myeloma transplant patients in the ambulatory setting.

The authors concluded that most of the post-transplant toxicities caused by Melphalan such as febrile neutropenia and mouth sores, were handled successfully in the outpatient setting. Patients were taught self-administration of medication by intravenous infusion connected to central venous catheters in order to lessen the need for emergency hospital admissions. Fever, mouth sores and nausea (all requiring intravenous therapy) were the most prevalent side-effects in the present study. The approach described by Jagannath (1997) might be feasible for ABSCT patients in Southern Alberta to avoid

hospitalization and maintain outpatients in their homes. Patients and caregivers could be educated to manage patient controlled infusion pumps and be provided with support from the community (eg. Home Care).

In the ABSCT program in Calgary at present, outpatients are required to return to the Cancer Centre on a daily basis for monitoring of toxicities and their condition. Ideally, outpatient care could be a more positive experience if care was maintained in the home setting away from the hospital. As mentioned in much of the literature concerning outpatient care of transplant patients, a Home Care Program providing clinical and psychological support is essential. At present, Southern Alberta has not incorporated Home Care into the management of transplant patients because of Home Cares' limited resources and lack of specialized expertise in caring for these patients. In light of the findings from the present study with respect to physical needs and evidence that suggests there are many benefits of outpatient care, a specialized Home Care Team that works in conjunction with the BMT team would be worthwhile.

Although slightly more outpatients in this study appeared to suffer from moderate to severe nausea and vomiting, nausea was perceived to be one of the most bothersome side-effects for both inpatients and outpatients. This difference in severity of nausea and perceived experience of nausea may be the result of error in grading and recording of nausea or in the variability of patients' perception.

Alternately, the higher prevalence of nausea among outpatients may be because they were not able to adequately manage these symptoms at home. That is, in the home environment, oral medications were used to control nausea and vomiting. In the hospital setting, medication was often administered intravenously. It is difficult for patients to take medications orally when they are

experiencing nausea, vomiting and mouth sores. If these side-effects are not controlled, patients may require hospitalization to resolve further complications such as dehydration and to manage pain. In the present study one-third of outpatients who were admitted to hospital, were hospitalized for treatment of dehydration.

A study by Lawrence, Gilbert and Peters (1996) included an evaluation of symptom distress and the effectiveness of symptom management in the outpatient environment. Although the treatment protocols were different from the present study, nausea and vomiting was found to be one of the most distressing symptoms patients experienced in the outpatient setting. Despite a combination of antiemetics (including the use of an ambulatory pump of intravenous infusion), nausea and vomiting occurred in the post transplant period. However, complete control of nausea was reported by more than 80% of the outpatients by 9 days after the transplant. As concluded by the authors and validated by the present study, further research is needed to establish a successful regimen for prevention of nausea and vomiting in the outpatient setting.

B. Psychological Well-being

Psychological well-being was measured by assessing a number of outcome variables including emotional well-being, anxiety, depression, perception of control and perception of satisfaction with care. Generally, patients in both study groups described their psychological well-being as very positive. Emotional well-being was marginally better for the outpatient group at baseline. In the early period after the transplant, emotional well-being for both study groups were similar. However, by day 30, outpatients' emotional well-

being improved more than inpatients.

Calgary based outpatients who were able to remain in their own home showed better emotional well-being at all three time intervals compared with Calgary based inpatients and out-of-town outpatients. It is possible that the difference in emotional well-being at day 4 to 6 for Calgary based inpatients and outpatients was the result of the different treatment protocols used in the two comparison groups. By day 12 to 16, the difference continued despite the side-effects from treatment were felt to be similar between the groups.

Although out-of-town outpatients (required alternate living arrangements) reported similar emotional well-being at day 4 to 6, they reported lower emotional well-being when compared to out-of-town inpatients at day 12 to 16. By day 30, most out-of-town patients from both study groups had returned to their home environment and their emotional well-being was the same for both study groups.

Outpatients with previous treatment failure prior to ABSCT seemed to experience better emotional well-being at baseline, day 4 to 6, day 12 to 16 and day 30, when compared to inpatients with previous treatment failure. This difference may be due to the inherent experiences of breast cancer patients versus patients with hematological malignancies. Another possible explanation for the difference in emotional well-being between the two study groups may be related to patients' perception of whether their experience with first line chemotherapy prior to treatment failure was positive or negative. Those patients who had a positive experience may have developed more positive emotional well-being with regard to their illness. Because of this previous positive experience these patients may have felt comfortable in the outpatient setting and therefore chose that mode of care.

Conversely, patients whose experience with previous chemotherapy prior to treatment failure was negative may indicate a less positive emotional well-being. Because of this negative experience, they may have felt unable to cope with cancer treatments on an outpatient basis and chose to be cared for in the hospital. It is possible that emotional well-being is, in some way, a reflection of patient's past experience with chemotherapy.

Perhaps this difference in emotional well-being at the outset influenced patients' self-selection into the respective modes of care. That is, patients who had better emotional well-being and previous treatment failure chose outpatient care. It would be of interest for a future study to assess patient's perception of their experience with the first line of chemotherapy as being positive or negative. Not only would such information provide further insight into understanding the effects of treatment failure on patients but it may be an important factor in screening patients for their ability to do well with outpatient care.

In the present study, among patients with a high level of morbidity, anxiety was found to be higher among outpatients than inpatients. The majority of all outpatients were admitted to hospital around day 6 or 7 and most of these admissions were at the request of the patient or family. Perhaps there was a short period of time around day 4 to 6, when side-effects were becoming difficult to manage at home, resulting in heightened anxiety and a request for inpatient care.

The level of anxiety of patients who had not experienced treatment failure prior to entering ABSCT were compared between groups. Outpatients showed a higher level of anxiety than inpatients. The fear of not knowing what to anticipate in terms of side-effects of the treatment protocol may cause patients in

the outpatient mode of care to experience high levels of anxiety. For patients who had experienced treatment failure, the opposite effect was seen as discussed earlier. The outpatient group had less anxiety when compared to inpatients.

In the present study, perception of control for both the inpatient and the outpatient groups was similar. Research by Thompson et al. (1993) suggests that high perception of control is associated with low levels of anxiety and depression. In this study, there was no linear relationship between control and anxiety or control and depression. Thus, it cannot be concluded from the results of the present study that outpatient care fosters a greater sense of control thereby leading to less anxiety and depression.

Patients in both study groups were asked to identify what they liked and disliked about the mode of care they received. By using this open-ended method of questioning, it was possible to identify issues that were important for patients. For example, inpatients consistently reported their comfort with having access to care and help, and the feelings of security and safety associated with inpatient care. This does not suggest that the outpatient mode of care failed to provide such support to the patients. In fact a number of outpatients reported they had good access to care and information. The information regarding feelings of safety and security, as described by the inpatient group, could be incorporated into the design of a formal outpatient program.

In contrast, outpatients liked being at home with family, being independent and having control and flexibility. This information may be useful in screening patients to identify who would suit outpatient care because of their need to be close to family and to maintain independence, control and flexibility.

The outpatient group identified a number of dislikes with respect to their

mode of care. Patients in this group commonly expressed concern about their physical condition and uncertainty with being able to care for themselves. These patients expressed concern about their responsibility for medication administration, monitoring vital signs and managing treatment side-effects. These specific concerns may have contributed to the elevated level of anxiety noted previously for the outpatient group at day 4 to 6, when side-effects were beginning to be severe. These responses from outpatients along with evidence regarding management of symptoms may suggest a need for written information in a booklet format. A booklet could provide detailed instructions concerning how to deal with side-effects, medications and self-monitoring of vital signs and progress in general.

Although satisfaction with care generally and satisfaction with specific aspects of care were positive for the outpatient group, one outpatient found that the experience was not positive. The individual felt that the support necessary to ensure safety while at home was not available. Although the patient had communication with a member of the medical staff while at home, the staff member was not part of the Bone Marrow Transplant team. The patient felt that inappropriate medical advice was given. For the particular patient and caregiver the situation developed into a crisis that could have been avoided. If outpatient care is to be successful, this situation may suggest that it is important that patients have 24 hour access to members of the Bone Marrow team. Patients and staff become familiar with each other thereby building a trusting relationship. This point highlights again, the importance of providing a safe and secure environment for outpatients as previously noted.

Prior to ABSCT, patients were asked about their preference for inpatient and outpatient care; 49% indicated outpatient care as their preference. At day

30 following ABSCT, the proportion preferring outpatient care was less at 27%. Thus a large proportion of patients who felt outpatient care was preferable prior to ABSCT changed their minds after experiencing outpatient mode of care. Again, security of the hospital environment and responsibility for their own care were given as reasons when a change in preference was reported. Not surprisingly, patients who preferred the hospital setting prior to ABSCT continued to prefer this mode after the ABSCT. Thus, it cannot be concluded that patients in this study were highly supportive of the outpatient mode of care. Notwithstanding, in reviewing the findings concerning satisfaction with care, including patients' likes and dislikes, patients were not overly critical of the outpatient mode of care. Perhaps, the preference for inpatient hospital care stems from a societal expectation that when one is ill, one must be cared for in hospital.

C. Social Interaction

The client-centered outcome of social interaction mainly focused on the relationship between the patient and the caregiver. Of particular interest was the burden placed on the caregiver as a result of providing care in the outpatient setting. McCorkle et al. (1993) found that in the period immediately after discharge from the hospital, there was a relationship between caregiver burden and patients' physical status and symptom distress. That is, high levels of morbidity or symptom distress were associated with an increase burden on the caregiver. In another study, (Schumacher, Dodd and Paul, 1993) functional status (as measured by Karnofsky Performance Status) had a moderate relationship with caregiver strain but less so with caregiver depression. With these results in mind, it was anticipated that in the present study, outpatient care

would be associated with increased caregiver burden compared to inpatient care. Caregiver burden included measures of impact on schedule, esteem and health, as well as extent of family support.

In the present study there was evidence to suggest that the impact on caregivers' schedule was significant regardless of the mode of care the patient received. In support of this evidence suggesting a large impact on schedule, a number of caregivers in both study groups made changes in their employment status in order to provide care to the patient. The impact on caregivers' schedule was particularly evident for outpatient caregivers who were required to make alternate living arrangements in the period after the transplant. These were individuals from out-of-town.

The present study also found that caregivers had a high level of esteem as indicated by high levels of fulfillment and a desire to provide care. Whether the patient was cared for as an inpatient or outpatient, caregiver esteem was consistently high in both groups. Schumacher, et al. (1993), found that male caregivers experience a higher level of strain compared with females. Caregiver strain (personal, family and employment adjustments, and other kinds of strain that result from caregiving) was not measured in the present study, however caregiver strain is similar to caregiver esteem as measured in the present study. Although a comparison between male and female caregivers was not the intent of the present study, it is instructive to examine the different experience of male caregivers according to inpatient and outpatient mode of care.

Caregiver esteem, as one aspect of caregiver burden, was slightly lower for males in the outpatient group than those in the inpatient group. However, impact on schedule and anxiety were found to be the same in male caregivers

of the two study groups. Perhaps, these specific measures of caregiver esteem, caregiver anxiety and impact on schedule provided greater insight into the understanding of caregiver burden, than the general measure of caregiver strain used by Schumacher et al. (1993).

Schumacher, et al. (1993) noted that caregivers of persons treated for recurrent disease (treatment failure) experienced less strain than caregivers of persons with nonrecurrence (first line of treatment). In the present study, although there were too few caregivers who had prior experience with serious illness, it was found that caregivers of outpatients with no prior experience in caring for someone with serious illness were found to have lower esteem compared to inpatient caregivers. Schumacher suggests that caregivers adapt to the stress of caregiving over the course of the illness. That is, experience in caring for someone is believed to be a positive factor aiding in caregivers ability to manage the illness. Conversely, perhaps lack of experience and the added responsibility of providing care in a outpatient setting contribute to uncertainty in the caregiver role thus leading to lower esteem.

In addition to high levels of esteem overall, caregivers of patients in both study groups generally had low levels of depression and anxiety even when patients' morbidity was high. As well, outpatient management appeared to have little impact on the physical and emotional health of the caregivers.

Generally caregivers in both the inpatient and outpatient groups felt that they had good family support and were not left alone to care for their loved one. As well, patients generally felt that they received good emotional and instrumental support from their caregiver/partner. Because of small numbers, this study was not able to describe the outcomes for patients and caregivers who did not have a strong support system in place. Further research is required

to confirm or refute that patients and caregivers with poor support are at risk for reduced psychological and physical well-being.

D. Global Quality of Life

Quality of life for the outpatient group was better at baseline compared with inpatients. During the period after the transplant outpatients' quality of life was diminished but always remained better than inpatients quality of life. However because of the between group differences of cancer diagnosis, treatment protocol and previous treatment failure, any one of these variables or all of these variables may have contributed in some way to the better quality of life of outpatients prior to undergoing stem cell transplant. The effects of the differences in treatment protocol was taken into consideration and it was found that quality of life for inpatients and outpatients was essentially similar.

Unfortunately, because of the large difference in the cancer diagnosis between the comparison groups, there were too few individuals with the same diagnosis in one or the other comparison group to allow further analysis. As previously stated, there may be something inherent about patients with a specific diagnosis that either positively or negatively affects their quality of life. The present study was not able to determine the effect of differences in cancer diagnoses.

Investigation of patients who experienced previous treatment failure between comparison groups was numerically possible. In the present study, it was found that previous treatment failure had a significant impact on between groups differences of emotional well-being and global quality of life. Because emotional well-being was a subscore of global quality of life, some of the differences observed in global quality of life may be attributable to differences in

emotional well-being. However, it may also be that patients who had previous treatment failure and with a higher quality of life chose outpatient care and this higher level of quality of life was maintained throughout the post transplant period. Like emotional well-being (as discussed earlier), quality of life may be influenced by patients' perception of whether their experience with first line chemotherapy prior to treatment failure was positive or negative.

E. Personal Financial Impact

In considering the impact of the two modes of care for ABSCT on patients personal finances, it was found that the costs of travel, parking and medication were the main expenses for the majority of patients in both study groups. Overall, expenses incurred by patients and their family were described as being fairly similar between groups. For inpatients, the expenses during the 30 day period after the transplant were largely the result of caregivers and family members being actively involved in providing support. Accommodation, parking and travel expenses were incurred in an effort to be physically close to their loved one in hospital.

It is acknowledged that the data collected for personal expenses lacks precision. Often the information was an estimate of expenses occurred (eg. travel expenses). For this reason it is important to interpret the expense figures with regard to how they relate to one another and compare between groups. The data should not be viewed in isolation as exact figures of expenses. The interpretation of the difference in median cost for a specific expense between the inpatient and outpatient group was based on what would be judged to be significant from a practical perspective as opposed to statistically significant. For example, the difference in the expense of medication between groups was

$57. Numerically, the difference between $100 and $43 is relatively large but on a practical level a difference of $57 over a 30 day period is not highlighted as a concern.

Baker (1994) describes the psychosocial impact of BMT on patients and families living in the United States. Although the financial implications are considered to be very different in the United States compared to Canada, similar factors were found to impact patients' finances. Similar to Baker, the present study highlighted the additional expenses of travel and lodging for BMT patients from out-of-town. Concern for the expenses incurred by patients from out of town is discussed along with other issues for patients later in this Chapter.

IV. Strengths and Limitations of the Study

A. Strengths

This study was intended to describe the experience of patients receiving outpatient care following high-dose chemotherapy and Autologous Blood Stem Cell Transplantation. The quasi-experimental design provided a comprehensive description of the patient's physical status, psychological well-being, social interaction and personal financial impact as compared to patients treated in hospital. The collection of baseline data strengthened the study design by providing a means to determine similarities and differences between the comparison groups at the outset. Although the sample was small, overall, this study revealed that individuals generally do no worse with respect to the above client-centered outcomes when cared for in the outpatient setting. This pilot study provides evidence to support further research to challenge the traditional inpatient mode of care for ABSCT. This study also provided information about the value of instruments for measuring client-centered

outcomes; hypotheses were generated and the study data can be used to estimate an appropriate sample size for a future study.

It would be desirable to replicate the study with a larger sample. This would result in greater precision in the results of the subgroup analysis. Calculations using data from this exploratory study suggests that a sample of 40 to 45 would be sufficient for each comparison group. In other words, the sample should be about double that of the sample size used for the present study.

A. Limitations

There are a number of limitations associated with a pilot study such as this. Because the sample was small any conclusions about differences or similarities in the measured outcomes may be misleading. At most, this pilot study provides a description of the experience of ABSCT patients in both modes of care.

Ethically, it was not possible to randomly assign patients to the control or experimental group. The study has limitations as a result of a non-equivalent control group. This weakness in design means that it can not be assumed that the control group and experimental group were similar. The collection of baseline measures provided evidence that the study groups were different with respect to a number of important variables. These between group differences can bias the results.

It is felt that the quasi-experimental design that was originally proposed requiring assignment to study groups based on geographic location (Calgary or Edmonton) remains the best study design. The original study design, as it was proposed, was also a non-equivalent control group design but stronger than the one actually used. It was believed that patients from Calgary and Edmonton

would be similar with respect to personal characteristics, type of cancers treated with ABSCT and treatment protocols. Patients would be living in one province with a common health care system. Patients from both cities would receive treatment and care from the one Cancer Board. The treatment protocols would have minimal variation, particularly because most patients receiving ABSCT are involved with clinical trials that are commonly shared between the two sites. The similarities as a result of these factors would contribute to a reduction in between group differences. As well, the selection of patients to study groups, using geographic location and eligibility criteria, would eliminate the problems of potential bias that were an issue in the present study. It allowed all patients treated in Calgary to be treated as outpatients unless they did not meet the established criteria. Patients treated in Edmonton would be cared for as inpatients and therefore be the control group. This approach was felt to be the next best thing to assigning patients to their mode of treatment randomly. For practical reasons, by involving Edmonton in the study, a larger number of patients would have been accrued to the study over a shorter period of time.

Unfortunately, Edmonton was not successful in accruing an adequate number of patients to the study to be of benefit in the ways mentioned above. Although 19 patients were treated with ABSCT in Edmonton during the six month period, only 5 were approached and admitted to the study. The reason for this poor rate of accrual is not fully understood. However, factors that may have affected accrual to the study were limited time and resources. The research nurse was a full-time staff member with other responsibilities. Because she received a salary for full-time work, it was not possible to pay her directly for each patient placed in the study as was initially intended. Accrual may have been better if a nurse was hired specifically for this study and

received pay for every patient entered into the study. Because of the difficulty in accruing patients to the study in Edmonton, this matter should be fully explored before a larger study is undertaken.

In discussing with the ABSCT team how patients were assigned to the control group or the experimental group, it was evident that patients had a great deal of say regarding the mode of care they would receive. Although eligibility criteria for outpatient care was established, often those patients that eventually were treated in the inpatient group were simply not willing to be treated as an outpatient despite their eligibility. When patients were asked for the mode of care they preferred, the majority of the patients preferred the mode of treatment that they actually received. Thus, assignment to the control group or the experimental group was not based on geographical location (as was originally intended) but rather on patient self-selection. Those patients who felt that the outpatient mode of care would be a good and positive experience became the experimental group. Self-selection into one mode of care or the other represents a potential source of bias and threat to internal validity. This was evident when initial analysis showed that comparison groups differed with respect to important characteristics such as diagnosis and treatment. All of these characteristics could influence the results.

However, this pilot study was undertaken to describe the experience of the patients in the two modes of care. It is of interest to understand the type of patient that would purposefully choose outpatient care and to describe their experience. Breast cancer patients tended to want to be cared for in the hospital setting, whereas patients with hematological malignancies expressed an interest in being cared for as an outpatient. Thus, patients' diagnosis appeared to influence their desire for a specific mode of care. As well,

something about patients' previous experience with treatment failure appeared to influence their chose in inpatient or outpatient care.

A sample of convenience was used in the present study. All patients who were undergoing ABSCT at the TBCC were approached for admission to the study with one exception. This patient was purposely omitted from the study because it was not certain that he could complete the research tools. It is possible that selection bias occurred in Edmonton. That is, the patients who were under the care of one particular doctor were admitted to the study whereas patients under the care of other doctors were omitted. In light of the small sample, self-selection into the comparison groups and selective sampling in Edmonton, the results of this study cannot be generalized.

V. Appropriateness of the Tools

The one purpose of the pilot study was to determine if patients and caregivers would be willing to and able to complete the battery of tools. Firstly, it was a concern that patients may refuse to participate in this study because this group of patients are already involved in clinical trials regarding the protocols they are receiving. Of the 43 patients and their caregivers who were approached to participate in this study, only 2 declined participation. Generally the patients were willing to participate in the study.

The burden of the battery of tools on the patients was also a concern. Would patients be able to complete the tools particularly at day 4 to 6 when they were most likely to feel unwell? At day 4 to 6 and day 12 to 16 only 2 patients at each time interval stated that they were too sick to complete the tools. One patient and caregiver refused to complete the tools. By day 12 to 16 and day

30, 2 and 3 patients respectively had not returned their questionnaires. These patients were from out of the province and had returned home at this point in time. Even though stamped envelopes were provided and phone calls made to remind patients to return the study questionnaires, the forms were not returned. Overall, it was concluded that both patients and caregivers were able and willing to complete the battery of tools. Although there is a large amount of paper work for patients and caregivers, the data were successfully collected, suggesting that the burden of the tools was not overwhelming.

Another purpose of this pilot study was to determine the appropriateness of the tools. All tools were useful as general measures of the identified client-centered outcomes. The tools were used for both the inpatient and outpatient groups allowing for comparison between the groups. A general picture of the study groups was therefore obtained by the use of these tools. Although the tools were not created specifically for outpatient care of ABSCT, they had been used by cancer patients and their caregivers in other research.

The tools that measured aspects of quality of life, such as physical well-being, emotional well-being and functional well-being were felt to be appropriate measures. At day 4 to 6, when the patients were experiencing the side-effects of the treatment at their worst, these measures also indicated poorer quality of life in all aspects as was predicted. Over time, as the symptoms improved, the quality of life scores also increased, indicating an improved quality of life.

The Centre for Epidemiological Study-Depression scale (CES-D) was used to measure patients' level of depression. The scale asks questions about symptoms that are indicative of depression. Many of the symptoms of depression are also symptoms caused by chemotherapy treatments (eg. I did

not feel like eating; my appetite was poor; I felt that everything I did was an effort and I could not get 'going'). Patients indicated that they were experiencing these symptoms thus elevating their scores on the CES-D. These high scores would indicate depression and thereby represent a false positive result. It is therefore concluded that the CES-D is not a useful tool for patients undergoing ABSCT. However, also included in the assessment was the Profile of Mood States (POMS) which has a subscale for depression. Because measures for both tools were taken at baseline, or prior to the high dose chemotherapy, correlational analysis of the CES-D and the POMS (depression) were done. Correlation of the CES-D and the POMS (depression) scores at baseline for the inpatient and outpatient groups were .748 and .814 respectively. Since the correlation of the two scores was high, the POMS depression score is recommended in place of the CES-D for the assessments completed on the patients after the transplant. However, the CES-D is appropriate for the caregiver group.

The tool designed to determine patients' perception of satisfaction with the care they received did serve a purpose in the pilot study but it is not likely an important aspect to repeat in a larger study. It was identified that in most cases patients were satisfied with all aspects of care. It is likely that no new information would be obtained by continuing to ask patients to rate their level of satisfaction in a larger study. Perhaps one reason for the positive response observed in this study is because of social desirability or the patients need to portray satisfaction with their care even if not fully satisfied. It is difficult for patients to be critical of the care received when they continue to be reliant on the staff for their care for a lengthy period of time. They may be concerned that being critical may jeopardise the future care they receive. By asking open-

ended questions about patients' likes, dislikes and recommendations, specific areas of concern were identified. Open-ended questions would be asked in a larger study in order for patients to voice any concerns they have.

VI. Implications of Findings

A. Patients from Out-of-town

One group of patients that are of concern when considering outpatient care are those patients who are from out-of-town. For this group of outpatients (9), their emotional well-being (a subscore of quality of life) was lower than the inpatient group while quality of life of Calgary outpatients was higher than inpatients. However, other aspects of psychological well-being such as global quality of life, depression and anxiety appeared to be similar between the two subgroups and the full sample. It was also noted that this subgroup of caregivers of outpatients indicated a greater impact on their schedule in providing care for the patient. As well, 'out-of-pocket' expenses for all patients from out-of-town were slightly greater than patients living in town. However, expenses did not differ according to mode of care. That is, expenses for inpatients and outpatients from out-of-town were the same. The out-of-town patients and caregivers did not express any greater concern about the financial impact of their care.

The two outpatients who stayed in the hostel expressed concerns about the hostel not being an appropriate place for accommodation during the post transplant period. Facilities for food storage and preparation were felt to be inadequate.

One out-of-town patient recommended that he should not have been allowed to travel home during the early period after the transplant. This concern

was also voiced by another patient. While at home they began to feel unwell and became very anxious as they felt they were too far from the hospital. Even for outpatients who were from in town, it is noted that their level of anxiety was elevated when they began to feel unwell. According to the eligibility criteria for outpatient care, patients are required to stay within 45 minutes driving time of the hospital. This rule appears to be important and should be maintained particularly in the early period after the transplant.

For the patients from out-of-town, it seems that the outpatient approach to care is appropriate. That being said, appropriate accommodation must be available to ensure that patients are able to follow the instructions given by the medical staff for food preparation. Although the hostel is inexpensive, it is not an appropriate facility when patients are required to prepare their meals. Perhaps for the outpatient experience to be more successful for patients from out-of-town, funding could be provided for patients who are unable to afford appropriate housing during the period after the transplant.

B. Potential for a Screening Tool for Use Prior to ABSCT

Factors that were found to be different between the inpatient and outpatient groups at baseline and at time intervals during the period after the transplant may identify patients who are high risk (i.e. require extra support) or who would manage well with the outpatient experience.

It may be possible that patients reporting strong emotional well-being at baseline will maintain this positive emotional well-being during the period after the transplant, particularly if they are able to remain in their own home. Although emotional well-being may be high at baseline, outpatients from out-of-town who are required to make alternate living arrangements may be at risk of

experiencing lower emotional well-being in the post transplant period. As well, the combination of previous treatment failure and strong emotional well-being at baseline may be a good indicator of those patients who will maintain a strong emotional well-being in the outpatient mode of care throughout the period after the transplant. Patients with previous treatment failure reported minimum concern about their physical and emotional health at baseline and appeared to have less concern about their health during the post transplant period.

The instrument used to measure physical well-being, additional health concerns and global quality of life showed a difference in the scores between inpatients and outpatients at baseline. The measures at the other time intervals were not different enough to suggest that the baseline measures could identify outcomes that may be of concern for outpatients in the post transplant period.

The impact of providing care on caregivers' schedule was significant for those caregivers who were required to make alternate living arrangements during the period after the transplant. The need for alternate living arrangements is easily assessed at baseline and may alert the Bone Marrow Program staff of the potential for feelings of increased burden when providing care for an outpatient.

An evaluation of caregivers' previous experience of providing care to someone with a serious illness can be achieved at baseline. Evidence from this study suggests that caregivers who have not had this experience may not feel comfortable in the caregiving role leading to a diminished sense of esteem. This reduced sense of esteem (sense of fulfilment and desire to provide care) will increase the caregivers' feelings of burden.

In this study, measures of patients' level of depression and anxiety were low at baseline suggesting that generally patients were not experiencing these

feelings. However, there were high outlier scores indicating that this was not true for all patients. As well, within this study sample most patients and caregivers reported having strong family support. Analysis of a subgroup who expressed high depression, anxiety or poor support from their families was not possible. Yet, these issues would be reality for some patients. Further research is necessary to understand how these subgroups of patients would manage in the outpatient setting. Perhaps baseline screening of these concerns would be beneficial to ensure that appropriate clinical support is available.

Generally, caregivers reported that providing care for the patient had little impact on their health. As noted in the results, very few caregivers were elderly (over 60 years of age). As well, caregivers' level of morbidity was not measured. The role of the caregiver is crucial to the success of outpatient mode of care, however if the caregiver is elderly or unwell, their health may be jeopardized. The outpatient mode of care may be difficult or inappropriate for this population. In discussing outpatient care with the patient and their caregiver, BMT staff must consider the age and health of the caregiver.

Patients who preferred inpatient care prior to undergoing treatment remained fairly consistent about the mode of care desired when asked to make a choice after treatment. The patients who chose the inpatient mode of care at baseline were aware of their need for the hospital environment and may require more support if in the outpatient setting. However, a decreased proportion of outpatients remained committed to the outpatient mode of care after their experience. One can not rely fully on outpatients knowing which mode of care they would prefer until after they have been through the transplant experience. Those patients who choose outpatient care at baseline may experience problems or difficulties in the post transplant period. As a result, they may

decide that inpatient care may have been a better option.

Mode of care may not always be an option in the future. Policy may require that all patients will be treated as outpatients. Therefore, to ask patients which mode of care they prefer may not be appropriate. Instead a screening tool asking an open-ended question concerning their feelings about outpatient care could provide information necessary to identify patients who may require more intense support from the BMT staff.

As a result of this study, it is felt that the development of a screening tool would be possible. The purpose of such a tool would allow nursing staff to evaluate patients and caregivers at baseline in order to identify areas of strength and weakness that may influence their outpatient experience. In turn, such a tool would identify the need for other support services to ensure the outpatient experience is possible. A screening tool may include patient measures of emotional well-being, anxiety and depression. The tool would also include information concerning the need for change in living arrangements, the treatment history to determine treatment failures and comments about outpatient care. Evaluation of caregivers would measure caregiver esteem, previous experience with someone with a serious illness, impact on schedule, the need for change in living arrangements, availability of family support, impact on health, age and level of morbidity.

VII. Conclusion

The main motivation for caring for ABSCT patients in the outpatient setting was the high cost of hospitalization for these patients. This objective of reducing cost is possible by reducing the number of nights patients spend in hospital. This study revealed that these patients generally do no worse

psychologically, physically, socially or financially when cared for in the outpatient setting. The present study found that outpatients experienced an elevated level of anxiety at day 4 to 6 and the majority of patients were admitted to hospital shortly there after at the request of patients and family. Few patients were admitted prior to day 6, indicating that they were managing at home. Patients were admitted to hospital when necessary and discharged when the problem was resolved. The number of nights in hospital was reduced significantly and therefore the cost to the health care system was reduced. By evaluating outcomes, it is suggested that the outpatient mode of care utilizes health care services more efficiently and therefore effectively.

Enthusiasm for the outpatient approach to care should be cautioned with the realization that some patients will lack caregivers or for whatever reason be concerned that outpatient care is not appropriate for them. These patients should not be coerced into participating in such programs. Because of the potential for increased anxiety and difficulty in managing the symptoms and side-effects of the high-dose chemotherapy adequate supportive resources are necessary.

The literature to date has generally explored the feasibility of outpatient care with respect to physical status and economics, whereas this study provides a comprehensive evaluation of client-centered variables that influence the success and planning of such programs. The present study has contributed significantly to our understanding of a group of individuals whose morbidity was high, yet managed reasonably well in an ambulatory setting. Because these patients are recognized to have complicated health concerns, this study acknowledges the potential for outpatient care of individuals with less acute health problems. At present, this outpatient program requires patients to travel

on a daily basis and to manage at home without direct professional support. However, in the future these hurdles of outpatient care may be resolved. In the future, recovery from BMT may be entirely community and home-based. Availability of a full range of clinical and support services will be the means to accomplish this important longer term goal.

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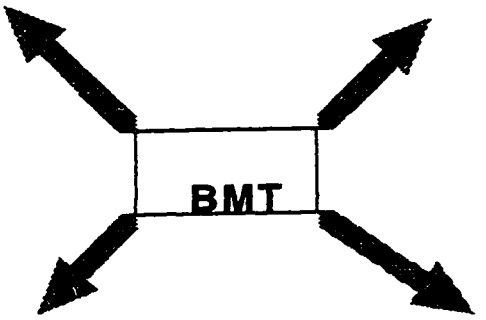
Appendix A
CONCEPTUAL FRAMEWORK:
Bone Marrow Transplantation Impacts the Dimensions of Quality of Life

Physical Well Being Symptoms

* Strengh and Stamina
*Functional Activities
*Visual Disturbances
*Recurrent Colds
*Infertility
*Nutrition

Psychological Well Being

*Anxiety
*Fear of Recurrence
*Depression
*Changed Priorities
*Cognition/Attention
*Normalcy
*Second Chance
*Coping with survival



Social Well Being

*Appearance
*Financial Burden
*Roles and Relationships
*Affection/Sexual Function
*Caregiver Burden
*Leisure Activities
*Return to Work

Spiritual Well Being

*Strengthened Belief
*Hope
*Despair
*Religiousity
*Inner Strength

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Appendix B.

The effect of outpatient management of cancer patients after autologous blood stem cell transplantation on psychological, social and physical well-being and quality of life.

Caregiver Consent Form

Principal Investigator: Ms. Nancy Summers
Co-investigators: Drs. D. Stewart, JM. Nabholtz, U. Dawe, E. Henderson,

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

Purpose of the Study

You have been identified as the primary caregiver for a patient undergoing high-dose chemotherapy and autologous blood stem cell transplantation for the treatment of cancer. During the period from the transplantation of the stem cells until the return of the patient's blood counts to normal (about twenty-one days), the patient will be cared in the hospital or as an outpatient.

The purpose of this study is to determine if psychological, social and physical well-being, and quality of life is the same for patients being cared for as outpatients compared to inpatients during the period after the transplantation of the stem cells.
As well, the economic impact of care with respect to 'out-of-pocket' cost to your family will be evaluated.

Like all patients who have autologous blood stem cell transplantation at the Tom Baker Cancer Centre, it will be determined by you, as the caregiver, the patient and members of the transplantation team whether the patient is able to be cared for as an outpatient during the period after transplantation. In order to

be an outpatient it is necessary for the patient to have someone that can provide patient care on a twenty-four hour a day basis. As well the patient must live within 45 minutes of the hospital and have available transportation to the hospital. All patients treated at the Cross Cancer Institute in Edmonton will be treated in the inpatient setting.

Description of Procedures

If you agree to participate in this study, you will be required to complete a paper and pencil questionnaires with the research nurse at four different periods of time: i) prior to starting the high-dose chemotherapy regimen; ii) four to six days after transplantation of stem cells iii) 12 - 16 days after transplantation and iv) 30 days after transplantation. You will be asked information concerning your feelings, the emotional and physical demands, ability to cope, amount of support from others and resources available to you in relation to providing care for the cancer patient. Different questions will also be asked of the patient at the above points in time. The questionnaires for you, the caregiver, will require 30 to 45 minutes to complete. You are also required to keep a 'expense diary' of the cost of all services and supplies needed for the patient's care. This diary is to be kept by yourself and the patient during the study period.

The care received and routine procedures to be undertaken by the patient will not be influenced by your involvement in this study. Completion of study sessions will be scheduled at times convenient to you and the patient. Study sessions may take place at times during scheduled return appointments to the cancer centre for follow-up with the patient's physician. Should admission to the hospital occur at any time after transplantation of the blood stem cells, it will be undertaken in the usual manner regardless of which method of care the patient is receiving.

Risks and Discomforts

There are no discomforts or risks involved in participating in this study. The inconveniences associated with participation in this study will be the amount of time and energy required to complete the questionnaires.

Benefits

By participating in this study and sharing your views, you will be helping the staff responsible for the autologous blood stem cell program to consider all the important aspects of a patient's life which are affected by care during the period after transplantation. With the information collected, future services and resources may be implemented to ensure smoother recovery during the period after transplantation.
The patient's medical treatment will not be affected by your choice to participate,

or not, in this study. There will be no financial cost to you if you participate in this study.

Confidentiality

Only the investigators of this study will have access to the questionnaires you fill out. Your responses are confidential. You will be assigned a participant number. All your information will be referenced by that number. Your name and phone number will be kept separately and will be used only to keep track of when the next scheduled interview will be.

All material and data obtained from this study will be stored and may be used for future analysis without obtaining further consent from you. However, each study arising as a result of information obtained in this study will be submitted for ethical approval.

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigator, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation. If you have further questions concerning matters related to this research, please contact: Ms. Nancy Summers @ 286-2009; Dr. Douglas Stewart @ 670-1761.

If you have any questions concerning your rights as a possible participant in this research, please contact the Office of medical Bioethics, Faculty of Medicine, University of Calgary, at 220-7990.

Name of Participant	Signature of Participant Date
Name of Witness	Signature of Witness Date
Name of Principal Investigator, or Delegate	Signature of Investigator Date

The effect of outpatient management of cancer patients after autologous blood stem cell transplantation on psychological, social and physical well-being and quality of life.

Principal Investigator: Ms. Nancy Summers
Co-Investigators: Drs. D. Stewart, JM. Nabholtz, U. Dawe,E. Henderson

PATIENT CONSENT FORM

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

Purpose of the Study

You have decided to undergo high-dose chemotherapy and autologous blood stem cell transplantation for the treatment of cancer. During the period from the transplantation of the stem cells until the return of your blood counts to normal (about twenty-one days), you may be cared for in the hospital or as an outpatient.

The purpose of this study is to determine if psychological, social and physical well-being, and quality of life is the same for patients being cared for as outpatients compared to inpatients during the period after the transplantation of the stem cells. As well, the economic impact of care with respect to 'out-of-pocket' cost to you and your family will be evaluated.

Like all patients who have autologous blood stem cell transplantation at the Tom Baker Cancer Centre, it will be determined by you, your caregiver and members of the transplantation team whether you are able to be cared for as an outpatient during the period after transplantation. In order to be an outpatient it is necessary for you to have someone that can help with your care on a twenty-

four hour a day basis. As well you must live within 45 minutes of the hospital and have available transportation to the hospital. All patients treated at the Cross Cancer Institute in Edmonton will be treated in the inpatient setting.

Description of Procedures

If you agree to participate in this study, you will be required to complete an interview and paper and pencil questionnaires with the research nurse at four different periods of time: i) prior to starting the high-dose chemotherapy regimen; ii) four to six days after transplantation of stem cells iii) 12 - 16 days after transplantation and iv) 30 days after transplantation. These interviews and questionnaires will require about an hour to complete. As well, the person whom you have identified as your caregiver will be asked to complete some questionnaires at the four time periods identified above. The questionnaires for the caregiver will require 30 to 45 minutes to complete. You are also required to keep a 'expense diary' of the cost of all services and supplies needed for your care that are not reimbursed by insurance coverage. This diary is to be kept by yourself and your caregiver during the study period.

The care received and routine procedures to be undertaken will not be influenced by your involvement in this study. Completion of study sessions will be scheduled at times convenient to you. If you are to be cared for in the hospital setting, a research
nurse will collect study information from you in your hospital room. If you are to receive care as an outpatient, the study sessions may take place at times you are scheduled to return to the cancer centre for follow-up with your physician. Should admission to the hospital occur at any time after transplantation of the blood stem cells it will be undertaken in the usual manner regardless of which method of care you are receiving. Data concerning your illness, reason for admission and number of days in hospital will be collected from your medical chart.

Risks and Discomforts

There are no discomforts or risks involved in participating in this study. The inconveniences associated with participation in this study will be the amount of time and energy required to complete the questionnaires. Because it is recognized that the questionnaires may not be able to be completed during one interview, arrangement may be made to complete questionnaires at another time.

Benefits

By participating in this study and sharing your views, you will be helping the staff responsible for the autologous blood stem cell program to consider all the important aspects of a patient's life which are affected by care during the period after transplantation. With the information collected, future services and

resources may be implemented to ensure smoother recovery during the period after transplantation.
Your medical treatment will not be affected by your choice to participate, or not, in this study. There will be no financial cost to you if you participate in this study.

Confidentiality

Only the investigators of this study will have access to the questionnaires you fill out. Your responses are confidential. You will be assigned a participant number. All your information will be referenced by that number. Your name and phone number will be kept separately and will be used only to keep track of when the next scheduled interview will be.

All material and data obtained from this study will be stored and may be used for further analysis without obtaining further consent from you. However, each study arising as a result of information obtained in this study will be submitted for ethical approval.

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigator, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation. If you have further questions concerning matters related to this research, please contact: Ms. Nancy Summers @ 286-2009, Dr. Douglas Stewart @ 670-1761.

If you have any questions concerning your rights as a possible participant in this research, please contact the Office of medical Bioethics, Faculty of Medicine, University of Calgary, at 220-7990.

Name of Participant	Signature of Participant, Date
Name of Investigator or Delegate	Signature of Investigator, Date
Name of Witness	Signature of Witness, Date

A copy of this consent form has been given to you to keep for your records and reference.

Appendix C

Baseline Measures of Inpatients Treated in Calgary & Edmonton

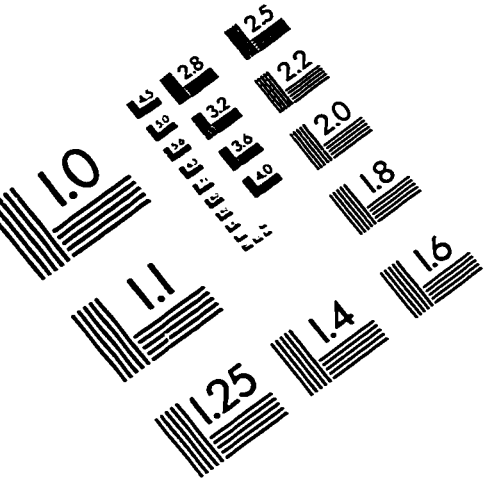
MEASURE	CALGARY		EDMONTON	
	Mean	Range	Mean	Range
FACT	108	71 to 148	107	98 to 114
FACT physical	19.6	10 to 28	15.5	7 to 21
FACT social/family	22.2	15 to 28	24.3	21 to 28
FACT doctor relationship	7.5	7 to 8	8	7 to 8
FACT emotional	13.9	7 to 20	15.8	13 to 18
FACT functional	16.2	6 to 27	17.3	15 to 18
FACT BMT	26.9	21 to 36	26.3	24 to 29
CES-D depression	16	1 to 39	14	8 to 27
POMS anxiety	7.5	3 to 16	5.2	3 to 9
Perception of Control	45	31 to 56	43.5	39 to 53

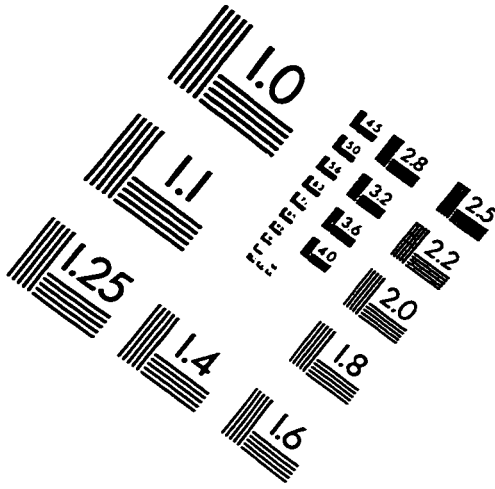
Appendix D

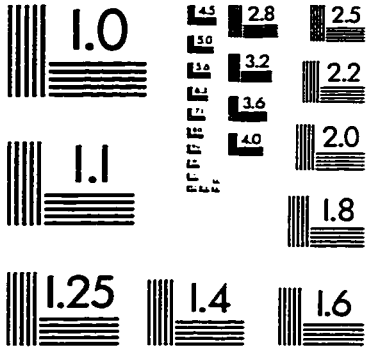
Baseline Measures of Outpatients Treated in Calgary & Edmonton

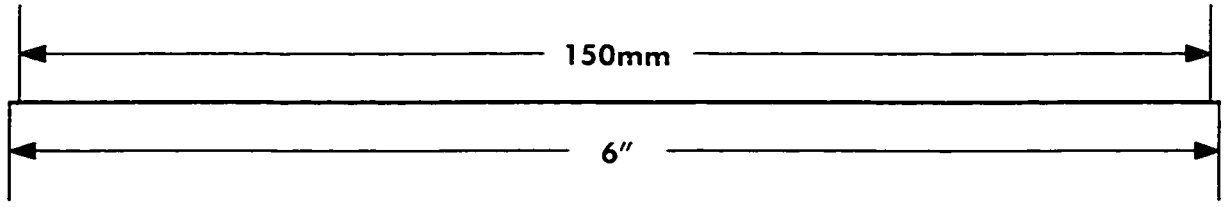
BASELINE MEASURE	CALGARY n=20		EDMONTON n=1	
	Mean	Range	Mean	Range
FACT	122	73 to 145	113	
FACT Physical	23	15 to 28	25	
FACT Functional	19	13 to 28	19	
FACT Social/Family	23	16 to 28	23	
FACT Dr. Relationship	7.5	7 to 8	8	
FACT Emotional	16	5 to 20	15	
FACT BMT	31	17 to 39	26	
CES-D Depression	8	0 to 46	8	
POMS Anxiety	4.5	0 to 14	5	
Perception of Control	48	32 to 56	not complete	

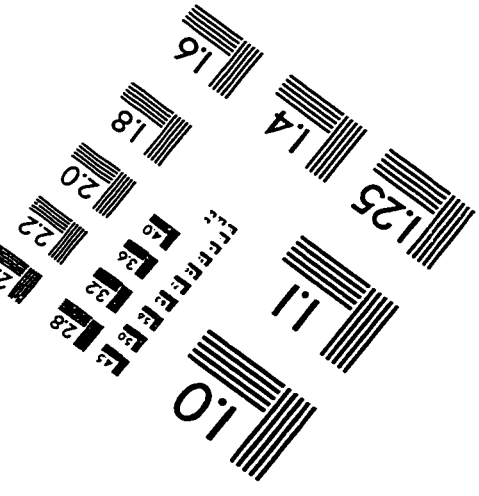
IMAGE EVALUATION
TEST TARGET (QA-3)

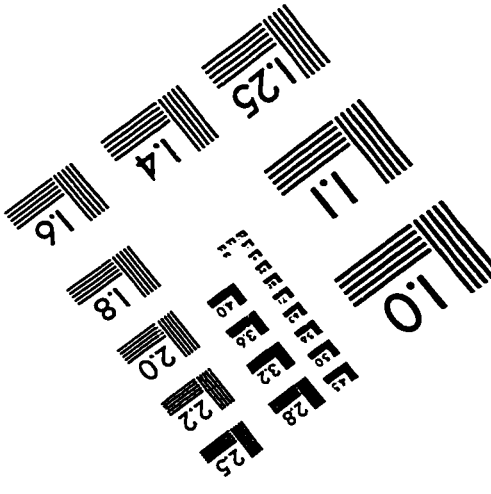












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