Evolution of Global Distress Amongst Patients With Advanced Cancer From Referral to Palliative Care Services to Death

KATHARINE LOUISE THOMPSON

MD
UNIVERSITY OF EDINBURGH
2008
DECLARATION

I Katharine Louise Thompson hereby declare that:

I have composed this thesis

I have conducted the work constituting this thesis

This work has not been submitted for any other degree or professional qualification

Signature

Date 04/08
ABSTRACT

Background
The global distress experience is derived from physical, psychological, social and spiritual interactions.

Objectives
To explore the evolution of distress amongst patients with advanced cancer at the end of life, from the time of referral to palliative care services to death. The primary outcome measure was global distress. Secondary measures were physical, psychological, social and spiritual distress.

Methods
A mixed methods longitudinal study: One hundred advanced cancer patients, newly referred to the community services of a central Scotland hospice, were recruited consecutively. A 20 patient sub-sample was purposively selected for qualitative study. Assessments were monthly for 6 months maximum, each comprising the NCCN Distress Thermometer (DT), Memorial Symptom Assessment Scale (MSAS), Edinburgh Depression Scale (EDS), FACIT-Sp-12 (FACIT); qualitative data were derived from in-depth interviews. Statistical analysis was largely descriptive; grounded theory was used in the qualitative analysis.

Results
Perception of receiving inadequate information and social dysfunction were independent predictors of global distress according to multivariate analysis. Increased opioid doses, out-of-hours home visits and unscheduled admissions were significantly associated with global distress. Over time, physical, psychological and spiritual distress levels initially fluctuated, prior to stabilising at a lower level, with occasional exacerbations of distress. Global Distress (DT) fluctuated constantly, yet correlated significantly ($p<0.001$) with MSAS, EDS and FACIT. Patients'
perspectives evolved with time, indicating reconciliation with death, despite unpredictable exacerbations of distress, reflecting transient loss of control.

Conclusions
Independent predictors of distress at the end of life have been identified. Global distress was associated with an increased healthcare burden through greater service input requirements. Patient perspectives qualified the quantitative data, together indicating that from the time of referral to palliative care services, patients with advanced cancer, receiving community palliative care input, appear to become reconciled to death. However, at the end of life, transient loss of control mediated episodic, unpredictable exacerbations of distress, which were detected by the NCCN Distress Thermometer.
ACKNOWLEDGEMENTS

I am eternally indebted and infinitely grateful to my supervisor, Professor Marie Fallon for her unwavering patience, enthusiasm, kindness and support throughout the entire process of this research. Without her input this thesis simply would not exist.

Professor Gordon Murray to whom I am extremely grateful and owe great thanks. Through the generous contribution of his extensive expertise he has rigorously conducted the statistical analysis, greatly enhancing the credibility of the study findings.

Mrs Marion Alcorn for her friendship and support as well as her expertise, knowledge and genuine patience in creating the Access database for the extensive longitudinal data with a foolproof “front end”.

Professor Scott Murray and Mrs Marilyn Kendall for their input and advice with the qualitative methodology and analysis.

Gail Allan, Sheila Brown, Janice Christie, Pam Clark, Susan High, Morven Kellet, Catherine Kelly, Sarah Lansdown, Alison Moodie, Dot Partington and Lesley Whitelaw; the Community Clinical Nurse Specialists who selflessly and determinedly facilitated and enhanced recruitment for this study amongst their patients. I am forever grateful to them all for their support and friendship throughout the data collection and beyond.

Rose Rose for tirelessly transcribing hours of emotionally intense interviews, Harriet Harris for going beyond the call of duty with secretarial support and Mrs Faye Gilmour for providing constant secretarial assistance with a smile and cup of tea. Faye is sadly missed, may she rest in peace.
Reverend Stuart Coates for psychological support and sanity maintenance throughout the intensive data collection period, and also for marrying my husband and I once it was completed.

With great thanks to my mum, Tanya Hubscher, for patiently and tirelessly proof reading this entire thesis without complaint, and to my dad, Peter, for assisting and supporting her in doing so.

Professor Frank Clark for having the vision and determination to succeed in encouraging an independent hospice to fund MD research in palliative medicine. For providing me with a unique opportunity I will be always grateful.

To each and every one of the terminally ill patients and their relatives who had the courage and determination to participate in this study, I will remain eternally grateful, humbled and privileged. Everything I have learnt from this, you have taught me, including the resilience to complete it. I hope that I have shared your stories and experiences accurately, as you would have wished, and that together we will make even a little difference.

Finally, to my most incredible husband Mark, for providing the eternal love and support that is needed to absorb the emotional intensity of this kind of work: Without you none of this would have been possible. Thank you for your endless encouragement and ultimate selflessness over the entire duration of this thesis.
## 1. INTRODUCTION

1.1 Background  
1.1.2 The Study of Distress

## 2. LITERATURE REVIEW

2.1 Background

2.2 Symptom Distress  
2.2.1 Symptom Prevalence  
2.2.2 Pain  
2.2.3 Symptom Distress and Survival Duration  
2.2.4 Risk Factors For Symptom Distress  
2.2.5 Summary of Physical Distress  
2.2.6 Reciprocal Relationship between Physical and Psychological Distress  
2.2.7 Summary of Relationship between Physical and Psychological Distress  
2.2.8 Pain, Depression and Fatigue Symptom Cluster

2.3 Psychological Distress  
2.3.1 Depression
3. METHODS

3.1 Introduction and Aims

3.2 Design
3.2.1 Longitudinal Design
3.2.2 Quantitative Methodology
3.2.3 Qualitative Methodology
3.2.4 Combining Quantitative and Qualitative Methodologies

3.3 Population
3.3.1 Identification

3.4 Quantitative Study Methods
3.4.1 Recruitment
3.4.2 Consent
3.4.3 Sample Size Calculation
3.4.4 Inclusion Criteria
3.4.5 Exclusion Criteria
3.4.6 Losses and Refusals

3.5 Quantitative Data

3.6 Assessment Tools
3.6.1 Social Distress Tools
3.6.2 Physical Distress Tools
3.6.3 Psychological Distress Tools
3.6.4 Spiritual Distress Tools
3.6.5 Performance Status Tools
3.6.6 Global Distress Tools
4.3 Qualitative Research Ethics 143

4.4 Study Ethics 145

5. ANALYSIS 151

5.1 Quantitative Data Analysis 152
  5.1.1 Outcome Measures 152
  5.1.2 Demographics 152
  5.1.3 Baseline Medical Data 157
  5.1.4 Classification of Socio-Demographic Variables 157

5.2 Non-Participation 157
  5.2.1 Demographics 157
  5.2.2 Reason For Non-Participation 159

5.3 Study Life Table 161

5.4 Statistical Methods 162

5.5 Analysis of Socio-Demographic Variables 162
  5.5.1 Socio-Demographic Risk Factors For Significant Global Distress 162
  5.5.2 Odds Ratios According To Died/Survived 164
  5.5.3 Socio-Demographic Risk Factors For Significant Physical Distress 167
  5.5.4 Socio-Demographic Risk Factors For Significant Psychological Distress 169
  5.5.5 Socio-Demographic Risk Factors For Significant Spiritual Distress 170

5.6 Analysis Of Assessment Tools 172
  5.6.1 Patterns Of Distress Over Time 172
    5.6.1.1 Profile Plots 172
    5.6.1.2 Box Plots 175
  5.6.1.3 Analysis According To Death During Study or Study Survival 177
5.7 Inter-Relations Between Distress Components

5.7.1 Correlations Between Distress Measures At Baseline
5.7.2 Correlations Between Changes In Distress Measures

5.8 The Distress Thermometer

5.8.1 Correlations Between Global Distress and Distress Components
5.8.2 Global Distress At the End of Life

5.9 Analysis of Medication Use

5.9.1 Drug Requirement and Social Status
5.9.2 Drug Requirement and Distress

5.10 Analysis of Healthcare Contacts

5.10.1 Analysis of Out-of-Hours Contacts
5.10.2 Analysis of Unscheduled Admissions

5.11 Analysis of Place of Death

5.12 Qualitative Data Analysis

5.12.1 Process of Analysis
5.12.2 Demographics
5.12.3 Comparison With Quantitative Study

5.13 Codes

5.13.1 Open and Axial Coding
5.13.2 Physical Themes
5.13.3 Psychological Themes
5.13.4 Social Themes
5.13.5 Spiritual Themes
5.13.6 Selective Coding
5.13.7 Inter-Relationships Between Domains
5.13.8 Core Theme: Control
5.14 Longitudinal Analysis

5.14.1 Frequency of Codes
5.14.2 Longitudinal Themes
5.14.3 Physical Distress
5.14.4 Psychological Distress
5.14.5 Social Distress
5.14.6 Spiritual Distress
5.14.7 Anomalous Cases

6. DISCUSSION

6.1 Introduction

6.2 Quantitative Data

6.2.1 Representation of Study Sample

6.3 Socio-Demographic Predictors Of Distress

6.3.1 Predictors of Global Distress Amongst Patients Who Died
6.3.2 Predictors Of Global Distress Amongst Patients Who Survived
6.3.3 Comparison Between Those Who Died and Those Who Survived
6.3.4 Socio-Demographic Predictors Of Physical Distress
6.3.5 Socio-Demographic Predictors Of Psychological Distress
6.3.6 Socio-Demographic Predictors of Spiritual Distress
6.3.7 Socio-Demographic Predictors Of Distress: Further Comparison With Previous Literature
6.3.8 Summary for Socio-Demographic Risk Factors For Distress

6.4 Patterns of Distress Over Time

6.4.1 Karnofsky Performance Status Over Time
6.4.2 Physical Distress Over Time
6.4.3 Psychological Distress Over Time
6.4.4 Spiritual Distress Over Time
6.4.5 Global Distress Over Time 293

6.5 Inter-Relations Between Distress Components 295
6.5.1 Karnofsky Performance Status: Inter-Relationships 296
6.5.2 Physical, Psychological and Spiritual Distress: Inter-relationships 298
6.5.3 Global Distress: Inter-relationships 305
6.5.4 Summary Of Longitudinal Distress Patterns and Inter-Relationships 308

6.6 Medication Requirement and Healthcare Service Input 309
6.6.1 Medication Requirement 309
6.6.2 Contacts 311
6.6.3 Place of Death 316
6.6.4 Summary of Healthcare Service Input and Medication Use 316

6.7 Qualitative Data 317
6.7.1 Study Population 317

6.8 Domain Themes 318
6.8.1 Physical Themes 318
6.8.2 Psychological Themes 320
6.8.3 Social Themes 321
6.8.4 Spiritual Themes 325
6.8.5 Core Theme 328

6.9 Inter-relationships Between Domains 328
6.9.1 Relationship Between Physical and Psychological 328
6.9.2 Relationship Between Physical and Social 330
6.9.3 Relationship Between Physical and Spiritual 331
6.9.4 Relationship Between Psychological and Social 332
6.9.5 Relationship Between Psychological and Spiritual 334
6.9.6 Relationship Between Social and Spiritual 335
6.9.7 Core Theme: Control 335
6.9.8 Summary of Emergent Themes 336

6.10 Longitudinal Themes 336
6.10.1 Physical Distress 337
6.10.2 Psychological Distress 338
6.10.3 Social Distress 339
6.10.4 Spiritual Distress 341
6.10.5 Control 342
6.10.6 Anomalous Cases 343
6.10.7 Summary 344

6.11 Qualitative and Quantitative Data 345

6.12 Aim 1: Risk Factors for Distress 345
6.12.1 Risk Factors for Global Distress 345
6.12.2 Risk Factors for Physical Distress 347
6.12.3 Risk Factors for Psychological Distress 349
6.12.4 Risk Factors for Spiritual Distress 350
6.12.5 Summary 351

6.13 Aim 2: The Relationship Between Distress and Time 352
6.13.1 Physical Distress 352
6.13.2 Psychological Distress 353
6.13.3 Spiritual Distress 354
6.13.4 Global Distress 356

6.14 Aim 3: The Contribution of Each Distress Domain to Global Distress over Time 357
6.14.1 Quantitative 357
6.14.2 Qualitative 358
6.14.3 Quantitative and Qualitative 359
6.14.4 Summary 359
6.15 Ethical Implications of the Study

6.15.1 Completion Rate
6.15.2 Affirmation
6.15.3 Appreciation
6.15.4 Findings In Relation To Other Studies Regarding Ethical Research

6.16 Study Limitations

6.16.1 Sample Size
6.16.2 Participation Rate
6.16.3 Attrition
6.16.4 Non-Participants
6.16.5 Effect of Sedation
6.16.6 Use of Self Report Measures
6.16.7 Social Distress
6.16.8 Social Dysfunction
6.16.9 Perception of Receiving Inadequate Information
6.16.10 Generation of Perspectives
6.16.11 Perspectives on Perspectives
6.16.12 Generalisation
6.16.13 Order of Assessment
6.16.14 Study Population

6.17 Study Implications

6.17.1 Predictors of Distress
6.17.2 Screening for Distress
6.17.3 Healthcare Burden of Distress
6.17.4 Summary

6.18 Future Research

7. STUDY SUMMARY
8. APPENDIX

A. Systematic Literature Review Plan 393
B. Patient Information Sheet 395
C. Significant Other Information Sheet 398
D. Patient Consent Form 401
E. Significant Other Consent Form 402
F. General Practitioner Information Sheet 403
G. Clinical Nurse Specialist Information Sheet 405
H. Consultant Information Sheet 407
I. Memorial Symptom Assessment Scale 409
J. Edinburgh Depression Scale 411
K. FACIT-Sp-12 412
L. Karnofsky Performance Status 413
M. Distress Thermometer 414
N. Ethical Approval 415
O. Publications and Peer Review 421

9. REFERENCES 425
INTRODUCTION
1.1

In 1967 Dame Cicely Saunders opened St Christopher’s Hospice, thus founding the Modern Hospice Movement. Her concept of “total pain” incorporating the physical, psychological, social and spiritual aspects of pain has become one of the philosophies underpinning palliative care. As a speciality, palliative care is dedicated to alleviating suffering, encouraging active living whilst dying and acknowledging the importance of personhood until the point of death: “You matter because you are you, and you matter to the last moment of your life” (Dame Cicely Saunders).

The speciality of palliative care has evolved considerably since 1967, with many advances in pain and symptom management. Despite this, I have witnessed, with a sense of helplessness, patients reaching the end of their life, even in palliative care units, in a state of unalleviated distress.

1.1.2

The Study of Distress

Our understanding of patients’ experiences of distress through the terminal phases of cancer is limited, as therefore, is our management. Research is essential in order to progress. However, the associated challenges are formidable. Distress is a complex human condition that evolves according to a dynamic balance of variables.

The available literature reveals fragmented research into various aspects of distress, as separate entities. Much of the evidence is cross-sectional in design and comparatively few studies have specifically examined the terminal phase of cancer.

The following section provides relevant definitions and examines in detail the available literature on distress, amongst patients with cancer. Literature relating to each of the individual physical, psychological, social and spiritual distress domains is reviewed independently, evidence for the effects of distress on service provision and drug use is examined and the undertaking of this research study is justified.
1.2 Definitions

1.2.1 Distress

Global Distress is difficult to define due to its complexity as a multidimensional phenomenon. The most comprehensive definition of distress is provided by the American National Comprehensive Cancer Network (NCCN) panel in their Distress Management Guidelines for Oncology (Holland et al. 2004):

“Distress is a multifactorial unpleasant emotional experience of a psychological (cognitive, behavioural, emotional), social, and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms and its treatment. Distress extends along a continuum, ranging from common normal feelings of vulnerability, sadness, and fears to problems that can become disabling, such as depression, anxiety, panic, social isolation, and existential and spiritual crisis.”

1.2.2 Cancer

Definition

Cancer is defined as “any malignant tumour including carcinoma and sarcoma. It arises from the abnormal and uncontrolled division of cells that then invade and destroy the surrounding tissues” (Martin 1998).

Statistics

The following statistics have been taken from the Cancer Research UK website (Cancer Research UK, 2006). The most recent statistics are from 2003.
The incidence of all cancers has increased by 24% in the last 25 year. Approximately 2% of the UK population (1.2 million people) were estimated to be living with a cancer diagnosis in 2003.

In 2003, breast, lung, colorectal and prostate cancer together accounted for over 50% of all cancers.

**Figure 1.1: The 20 most commonly diagnosed cancers (ex NMSC), UK, 2003**

![Bar chart showing the 20 most commonly diagnosed cancers in the UK, 2003.](image)

**Figure 1: Most Common Cancers in the UK 2003**

The 2002 UK statistics for these 4 most common tumours are as shown in Table 1:

<table>
<thead>
<tr>
<th>Tumour Type</th>
<th>Annual Incidence</th>
<th>% of all Cancers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>42 000</td>
<td>16</td>
</tr>
<tr>
<td>Lung</td>
<td>38 000</td>
<td>13</td>
</tr>
<tr>
<td>Colorectal</td>
<td>34 900</td>
<td>13</td>
</tr>
<tr>
<td>Prostate</td>
<td>32 000</td>
<td>12</td>
</tr>
</tbody>
</table>

**Table 1: Most Common Tumours in the UK, 2002**
In Scotland lung tumours are the most common; followed by breast, colorectal and prostate tumours. Therefore, although the 4 most common tumour types are the same, their incidence differs slightly in Scotland as shown in Table 2:

<table>
<thead>
<tr>
<th>Tumour Type</th>
<th>% of all Cancers Scotland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>17</td>
</tr>
<tr>
<td>Breast</td>
<td>15</td>
</tr>
<tr>
<td>Colorectal</td>
<td>13</td>
</tr>
<tr>
<td>Prostate</td>
<td>9</td>
</tr>
</tbody>
</table>

Table 2: Most Common Tumours in Scotland, 2002

Table 3 shows the UK figures compared with Scotland in 2002:

<table>
<thead>
<tr>
<th>Tumour Type</th>
<th>% of all Cancers Scotland</th>
<th>% all UK Cancers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>17</td>
<td>13</td>
</tr>
<tr>
<td>Breast</td>
<td>15</td>
<td>16</td>
</tr>
<tr>
<td>Colorectal</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Prostate</td>
<td>9</td>
<td>12</td>
</tr>
</tbody>
</table>

Table 3: Most Common Tumours in the UK compared with Scotland, 2002

The notable difference in these figures is the greater incidence of lung tumours amongst the Scottish population.

Cancer results from damage to cell DNA. The majority of tumours result from cumulative damage to DNA over an individual’s lifetime. The elderly are therefore more likely to develop cancers. DNA damage is increased as a result of contact with carcinogens. Specifically, tobacco smoke is associated with lung tumours, ultraviolet radiation with skin cancers and asbestos is known to cause mesothelioma. Certain viruses are also associated with an increased risk of cancer: Human Papilloma Virus (HPV) is implicated in carcinoma of the cervix, Hepatitis B and C viruses cause
primary liver tumours and Human Immunodeficiency Virus (HIV) is associated with several tumour types. Rarely, individuals may have a genetic predisposition to developing cancer.

**Prevention**

Primary prevention: National campaigns have been launched in an attempt to encourage healthier lifestyles that limit exposure to carcinogens. They advocate avoidance of tobacco smoke, strong sunlight and asbestos. Diet and exercise are thought to reduce the risk of colorectal cancer and advice regarding this has been issued. In addition, information regarding protection against HPV, Hepatitis and HIV has been disseminated widely.

Secondary prevention involves screening for cancer at an early stage. The aim is to discover and cure cancer that has caused detectable pathological changes prior to the appearance of clinical evidence. Strict criteria dictate the approval of a screening programme. The natural history of the disease must be understood and have an identifiable early stage, the test must be acceptable to the population as well as suitably sensitive and specific, accepted treatment options must be available and the economic cost-benefit ratio must be favourable (Wilson and Jungner, 1968). Essentially, the individual, population and economic advantages must outweigh the potential disadvantages.

Therefore, in keeping with these criteria, cancers of the breast and cervix are currently screened for successfully in the UK. Programmes for prostate and colorectal cancers remain controversial.

**1.2.3 Disease Trajectory**

The natural history of cancer has a relatively predictable pattern according to tumour type, stage of disease and treatment. Amongst affected patients and their relatives, the disease trajectory is often referred to, as the "cancer journey". The distinct phases are as follows.
Diagnosis

Diagnosis of cancer may result from screening, from investigation of clinical signs or incidentally. Receiving a cancer diagnosis generally induces some degree of distress amongst patients. This is recognised by Holland et al. (Holland et al. 2004) in the National Comprehensive Cancer Network distress management guidelines and has been shown by Zabora et al. (Zabora et al. 1997) in a study of distress across the disease continuum.

Norton et al. (Norton et al. 2004) also showed that levels of psychological distress are higher amongst patients at the time of diagnosis, in their study of psychological distress amongst 143 patients with ovarian cancer. The data were collected from participants of a 1-year study into psychological intervention for patients with ovarian cancer. Therefore, the data were subject to selection bias, according to recruitment into the intervention study and was also cross-sectional. However, the statistical methods were robust and do indicate that, amongst other factors, psychological distress was higher amongst patients at the time of diagnosis.

Distress at the time of diagnosis is normally followed by an adjustment period, during which distress levels fall. This does not happen in cases of extreme reaction (Zabora et al. 1997). The extreme reaction was described by Weisman and Worden (Weisman and Worden, 1976-1977) (Weisman, 1976) in the 1970s, in papers which to date remain widely quoted. They produced evidence suggesting that a patient’s inability to cope effectively with the challenges of cancer was predictable from the time of diagnosis, according to pre-morbid psychosocial vulnerability.

Treatment

Certain cancers diagnosed at an early stage may be completely cured by appropriate treatment. All tumour types have higher survival rates if diagnosed at an early stage, before metastasising.

According to tumour type and stage, cancer treatment is usually a combination of surgery; physically removing the tumour, chemotherapy; chemically killing cancer
cells and radiotherapy, which uses radiation to kill cancer cells. Treatment regimens vary and new treatment protocols are clinically trialled on an on-going basis.

Treatment may be intended either to cure, or to induce a period of remission, or to palliate symptoms if the tumour is advanced. The effect of treatment on distress levels is debated and varies according to the literature reviewed.

According to Carlson et al. (Carlson et al. 2004), patients in active treatment are more distressed than those on follow up treatment. In their large study of 2776 patients attending a regional tertiary cancer centre, Carlson et al. compared distress levels according to the General Severity Index of the Brief Symptom Inventory. They found that those patients being treated actively were significantly more distressed than those receiving follow up treatment ($r = 3.72$, $p < 0.05$). This study is robust due to the sample size and rigour, despite relying on cross-sectional data.

In a small descriptive study of 41 patients with breast cancer, Northouse (Northouse, 1989) used the Brief Symptom Inventory and the Psychological Adjustment to Illness Scale to assess levels of distress at 3 time points, from the time of mastectomy, over a period of 18 months. The study found distress levels to be similar at each time point throughout the treatment phase, despite improvements in mood and role functioning.

In their descriptive study of 235 patients with breast cancer, Hanson Frost et al. (Hanson Frost et al. 2000) assessed groups of patients at 4 distinct points in the disease trajectory (diagnosis, adjuvant treatment, stable disease and recurrence), for their physical, psychological and social well-being using several research questionnaires including the Brief Symptom Inventory (BSI) and the Short Form-36 amongst others. Women in the newly diagnosed, adjuvant and recurrent groups experienced significantly more difficulties with fatigue and social function than the stable group. Overall, the women in the stable group (median of 4 years from diagnosis) did better than those in the other groups, and in fact their social function scores were found to return to those of the general population. Although the study
was limited by the use of a cross-sectional convenience sample and use of breast cancer patients only, the results suggest that levels of well-being may normalise following treatment and prior to potential recurrence.

**Recurrence**

Disease recurrence may follow a period of treatment-induced remission. Depending on tumour type and stage, further treatment may be offered. This is known to be a period of vulnerability for patients who need to readjust to their circumstances (Holland et al. 2004). Studies have shown that distress levels increase at this time. The study by Hanson Frost et al. (Hanson Frost et al. 2000) described previously, indicates that women with recurrent disease, experienced more difficulties than the other groups (newly diagnosed, adjuvant treatment and stable) in terms of health perceptions, physical function, somatisation, impact on life and medical interactions. Despite these findings, when compared with the other groups, those with disease recurrence did not show increased psychological distress other than somatisation on the BSI.

Another study conducted by Jenkins et al. (Jenkins et al. 1991) is also indicative of distress associated with disease recurrence. However the results must be regarded cautiously due to the very small sample. They carried out psychometric assessment on 22 patients with locally recurrent breast cancer using various validated research tools, clinical evaluation and structured interviews. They found that 10 of the patients (45%) had psychiatric illness (depression and anxiety) at the time of recurrence and that those with previous psychiatric illness and trait neuroticism were more susceptible.

Norton et al. (Norton et al. 2004) carried out a study of psychological distress amongst 143 patients with ovarian cancer, as described previously. As well as showing increased psychological distress at the time of diagnosis, they also found levels to be higher amongst patients with disease recurrence.
End Stage
Cure is not possible and cancer is advanced at this stage of the trajectory. The purpose of any treatment is purely symptomatic relief. Reaching this final phase of the cancer journey marks a monumental milestone that requires patient reorientation, revaluation and once again, readjustment. According to Holland et al. (Holland et al. 2004), both advanced cancer and end of life are considered to be periods of increased vulnerability to distress. This is supported by the findings of a cross-sectional survey of 386 ambulatory patients with cancer across 12 sites in America. Zabora and colleagues (Zabora et al. 1997) used the Brief Symptom Inventory and the Functional Living Index-Cancer (FLIC) to evaluate functionality and psychological distress over the 5 stages of the disease continuum. One third of patients across the spectrum were distressed, rising to 68% amongst those who were terminally ill. Terminally ill patients also scored significantly lower on the FLIC. These cross-sectional study results must be interpreted with caution as data from only 8 terminally ill patients were analysed.

Nonetheless, these findings do confer with results from a small study of 44 patients with metastatic breast carcinoma conducted by Fulton (Fulton, 1997) in Scotland. These patients were assessed during the period of 1-7 weeks prior to death using the Hospital Anxiety and Depression Scale. Analysis revealed that 66% of the patients scored in the case range for anxiety and 50% for depression.

Butler et al. (Butler et al. 2003) studied psychosocial distress amongst 59 women with metastatic breast cancer as part of a larger study of 125 women who were randomised into an on-going clinical trial comparing psychotherapy and education with an education only control. They retrospectively studied data taken over time from women who died. In order to be included, these women had to have been assessed at least 3 times; at baseline (T1), second-to-last assessment prior to death (T2) and last assessment prior to death (T3). Several validated research questionnaires were used for psychosocial assessment, including the Profile of Mood States. Different numbers of women had completed each of the questionnaires however this was accounted for in the analysis. Across the measures of mood
disturbance, trauma symptoms, depressive symptoms, ability to experience positive states of mind and pain, there was a significant increase in distress and pain, together with a significant decrease in well-being at the final assessment prior to death. This study was adversely affected by the inherent selection bias of patients who may have already been distressed and seeking therapy. In addition, the assessment prior to death was done on average 6 months before death, and therefore no information is provided for the time imminently preceding death. Despite the caution required in interpretation of the results, this study may provide an indication that levels of psychological distress may increase as the end of life approaches.

Referral to palliative care services is often made at this final stage of the disease trajectory. However, pre-emptive referrals at an earlier stage are encouraged when future palliative care input is inevitable: Earlier referral can maximise the potential benefits that patient can derive from the service.

This study is focuses on the final stage of the cancer journey.

1.2.4 Palliative Care

The World Health Organisation defined Palliative Care in 1990:

“Palliative care is the active total care of patients whose disease is not responsive to curative treatment. Control of pain, of other symptoms, and of psychological, social and spiritual problems is paramount. The goal of palliative care is achievement of the best quality of life for patients and their families...” (WHO Expert Committee on Cancer Pain Relief and Active Supportive Care Cancer pain relief and palliative care: report of a WHO expert committee., 1990).

Thus in delivering care to patients with progressive, advanced disease, this speciality aims to:
• Affirm life and regard dying as normal process
• Relieve pain and other distressing symptoms
• Provide a support system that facilitates active living of patients until death
• Provide a support system for the family, helping them to cope during the patient’s illness and their subsequent bereavement

“Total” care implies the provision of holistic care of the physical, psychological, social and spiritual elements that comprise the “whole” individual. A multidisciplinary approach is therefore required. Specialist palliative care teams generally include doctors, nurses, chaplain, social worker, occupational therapist, physiotherapist and in some cases also psychologist, complementary therapist and pharmacist.

Traditionally, palliative care was hospice based. However, due to demand, service provision now extends to both community and hospital settings. Service provision is also expanding to include other chronic diseases considered to also fall within the speciality’s remit. Although the majority of patients receiving palliative care still consists of patients with a cancer diagnosis, patients with HIV/AIDS, progressive neurological conditions, end-stage respiratory, cardiac and renal disease are now also variably included, depending on local resources.

Palliative care is growing as a speciality. Across the UK, in January 2006 there were 221 adult in-patient units providing 3180 beds, 356 community teams, 257 day care centres and 352 hospital support teams in palliative care (Ward 2006).

Figures from The National Survey of Patient Activity Data (excluding Scotland) conducted by the National Council for Palliative Care for 2004-2005 revealed that over this time 42 000 new patients were admitted to an in-patient unit, 95% of patients had a cancer diagnosis and 30 000 died. The average in-patient stay was 13 days. Home care teams were involved for an average of 3-4 months and saw 160 000 patients over this time (Eve, 2006).
LITERATURE
2.1

Background

The term “distress” provides a rather simple definition for an extremely intricate balance of variables. The experience of distress results from the interactions of internal and external factors. Internal factors comprise of physical, psychological and spiritual domains, whilst external factors relate to the social environment.

The experience of distress at any single time point is the result of the dynamic interplay between these four domains. The individual impact of each of these domains is constantly changing and therefore, any distress experienced evolves over time.

An extensive, systematic literature review of the Medline, PsychInfo, Embase and Cinahl databases (see Appendix A) was conducted, in order to retrieve all of the relevant literature available, regarding distress amongst terminally ill cancer patients.

From the outset, it became apparent that the four distress domains have been largely considered as separate entities in the current literature.

2.2

Symptom Distress

“Symptom distress” refers to the physical domain and is defined as “the degree of discomfort reported by the patient in relation to his/her perception of the symptoms being experienced” (McCorkle and Young, 1978). This is in keeping with Rhodes and Watson’s (Rhodes and Watson, 1987) suggestion that “meanings ascribed to symptoms are relative to one’s life situation”.

14
2.2.1
Symptom Prevalence

Any symptom may cause distress. The most prevalent physical symptoms in advanced cancer include weakness, fatigue, pain, anorexia, constipation and dyspnoea (Potter et al. 2003). Curtis et al. (Curtis et al. 1991) found the 3 most common symptoms to be pain, weight loss and anorexia amongst 100 consecutive patients with advanced cancer in America.

Coyle et al. (Coyle et al. 1990) carried out a retrospective study of prospectively collected data from 90 consecutive patients in a supportive care programme. They analysed the symptoms reported by patients on a weekly basis, from 4 weeks prior to death. They found that 4 weeks prior to death 71% of patients reported 3 or more distinct symptoms, the most prevalent of which were fatigue (58%), pain (54%), weakness (43%), sleepiness (24%) and cognitive impairment (24%). At 1 week prior to death, the prevalence of these symptoms changed. The greatest increase at this stage was in sleepiness (57%), causing it to become the most prevalent symptom. The greatest decrease was in pain (34%). Symptom prevalence may well be under represented in these findings, as the authors only documented symptoms spontaneously reported by patients and did not seek to elicit information about symptoms not mentioned. Patients are likely to only report those symptoms that are of greatest concern to them.

Grond et al. (Grond et al. 1994) conducted a 7 year prospective study of cancer patients referred to a pain clinic with intractable pain. One thousand six hundred and thirty five patients rated their pain, mood, and a further 15 symptoms were evaluated using a standardised questionnaire. In addition to pain, the patients had on average a further 3.3 symptoms. The most common symptoms were insomnia (59%), weakness (54%) and anorexia (48%). Ninety four percent of patients suffered symptoms additional to pain and cancers of the respiratory system were associated with the highest number of symptoms. Higher pain intensity was also associated with an increased number of other symptoms. In this study, there was no difference in the number of symptoms amongst patients with advanced cancer and those with earlier stage disease. This may be attributed to the pre-selection of all patients with
“intractable pain”. Although this study is cross-sectional and the only symptoms studied were predetermined, this was in fact a large, clinically significant study with a high proportion of patients with advanced cancer (n=1006).

The case notes of 1103 patients hospitalised for terminal care of advanced cancer in America were retrospectively analysed (Brescia et al. 1990). Information was taken from data documented at the time of admission, at 2 weeks prior to death and every day of the last 5 days of life. This method of data collection limits the study’s value due to reliance upon the perception of various healthcare professionals and the level of detail in their documentation. However, the large sample provides an indication of symptom prevalence. According to the case notes, pain, confusion and anorexia were the 3 most common symptoms. Seventy three percent of patients had pain on admission and 38% suffered severe pain. One third of the patients were confused on admission and anorexia was present amongst 31% of the patients.

In a study conducted in Spain (Conill et al. 1997), data were collected prospectively from 176 consecutive patients who died from cancer in the hospital, hospice or at home in a regional area. Patients completed a questionnaire regarding the presence or absence of common symptoms during their first consultation and again in the last 7 days of life. Weakness, anorexia and dry mouth were the three most frequent symptoms at both the first and final evaluation: Weakness (76.7% and 81.8%), anorexia (68.2% and 80.1%) and dry mouth (61.4% and 69.9%) respectively. Notably, pain prevalence fell from the time of the first consultation (52.3%) to the week before death (30.1%), whilst confusion increased from 30.1% at first consultation to 68.2% in the week prior to death. This was a straightforward study of symptom prevalence that did not focus on associated severity or intensity. Patients were asked to report on pre-defined symptoms. This is less reliable than allowing patients to volunteer information regarding their symptoms. Therefore, these results are useful as guidance, particularly the comparisons between the first consultation and the week prior to death.
A study carried out in Hong Kong (Oi-Ling et al. 2005) compared symptom distress in the last week of life, as rated by advanced cancer patients, caregivers and physicians. The prospective study recruited consecutive patients with a life expectancy of less than 2 weeks who were admitted to a hospice ward. Patients were asked to rate their distress from 0-4, according to severity in relation to the 13 of the most common symptoms. Physicians and caregivers completed the rating according to their perception of the patient’s level of distress. All 3 parties completed the questionnaire on the same day and this was repeated every 7 days until death. Only the data from the last week of life was analysed and was therefore available for just 30 patients. The 4 most distressing symptoms for patients were fatigue, cachexia, anorexia and dry mouth. These were also the most frequent symptoms. Importantly, the physicians underestimated the distress caused to patients by all of the symptoms. The small numbers and use of a non-validated measure however, limit the generalisation of these findings. Symptoms may have been over-represented, as patients were asked about their presence rather than asked to volunteer distressing symptoms themselves. Finally, the cultural differences of patients in Hong Kong may also impact on the generalisation of the findings. Specifically, eating well reflects good quality of life in Chinese culture and this is potentially reflected in the high ratings given to cachexia and anorexia, implying they are highly distressing symptoms.

Walsh et al. (Walsh et al. 2000) conducted a prospective analysis of symptoms amongst 1000 patients from the time of their referral to a palliative medicine programme. They concluded that patients with advanced cancer are polysymptomatic with 10 highly prevalent symptoms (ranging from 50%-84%) included amongst them. In addition to those previously stated, symptoms include dry mouth, early satiety and a greater than 10% weight loss.

**Xerostomia**

Sweeney et al. (Sweeney et al. 1998) suggest that up to 97% of patients in the terminal phase of cancer may suffer from xerostomia and in a study by Davies et al.
(Davies et al. 2001), xerostomia was ranked as the third most distressing symptom for patients with advanced cancer.

McMillan and Small (McMillan and Small, 2002) evaluated 178 hospice homecare patients at home. Patients were identified from hospice records and assessed within 48 hours of their referral, using several self-assessment questionnaires. These included the Memorial Symptom Assessment Scale Symptom Subscale (24 questions). Although the participants were representative of the hospice population, they were acknowledged as being those well enough to complete the assessment. Dry mouth was the third most prevalent symptom (78%) and the second most distressing symptom. Although cross-sectional, this representative study provides a helpful indication of symptom prevalence and distress.

Rydholm and Strang (Rydholm and Strang, 2002) examined in detail the physical and psychosocial impact of xerostomia amongst 16 patients with “disseminated terminal cancer” who had been admitted to a palliative hospital-based home care programme. They used semi-structured interviews to establish the main issues for patients who had spontaneously described dryness of mouth. The patients’ main physical concerns were discomfort, difficulties with articulation and weak voice, together with tendency to develop infection. Psychosocial issues related to loss of pleasure in eating, reduced socialisation due to difficulties with articulation and resultant loss of confidence. Although this was a small qualitative study providing descriptive data, the methods used were rigorous and the data were validated.

**Fatigue**

Cancer-related fatigue is unique in that it may be profound, and occurs despite adequate sleep. Fatigue is the most common symptom associated with cancer and its treatment. According to the diagnostic criteria used, prevalence appears to vary (Barnes and Bruera, 2002).

In a large Canadian study conducted by Carlson et al. (Carlson et al. 2004), 2776 patients were recruited consecutively from all of the patients visiting a regional
tertiary cancer centre, in order to provide a representative sample. The patients completed several self-rated questionnaires, including the Brief Symptom Inventory. Their analysis indicated that the sample was in fact demographically and medically representative. By far the most common symptom, affecting 48.5% of the patients was fatigue (pain was next, affecting 26.4%). This study was cross-sectional, providing an indication of prevalence within a representative Canadian out-patient cancer population.

In the previously described study by McMillan and Small (McMillan and Small, 2002), fatigue was both the most prevalent (89%), as well as the most distressing symptom.

Fatigue also appears to be consistently the most distressing symptom of cancer and its treatment. Patients with cancer have rated fatigue as the longest lasting and most disruptive symptom (Barnes and Bruera, 2002), resulting in the greatest impact on quality of life.

Noyes et al. (Noyes Jr et al. 1990) recruited 438 patients with solid tumours, from both in and out patient departments of an American centre, and asked them to complete the Beck Depression Inventory together with an Illness Distress Scale devised by the authors. In this cross-sectional study Noyes et al. found that physical symptoms were the greatest source of distress to patients with cancer and that fatigue and pain caused the most severe distress.

In 2 tertiary referral centres in Manitoba, Degner and Sloan (Degner and Sloan, 1995) asked 434 consecutive patients with a new diagnosis of cancer (less than 6 months) to complete the Symptom Distress Scale. They found that overall levels of distress were in fact low in this population but that fatigue appeared to be the most problematic symptom, rated highly by 38.9%. This was a simple descriptive study and is compromised by the fact that most patients (63%) had received radiotherapy prior to the study. Radiotherapy directly induces fatigue and may have therefore been the source of distress in this population. In addition, the Symptom Distress Score
does not provide an indication of the relative importance of symptoms, only the level of distress they induce.

Holley (Holley, 2000) looked qualitatively at fatigue from the patient’s perspective using content analysis of 23 in-depth interviews with 17 patients. The patients were sampled purposively from in-patients and out-patients attending a cancer centre in an American hospital. They included patients having a variety of tumour types, stages of disease and treatments. The main finding was that patients consider “cancer related fatigue” to be unique and different to the typical fatigue experienced by healthy individuals. As a result, the fatigue was unfamiliar and regarded as a negative consequence of illness and a sign that health was declining. Despite the ability to perform essential tasks, as indicted by an average Karnofsky Performance Status of 75, fatigue impacted on every aspect of life (physical, psychological, social and spiritual) and induced distress. This rigorously designed and implemented qualitative study provides some insight into the fatigue-induced distress suffered by patients with cancer.

Several studies have evaluated lung cancer, specifically with regard to fatigue. Cooley (Cooley et al. 2003) assessed symptoms amongst patients being treated for newly diagnosed (within 100 days of diagnosis) lung cancer. The study retrospectively evaluated longitudinal data from 1983-1993, taken at 0, 3 and 6 months through treatment. The data included a combination of self-rated questionnaires, including the Symptom Distress Scale, together with socio-demographic factors. Analysis revealed that fatigue was consistently the most distressing symptom at each stage of treatment. This implies a high prevalence of fatigue amongst patients with lung cancer going through treatment. However, this should be considered with caution as this study presents a secondary analysis, conducted on data collected 20 years prior to the time of publication.

At national cancer centres in Japan, Okuyama et al. (Okuyama et al. 2001) studied 157 consecutive ambulatory patients with a diagnosis of advanced lung cancer who had not received treatment in the 4 weeks prior to study. Patients completed a
number of self-administered questionnaires, including the Cancer Fatigue Scale and the HADS, on 2 occasions, on average 7 days apart. Eighty one point five percent of the patients suffered from some degree of fatigue, approximately 50% had clinically significant fatigue. Fatigue was also found to impact upon physical and psychological well being. Those who did not participate were physically less well with poorer performance status. This suggests that levels of fatigue may be under reported in this descriptive study of ambulatory patients with advanced cancer.

2.2.2 Pain

Pain is an important symptom for patients with cancer and is often studied independently. Approximately one third of all patients with cancer suffer chronic pain (Portenoy, 1992) and 70% of cancer patients will experience severe pain at some time during their illness (Foley, 1985). Although disputed, pain prevalence may be as high as 82% amongst those with terminal cancer (Tay et al. 1994) (Portenoy, 1992). Despite this, Oster et al. (Oster et al. 1978) found that approximately one quarter of cancer patients died without pain or analgesic use. Additionally, in a later described study, Spiegel and Bloom (Spiegel and Bloom, 1983) found that pain intensity, duration and frequency did not distinguish patients in the terminal phase of metastatic breast cancer from those with more than 1 year’s survival duration.

In the previously discussed retrospective study of 90 patients, Coyle et al. (Coyle et al. 1990) found that 100% of the patients surveyed reported pain at some point. Interestingly, at 4 weeks prior to death, the pain was in fact described as mild to moderate by a large majority (80%) and as moderate to severe by only 20%. In addition, the prevalence of pain reported fell from 54% at 4 weeks prior to death to 34% one week before death. These patients were, however, in a palliative care programme.

In a longitudinal study carried out by McKegney and colleagues (McKegney et al. 1981) in Vermont, 199 patients with terminal cancer and prognosis of more than 3
months but less than one year, were recruited from each county. The counties were paired according to socio-demographic factors and assigned to either the “intensive group” (n=98) receiving regular specialist palliative home nursing care, or the “non-intensive group” (n=101) who did not receive home care. Both groups received the same on-going multidisciplinary care. The nurses visited monthly until prognosis was considered to be less than 3 months, at which point they visited bi-weekly. They provided holistic care and were provided with a “Protocol for the Management of Pain” by the study authors. Trained “raters” asked patients to complete a selection of self-rated questionnaires, including a pain estimate and a modified “Rotter Locus of Control” on entry into the study and then regularly with the same frequency as the nurses’ visits.

No socio-demographic differences were found between the intensive and non-intensive groups. The analysis was conducted in blocks of days prior to death. Eighty percent of those who died reported pain of varying levels at some point during the study. Pain increased in frequency and severity as death approached. Initially, both groups had the same mean pain scores but at 90 days prior to death, pain continued to increase amongst the non-intensive group whilst reaching a plateau amongst the intensive group: This difference reached near significance (p=0.06) in the last 30 days of life. These findings were considered to advocate strong support for palliative home nursing care, at least in terms of pain control. This study is one of the very few longitudinal studies to follow patients to the end of life. Its impact is however limited by the incomplete data that required analytical adjustment.

In a study of 208 consecutive ambulatory cancer patients, Ahles et al. (Ahles et al. 1984). screened patients for the presence or absence of pain in the previous week. If pain was present, patients were asked whether this related to the cancer itself, cancer-related treatment or if the pain was non-malignant. The research team studied the patients’ records, in order to ascertain the likely cause of pain and to establish other relevant clinical factors. Patient’s performance status was also documented. This was a relatively straightforward study with a representative population that found 33.5% of patients had cancer-related pain and 6.7% had treatment-related pain. Pain was
less of an issue amongst those with local or regional disease only, and in this case the tumours associated with an increased risk of pain, were head and neck or brain tumours. This is in fact contrary to the findings of Morris et al. (Morris et al. 1986) who report on data from the National Hospice Study, in which brain tumours were less likely to cause pain. An important limitation of Ahles’s study is that no indication is given as to whether they used the patient’s or the doctor’s interpretation of the cause of pain in the analysis.

In a study with similar aims, Banning et al. (Banning et al. 1991) studied 200 patients in a multidisciplinary cancer pain clinic over 10 months. One hundred and seventy two of these patients had disseminated malignancy and the median survival following referral to the clinic was 10 weeks. Their sample was representative. Patients were fully assessed, examined and their records analysed, in order for the doctor to establish the cause of pain. One hundred and eighty six (93%) had pain attributable to cancer and this was directly caused by tumour growth in 158 of the patients. In this study, 116 patients had treatment-related pain and the majority of patients had pain related to more than one cause.

Tumour site is clearly important (Daut and Cleeland, 1982) and in the previously reported study by Brescia et al. (Brescia et al. 1990), patients with cervical carcinoma were most likely to suffer severe pain, with 68% reporting severe pain on admission to hospital. Tumours of the prostate were the next most likely to cause severe pain (57%), followed by recto-sigmoid tumours (49%). In their study of 667 cancer patients, 75% of those suffering pain in the last 30 days of life had metastatic carcinoma of the prostate, compared with only 14% pain amongst patients with local uterine carcinoma (Daut and Cleeland, 1982).

Clearly, stage of disease is an important factor that has not necessarily been controlled for in studies of pain prevalence according to cancer site. There is a consensus in the literature regarding the increased prevalence of pain amongst patients with bone metastases. This was evident in the data from the National Hospice Study of patients with terminal cancer (Morris et al. 1986). Brescia et al.
(Brescia et al. 1992) (Brescia et al. 1990) found 49% of patients with bone metastases reported severe pain, compared with only 31% of the patients who did not have bone involvement. This is in keeping with the findings of Ahles et al. (Ahles et al. 1984) who found a statistically significant increase in pain amongst patients with metastatic disease (56% compared with 17%). Of the patients reporting pain, 54.4% had bone metastases, compared with only 20% with bone metastases in the pain-free group. In an American study of 397 hospitalised cancer patients 38% had pain. The pain was due to tumour invasion or compression in 78% and 50% of this related to bone metastases (Foley, 1979). Banning et al. (Banning et al. 1991) further substantiate these findings. In their previously described study, the most common cause of cancer related pain was tumour growth and the single most frequent cause of this was bone metastases.

Pain is a significant factor in causing disruption to function and quality of life. Portenoy et al. (Portenoy et al. 1992) studied the effects of pain amongst 91 ambulatory patients with cancer of the lung or colon, undergoing active treatment. Three hundred and twenty six patients were initially screened by telephone for frequent or persistent pain in the previous 2 weeks. Ninety-one of these patients were then interviewed in depth. Other than pain location, no significant differences were found between the lung and colon cancer patients. Approximately 90% of patients had pain more than 25% of the time and this interfered moderately or more with the general activity or work in approximately 50% of patients. Interestingly, 52.1% of the variance in the derived measure of pain interference in function was explained by the mood score, frequency of the worst pain, number of pains and the pain intensity. An important limitation of this study is that the authors provide no explanation of the criteria used for the selection 91 patients identified by the telephone screening.

Cleeland et al. (Cleeland et al. 1994) studied 1308 outpatients with metastatic cancer, across 54 treatment sites affiliated to the Eastern Cooperative Oncology Group (ECOG). The patients were asked to rate the severity of their pain in the previous week, along with pain related functional impairment and relief from analgesia. Sixty seven percent of the patients had pain and 36% had pain severe
enough to cause functional impairment. Forty two percent of patients were found to be receiving inadequate analgesia and this was linked to an increased likelihood of pain related functional impairment. Again this study relied upon self-rated measures. However, these are relevant as they reflect patient perception.

Strang (Strang, 1992) studied 93 consecutive in-patients with cancer-related pain using visual analogue scales, interviews and self-questionnaires. He found that ability to perform activities of daily living was impaired in approximately two thirds of patients and cognitive activities, such as reading, were impaired in 48% of the patients. Social activities were reduced and familial role was altered as a result of the impact of pain.

In the previously described study of pain amongst 208 ambulatory cancer patients by Ahles et al. (Ahles et al. 1984), the authors found that performance status was significantly more likely to be reduced amongst patients suffering from pain, when compared with those who were pain-free.

2.2.3
Symptom Distress and Survival Duration
Symptom distress may be related to survival duration. In America, Kukull et al. (Kukull et al. 1986) studied 53 patients newly diagnosed with lung cancer. Patients were recruited consecutively from 4 radiation centres and assessed using various self-rated measures, including the Symptom Distress Scale and a Pain Score, at 1 month and again at 2 months post diagnosis. Patients were then followed up for 3 and half years and survival data were analysed according to the Proportional Hazards Model. Analysis at several levels showed that symptom distress scores shortly after diagnosis are the best predictor of subsequent survival, and that this predictive value remains even after adjusting for other variables. The authors hypothesise that this relationship may perhaps result from patients with greater disease burden at diagnosis receiving more radiotherapy and thus suffering from additional symptoms. Increased radiotherapy was required by patients with a greater disease burden and this may have been reflected in the survival analysis. However, the data for the
radiotherapy dosing and extent was neither provided nor further considered. The authors were however confident that most patients had similar stage disease. Despite this, the small sample size and only assessing patients twice, the survival analysis itself was robust and meaningful.

In the simple descriptive study of 434 newly diagnosed patients with lung cancer, conducted by Degner and Sloan (Degner and Sloan, 1995), results of the survival analysis showed that symptom distress scores on the Symptom Distress Scale were “unquestionably” associated with survival. The survival analysis was conducted 5 years after the onset of data collection for the original study, using standard analysis techniques for time-censored data. Using both parametric (Wilcoxon ratio test) and non-parametric (log rank test) testing, symptom distress was significantly associated with survival (p=0.0001). The correlation of symptom distress from time of diagnosis was -0.49 (p=0.0001) and from the time of interview was -0.54 (p=0.0001). Almost all patients with high symptom distress had short survival times, suggesting this may be a useful prognostic indicator. The authors hypothesise that this correlation results from patient awareness of changes in their body, indicative of sub-clinical tumour load or progression or that there may be an interactive effect between symptom distress and survival amongst patients in poor prognostic groups.

Both of these studies were carried out on newly diagnosed patients with lung cancer and were limited in various ways. Nonetheless, the concept that symptom distress close to diagnosis may negatively affect survival duration is both interesting and important. There is currently no literature available examining the subsequent effects of symptom distress at the time of entry into palliative care services.

2.2.4

Risk Factors For Symptom Distress

The overall distress caused as a result of physical symptoms has been analysed in numerous studies and various risk factors have been identified. In Degner and Sloan’s (Degner and Sloan, 1995) previously reported descriptive study of 434 consecutive patients with a new diagnosis of cancer, patients completed the
Symptom Distress Scale. They found that women reported more distress than men (p=0.041), patients with advanced disease had significantly more distress than those with early disease at the time of diagnosis (p=0.0001) and that patients with lung cancer were the most distressed and men with genitourinary cancers were the least distressed.

The low symptom distress scoring for men with genitourinary cancers in this study is interesting, as previously reported studies (Brescia et al. 1990) (Daut and Cleeland, 1982) indicate that metastatic carcinoma of the prostate is highly likely to cause severe pain. This result may reflect the study sample chosen of patients with a new diagnosis who may not therefore, have had metastatic disease. Alternatively, men with genitourinary cancers may have low distress despite the pain, indicating the influence of other determinants of symptom distress.

In the previously reported retrospective longitudinal study of newly diagnosed lung cancer patients, Cooley et al. (Cooley et al. 2003) found that the best predictor for symptom distress (according to the Symptom Distress Scale) over time, was symptom distress at baseline. Symptom distress at study entry predicted symptom distress for 9 symptoms at 3 months and 7 at 6 months (odds ratios from 1.6 (p=0.005) to 3.4 (p=0.000)). Again, these findings must only be used to provide an indication and should be considered with caution, due to both the vague reporting of statistical analysis, and the use of data collected 20 years prior to publication.

In previously reported large, representative Canadian study conducted by Carlson and Bultz (Carlson et al. 2004), 2776 ambulatory cancer patients completed several self-rated questionnaires including the Brief Symptom Inventory. Patients who had the most symptom distress were from ethnic minorities (p=<0.001), were from lower income households (p<0.001) and were undergoing active treatment rather than follow up treatment (p<0.05). In keeping with the findings of Degner and Sloan, patients with prostatic carcinoma were the least distressed when results were analysed by tumour site (p<0.001). In multiple linear regression directionality
indicated that in addition to these factors; younger age, female gender and longer duration of illness were all associated with higher distress levels.

The increased risk of symptom distress amongst ethnic minority groups is also highlighted in studies of pain conducted by Cleeland et al. (Cleeland et al. 1997) amongst the ECOG affiliated sites. They studied 281 ethnic minority patients with recurrent or metastatic cancer using self-rated measures of pain. They found that 77% of patients had disease-related pain and that 41% of them had severe pain. Sixty five percent of minority patients did not receive guideline recommended analgesia, compared with 50% of non-minority patients (P < 0.001). This was most noted amongst Hispanic patients. Data from the previously described larger study (Cleeland et al. 1994) of 1308 patients in ECOG affiliated sites indicate that patients seen in clinics that “treated predominantly minorities were 3 times more likely than those treated elsewhere to have inadequate pain management”.

A potential factor in minimising symptom distress may be the provision of specialist home care support. McCorkle et al. (McCorkle et al. 1989) carried out a longitudinal study of 166 homebound patients with Stage II or higher lung carcinoma in America using self-rated questionnaires, including the Symptom Distress Scale and the McGill-Melzack pain questionnaire. Patients were recruited consecutively from 20 sites, including 19 hospitals. The patients were assessed every 6 weeks for 6 months (total of 5 assessments). The first assessment was a maximum of 10 weeks post diagnosis and following this, patients were randomised into 1 of 3 groups: “Oncology Home Care” (equivalent to Macmillan nurse input), “Standard Home Care” (equivalent to primary care team support) and “Outpatient Clinic Care Only”. The home care started within 2 weeks of the first assessment.

Their sample was not entirely representative, including 105 males and 61 females, a younger population and more patients receiving radiotherapy (although this was due to the nature of the recruitment sites). Sixty six percent of the patients died or withdrew with less than 5 interviews. The analysis was therefore based on the 78 patients who completed 4 interviews. The authors found that despite randomisation,
the Oncology Home Care group did better on most variables on the first visit which was done prior to the intervention commencing. Analysis was therefore adjusted for this and data from the first visit were used as covariates in predicting scores on visits 2, 3 and 4.

The authors found that all of the patients experienced increasing symptom distress over time but that this was delayed by 1 visit (6 weeks) in the 2 home care groups, compared with those receiving outpatient clinic care only (p=0.03). Although not statistically significant, patients receiving oncology home care support showed trends of relatively fewer hospital admissions for management of symptoms and disease complications. In addition, patients receiving home care remained independent for a longer period of time than those receiving outpatient clinic care only (p=0.02). Interestingly and despite this, the patients receiving outpatient clinic only reported improving health perceptions over time, whilst the two home nursing groups reported declining health perceptions.

This study was limited by the skewed patient population, significant attrition and the requirement to adjust the analysis in order to account for the Oncology Home Care group doing better on most variables from the outset. Despite this, the study does provide helpful longitudinal data from a randomised study of intervention and therefore, the findings provide a good initial indication.

In the previously reported study conducted by Noyes et al. (Noyes Jr et al. 1990), 438 patients with cancer in America completed the Illness Distress Scale devised by the authors. Physical symptoms were the greatest source of distress to patients. In keeping with the other studies, patients scoring most highly for physical distress were in-patients (p<0.001) and patients with metastatic disease (p<0.05). Overall, symptom distress, as rated by the Illness Distress Scale (incorporating physical, treatment, social isolation and loss of meaning subscales), was highest amongst patients who were younger (p<0.001) and had a lung cancer diagnosis (as opposed to prostatic carcinoma which was associated with the least distress) (p<0.05) and a trend was apparent towards a higher score for those who were not married (p<0.07).
The study does not report any regression analysis, which would have evaluated the independent effect of each of these factors. This study highlights the ambiguity in studies of symptom distress.

2.2.5
Summary of Physical Distress
Several studies provide conferring evidence that fatigue, pain and weakness are the most prevalent symptoms associated with cancer. Fatigue appears to be the most distressing symptom.

Pain prevalence is disputed, as is the tumour type most predictive of pain. However, consistent evidence suggests that bone metastases increase pain and that pain impacts adversely upon quality of life.

Predictors of symptom distress are not well-defined, with several studies contributing variably to the evidence. Most of the studies use self-rated tools that incorporate a mixture of physical, psychological, social and spiritual domains and do not clearly report on the independent effects of each. In my opinion, confounding variables result in a distinct lack of clarity of cause and effect, especially as the variables associated with distress are recognised to be inter-dependent.

2.2.6
Reciprocal Relationship between Physical and Psychological Distress
Symptom distress and psychological distress are inextricably linked. Physical symptoms increase psychological distress and vice versa (Zabora et al. 1997).

The multidimensionality of physical pain is particularly well recognised (Breitbart et al. 2005) (Stiefel, 1993). Chapman and Gavrin (Chapman and Gavrin, 1999) discuss the contribution of persistent pain to suffering amongst individuals, detailing the biological pathways involved. They describe the concept of “self” on multiple levels accounting for the complexity of identity and recognising that patients are dynamic psychosocial entities. Persistent pain stimulates a maladaptive stress reaction, which
involves an excessive neuroendocrine response with cortisol hypersecretion and circadian dysregulation. Approximately half of patients with severe depression are known to have raised cortisol levels and tend to lose their circadian rhythm with increased cortisol secretion in the afternoons and evenings. Studies have shown that patients with depression and chronic pain have common behavioural markers of a maladaptive sustained stress response which include fatigue, myalgia, disrupted or non-restorative sleep, reduced appetite, impaired physical functioning and concentration. This indicates the physiological nature of the reciprocal relationship between physical and psychological symptoms.

Understanding of this reciprocal relationship has recently further improved: Evidence now indicates that physical injury, pain pathways and the emotional processing of this information is interlinked within the nervous system (Fallon et al. 2006) (Bair et al. 2003). Anxiety, fear and lack of sleep feed into the limbic system. In response to this, the brain modifies pain input at the spinal level. This information then feeds back to the brain, establishing a loop (Fallon et al. 2006) (Fallon and McConnell, 2006). Additionally, depression specifically affects levels of serotonin and noradrenaline neurotransmitters. These neurotransmitters have been shown to dampen peripheral pain signals in the complex central pain modulation system: Therefore, the depression associated decrease in levels of one or both of these neurotransmitters, may result in an increase in peripheral pain messages, thus contributing to persistent pain (Bair et al. 2003).

A comprehensive review paper (Sutton et al. 2002) discusses the empirical evidence for each of the physical, psychological and social components of the biopsychosocial model of cancer pain at the end of life. The collection of evidence indicates that physical pain relates to tumour location, tumour stage, suffering of breakthrough pain, perceived pain related debility, number of co-morbidities, age and cognitive impairment. More recent studies are investigating a translational approach of the transgenic contribution to pain and analgesia through phenotypic differences in nociception, hypersensitivity and analgesia that have been found with genetic alterations in mice. Regarding the reported empirical evidence for the contribution of
psychological factors to pain; pain intensity relates to increased mood disturbance, maladaptive coping responses, belief that pain relates to disease progression, greater life stress, feelings of anger, frustration and exhaustion, helplessness and hopelessness. In addition, barriers to effective pain control have been described and include misconceptions regarding addiction, side effects and concern that focus on pain, may detract from treatment of the cancer itself. Studies indicate an improvement in pain has been associated with psychological intervention and/or support, as well as an educational intervention providing information regarding analgesic use and correcting common misconceptions. Finally, the empirical evidence presented for the social factors contributing to pain are as follows: Patients become reliant upon caregivers for care and advocacy however, studies show that caregivers over estimate symptoms, in particular pain intensity. Patients in non-congruent patient-caregiver dyads report significantly higher levels of anger and fatigue, as well as poorer psychological well-being and quality of life, when compared with those in congruent dyads. Studies have also shown that higher caregiver self-efficacy in managing the patient’s pain correlates with the patient’s physical well being. In summary, this review article collates the substantial empirical evidence for the physical, psychological and social contributions to cancer related pain. Despite the available evidence, the authors advocate an increase in longitudinal and interventional research into the biopsychosocial aspects of cancer pain, in order to improve its quality.

Another study (Syrjala and Chapko, 1995) has assessed the biopsychosocial model of cancer treatment-related pain in 358 bone marrow transplant patients (BMT) in America. Patients were evaluated prior to transplant and then daily for 25 days post transplant with measures of physical, psychological and social functioning. Many measures were used and complex analysis revealed that the strongest psychological predictor of pain was distress specific to BMT pre-transplant. In addition, females using avoidance as a coping mechanism experienced increased pain, and those using greater support seeking strategies had lower pain. The authors conclude that the biopsychosocial relationships are complex and whilst their clearest finding was that in this sample, observable tissue damage and other biomedical factors were “by far
and away the strongest predictors of pain”, psychological factors have a modest predictive power. It is important to note that this study relates to a specific treatment and its associated pain, therefore the findings may not reflect the models of chronic cancer-related pain.

In Canada, Sela and colleagues (Sela et al. 2002) studied 111 patients with cancer and related pain, who were attending an out-patient pain and symptom control clinic. The representative sample of patients completed 7 visual analogue scales relating to pain intensity and the accompanying aspects of affect. The mean pain intensity was scored at 87 out of 100, though these patients were known to be attending clinic for pain control. The associations between pain and affect were analysed. Significant correlations were identified between pain and every emotional aspect measured (frustration, anger, exhaustion, helplessness and hopelessness) except fear, for which no significant association was found. The correlations varied slightly according to gender, with males (p<0.01) more significantly frustrated than females (p<0.05), and vice versa for exhaustion. Overall, frustration and exhaustion were the most significant affective aspects of pain. Nonetheless, despite these significant correlations, the mean level of physical-sensory pain experienced by patients was higher than the mean level of any of the affective aspects associated with the pain. Inference cannot be made regarding causal relationships due to the cross-sectional nature of this study. In addition, the analysis must be considered as simply descriptive, due to the use of self-report measures.

Ahles et al. (Ahles et al. 1983) conceptualise pain into 5 components, physiological (organic aetiology of pain), sensory (intensity, quality of pain), affective (associated depression and anxiety), cognitive (influence of pain on thought processes) and behavioural (associated behaviour such as analgesic use). In their study of cancer patients in America, the authors recruited 40 consecutive patients with cancer-related pain of organic aetiology and 37 pain-free cancer patients matched as closely as possible for diagnosis, disease stage, age, sex and in-patient/out-patient status. Eighty two point five percent of the patients had metastatic disease and 75% of the pain group were experiencing constant pain. Patients were assessed with measures
enabling evaluation of the 5 components of pain described above. These included interviews and pain diaries, involving numerical and visual pain ratings, together with a log of medications and activities. The diaries were completed 4 times daily. In addition, patients completed the McGill Pain Questionnaire, the Beck Depression Inventory (BDI), Symptom Checklist-90 (SCL-90) and visual analogue scales of depression and anxiety (VAS-Depression and VAS-Anxiety), amongst others. Out-patients were asked to complete more measures than in-patients who were less well and therefore less able.

Analysis revealed that patients with pain scored more highly for depression on the BDI (p<0.05) and the VAS-Depression (p<0.004) and also higher for anxiety on the VAS-Anxiety (p<0.05). The interview data were also analysed and showed that an increased number of the patients with pain admitted to depression (p<0.007) and irritability (p<0.001). According to the interview data, there was no difference in the anxiety levels. When in-patient and out-patient data were compared, in-patients with pain scored highest of all the groups on the VAS-Anxiety (p<0.04). Patients with pain spent significantly less time walking and standing than those who were pain-free (p<0.001). In the interview, patients were asked whether they considered their pain to be related to disease progression and 61% did. The patients who believed pain was secondary to disease progression were compared with those who didn’t using one-tailed t tests. Analysis revealed that those who did believe their pain resulted from disease progression scored significantly more highly on the Depression-SCL-90, BDI and Anxiety-SCL-90 (p<0.05). Seventy three point seven percent of the patients did not remember receiving information from their oncologist regarding the cause or likely course of their pain. The authors conclude therefore, that pain is in fact multi-dimensional and relationships between the physical and psychological are reciprocal. Small sample size and incomplete matching limit the value of this study, although the methodology and analysis were robust and the development of the concepts is clear.

Spiegel and Bloom (Spiegel and Bloom, 1983) suggest that pain is a “psychosomatic” composite. They conducted a cross-sectional study of 86 patients
with metastatic breast carcinoma, recruited from outpatient oncology clinics. Patients completed a battery of self-rated questionnaires relating to psychosocial variables (including the Profile of Mood States (POMS) and Heimler’s Scale of Social Functioning), as well as pain assessment in which pain was rated according to related distress, belief, frequency and duration. Multiple regression analysis showed that 50% of the variance in pain experience was accounted for by the level of mood disturbance as measured by the POMS and including depression, anxiety, fatigue, confusion, patient’s belief that pain signified disease progression and the use of analgesia. Although the authors conclude that psychological factors are significant in accounting for differences in pain experiences such that pain is the somatic manifestation of anxiety. The cross-sectional methodology precludes any inference about causal relationships.

Self-efficacy, which appears to include the perception of control and active coping, may be one mediator within this relationship. Hirai et al. (Hirai et al. 2002) found that patients with advanced cancer, in good physical condition had a higher self-efficacy, and this was associated with reduced emotional distress. This Japanese study assessed 85 patients with advanced cancer receiving palliative care. Patients completed the Self-efficacy scale for Advanced Cancer, HADS and Karnofsky Performance Status was noted. Complex structural equation modelling was used for statistical analysis. The model showed that self-efficacy accounted for 71% of the variance in emotional distress and that physical condition accounted for 8% of the variance in self-efficacy, indicating close relationships between physical condition, self-efficacy and emotional distress. The study shows directionality towards this relationship, although the results were not statistically significant. The study was limited by the relatively small sample size and again, the cross-sectional methodology precludes inference of causal relationships.

Turk et al. (Turk et al. 1998) compared patients with cancer-related pain (n=184) to those with chronic non-cancer related pain (n=105) in a study conducted in an American pain clinic. The 2 groups were significantly different in terms of gender, with more females in the chronic pain group, and the duration of pain (longer
amongst the chronic pain group). Patients were assessed using a variety of self-rated measures of pain, depression and anxiety including the McGill Pain Questionnaire, the Pain Disability Index, Beck Depression Inventory (BDI) and the Pain Anxiety Symptoms Scale (PASS). The BDI and the PASS were added in, 1 year into the 4 year study and this was accounted for in the analysis. Patients with cancer-related pain were found to have significantly higher levels of perceived pain-related disability (p<0.005), increased fear of pain (p<0.03) and greater somatic symptoms of depression (p<0.007) than those with chronic non-cancer pain. The difficulty in distinguishing the physical or psychological source of the somatic symptoms related to depression is well recognised. However, as both groups had similar levels of pain severity, the psychological contribution to cancer pain is apparent due to increased associated fear and perceived disability.

Wilson et al. (Wilson et al. 2007) studied 381 patients receiving palliative care for cancer across 8 Canadian sites (detailed below). They found that 55.9% of patients diagnosed with an anxiety or depressive disorder characterised their overall global experience as one of “moderate-to-extreme suffering”, compared to 16% of those without a disorder. They also found that patients diagnosed with an anxiety or depressive disorder had lower performance status but not shorter survival duration than those without a disorder, suggesting that the “psychological state contributed to the disability beyond that caused by the medical condition”.

In the previously discussed longitudinal study of patients with terminal cancer in Vermont, McKeegney and colleagues (McKegney et al. 1981) used self-rated questionnaires to assess patients’ levels of pain and emotional factors over time. The analysis was done in blocks of days prior to death. Between 180-120 and 120-60 days prior to death, patients with high emotional disturbance (as measured by the modified Rotter Locus of Control), had significantly higher mean pain scores than those with low emotional disturbance (p<0.05). This correlation persisted into the last 60 days of life but was no longer statistically significant at this time. This relationship was the same for both the “intensive group” receiving regular home nursing care and the “non-intensive” group who did not receive home care. In the last
90 days, two thirds of the nurse interventions involved pain management. The authors conclude that although pain and emotional disturbance do not correlate initially, emotional disturbance predicts pain problems further into the disease trajectory.

In a previously described study, Strang (Strang, 1992) assessed 93 consecutive patients with cancer related pain using visual analogue scales, standardised interviews and self-questionnaires. Fifty one percent experienced pronounced anxiety as a result of their pain and 71% had depressive symptoms that correlated highly with pain intensity.

In a small study (Smith et al. 1998), 32 patients with cancer and movement related pain were referred for physical therapy at one centre as either in or out patients. Patients rated their pain intensity, pain affect (unpleasantness) and mood on Likert Scales. This was done both before and after the physical therapy. The authors found that pain intensity increased following physical therapy (p<0.01) but that pain affect improved slightly whilst mood increased significantly (p<0.001). Patients were grouped according to their pain belief, either that pain was directly related to the cancer, or that pain was due to other causes, for example treatment. Prior to the physical therapy there was no difference in pain intensity, affect or mood between these groups. Following the pain inducing therapy, those who believed the cancer was the cause of their pain, reported significantly increased pain intensity (p<0.05) and affect (p<0.05) but no difference in mood, when compared with those who believed their pain was due to other causes. These findings imply that pain intensity and affect may be dissociated and that pain belief effects pain experience.

Similarly, Daut and Cleeland (Daut and Cleeland, 1982) showed that amongst 667 cancer patients, pain was more likely to interfere with activity and enjoyment of life, if considered to be secondary to cancer rather than another cause.

Portenoy et al. (Portenoy et al. 1999) studied breakthrough pain amongst 164 in-patients with cancer in America. The authors carried out a cross-sectional survey in
which patients completed various self-rated measures of pain, breakthrough pain, depression, anxiety and functionality. Those with breakthrough pain had significantly greater functional impairment on the Pain Interference Scale than those with controlled background pain (p<0.001). In addition, patients suffering breakthrough pain had significantly greater affective disturbance than those with stable pain (p<0.05) on the visual analogue scale, (p<0.001) on the Beck Depression Inventory and (p<0.001) on the Beck Anxiety Inventory. Multivariate analysis of this data confirmed that breakthrough pain independently contributed to impaired functioning and psychological distress (anxiety and depression). Unfortunately, the direction of causation of these relationships cannot be determined from this cross-sectional data. As the assessment algorithm was not validated, slight caution should be exercised in interpretation of these findings. However, breakthrough pain has been a notoriously difficult phenomenon to evaluate and this study provides helpful preliminary data.

2.2.7
Summary of the Reciprocal Relationship between Physical and Psychological Distress
In their review article, Bair et al. (Bair et al. 2003) conclude that, “the prevalence of pain in a depressed sample and the prevalence of depression in a pain sample are higher than the prevalence rates when the conditions are individually examined”. I consider this to be a very helpful summary statement. Essentially, convincing evidence links pain pathways and emotional response through neuroendocrine and neurotransmitter mechanisms.

Various small, cross-sectional studies, mainly relating to pain, use self-report measures to indicate that physical and psychological aspects of disease are reciprocal. In my opinion, the studies mentioned latterly, taken in conjunction with the translational research mentioned formerly, together provide compelling evidence for the reciprocal relationship between physical and psychological distress.
2.2.8 Pain, Depression and Fatigue Symptom Cluster

Recent work has begun to focus on the concept of symptom clusters. Clusters refer to a group of specific symptoms that appear to frequently co-exist. The concept of clusters is interesting and important, as it embraces the multi-dimensionality of disease, acknowledging that certain aspects cannot be successfully addressed in isolation.

In the previously reported paper by Chapman and Gavrin (Chapman and Gavrin, 1999), they conclude that chronic pain does not exist in isolation but is related to a cluster of other problems, including fatigue and mood disorder. Studies show that one of the most common symptom clusters amongst patients with cancer is that of pain, depression and fatigue (Patrick et al. 2003) (Paice, 2004) (Reyes-Gibby et al. 2006).

In their study, Reyes-Gibby et al. (Reyes-Gibby et al. 2006) used data from the 2000 Health and Retirement Study, a survey of a nationally representative sample (in America) of the population of 50 years or over. The authors compared those with a history of cancer to those without. They found that after controlling for confounding factors, those with a history of cancer were at higher risk of pain, depression and fatigue. Additionally, symptom clusters were more prevalent amongst those with a history of cancer; the pain, depression and fatigue cluster being the most prevalent.

Wilson et al. (Wilson et al. 2007) comprehensively studied 381 patients with cancer receiving palliative care (detailed below) and found that patients diagnosed with anxiety or depressive disorder (24.4%) were also more likely to experience more severe symptoms, particularly pain, weakness and fatigue.

In July 2002, the American National Institutes of Health State-of-the-Science Conference undertook a detailed assessment of symptom management in pain, depression and fatigue (Patrick et al. 2003). The authors acknowledge that even though it is known that these symptoms are related, controversy exists as to whether
to consider them individually or in combination. They suggest assessing overall distress initially and then exploring potential contributors, such as these symptoms. Fleishman (Fleishman, 2004) confers on this approach, suggesting standardised screening using the Distress Thermometer.

Patrick et al.'s conclusions are later supported by Miaskowski et al. (Miaskowski et al. 2004) who advocate research into symptom clusters, the most valid and reliable tools for their assessment and specific interventions and patient outcomes. In terms of assessment of this symptom cluster, Paice (Paice, 2004) recommends and discusses valid and reliable tools that are multidimensional, incorporating all of the symptoms.

### 2.3 Psychological Distress

Psychological distress per se and normal emotional response to the stresses associated with cancer may be difficult to distinguish. The Psychosocial Collaborative Oncology Group in America assessed psychiatric disorders in 215 ambulatory cancer patients in 3 centres using criteria from the Diagnostic and Statistical Manual-III. They discovered that 53% were in fact adjusting normally to stress. Of the remaining 47%, 68% had reactive anxiety and depression (adjustment disorders) and 13% had major depression. Almost 90% of the psychiatric disorders noted were manifestations of, or reactions to, disease or treatment (Derogatis et al. 1983). In their review paper comments regarding this study, Massie and Holland (Massie and Holland, 1992) suggest that the findings imply that the majority of cancer patient population comprises psychologically healthy individuals “who have emotional reactions” to the stresses associated with cancer and its treatment.

Psychological distress per se has a prevalence rate of approximately 35% amongst cancer patients. Many studies have provided widely varying estimates of the prevalence of psychological distress amongst cancer patients. The variability in rates reported has been attributed to differences in definition used and populations studied.
There are four major studies of psychological distress amongst cancer patients, all of which are cross-sectional.

Derogatis et al. (Derogatis et al. 1983) used the SCL-90 and psychiatric interview to evaluate 215 ambulatory patients with cancer. They discovered 47% met DSM-III diagnostic criteria and 68% of these were adjustment disorders.

Farber and colleagues (Farber et al. 1984) in Canada used the SCL-90 to assess 141 ambulatory patients with cancer. They found that 34% of these patients had clinically significant levels of psychological distress.

Stefanek and colleagues (Stefanek et al. 1987) in America asked 126 ambulatory patients with cancer to complete the Brief Symptom Inventory at their first visit to clinic. Twenty-eight percent of the patients reported moderate to high levels of depression and anxiety.

Finally, Zabora and colleagues (Zabora et al. 2001) in America conducted a large study of psychological distress amongst 4496 ambulatory cancer patients using the Brief Symptom Inventory (BSI). Fifty-eight percent of these patients were newly diagnosed (<90 days from diagnosis). The analysis was complex, incorporating a combination of the subscales using T scores. The overall prevalence of psychological distress in this large sample was 35.1%.

Zabora and colleagues (Zabora et al. 2001) also examined the prevalence of psychological distress according to demographic factors. No significant differences were found in psychological distress levels according to gender. In terms of ethnicity, small differences were found with African Americans displaying greater psychological distress than white Americans. Patients who were married reported least psychological distress, although the differences between the marital status categories were not significant. In addition, psychological distress was greatest in the young and the very old, reaching a plateau in between these age groups. The lack of statistical significance of these findings, despite the very large sample size, reflects
the complexity of predisposition to psychological distress. The authors conclude that the most compelling predictor of psychological distress, is in fact the BSI score in the first 2 weeks after diagnosis.

Akechi et al. (Akechi et al. 1998) conducted a Japanese study of demographic factors associated with psychological distress amongst ambulatory lung cancer patients. Eighty-seven patients completed a structured interview relating to socio-demographic factors, together with the Profile of Mood States and the Mental Adjustment to Cancer scale. Multiple regression analysis indicated that psychological distress was predicted by female gender, living alone, having no children as confidants, using nurses as confidants and using a helplessness/hopelessness coping strategy. These findings do not confer with those of Zabora et al., in the previously discussed study. In a much larger study, Zabora et al. did not find socio-demographic factors to be predictive of psychological distress. Akechi’s findings in Japan may relate to cultural differences, or may be less reliable due to the small, homogenous sample.

In a separate study, Akechi et al. (Akechi et al. 2006) conducted a longitudinal study of psychological distress amongst patients with advanced non small cell lung carcinoma in Japan. Consecutive patients, newly diagnosed with non-resectable, non small cell lung carcinoma were assessed using the Profile of Mood states (POMS) and an interview based on the Mental Adjustment to Cancer scale and the DSM IV. Assessments were done after diagnosis and prior to treatment, again at 2 months and finally at 6 months from diagnosis. One hundred and twenty nine patients completed baseline assessment and 85 completed the second and third assessments. Non-participants had a lower performance status than participants, and non-completers had a lower performance status and greater dyspnoea than completers.

Analysis conducted on the complete longitudinal data for the 85 patients indicated that tension-anxiety fell significantly and consistently over time, from diagnosis to 6 months (p<0.001). Depression-Dejection fell significantly from diagnosis to 2 months (p<0.001), although there was no significant difference from diagnosis to 6
months. Multiple regression analysis revealed that mood disturbance at diagnosis significantly predicts psychological distress at 6 months. However, there was no significant change in total mood over time. The authors suggest that these findings indicate that overall psychological distress does not reduce naturally over time.

This study was limited by the high rates of attrition; 40% of patients did not have longitudinal data available for analysis. Patients were only followed for 6 months therefore inferences regarding associations can only be made in reference to this time period of the disease, and not beyond. Finally, the findings rely upon the Profile of Mood states, a self-report measure which assesses mood only. However, these findings are more in keeping with those of Zabora et al., suggesting that psychological distress at the time of diagnosis, either according to BSI (Zabora) or POMS (Akechi), predicts psychological distress over time.

Several authors have evaluated psychological distress in relation to tumour site. The study by Zabora and colleagues (Zabora et al. 2001) is the major paper with at least 100 patients in each diagnostic category. The prevalence of psychological distress was found to be highest amongst those with lung cancer (43.4%) and lowest amongst patients with gynaecological cancer (29.5%). Despite lung cancer patients displaying the highest levels of distress, there was in fact no significant difference, when compared with the distress levels amongst patients with tumours of the brain, pancreas, liver and head and neck. As previously reported, symptom distress appears to be greatest amongst patients with lung cancer. The authors postulate that this together with self-blame for disease acquisition, due to their own lifestyle choice, contributes to the high levels of psychological distress.

In Germany, Herschbach et al. (Herschbach et al. 2004) used the “Questionnaire on Stress In Cancer Patients Revised Version” to assess psychological distress amongst 1721 heterogeneous in and out patients with cancer. This tool, in which patients respond to 23 cancer-specific stress situations according to relevance and distress, was developed and psychometrically evaluated in Germany. The authors found that 40.9% of patients with breast cancer were highly distressed, this being the most
distressed sub group along with patients with soft tissue tumours (23.4% upper gastrointestinal tumours). Similarly to Zabora and colleagues, the authors here did not identify any significant global demographic risk factors for psychological distress either. This was a well-conducted large study, although it is again limited by the cross-sectional methodology and to some degree, by the choice of research tool which is not well recognised.

In a retrospective cross sectional survey, Balderson and Towell (Balderson and Towell, 2003) evaluated psychological distress amongst 94 males with varying stages of prostate carcinoma. Patients were assessed using the self-rated FACIT-Prostate Instrument, Hospital Anxiety and Depression Scale (HADS) and questions relating to satisfaction with medical care. Thirty eight percent of the men scored above the HADS cut off for psychological distress. Multivariate regression analysis showed that social, physical and functional well-being were significantly inversely predictive of psychological distress. In view of the weak methodology and small numbers, these findings should be interpreted with caution.

Evidence also suggests that psychological distress varies according to disease status, as discussed earlier: Distress is increased amongst patients at the time of diagnosis, recurrence, and during the terminal phase (Zabora et al. 1997) (Norton et al. 2004) (Carlson and Bultz, 2003b) (Butler et al. 2003). The reported trends in psychological distress over time are inconsistent: Distress levels may fall following diagnosis but rise significantly prior to death (Butler et al. 2003). Distress levels may remain constant throughout disease, with an increase over the terminal phase (Carlson and Bultz, 2003b) or high initial distress levels may remain high over the disease course (Zabora et al. 1997).

2.3.1 Depression
Depression and distress are distinct. Depression has distinct diagnostic criteria (American Psychiatric Association, 1980), despite causing similar symptoms.
Depression is an important independent component of psychological distress it is known to contribute independently to quality of life in cancer patients. Smith and colleagues (Smith et al. 2003) in the UK studied a consecutive sample of 68 patients from 2 hospices (in-patients and day patients), as well as in-patients referred to the Hospital Palliative Care Team. Their sample consisted mainly of in-patients and appeared to be representative. Patients completed the Hospital Anxiety and Depression Scale (HADS), the EORTC QLQ C30 quality of life scale, a Pain Visual Analogue Scale and the Karnofsky Performance Status. Using multiple linear regression analysis, they found that anxiety and depression remained significantly associated with the impairment of physical, social and psychological dimensions of quality of life even when pain and illness severity (other contributing factors) were controlled for. As the most unwell patients were unable to participate, these findings may be underestimated. No inference can be made regarding causal relationships, due to the cross-sectional nature of the study.

The study of depression amongst cancer patients is challenging. Depressive symptoms range from sadness to major affective disorders and may be associated with the normal process of adjustment during life threatening illness (Massie and Holland, 1992) (Lloyd-Williams et al. 2001).

In addition, somatic symptoms such as fatigue and insomnia, used to diagnose depression amongst physically healthy individuals, are prevalent amongst patients with a cancer diagnosis irrespective of depression. Therefore, applying the usual diagnostic criteria for major depression to patients with severe physical illness is likely to result in a high rate of false positives, as the physical symptoms experienced by patients are often incidentally the same as those resulting from depression (Kelly et al. 2006).

Therefore, the criteria used to assess depression are much debated. Various authors (Endicott, 1984) (Kathol et al. 1990) have advocated replacing somatic symptoms in the criteria for non-somatic alternatives. Others (Massie and Holland, 1992) (Casey, 1994) suggest that diagnosis of depression amongst cancer patients should perhaps
rely on the presence of psychological symptoms such as helplessness, hopelessness, loss of self-esteem and guilt.

The prevalence of depression amongst cancer patients has been well documented and varies widely, according to the criteria and populations studied. Chochinov et al. (Chochinov et al. 1994) studied 130 terminally ill patients with cancer receiving palliative care in Canada. The authors used two different criteria to diagnose depression in this population: The Research Diagnostic Criteria (RDC) and Endicott’s Revised Criteria. They used both low and high-severity thresholds for classifying RDC Criterion A symptoms. Using the low thresholds greatly increased the prevalence of both, major and minor depressive episodes, using both RDC and Endicott’s Revised Criteria. The overall combined prevalence of depression amongst this population using the RDC was 26.1% (low threshold) and 13% (high threshold), compared with 23.1% (low threshold) and 13% (high threshold), using Endicott’s Revised Criteria. The authors suggest that including the somatic symptoms only increases depression rates when “used in conjunction with a low threshold approach”.

In the UK, Lloyd-Williams and colleague (Lloyd-Williams and Friedman, 2001) recruited 100 patients with a prognosis of 6 months or less who were receiving palliative care for advanced metastatic cancer. Patients were interviewed using the Present State Examination (PSE), a semi-structured psychiatric interview, aimed at establishing the presence and severity of specific symptoms. The PSE is designed so that the information acquired may be used to make a psychiatric diagnosis according to International Classification Criteria (ICD10). Using this method, the prevalence of depression amongst this representative sample was 22%, with the majority of cases identified as depressive episodes of moderate severity.

In the previously described study by Smith et al. (Smith et al. 2003), rates of depression amongst 68 palliative care patients with advanced cancer were 22% according to the HADS.
In his extensive review paper, Breitbart (Breitbart, 1995) summarises the evidence on prevalence of depression amongst cancer patients, stating that figures range from 20-25%, increasing with greater levels of disability, pain and advanced disease. However, evidence does suggest that amongst those with advanced disease, depression rates appear to remain stable over time. Lloyd-Williams and Riddleston (Lloyd-Williams and Riddleston, 2002) screened 50 patients with advanced cancer, receiving palliative day care for depression on a weekly basis for 12 weeks using a tool validated for use in the palliative care population. Those who scored below the cut off threshold score at initial assessment showed a very small mean change of only +/-0.56 over the 12 weeks.

Other studies have also evaluated the predictors of depression amongst patients with cancer. In the previously discussed study of prevalence of depression amongst terminally ill cancer patients by Lloyd-Williams and Friedman (Lloyd-Williams and Friedman, 2001), 42% of patients with breast cancer received a diagnosis of depression according to ICD10 criteria. Analysis revealed that breast cancer patients were statistically more likely to be identified as having depression than patients with any other cancer diagnosis (p=0.001). Although not statistically significant, patients diagnosed with depression were younger than average (56.6 years compared with 57.2 years) and the perceived need for information amongst patients also weakly correlated with depression.

Wilson et al. (Wilson et al. 2007) studied 381 patients receiving hospice, community or hospital palliative care input for cancer, across 8 sites in Canada. They collected socio-demographic data and interviewed patients regarding the frequency, intensity and distress caused physical, existential and social concerns, using their Structured Interview of Symptoms and Concerns. Anxiety and Depression were assessed using the modified PRIME-MD taken from the DSM-IV. Twenty four point four percent of the patients fulfilled criteria for at least one anxiety or depressive disorder. The single largest contributor was major depression (13.1%). Anxiety or depressive disorders were more common amongst patients who were female, younger, received less social support and were not involved in organised religion. This was a large and
detailed study, with credible results regarding anxiety and depressive disorders. The main limitations were that their Structured Interview of Symptoms and Concerns was not validated and that they did not attempt to diagnose adjustment disorders.

2.3.2
Coping Strategy
Coping strategy also impacts directly on psychological distress. Manne and Glassman (Manne and Glassman, 2000) conducted a cross sectional study of 191 married cancer patients in America. Patients were consecutively recruited from two Cancer Centre Outpatient sites. Patients completed questionnaires upon recruitment and again at 3 months, when they were posted to them. Their paper reports only on the results of the second set of questionnaires. Although this was a heterogeneous sample of cancer patients, analysis revealed that those completing second surveys were more likely to be better educated, male and less functionally impaired. Patients completed scales that were either established or derived, in order to assess variables including avoidance coping and coping efficacy, as well as psychological distress (anxiety and depression subscales of the Mental Health Inventory).

They found that older patients had increased coping efficacy (p<0.05), decreased avoidance coping (p<0.05), anxiety (p<0.05) and depression (P<0.01), whilst females used increased avoidance coping (p<0.01). Following a very complex structural equation analysis, a model was produced showing that increased coping efficacy was significantly associated with reduced psychological distress (p<0.01) and avoidance coping was significantly associated with increased psychological distress (p<0.01). These results are interesting but should be used with caution due to the numerous limitations of this study. These relate to both, the population (55% participation rate with participants more likely to be white, well-educated and middle class), as well as the analysis, as this was conducted in a way, which potentially enhanced the fit of the model in which the variables only explained a small amount of the variance in psychological distress.
In America, another study (Dukes Holland and Holahan, 2003) evaluated coping strategies amongst 56 patients with breast cancer. Patients were recruited from private oncology or surgical clinics across the city if they had Stage I or II disease and were middle aged. All patients had had surgery, were in a committed relationship and had been diagnosed 1-26 months earlier. Patients completed The Social Provisions Scale, the revised Ways of Coping Scale and the Scale of Psychological Well-Being Short Form. Descriptive statistical analysis involved the computation of an exploratory path model that was tested using multiple regression techniques. Approach coping was significantly related to improved psychological well-being (p<0.001), whilst avoidance coping was significantly associated with reduced psychological well-being (p<0.05). Caution must be used in the interpretation of these findings. As well as being a cross-sectional study, the results cannot be generalised due to the small homogeneous sample of female patients attending private clinics.

Classen et al. (Classen et al. 1996) have also assessed coping styles amongst breast cancer patients: They evaluated the baseline data taken pre-randomisation from 101 females who had been recruited into an intervention trial for group psychotherapy. The participants were either recruited by oncologists in a cancer centre or were self-referred, having heard about the trial. They completed Profile of Mood States (POMS), Courtauld Emotional Control Scale and the Mental Adjustment to Cancer Scale (MAC). Multiple regression analysis revealed that use of emotional control was significantly associated with increased mood disturbance (p<0.001) and that having “fighting spirit” was significantly associated with reduced mood disturbance (p<0.01). Thus suggesting that emotional control is negatively associated with psychological adjustment although no inference can be made regarding direction of causality due to the cross-sectional nature of the study.

Such coping strategies appear to have significant implications. Faller et al. (Faller et al. 1999) in Germany evaluated 103 patients admitted to cancer centre with newly diagnosed lung cancer (on the whole within 3 days of diagnosis). Patients completed the Freiburg Questionnaire of Coping with Illness, the Depression D-S Scale, an
Emotional Distress Scale derived by the authors and the Karnofsky Performance Status. Using Kaplan-Meier analyses of survival prediction, depressive coping was significantly associated with reduced survival (p<0.007). Cox regression was conducted using multiple covariates, adjusting for biomedical risk factors this relationship remained significant. The study is limited firstly by the small, homogeneous sample in which advanced tumours and small cell cancers are over-represented, and also by the cross-sectional methodology, which precludes inference of causal relationships. The authors hypothesise on the potential mediators of the relationship between depressive coping and survival, suggesting that psychoneuroimmunological mechanisms or compliance issues may be involved. They conclude that they have provided evidence “pointing to a relationship” between coping and survival amongst patients with lung cancer.

Conversely, optimism as well as fighting spirit (Classen et al. 1996) may facilitate adjustment, mediating improved psychological outcomes: In Australia Clavarino and colleagues (Clavarino et al. 2003) conducted a longitudinal mixed methods study of 100 heterogeneous patients with locally recurrent or metastatic cancer, consecutively recruited from several out-patient cancer centres. Patients had a prognosis of >3 months but less than 2 years and were assessed within 2 weeks of their first visit and then 3 monthly. Assessment involved questions regarding “Will to Live”, “Beliefs about Curability” and a Subjective Well-Being Measure. In addition, the first consultation with the oncologist was recorded in order to establish whether incurability had been discussed. Patients took the tapes home and were asked to return them. Sixty-nine tapes were retuned and incurability was mentioned in all of them, therefore, the authors assumed that the remainder (31) were also likely to have heard their cancer was incurable, as the same oncologists were involved.

The paper reports on 46 patients who had 3 assessments and includes the first and last of these for each patient. Thirty-six (78.3%) patients acknowledged that the doctor had said the cancer was incurable but 22 of these felt unsure or disagreed with the statement, indicating a high level of optimism. Multivariate analysis revealed that “Will to Live” and “Belief in Curability” accounted for 13% of the variance in
Subjective Well-Being. Patients reporting higher “Will to Live” also reported a stronger “Belief in Curability” and together, this was reflected in greater Subjective Well-Being, although not all relationships within this model were significant. The authors conclude that a strong will to live enhances optimistic beliefs regarding curability, thus enhancing subjective well-being. The study’s strength is in the longitudinal mixed methodology, although the small sample size and self-reported, non-validated questionnaires limit the ability to generalise the findings.

Coping strategies are diverse and include information seeking as a means of modifying uncertainty. Lazarus and Folkman (Lazarus and Folkman, 1984) consider information seeking as the most frequent method used to cope with a stressful event for which information is limited. In a review paper, van der Molen (van der Molen, 1999) suggests that, “information is conceptualised as a form of cognitive control” as it facilitates participation in decision-making.

The exception here appears to be those who use an avoidant coping strategy. Steptoe et al. (Steptoe et al. 1991) in the UK recruited (in two 12-week rounds) consecutive in-patients with metastatic cancer who had been admitted to an oncology ward for investigations. They recruited 77 patients of whom 63 were female. Patients were assessed for satisfaction with information (seven 5-point scales), for general medical knowledge (8 questions) and for cancer knowledge (5 questions). Psychological coping was assessed using the modified Miller Behavioural Style Scale and patients completed the State-Trait Anxiety Inventory (STAI) as well as the Hospital Anxiety and Depression Scale (those recruited in the second round). The analysis showed that although not quite statistically significant; those with less cancer knowledge were in fact more satisfied with the information provided (p=0.075). In addition, those who were completely satisfied with the information were significantly less anxious on both STAI and HADS (p<0.05) and used avoidant coping strategies (p<0.01). The results imply that information requirements may differ according to general level of medical knowledge and coping style. Although not clearly discussed in the paper, this study is limited by the small sample size of mainly female patients. The cross-sectional survey precludes inference of causality in the relationships reported.
Despite this, it is important to note that in the UK a large, multi-centre centre survey of information needs (Jenkins et al. 2001) amongst 2331 oncology out patients (36% of whom were receiving palliative treatment) revealed that 87% wanted as much information as possible and 98% felt they needed to know if their diagnosis was cancer. As expected, the older population (>70 years old) were significantly more likely to “leave the details of disclosure up to the doctor” (p<0.0001), even though 81% wanted as much information as possible.

2.3.3
Summary Of Psychological Distress
Prevalence of psychological distress and depression vary according to population studied and criteria used. Well-designed studies confer that prevalence of psychological distress is approximately 35% amongst cancer patients, although firm figures not available for the palliative care population. Similarly rigorous prevalence studies of depression indicate that 20-25% of the palliative care population meet criteria for depression.

Coping strategy has been examined largely through small studies of breast cancer patients. The available evidence, although in my opinion limited in its methodological rigour, does confer to indicate that effective coping strategies reduce psychological distress.

2.4
Social Distress

2.4.1
Communication
Communication is a distinct area of extensive research that is beyond the scope of this literature review. Aspects specific and relevant to this study are briefly discussed.
A recent review of the literature on communication in palliative care found a consensus that trust is the major factor in relationship forming for quality communication. However, it is important to note that the authors also highlight the issue that the majority of available information relates to patients' perception only. As observer-based studies are scarce, most of the actual communication itself, in fact remains unseen (de Haes and Teunissen, 2005). This is of particular significance in view of the fact that average recall of consultations regarding cancer has been found to be only approximately 25%, in an Australian study of 142 patients' information recall, at 4-20 days post oncology consultation (Dunn et al. 1993).

From the extensive literature, it is well recognised that poor communication has a significant negative impact on quality of life (Thorne et al. 2005). Fallowfield and colleagues (Fallowfield et al. 2002) produced a review of the issues pertinent to communication with the palliative care population. The authors have gathered evidence suggesting that ambiguous information increases fear, anxiety and confusion and thus urge healthcare professionals to provide honest information regarding diagnosis and prognosis, in order to assist patients in appropriate planning and decision-making. As far back as 1960, when collusion was the more accepted practice, Gerle et al. (Gerle et al. 1960) found that of 101 patients with inoperable cancers, those patients who had not been given complete, honest information regarding their disease, were the most anxious and depressed and had the greatest medication requirement of the sample.

In a small Swedish study (Berglund and Sjödén, 1987), 40 patients (half with small cell lung cancer and half with carcinoid tumours) receiving chemotherapy (90% with anti-emetics) completed the Swedish Version of The Cancer Inventory of Problem Situations (CIPS). Analysis revealed patients who were experiencing communication problems with medical staff were significantly more anxious regarding medical situations (p<0.01) and this relationship was even stronger when examined for those scoring above the median communication problem score (p<0.001). In addition, experience of communication difficulties with healthcare professionals was strongly and significantly associated with anticipatory nausea prior to chemotherapy (p<0.05).
These interesting findings must be carefully considered albeit within the limitations of the small, cross-sectional, non-heterogeneous sample.

Despite the well-recognised importance of effective communication, a recent review of the present literature regarding the communication needs and goals suggests that cancer patients continue to have unmet communication needs (Hack et al. 2005). In a large, multi-national palliative care study (Higginson and Costantini, 2002) involving approximately equal numbers of patients across England, Ireland and Italy, 1326 patients in receiving community or hospital palliative care were recruited. In England 2 community and 3 hospital teams volunteered to participate, 6 hospice community teams did so in Ireland and in Italy all 58 teams across the country were involved. Full socio-demographic and clinical information was documented at the time of referral of participants. Within 1-5 days of the patients’ death, the multidisciplinary palliative care team met and completed the Support Team Assessment Schedule (STAS) for the last week of the patient’s life. The STAS tool is validated in this population.

In all 3 countries, most of the communication difficulties existed between the patient and family at the end of life (<30-40%) with least problems in communication between professionals and the patient and family (10-20%). Most communication difficulties were found in Italy and least in Ireland.

Both univariate and multivariate analysis revealed (consistently in all 3 countries), significantly greater problems in communication between patients and family amongst participants with tumours of the respiratory and digestive systems and significantly less amongst participants who had received palliative care for longer and those who died at home. In terms of communication problems between professionals and patient and family, those with breast and respiratory cancer were at significantly greater risk. When the relationship between communication problems and other quality of life domains was analysed, greater communication problems were significantly associated with increased spiritual problems, increased need for care planning and reduced patient and family insight.
Although this large, collaborative study produced convincing and statistically significant results, there are several important limitations. Firstly, the increased communication issues noted in Italy may relate to the fact that almost all Italian palliative care teams participated, compared with England and Ireland in which participation was voluntary and therefore, this self-selection may reflect best practice, thus introducing bias. A greater issue of bias relates to the STAS scoring in which, the week following the patient’s death, trained palliative care team members attempted to identify problems, as perceived by the patient during the week of their death. The authors suggest that the effect of this is likely to result in under-estimation of communication difficulties: This may certainly account for the small percentage of communication difficulties noted between professionals and patients and families. Therefore, caution should be used in the interpretation of these results, although the similarities between the results in each country provide a degree of reassurance. Use of STAS scoring as the end point in this study highlights the point made by de Haes and Teunissen (de Haes and Teunissen, 2005), that the majority of available information from communication studies relates to patients perception only.

Communication needs may be influenced by other social factors. Macleod et al. (Macleod et al. 2004) in Scotland sent a postal survey to women 3-5 years post diagnosis of early breast cancer who were already participating in larger study of primary and hospital care for breast cancer. Questionnaires included measures of general health status, psychological well-being and questions regarding information sources and help-seeking behaviour. Seventy seven women were considered to be affluent and 100 deprived. Women living in affluent areas were more likely to have received information from their hospital specialist than those living in deprived areas (94.8% versus 76.0%, p=0.0007), as well as from breast care nurses (70.1% versus 40.0%, p=0.00007) and from family and friends (29.9% versus 16.0%, p=0.027). In addition, women living in affluent areas were also significantly more likely to have acquired information from the media. The authors report on the potential bias relating to the initial appointment of a breast care nurse late into the second year of the study at one of the hospitals seeing only deprived patients. No information is provided regarding the characteristics of the two groups of women or how their level
of affluence was determined. Nonetheless, this study provides a helpful indication of the apparent difficulties in communication and accessing of information experienced by socially deprived females with breast cancer. These findings are in keeping with those previously discussed in the study conducted by Steptoe and colleagues, suggesting that patients with a lower educational level are more likely to be satisfied with the available information.

However, satisfaction with available information may reflect the inability to access more and may not equate entirely to satisfaction with care. Self-efficacy may mediate the relationship between deprivation and communication needs. In California, Maliski et al. (Maliski et al. 2004) recruited 228 males from a treatment program established to provide free treatment to uninsured, impoverished males with biopsy proven prostate carcinoma. Patients completed a telephone interview, followed by a postal questionnaire. Several measures were used, including the Perceived Efficacy in Patient-Physician Interactions (PEPPI) short form, as well as the General Health Questionnaire (GHQ), the Symptom Distress Scale and the prostate-specific HRQOL. Univariate analysis was carried out and statistically significant variables were entered into a multivariate backward logistic regression analysis. Twenty three percent of the patients scored below cut off for low self-efficacy for interacting with physicians on the PEPPI. Following multivariate regression, those with low-self efficacy for interacting with physicians remained significantly less satisfied with their care (p=0.0376) and less confident in their healthcare providers (p=0.0319). The inference of these findings is limited by the lack of comparison group in this study, as well as the cross sectional methodology. Recruitment bias may potentially have resulted from the small fee paid to participants upon completion of each questionnaire.

2.4.2
Spousal Relationships
Spousal interaction is particularly important as adjustment and distress are directly related and mutually influential amongst couples. A study in America (Fang and Manne, 2001) evaluated a heterogeneous population of 197 ambulatory patients with
varying stages of cancer together with their spouses. The completion rate was 39.4%, though the only differences between participants and non-participants were in functional impairment and reduced prognosis. Patients and their spouses were evaluated at 3 time points (0, 3 and 6 months) using various measures, including the Mental Health Inventory, the Dyadic Adjustment Scale and the Cancer Rehabilitation Evaluation System. Analysis revealed that patient distress is negatively correlated with marital quality (p<0.05). Confirmatory factor analysis resulted in a model suggesting that increased functional impairment increased patient distress, which in turn reduced marital satisfaction. Patient and spousal distress were significantly associated over time (p<0.001). These findings provide an indication of the disease related influences of social support. However gender differences were not studied and, adding to the limitations of the findings, are the high refusal and attrition rates, the greater marital quality and educational level of the ethnically homogeneous sample, as well as the exclusion of spouses with poor health.

These findings are supported by the previously discussed study by Manne and Glassman (Manne and Glassman, 2000), of 191 married patients enrolled in cancer treatment. They considered the marital relationship with respect to negative, unsupportive spousal behaviours and found that this was significantly associated with reduced coping efficacy (p<0.01), perceived control (p<0.01) and increased use of avoidance coping (p<0.01). As these factors had been shown to increase psychological distress, further analysis was conducted and revealed that unsupportive, negative spousal behaviour did in fact significantly mediate psychological distress (p<0.01).

Further, albeit weak, evidence of a similar relationship is provided by Norton and colleagues (Norton et al. 2004), who studied 143 ambulatory females with varying stages of ovarian carcinoma. Patients completed self-reported questionnaires regarding aspects of physical impairment, unsupportive behaviours of family and friends, control, self-esteem and psychological distress. They used structural equation modelling to determine that higher perceived levels of unsupportive behaviours were associated with lower self-esteem (p<0.001), lower self-esteem
correlated with increased psychological distress (p<0.001), and that the indirect impact of unsupportive behaviours, as mediated by low self-esteem upon psychological distress, was significant (p<0.001). This evidence is weak for several reasons, including the homogeneous, cross-sectional sample, as well as use of best-fit modelling for analysis of complex associations when causation may not be inferred. Importantly, a questionnaire asking directly about unsupportive behaviours may encourage responses that potentially would not have been given spontaneously.

Specifically regarding spousal relationship, another study (Northouse et al. 1995) evaluated 81 ambulatory females with recurrent breast carcinoma and 74 husbands using the Social Support Questionnaire, the Mishel Uncertainty in Illness Scale (and the family member version for spouses), the Symptom Distress Scale, Beck Hopelessness Scale, Brief Symptom Inventory (BSI) and the Psychosocial Adjustment to Illness Scale. Analysis found that females who received increased support were less emotionally distressed. Independent variables accounted for 43% variance in emotional distress on the BSI with symptom distress, hopelessness and reduced support contributing significantly to the regression equation. Regression analysis of the husbands’ adjustment scores found several variables contributed significantly to their ability to carry out their psychosocial roles and these included their wife’s symptoms distress and perceived support. Significant correlations were found between patient and spousal emotional distress (p<0.05) and adjustment difficulties (p<0.01). The authors suggest that partners therefore, have a mutual influence on adjustment. Caution must be exercised in reviewing these results from a cross-sectional study of a homogeneous female cancer population.

2.4.3 Gender

Gender in fact appears to have significant implications with respect to spousal relationship, as well as other aspects of illness-related distress. In Germany, 149 consecutive referrals to an outpatient cancer centre were recruited into a study (Keller and Henrich, 1999). Eighty two males and 67 females who were married, or in a stable relationship completed extensive self-rated questionnaires covering
physical, psychological, social (partner relationship and communication and support) aspects of illness-related distress. The sample was representative of the German population. The only difference between genders was that the males were more likely to have a poorer prognosis and to be receiving only palliative treatment.

Extensive analysis revealed several interesting findings. Both genders reported similarly on perception of illness-related changes in physical and psychological areas, suggesting that males and females experience illness similarly. However, women scored more highly for severe overall distress compared with males (54% versus 28%), but there was no difference in psychological distress. Ultimately, the authors used their findings to determine a profile for gender illness-related distress. They suggest that females experience more physical distress, and hypothesise that this relates to their loss of social role, that support from their husbands creates no impact whilst an apparent, but not significant, trend exists towards support-seeking from family and friends. Males appear to experience more psychological effects of illness, the authors postulate this relates to conflicts of identity; whilst a relationship exists between better marital relationship and spousal support and reduced levels of distress. Caution is required in interpretation of these findings, which are based on non-standardised, self-rated measures taken from a cross-sectional sample.

The findings regarding female support-seeking are in keeping with those of Hann and colleagues (Hann et al. 2002), who evaluated a heterogeneous sample of 342 ambulatory cancer patients across 4 states with self-reported measures of depression and social support. They found that better social support was associated with less depression amongst both genders. However, having a larger social network was significantly associated with less depression for females but was unrelated amongst males. A study of 102 women with metastatic breast carcinoma in America provides findings consistent with this. Using similar measures to Hann, Koopman et al. (Koopman et al. 1998) found that reduced mood disturbance was significantly associated with increased social support. They also found that for those females reporting increased life stress, larger social networks were associated with reduced mood disturbance. In addition, further evidence is provided in the previously
discussed study by Dukes-Holland and Holahan (Dukes Holland and Holahan, 2003),
adjustment was greater amongst females with a larger perceived network.

Keller and Henrich's findings regarding the male profile of illness-related distress are
in keeping with those of Zakowski et al. (Zakowski et al. 2003) in America, who
conducted a cross-sectional study of 82 patients (41 male and 41 female) who had
been diagnosed with prostate or gynaecological cancer in the previous 5 years.
Patients completed questionnaires regarding mood, social constraints and emotional
expression. Multiple regression analysis revealed that males experienced
significantly higher distress in association with perceived social barriers to emotional
expression from their spouse or partner than females did. This association existed
with respect to spousal constraints alone.

Findings from a Japanese study (Taniguchi et al. 2003) indicate a culturally similar
profile to the previously discussed studies. Taniguchi et al. studied 272 males and
252 females with cancer using a structured interviewed together with the Profile of
Mood States and Mental Adjustment to Cancer scale. Multivariate analysis
controlling for confounding variables revealed that unmarried men had significantly
higher levels of psychological distress and lower levels of fighting spirit than married
men. In addition, married men with spousal support had higher levels of fighting
spirit than those without spousal support. No such differences were found for
females, neither between married and unmarried women nor between those with or
without spousal support. This further supports the evidence that the wife or partner is
the main provider of emotional support for males.

2.4.4
Social Support
Social support provides clear benefits to patients with cancer. In some respects,
patients with a cancer diagnosis may elicit increased support. In the previously
discussed study by Turk et al. (Turk et al. 1998), patients with cancer-related pain
reported higher levels of support (p<0.03) and lower levels of negative responses
from significant others (p<0.003) than those with chronic non-cancer pain, indicating that cancer pain is considered “valid” and more likely to evoke support.

Conversely however, social relationships may in fact constitute an additional source of distress amongst cancer patients, in view of the negativity induced by a cancer diagnosis. The stigma that is still attached to a cancer diagnosis may increase the risk of isolation for patients (Krishnasamy, 1996).

Bloom and Spiegel (Bloom and Spiegel, 1984) explore the multidimensional social constructs resulting in social isolation. In their study of females with metastatic breast carcinoma and their families, they showed that one aspect of social isolation results from declining physical function. This reduces the number of social activities in which the patient can be involved, resulting in an increasingly restricted social network. The authors conclude that ironically, for cancer patients, as their need for social support is at its greatest, this is the time when it becomes less available.

2.4.5
Financial
The effect of social deprivation on health is a major area of ongoing research and input across the public health sector, the detail of which is far beyond the scope of this study. The well-established relationships between social deprivation and health are equally reflected amongst cancer patients. Deprived women with breast cancer appear to have more financial and family concerns, along with increased co-morbidity and depression than their more affluent counterparts, according to Macleod’s (Macleod et al. 2004) previously discussed study.

In a study of social class and access to palliative care, Kessler et al. (Kessler et al. 2005) analysed all 960 adult cancer deaths in one English region over approximately 3 years. Data were taken from the Public Health Mortality computer database and each individual’s occupation was coded and classified using the Standard Occupational Classification. The deprivation categories of each area within the
region were noted and their distance from the hospice. In addition, qualitative interviews were carried out with 18 carers of patients who had died.

Analysis revealed that 12.7% of the patients overall had died in the hospice, but that only 6.9% of patients in social class V died in the hospice. From logistic regression, the odds ratio was 0.47 (95% CI :0.22, 1.05; P=0.043) and changing only to 0.49 (95% CI :0.22, 1.09; P=0.041) after adjusting for proximity to hospice, age and sex. Proximity to hospice did not affect the likelihood of a patient of social class V dying in the hospice (interaction odds ratio 0.98, 95% CI :0.79, 1.22; P=0.88). In the discussion, the authors state that proximity to hospice did influence admission for other social classes, although the data for this is not provided. Nonetheless, the evidence does indicate that patients of the lowest social class were less likely to be admitted, despite the hospice being situated in the most deprived area. These findings appeared to be explained to some degree, by the findings of the interviews in which carers of patients of lower social classes admitted to being less active in seeking hospice admission and more likely to receive support from family and the community. Therefore, although the lowest social classes may access in-patient palliative care services less, this may be to some degree due to culture and choice.

### 2.4.6 Culture

Detailing the specific cultural differences in physical, psychological, social and spiritual aspects of distress amongst ethnic minority cancer patients is beyond the scope of this study, which has been conducted in a non-ethnically diverse setting. Nonetheless, it is important to note that cultural diversity in illness-behaviours and access to care is a well-recognised and widely researched phenomenon.Having established this, we should also appreciate that such research has been, to date, highly specific in this remit. Therefore, the majority of studies regarding cancer and the end of life have been conducted in America and the UK, predominantly on white, middle class populations.
2.4.7

Summary of Social Distress

Several aspects of social distress, including communication, affluence and culture, were considered beyond the scope of this literature review. However, although not extensively reviewed, the communication literature was considered. Most of this is inherently flawed by the lack of observational studies, evaluating unseen communication. In my opinion, this limitation simply reflects the challenges of researching communication. However the consensus is clear, that effective communication is of great importance, with poor communication impacting negatively upon patients.

Social support literature provides evidence that spousal distress is mutually influential. Males are more reliant upon spousal support, whilst females engage their wider social network.

2.5

Spiritual Distress

2.5.1

Definition and Understanding

The most comprehensive and straightforward definition of spiritual well-being is provided by Laubmeier (Laubmeier et al. 2004) who suggests that spiritual well-being comprises the religious aspect; achieving harmony with God and the existential, finding meaning and purpose in life.

Spiritual distress is perhaps the least extensively evidenced component of distress in the literature (Cherny et al. 1994). It also appears to be poorly addressed by healthcare professionals. A review paper (de Haes and Teunissen, 2005) regarding communication suggested that “existential issues are often overlooked in communication with healthcare providers at the end of life”. This is an important omission. In a small Swedish qualitative study (Bolmsjo, 2000), 10 terminally ill patients were interviewed regarding existential issues and communication. The data
were content analysed and findings revealed that the patients were aware of their spirituality and keen to discuss related questions.

However, in an extensive 3 phase qualitative study involving interviews with 120 terminally ill cancer patients, Greisinger et al. (Greisinger et al. 1997) discovered that patients’ most important concerns included existential and spiritual issues (amongst others), and that although their disease was regularly assessed, these issues were rarely the focus of care.

Frankl’s (Frankl, 1963) well-known existential theory implies that individuals have the ability to find meaning in life when life is threatened. In this context, terminal illness may be regarded as that threat. Studies have indicated that spirituality is heightened amongst patients with terminal illness. Reed (Reed, 1987) studied 3 groups of 100 socio-demographically matched patients (terminally ill adults, hospitalised adults and healthy adults). All 300 participants completed the Spiritual Perspective Scale and Index of Well-Being, as well as providing other information. Analysis revealed that a significantly larger number of terminally ill adults indicated a change toward increased spirituality than was found amongst the non-terminally ill and healthy adults.

2.5.2 Spiritual Pain
Strang (Strang, 1997) provides evidence for the association between spirituality and symptom distress. He studied 78 patients with cancer who were being treated for pain related problems in Sweden. Patients were assessed using visual analogue scales for pain intensity as well as semi-structured interviews. Analysis revealed that patients with greater overall mean pain scores or mean worst pain scores were significantly more fearful regarding the future (p<0.01), had greater worries about pain progression (p<0.05), and had more fear and general anxiety that resulted impaired daily living (p<0.05). Although compromised by the tools used and the inability to comment on causal relationships, these findings imply an association between physical and existential distress.
2.5.3

Spiritual Well-Being

In an Australian qualitative study (Thomas and Retsas, 1999), 19 patients with terminal cancer participated in semi-structured, in-depth interviews regarding aspects of spirituality and meaning. Constant comparative technique was used and grounded theory analysis established a core theme, this was found to be “transacting self-preservation” which has 3 components “taking it in, getting on with things and putting it all together”. Development of these spiritual perspectives strengthened the patients’ approach to life and death through reaching a deeper understanding of self. This analysis appeared to be rigorous within the parameters of qualitative research, although the results cannot be generalised.

Coping

In facilitating acceptance through discovery of meaning and purpose in adverse circumstances, spirituality may be regarded as coping mechanism (Laubmeier et al. 2004). Holland et al. (Holland et al. 1999) evidence this in their study of 117 ambulatory patients with varying stages of malignant melanoma in America. Assessment tools included the Systems of belief Inventory (SBI-54), The Dealing with Illness-Coping Inventory, Brief Symptom Inventory, Profile of Mood States together with measures of social support. The variation in religions amongst the sample was considered representative of the area. The BSI-54 was significantly associated with active-cognitive coping style (p<0.0001) and this remained following multivariate analysis. An active-coping cognitive style has been defined as an acceptance of illness and an attempt to view its effects in a positive and meaningful way (Fawzy et al. 1990). These results are not surprising. Spirituality facilitates these precise aspects of illness and in addition, The Dealing with Illness-Coping Inventory is based on a modification of the Lazarus-Folkman Coping With Illness Scale which includes a subscale regarding existential and religious belief (Lazarus and Folkman, 1984). Hence spirituality may be considered an integral part of the active-coping style.
Meaning and Faith

The general consensus in the literature is that enhanced existential well-being has multidimensional benefits. McClain et al. (McClain et al. 2003) in America evaluated 160 terminally ill cancer patients (prognosis <3 months) during the first week of their admission to a palliative care hospital. Patients completed the FACIT-Sp-12, Beck Hopelessness Scale and Schedule of Attitudes Towards Hastened Death. The socio-demographically representative sample included patients with a variety of religious backgrounds as well as those with no religion. Analysis revealed significant correlations between increased overall (religious and meaning) spiritual well being (FACIT-Sp-12) and reduced desire for hastened death, reduced hopelessness and reduced suicidal ideation (all p values <0.0001). Multiple regression analysis indicated that spiritual well being (SWB) was the strongest predictor of each of the outcome variables. In addition, depression was significantly associated with an increased desire to hasten death if SWB was low (p<0.001), but not associated if SWB was high (p=0.06). Interestingly, the analyses were re-run separately for the meaning and faith subscales of the FACIT-Sp-12 and the meaning subscale maintained all significant correlations. However, the faith subscale was only associated with hopelessness and was not an independent predictor of desire for hastened death or suicidal ideation. The subscales did not affect the effect of depression on end of life despair. Therefore SWB appears to provide some protection against end of life despair amongst terminally ill patients. The cross-sectional methodology of this study precludes inference of causal relationships.

Morita et al. (Morita et al. 2000) in Japan carried out an exploratory factor analysis of existential distress amongst 162 consecutive patients admitted to a palliative care unit. Physicians noted any spontaneous expressions of existential distress made by patients on a pre-designed checklist. The frequency of expression of each category was documented. The most common expressions of existential needs related to dependency (39%), meaninglessness (37%), hopelessness (37%) and burden (34%). Interestingly, faith was expressed the least (2.5%). Further analysis revealed that existential distress appeared to be a multidimensional phenomenon and that meaninglessness was the underlying theme, significantly associated (p<0.01) with
each aspect (dependency, loss of social role, burden on others and hopelessness). Clearly, this cross-sectional study is further greatly limited by the data collection methods used. No tool was used to assess the existential issues, severity was not established and the study relied upon physicians to be present, accurate and remember to document patients expressions of existential distress. This was done out of context, on a checklist. Despite the weakness of the evidence and the fact that Japan is not known to have a specific religion, the study demonstrates the polar separation in meaning and faith, in the context of patients’ spontaneous expressions of spirituality.

The difference between “faith” and “meaning” in spirituality was also evidenced in a study of 162 terminally ill cancer (n=84) and AIDS (n=78) patients (prognosis < 6 months), recruited from palliative care facilities (Nelson et al. 2002). These patients completed the FACIT-Sp-12, a religiosity index as well as the Hamilton Depression Rating Scale (HDRS) and measures of functionality, including the Memorial Symptom Assessment Sale. The analyses are described separately for the patients with cancer and for those with AIDS. For the patients with cancer, the HDRS correlated moderately with the total FACIT-Sp-12 score (-0.40, p<0.01). However, the HDRS correlated more strongly with the meaning and peace subscale of the FACIT-Sp-12 (-0.51, p<0.01), whilst there was no correlation with the faith subscale of the FACIT-Sp-12. These findings suggest that patients with increased meaning and peace are significantly less depressed, whilst the religiosity component of spirituality does not appear to influence levels of depression amongst terminally ill cancer patients. The authors suggest this finding implies that the beneficial aspect of spirituality lies in the patient’s ability to “search internally for strength and meaning to place their illness in a broader context and accept their circumstances”. Although causal relationships cannot be assumed due to the cross-sectional nature of this study, these findings provide evidence that improved SWB (with respect to meaning), is associated with reduced psychological distress.

Further evidence regarding the association between SWB and reduced psychosocial distress is provided by Smith et al. (Smith et al. 1994). The authors assessed 116
ambulatory cancer patients using the Transpersonal Development Inventory (designed by the author), Death Attitude Profile and the Brief Symptom Inventory. Transpersonal development is conceptualised as a relationship between an individual’s perspective on death and level of spiritual awareness. A significant association was found between increased transpersonal development and lower psychosocial distress. This cross-sectional study is also limited by the use of a non-standardised tool as an end point.

Meraviglia (Meraviglia, 2004) adds to this evidence by additionally showing that increased SWB is also associated with reduced symptom distress. A convenience sample of 60 ambulatory patients with varying stages of lung cancer completed measures of existential meaning, prayer activities, symptom distress (SDS) and psychological distress (Index of Well-Being). The majority of patients were female (61%) and Christian (66%). Predictor variables were identified in univariate analysis and multiple regression analysis was carried with these and 2 mediator variables (meaning and prayer). The findings were that increased functional status was associated with increased existential transcendence (meaning in life) and that increased meaning in life was associated with reduced psychological distress and together this significantly predicted symptom distress, explaining 9% variance. However, this evidence is weak and caution must be exercised in the interpretation of these results from a cross-sectional, homogenous convenience sample of mainly Christian females.

Significant evidence therefore indicates the positive benefits of SWB for patients with cancer. However, this has not been universally found. In the previously described study of 117 ambulatory patients with varying stages of malignant melanoma, by Holland et al. in America, The Systems of Belief Inventory (SBI-54) did not correlate with the POMS or the BSI or with specific measures within each of these. An explanation for the lack of correlation of the BSI-54 and measures of physical and psychological distress may be the very small numbers who were in fact distressed in this population who had a mean Karnofsky Performance Status score of
97 (range 0-100). This limitation of the population may have affected the results, along with the homogeneous tumour type and resultant ethnicity.

### 2.5.4 Dignity

As a component of existentiality, loss of dignity relates similarly to the other components of distress. Chochinov and his team (Chochinov et al. 2002) in Canada have produced the majority of the dignity-related literature. In a significant study done over 4 years, they recruited 213 terminally ill cancer patients (prognosis <6 months) from the in and out patients of 2 palliative care teams. There were no significant differences between participants and non-participants. Patients rated their sense of dignity on a 7-point scale and then completed a battery of measures relating to symptom distress, pain, functionality, quality of life and social support. They found that in fact, over half had a strong or intact sense of dignity. Forty-six percent of patients had some level of concerns regarding their dignity and 7.5% considered loss of dignity a major issue. The analysis was split into 2 groups: Dignity Intact (DI) and Dignity Fractured (DF). There were no socio-demographic differences between these groups and proximity to death was similar. Those with DF were all seen in hospital (compared with 78% of the DI group) and were younger (p=0.024).

The DI group were found to have less desire for death; depression; hopelessness; anxiety; incontinence; bowel problems; body image concerns or need for assistance with activities of daily living. In addition, this group had greater quality of life (p =0.002). A stepwise multiple logistic regression analysis was conducted with these variables and body image was found to be the greatest predictor of loss of dignity (p =0.007), followed by feeling a burden to others (p=0.004), requiring assistance to wash (p=0.047), pain (p=0.03) and location of care (p=0.04). The significance of this overall model was great (p<0.0001).

Although this was a cross-sectional, cohort study in which all patients were receiving specialist palliative care, the evidence is solid due to the robust methods and large (for this population) sample size. We must consider though that amongst those who
are dying, concerns regarding dignity may change as death approaches. The authors conclude; that “dignity is a resilient construct with the ability to withstand many of the physical and psychological challenges faced by the terminally ill patient”. Despite this, those at risk of losing their dignity appear to have more physical and functional impairment, as well as fear of becoming a burden.

Based on qualitative research, Chochinov et al. (Chochinov et al. 2002) have developed an empirical model of dignity amongst terminally ill patients. The study comprised a heterogeneous sample of 50 consecutively recruited terminally ill cancer patients from a specialised palliative care unit. Patients were interviewed through semi-structured interviews regarding all aspects of dignity. Latent content analysis and constant comparative techniques were used. All 4 investigators coded the transcripts and consensus was reached, first on the codes and then on the emergent themes. The three major themes were “Illness-Related Issues” (IRI), “Dignity-Conserving Repertoire” (DCR) and “Social Dignity Inventory” (SDI). IRI related to illness mediated impact on dignity and sub themes included symptom distress and level of independence. DCR related to perspectives and practice used to maintain dignity. SDI reflects the social dynamics affecting dignity, for example privacy, support and feeling a burden. The authors developed a conceptual model defining the inter-relationship of these constructs in which the Dignity Conserving Repertoire buffers the negative impacts of Illness-Related Issues and the Social Dignity Inventory upon maintenance of dignity. This model implies that illness-related concerns together with difficult social dignity inventory have a negative impact on dignity. However, this process may be “buffered” by a strong dignity-conserving repertoire, thus conserving dignity to some extent.

The same limitations apply, as in the previous study. In terms of qualitative research, this was not only a large study, but was also methodologically rigorous and validated by consensus analysis.

A further review paper by Chochinov and team (Chochinov et al. 2004) further details the components of their model. Key elements comprise the Illness-Related
Issues and include maintenance of cognitive and functional independence and the impact of symptom distress, both physical and psychological. The psychological impact relates particularly to uncertainty. Dignity-Conserving Repertoire includes several factors, namely preservation of sense of self, social role, autonomy/control, hope, pride and acceptance. This also involves leaving a legacy and maintaining resilience. Social Dignity Inventory “refers to the quality of interactions with others that enhance or detract from one’s sense of dignity”. This paper describes the basis of this empirically derived theoretical framework in their on-going development of individualised “dignity therapy”.

2.5.5 Hope

Hope is another important aspect of spirituality: Snyder conceptualises and defines hope as “a cognitive set that is based on a reciprocally derived sense of successful (a) agency (goal-directed determination) and (b) pathways (planning to meet goals) (Snyder et al. 1991) (Gum and Snyder, 2002).

In a qualitative study in the UK (Buckley and Herth, 2004), 16 terminally ill patients (11 female), with a prognosis of only months, were recruited from a hospice palliative care team and completed the Herth Hope Index (HHI) and a semi-structured interview. Four patients completed a second assessment. The interviews were analysed using a data reduction technique and content analysis. The transcripts were coded and emergent themes derived, the codes and themes were checked by an independent reviewer for credibility.

The mean HHI scores were high at 39 (maximum 48) for the initial assessments. The main themes from the interviews were categorised as “Hope Fostering” (love of family and friends, spirituality, setting goals and maintaining independence, positive relationships with professional carers, humour, personal characteristics and uplifting memories) and “Hope Hindering” (isolation, uncontrolled pain, devaluation of personhood). The second interviews revealed similar findings, indicating maintenance of hope. Of the 4 patients with a second interview, the HHI score fell
amongst two patients, improved in one patient (who had since been admitted to hospice) and stayed the same in the other (who died within 8 hours of the interview). All 4 patients died within 23 days of the second interview. This study is clearly limited by numbers, the potential bias introduced by the use of a mainly female convenience sample that may have been more hopeful and therefore willing to participate, and the inability to generalise the results. However, it is one of the few studies of hope at the end of life and appears to potentially indicate that hope remains present, regardless of approaching death.

2.5.6
Summary of Spiritual Distress

Spiritual distress is the least evidenced distress domain, with the scant literature consisting of small studies, which have used a variety of self-report measures. Despite these limitations, the available evidence does, in my opinion, indicate that spiritual well-being has multidimensional benefits.

Chochinov and colleagues have shown that physical, psychological, social and spiritual elements, all input into the complex construct of an individual’s dignity. Dignity appears to be a resilient feature amongst terminally ill patients receiving palliative care. Although changes in dignity as death approaches have not been studied, in a cross-sectional sample of terminally ill cancer patients, over half considered their dignity to be intact.

2.6
End of Life Distress

Each one of the distress domains comprises many factors, each contributing variably to the distress experience. The evidence that patients are particularly vulnerable to distress during the end stages of disease has been discussed in the previous relevant sections.
2.6.1
Quality of Life

Quality of life is considered to be a “central concept” in palliative care and is therefore a priority for healthcare professionals managing patients during the end stages of disease (Kaasa and Håvard Loge, 2004): Distress has a direct negative impact on patient quality of life (McMillan and Small, 2002). Thus by this association alone, distress itself becomes a fundamental concept in palliative care. Quality of life has itself been defined in sociological, psychological and medical contexts. In palliative medicine, quality of life is related to symptom control, physical functioning, psychological well-being, and spiritual and existential issues (Kaasa and Håvard Loge, 2004).

Quality of life is a complex concept in its own right, and shares similar components to those of “total distress”. As these two concepts are inextricably linked, attempting to define the independent contribution of quality of life to distress is beyond the scope of this study. Therefore, the extensive quality of life literature has not been reviewed for the purposes of this current study.

2.6.2
Service Input

Data from Palliative Care Service evaluation is now becoming increasingly available. Figures from 1998 indicate that two-fifths of patients, who died from cancer in the United Kingdom in the year ending March 1995, were thought to have had support from community palliative care nurse specialists (Addington-Hall and Altmann, 2000).

Addington-Hall and colleague (Addington-Hall and Altmann, 2000) conducted a regional study of care for the dying in England. Twenty self-selected, nationally representative districts were recruited and 270 deaths in the last quarter of 1990 were “randomly” sampled in each district. Cancer deaths were sampled disproportionately as they were of greater interest to the study, 54% of the sample, compared with 26%
expected according to national mortality statistics. Researchers then conducted semi-structured interviews with willing bereaved relatives within the 10-month period following the death. The interviews assessed the last 12 months of the patient’s life with respect to symptoms, dependency, care needs and services provided. The response rate for cancer deaths was 71%, and these are the sole focus of the published data.

Logistic regression analysis revealed that patients with cancer were more likely to have received Community Specialist Palliative Care Nurse (CSPCN) input if they were younger, married, living with their main carer, the carer was their spouse, they were living with children, owned their house and were dependent in their activities of daily living (p<0.01). They were less likely to receive CSPCN input if they had been dependent for over a year, lived alone, or in a nursing home (p<0.01), or if they had a haematological malignancy (p<0.0001). Independent variables associated with an increased likelihood of requiring CSPCN input were, dependence, requiring assistance at night, symptoms of constipation, nausea, vomiting or confusion, a diagnosis of breast cancer, and age younger than 75 years.

This study provides an initial, helpful indication of the patient characteristics associated with an increased need for palliative care service input in the community. The study was however, limited by several factors including the retrospective data collection, reliance upon the retrospective perspectives of bereaved relatives, and the sampling of patient deaths, which was described as random but acknowledged to be biased towards cancer deaths.

Patient distress also has a direct impact on healthcare services in terms of increased use and associated cost. Holland et al. (Holland et al. 2004) suggest that distressed patients with cancer attend more frequently and require increased consultation time. Bruera et al. (Bruera et al. 2000) evaluated the nature of referrals to the centres in the Edmonton Regional Palliative Care programme. These consist of a Tertiary Palliative Care Unit (TPCU), 3 hospices and 2 acute hospital teams. Patients referred to any aspect of the programme completed measures of symptom distress, pain and
alcohol use. The admission data generated over one year was reviewed. The analysis revealed that when compared with the other settings, patients referred to the TPCU were more likely to be younger, \((p<0.0001)\), have alcohol dependence \((p<0.0001)\), have a poorer pain prognosis \((p<0.0001)\) and have more frequent and severe symptoms, particularly pain, anxiety and depression \((p<0.0001)\).

Few have assessed the impact of various forms of psychotherapy upon quality of life and healthcare contacts for patients with cancer. Ashbury and colleagues (Ashbury et al. 1998) conducted a review of 913 patients treated for cancer in the previous 2 years. Patients were recruited through local advertisement and comprised mainly females (66%) and breast and prostate cancers. Seventy eight percent of patients reported fatigue and this was associated with increased healthcare utilisation, particularly visits to the primary care team, pharmacist, hospital accident and emergency departments and out patient clinics. Although the recruitment bias in this study is evident, it has been included to simply illustrate the link between symptoms and healthcare utilisation. No monetary evaluation was carried out.

A small pilot intervention study (Rosenberg et al. 2002) was carried out in America amongst 30 men with prostate cancer. Patients were randomly assigned to intervention (written expressive emotional disclosure regarding personal cancer experience on 4 occasions) or control (normal treatment). Patients completed questionnaires regarding healthcare contacts, medication use and health-behaviours prior to invention and at 3 and 6 months post invention. Those in the intervention group reported less physical symptoms, particularly pain and less healthcare contact, falling from 10 to 4.4 at 6 months. This compares with a stable average of 8 healthcare contacts over the 6 months for patient in the control group. This study is included mainly, as there are very few studies of the relationship between distress and healthcare cost. Clearly, the results must be interpreted cautiously. Nonetheless, the study does add a little evidence regarding the impact of distress upon healthcare contact, despite the fact that no monetary evaluation was done.
Finally, one study (Simpson et al. 2001) randomised 89 women with early breast cancer to intervention (six sessions of 6-weekly cognitive behaviour therapy) or control (normal treatment plus self-study materials from the intervention). Patients completed measures of psychiatric symptoms, mood, depression and coping strategies prior to intervention, immediately post intervention, 1 year and finally, 2 years post intervention. The healthcare billing data for this period was then reviewed. Women in the intervention group had less psychiatric symptoms, less depression and mood disturbance and improved quality of life, from immediately post intervention to final follow up at 2 years. The reduction in billing costs correlated directly with the fall in distress levels following the intervention. Accounting for the cost of the therapy a saving of $70 (Canadian) per patient was made through intervention reducing distress levels. The authors suggest that this effect would be maximised by using team psychologists rather than psychiatrists, as used in the study, as well as targeting patients with the highest distress. Certainly this study provides evidence that healthcare costs relate directly to distress levels.

The relationship between patient distress and healthcare use is highlighted in a review article (Carlson and Bultz, 2003a) arguing that the benefits of improved quality of life associated with psychosocial oncology input may offset medical costs relating to cancer patient care.

2.6.3 Sedation

The issue of sedation in end of life decision-making is widely debated and extensively researched. A brief overview is included in this literature review, in order to evidence the use of sedation as the common treatment for refractory distress amongst patients with terminal cancer.

"Refractory" refers to any symptom that “cannot be adequately controlled despite aggressive efforts to identify tolerable therapy that does not compromise consciousness” (Cherny and Portenoy, 1994). Although sedation provides effective
palliation of refractory distress, survival duration may be compromised (Fürst and Doyle, 2004).

A survey of 120 Italian Cancer Patients receiving community palliative care revealed that 52% required deep sedation for unbearable symptoms, on average 2 days before death (Ventafridda et al. 1990). Dyspnoea and pain accounted for the majority of these symptoms, with 17% requiring sedation for agitated delirium.

A large multi-national survey (Fainsinger et al. 2000) analysed data from all consecutive patients dying under the care of the participating physicians in 4 palliative care units: Israel (100 patients), Spain (100 Patients), and two South African regions (Cape Town, 93 patients and Durban 94 patients). The intent to sedate varied from 15% in Israel to 36% in Cape Town. Delirium was the most common reason for this, except in Durban where dyspnoea was the main reason. The length of time of sedation was consistently 1-6 days in all 4 centres.

Chater and colleagues (Chater et al. 1998) conducted a survey of 53 multi-national experts in palliative care regarding terminal sedation. Analysis revealed that 77% of the physicians had used terminal sedation in the previous 12 months and over half of these (56%) had used it for 1-4 patients in this time. Of the 41 who had sedated patients, 38 provided details on a total of 100 patients. Pain was the most common reason for terminal sedation (20%) and “anguish” the second (14%). Overall, over half of the reported reasons for terminal sedation were physical and one third psychological.

Morita (Morita et al. 2002) conducted a similar survey of palliative care physicians and oncologists in Japan. Physicians were asked to complete a questionnaire regarding attitudes towards end of life care that included questions about clinical experience, as well as hypothetical vignettes. The authors received 697 responses and some duplicates were included in the analysis due to technical problems. Data analysis revealed that of those who had used continues deep sedation at the end of life, the reason for it was refractory physical distress in 66% and psychological
distress in 38%. This study is limited by the very low response rate (49.6%) and the inclusion of duplicate data in the analysis.

All of these cross-sectional retrospective surveys are limited by their reliance upon physicians providing accurate information regarding previous practice, up to a year previously. Data must be considered with caution but the multi-national consistency of data is reassuring.

2.6.4 Prognosis

Survival duration is notoriously difficult to predict amongst patients with advanced cancer. The current literature suggests that prognostication may be assisted by the evaluation of a combination of clinical, biochemical and psychosocial factors. Two large review articles regarding prognostication have been published. Evidence for prognostic factors amongst terminally ill patients has often been derived from studies with methodological shortfalls. These have been identified as follows: Using retrospective cohorts, providing little information on sampling procedures, inadequate analytical procedures and the effect of co-morbidity (Maltoni and Amadori, 2002).

According to Maltoni and Amadori’s (Maltoni and Amadori, 2002) extensive literature review, available evidence suggests that the following have proven prognostic capacity. Clinical prediction of survival, Karnofsky Performance Status, nutritional status and symptoms associated with cachexia (weight loss, anorexia), dyspnoea, cognitive failure and prognostic scores. Probable prognostic capacity is evidenced for xerostomia, dysphagia, asthenia and hypoalbuminaemia, leukocytosis, lymphocytopenia.

Three significant systematic literature review papers agree that the strongest predictors of prognosis amongst patients with advanced cancer are performance status and the “terminal syndrome” (cognitive failure, anorexia, weight loss, dyspnoea). When used in combination with biochemical and medical factors,
clinician prediction of poorer survival duration is also a proven aid to prognostication (Maltoni and Amadori, 2002) (Chow et al. 2001) (Vigano et al. 2000b). In addition to the albumin, lymphocyte and leukocyte count (Vigano et al. 2000a) (Maltoni and Amadori, 2002), a raised C-Reactive Protein is another important biochemical marker for prognostication (Engelken F J. et al. 2003) (Gockel et al. 2006) (Crozier et al. 2006).

These systematic literature reviews did not focus on the psychological predictors of prognosis. In one study (Brown et al. 2003) of 205 cancer patients of heterogeneous site, state and progression, patients completed measures of emotional and cognitive functioning immediately post diagnosis and then at 4 month intervals for 15 months. Survival was followed for 10 years. Multivariate analysis revealed that depressive symptoms were the most consistent and independent predictors of survival with increased depressive symptoms predicting reduced survival.

In the previously discussed study, Faller et al. (Faller et al. 1999) in Germany evaluated 103 patients admitted to cancer centre with newly diagnosed lung cancer (on the whole within 3 days of diagnosis). Patients completed measures of coping and mood. Using Kaplan-Meier analyses of survival prediction, depressive coping was significantly associated with reduced survival (p<0.007). Cox regression was carried using multiple covariates, adjusting for biomedical risk factors this relationship remained significant, suggesting the evidence indicates a relationship between coping and survival amongst patients with lung cancer.

Butow et al. (Butow et al. 2000) examined psychosocial predictors of survival amongst 99 women with metastatic breast carcinoma using measures of coping and cognitive and psychosocial functioning. Patients completed the questionnaires 4 months after diagnosis and survival was followed. Multivariate analysis revealed that patients who minimised the impact of cancer survived longer (p<0.01).

The evidence for psychosocial predictors of survival must be regarded with caution in view the inherent complexities of analysis. Many of the factors are inter-related
and therefore, true independence in terms of predictive value is dubious. In addition, the sample sizes are small and, in the case of the previous two studies, cross-sectional and homogeneous. The evidence has mainly been included in order to highlight the multidimensionality of prognostication.

2.6.5
Summary of End of Life Distress
The literature indicates that distress at the end of life impacts adversely upon quality of life and healthcare services. In addition, survival duration may be compromised if sedation is required for refractory distress. Finally, evidence suggests that prognostic factors amongst patients with cancer are multidimensional. I believe that collectively, this literature shows the relevance of distress at the end of life as a fundamental issue.

2.6.6
Key Researchers
Holland and colleagues (Holland et al. 2004), particularly Breitbart and Jacobsen have been central in researching distress amongst cancer patients in America. This group were involved in the production of the National Comprehensive Cancer Network distress management guidelines for oncologists in 2005 and have developed a simple distress screening tool. However, their studies mainly involve ambulatory cancer patients attending oncology outpatient services. A direct comparison cannot therefore, be made with the palliative care population.

The key authors in each specific area are as follows: Portenoy is well-established authority on symptom distress; Zabora has published widely on psychological distress, Manne contributes largely to evidence for social distress, whilst Chochinov is well recognised for his research into spiritual distress.
2.6.7
Global Literature Summary: Challenges and Limitations

I have presented an extensive literature review. Through critical appraisal of the available evidence I have identified several recurring themes regarding study limitations. The main issues are methodological and are as follows:

- Lack of Randomised Controlled Trials
- Small numbers
- Descriptive studies
- Cross-sectional studies
- Self-assessment tools with associated inherent bias
- Largely oncology outpatient recruitment with few end of life studies
- Non-standardised methods of data collection or of study populations

A significant lack of evidence in the form of Randomised Controlled Trials exists in the literature, and I have included many methodologically limited studies in this review as they form the main body of currently available evidence in this area. The reason for this relates largely to the well-recognised challenges presented to patients and researchers alike by end of life research (Bowling, 2000).

Kendall et al. (Kendall et al. 2007) conducted a qualitative in-depth interview and focus group study of researchers, patients and carers involved in end of life research. The researchers disclosed several inherent problems in conducting end of life research, the first being actually defining the end of life. Other difficulties included overprotective gate-keeping by ethics committees, high attrition rates and managing the emotions of research staff, patients and carers. The patients themselves indicated a willingness to participate in research conducted sensitively. They conclude that the taboos associated with death and dying still raise barriers to research which can be overcome to produce ethically and methodologically rigorous studies. They do however recommend that psychological support should be provided for the staff and patients involved.
Addington-Hall (Addington-Hall, 2002) also addresses the methodological challenges of healthcare research amongst patients receiving palliative care. These include identifying eligible patients appropriately, as palliative care is not restricted to stage of disease. They raise ethical concerns (considered in detail in the ethics chapter), particularly using the limited time and energy resources of vulnerable patients for research from which they will not directly benefit. They discuss the methodological issues, which include the sensitive recruitment of patients; avoiding the potential to exacerbate distress in explaining the nature of the study for which they are considered appropriate. In keeping with the findings of Kendall et al., they also describe the issues of gate-keeping, patient frailty and high attrition rates in longitudinal studies.

Lawton (Lawton, 2001) describes the difficulties associated with conducting a qualitative participant observation study in an in-patient hospice. These included difficulties in establishing the validity of consent as patients’ conditions deteriorated, as well as the issue specific to this particular research method that relates to the conflict and ambiguity of maintaining the role of participant observer.

Beaver (Beaver et al. 1999) explores the difficulties that arose during the conduct of research amongst patients with terminal illness and their carers. The issues raised are all in keeping with those previously discussed by other authors and include approaching patients for recruitment ethically, without inducing distress; maintaining on-going informed consent, and balancing the need to adhere to stringent protocols as well as ethical principles.

Many of the challenges presented to end of life research are methodological. Attempts to overcome these difficulties are being made in order to progress and expand the evidence base for end of life care.

The relatively recent concept of longitudinal qualitative research has significant potential in palliative care, with the advantage of capturing the dynamic illness experience. Although this method has been rarely used in medical research, it is
considered to be effective in demonstrating changing perspectives and needs (Murray and Sheikh, 2006).

Serial interviews capture change over time, giving a detailed and contextualised account of the dynamic experience of illness (Boulton et al. 1999). Further benefits result from the continued development of the researcher-patient relationship over the course of the interview series. The data is enriched through the establishment of trust and understanding, with evidence suggesting that patients are more likely to discuss deeply personal issues in subsequent interviews, allowing narratives to unfold (Murray and Sheikh, 2006). Serial interviews also facilitate the understanding of contradictory patient accounts (Murray et al. 2002)

Furthermore, despite the high dropout rates seen in end of life research, studies have shown that terminally ill patients are able to sustain commitment to serial interviews (Murray and Sheikh, 2006): Emmanuel et al. (Emanuel et al. 2004) carried out a prospective cohort study in 6 randomly selected centres in America. They randomly selected physicians from lists and asked them to refer patients with significant illness and less than 6 months prognosis. Patients were asked 133 questions regarding the experiences of illness and thoughts on death and dying. Although the initial response rate was 87.4%, significantly the response rate for re-interview was 95.3%.

Another study (Yedidia and MacGregor, 2001), with the aim of identifying themes and characterising patients’ perspectives on death, involved serial, in-depth, semi-structured interviews with 30 terminally ill patients. Patients were followed until as close to their death as possible, completing a mean number of 4.2 interviews, indicating the ability and willingness of terminally ill patients to commit to a longitudinal, qualitative study.
2.7
Study Justification

The literature provides evidence of the many variables involved in determining the patient experience of distress. The physical, psychological, social and spiritual components are each complex constructs, comprising many dynamic internal variables that are constantly evolving as disease progresses.

These complexities present significant challenges to research into the global distress concept amongst cancer patients at the end of life. However, the evident impact of global distress upon patient quality of life, quantity of life and service utilisation must be addressed in order to ensure future provision of effective, evidence-based healthcare for terminally ill patients with advanced cancer.

At present, no single study focuses entirely on the evolution of global distress over final phase of cancer; neither is there a single study specifically exploring each of the physical, psychological, social and spiritual domains, their interactions, and the subsequent impact on the distress experience.

A gap in the current literature has been identified and must be addressed through further research into the core issues relating to the patient experience of distress over the final phases of advanced cancer.

2.7.1
Research in Palliative Care

The National Institute for Clinical Excellence (NICE) in England produced guidelines for improving supportive and palliative care for adults with cancer in March 2004 (National Cancer Research Institute Strategic Planning Group on Supportive and Palliative Care, 2004). Their recommendations include investment into "longitudinal studies of patient and carer experiences and expectations of illness and health and social care, to describe changes in perspectives as illness evolves and
the best ways of meeting needs at different points in time.” NICE. This recommendation was supported by The National Cancer Research Institute Strategic Planning Group on Supportive and Palliative Care in their report suggesting that there is a need for “longitudinal studies of preference and experience”.

2.8
Research Question

This detailed longitudinal study will contribute uniquely to the evidence for global distress amongst patients with advanced cancer by exploring the research question:

How do global distress and its components evolve over the final phase of the cancer disease trajectory, from the time patients are referred to palliative home care services to time of death?
METHODS
3.1 Introduction and Aims

The purpose of this study was to explore the challenging questions relating to the complex concept of global distress amongst patients in the terminal phases of advanced cancer. The overall question was: *How do global distress and its components evolve over the final phase of the cancer disease trajectory, from the time patients are referred to palliative home care services to time of death?*

Specifically, the aims were to:

- Define the risk factors for distress in the terminal phase of advanced cancer
- To examine the relationship between distress and time
- To evaluate the contribution of each domain of distress to global distress over this time

This section initially provides an overview of the overall study design and population, explaining the use of combined quantitative and qualitative methods. This is followed by separate, detailed descriptions of the quantitative, and subsequently the qualitative methods. The methodological descriptions have been separated for clarity.

3.2 Design

A prerequisite for the design of this study was to account for both the scope of these broad questions, as well as the multidimensionality of the global distress concept. This required a combination of methods in order to provide comprehensive evidence.

The overall study design was longitudinal, combining quantitative and qualitative methods.
3.2.1

Longitudinal Design

Longitudinal study involves the collection of data from a patient cohort at regular intervals, prospectively over a predetermined period of time. Time-invariant data is collected only initially, whilst time-variant data is collected at each interval. Studying events over time avoids recall bias and maximizes the opportunity to obtain clinically meaningful data.

The prospective longitudinal design is fundamental to ensuring representative documentation of events precisely, as they occur, thus accurately tracking the course of the disease trajectory in each individual. With regular documentation, changes in time-variant data are evident and available for analysis. The longitudinal structure facilitates the demonstration of both temporal sequences, together with the consideration of causal relationships. Time may be either a predictor, or an outcome in the analysis of data.

An adequate length of study is required, in order to register sufficient changes and for their presence to be representative and valid. Additionally, the time interval between each episode of data collection must be carefully considered, in order to completely capture the fluctuation of time-variant data. The assessment schedule follows.

3.2.2

Quantitative Methodology

The majority of medical research is based on quantitative data. Quantitative research provides the connection between empirical observation and numerical expression. Observations are numerically represented and manipulated in order to describe and explain the phenomena they reflect. Data is collected according to the underlying theory and inferential statistical methods are applied to it. This is an iterative, deductive process, used to explore relationships between independent and dependent variables in a population.
Quantitative methods are therefore fundamental to achieving the aims of this study, which include the identification of predictors, contributors and patterns in the global distress experience.

### 3.2.3 Qualitative Methodology

Qualitative research originates from the social sciences and remains a relatively recent concept in healthcare research. Qualitative research "explores the dimensions of the social world" and aims to understand the working of social processes and the meanings they generate for individuals (Mason, 2002). Human behaviour and social life are studied (Clark, 1997) in order to provide a comprehensive understanding of complex, subjective, social phenomena (Strang, 2000).

Qualitative data consists of words describing perspectives, experiences and memories, whilst reflecting behaviours, relationships and the subconscious. There are several methods for qualitative data analysis, all of which are ultimately inductive, aiming to create a theory from the available data (Strang, 2000).

Qualitative analysis of patient interviews will therefore provide an insight into their perspectives and the meanings attributed to living through the terminal phases of cancer. This additional dimension complements and enhances the comprehensive understanding of the global distress experience.

In 2003, Clark (Clark, 2003) made recommendations regarding end of life research, specifically suggesting the use of qualitative methods to research this area. The concept of longitudinal qualitative research is relatively recent and is considered to be effective in demonstrating changing perspectives over time (Murray and Sheikh, 2006). The evidence for the advantages relating to serial interviews is discussed in the literature review section 2.6.6.
3.2.4

Combining Quantitative and Qualitative Methodologies

In the simplest terms: “Deductive (quantitative) researchers hope to find data to match a theory; inductive (qualitative) researchers hope to find a theory that explains their data” (LeCompte and Preissle, 1993).

Qualitative and quantitative methodologies have evolved from fundamentally diverse epistemological positions in their underlying traditions. Belonging to such distinct paradigms, on-going intense debate about the core philosophies of each tradition has resulted in the historic polarization of these methodologies.

Purists would argue that qualitative and quantitative research strategies are mutually exclusive, fundamentally dichotomous. However more recently, the inherent advantages of combining these research strategies in specific circumstances, has become apparent and largely well accepted (Tashakorri and Teddlie, 1998) (Kissane and Street, 2004) (Pope and Mays) (Strang, 2000) (Casebeer and Verhoef, 1997) (Kelle, 2001). These specific circumstances include aspects of health care research.

Combining methods adds the obvious advantage of enhancing the depth of the research, as each method brings inherent epistemological and theoretical assumptions (Kelle, 2001), resulting in systematic distortion if used alone (Maxwell, 1998). Validity may be improved if data from the different sources is confirmatory (Casebeer and Verhoef, 1997).

Advantage may in fact, be gained from comparing the results originating from the dichotomous standpoints, in order to inform each other in research development and complement each other by adding information that may otherwise be omitted (Casebeer and Verhoef, 1997).

Conversely, on comparison, the qualitative and quantitative data may be contradictory. Conflicting perspectives may facilitate the development of new ideas, approaches and thought (Casebeer and Verhoef, 1997).
Hence, there are many evident advantages to combining qualitative and quantitative methodologies. With respect to this particular study, the incorporation of mixed methodologies is clearly justified. The study has broad aims with both, confirmatory and exploratory elements requiring deductive and inductive approaches to analysis, respectively.

The study aims to explore a complete, evolving concept; global distress over the terminal phases of cancer. The challenge becomes apparent when the numerous components (each with individual predictors, patterns and outcomes) are separated: The physical, psychological, social and spiritual domains of distress, global distress itself, medical factors, demographic factors, drug use and service input. Additionally, each component is considered over a period of time.

In order to produce information that may be generalized and easily manipulated, these components must be quantified for meaningful comparison. In order to gain valuable insight into the lived experience of each of these components of distress during the terminal phases of cancer, patients’ perspectives must be sought and qualitatively analysed.

Therefore, both qualitative and quantitative data is essential, in order to provide a complete, multidimensional answer to the question: *How do global distress and its components evolve over the final phase of the cancer disease trajectory, from the time patients are referred to palliative home care services to time of death?*

### 3.3

**Population**

#### 3.3.1

**Identification**

The study was conducted at Strathcarron Hospice in Denny, Stirlingshire. The hospice serves the Forth Valley. The catchment area is large and includes a diverse
population ranging from the busy urban towns of Falkirk, Stirling and Cumbernauld, to the sparsely populated rural areas surrounding Loch Lomond and Lanarkshire. Referral to the hospice home care service requires a completed proforma, irrespective of referral source. Sources include GP, oncologist, clinical nurse specialist and hospital palliative care team.

All referral proformas are initially reviewed by the consultants. Appropriate referrals are then distributed to the community clinical nurse specialists (Ccns), according to locality. Patients with advanced cancer were identified once their proforma had been reviewed and accepted by the consultants.

3.4
Quantitative Study Methods

3.4.1 Recruitment
Every patient with advanced cancer was identified and noted. A patient information sheet regarding the research was sealed in an envelope and placed inside the case notes of every patient with advanced cancer, prior to distribution to the Ccns. The Ccns were asked to present the research information envelopes to their new patients. They were given the following guideline to assist with and standardise their explanation.

Explanation Of Research Information Sheet
- A doctor at the hospice is doing the study
- The study is about how different people cope with illness
- It is to try to understand why it is easier for some people and harder for others
- You will only be asked about your personal experiences and it just involves talking
- You do not have to discuss anything you do not feel like talking about
- Have a read of the information at your leisure over the next couple of days
The Ccns were asked to give the envelope at the end of their first visit to every new patient, unless obviously ineligible.

**Obvious Ineligibility Guideline For Community Clinical Nurse Specialists:**
“The research information envelope should be given to every patient, except those evidently extremely medically unwell and actively dying, at the time of the first visit. These patients are obviously ineligible from the outset.”

The Ccns were asked to present the research information to all of their new patients with advanced cancer, except those “obviously ineligible from the outset” for the following reasons:

1. To prevent well-intentioned gate-keeping of potentially eligible and willing patients.
2. To absolve the Ccns from any responsibility for prognostication and application of inclusion and exclusion criteria.
3. To ensure standardisation and avoid introduction of potential recruitment bias.

It became quickly apparent that it was not appropriate to give the research information envelope to every patient at the end of the first visit. There were several reasons for this, but the major concern was that distressed patients in particular, would be omitted. Such patients were either too distressed at the first visit to contemplate the research, or the Ccns considered asking distressed patients after an initial visit to be ethically inappropriate. It was therefore agreed that in exceptional circumstances, research information could be given to patients up to one month after referral. Most Ccns initially visit patients fortnightly.

This was a slight compromise in recruiting patients at the time of referral to palliative care services but was considered acceptable in order to avoid inadvertent and unnecessary exclusion of potentially distressed patients.
The Ccns’ role in recruitment was therefore to simply present the research information with a brief explanation to their new patients with advanced cancer. They were specifically asked to avoid engaging in detailed conversation regarding the research. The reasons for this included:

1. The ease of distribution of the research information for the Ccns was a primary concern, as their involvement was fundamental. An important prerequisite of information distribution was therefore, that it should not add any time onto a patient visit.
2. Discussing the research with patients may have been considered to compromise the Ccns’ role.
3. The Ccns’ personal perspectives on the research may have introduced recruitment bias.

The research information sheet (see Appendix B) explained to patients that they would be contacted by the Research Doctor (RD) within approximately 48 hours. They were asked to contact their Ccn if they did not wish the RD to make contact. They were also advised that allowing the RD to make contact would not result in obligation or pressure to participate.

The RD personally contacted all of the patients, except those who had declined contact through their Ccn. The Ccns’ provided regular updates for the RD regarding the patients they had given information sheets to each day. Patients were telephoned approximately 72 hours after they had received the research information. Calls were initially made within 48 hours, however this time period was extended for the following reasons:

1. Many patients had not had the opportunity to read the information within 48 hours.
2. Patients often wanted time to consider the implications of participation and to discuss this with family members, who were also provided with written information (see Appendix C).
3. In view of the above reasons, it was important to extend the time period, in order to avoid refusal on the basis of pressure due to inadequate opportunity for contemplation.

During this phone call, the RD asked initially whether patients had read the research information. Following this, patients were asked if they were interested in participating. Any questions regarding involvement were answered. For those who refused without explanation, a reason was sought, if considered appropriate, within the context of the conversation.

**Sampling**
Recruitment was consecutive. For those who were willing to participate, a date was agreed for the RD to visit. The first visit was usually within 1 week of this initial contact, in order to accurately evaluate the time of referral as closely as possible. The first visits were arranged in the order, according to which the RD had made the initial contact by telephone.

**3.4.2 Consent**
During the first visit any further questions were answered and those patients selected for interview were informed of this, prior to obtaining written consent (see Appendix D) from the patient and any carer wishing to remain present and potentially contribute (see Appendix E). Subsequently, socio-demographic and medical details were collected and finally, the regular visit data (assessment tools/interview) was completed. Details of this data follow.

On completion of the first visit, written information was sent to the GP (see Appendix F), Ccn (see Appendix G) and Hospice Consultant (see Appendix H) regarding participation of their patient in the research. Contact details for the RD were provided, in order to facilitate any necessary communication. A red label was attached to the front of the patient’s Hospice case notes for ease of identification and
to provide a reminder for the healthcare professionals involved to contact the RD with change of circumstances, such as death or admission of the patient.

Patients were consecutively recruited in this way until 100 participants had consented. This took precisely 9 months from 16\textsuperscript{th} March 2005 to 16\textsuperscript{th} December 2005.

3.4.3
Sample Size Calculation
100 patients in total would provide 80\% power to detect an absolute difference of 28\% in the comparison of proportions distressed in equally sized subgroups of patients (e.g. men 20\% vs women 48\%), with a false positive rate (alpha) of 5\%.

Recruitment was intended to be generally inclusive.

3.4.4
Inclusion Criteria
All patients newly referred to the Strathcarron Hospice home care service with a diagnosis of advanced cancer were eligible for the study. An interpreter was appointed in order to include those who did not speak English.

3.4.5
Exclusion Criteria
Patients with an estimated life expectancy of less than 3 months and those with significant cognitive impairment, learning difficulties or mental health problems were excluded from the study.

The reason for excluding those with a life expectancy of less than 3 months was to limit the number of patients for whom there would be potentially only one set of data. Thus, in order to maximise the potential for a rich longitudinal data yield, the 3-month cut off was agreed. As discussed in the introduction, prognostication can be
extremely difficult in this patient population, the 3-month cut off was therefore chosen as an approximate guideline.

Patients with cognitive impairment and learning difficulties were excluded, in order to maintain standards of both ethics and validity. Firstly, with respect to ethics, obtaining genuinely informed consent from patients with limited capacity would be impossible. Secondly, yet importantly, to extensively question such patients regarding every aspect of their disease experience would also be considered unethical. Additionally, any answers provided by such patients may not be credibly reproducible.

The reasons for excluding patients with mental health problems included ethics and reliability. Although consent from such patients would be valid, these patients may be psychologically unstable. The potentially detrimental effect of extensively and repeatedly questioning such patients about each aspect of their disease experience is evident, therefore, doing so would be considered unethical.

The secondary issue regarding patients with mental health problems is that of consistency. To expect psychologically unstable patients to reliably and consistently complete assessments over a period of time would be unrealistic. One of the unique strengths of this study is the potential to acquire rich, longitudinal data, which would be compromised by recruiting patients for whom giving reliable data could be an inherent problem.

3.4.6
Losses and Non-Participation
Losses were expected in this study, which aimed to follow terminally ill patients to death. Anticipated losses were calculated according to previous hospice statistics and accounted for in the analysis plan.

The Local Research Ethics Committee ruled that data relating to those refusing to participate should not be collected. Therefore, for necessary comparison and
validation of the participating group, the tumour type, age and reason for not participating, if given, were documented.

3.5 Data

This section describes the data collected for each study participant. The social factors and medical history were collected at the first visit only. The remaining data were collected at each visit.

Medical Factors
Medical History
- Tumour type
- Past medical history
  - Physical illness
  - Depression
  - Anxiety
  - Other psychiatric

Drug Use
Drugs documented:

Opiates
Anxiolytics
Anti-Depressants
Sedatives

- Drug requirement
- Drug dose
- Drug dose escalation
- Drug induced toxicity
- Length of drug use
In addition, use of:

- Neuropathic drugs
- Alternative/Complementary therapy
- Syringe Driver
  - Drugs used
  - Drug dose
  - Duration of use

**Health Service Attendance**

- Hospice day care service
- Chemotherapy
- Psychiatric service

**Healthcare Professional Attendance**

- Social service carers
- District nurses
- Marie Curie carers
- Private carers

**Healthcare Professional Contact**

Documented individually for: GP, GP out of hours service, Hospice Ccns and District Nurse

- Number of phone calls made from patient
- Number of visits to patient

**Admissions**

- Place
- Length of stay
- Frequency
Social Factors

Demographics
- Age
- Sex
- Religion
- Ethnicity
- Deprivation Category (DEPCAT)*

Personal
- Financial concerns
- Previous bereavement problem

Adequacy of Information Communication From
- Oncologist
- Oncology nurses
- GP

Family
- Marital Status
- Living situation (housing occupants)
- Family medical status
  - Physical health
  - Psychiatric health
- Family medical history
  - Physical
  - Psychiatric
- Significant dysfunction

Carer Details
- Relationship to patient
- Living situation
- Age
- Sex
- Health

**Distress status**
Assessed using validated research tools:

- Symptom Distress
- Performance Status
- Psychological Distress
- Spiritual Distress
- Global Distress

### 3.6 Assessment Tools

The assessment tools used in this study were carefully selected on the basis of:

- Validity and reliability in the terminally ill study population
- Brevity

Kelly et al. (Kelly et al. 2006) suggest that we must “balance the need to retrieve reliable data [in order to answer the research question, whilst simultaneously] minimising patient burden and maintaining the highest standards of ethical research conduct.” These principals were applied.

Careful consideration was given to the special circumstances of the study in which a population of terminally ill patients required to be assessed repeatedly until their time of death. Patients were expected to become easily fatigued, more so over time and therefore, the decision was made that completion of full patient assessment should take no longer than 30 minutes. Additionally, in order to minimise patient fatigue and to maximise both efficiency and collection of compete data, all assessment tools were read to patients.
3.6.1
Social Distress

Deprivation Category
Following a significant Scottish national survey, in 1991 Carstairs and Morris (Carstairs, 1991) published an index of Deprivation Category by postcode in Scotland. Each postcode is assigned a Deprivation Category (DEPCAT), according to the relative affluence of the population residing within it. In total there are 7 deprivation categories, DEPCAT 1 indicating the areas of highest affluence and 7 the least.

This index has become the standard in Scotland for defining social status simply and numerically.

Social Adjustment Scales
Several tools have been validated as measures of social adjustment. The Modified Social Adjustment Scale (SAS-M) is a 42 item scale that is most useful in measuring social adjustment during an intervention (Kissane and Street, 2004). This has been evaluated amongst women undergoing sterilisation, by Cooper et al. (Cooper et al. 1982). Their study considered the SAS-M to be sensitive and possibly useful in psychiatric research where interview was not feasible. With 42 items requiring a 5-point response, the SAS-M was considered too lengthy to be included in a battery of assessment tools designed to evaluate patients with advanced cancer until their death.

Similarly, the Psychological Adjustment to Illness Scale (PAIS) has 46 items each requiring a 4 point response and takes a total of 20-30 minutes to complete. Although this is a very comprehensive measure evaluating seven domains (healthcare, work environment, domestic environment, sexual relationships, extended family relationships, social and leisure environment and psychological distress), in addition to the time required for completion, its validity is considered only as “acceptable” amongst cancer patients (Derogatis, 1986) (Kissane and Street, 2004). Therefore, this tool was considered inappropriate for inclusion in the current study.
Also considered, but dismissed as too lengthy for use in this study, was the Interpersonal Support Evaluation List (Kissane and Street, 2004) which includes 40 items assessing perception of support, self-esteem and sense of belonging. Scales specific to family support, the Family Environment Scale and the Family Assessment Device, were excluded, as they relate to only one aspect of social functioning.

In summary, validated research tools for social adjustment were carefully considered for inclusion in the evaluation of total patient distress in this study. However, all of these tools are individually lengthy and would significantly prolong the time taken for patient assessment. In view of the expected poor condition of cancer patients approaching death, such a protracted assessment was considered inappropriate. Additionally, detailed socio-demographic data, together with in depth interviews, was thought to provide adequate information regarding social adjustment.

Therefore, in terms of quantification, the evaluation of the social domain of distress in this study was determined by the DEPCAT, which was used as the surrogate for social status.

3.6.2 Physical Distress

*Memorial Symptom Assessment Scale-Short Form (MSAS)*

See Appendix I

This symptom assessment scale was developed at the Memorial Sloan-Kettering Cancer Center in New York, as a measure of the prevalence and characteristics of the physical and psychological symptoms experienced by cancer patients (Portenoy et al. 1994). The scale refers to symptoms experienced by patients in the previous 7 days. The MSAS evaluates 32 symptoms 3 dimensionally, using separate 4 or 5 point Likert scales for:
- Severity of symptom
- Frequency of symptom occurrence
- Distress induced by the symptom

Therefore symptom severity, frequency and distress may be measured independently. In addition, specific physical, psychological and global distress subscales have been derived by grouping relevant symptoms.

The MSAS and its subscales have been validated as reliable measures of symptom prevalence, characteristics and distress amongst patients with cancer (Portenoy et al. 1994) (Chang et al. 2000).

The MSAS was chosen for several reasons. Comprehensive evaluation of symptoms is assured, due to the multidimensional assessment (see previous). Additionally, the assessment is time efficient; the simplicity of the Likert scales facilitates ease of completion by patients. Thus, the prevalence and characteristics of numerous symptoms are easily documented. The analysis of this information then allows the independent, detailed evaluation of each symptom, each symptom characteristic and the distress associated.

**The Rotterdam Symptom Checklist (RSC)**

The Rotterdam Symptom Checklist (RSC) was also considered. The RSC is well validated and reliable (de Haes et al. 1990). However, symptoms are evaluated according to distress alone. Although symptom distress was the main determinant in this study, the additional facets of the MSAS provide a more detailed understanding of patients’ experience of symptoms.

**The Symptom Distress Scale (SDS)**

The Symptom Distress Scale (SDS) (McCorkle and Young, 1978) was also evaluated for use in this study as the surrogate for physical distress. This scale was developed on the basis of symptoms concerning patients attending medical and oncology out-
patient clinics. Ten items were identified and tested on 53 patients, 45 of whom had cancer.

This scale includes 10 physical symptoms, each of which are rated on Likert Scales, ranging from 1-5 (least to most) distress. This scale is uni-dimensional and measures only 10 symptoms. In addition, patients are asked to rate their symptoms from “not having the symptom at all”, to the symptom being “the worst it could be”. Therefore, it is unclear as whether or not the SDS is in fact discriminatory as a measure of the symptom related “distress”, or more a measure of symptom severity. For these reasons, the SDS was not considered to be adequately powerful or discriminatory as a measure of symptom distress amongst terminally ill patients with cancer in this study.

Therefore, the evaluation of the physical domain of distress in this study was done according to the MSAS, which was used as the surrogate for physical symptom distress.

3.6.3 Psychological Distress

The Edinburgh Depression Scale (EDS)
See Appendix J

The Edinburgh Postnatal Depression Scale was developed by Cox et al. (Cox et al. 1987) as a method of assessing postnatal women. They originally validated the tool in a study of 84 postnatal mothers, proving satisfactory sensitivity and specificity. Additionally, the scale appeared to be sensitive to change in severity of depression over time. The tool was also found to be predictive of depression severity in a large community study of postnatal women (Carothers and Murray, 1990). In 1996 Cox et al. (Cox et al. 1996) validated the scale in non-postnatal mothers, again finding satisfactory sensitivity and specificity. They proposed the tool should be called the Edinburgh Depression Scale when used in community settings.
The scale refers to the data from the previous week and has 10 items each rated on a 4 point scale. The 10 items were selected from the Hospital Anxiety and Depression Scale, The Irritability, Depression and Anxiety Scale, and the Anxiety and Depression Scale (Lloyd-Williams et al. 2000). The questions do not relate to any somatic symptoms but focus on hopelessness, guilt and notions of self-harm.

Measurement of non-somatic symptoms alone is particularly important when rating depression amongst patients with advanced cancer: Amongst these patients, symptoms resulting from genuine physical debility may be indistinguishable from the somatic symptoms of depression (Endicott, 1984) (Lloyd-Williams et al. 2000). In addition, Endicott (Endicott, 1984) emphasizes the importance of determining suicidal ideation in patients with cancer.

Lloyd-Williams et al. (Lloyd-Williams et al. 2000) have extensively studied the application, acceptability and appropriateness of screening tools for depression in the palliative care population. From these studies, the Edinburgh Depression Scale appears to be well validated in this population. In a study of 100 in-patients receiving palliative care, the EDS was 81% sensitive and 79% specific for detecting cases of depression when a cut off of 13 was used.

The Edinburgh Depression Scale was chosen as the tool to measure severity of depression in this study, due to favourable positive and negative predictive values in this population, detection in change in severity of depression over time and ease of use and brevity.

However, other screening tools were also carefully considered.

**The Hospital Anxiety and Depression Scale (HADS)**

Zigmond and Snaith (Zigmond and Snaith, 1983) devised the 14-item HADS in 1983 as a tool for detecting states of depression and anxiety amongst medical patients. Although somatic symptoms are excluded, the HADS is based on the construct of anhedonia, the inability to derive pleasure from any aspect of life (Lloyd-Williams et
This aspect of depression may be less discriminatory in the palliative care population who potentially experience anhedonia naturally with increasing debility.

In a study (Lloyd-Williams et al. 2001) of 100 patients receiving palliative care, the separate depression and anxiety subscales showed poor screening efficacy when considered alone. In combination and using a cut off of 19, the HADS had 68% sensitivity and 67% specificity in palliative care patients with a prognosis of less than six months.

The HADS therefore not only takes longer to administer, but is also less sensitive and specific for this study population.

**The Beck Depression Inventory (BDI)**

Beck et al. (Beck et al. 1961) validated this 21-item depression inventory for psychiatric patients in 1961. The BDI was assessed amongst 152 cancer patients and found to be useful, although patients with depressive symptoms and major depression were misclassified (Kathol et al. 1990).

The length of inventory, together with the lack of evidence for use in the palliative care population, rendered the BDI a less favourable choice of screening tool for this study.

Although several other screening tools exist, none have been extensively validated in the palliative care population. Therefore, the evaluation of the psychological domain of distress in this study was done according to the Edinburgh Depression Scale, which was used as the surrogate for psychological distress.
3.6.4

Spiritual Distress

The Functional Assessment of Chronic Illness Therapy Spiritual Well-Being; The 12-item Spiritual Well-Being Scale (FACIT-Sp-12)

See Appendix K

FACIT (Cella) is a measurement system for aspects of quality of life amongst patients with chronic illness. The development of this system for cancer patients began in 1987 and was known as the Functional Assessment of Cancer Therapy (FACT). In 1997 the name FACT was changed to FACIT, in order to acknowledge the incorporation of other chronic illnesses.

The FACIT-Sp-12 was designed relatively recently as a research tool to assess the spiritual well being amongst patients with chronic illness. This measure refers to the patients’ experience in the previous week and is a 12 item scale each with 5 possible responses, which are scored. The scores may be totalled or separated into 2 subscales, Meaning/Peace and Faith.

Peterman et al. (Peterman et al. 2002) in America have validated the FACIT-Sp-12 in 2 large, ethnically diverse studies. The first study of 1617 patients, 83.1% of whom had cancer, proved the validity and reliability of the tool amongst this population. Having established this, the second study further validated the FACIT-Sp-12 by examining its relation to existing measures of spirituality. The FACIT-Sp-12 total score and Faith subscales were found to have good concurrent validity with these other measures.

The Meaning/Peace subscale appears to be a good measure of spirituality, based on the face validity of the items in the subscale. Additionally, this subscale appears to measure a concept not assessed by the other measures in the second study, which included the Spiritual Beliefs Inventory and Reker’s Life Attitude Profile-Revised.
Importantly, the unique concept of spirituality assessed by the Meaning/Peace subscale of the FACIT-Sp-12 is not associated with religion. Recent trends indicate a move from organised religion to a more personal spirituality and controversy surrounds the inter-relationship between religion and spirituality (Peterman et al. 2002). Highly spiritual patients may therefore not necessarily relate to religiosity and vice versa. This must be reflected and incorporated into any assessment of existentiality. With well-validated separate subscales for Faith and Meaning/Peace, the FACIT-Sp-12 comprehensively accounts for each dimension of spirituality. The FACIT-Sp-12 was used by McClain et al. (McClain et al. 2003) in their study of the effect of spiritual well being on end-of-life despair in terminally-ill cancer patients which was published in the Lancet. They assessed 160 patients receiving palliative care with a life expectancy of less than 3 months, using tools to measure the following: Spiritual well-being (FACIT-Sp-12), cognition, depression, suicidal ideation, pessimism, hopelessness, desire for hastened death, perceived social support, symptom prevalence, frequency and distress and physical functioning ability.

Amongst the terminally-ill, the FACIT-Sp-12 total score and each subscale score were found to correlate with every outcome variable. Spiritual well-being was found to be a strong correlate of end of life despair, contributing to the prediction of hopelessness, desire for hastened death and suicidal ideation.

The FACIT-Sp-12 was therefore selected for use in this study, as it has been validated and successfully used to measure spirituality amongst both cancer patients and terminally ill patients. It incorporates every dimension of spirituality; it is easy to use and it is brief.

Other tools were considered and discounted:

The Systems of Belief Inventory
This is a 15 item assessment tool that considers aspects of religion and support derived from a religious community. The scale does not account for existential issues
(Holland et al. 1998). As the scale is longer than the FACIT-Sp-12 and covers a smaller dimension of spirituality, it was considered to be less appropriate.

**The Royal Free Spirituality Scale**

This scale has 20 items and is based on a structured interview format, as well as 10-point linear analogue scales. The tool measures spiritual, religious and philosophical beliefs. The scale was designed for use amongst acutely ill medical patients and validated amongst hospital staff, people with devout religious beliefs and patients attending an inner city General Practice (King et al. 1995).

The complexity of its use, and lack of evidence for use amongst cancer patients, precluded the use of the Royal Free Spirituality Scale in this study.

After careful consideration, other measures of spirituality were less favourable and therefore, the evaluation of the spiritual domain of distress in this study was according to the FACIT-Sp-12, which was the surrogate for spiritual distress.

### 3.6.5

**Performance Status**

*The Karnofsky Performance Status Scale (KPS)*

See Appendix L.

In 1948 Karnofsky and Burchenal (Karnofsky and Burchenal, 1949) designed a numerical measure of patient independence in carrying out activities of daily living, The Karofsky Performance Status Scale. The scale has 10 points, scored from 0-100. Each point on the scale has a description of patient functionality from 0 denoting death to 100 indicating normal function. The observer rates the patient according to the description on the scale that best fits the patient’s current functional status.

Since 1948, the scale has been widely used for assessment of patients with cancer, particularly in the evaluation of clinical trials of chemotherapeutic agents. In a study
published in 1980, Yates et al. (Yates et al. 1980) validated the KPS amongst patients with advanced cancer with an expected prognosis of 3 months to 1 year: They found the KPS to be a substantially valid indicator of overall physical status, as well as having a close correlation with deterioration in function. Observer consistency was also noted.

*The Eastern Cooperative Oncology Group Performance Status Scale (ECOG)*

Designed for use amongst cancer patients, the ECOG (Oken et al. 1982) was also considered for use in this study. The ECOG scale is graded from 0-5; 0 indicating normal and 5 denoting death. The categories are therefore larger and less specific than those of the KPS, which has 10 distinct scoring options.

The Karnofsky Performance status was selected for use in this study for the following reasons: It has been validated amongst the palliative care population and it has a wider range of specific user ratings that allow more precise quantification of patient functionality.

**3.6.6 Global Distress**

*The National Comprehensive Cancer Network Distress Thermometer (DT)*  
See Appendix M

This measure was designed by the Distress Management Panel of the American National Comprehensive Cancer Network in 2004 (Holland et al. 2004) as a simple tool to screen for distress amongst ambulatory cancer patients. The thermometer itself is essentially a linear analogue scale on which 0 indicates having experienced no distress and 10 represents extreme distress. Patients are asked to mark the number on the thermometer according to their level of distress in the past week.
The NCCN version of the thermometer has an attached problem list with the following categories: Practical problems, family problems, emotional problems, spiritual/religious concerns and physical problems. There is also an option to add any other problems. This is designed to identify the source of any distress.

The thermometer was used alone, without the additional problem list in this study. The reason for this was that each of the problem list categories were already fully covered by more extensive and independently validated research tools chosen for use in this study (see above). The problem list is an essential component of the DT when used independently as a screening tool for distress. However, in this study the problem list was considered to be superfluous and therefore excluded to avoid both repetition, and the risk of increasing the time burden on the terminally ill patient population.

The thermometer has been well validated in America. Roth et al. (Roth et al. 1998) found it to be acceptable amongst patients with prostate carcinoma where it was successfully compared with the validated HADS. Jacobsen et al. (Jacobsen et al. 2005) found that the DT compared favourably with both the HADS and the Brief Symptom Inventory used at their established cut offs.

In a Japanese study (Akizuki et al. 2003) of 275 patients with cancer, patients completed the DT, along with the HADS. Psychiatrists used the DSM IV criteria to diagnose adjustment disorders and major depression amongst these patients. The DT correlated significantly with the HADS (r=0.71, p<0.01), and was also found to be 84% sensitive and 61% specific for the detection of adjustment disorders and major depression according to DSM IV criteria. This was a cross-sectional study therefore inference regarding causal relationships cannot be made.

Recently, Ransom and colleagues (Ransom et al. 2006) evaluated the operating characteristics of the DT amongst bone marrow transplant patients. Four hundred and ninety one patients completed measures of depression (Center for Epidemiological Studies-Depression Scale, CES-D), anxiety and performance status together with the
Raised DT scores were associated with increased depression, anxiety and lower performance status. ROC curves analyses of the DT scores indicated acceptable overall accuracy when compared with the established cut-off score for the CES-D.

Trask et al. (Trask et al. 2002) studied 50 patients at a consultation to determine whether or not Bone Marrow Transplant would be appropriate prior to consent. Fifty percent scored 5 or greater on the DT indicating distress, 51% were anxious and 20% were depressed, according to the HADS. The anxiety subscale of the HADS correlated significantly with the DT ($r=0.415$, $p<0.05$), although the HADS depression subscale did not. In addition, the HADS anxiety subscale correlated significantly with the DT, even after adjusting for the HADS depression subscale ($r=0.355$, $p<0.02$). Regression analysis revealed that 17.4% of the variability in the DT was accounted for by the HADS, and most of this was attributed to the anxiety component, with depression contributing a negligible amount. The authors therefore suggest that the distress detected by the DT is related more to anxiety than depression. The study sample was small, predominantly male, and taken from a highly specific population, thus limiting the ability to generalise the results. The findings are further limited by the cross-sectional study design.

Hoffman and colleagues (Hoffman et al. 2004) studied 72 ambulatory patients with cancer, although analysis was only conducted on the 68 patients who had complete data. Patients completed the DT, the BSI and the BSI-18. The mean DT score for the sample was 3.99 indicating a low to moderate level of distress for the sample. In contrast to the previous study by Trask et al., which found no correlation between the DT and depression subscale on the HADS, in this study, the DT correlated significantly with the depression subscale of the BSI ($r=0.54$, $p<0.001$), as well as the anxiety subscale ($r=0.68$, $p<0.001$) and the hostility subscale ($r=0.50$, $p<0.001$). There were either weak, or no correlations between the DT and the other subscales of the BSI. ROC curves analyses revealed that the DT has a moderate ability to detect distress identified by the BSI and the BSI-18 (area under curve = 0.74 and 0.80 respectively, and $p<0.001$ and $p<0.01$ respectively). ROC curve analysis also indicated that the DT lacks a single cut off that maximises sensitivity and specificity.
The authors conclude that the significant correlations between the BSI subscales that relate to emotional distress, and the DT, support the validity of the DT. They also suggest, that through the employment of multiple cut offs, the DT would be an effective, rapid screening measure for cancer patients. The evidence from this well-conducted study is helpful, although it is limited by the cross-sectional design and use of a small, primarily Caucasian sample.

In the current study, a cut off score of >5 was used to indicate distress amongst this population of patients with advanced cancer: These patients are expected to be more distressed than the ambulatory cancer population (Zabora et al. 1997) (Carlson and Bultz, 2003b) (Carlson et al. 2004) amongst whom the cut off has been determined and recently reduced to ≥4 (Holland et al. 2004) (Gessler et al. 2007) (Jacobsen et al. 2005) (Ransom et al. 2006). This cut off was chosen for the clinical setting of an ambulatory cancer population, in order to initially capture any potentially distressed patients and then filter out false positives on review. However, there is no specific universally agreed cut off for the distress thermometer (clarified directly through correspondence with Jacobsen and colleagues). Therefore, in the research setting of a population with advanced cancer, a cut off of >5 was taken, in order to provide a reasonable split between those classified as being distressed, versus those who are not.

To date, the DT has only been validated amongst the American ambulatory cancer population. Gessler et al. (Gessler et al. 2007) at University College London have studied the DT amongst cancer patients in England, although this work has not been formally published. A validation study is also in progress in Scotland where the Big Lottery Fund Cancer Distress Management Project in Ayrshire is also evaluating the DT as a screening tool.

The distress thermometer provides a simple and direct quantification of perceived overall, global distress. It was therefore chosen as the surrogate for global distress and hence the primary end point in this study.
3.6.7
Health-Related Quality of Life

Quality of life was not formally quantified in this study. Quality of life has itself has been defined in sociological, psychological and medical contexts and is, in palliative medicine, related to symptom control, physical functioning, psychological well-being, and spiritual and existential issues (Kaasa and Håvard Loge, 2004).

**EORTC QLQ-C15-PAL**

This is a shortened version of the EORTC QLQ-C30, the main health-related quality of life questionnaire used in oncology settings. The shortened version was developed specifically for Palliative care research, using only the appropriate and relevant questions for this population. This is recommended as the core questionnaire for health-related quality of life in palliative medicine (Groenvold et al. 2006).

This questionnaire contains sections relating to performance status, physical symptoms, psychological symptoms and an overall quality of life rating question. In this study, assessment of performance status was quantified using the Karnofsky Performance Status. Physical symptoms were assessed in detail using the Memorial Symptom Assessment Scale, and psychological assessment was done through the Edinburgh Depression Scale. Therefore, the only area on the EORTC QLQ-C15-PAL not covered by the complete assessment in this study, is the self-rating of quality of life question.

Therefore, health-related quality of life is a complex concept in its own right and shares similar components to those of global distress. As these two concepts are inextricably linked, attempting to define the independent contribution of quality of life to distress would be extremely complex and is beyond the scope and intent of this study.

Although this study did not aim to formally quantify health-related quality of life, this concept was qualified through patients’ perspectives in the qualitative study.
3.7
Assessment Content

*Initial Visit*

The initial visit consisted of:

- Clarification of any queries
- Acquisition of written consent
- Documentation of the social and medical factors:
Figure 2: Demographic Data Collection Sheet
**Patient Background**

- **Previous Depression**: Yes
- **Previous Treatment for Depression**: Yes
- **Previous Anxiety**: Yes
- **Previous Treatment for Anxiety**: Yes
- **Previous Psychiatric Illness**
  - **Yes**: Not recorded
  - **No**: Not recorded
- **Previous Significant Physical Illness**
  - **Yes**: Not recorded
  - **No**: Not recorded
- **Current Significant Mental/Physical Illness in Family**
  - **Yes**: Not recorded
  - **No**: Not recorded
- **Previous Bereavement Problems for Patient**
  - **Yes**: Not recorded
  - **No**: Not recorded

**Communication of Information**

- **Received adequate information from Oncology Doctors**
  - **Yes**: Not recorded
  - **No**: Not recorded
- **Received adequate information from Oncology Nurses**
  - **Yes**: Not recorded
  - **No**: Not recorded

**Tumour Type**

<table>
<thead>
<tr>
<th>Location</th>
<th>Lung</th>
<th>Breast</th>
<th>Prostate</th>
<th>Oesophageal</th>
<th>Gastric</th>
<th>Colon</th>
<th>Rectal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pancreas</td>
<td>Bladder</td>
<td>Ovarian</td>
<td>Cervical</td>
<td>Uterine</td>
<td>Testicular</td>
<td>Renal</td>
</tr>
<tr>
<td></td>
<td>Head Neck</td>
<td>Brain</td>
<td>Penile</td>
<td>Vulval</td>
<td>Vulval</td>
<td>Lymphoma</td>
<td>Leukaemia</td>
</tr>
<tr>
<td></td>
<td>Myeloma</td>
<td>Neuroendocrine</td>
<td>Penile</td>
<td>Thyroid</td>
<td>Sarcoma</td>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>
The following data were routinely documented at the initial visit and also at each subsequent visit:

**Distress status**

- Symptom Distress: MSAS
- Performance Status: KPS
- Psychological Distress: EDS
- Spiritual Distress: FACIT-Sp-12
- Global Distress: DT

Drug Use: Documented as below

Service Use: Documented as below
**Figure 4: Drugs Data Collection Sheet**
Figure 5: Service Input Data Collection Sheet
3.8

Assessment Schedule

The assessment schedule was designed to account for:

- Attrition rates for patients referred to the Hospice Community Team
- Disease trajectory

3.8.1

Attrition Rates

*Figures are for death related attrition only*

The attrition rate for patients referred to the Home Care Service was taken from 2002-2003 hospice data. In order to account for any seasonal variations, data were taken for patients admitted between 3 pre-determined intervals:

- July-December 2002
- January-June 2003
- July-December 2003

Table 4 below shows the attrition figures in 30 day intervals over a total period of 7 months. The figures are shown for all patients and also separately for each of the 3 groups defined above. There is very little variation between groups, indicating consistent attrition throughout the year irrespective of time of year of referral.

<table>
<thead>
<tr>
<th>Days</th>
<th>All patients</th>
<th>Jul-Dec 2002</th>
<th>Jan-Jun 2003</th>
<th>Jul-Dec 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>0</td>
<td>881</td>
<td>100</td>
<td>288</td>
<td>100</td>
</tr>
<tr>
<td>30</td>
<td>663</td>
<td>75</td>
<td>218</td>
<td>76</td>
</tr>
<tr>
<td>60</td>
<td>492</td>
<td>56</td>
<td>162</td>
<td>56</td>
</tr>
<tr>
<td>90</td>
<td>387</td>
<td>44</td>
<td>131</td>
<td>45</td>
</tr>
<tr>
<td>120</td>
<td>315</td>
<td>36</td>
<td>103</td>
<td>36</td>
</tr>
<tr>
<td>150</td>
<td>266</td>
<td>30</td>
<td>91</td>
<td>32</td>
</tr>
<tr>
<td>180</td>
<td>224</td>
<td>25</td>
<td>79</td>
<td>27</td>
</tr>
<tr>
<td>210</td>
<td>183</td>
<td>21</td>
<td>66</td>
<td>23</td>
</tr>
</tbody>
</table>

Table 4: Home Care Attrition Rates 2002-2003
Average attrition:

<table>
<thead>
<tr>
<th>Days after referral</th>
<th>% Dead</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>25</td>
</tr>
<tr>
<td>60</td>
<td>44</td>
</tr>
<tr>
<td>90</td>
<td>56</td>
</tr>
<tr>
<td>120</td>
<td>64</td>
</tr>
<tr>
<td>150</td>
<td>70</td>
</tr>
<tr>
<td>180</td>
<td>75</td>
</tr>
<tr>
<td>210</td>
<td>79</td>
</tr>
</tbody>
</table>

Figure 6 below demonstrates how attrition rate slows for those surviving beyond 150 days:

Figure 6: Home Care Patient Attrition Over Time

This would imply that those patients surviving beyond 150 days are more likely to go on to survive longer, as they are likely to have been referred at an earlier stage in their disease trajectory or may be on a slower trajectory.
Disease Trajectory

Prototypal death trajectories have been described for typical deaths from cancer, sudden death, end-organ failure and frailty, as shown in Figure 7 (Glare and Christakis, 2005) (Lunney et al. 2003) (Murray et al. 2005).

The cancer trajectory is considered to be a relatively predictable decline over a period of weeks, months or rarely years. Although the course may be punctuated by the positive or negative effects of oncological treatment, the decline and death ultimately results from cancer-cachexia syndrome and coma precipitated by the underlying tumour (Glare and Christakis, 2005).
Some authors have attempted to clarify the terminology used, defining “Advanced Cancer” as widespread disease retaining some realistic hope of control, as opposed to “Terminal Cancer”; widespread disease with no realistic hope of control. Using this definition, the terminal phase of cancer appears to be approximately 2-4 months (Glare and Christakis, 2005).

As the inclusion criteria for this study was a diagnosis of “advanced cancer”, the point of referral on the trajectory may vary. With the initiation of NHS End of Life Care Programme in 2005, the emphasis on advanced planning of death has encouraged earlier referral to palliative care services. Therefore, despite a diagnosis of advanced cancer, some of the patients in this study will have been referred early in their disease trajectory, prior to their terminal phase.

3.8.3
The Schedule
The assessment schedule was therefore devised taking into account the following:
The attrition rates for referrals to Home Care Services at Strathcarron Hospice, typical disease trajectories and early referral to Home Care Services.

Assessments were therefore planned as follows:

<table>
<thead>
<tr>
<th>Assessment Number</th>
<th>Time from Baseline (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

Patients were reviewed monthly for the first 3 months from the time of referral. Those surviving beyond the 3 months were reviewed for a final assessment at 5 months from referral. A 2-month interval was given prior to the final assessment.
The initial assessments were done monthly, in order to maximise the collection of rich data, prior to the death of those 56% of patients who would have been beginning their terminal phase decline at the time of referral. As shown by the above graph of attrition rates, attrition rate falls from approximately 90 days onwards. Therefore, those patients surviving beyond 3 months in the study were considered to have been referred earlier in their disease trajectory, allowing for a longer interval between final assessments.

Additional Assessments

Patients were assessed in addition to the above schedule, at times considered to be influential in the experience of distress. This included admission to:

- Hospital
- Hospice
- Care Home
3.9
Qualitative Study Methods

3.9.1
Recruitment
A sub-sample of the quantitative study patients was recruited into the qualitative study. The initial recruitment into the quantitative study is described previously. Patients were informed during RD’s initial telephone conversation, if they had been additionally selected for the qualitative study. The procedure for this was also fully explained at this time.

Sampling
Patients were sampled purposively. This is a method of strategically selecting a specified and relevant sample range and is commonly used in qualitative research in which sampling aims to represent diversity and depth, rather than population as a whole (Malterud, 1993).

The sample range is selected according to the research question. The qualitative aspect of this study aimed to identify patients’ perspectives regarding aspects of distress in the terminal phase of cancer. Ultimately, the selection is guided by the Researcher’s own theoretical and empirical logic (Mason, 2002). The categories within the sample should contain characteristics that enable comparisons to be made that will develop and test the research hypothesis. In order to establish a meaningful sample range, it is therefore important to avoid assumptions and bias in selecting a sample to substantiate a preconceived theory.

Sample Matrix
In considering the social phenomenon relating to the end stages of the cancer disease trajectory, the most obvious sampling strategy involved selection according to gender, age, demographics and tumour type:

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Tumour</th>
<th>DEPCAT</th>
<th>Marital Status</th>
<th>Religion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

127
Constant Comparative Technique

The purposive sampling strategy is intended to facilitate inductive reasoning. The generation and testing of theory from data analysis (Mason, 2002). In order to achieve this, sampling must be dynamic and interactive, as opposed to predetermined and rigid. Data generation and data analysis are interdependent. Therefore, although the Researcher’s theoretical and empirical position determines initial sampling, the early analysis of the data informs the on-going sampling, according to the developing theories and explanations.

In their guidelines on developing a sampling frame Miles and Huberman (Miles and Huberman, 1994) suggested that useful data would:

- Identify new leads
- Extend the area of information
- Relate existing elements
- Reinforce and provide more evidence for main trends
- Qualify or refute existing information

Miles and Huberman (Miles and Huberman, 1994) also highlight the importance of 3 specific instances:

- The Representative Case: Is typical and more should be sought
- The Negative Case: Provides limits to the conclusions
- The Discrepant Case: Allows specification of variations in key themes

Therefore, following these guidelines, the sampling frame expanded and developed according to the emerging themes and theories:
<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Tumour</th>
<th>DEPCAT</th>
<th>Marital Status</th>
<th>Religion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>55</td>
<td>Renal</td>
<td>4</td>
<td>Married</td>
<td>Christian</td>
</tr>
<tr>
<td>Female</td>
<td>51</td>
<td>Breast</td>
<td>3</td>
<td>Single</td>
<td>Christian</td>
</tr>
<tr>
<td>Male</td>
<td>24</td>
<td>Testicular</td>
<td>4</td>
<td>Partner</td>
<td>Atheist</td>
</tr>
<tr>
<td>Male</td>
<td>46</td>
<td>Pancreatic</td>
<td>4</td>
<td>Divorced</td>
<td>Christian</td>
</tr>
<tr>
<td>Female</td>
<td>79</td>
<td>Colonic</td>
<td>1</td>
<td>Widowed</td>
<td>Christian</td>
</tr>
<tr>
<td>Male</td>
<td>64</td>
<td>Bladder</td>
<td>1</td>
<td>Divorced</td>
<td>Christian</td>
</tr>
<tr>
<td>Male</td>
<td>82</td>
<td>Colonic</td>
<td>5</td>
<td>Widowed</td>
<td>Christian</td>
</tr>
<tr>
<td>Male</td>
<td>71</td>
<td>Lung</td>
<td>5</td>
<td>Married</td>
<td>Christian</td>
</tr>
<tr>
<td>Female</td>
<td>65</td>
<td>Lung</td>
<td>4</td>
<td>Widowed</td>
<td>Christian</td>
</tr>
<tr>
<td>Male</td>
<td>54</td>
<td>Colon</td>
<td>4</td>
<td>Married</td>
<td>Christian</td>
</tr>
<tr>
<td>Female</td>
<td>78</td>
<td>Tongue</td>
<td>4</td>
<td>Divorced</td>
<td>Christian</td>
</tr>
<tr>
<td>Female</td>
<td>60</td>
<td>Ovary</td>
<td>5</td>
<td>Married</td>
<td>Christian</td>
</tr>
<tr>
<td>Male</td>
<td>74</td>
<td>Prostate</td>
<td>3</td>
<td>Widowed</td>
<td>Christian</td>
</tr>
<tr>
<td>Female</td>
<td>66</td>
<td>Lung</td>
<td>3</td>
<td>Widowed</td>
<td>Christian</td>
</tr>
<tr>
<td>Female</td>
<td>43</td>
<td>Unknown</td>
<td>5</td>
<td>Divorced</td>
<td>Christian</td>
</tr>
<tr>
<td>Female</td>
<td>58</td>
<td>Bronchial</td>
<td>3</td>
<td>Married</td>
<td>Muslim</td>
</tr>
<tr>
<td>Male</td>
<td>65</td>
<td>Oesophagus</td>
<td>4</td>
<td>Divorced</td>
<td>Atheist</td>
</tr>
<tr>
<td>Female</td>
<td>51</td>
<td>Colon</td>
<td>5</td>
<td>Divorced</td>
<td>Atheist</td>
</tr>
<tr>
<td>Male</td>
<td>52</td>
<td>Lung</td>
<td>3</td>
<td>Divorced</td>
<td>Atheist</td>
</tr>
<tr>
<td>Female</td>
<td>57</td>
<td>Melanoma</td>
<td>4</td>
<td>Married</td>
<td>Christian</td>
</tr>
</tbody>
</table>

Table 5: Complete Sample Framework

3.9.2 Sample Size

The size of the sample was initially estimated and finalised according to data generation through constant comparison.

The estimate was based on the total number interviews likely to be generated. The implications of the total number of interviews were:

1. *Data Saturation:* Obtaining sufficient data to minimise the chances of any new themes emerging, even if data collection was to continue further.
2. *Data Management:* Small sample sizes generate large volumes of qualitative data and analysis is labour intensive. This was carefully considered in terms of time management of the entire project. The time taken for qualitative data collection and analysis required to be appropriately proportionate to the time allocated to the overall study.

Although the intricacies of concept of data saturation are disputed, these sample size criteria are widely accepted amongst qualitative researchers (Miles and Huberman, 1994) (Mason, 2002).

The criteria for this study were discussed with experienced qualitative researchers. They considered that 60 interviews would be likely to provide data saturation, whilst generating a manageable amount of data within the specified time constraints.

Attrition figures were used to estimate the number of patients required to generate 60 interviews. Data collection was expected to take place over 9 months. The intention was to collect the majority of the qualitative data earlier within this time period, in order to allow constant comparative sampling. Manageable and necessary monthly recruitment into the qualitative study was therefore also calculated, as shown in Table 6:
Table 6: Monthly Recruitment Calculations

The decision was therefore made to recruit 20 patients in total into the qualitative sub-sample, beginning with a recruitment rate of 6 per month. Ultimately, the number recruited remained at 20, having used constant comparative sampling. A higher number of interviews than expected were generated, resulting in data saturation. See the analysis section for details.
3.9.3
Inclusion Criteria
The previous sampling guidelines were applied to all patients with advanced cancer, newly referred to the Strathcarron Hospice Home Care Team who had agreed to participate in the quantitative study. An interpreter was appointed for those patients who did not speak English.

3.9.4
Exclusion Criteria
These were identical to those detailed above for the quantitative study. In addition, those who chose not to participate in the quantitative study were excluded. The reason for this was that the qualitative study was intended to gather the perspectives of those patients within the quantitative study, with the aim of data comparison. In order to qualify the quantitative data, it was therefore essential that a study population sub-sample was used rather than separate cases.

3.9.5
Losses and Non-Participation
These were managed as explained previously, for the quantitative data. However, any patients refusing to participate in the qualitative study remained eligible for the quantitative study alone, if this was their preference.

3.9.6
Consent
The process of obtaining written consent is documented above. Those participating in the qualitative study additionally consented to audio-recording of interviews and use of their anonymous quotes in the writing of this thesis. Any relatives remaining present through the interviews consented to the same, regardless of whether or not they intended to contribute.
3.10
Data

3.10.1
Grounded Theory and Narrative Approach

Grounded theory was originally introduced and developed by Glaser and Strauss (Glaser and Strauss, 1967), in the 1960s. Their concept is that of inductive research in which the theory is derived from, and grounded in the data. This is established through comparative analysis. Data analysis and data collection are simultaneous, with constant comparison of data informing sampling and leading to the emergence of conceptual categories that will explain the phenomenon under study (Miller and Dingwall, 1997).

In this study, the constant comparative method of analysis was applied according to Glaser and Strauss’s (Glaser and Strauss, 1967) original work, in terms of concurrent data collection and analysis and also saturation. However, the coding stages advocated by Strauss and Corbin (Strauss and Corbin, 1998) were also used.

Purists would argue that combining these processes precludes their definition as “grounded theory”. Since publishing their original work on grounded theory in 1967, Glaser and Strauss have notoriously disagreed on the true meaning of “grounded theory”. Glaser argues that theory should be allowed to emerge from the data, suggesting that the structured, systematic approach advocated by Strauss results in the “forcing” of data into categories.

Although Glaser would deny that Strauss’s extrapolation of the original theory could be defined as grounded theory, it is. Therefore, the analysis of this study may be legitimately considered to be grounded theory, although it combines the basis of the original method with its controversial evolutionary adaptation. The reason for incorporating Strauss’s procedural coding stages into the analysis of this study is to facilitate the justification of the outcomes for the medical audience through a transparent systematic approach. Glaser’s (Glaser, 1992) concept of emergent theory
is difficult to define and defend in this way, as he believes that through constant comparison the theory will emerge by itself.

Therefore, and perhaps despite it appearing incomprehensible to the purist qualitative researcher, this combination of grounded theory methods seems justifiable. In terms of medical research, this is the most appropriate, rigorous and defensible method for comprehensively analysing this specific study data.

3.10.2 Coding
Analysis begins with coding the transcribed interview texts. A code is a textual unit of analysis.

Open Coding
This is the primary stage of the analytical process according to Strauss and Corbin (Strauss and Corbin, 1998). The entire interview text is taken and “fractured” into discrete pieces. These pieces of text may be words, sentences or even paragraphs. The examination of these pieces involves comparing and contrasting them, considering their similarities and differences, both within and between interview texts. This examination is continuous and forms the basis of the constant comparative analysis, as described by Glaser and Strauss (Glaser and Strauss, 1967).

The pieces are selected for their meaning within the context of their relationship to each other and the wider text or overall picture. The coding is done according to a framework derived from the researcher’s theoretical standpoint, from the research questions, as well as from issues arising from earlier analysis of the data itself. The selected data pieces become the “codes” and their meaning is used to identify and develop “concepts”.

The codes are initially used to identify themes within the data. Themes are derived from common characteristics amongst the codes. The themes are then considered for their meaning within the study context, and concepts are then developed from this.
The discrete concepts are distinct in terms of their unique properties or characteristics. According to Strauss and Corbin (Strauss and Corbin, 1998), concepts are the basic units of analysis.

The concepts with similar or related properties can then be grouped into categories. As categories may be broad, due to incorporating a range of concepts, for clarification and organisation, sub-categories are developed.

**Axial Coding**

This is the method of connecting categories and sub-categories. The connections are made through the further analysis of meaning and context.

Strauss and Corbin (Strauss and Corbin, 1998) describe organisational schemes as “paradigms” in which a phenomenon is considered according to context, condition and consequences. Therefore, consideration is given to the reasons for the occurrence of the phenomenon, the conditions present at this time, along with the consequences leading to a specific result.

As axial coding proceeds, patterns in the data become apparent and it is possible to tentatively generate hypotheses about the relationships between phenomena. These are then tested against the rest of the data to ensure they are robust. In addition to seeking confirmation of these hypotheses, variations and contradictions are also considered. This either negates the hypothesis, if evidence is insufficient or adds depth of understanding (Strauss and Corbin, 1998).

Although open coding and axial coding are distinct processes, they are often simultaneous. The Axial coding process ensures a systematic approach to analysis.

**Selective Coding**

This is the final phase of coding, according to Strauss and Corbin (Strauss and Corbin, 1998). During this phase, one or two categories are identified as the core categories, to which all of the remaining categories and sub-categories relate. This forms a conceptual framework from which the final grounded theory is developed.
3.10.3
Data Collection
The data were collected by the RD, in the form of patient narratives, from audio-recorded in-depth interviews.

The interviews were conducted as informal conversations, in order to facilitate patient relaxation and open dialogue. This was achieved by using a discrete digital recorder, which was left on a table or nearby chair. Patients were therefore neither distracted nor intimidated by the recorder. Additionally, the RD did not take any notes during the interviews and tidied away paperwork, in order to appear relaxed and informal, so that the patient would reciprocate this. Field notes were written up afterwards and included comments on issues peripheral, yet relevant to the interviews.

The interviews were not formally structured. Interviews began with an open question and patients were encouraged to lead the conversation, which was followed through with further open questions.

Nonetheless, the interviews were required to cover specific areas. The RD was aware of this and had an unwritten check-list of essential questions. Although the patients led the conversation, the RD guided it to ensure that each topic area had been sufficiently discussed.

3.11
Assessment Content
The check-list memorised by the RD was as follows:

Tell me the story so far
What is troubling you the most?
Physical elements
- Pain
- Specific physical symptoms
• Mobility
• Activities of Daily Living

Psychological elements
• Frame of mind
• Mood/Emotions
• Specific anxieties
• Understanding of disease/prognosis/symptoms

Social elements
• Family: members/cohesion/concerns/support/understanding of disease
• Finances/Housing/Employment
• Feelings towards Health Care Professionals
• Ability to communicate thoughts and feelings

Spiritual elements
• Control
• Faith issues
• Sense of purpose/meaning
• Fear of Death/Beliefs surrounding death
• Normality

What has been helpful?

GP
• Information (adequacy, nature)
• GP Support
• Support of District Nurses

Hospice
• Information (adequacy, nature)
  o Support
  o Services used

Hospital
• Oncology Dr input
  o Information (nature, adequacy)
  o Communication of diagnosis/prognosis
• Oncology Nurses input
**Interview Timing**

Interviews were conducted after the quantitative data collection was complete. The reasons for this were:

- To standardise the process of quantitative data collection. Asking patients the assessment tool questions prior to interview ensured that the interviews did not influence answers amongst patients in the qualitative study.

- To use the assessment tool questions as a framework for discussion points and as an initial reminder of specific issues for both, patients and for the RD to refer back to during interview.

- To minimise the effects of fatigue. The numerous, complex and detailed questions of the assessment tools were asked first, whilst patients were most alert. This was to maximise the potential for complete quantitative data collection. The open and unstructured interview followed, accepting that length, detail and content would be dependent on level of fatigue.

- To encourage relaxed conversation without the pressures of pending tasks, once the patients had become comfortable with discussing similar issues with the RD through the assessment tool questions.

### 3.12 Assessment Schedule

The in-depth interviews were done after the assessment tools at each review, including additional assessments. The assessment schedule is described in detail in the quantitative methods section.
ETHICS
4.1 Ethical Approval

The study was reviewed and approved by the Fife and Forth Valley Local Research Ethics Committee in January 2005, following 4 minor protocol amendments. See Appendix N.

4.2 Palliative Medicine Research Ethics

Research ethics in palliative medicine have long been a contentious issue. Patients dying as a result of terminal disease are considered to be a particularly vulnerable group, worthy of special consideration. The ethical uniqueness of research amongst the palliative care population has been keenly debated. Casarett and Karlawish (Casarett and Karlawish, 2000) considered 4 arguments proffered, as confirming this unique status:

1. Dying patients are especially vulnerable
2. Adequate informed consent may be difficult to obtain
3. Balancing clinical and research roles is particularly difficult
4. The risks and benefits of palliative research are difficult to assess

The authors concluded that the first 3 arguments were weak, as they are not unique to palliative care research and these issues have been previously successfully addressed in other areas of research. The fourth argument was considered to be relevant, but not insurmountable. This has been affirmed in other literature.

Vulnerability

The reasons given for vulnerability at the end of life, include (MacDonald and Weijer, 2004):

- Increased risk of adverse effects of experimental treatment
- Temporary, intermittent or permanent inability to make informed decisions
- Undue dependence on others
- Desperate situation with consequent willingness to participate in trials with low probability of success

As a vulnerable group, the palliative care population are considered to be incapable of protecting their own interests because they lack decision making capacity or their choices are not voluntary (Casarett and Karlawish, 2000).

The issue of vulnerability is challenged by the ethical tenets of justice and autonomy. Stevens et al. (Stevens et al. 2003) interviewed the Chairperson and Vice-Chairperson of each Multi-centre Research Ethics Committee throughout England, Wales and Scotland, to ascertain their attitudes to palliative medicine research. They concluded that in the interests of justice, patients should be entitled to make their own decision regarding their involvement in research, as participation may in fact prove beneficial. In their response to an article against palliative care research, Mount et al. (Mount et al. 1995) expressed concerns that exclusion of these patients under the auspices of protection is “paternalistic, demeaning and disrespectful”. Depriving these patients of the choice to participate, devalues their personhood by implying they are unable to contribute to society, seek purpose and meaning and realise any altruistic motives. In a review article, Fine (Fine, 2003) agrees with this, suggesting that if subjects are protected through normally accepted and ethically sound methods, then exclusion of patients with far advanced disease from research is “in itself unethical”.

MacDonald and Weijer (MacDonald and Weijer, 2004) conclude that 2 criteria must be met, in order to include vulnerable patients in research:

1. The research is directly relevant to their medical condition and provides the opportunity of medical benefit to the participant directly, or the opportunity to advance knowledge for the group of patients to which the participant belongs.
2. Recognising the risk of increased vulnerability, safeguards should be in place.
Informed Consent

Although informed consent is not an issue unique to Palliative Care research, it is especially relevant. As well as providing the patient with sufficient, clear information, the Researcher is responsible for ensuring that appropriate safeguards exist within the consenting process (Kristjanson and Coyle, 2004). Specifically, careful consideration must be given to (MacDonald and Weijer, 2004):

1. *Cognitive Ability:* Patients may be cognitively compromised permanently, intermittently or temporarily through disease or delirium. Patients must have capacity to provide informed consent.
2. *Unrealistic Patient Expectations:* Therefore showing to willingness to participate through a sense of desperation.
3. *Patients Sense of Gratitude:* Therefore feeling compelled to consent, or doing so due to concern that care may be compromised.
4. *Longitudinal Studies:* These may require review and repetition of consent as progression through the terminal phase of illness will alter circumstances.

Dissonance between Research and Clinical Roles

Again, this debate is not unique to research in Palliative Care. Throughout clinical research, in their Research role, healthcare providers must balance their competing responsibilities of patient care and scientific rigour (Casarett and Karlawish, 2000) (MacDonald and Weijer, 2004) (Jubb, 2002). However, due to the holistic nature of palliative care, it is conceivable that the more diverse issues may be raised through research with more potentially far-reaching implications; researchers are particularly likely to discover unrecognised or inadequately controlled symptoms. This potential problem may be prevented by prior consideration, delivered through protocol guidance. The solution is often to instigate an independent review by the appropriate healthcare professional(s) (Casarett and Karlawish, 2000) (Jubb, 2002). In addition, the researcher should not be involved in the medical care of the participant. This
would also minimise the risk of patients agreeing to participation as repayment for gratefully received care (Kristjanson and Coyle, 2004).

**Difficulties in Assessment of Research Risks and Benefits**

The Declaration of Helsinki states that “research should not be carried out unless the importance of the objective is in proportion to the inherent risk to the subject” (The World Medical Association, 1989).

Although patients in palliative care services are at different points in their disease trajectories, it is generally accepted that this population is dying. As a result, the standard measures of research success, such as survival rates or disease remission are rendered irrelevant. Assessment of the potential benefits of research against the risks amongst this population is therefore inherently difficult and unique to this situation.

In order to best resolve the risk versus benefit debate, MacDonald and Weijer (MacDonald and Weijer, 2004) recommend addressing the following, even when patients’ competence is assured:

- Will participation in research compromise patient well-being which is the first priority?
- Would research participation have reasonable potential to improve the patient’s situation with minimal associated risk?
- If participation is associated with appreciable risks, are these easily identifiable at the earliest possible stage and will adequate opportunity be provided for renegotiation of continuing patient participation.

4.3

**Qualitative Research Ethics**

Further specific consideration must be given to qualitative research methodologies. The risks relating to qualitative research are more difficult to quantify. Exploring patients’ perspectives of disease with them may result in greater self-awareness, and
may potentially release, uncover or heighten emotions. Discussion may include potentially distressing issues, not normally discussed by healthcare professionals, as little practical help can be offered (Hopkinson et al. 2005). The psychological impact of such interaction is not fully understood (Wilkie, 1997), although this can be minimised by appropriate use of communication skills, combined with sensitive and empathic interviewing. An interviewer with a clinical background in particular, was found to be especially beneficial in Barnett’s study (Barnett, 2001) of interviewing terminally ill patients.

The skills of the interviewer are particularly important amongst this vulnerable population. Wilkie (Wilkie, 1997) describes the issue of inexperienced researchers inadvertently providing false hope, raising expectations by questions asked and management of those answered. Again, dependent on the individual, this may be avoided by an experienced clinical researcher with appropriate knowledge (Barnett, 2001).

Wilkie (Wilkie, 1997) raises the issue of intrusion. Research participants are asked personal, probing questions in interviews, often regarding their innermost feelings. For some this may be disconcerting. However, the research may also be welcomed, if seen as the first opportunity for patients to express their feelings and reflect upon them, resulting in a therapeutic effect (Wilkie, 1997) (Kristjanson and Coyle, 2004). This is substantiated in Barnett’s (Barnett, 2001) study, in which a number of patients reported that an interview regarding their experience of medical care allowed them to express their feelings and was in fact therapeutic.

In another study, Emanuel et al. (Emanuel et al. 2004) assessed whether interviewing terminally ill patients and their caregivers was stressful or helpful. Of the 988 interviewed, 16.9% of patients considered the first interview to be “very helpful” with 14% finding the second interview “very helpful”. Only 1.9% of patients experienced “a great deal” of stress from the first interview and 3.1% from the second. Those significantly more likely to find the interview helpful, were of ethnic minority, had more personal meaning in dying and were more spiritual and
serene. Conversely, those experiencing more pain, were more likely to report stress and were less comfortable with taking about the end of life and more anxious about it.

The therapeutic effects of qualitative research are well documented and therefore the potential for the blurring of boundaries between research and therapy is evident. The role of the researcher is not to provide therapy. The researcher must consider the implications of this and possible alternatives for the patient, both over the study period, and at the time of completion (Kristjanson and Coyle, 2004) (Wilkie, 1997).

On the whole, terminally ill patients appear to be generally keen and willing to participate in research for altruistic reasons and may even be grateful for the opportunity (Kristjanson and Coyle, 2004) (Dobratz, 2003) (Terry et al. 2006) (Barnett, 2001).

4.4 Study Ethics

This study has adhered to the general ethical principles for research on patients, defined by the World Medical Association in the Declaration of Helsinki (The World Medical Association, 1989).

Patient confidentiality was protected and all patient data were stored anonymously and securely, in keeping with The Data Protection Act 1998. All study material was fully anonymised immediately. For the quantitative study, patients were assigned a number and for the qualitative analysis pseudonyms were chosen. The Researcher only knew the numbers and pseudonyms and these were kept completely confidential. The numbers were used on all documentation and as an identifier on the digital audio recordings. Written documents were stored in a locked filing cabinet in the Researcher's office that was locked when not in use. The Researcher alone held the keys to the filing cabinet and office. During the study, data were stored on the Researcher's password protected laptop. All information was stored anonymously in
the laptop. The laptop was never left unattended and when not in use, it was stored securely.

Once the study was completed including all associated publications, all of the data were stored in locked boxes. These boxes are marked as confidential and will be kept in the Hospice medical record office for 5 years. Following this, they will be destroyed. Data will be deleted from the laptop at this time.

With respect to the specific ethical issues raised as important in Palliative Care Research by Casarett and Karlawish:

**Vulnerability**

As described above, MacDonald and Weijer (MacDonald and Weijer, 2004) consider 2 criteria must be met, in order to include vulnerable patients in research:

1. The research is directly relevant to their medical condition and provides the opportunity of medical benefit to the participant directly or the opportunity to advance knowledge for the group of patients to which the participant belongs.
2. Recognising the risk of increased vulnerability, safeguards should be in place.

This study fully satisfies the first, in that it aims to advance knowledge relating to distress amongst the palliative care population.

With regard to safeguards, patient vulnerability was fully accounted for in the design of this study. The tools used in the quantitative study were specifically selected to provide maximum information in minimum time, thus limiting the potential for patient fatigue. The quantitative tools and the qualitative interviews were conducted sensitively by the medically qualified researcher and at a pace dictated by the patient. Interviews were terminated prematurely, if fatigue became evident. In order to reduce time, travel and pressure, interviews were carried out in patient’s own homes.
As one of the historical tenets of medical ethics, even the most vulnerable patients must have their autonomy respected. This study was designed to support autonomy in that the inclusion criteria were purposely very broad. The intention was to be inclusive and minimise potential Ccn gate-keeping. However, if ineligibility was immediately obvious to the Ccn, then leaving the research information would have been inappropriate and unethical. Hence predetermined guidelines on circumstances constituting “obvious ineligibility at the outset” were used, in order to standardise procedure and maintain equity.

Informed Consent

Again, Macdonald and Weijer (MacDonald and Weijer, 2004) suggest that careful consideration must be given to:

1. Cognitive Ability
2. Unrealistic Patient Expectations
3. Patients Sense of Gratitude
4. Longitudinal Studies
5. The principle of the Declaration of Helsinki that states “concern for the interests of the subjects must always prevail over the interests of science and society” (The World Medical Association, 1989).

Prior to discussion regarding consent, patients were given a fully comprehensive information sheet providing an explanation of the research purpose and procedure (see Appendix B). This information was written in clear and simple terms and patients were asked to read it at their leisure. The Researcher then contacted patients by telephone to ascertain their views on participation. Under no circumstances was any attempt made to persuade or coerce those patients who did not wish to participate. The Researcher made an appointment with those patients who were considering participation, at a time and place suitable for the patient. At this time patients were encouraged to ask questions, to which open and honest answers were given. The Researcher used this discussion to ascertain the following:
1. That the patient was not cognitively impaired as this was an exclusion criterion for reasons previously explained.
2. That the patients understood the purpose of the study and their role as a participant. Patients were explicitly informed that their involvement in the study would not alter their disease progress or outcome.
3. That the patients felt no compulsion or obligation to participate in appreciation for care received; care would continue in the same way regardless and the Researcher would not be involved in this.

Those patients who remained agreeable at this stage were only then asked to provide written consent and the Researcher emphasized their freedom to withdraw at any time during the study. Rolling consent is considered essential for this population, in view of the expected deterioration in patient condition over the longitudinal study period. On-going consent was therefore ascertained prior to each assessment, although written consent was only obtained initially.

**Dissonance Between Research and Clinical Roles**

By design, the Researcher was not involved in the medical care of study participants. This precaution was taken for the following reasons:

- To avoid patient participation as a gesture of appreciation for care received.
- Issues of dissonance for the medically qualified Researcher.

The possibility that patients may divulge information regarding symptoms or concerns never previously discussed with a professional was considered. It is unacceptable to compromise patient health, yet it is undesirable to compromise the role and integrity of the Researcher. The appropriate outcome of such situations was reliant upon the communication skills of the Researcher. On occasions, patients were advised to discuss certain issues with a specific professional involved in their care, or the Researcher did so with the patient's permission. Although this situation did not arise, the Researcher had considered the extreme case of a high-risk patient unwilling to seek professional help. The predetermined management of such circumstances
would have been to seek independent advice on the assessment of potential for harm versus the implications of breaching confidentiality.

Consideration was also given to potential problem of patients missing their research involvement and the opportunities within this. The design of the interview schedule was such that patients were unlikely to become reliant upon interaction with the Researcher. Again, although the situation did not arise, the extreme case where termination of the research may be detrimental was considered and would have been managed through input from another health professional.

**Assessment of Research Risks and Benefits**

MacDonald and Weijer (MacDonald and Weijer, 2004) suggest addressing the following even though patient competence is assured:

- Will participation in research compromise patient well-being which is the first priority?

This study did not consist of any experimental treatments, interventions or techniques, therefore physical well-being was not affected. The debate about the potential psychological implications of qualitative research is discussed previously and indicates that the therapeutic benefits generally outweigh the negative features.

- Would research participation have reasonable potential to improve the patient’s situation with minimal associated risk?

Again, the previously discussed therapeutic benefits of qualitative research could be regarded as improving a patient’s situation. The participants in this study were at no physical risk. Psychological risk was carefully assessed and monitored with pre-emptive management guidelines written into the protocol.

- If participation is associated with appreciable risks, are these easily identifiable at the earliest possible stage and will adequate opportunity be provided for renegotiation of continuing patient participation.
The minimal risks are identified above, along with their management plan. The rolling consent procedure described previously provided sufficient and genuine opportunity for patients to withdraw from the study, if preferable.

Ultimately the Researcher always adhered to the universally acknowledged pillars of medical ethics:

- Beneficence
- Non-maleficence
- Justice
- Autonomy
ANALYSIS
5.1
Quantitative Data Analysis

5.1.1
Outcome Measures
Primary: Global Distress

Secondary: Medical Factors
Social Factors
Symptom Distress
Psychological Distress
Spiritual Distress
Performance Status
Patient Perception

5.1.2
Demographics
Strathcarron Hospice provides services within Forth Valley to a population of 300 000. Forth Valley encompasses Clackmannanshire, Falkirk and Stirling. Geographically this area is large covering Killin and Tyndrum in the North and stretching to Strathblane and Bo’ness in the South.

Ethnicity

Forth Valley
The population of Forth Valley is largely White, with less ethnic diversity than Scotland as a whole, as shown in Table 7:
<table>
<thead>
<tr>
<th>ETHNICITY</th>
<th>Scotland</th>
<th></th>
<th>Forth Valley</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>White</td>
<td>4960334</td>
<td>98.9</td>
<td>276300</td>
<td>98.9</td>
</tr>
<tr>
<td>Indian</td>
<td>15037</td>
<td>0.3</td>
<td>344</td>
<td>0.12</td>
</tr>
<tr>
<td>Pakistani</td>
<td>31793</td>
<td>0.63</td>
<td>1125</td>
<td>0.4</td>
</tr>
<tr>
<td>Bangladeshi</td>
<td>1981</td>
<td>0.04</td>
<td>35</td>
<td>0.01</td>
</tr>
<tr>
<td>Other South Asia</td>
<td>6196</td>
<td>0.12</td>
<td>126</td>
<td>0.05</td>
</tr>
<tr>
<td>Chinese</td>
<td>16310</td>
<td>0.32</td>
<td>455</td>
<td>0.16</td>
</tr>
<tr>
<td>Caribbean</td>
<td>1778</td>
<td>0.35</td>
<td>79</td>
<td>0.03</td>
</tr>
<tr>
<td>African</td>
<td>5118</td>
<td>0.1</td>
<td>142</td>
<td>0.05</td>
</tr>
<tr>
<td>Other Black</td>
<td>1129</td>
<td>0.02</td>
<td>35</td>
<td>0.01</td>
</tr>
<tr>
<td>Any Mixed Background</td>
<td>12764</td>
<td>0.25</td>
<td>516</td>
<td>0.18</td>
</tr>
<tr>
<td>Other Ethnic Groups</td>
<td>9571</td>
<td>0.19</td>
<td>323</td>
<td>0.12</td>
</tr>
<tr>
<td>TOTAL</td>
<td>5062011</td>
<td>100</td>
<td>279480</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 7: Ethnicity in Forth Valley Compared With All of Scotland (Source 2001 Census)

**Study Population**

The study population was in keeping with that of Forth Valley as whole. Ninety nine percent of patients were white. One patient was Pakistani, representing 1% of the 100 patients. Although 0.4% of the Forth Valley population is Pakistani, this is the largest ethnic minority group. Therefore, the study population appears to be culturally representative. The religious beliefs of the study population reflect their ethnicity, with 80% of patients Christian and 1% Muslim.

**Affluence**

**Forth Valley**

The mean Deprivation Category (DEPCAT) scores for each of the areas within Forth Valley are:

- Clackmannanshire: 3
- Falkirk: 4
- Stirling: 3

Source: (Carstairs, 1991)
**Study Population**

DEPCAT scores of 1 to 6 were represented amongst the study population. The median score was 4, indicating that the study population was representative of the Forth Valley population in terms of social status. Despite the median score of 4 indicating that this is not an affluent population, only 25% considered themselves to have financial concerns.

**Gender**

An almost equal number of males 51% (n=51) and females 49% (n=49) were recruited into the study.

**Age**

The mean age was 65.4 years, median 67 years with a range of 24-89 years.

![Age Groups](image)

Figure 8: Graph Illustrating Percentage of Patients in Each Age Group

**Personal Circumstances**

Over half of the study population was married. Interestingly a high proportion of this population had been widowed (24%). This may reflect the relatively older mean age of 65.4 years amongst the study population.
The majority of patients (46%) were living with their spouse/partner and a further 14% were also living with their children; the widowers are reflected in the 31% living alone.

The majority of patients (68%) were living with their main carer. A small number did not have a carer (7%).

In general the spouse or partner was the main carer for the patient and was therefore of a similar age, as illustrated by Figure 9:

![Figure 9: Graph Illustrating Relationship Between Patient and Carer Ages](image)

**Tumour Type**

A wide variety of tumour types were represented amongst the study population. The 4 most common tumour sites amongst study patients were compared with the 2002 Scottish statistics and the annual figures for all new cancer referrals to the Strathcarron Hospice home care service from 01/07/2005 to 30/06/06. This time period was taken in order to incorporate a period within which the study was conducted.
The study population appears to be representative: The 4 most common tumours amongst the study population are identical to the 4 most common tumours in the Scotland.

As shown in Table 8 the figures for Strathcarron Hospice are slightly different to those for Scotland as a whole. The percentage of lung tumours is greater amongst the Strathcarron Hospice home care population, whilst there are fewer breast and prostate cancers than in Scotland as a whole.

When compared with figures for Strathcarron Hospice, breast tumours are over-represented in the study population (16% compared with 8%). However, when compared with Scotland as a whole, breast cancer amongst the study population is representative.

Colorectal tumours are over-represented amongst the study population (17%) when compared with the figures for both, newly referred cancer patients to Strathcarron Hospice (13.5%), and Scotland as a whole (13%). Amongst the study population, cancers of the lung and prostate are largely in keeping with the statistics for patients with cancer newly referred to Strathcarron Hospice.

<table>
<thead>
<tr>
<th>Tumour Site</th>
<th>Percentage</th>
<th>Scotland</th>
<th>Strathcarron</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>17</td>
<td>26</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>15</td>
<td>8</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Colorectal</td>
<td>13</td>
<td>13.5</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Prostate</td>
<td>12</td>
<td>6</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

Table 8: Comparison Of Most Common Tumour Types in Scotland, Strathcarron Hospice and The Study Population
5.1.3
Baseline Medical Data

Opioid Use
Forty five percent of patients were using opioids.

Common Symptoms
The most common physical symptom on the Memorial Symptom Assessment Scale was “Lack of Energy”, with 91% experiencing this symptom. This was followed by “dry mouth”, 82% of patients experienced this.

Distress
Forty percent of patients were distressed at the time of referral to palliative care services.

5.1.4
Classification of Socio-Demographic Variables
Each of the demographic variables has a large number of categories with small numbers in each due to the sample size of 100. In order to ensure meaningful analyses with potential for statistical significance, the categories were condensed.

5.2
Non-Participants

5.2.1
Demographics
During the consecutive recruitment, 91 newly referred patients with advanced cancer did not wish to participate. Based on the limited information gathered on these patients (in accordance with medical ethics), those who refused participation did not differ significantly from the study population:
Gender

There were fewer males (48%) and more females (52%) amongst the non-participants in comparison with the participants (51% and 49% respectively). However, as there were almost equal numbers of each gender in both groups, this is of little significance.

Age

The majority of patients who both did, and did not participate, were between the ages of 71 and 80. Patients who refused tended to be older, with more patients under the age of 61 participating (39% compared with 19%) and more over the age of 61 not participating (81% compared with 61%). This may be in keeping with general condition, as the older population may have been frailer at the outset and daunted by the prospect of commitment to a longitudinal study.

Tumour Type

Lung cancer was the most common tumour amongst both groups, even though these patients accounted for 29.7% of the refusal group and only 23% of the study group. Many tumour types were almost equally represented amongst each group: These include tumours of the breast, rectum, ovary, pancreas and unknown primary.

Discrepancies

The main discrepancies between the groups are:

1. Tumours of the colon were particularly well represented amongst the study group: Almost 3 times the number of patients in the study group had colon cancers compared with those who refused. There is no obvious reason for this.

2. Tumours of the prostate were also well represented amongst the study group, with almost double the number of patients with prostate cancer amongst the study group compared with those who refused. This may potentially reflect the generally more protracted course of prostatic carcinoma and its presentation amongst older males;
these patients were perhaps more likely to feel physically and psychologically well enough to participate.

3. Oesophageal tumours were more common amongst the refusal group; 7.7% compared with 3.7%. This may potentially be due to the large symptom burden often associated with oesophageal tumours. This may have discouraged patients from becoming involved in a longitudinal study. Additionally, oesophageal tumours may be related to a history of alcohol excess. It seems reasonable to consider that the lifestyles of patients with alcohol related problems would not be easily compatible with a regular commitment to a longitudinal study.

4. Mesothelioma represented 4.4% of the refusal group but was not present at all amongst the study group. This may reflect the known significant symptom burden of this disease, potentially limiting patient’s tolerability of additional commitments. Additionally, this disease is related to Asbestos exposure, usually in the work place. As a result, these patients are often involved in protracted legal battles for compensation; this may be physically and psychologically demanding.

5.2.2

Reason for Non-Participation

The majority of patients (34%) were simply “not interested” in participating in this research study. Most of them did not stipulate any further reason as to why, although some mentioned involvement in other research.

The second largest category (14%) comprises those who did not want to talk about their illness. Again, most did not expand on this although a few of the explanations included anger and some degree of emotional fragility. For example “I’m coping well at the moment but I’m afraid to talk too much about it in case it opens a can of worms”.

159
This group must be considered carefully: These patients may have preferred not to discuss their illness due to either feelings or fear of distress. Although this issue had been predicted, it was unfortunately unavoidable because patients were not obliged to participate. Less patients than had been considered admitted directly to not wanting to talk about their illness; although obviously this may have been the real reason for many more who did not provide any explanation for not wanting to participate, or who simply said they were not interested.

Without coercing vulnerable patients, as much encouragement as considered reasonable was given to those who were uncertain about the effects of discussing their illness. However, no attempt was made to persuade anybody. Therefore it is both possible and unavoidable, that through self-selection, some of the more distressed patients did not participate in this study.

In 9 cases patient’s families decided on their behalf that they would not participate. This mainly involved the partners and children of older patients. As far as possible, explanations were sought. However, it was essential to ensure that the relatives did not feel pressured or questioned in anyway, respecting their vulnerability as well as ensuring maintenance of good relationships with the Hospice.

In 9 cases the patients felt they had “enough to do without it”. In general, these patients were referring to appointments with other healthcare professionals for investigations and treatment. Due to the nature of a longitudinal study, participation may reasonably be considered to be a significant commitment of time and energy. For some patients, the offer to participate in the study may have come at a time when they were already feeling overwhelmed.
5.3

Study Life Table

The patients’ progress through the study is illustrated below in Figure 10:

<table>
<thead>
<tr>
<th>No Patients</th>
<th>Timeline</th>
<th>No. Withdrew</th>
<th>No. Died</th>
<th>Place of Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>83</td>
<td>Month 1</td>
<td></td>
<td>1</td>
<td>Hospice 7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Home 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute 5</td>
</tr>
<tr>
<td>73</td>
<td>Month 2</td>
<td></td>
<td>1</td>
<td>Hospice 5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Home 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Other 1</td>
</tr>
<tr>
<td>65</td>
<td>Month 3</td>
<td></td>
<td>8</td>
<td>Hospice 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Home 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Hospice 3</td>
</tr>
<tr>
<td>52</td>
<td>Month 4</td>
<td></td>
<td>13</td>
<td>Acute 5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Nursing home 1</td>
</tr>
<tr>
<td>51</td>
<td>End point</td>
<td></td>
<td>1</td>
<td>Hospice 1</td>
</tr>
</tbody>
</table>

Figure 10: Study Life Table Illustrating Attrition Over The Study Period
5.4

Statistical Methods

On the whole, descriptive statistical methods have been used in the data analysis of this study with broad, general aims and a relatively modest sample size. In order to summarise data distributions, medians, inter-quartile ranges, means and standard deviations were used. Spearman rank correlation coefficients evaluated the associations between both ordinal and continuous variables. As patients were assessed repeatedly over time, attrition resulted in variable numbers of measurements amongst the patients. In accordance with published literature (Matthews, JNS, Altman DG, Campbell MJ and Royston P. Analysis of serial measurements in medical research. BMJ 1990; 300: 230-235.), profile plots present the data, and summary measures, mainly the worst score recorded for any given patient, were used to conduct the analyses. An additional summary measure for those who died during the study was the difference between their penultimate and final measurements.

In order to examine the associations between distress and the baseline socio-demographic variables using logistic regression, the scale was collapsed to a binary variable for a number of these variables, as well as for the worst distress thermometer score. The resultant findings are presented as odds ratios together with corresponding 95% confidence intervals and p-values. Multiple stepwise logistic regression analysis was used to identify independent predictors of distress. As no formal adjustment has been made to any of the p-values to account for multiplicity, the increased risk of finding false positive results must be considered when interpreting the p-values.

5.5

Analysis Of Socio-Demographic Variables

5.5.1

Socio-Demographic Risk Factors For Significant Global Distress

The socio-demographic and clinical factors were evaluated for their association with significant global distress. Significant global distress was taken as the cut off of a score >5 on the DT. The odds ratios (OR) are shown in Table 9 below.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Total</th>
<th>Significant distress (n (%))</th>
<th>Odds ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.56</td>
</tr>
<tr>
<td>≤ 55</td>
<td>25</td>
<td>15 (60%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>56 - 65</td>
<td>21</td>
<td>15 (71%)</td>
<td>1.67 (0.48 to 5.76)</td>
<td></td>
</tr>
<tr>
<td>66 - 75</td>
<td>25</td>
<td>14 (56%)</td>
<td>0.85 (0.28 to 2.61)</td>
<td></td>
</tr>
<tr>
<td>&gt; 75</td>
<td>29</td>
<td>15 (52%)</td>
<td>0.71 (0.24 to 2.11)</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.40</td>
</tr>
<tr>
<td>Male</td>
<td>51</td>
<td>28 (55%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>49</td>
<td>31 (63%)</td>
<td>1.41 (0.63 to 3.15)</td>
<td></td>
</tr>
<tr>
<td><strong>Primary cancer site</strong></td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.88</td>
</tr>
<tr>
<td>Lung</td>
<td>23</td>
<td>13 (57%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>13</td>
<td>9 (59%)</td>
<td>1.73 (0.41 to 7.29)</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>25</td>
<td>14 (56%)</td>
<td>0.98 (0.31 to 3.07)</td>
<td></td>
</tr>
<tr>
<td>Gynaecological</td>
<td>6</td>
<td>4 (67%)</td>
<td>1.54 (0.23 to 10.2)</td>
<td></td>
</tr>
<tr>
<td>Genitourinary</td>
<td>10</td>
<td>7 (70%)</td>
<td>1.79 (0.37 to 8.75)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>23</td>
<td>12 (52%)</td>
<td>0.84 (0.26 to 2.68)</td>
<td></td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.85</td>
</tr>
<tr>
<td>Married</td>
<td>59</td>
<td>33 (56%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>5</td>
<td>3 (60%)</td>
<td>1.18 (0.18 to 7.60)</td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>12</td>
<td>7 (58%)</td>
<td>1.10 (0.31 to 3.88)</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>24</td>
<td>16 (67%)</td>
<td>1.58 (0.58 to 4.25)</td>
<td></td>
</tr>
<tr>
<td><strong>Living Situation</strong></td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.53</td>
</tr>
<tr>
<td>With spouse</td>
<td>61</td>
<td>34 (56%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Other family member</td>
<td>6</td>
<td>3 (50%)</td>
<td>0.79 (0.15 to 4.25)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>33</td>
<td>22 (67%)</td>
<td>1.59 (0.66 to 3.84)</td>
<td></td>
</tr>
<tr>
<td><strong>Main Carer Relationship</strong></td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.46</td>
</tr>
<tr>
<td>Spouse</td>
<td>59</td>
<td>33 (56%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>41</td>
<td>26 (63%)</td>
<td>1.37 (0.60 to 3.09)</td>
<td></td>
</tr>
<tr>
<td><strong>DEPCAT</strong></td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.82</td>
</tr>
<tr>
<td>1/2</td>
<td>26</td>
<td>14 (54%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>3/4</td>
<td>49</td>
<td>30 (61%)</td>
<td>1.35 (0.52 to 3.54)</td>
<td></td>
</tr>
<tr>
<td>5/6</td>
<td>25</td>
<td>15 (60%)</td>
<td>1.29 (0.42 to 3.91)</td>
<td></td>
</tr>
<tr>
<td><strong>Financial Concerns</strong></td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.56</td>
</tr>
<tr>
<td>No</td>
<td>75</td>
<td>43 (57%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>25</td>
<td>16 (64%)</td>
<td>1.32 (0.52 to 3.37)</td>
<td></td>
</tr>
<tr>
<td><strong>Previous Depression</strong></td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.083</td>
</tr>
<tr>
<td>No</td>
<td>82</td>
<td>45 (55%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>18</td>
<td>14 (78%)</td>
<td>2.88 (0.87 to 9.49)</td>
<td></td>
</tr>
<tr>
<td><strong>Previous Anxiety</strong></td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.57</td>
</tr>
<tr>
<td>No</td>
<td>88</td>
<td>51 (58%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12</td>
<td>8 (67%)</td>
<td>1.45 (0.41 to 5.18)</td>
<td></td>
</tr>
<tr>
<td><strong>Previous Significant Physical Illness</strong></td>
<td>100</td>
<td>59</td>
<td>1.0</td>
<td>0.50</td>
</tr>
<tr>
<td>No</td>
<td>52</td>
<td>29 (56%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48</td>
<td>30 (62%)</td>
<td>1.32 (0.59 to 2.94)</td>
<td></td>
</tr>
<tr>
<td><strong>Previous Significant Mental/ Physical Illness in Family</strong></td>
<td>100</td>
<td>59</td>
<td>1.0</td>
<td>0.31</td>
</tr>
<tr>
<td>No</td>
<td>50</td>
<td>27 (54%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>50</td>
<td>32 (64%)</td>
<td>1.51 (0.68 to 3.38)</td>
<td></td>
</tr>
<tr>
<td><strong>Significant Social Dysfunction with Patient/Family</strong></td>
<td>100</td>
<td>59</td>
<td>1.0</td>
<td>0.031</td>
</tr>
<tr>
<td>No</td>
<td>85</td>
<td>46 (54%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>15</td>
<td>13 (87%)</td>
<td>5.51 (1.17 to 25.9)</td>
<td></td>
</tr>
<tr>
<td>Variable</td>
<td>Total</td>
<td>Significant distress (n (%))</td>
<td>Odds ratio (95% CI)</td>
<td>P-value</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------</td>
<td>------------------------------</td>
<td>---------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Previous Bereavement Problems for Patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>90</td>
<td>52 (58%)</td>
<td>1.0</td>
<td>0.46</td>
</tr>
<tr>
<td>Yes</td>
<td>10</td>
<td>7 (70%)</td>
<td>1.71 (0.41 to 7.02)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from Oncology Doctors</td>
<td>99</td>
<td>59</td>
<td></td>
<td>0.008</td>
</tr>
<tr>
<td>Yes</td>
<td>77</td>
<td>40 (52%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>22</td>
<td>19 (86%)</td>
<td>5.86 (1.60 to 21.4)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from Oncology Nurses</td>
<td>99</td>
<td>59</td>
<td></td>
<td>0.023</td>
</tr>
<tr>
<td>Yes</td>
<td>80</td>
<td>43 (54%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>19</td>
<td>16 (84%)</td>
<td>4.59 (1.24 to 17.0)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from GP</td>
<td>99</td>
<td>59</td>
<td></td>
<td>0.12</td>
</tr>
<tr>
<td>Yes</td>
<td>79</td>
<td>44 (56%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>20</td>
<td>15 (75%)</td>
<td>2.39 (0.79 to 7.21)</td>
<td></td>
</tr>
</tbody>
</table>

Table 9: Results of univariate logistic regression investigating the associations of significant distress (defined as worst thermometer score over 5) with other patient characteristics

Multivariate analysis revealed weak evidence indicating that inadequate information (from oncologist, oncology nurse or GP), and social dysfunction are independent predictors of significant distress: (OR 3.10, 95% CI 1.10 to 8.74, p = 0.033) for inadequate information and (OR 4.28, 95% CI 0.88 to 20.9, p = 0.072) for social dysfunction.

5.5.2

Odds Ratios According To Died/Survived
The analysis was further refined; those who died during the study were examined separately from those survived. These two groups were considered to have potentially unique predictors of distress, being at different points on the disease trajectory. Unfortunately, this was largely unproductive in terms of defining statistical significance as the numbers of patients in each category became very small.
Odds Ratios For Those Who Died

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total</th>
<th>Significant distress</th>
<th>Odds ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous Depression</td>
<td>47</td>
<td>26</td>
<td></td>
<td>0.55</td>
</tr>
<tr>
<td>No</td>
<td>41</td>
<td>22 (54%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6</td>
<td>4 (67%)</td>
<td>1.73 (0.28 to 10.5)</td>
<td></td>
</tr>
<tr>
<td>Previous Significant Physical Illness</td>
<td>47</td>
<td>26</td>
<td></td>
<td>0.28</td>
</tr>
<tr>
<td>No</td>
<td>25</td>
<td>12 (48%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>22</td>
<td>14 (64%)</td>
<td>1.90 (0.59 to 6.10)</td>
<td></td>
</tr>
<tr>
<td>Previous Significant Mental/Physical Illness in Family</td>
<td>47</td>
<td>26</td>
<td></td>
<td>0.37</td>
</tr>
<tr>
<td>No</td>
<td>28</td>
<td>17 (61%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>19</td>
<td>9 (47%)</td>
<td>0.58 (0.18 to 1.89)</td>
<td></td>
</tr>
<tr>
<td>Significant Social Dysfunction with Patient/Family</td>
<td>47</td>
<td>26</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>44</td>
<td>23 (52%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3</td>
<td>3 (100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from Oncology Doctors</td>
<td>46</td>
<td>26</td>
<td></td>
<td>0.082</td>
</tr>
<tr>
<td>Yes</td>
<td>38</td>
<td>19 (50%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>8</td>
<td>7 (87%)</td>
<td>7.00 (0.78 to 63)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from Oncology Nurses</td>
<td>46</td>
<td>26</td>
<td></td>
<td>0.19</td>
</tr>
<tr>
<td>Yes</td>
<td>40</td>
<td>21 (53%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>6</td>
<td>5 (83%)</td>
<td>4.52 (0.48 to 42)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from GP</td>
<td>46</td>
<td>26</td>
<td></td>
<td>0.50</td>
</tr>
<tr>
<td>Yes</td>
<td>37</td>
<td>20 (54%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>9</td>
<td>6 (67%)</td>
<td>1.70 (0.37 to 7.85)</td>
<td></td>
</tr>
</tbody>
</table>

Table 10: Results of univariate logistic regression investigating the associations of significant distress (defined as worst thermometer score over 5) with other patient characteristics. Analysis restricted to patients who died during the study.

NOTE: For “Significant Social Dysfunction” there was a 100% response rate (n=3), as a result of this the p value would be infinite and the OR cannot be derived.

Table 10 details the analysis of the categories that were relevant for the overall study population, in order to provide a comparison (none of the other categories elicited significant results or trends). Due to the small numbers, there were no statistically significant results for socio-demographic predictors of distress amongst the subgroup of patients who died during the study. There is a trend towards an association
between significant distress and the perception of receiving inadequate information from oncology doctors (OR 7.0, 95% CI 0.78 to 63, p = 0.082).

**Odds Ratios For Those Who Survived**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total</th>
<th>Significant distress n (%)</th>
<th>Odds ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous Depression</td>
<td>53</td>
<td>33</td>
<td></td>
<td>0.10</td>
</tr>
<tr>
<td>No</td>
<td>41</td>
<td>23 (56%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12</td>
<td>10 (83%)</td>
<td>3.91 (0.78 to 20.0)</td>
<td></td>
</tr>
<tr>
<td>Previous Significant Physical Illness</td>
<td>53</td>
<td>33</td>
<td></td>
<td>0.92</td>
</tr>
<tr>
<td>No</td>
<td>27</td>
<td>17 (63%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>26</td>
<td>16 (62%)</td>
<td>0.94 (0.31 to 2.86)</td>
<td></td>
</tr>
<tr>
<td>Previous Significant Mental/Physical Illness in Family</td>
<td>53</td>
<td>33</td>
<td></td>
<td>0.037</td>
</tr>
<tr>
<td>No</td>
<td>22</td>
<td>10 (45%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>31</td>
<td>23 (74%)</td>
<td>3.45 (1.08 to 11.0)</td>
<td></td>
</tr>
<tr>
<td>Significant Social Dysfunction with Patient/Family</td>
<td>53</td>
<td>33</td>
<td></td>
<td>0.10</td>
</tr>
<tr>
<td>No</td>
<td>41</td>
<td>23 (56%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12</td>
<td>10 (83%)</td>
<td>3.91 (0.76 to 20.0)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from Oncology Doctors</td>
<td>53</td>
<td>33</td>
<td></td>
<td>0.048</td>
</tr>
<tr>
<td>Yes</td>
<td>39</td>
<td>21 (54%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>14</td>
<td>12 (86%)</td>
<td>5.14 (1.01 to 26.1)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from Oncology Nurses</td>
<td>53</td>
<td>33</td>
<td></td>
<td>0.071</td>
</tr>
<tr>
<td>Yes</td>
<td>40</td>
<td>22 (55%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>13</td>
<td>11 (85%)</td>
<td>4.50 (0.88 to 23.0)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from GP</td>
<td>53</td>
<td>33</td>
<td></td>
<td>0.15</td>
</tr>
<tr>
<td>Yes</td>
<td>42</td>
<td>24 (57%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>11</td>
<td>9 (82%)</td>
<td>3.37 (0.65 to 17.6)</td>
<td></td>
</tr>
</tbody>
</table>

Table 11: Results of univariate logistic regression investigating the associations of significant distress (defined as worst thermometer score over 5) with other patient characteristics. Analysis restricted to patients who survived to the end of the study.

Table 11 details the analysis of the categories that were relevant for the overall study population, in order to provide a comparison (none of the other categories elicited significant results or trends). For those who survived the study, the sociodemographic factors associated with an increased risk of significant distress appear to be having a previous significant mental or physical illness in the family (OR 3.45, 95% CI 1.08 to 11, p = 0.037), and perception of receiving inadequate information
from oncology doctors (OR 5.14, 95% CI 1.01 to 26.1, p = 0.048). Again, the numbers in each category are small, therefore limiting the ability to reach statistical significance.

5.5.3 Socio-Demographic Risk Factors For Significant Physical Distress

The socio-demographic categories for the whole study population were evaluated for their association with significant physical distress. Significant physical distress for this population was calculated and taken as the cut off of a score of >1.5 on the MSAS physical subscale score at any time during the study. The odds ratios shown in Table 12 below are comparable with those previously included to illustrate socio-demographic associations with global distress. None of the categories that have been omitted yielded statistically significant results.
Table 12: Results of univariate logistic regression investigating the associations of physical distress (defined as worst MSAS physical score of over 1.5) with other patient characteristics

Previous significant physical illness is a significant predictor of physical distress (OR 2.95, 95% CI 1.28 to 6.80, p = 0.011). This finding appears to support the validity and reliability of the patient histories and the use of the MSAS as a surrogate for physical distress.

In keeping with the socio-demographic factor associations with global distress, perception of receiving inadequate information from the GP was also a significant predictor of physical distress (OR 2.89, 95% CI 1.05 to 7.92, p = 0.039), and a trend was elicited towards the association between significant social dysfunction and physical distress.
5.5.4
Socio-Demographic Risk Factors For Significant Psychological Distress
The socio-demographic categories for the whole study population were also analysed for their association with significant psychological distress. The standard EDS cut off of ≥13 at any time during the study was taken for significant psychological distress.
The odds ratios in Table 13 below are comparable with those previously included to illustrate socio-demographic associations with global and physical distress. None of the categories that have been omitted yielded statistically significant results.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total</th>
<th>Worst EDS ≥ 13 n (%)</th>
<th>Odds ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marital Status</td>
<td>100</td>
<td>32</td>
<td></td>
<td>0.08</td>
</tr>
<tr>
<td>Married</td>
<td>59</td>
<td>21 (36%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>5</td>
<td>4 (80%)</td>
<td>7.24 (0.76 to 69.0)</td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>12</td>
<td>3 (25%)</td>
<td>0.60 (0.15 to 2.47)</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>24</td>
<td>4 (17%)</td>
<td>0.36 (0.11 to 1.20)</td>
<td></td>
</tr>
<tr>
<td>Previous Depression</td>
<td>100</td>
<td>32</td>
<td></td>
<td>0.022</td>
</tr>
<tr>
<td>No</td>
<td>82</td>
<td>22 (27%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>18</td>
<td>10 (56%)</td>
<td>3.41 (1.19 to 9.74)</td>
<td></td>
</tr>
<tr>
<td>Previous Anxiety</td>
<td>100</td>
<td>32</td>
<td></td>
<td>0.92</td>
</tr>
<tr>
<td>No</td>
<td>88</td>
<td>28 (32%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12</td>
<td>4 (33%)</td>
<td>1.07 (0.30 to 3.86)</td>
<td></td>
</tr>
<tr>
<td>Previous Significant Physical Illness</td>
<td>100</td>
<td>32</td>
<td></td>
<td>0.48</td>
</tr>
<tr>
<td>No</td>
<td>52</td>
<td>15 (29%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48</td>
<td>17 (35%)</td>
<td>1.35 (0.58 to 3.14)</td>
<td></td>
</tr>
<tr>
<td>Previous Significant Mental/Physical Illness in Family</td>
<td>100</td>
<td>32</td>
<td></td>
<td>0.67</td>
</tr>
<tr>
<td>No</td>
<td>50</td>
<td>17 (34%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>50</td>
<td>15 (30%)</td>
<td>0.83 (0.36 to 1.93)</td>
<td></td>
</tr>
<tr>
<td>Significant Social Dysfunction with Patient/Family</td>
<td>100</td>
<td>32</td>
<td></td>
<td>0.062</td>
</tr>
<tr>
<td>No</td>
<td>85</td>
<td>24 (28%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>15</td>
<td>8 (53%)</td>
<td>2.90 (0.95 to 8.89)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from Oncology Doctors</td>
<td>99</td>
<td>32</td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Yes</td>
<td>77</td>
<td>17 (21%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>22</td>
<td>15 (68%)</td>
<td>7.54 (2.66 to 21.5)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from Oncology Nurses</td>
<td>99</td>
<td>32</td>
<td></td>
<td>0.002</td>
</tr>
<tr>
<td>Yes</td>
<td>80</td>
<td>20 (25%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>19</td>
<td>12 (63%)</td>
<td>5.14 (1.78 to 14.9)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from GP</td>
<td>99</td>
<td>32</td>
<td></td>
<td>0.005</td>
</tr>
<tr>
<td>Yes</td>
<td>79</td>
<td>20 (25%)</td>
<td>1.0</td>
<td></td>
</tr>
</tbody>
</table>

Table 13: Results of univariate logistic regression investigating the associations of distress (defined as worst EDS score of 13 or more) with other patient characteristics
Previous depression is a significant predictor of significant psychological distress (OR 3.41, 95% CI 1.19 to 9.74, p = 0.022). This finding appears to support the validity and reliability of the patient histories and the use of the EDS as a surrogate for psychological distress.

In keeping with findings for the global and physical distress, perception of receiving inadequate information from oncology doctors, nurses and General Practitioners, predicts significant psychological distress. In addition, a trend towards an association between significant social dysfunction and significant psychological distress is also apparent (OR 2.90, 95% CI 0.95 to 8.89, p = 0.062).

Finally, a trend is evident towards an association between marital status and significant psychological distress; the odds ratio for the association between single status and significant psychological distress is (OR 7.24, 95% CI 0.76 to 69.0, p = 0.08). This trend was not found for global distress or any of the other distress components.

5.5.5

Socio-Demographic Risk Factors For Significant Spiritual Distress

The socio-demographic categories for the whole study population were evaluated for their association with significant spiritual distress. Significant spiritual distress for this population was calculated and taken as the cutoff of a score of <20 on the FACIT at any time during the study. The odds ratios in Table 14 are below comparable with those previously included to illustrate socio-demographic associations with global, physical and psychological distress. None of the categories that have been omitted yielded statistically significant results.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Total</th>
<th>Worst FACIT&lt;20 n (%)</th>
<th>Odds ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous Depression</td>
<td>100</td>
<td>35</td>
<td></td>
<td>0.014</td>
</tr>
<tr>
<td>No</td>
<td>82</td>
<td>24 (29%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>18</td>
<td>11 (61%)</td>
<td>3.80 (1.31 to 11.0)</td>
<td></td>
</tr>
<tr>
<td>Previous Anxiety</td>
<td>100</td>
<td>35</td>
<td></td>
<td>0.61</td>
</tr>
<tr>
<td>No</td>
<td>88</td>
<td>30 (34%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>12</td>
<td>5 (42%)</td>
<td>1.38 (0.40 to 4.72)</td>
<td></td>
</tr>
<tr>
<td>Previous Significant Physical Illness</td>
<td>100</td>
<td>35</td>
<td></td>
<td>0.93</td>
</tr>
<tr>
<td>No</td>
<td>52</td>
<td>18 (35%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48</td>
<td>17 (35%)</td>
<td>1.04 (0.45 to 2.36)</td>
<td></td>
</tr>
<tr>
<td>Previous Significant Mental/Physical Illness in Family</td>
<td>100</td>
<td>35</td>
<td></td>
<td>0.83</td>
</tr>
<tr>
<td>No</td>
<td>50</td>
<td>18 (36%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>50</td>
<td>17 (34%)</td>
<td>0.92 (0.40 to 2.08)</td>
<td></td>
</tr>
<tr>
<td>Significant Social Dysfunction with Patient/Family</td>
<td>100</td>
<td>35</td>
<td></td>
<td>0.31</td>
</tr>
<tr>
<td>No</td>
<td>85</td>
<td>28 (33%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>15</td>
<td>7 (47%)</td>
<td>1.78 (0.59 to 5.41)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from Oncology Doctors</td>
<td>99</td>
<td>35</td>
<td></td>
<td>0.26</td>
</tr>
<tr>
<td>Yes</td>
<td>77</td>
<td>25 (32%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>22</td>
<td>10 (45%)</td>
<td>1.73 (0.66 to 4.55)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from Oncology Nurses</td>
<td>99</td>
<td>35</td>
<td></td>
<td>0.23</td>
</tr>
<tr>
<td>Yes</td>
<td>80</td>
<td>26 (33%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>19</td>
<td>9 (47%)</td>
<td>1.87 (0.68 to 5.16)</td>
<td></td>
</tr>
<tr>
<td>Received Adequate Information from GP</td>
<td>99</td>
<td>35</td>
<td></td>
<td>0.13</td>
</tr>
<tr>
<td>Yes</td>
<td>79</td>
<td>25 (32%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>20</td>
<td>10 (50%)</td>
<td>2.16 (0.80 to 5.85)</td>
<td></td>
</tr>
</tbody>
</table>

Table 14: Results of univariate logistic regression investigating the associations of spiritual distress (defined as worst FACIT score of less than 20) with other patient characteristics

A previous history of depression predicts significant spiritual distress (OR 3.80, 95% CI 1.31 to 11.0, p = 0.014). Unlike global distress and its other components, there does not appear to be any association between significant spiritual distress and significant social dysfunction and perception of receiving inadequate information.
5.6 Analysis of Assessment Tools

5.6.1 Patterns of Distress Over Time
Due to the large volume of longitudinal data, analysis began with an overview of the trends amongst each assessment score (MSAS, EDS, FACIT, DT and KPS) over time. This was done in order to gain an early insight into any obvious emergent trends and also to inform the direction of the potentially vast analysis.

5.6.1.1 Profile Plots
These were drawn for each of the assessment tools. The assessment scores over time for each one of the 100 patients are depicted on the same graph:

*Physical Distress (MSAS)*

![Profile Plot for Physical Symptom Scores](image)

Figure 11: Profile Plot Showing MSAS Scores for Each Participant Over Time

Figure 11 shows no obvious general trend in MSAS scores. However, physical symptoms do appear to fluctuate more initially before generally stabilising from 3 months onwards.
Psychological Distress (EDS)

Figure 12: Profile Plot Showing EDS Scores for Each Participant Over Time

Figure 12 shows no obvious general trend in EDS scores. However, it would appear that patients generally either maintain a similar level of psychological distress throughout; or their level fluctuates greatly over the course of their illness.

Spiritual Distress (FACIT-Sp-12)

Figure 13: Profile Plot Showing FACIT Scores for Each Participant Over Time

Figure 13 shows no obvious general trend in FACIT scores. However, levels of spiritual distress appear to remain relatively stable during the course of illness. For those with fluctuating levels, this seems to occur mostly between months 1 and 3.
Global Distress (DT)

Figure 14: Profile Plot Showing DT Scores for Each Participant Over Time

Figure 14 shows no obvious general trend in DT scores. However, overall distress levels appear to fluctuate greatly throughout the course of illness, much more so than the other variables.

Performance Status (KPS)

Figure 15: Profile Plot Showing KPS Scores for Each Participant Over Time

Figure 15 shows that, in general, for those completing the data collection, their performance status remained stable throughout the study. As expected, the Performance Status of those who died within the first 2 months of the study declined rapidly prior to death.
5.6.1.2

**Box Plots**

Following inspection of the profile plots; box plots were drawn in order to highlight the trends in average scores, as opposed to the individual variability, which is emphasised by the profile plots.

*Physical Distress (MSAS)*

Figure 16: Box Plot Showing Average MSAS Scores Over Time

Figure 16 shows that there is not a great deal of fluctuation in average levels of physical distress over time. There is a slight variation in levels over the months but essentially, over time, the average physical distress levels remain persistently lower than at baseline.

*Psychological Distress (EDS)*

Figure 17: Box Plot Showing Average EDS Scores Over Time
Figure 17 shows that there is some fluctuation in the average psychological distress scores over time. However, the average level of psychological distress tends to fall over time. Average psychological distress levels are highest at baseline and are consistently at the lowest from 3 months onwards.

**Spiritual Distress (FACIT-Sp-12)**

![Box Plot Showing Average FACIT Scores Over Time](image)

Figure 18: Box Plot Showing Average FACIT Scores Over Time

Figure 18 shows that again, there is not a great variation in the average levels of spiritual distress over time. However, average levels of spiritual distress appear to increase (i.e. the average scores tend to decrease) over the first 2 months, and although there is some persistent improvement from month 3, the average spiritual distress levels remain lowest at baseline.

**Global Distress (DT)**

![Box Plot Showing Average DT Scores Over Time](image)

Figure 19: Box Plot Showing Average DT Scores Over Time
Figure 19 shows that the distribution of global distress scores is relatively stable over time, even though the profile plots showed that there is substantial variability within individual patients. Average global distress levels are lowest in the fifth month.

**Performance Status (KPS)**

![Box Plot Showing Average KPS Scores Over Time](image)

Figure 20: Box Plot Showing Average KPS Scores Over Time

Figure 20 shows that in the majority of cases there is little fluctuation in performance status, with average KPS scores of 60-70 over the course of the study. Again, this may reflect the longer disease trajectory of those patients surviving the study, as KPS evidently falls dramatically prior to death as indicated by the *.

**5.6.1.3 Analysis According To Death During Study or Study Survival**

Having examined the trends of the whole study group initially, the analysis was refined. Those who died during the study and those who survived were evaluated separately as discrete groups. This distinction was made as these two groups were at different stages of their disease trajectory, with their distress levels potentially reflecting this.
Patients Who Died (No V4): Profile Plots and Box Plots

Physical Distress (MSAS)

Figure 21: MSAS Scores Over Time Amongst Those Who Died

Figure 22: Average MSAS Scores Over Time Amongst Those Who Died

Figures 21 and 22 appear to show similar trends to those of the whole study population: Amongst individuals, the levels of physical distress appear to fluctuate most initially, before stabilising to chronic level. Average levels of physical distress are generally highest at the time of referral and lower prior to death.
Psychological Distress (EDS)

Figure 23: EDS Scores Over Time Amongst Those Who Died

Figure 24: Average EDS Scores Over Time Amongst Those Who Died

Again, Figures 23 and 24 appear to reveal similar trends to the overall, whole study sample: Levels of psychological distress amongst individuals fluctuate initially, before stabilising to chronic level. Average levels of psychological distress appear to be highest at the time of referral and lower prior to death.
Spiritual Distress (FACIT-Sp-12)

Figure 25: FACIT Scores Over Time Amongst Those Who Died

Figure 26: Average FACIT Scores Over Time Amongst Those Who Died

Figures 25 and 26 show that the trends in spiritual distress for those who died during the study, are similar to those of the overall study population. The average levels of spiritual distress are generally relatively stable over time, but are initially lowest at the time of referral, before increasing initially. The average distress levels are lower for those who survived to 3 months.
Global Distress (DT)

**Figure 27: DT Scores Over Time Amongst Those Who Died**

**Figure 28: Average DT Scores Over Time Amongst Those Who Died**

Figures 27 and 28 illustrate that, much like the distress scores for the overall study population, there is no obvious trend, with individual’s scores fluctuating widely over time. The average global distress levels for those who died are lowest at the time of referral.
Performance Status (KPS)

Figure 29: KPS Scores Over Time Amongst Those Who Died

Figure 30: Average KPS Scores Over Time Amongst Those Who Died

As expected, the KPS levels remain stable and fall dramatically prior to death, as shown in Figures 29 and 30.

Summary Statistics For Those Who Died (No V4)

Table 15 below summarises the statistics for each of the distress measures at each time point amongst those who died during the study.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Sample size</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Inter-quartile range Q1-Q3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical Symptom Scores (MSAS)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>47</td>
<td>1.22</td>
<td>0.57</td>
<td>1.16</td>
<td>0.85 to 1.57</td>
</tr>
<tr>
<td>1 Month</td>
<td>27</td>
<td>1.06</td>
<td>0.70</td>
<td>0.86</td>
<td>0.59 to 1.64</td>
</tr>
<tr>
<td>2 Months</td>
<td>20</td>
<td>1.03</td>
<td>0.37</td>
<td>0.99</td>
<td>0.82 to 1.40</td>
</tr>
<tr>
<td>3 Months</td>
<td>12</td>
<td>0.87</td>
<td>0.47</td>
<td>0.89</td>
<td>0.49 to 1.24</td>
</tr>
<tr>
<td><strong>Psychological Distress (EDS)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>47</td>
<td>8.2</td>
<td>6.6</td>
<td>7.0</td>
<td>2.0 to 13.0</td>
</tr>
<tr>
<td>1 Month</td>
<td>27</td>
<td>5.7</td>
<td>4.9</td>
<td>4.0</td>
<td>2.0 to 9.0</td>
</tr>
<tr>
<td>2 Months</td>
<td>20</td>
<td>6.4</td>
<td>5.6</td>
<td>5.5</td>
<td>1.2 to 9.7</td>
</tr>
<tr>
<td>3 Months</td>
<td>12</td>
<td>4.9</td>
<td>5.3</td>
<td>3.0</td>
<td>0.5 to 9.0</td>
</tr>
<tr>
<td><strong>Spiritual Distress (FACIT)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>47</td>
<td>30.8</td>
<td>11.1</td>
<td>35.0</td>
<td>22.0 to 42.0</td>
</tr>
<tr>
<td>1 Month</td>
<td>27</td>
<td>30.2</td>
<td>9.2</td>
<td>31.0</td>
<td>22.0 to 39.0</td>
</tr>
<tr>
<td>2 Months</td>
<td>20</td>
<td>29.7</td>
<td>10.7</td>
<td>28.5</td>
<td>22.3 to 39.0</td>
</tr>
<tr>
<td>3 Months</td>
<td>12</td>
<td>29.8</td>
<td>7.6</td>
<td>29.0</td>
<td>24.0 to 36.8</td>
</tr>
<tr>
<td><strong>Global Distress (DT)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>47</td>
<td>3.7</td>
<td>3.2</td>
<td>3.0</td>
<td>0.0 to 7.0</td>
</tr>
<tr>
<td>1 Month</td>
<td>28</td>
<td>3.6</td>
<td>3.1</td>
<td>4.3</td>
<td>0.0 to 6.0</td>
</tr>
<tr>
<td>2 Months</td>
<td>20</td>
<td>3.9</td>
<td>3.6</td>
<td>4.0</td>
<td>0.0 to 7.0</td>
</tr>
<tr>
<td>3 Months</td>
<td>12</td>
<td>3.5</td>
<td>2.9</td>
<td>3.5</td>
<td>0.3 to 6.5</td>
</tr>
</tbody>
</table>
Karnofsky Performance Status (KPS)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>1 Month</th>
<th>2 Months</th>
<th>3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Karnofsky</td>
<td>47</td>
<td>32</td>
<td>23</td>
<td>12</td>
</tr>
<tr>
<td>61.3</td>
<td>52.8</td>
<td>52.6</td>
<td>59.2</td>
<td></td>
</tr>
<tr>
<td>9.2</td>
<td>16.5</td>
<td>17.4</td>
<td>7.9</td>
<td></td>
</tr>
<tr>
<td>60.0</td>
<td>50.0</td>
<td>60.0</td>
<td>60.0</td>
<td></td>
</tr>
<tr>
<td>50.0 to 70.0</td>
<td>50.0 to 60.0</td>
<td>50.0 to 60.0</td>
<td>50.0 to 67.5</td>
<td></td>
</tr>
</tbody>
</table>

Table 15: Summary Statistics for Patients Who Died

Patients Who Survived (V4): Profile Plots and Box Plots

Physical Distress (MSAS)

Figure 31: MSAS Scores Over Time Amongst Those Who Survived

Figure 32: Average MSAS Scores Over Time Amongst Those Who Survived
Similarly to the overall study population, the physical distress scores amongst those who survived are variable over time, perhaps stabilising to chronic level, as illustrated in Figures 31 and 32. The average physical distress levels are highest at the time of referral.

*Psychological Distress (EDS)*

**Figure 33: EDS Scores Over Time Amongst Those Who Survived**

**Figure 34: Average EDS Scores Over Time Amongst Those Who Survived**

Levels of psychological distress amongst those who survived the study are very similar to those displayed by the whole study population, as shown in Figures 33 and 34. Some individuals have widely fluctuating levels over time, whilst others have chronic, stable levels. The highest average levels of psychological distress are seen at the time of referral to palliative care services.
Spiritual distress levels amongst those who survived also reflect those of the overall study population in their stability over time, as shown in Figures 35 and 36. Average levels of distress initially increase before falling again over time.
Global Distress (DT)

Figure 37: DT Scores Over Time Amongst Those Who Survived

Figure 38: Average DT Scores Over Time Amongst Those Who Survived

Global distress levels amongst those who survived have similar variability to those of the overall study population: The levels fluctuate widely over time, as illustrated in Figures 37 and 38. The average global distress levels appear to fall initially from baseline levels, and are at their lowest at Month 5.
For those who survived the study, performance status was largely stable over time, as shown in Figures 39 and 40.

**Summary Statistics For Those Who Survived (V4)**

Table 16 below summarises the statistics for each of the distress measures at each time point amongst those who survived the study.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Sample size</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Inter-quartile range Q1 to Q3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical Symptom Scores (MSAS)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>53</td>
<td>0.99</td>
<td>0.51</td>
<td>0.93</td>
<td>0.6 to 1.3</td>
</tr>
<tr>
<td>1 Month</td>
<td>53</td>
<td>0.84</td>
<td>0.51</td>
<td>0.79</td>
<td>0.4 to 1.1</td>
</tr>
<tr>
<td>2 Months</td>
<td>53</td>
<td>0.85</td>
<td>0.53</td>
<td>0.86</td>
<td>0.4 to 1.2</td>
</tr>
<tr>
<td>3 Months</td>
<td>53</td>
<td>0.73</td>
<td>0.52</td>
<td>0.61</td>
<td>0.3 to 1.1</td>
</tr>
<tr>
<td>5 Months</td>
<td>52</td>
<td>0.78</td>
<td>0.53</td>
<td>0.67</td>
<td>0.4 to 1.1</td>
</tr>
<tr>
<td><strong>Psychological Distress (EDS)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>53</td>
<td>6.5</td>
<td>4.6</td>
<td>6.0</td>
<td>3.0 to 9.0</td>
</tr>
<tr>
<td>1 Month</td>
<td>53</td>
<td>5.1</td>
<td>4.9</td>
<td>3.0</td>
<td>1.5 to 8.0</td>
</tr>
<tr>
<td>2 Months</td>
<td>53</td>
<td>5.4</td>
<td>5.6</td>
<td>4.0</td>
<td>0.0 to 7.0</td>
</tr>
<tr>
<td>3 Months</td>
<td>53</td>
<td>5.2</td>
<td>5.7</td>
<td>3.0</td>
<td>0.0 to 8.5</td>
</tr>
<tr>
<td>5 Months</td>
<td>52</td>
<td>4.8</td>
<td>5.6</td>
<td>3.0</td>
<td>1.0 to 7.0</td>
</tr>
<tr>
<td><strong>Spiritual Distress (FACIT)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>53</td>
<td>29.7</td>
<td>10.4</td>
<td>30.0</td>
<td>22.0 to 37.5</td>
</tr>
<tr>
<td>1 Month</td>
<td>53</td>
<td>28.5</td>
<td>10.0</td>
<td>28.0</td>
<td>22.0 to 36.0</td>
</tr>
<tr>
<td>2 Months</td>
<td>53</td>
<td>27.8</td>
<td>9.3</td>
<td>28.0</td>
<td>20.0 to 34.0</td>
</tr>
<tr>
<td>3 Months</td>
<td>53</td>
<td>27.9</td>
<td>9.7</td>
<td>30.0</td>
<td>21.0 to 35.0</td>
</tr>
<tr>
<td>5 Months</td>
<td>52</td>
<td>28.9</td>
<td>10.2</td>
<td>30.0</td>
<td>23.0 to 37.0</td>
</tr>
<tr>
<td><strong>Global Distress (DT)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>53</td>
<td>3.3</td>
<td>2.8</td>
<td>3.0</td>
<td>0.0 to 5.6</td>
</tr>
<tr>
<td>1 Month</td>
<td>53</td>
<td>2.8</td>
<td>2.9</td>
<td>2.0</td>
<td>0.0 to 5.0</td>
</tr>
<tr>
<td>2 Months</td>
<td>53</td>
<td>2.9</td>
<td>3.3</td>
<td>1.0</td>
<td>0.0 to 5.0</td>
</tr>
<tr>
<td>3 Months</td>
<td>53</td>
<td>3.6</td>
<td>3.5</td>
<td>3.0</td>
<td>0.0 to 7.0</td>
</tr>
<tr>
<td>5 Months</td>
<td>52</td>
<td>3.1</td>
<td>3.6</td>
<td>0.5</td>
<td>0.0 to 6.0</td>
</tr>
<tr>
<td>Karnofsky Performance Status (KPS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------</td>
<td>-----------------</td>
<td>-----------------</td>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>53</td>
<td>70.2</td>
<td>8.9</td>
<td>70.0</td>
<td>65.0 to 75.0</td>
</tr>
<tr>
<td>1 Month</td>
<td>53</td>
<td>69.6</td>
<td>7.8</td>
<td>70.0</td>
<td>60.0 to 70.0</td>
</tr>
<tr>
<td>2 Months</td>
<td>53</td>
<td>70.0</td>
<td>7.1</td>
<td>70.0</td>
<td>70.0 to 70.0</td>
</tr>
<tr>
<td>3 Months</td>
<td>53</td>
<td>69.1</td>
<td>9.9</td>
<td>70.0</td>
<td>65.0 to 70.0</td>
</tr>
<tr>
<td>5 Months</td>
<td>53</td>
<td>66.4</td>
<td>11.6</td>
<td>70.0</td>
<td>60.0 to 70.0</td>
</tr>
</tbody>
</table>

Table 16: Summary Statistics for Patients Who Survived

5.7

Inter-Relations Between Distress Components

Correlations

The assessment scores for each component of distress were correlated with each other in order to examine their inter-relationships. In particular, each distress component was correlated with global distress in order to establish which aspects of distress are most influential in the overall experience of distress.

5.7.1

Correlations between the various scores at baseline

<table>
<thead>
<tr>
<th></th>
<th>EDS</th>
<th>MSAS</th>
<th>FACIT</th>
<th>KPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSAS</td>
<td>0.48</td>
<td>0.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FACIT</td>
<td>-0.49</td>
<td>-0.35</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>KPS</td>
<td>-0.09</td>
<td>-0.23</td>
<td>-0.05</td>
<td></td>
</tr>
<tr>
<td>DT</td>
<td>0.71</td>
<td>0.44</td>
<td>-0.43</td>
<td>-0.01</td>
</tr>
</tbody>
</table>

Cell Contents: Pearson correlation

P-Value

EDS  Edinburgh Depression Score
MSAS Physical Symptom Score (MSAS subscale)
FACIT Spiritual Distress Score
KPS  Karnofsky Performance Status
DT   Global Distress (Thermometer)
Table 17: Correlations Between All of the Distress Measures At Baseline Showing Correlation Coefficients and P Values

Table 17 shows that there are many significant correlations between the assessment scores at baseline.

Note: The correlation coefficients related to Spiritual Distress are negative as the FACIT score falls with increasing distress.

Performance Status (KPS) At Baseline:

<table>
<thead>
<tr>
<th></th>
<th>EDS</th>
<th>MSAS</th>
<th>FACIT</th>
<th>DT</th>
</tr>
</thead>
<tbody>
<tr>
<td>KPS</td>
<td>0.37</td>
<td>0.02</td>
<td>0.65</td>
<td>0.92</td>
</tr>
</tbody>
</table>

Cell Contents: Pearson correlation
P-Value
EDS    Edinburgh Depression Score
MSAS   Physical Symptom Score
FACIT  Spiritual Distress Score
KPS    Karnofsky Performance Status
DT     Global Distress (Thermometer)

Table 18: Correlations Between KPS and Distress Measures At Baseline Showing Correlation Coefficients and P Values

Table 18 shows that the KPS correlates least well with all other components at baseline. This result was predictable in this study because the KPS was generally very stable throughout the course of disease. However, the KPS does have a significant negative correlation with physical distress, suggesting that as performance status declines, physical distress increases.
Physical, Psychological and Spiritual Distress At Baseline

Table 19: Correlations Between MSAS, EDS and FACIT At Baseline
Showing Correlation Coefficients and P Values

Table 19 shows that physical, psychological and spiritual distress all correlate significantly (p<0.001) with one another at baseline. The correlation coefficients between these measures are also relatively similar. Although the relationship between physical and spiritual distress remains significant, it is slightly weaker.

This implies that the components of distress impact upon one another, with increase in one component of distress apparently associated with increase in another.

5.7.2
Correlations between the changes in the various scores from baseline to 3 months

<table>
<thead>
<tr>
<th>EDS</th>
<th>MSAS</th>
<th>FACIT</th>
<th>KPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSAS</td>
<td>0.45</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>FACIT</td>
<td>-0.62</td>
<td>-0.55</td>
<td>0.00</td>
</tr>
<tr>
<td>KPS</td>
<td>-0.15</td>
<td>-0.28</td>
<td>-0.26</td>
</tr>
<tr>
<td>DT</td>
<td>0.74</td>
<td>-0.57</td>
<td>-0.5</td>
</tr>
<tr>
<td></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>
Table 20: Correlations Between The Changes in All of the Distress Measures From 0-3 Months, Showing Correlation Coefficients and P Values

Table 20 shows that many significant correlations exist between changes in assessment scores over the first 3 months.

NOTE: Changes over 0-3 months only were evaluated. This was done intentionally as the 0-3 month time period provided an adequate duration to detect a measurable change over time. The period beyond 3 months was excluded in order to avoid the effects of attrition upon the data analysis.

Performance Status (KPS) Over 0-3 Months:

<table>
<thead>
<tr>
<th>KPS</th>
<th>EDS</th>
<th>MSAS</th>
<th>FACIT</th>
<th>DT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-0.15</td>
<td>-0.28</td>
<td>-0.28</td>
<td>-0.14</td>
</tr>
<tr>
<td></td>
<td>0.23</td>
<td>0.02</td>
<td>0.03</td>
<td>0.25</td>
</tr>
</tbody>
</table>

Table 21: Correlations Between The Changes in KPS and the Distress Measures From 0-3 Months, Showing Correlation Coefficients and P Values

Table 21 shows the changes in the KPS correlate least well with the changes in all other components of distress over the first 3 months from referral. As at baseline, a significant negative correlation exists between physical distress and performance status. This suggests that over time, as performance status falls, physical distress increases. In addition, a significant negative correlation exists between spiritual
distress and performance status. This implies that as performance status declines over time, spiritual distress levels increase.

*Physical, Psychological and Spiritual Distress Over 0-3 Months:*

<table>
<thead>
<tr>
<th></th>
<th>EDS</th>
<th>MSAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSAS</td>
<td>0.45</td>
<td>0.00</td>
</tr>
<tr>
<td>FACIT</td>
<td>-0.62</td>
<td>-0.55</td>
</tr>
<tr>
<td></td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Cell Contents: *Pearson correlation P-Value*

EDS  Edinburgh Depression Score  
MSAS Physical Symptom Score  
FACIT Spiritual Distress Score

Table 22: Correlations Between The Changes in MSAS, EDS and FACIT From 0-3 Months, Showing Correlation Coefficients and P Values

Table 22 shows that the changes in physical, psychological and spiritual distress all correlate significantly (p<0.001) with one another over 0-3 months. The correlation coefficients between all of these measures are also relatively similar, although over 0-3 months, the correlation coefficient is highest between the spiritual and psychological components (r = -0.62).

This implies that the components of distress impact upon one another over time, with increase in one component of distress apparently associated with increase in another.

### 5.8

**The Distress Thermometer**

#### 5.8.1

**Correlations Between Global Distress and Distress Components**

As shown in Table 23, the DT correlates strongly with each of the EDS, MSAS, and FACIT both at baseline and for the change from baseline to the three-month
assessment. Note that these values differ marginally from those in the earlier tables, as the values given below are Spearman rank correlation coefficients.

<table>
<thead>
<tr>
<th></th>
<th>EDS</th>
<th>MSAS</th>
<th>FACIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Baseline</td>
<td>0.682</td>
<td>0.433</td>
<td>-0.412</td>
</tr>
<tr>
<td>(b) Change from baseline to 3 months</td>
<td>0.710</td>
<td>0.385</td>
<td>-0.477</td>
</tr>
</tbody>
</table>

Table 23: Spearman rank correlation between DT and other distress measures (a) at baseline, and (b) for change of measures from baseline to 3 months. Each correlation coefficient is statistically significant (p<0.001 in each case except for change in DT versus change in EDS, for which p=0.002).

Correlations Between Highest Levels of Global Distress and Distress Components

The worst scores (highest distress), over the entire study, on each of these measures were also compared with the worst DT scores and a strong, significant association was found, as shown in Table 24.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total</th>
<th>Significant distress (%)</th>
<th>Odds ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worst EDS ≥ 13</td>
<td>100</td>
<td>59</td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No</td>
<td>68</td>
<td>30 (44%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>32</td>
<td>29 (91%)</td>
<td>12.2 (3.40 to 44.1)</td>
<td></td>
</tr>
<tr>
<td>Worst MSAS physical score &gt; 1.5</td>
<td>100</td>
<td>59</td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>No</td>
<td>61</td>
<td>25 (41%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>39</td>
<td>34 (87%)</td>
<td>9.79 (3.36 to 28.5)</td>
<td></td>
</tr>
<tr>
<td>Worst FACIT score &lt; 20</td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.025</td>
</tr>
<tr>
<td>No</td>
<td>65</td>
<td>33 (51%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>35</td>
<td>26 (74%)</td>
<td>2.80 (1.14 to 6.89)</td>
<td></td>
</tr>
</tbody>
</table>

Table 24: Association between significant distress (defined as a worst thermometer score over 5) and the worst level of distress on the psychological, physical and spiritual measures.
5.8.2

Global Distress at the End Of Life
The DT scores at the time of death were evaluated for patients who died during the study. Of the 47 who died, 31 patients had been able to complete a penultimate and final DT score in the immediate period prior to death.
At both of these assessments, the median DT score was 5, with an inter-quartile range of 0-7. The median change between these final two assessments was 0, with an inter-quartile range of -2 to 2. In detail, the DT scores remained unchanged for 6 patients, increased amongst 14 patients and decreased for 11 patients.

The mean distress score increased at the end of life from 4.0 (SD 3.4) to 4.2 (SD 3.3), a mean change of 0.2 (SD 4.4). Therefore, in summary, no systematic change was found between distress levels documented at the penultimate and final assessments in the period immediately prior to death. Therefore, distress levels did not appear to be influenced by immediate proximity to death.

5.9

Analysis of Medication Use
The use of opiates and sedatives was recorded and the data were analysed. The doses were classified as follows:

- Extreme opiate dose: >200mg oral morphine equivalent
- Extreme sedation: >60mg midazolam or
  >30mg midazolam + levomepromazine or haloperidol

Most patients in this study (57%) were using either no opioid, or low doses. Nine patients required extreme doses of opioid. Of these patients, 6 were also using sedatives, although only 2 of them required a sedative dose.

Very few patients required complete sedation (n=8). Only 1 patient required an extreme sedative dose, and this was used together with a low opiate dose. The small
numbers of sedated patients may be accounted for by the effect of sedation on conscious level: Data were often not available from those who were fully sedated.

There does not appear to be a clear association between opiate and sedative doses, although 30 patients (the largest single group) required neither.

5.9.1
Opioid Dose and Social Status
The use of opiate was compared with social status. This is illustrated in Table 25 below.

<table>
<thead>
<tr>
<th>Maximum Opiate Dose</th>
<th>DEPCAT 1&amp;2</th>
<th>DEPCAT 3&amp;4</th>
<th>DEPCAT 5&amp;6</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>10</td>
<td>15</td>
<td>9</td>
<td>34</td>
</tr>
<tr>
<td>Zero</td>
<td>% With DEPCAT</td>
<td>38.4</td>
<td>30.6</td>
<td>36</td>
</tr>
<tr>
<td>Count</td>
<td>4</td>
<td>14</td>
<td>5</td>
<td>23</td>
</tr>
<tr>
<td>1-50mg</td>
<td>% With DEPCAT</td>
<td>15.4</td>
<td>28.6</td>
<td>20</td>
</tr>
<tr>
<td>Count</td>
<td>6</td>
<td>12</td>
<td>8</td>
<td>26</td>
</tr>
<tr>
<td>51-100mg</td>
<td>% With DEPCAT</td>
<td>23.1</td>
<td>24.5</td>
<td>32</td>
</tr>
<tr>
<td>Count</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>200mg</td>
<td>% With DEPCAT</td>
<td>11.5</td>
<td>6.1</td>
<td>8</td>
</tr>
<tr>
<td>Count</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>&gt;200mg</td>
<td>% With DEPCAT</td>
<td>11.5</td>
<td>10.2</td>
<td>4</td>
</tr>
<tr>
<td>Count</td>
<td>26</td>
<td>49</td>
<td>25</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>% With DEPCAT</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Note: DEPCAT 1 = Most Affluent, DEPCAT 6 = Least Affluent

Table 25: Opioid Dose Compared With Social Status (DEPCAT)

There is no apparent trend between social status and opioid use for the study sample. Patients who were the least affluent (DEPCAT 5 & 6) appeared to use the lowest percentage of extreme opioid doses (4%). However, the significance of this is dubious due to the small numbers in each category.
The sample was further divided into those who died and those who survived and the analysis was repeated. There was no obvious difference between these groups, for whom the numbers in each category were very small.

**Sedative Dose and Social Status**

The use of sedatives was also compared with social status. This is illustrated in Table 26 below.

<table>
<thead>
<tr>
<th>Maximum Sedative Dose</th>
<th>DEPCAT 1&amp;2</th>
<th>DEPCAT 3&amp;4</th>
<th>DEPCAT 5&amp;6</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>19</td>
<td>30</td>
<td>14</td>
<td>63</td>
</tr>
<tr>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% With DEPCAT</td>
<td>73.1</td>
<td>61.2</td>
<td>56</td>
<td>63</td>
</tr>
<tr>
<td>Count</td>
<td>7</td>
<td>11</td>
<td>11</td>
<td>29</td>
</tr>
<tr>
<td>Sub-Sedative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% With DEPCAT</td>
<td>26.9</td>
<td>22.4</td>
<td>44</td>
<td>29</td>
</tr>
<tr>
<td>Count</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Sedative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% With DEPCAT</td>
<td>0</td>
<td>14.3</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Count</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Extreme</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% With DEPCAT</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Count</td>
<td>26</td>
<td>49</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% With DEPCAT</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 26: Sedative Dose Compared With Social Status (DEPCAT)

There is no apparent trend between social status and sedative use for the study sample. The analysis was repeated separately for those who died and those who survived. There was no apparent difference between these two groups, for whom the numbers in each category were very small.

**5.9.2**

**Opioid Dose and Global Distress**

The opioid doses were categorised and analysed for their association with significant global distress. The analysis reveals a significant association between opioid dose and significant global distress. The odds ratios indicate that greater opioid doses are associated with an increased likelihood of significant global distress, for a morphine equivalent dose of >100mg, (OR 3.66, 95% CI 0.99 to 13.5, p = 0.022).
**Opioid Dose and Physical Distress**

The maximum (worst) physical symptom scores (MSAS) were analysed according to the maximum dose of opiates used. The findings are illustrated below in Figures 41 and 42:

**MSAS According to Opioid Score Overall Study Group**

![Box Plot Illustrating The Relationship Between The Average Worst MSAS Scores and Maximum Opioid Doses](image)

**Figure 41: Box Plot Illustrating The Relationship Between The Average Worst MSAS Scores and Maximum Opioid Doses**

The Spearman rank correlation between maximum physical score and maximum opioid dose is 0.29 (p=0.004) for the overall group, indicating a significant correlation between increasing physical symptoms and increasing opioid dose.
Figure 42: Box Plot Illustrating The Relationship Between The Average Worst MSAS Scores and Maximum Opioid Doses Separated For Those Who Died and Those Who Survived

The numbers for those who died and those who survived were too small to further analyse separately. In each case, the trend appears to be similar to the overall group. Interestingly however, the separated box plot appears to show that at the highest dose of opioid, physical symptoms were also highest for those who died, but this was not so amongst those who survived. The numbers are however too small to provide an indication of the validity of this finding.

**Sedative Dose and Global Distress**

The sedative doses were analysed for their association with significant global distress, as shown in Table 27. The categories were slightly expanded in order to include adequate numbers for meaningful analysis.
Table 27: Results of univariate logistic regression investigating the associations of significant distress (defined as worst thermometer score over 5) with sedative dose. The P-values were obtained by treating the covariates as continuous variables.

No association was found between sedative dosage and significant global distress. This may be related to the small numbers analysed. The small numbers may have been due to the adverse effect of extreme, or even sedative doses of sedation upon conscious level, which would have compromised the ability of these patients to complete the assessment.

Further Analysis of Medication Use

The associations between doses of opiates and sedatives and various clinical criteria were also analysed and are reported in each relevant section as follows.

5.10 Analysis of Healthcare Contacts

Contacts were considered as unscheduled contact with healthcare professionals or services. These were divided into out-of-hours home visits from community teams and unscheduled admissions into hospital or hospice over the course of the study.

5.10.1 Analysis of Out-Of-Hours Contacts

The numbers of contacts was initially considered separately for those who survived and those who died during the study. These two groups were at different points in their disease trajectory and were therefore considered to have potentially distinct healthcare needs. Table 28 below illustrates the numbers of out-of-hours home visits recorded for those who died and those who survived.
<table>
<thead>
<tr>
<th>Out of hours home visits</th>
<th>Surviving to end of study</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td></td>
<td>35</td>
<td>24</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(66%)</td>
<td>(51%)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>11</td>
<td>12</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(21%)</td>
<td>(26%)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>5</td>
<td>8</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(9%)</td>
<td>(17%)</td>
<td></td>
</tr>
<tr>
<td>3 or more</td>
<td></td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(4%)</td>
<td>(6%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>53</td>
<td>47</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 28: Number of Out-Of-Hours Home Visits Recorded, Separated According To Those Who Died and Those Who Survived

These figures indicate that a greater percentage of the patients who survived the study, did not require any out of hours visits, compared with those who died during the study (66% compared with 51%). Conversely, a greater percentage of the patients who died during the study required 1 or more out-of-hours home visits. This is perhaps a reflection of the differing healthcare needs of these groups. Those who died during the study were likely to have been frailer with poorer health than those who survived the study.

**Out-of-Hours Contacts And Distress Levels**

The numbers of out-of-hours home visits were categorised and evaluated for their association with significant global distress, as shown in Table 29. Separate analysis of those who died and those who survived was not possible, as the numbers were too small.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total</th>
<th>Significant distress (%)</th>
<th>Odds ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Out of Hours Home Visits</td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.036</td>
</tr>
<tr>
<td>0</td>
<td>59</td>
<td>31 (53%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>23</td>
<td>13 (57%)</td>
<td>1.17 (0.44 to 3.10)</td>
<td></td>
</tr>
<tr>
<td>≥ 2</td>
<td>18</td>
<td>15 (83%)</td>
<td>4.52 (1.18 to 17.3)</td>
<td></td>
</tr>
</tbody>
</table>

Table 29: Results of univariate logistic regression investigating the associations of significant distress (defined as worst thermometer score over 5) with out-of-hours home visits. The P-values were obtained by treating the covariates as continuous variables.
Although the categories were broad, in order to ensure the numbers were meaningful, univariate logistic regression indicates a significant association between the number of out-of-hours home visits and significant global distress. Odds ratios suggest that the greater number of out-of-hours home visits, the greater the likelihood of significant global distress, for ≥2 visits (OR 4.52, 95% CI 1.18 to 17.3, p = 0.036).

**Out-Of-Hours Contacts and Medication Use**

Opioid doses used were compared with numbers of out-of-hours home visits. A significant association was found between opioid dose and the number of out-of-hours home visits: More visits are associated with higher doses of opioids ($\chi^2 = 4.23$, 1 df, p=0.04).

Sedative use was analysed in the same way and a significant association was also found between sedative dose and the number of out-of-hours home visits: Increased sedation is associated with more visits ($\chi^2 = 10.9$, 1 df, p<0.001).

**5.10.2**

**Analysis of Unscheduled Admissions**

The admissions were also initially considered separately for those who died and those who survived. Table 30 below illustrates the number of admissions recorded for those who died and those who survived.

<table>
<thead>
<tr>
<th>Admissions</th>
<th>Surviving to end of study</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>0</td>
<td>20 (38%)</td>
<td>5 (11%)</td>
</tr>
<tr>
<td>1</td>
<td>13 (25%)</td>
<td>10 (21%)</td>
</tr>
<tr>
<td>2</td>
<td>6 (11%)</td>
<td>11 (23%)</td>
</tr>
<tr>
<td>3</td>
<td>3 (6%)</td>
<td>11 (23%)</td>
</tr>
<tr>
<td>≥4</td>
<td>11 (21%)</td>
<td>10 (21%)</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>47</td>
</tr>
</tbody>
</table>

Table 30: Number of Admissions Recorded, Separated According To Those Who Died and Those Who Survived
These figures do not present an obvious trend. However, it does appear that a greater percentage of those who survived did not require admission compared with those who died during the study (38% compared with 11%). Again, this may reflect the potentially greater healthcare needs of those patients in the study who were nearer the end of life.

** Unscheduled Admissions and Distress Levels **

The numbers of unscheduled admissions were categorised and evaluated for their association with significant global distress, as shown in Table 31. Separate analysis of those who survived and those who died was not possible, due to the small numbers.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total</th>
<th>Significant distress n (%)</th>
<th>Odds ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admissions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>100</td>
<td>59</td>
<td></td>
<td>0.004</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>10 (40%)</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>23</td>
<td>12 (52%)</td>
<td>1.64 (0.52 to 5.14)</td>
<td></td>
</tr>
<tr>
<td>2 or 3</td>
<td>31</td>
<td>20 (65%)</td>
<td>2.73 (0.92 to 8.09)</td>
<td></td>
</tr>
<tr>
<td>≥ 4</td>
<td>21</td>
<td>17 (81%)</td>
<td>6.37 (1.65 to 24.6)</td>
<td></td>
</tr>
</tbody>
</table>

Table 31: Results of univariate logistic regression investigating the associations of significant distress (defined as worst thermometer score over 5) with admissions. The P-values were obtained by treating the covariates as continuous variables.

Univariate logistic regression reveals a significant association between the number of unscheduled admissions and significant global distress. Odds ratios imply that the greater the number of unscheduled admissions, the greater the likelihood of experiencing significant global distress, for ≥4 admissions (OR 6.37, 95% CI 1.65 to 24.6, p = 0.004).

** Unscheduled Admissions and Medication Use **

Opioid doses used were compared with the number of unscheduled admissions. Analysis revealed a significant association between the strength of opioid required
and the number of unscheduled admission: More admissions are associated with higher doses of opioids ($\chi^2 = 15.5$, 1 df, $p<0.001$).

Sedative requirement was analysed in the same way also revealing a significant association was found between sedative dose and the number of unscheduled admission: Increased sedation is associated with more admissions ($\chi^2 = 14.5$, 1 df, $p<0.001$).

5.11
Analysis of Place of Death

For those patients who died during the study, the place of death was recorded. Table 32 illustrates the percentage of patients who died in each of the places:

<table>
<thead>
<tr>
<th>Place of Death</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospice</td>
<td>20 (44%)</td>
</tr>
<tr>
<td>Home</td>
<td>12 (27%)</td>
</tr>
<tr>
<td>Nursing Home</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Acute Hospital</td>
<td>13 (29%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Total</td>
<td>45</td>
</tr>
</tbody>
</table>

Table 32: Place of Death of Patients

The most frequent place of death was the Hospice, followed by similar numbers of deaths in acute hospitals and at home.

Place of Death and Distress Levels

Each place of death was analysed according to the numbers of patients who were, and who were not significantly distressed. Unfortunately the numbers in each category are very small, prohibiting detailed analysis and derivation of meaningful associations. There are no obvious differences in the percentages of patients who were distressed, compared with those who were not distressed, in each place of death.
Place of Death and Medication Use

Analysis was conducted in order to establish the association between place of death and opioid dosage. Unfortunately the numbers were too small for any formal analysis. Sedative use was also analysed in relation to place of death. Unfortunately, the numbers were again, too small for formal analysis.
5.12 Qualitative Data Analysis

Recruitment, sampling and data generation have been described in detail in the methods chapter, in sections 3.9 and 3.10.

5.12.1 Process of Data Analysis

Transcription

The digital interview recordings were downloaded and transcribed verbatim by trained secretarial staff. Of the 71 interviews, 60 were transcribed by one individual, 9 were done by a second person and a third person transcribed 3 interviews in total. Each of the secretaries annotated the spoken words with descriptions of associated behaviours, such as “crying”, “laughing”, “silence” etc. The research doctor listened to a random selection of interviews recordings whilst reading the associated transcripts, in order to ensure accuracy of transcription.

With longitudinal data, consistency and continuity of transcription are essential. An individual transcribing data verbatim, without having been involved in the interview, will obviously do so subjectively, this is inherent in the process. Therefore, for sequential interviews with the same patient, it is important to ensure that the same level of subjectivity is applied, in order to minimise the associated distortion.

The completed transcripts were returned to the RD via email, in Word documents. These were then imported into the NVivo 2.0 qualitative data analysis software package, which was used to assist with coding. The package does not produce codes or themes, it simply organises data in such a way as to facilitate the process of coding.

Thematic Approach and Interpretive Analysis

Analysis was thematic, according to the research question. Narratives were preserved and analysed in their entirety. Both interview transcripts and field notes were analysed.
Coding

Data were coded according Strauss and Corbin’s (Strauss and Corbin, 1998) system of open, axial and selective coding described in the methods chapter.

Longitudinal Themes

Once the initial coding was completed and themes were identified, the data were analysed longitudinally. All of the first interviews were analysed as a group, followed by each group of subsequent interviews. Pre-death interviews occurred at different time points for each individual and therefore these were also collated and studied as group. Additionally, the series of interviews completed by each individual patient were analysed in sequence. The themes were considered longitudinally for their content and frequency. This process was assisted by use of the NVivo 2.0 qualitative data analysis software package.

Rigour

Analysis and interpretation was conducted by the author and strengthened through the input and validation of an established qualitative researcher, with specific extensive experience in qualitative end of life research.

5.12.2

Demographics

Twenty patients were identified from consecutively recruited patients into the quantitative study (10 male, 10 female). The recruitment rate into the quantitative study was 52%. One hundred percent of the patients approached, having been already recruited into quantitative study, agreed to participation in the qualitative study. As intended through purposive sampling, a wide range of ages (average 60 years), tumour types and deprivation categories (DEPCAT) were included. In total, 71 interviews were completed (range 1 to 6 per patient). Fifty percent (n = 10) of this population died during the course of the study, 40% (n = 8) survived the study and 10% (n = 2) withdrew. Table 33 below summarises the socio-demographics of the qualitative study sample:
### Summary Demographics Table for Qualitative Patients

<table>
<thead>
<tr>
<th>ID</th>
<th>Sex</th>
<th>Age</th>
<th>Tumour</th>
<th>DEPCAT</th>
<th>Study Status</th>
<th>Marital Status</th>
<th>Ethnicity</th>
<th>No. Interv</th>
<th>Ethnicity</th>
<th></th>
<th>No.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>55</td>
<td>Renal</td>
<td>4</td>
<td>Died: Hospice</td>
<td>Married</td>
<td>White</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>51</td>
<td>Breast</td>
<td>3</td>
<td>Completed</td>
<td>Single</td>
<td>White</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>24</td>
<td>Testicular</td>
<td>4</td>
<td>Completed</td>
<td>Partner</td>
<td>White</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>46</td>
<td>Pancreatic</td>
<td>4</td>
<td>Died: Home</td>
<td>Divorced</td>
<td>White</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>79</td>
<td>Colon</td>
<td>1</td>
<td>Died: Home</td>
<td>Widowed</td>
<td>White</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>64</td>
<td>Bladder</td>
<td>1</td>
<td>Died: Hospice</td>
<td>Divorced</td>
<td>White</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>82</td>
<td>Colon</td>
<td>5</td>
<td>Died: Hospice</td>
<td>Widowed</td>
<td>White</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>71</td>
<td>Lung</td>
<td>5</td>
<td>Completed</td>
<td>Married</td>
<td>White</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>66</td>
<td>Lung</td>
<td>4</td>
<td>Withdrawn</td>
<td>Widowed</td>
<td>White</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>M</td>
<td>54</td>
<td>Colon</td>
<td>4</td>
<td>Died: Hospice</td>
<td>Married</td>
<td>White</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>78</td>
<td>Tongue</td>
<td>4</td>
<td>Died: Hospice</td>
<td>Divorced</td>
<td>White</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>F</td>
<td>60</td>
<td>Ovary</td>
<td>5</td>
<td>Completed</td>
<td>Married</td>
<td>White</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>M</td>
<td>74</td>
<td>Prostate</td>
<td>3</td>
<td>Completed</td>
<td>Widowed</td>
<td>White</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>F</td>
<td>66</td>
<td>Lung</td>
<td>3</td>
<td>Completed</td>
<td>Widowed</td>
<td>White</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>F</td>
<td>43</td>
<td>Unknown</td>
<td>5</td>
<td>Died: Hospice</td>
<td>Divorced</td>
<td>White</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>F</td>
<td>58</td>
<td>Lung</td>
<td>3</td>
<td>Withdrawn</td>
<td>Married</td>
<td>Pakistani</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>M</td>
<td>65</td>
<td>Oesophagus</td>
<td>4</td>
<td>Completed</td>
<td>Divorced</td>
<td>White</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>F</td>
<td>51</td>
<td>Colon</td>
<td>5</td>
<td>Completed</td>
<td>Divorced</td>
<td>White</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>M</td>
<td>52</td>
<td>Lung</td>
<td>3</td>
<td>Died: Hospice</td>
<td>Divorced</td>
<td>White</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>F</td>
<td>57</td>
<td>Melanoma</td>
<td>4</td>
<td>Died: Hospital</td>
<td>Married</td>
<td>White</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 33:** Summary of the Socio-Demographics of the Qualitative Sample

**Ethnicity**

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>British</td>
<td>19</td>
<td>95</td>
</tr>
<tr>
<td>Pakistani</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>100</td>
</tr>
</tbody>
</table>

**Table 34:** Ethnicity of the Qualitative Sample

Table 34 shows that the majority of patients were white. The one Pakistani patient was represented in the qualitative study.
Religion

<table>
<thead>
<tr>
<th>Religion</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Christian</td>
<td>15</td>
<td>75</td>
</tr>
<tr>
<td>Muslim</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Atheist</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 35: Religion of the Qualitative Sample

Table 35 shows that the majority of patients are Christian. The Pakistani patient was Muslim.

Social Status

<table>
<thead>
<tr>
<th>DEPCAT</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>40</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>25</td>
</tr>
</tbody>
</table>

Table 36: Social Status (DEPCAT) of the Qualitative Sample

Figure 43: Graph Illustrating The Percentage of Qualitative Sample Patients in Each Deprivation Category
Table 36 and Figure 43 show that other than DEPCAT 2, the full range of deprivation categories was represented in the qualitative study group. The majority of patients were in DEPCAT 4.

**Gender**

<table>
<thead>
<tr>
<th>Gender</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Female</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 37: Gender Ratio in the Qualitative Sample

Table 37 shows the ratio of male: female recruited into the qualitative study was 1:1.

**Age**

<table>
<thead>
<tr>
<th>Age</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;51</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>51-60</td>
<td>8</td>
<td>40</td>
</tr>
<tr>
<td>61-70</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>71-80</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>&gt;81</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 38: Ages of the Qualitative Sample

Figure 44: Graph Illustrating The Percentage of Qualitative Sample Patients in Each Age Category
As intended, and illustrated by Table 38 and Figure 44, a wide range of ages was represented within the qualitative study group, from very young to very old. Most patients were between the ages of 51 and 60.

**Marital Status**

<table>
<thead>
<tr>
<th>Marital Status</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married</td>
<td>6</td>
<td>30</td>
</tr>
<tr>
<td>Divorced</td>
<td>6</td>
<td>30</td>
</tr>
<tr>
<td>Widowed</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>Co-habiting</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Separated</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Single</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 39: Marital Status of the Qualitative Sample

Table 39 shows that marital status differed amongst the qualitative study group, with representation from each category. Most patients were either married or divorced (30% and 30%), 25% were widowed.

**Tumour Type**

<table>
<thead>
<tr>
<th>Tumour Type</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>Colon</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>Breast</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Prostate</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Bladder</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Melanoma</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Oesophagus</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Ovary</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Pancreas</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Renal</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Testicular</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Tongue</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 40: Tumour Types Amongst the Qualitative Sample
A wide variety of tumour types were represented, as was the intention of the sampling. Table 40 shows that there was a majority with lung tumours (25%) and 20% had colorectal tumours. The 4 most common tumours in Scotland are carcinomas of the lung, colon, breast and prostate. Carcinomas of the breast and prostate were also both represented in the qualitative study group, by 1 patient with each tumour type.

Non-Participation
Of those recruited into the quantitative study, no patients chose not to participate in the qualitative study.

Withdrawal
The 2 patients who withdrew from the study were in the qualitative group.

5.12.3
Comparison With Quantitative Study

Ethnicity
In terms of ethnic diversity, there was only 1 Pakistani patient in the whole study and she was included in the qualitative study. The rest of the patients were white, corresponding with the ethnic population statistics of the Forth Valley area (see previous). Therefore, there were no differences in ethnicity between the overall quantitative study and the qualitative sub-group.

<table>
<thead>
<tr>
<th>Religion</th>
<th>Quantitative</th>
<th>Qualitative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>Christian</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>Muslim</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Atheist</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>None</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>
Table 41: Comparison Of The Religious Beliefs Of The Qualitative Sample With The Whole Study Population

As shown in Table 41, the main difference between the 2 groups is that the group with “no religion” was not represented at all in the qualitative study, whilst the atheist group was over represented in the qualitative study (20% compared with 2%). Therefore, the results of the qualitative study may not be directly applicable to patients without religion, as they were not studied. This was not an intentional omission.

**Social Status**

![Comparison Of Social Status](image)

**Figure 45: Graph Comparing The Social Status (DEPCAT) Of The Qualitative Sample With The Whole Study Population (Quantitative)**

Figure 45 shows that, on the whole, DEPCAT was similarly represented in both the qualitative and quantitative groups. The main difference between the 2 groups, in terms of DEPCAT was that DEPCAT 2 and 6 were not represented in the qualitative study, whilst DECPAT 4 was slightly over represented. However, a wide range of DEPCAT was represented in the qualitative sub-group.

**Gender**

There was no real difference in gender representation between the 2 groups, with (almost) equal representation in each. In the qualitative study, 50% were male and 50% female, compared with 51% and 49% respectively, in the overall quantitative study.
### Age

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Quantitative</th>
<th>Qualitative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>&lt;51</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>51-60</td>
<td>26</td>
<td>26</td>
</tr>
<tr>
<td>61-70</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>71-80</td>
<td>31</td>
<td>31</td>
</tr>
<tr>
<td>&gt;81</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

**Table 42:** Comparison Of The Ages Of The Qualitative Sample With The Whole Study Population

![Comparison of Age Groups](image)

**Figure 46:** Graph Comparing The Ages Of The Qualitative Sample With The Whole Study Population (Quantitative)

Table 42 and Figure 46 show that a wide range of ages is similarly represented in both the qualitative sample and the overall study population. There are no major differences although the 51-60 age group may be slightly over represented in the qualitative study.
Tumour Type

Figure 47: Graph Comparing The Tumour Types Of The Qualitative Sample With The Whole Study Population (Quantitative)

As illustrated by Figure 47, there are no major differences between the tumour types represented by each group. Breast tumours were perhaps under-represented in the qualitative sub-group, but this was intended, in order to reflect the diversity of tumour type within the population, rather than to provide a directly representative sample.

Study Survival
In the qualitative sub-group, 50% of the patients died, compared with 47% in the overall quantitative study.

Summary Of Comparison
The qualitative sub-group was largely similar and representative of the overall quantitative study group and hence, the wider Hospice Home Care population. In addition, the sample incorporates the diversity in demographics and tumour type of the population. This implies that generalisation to this group of patients is appropriate, without significant bias.
5.13 Codes

5.13.1 Open and Axial Coding

The described coding procedure was followed. Open coding resulted initially in an extensive list of over 200 free codes. Using the constant comparative technique to further the analysis, axial coding produced 22 tree concepts with over 300 branches in total.

At this stage of the analysis, the appropriate categorisation of the concepts according to context, condition and consequences, became evident: Each concept clearly belonged to a physical, psychological, social or spiritual category. The trees were therefore subsequently condensed into “key” physical, psychological, social and spiritual themes. This resulted in these four categories, each with 8-11 sub-categories. These are summarised in Table 43 below:

<table>
<thead>
<tr>
<th>Key Physical</th>
<th>No.</th>
<th>Key Psychological</th>
<th>No.</th>
<th>Key Social</th>
<th>No.</th>
<th>Key Spiritual</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom Debility</td>
<td>107</td>
<td>Coping Strategy*</td>
<td>75</td>
<td>Family*</td>
<td>282</td>
<td>Control</td>
<td>253</td>
</tr>
<tr>
<td>Expectations</td>
<td>80</td>
<td>Accepting*</td>
<td>73</td>
<td>Communication*</td>
<td>176</td>
<td>Reflective</td>
<td>181</td>
</tr>
<tr>
<td>Dependence</td>
<td>68</td>
<td>Uncertainty</td>
<td>65</td>
<td>Professionals*</td>
<td>138</td>
<td>Hope</td>
<td>120</td>
</tr>
<tr>
<td>Fatigue</td>
<td>38</td>
<td>Impact of Physical</td>
<td>64</td>
<td>Friends</td>
<td>73</td>
<td>Faith</td>
<td>107</td>
</tr>
<tr>
<td>Quality of Life</td>
<td>33</td>
<td>Information Needs</td>
<td>52</td>
<td>Healthcare Services</td>
<td>59</td>
<td>Purpose</td>
<td>103</td>
</tr>
<tr>
<td>Related Psychological</td>
<td>29</td>
<td>Frustration</td>
<td>48</td>
<td>Independence</td>
<td>42</td>
<td>Normality</td>
<td>81</td>
</tr>
<tr>
<td>Symptom Significance</td>
<td>26</td>
<td>Positive*</td>
<td>47</td>
<td>Financial Affairs</td>
<td>27</td>
<td>Isolated</td>
<td>60</td>
</tr>
<tr>
<td>Pain Debility</td>
<td>25</td>
<td>Vulnerable</td>
<td>45</td>
<td>Culture</td>
<td>24</td>
<td>Dignity</td>
<td>23</td>
</tr>
<tr>
<td>Effects of Treatment</td>
<td>18</td>
<td></td>
<td></td>
<td>Work</td>
<td>12</td>
<td>What If</td>
<td>12</td>
</tr>
<tr>
<td>Symptoms Negligible</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Embarrassment</td>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Sub-Categories

Table 43: Number of Codes Recorded In Each Category and Sub-Category

The functions in Nvivo were then used to assist the further reduction of these sub-categories. This was done according to the frequency of use of each individual subsidiary code, within the context of the relative importance of the code’s underlying concept, and in relation to the other concepts, as well as the wider picture according to the coding framework (derived from the researcher’s empirical
standpoint, research question and the earlier data analysis). The condensation structure of each category is demonstrated below.

**Fundamental Physical Themes**

<table>
<thead>
<tr>
<th>Debility</th>
<th>Dependence</th>
<th>Expectations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom Debility</td>
<td>Related Psychological Symptoms Negligible</td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>Symptom Significance</td>
<td></td>
</tr>
<tr>
<td>Quality of Life</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain Debility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effects of Treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Embarrassment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Fundamental Psychological Themes**

<table>
<thead>
<tr>
<th>Uncertainty</th>
<th>Vulnerability</th>
<th>Understanding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coping Strategy</td>
<td>Impact of Physical</td>
<td>Accepting</td>
</tr>
<tr>
<td></td>
<td>Frustration</td>
<td>Positive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Information Needs</td>
</tr>
</tbody>
</table>

**Fundamental Social Themes**

<table>
<thead>
<tr>
<th>Family</th>
<th>Communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Friends</td>
<td>Professionals</td>
</tr>
<tr>
<td>Independence</td>
<td>Healthcare Services</td>
</tr>
<tr>
<td>Finances</td>
<td>Culture</td>
</tr>
<tr>
<td>Work</td>
<td></td>
</tr>
</tbody>
</table>

**Fundamental Spiritual Themes**

<table>
<thead>
<tr>
<th>Reflective</th>
<th>Hope</th>
<th>Faith</th>
</tr>
</thead>
<tbody>
<tr>
<td>What If</td>
<td>Purpose</td>
<td></td>
</tr>
<tr>
<td>Isolated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dignity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: Control is intentionally excluded and is discussed later*

**Summary of the Fundamental Themes**

<table>
<thead>
<tr>
<th>Physical</th>
<th>Psychological</th>
<th>Social</th>
<th>Spiritual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Debility</td>
<td>Uncertainty</td>
<td>Family</td>
<td>Reflection</td>
</tr>
<tr>
<td>Dependence</td>
<td>Understanding</td>
<td>Communication</td>
<td>Hope</td>
</tr>
<tr>
<td>Expectations</td>
<td>Vulnerability</td>
<td></td>
<td>Faith</td>
</tr>
</tbody>
</table>

The concepts within each category are described separately, for the purpose of clarity. However, all of these concepts, within and between categories, are inter-
related and mutually influential upon one another. These relationships will be described later.

5.13.2
Physical Themes
The three key themes are inter-related. Debility is often the recognised cause of dependence and this relationship is moderated by the effect of personal expectations.

Debility  →  Dependence

Debility
The main physical issues for patients relate to the debility associated with symptoms, in particular fatigue. The following are three selected examples from many:

“Physically? I am just as weak as a kitten, just as weak as a kitten, very weak. My legs are very weak. I couldn’t walk a big distance without my sticks or anything like that. Out of breath, couldn’t do anything like that.” Interview 1: #17

I was always a great one for walking, I was always a great one for getting... it’s come to the time of year where the garden is starting to come to life: I want to be out in my garden. I want to do these things. I tried to get out in my garden and I made myself ill, just through trying to, not doing too much but I cut the front garden and the back garden and it was just too much, I ended up in bed. I’ve ended up in bed from a lot of different things now that I cannae handle.” Interview 2: #1

“I am not out of breath, I just don’t have the energy to walk about. Up the stairs is just a nightmare; it takes me ages to get to the top. The other day there I was not well, I got to the top of the stairs and I thought what did I come up for? That was really annoying because it takes me a long time to get up there and I had to come away back down again. After I sat down I could remember what I went up for, I
thought I will leave it because I am not going back up those stairs just now.”

Interview 5: #18

Dependence
Physical dependence was a major concern for patients. Again, this is illustrated by three exerts taken from many similar examples.

Talking about his wife’s birthday card:
“...but I got the card written out, it was all done in wee bits and pieces: I had to get my sister in law to get the card and I had to put money in the card cos I couldnae manage to get out and do it for myself which again annoys me, it's just something that you want to do, but these things are all disappearing. I've no even got the car, my licence was taken off me because of the thing on the brain, so these are all wee things but it’s stripping it away from me.” Interview 2: #1

“It’s my helplessness I cannæ get over...oh it’s awful! It’s a terrible feeling to depend on someone from morning to night.” Interview 1: #11

“I’d far rather go and get a glass or get a drink or whatever for myself than have to ask somebody to have to go and get it for me. And it doesn’t matter how big a struggle I’ve got, I’d rather do it myself and my daughter doesn’t understand that and it’s frustrating for her cos she wants to help but she wants to do it her way and I find that frustrating because I am wanting it my way.” Interview 1: #19

Expectations
Patients’ own expectations of quality of life affect the relationship between debility and dependence. Expectations of life are often originally derived from patients’ life experiences, their age and their pre-morbid quality of life and lifestyle. This is illustrated in the following three quotes:

Gentleman of 71 years with a long history of COPD
"I’m usually out nearly every day for a pint but I havenae been out since Monday. I got this pain in my back in the pub and I’d to get a taxi back and I haven’t been down since. I am going to go out today to see if it’s a one off that thing that happened on Monday. If it happens today again I’ll know that that pain is not right, cos I couldn’t go out and sit in pain in front of people. I couldn’t go back out again you know but I’d be quite happy to stay in the house, I would if I was lying in my bed and my kids come in to see me and everything was going normal aye I’d be happy.”

Interview 4: #8

Gentleman of 24 years, previously very athletic

"why me? What’s happening to me? I don’t know if it’s the same for people who are older but it’s just my age; when you know that you can do something but your body doesn’t let you, it’s really hard to get to grips with.”

Interview 2: #3

Gentleman of 46 years

“My dad died from cancer. Before you actually see someone dying from the disease you are basically ignorant of it as you are with most illnesses, you really don’t know much about how things progress but when someone, like your parent, suffers from that disease you are learning all the time and you start to see the changes in them day by day. So if you are unfortunate enough, as I am, to be hit by one of the worse types you are prepared already, you know the signs within yourself.”

Interview 1: #4

5.13.3

Psychological Themes

The three fundamental psychological themes are inter-related. Living with the terminal illness inherently causes uncertainty in everyday life. The level and impact of the uncertainty can be moderated by improving understanding of the disease through information seeking and also by developing appropriate coping strategies. Vulnerability and associated frustration result from the combination of uncertainty and lack of understanding, together with the physical impact of disease.
Understanding Uncertainty

These key psychological themes are illustrated in the examples below.

**Understanding**
Understanding is important in making sense of symptoms, minimising uncertainty and developing realistic expectations.

"I think it could have been explained a bit more about the treatments and what I can expect... you've got to have confidence in the doctors, it's not the nurses fault to tell you what to expect you know, but the doctors didn't tell me. It would have been nice to have more insight to prepare myself might have handled it a bit better."  **Interview 2: #3**

"It's information that I want. I don't think at the moment I need, I need pain control. I don't think at the moment I need really much else; I don't need surgery. I don't need this, I don't need that, I don't need the next thing all I need is information."  **Interview 1: #19**

"From the first time that I went into the hospital when they asked me "do you know anything about your cancer?" and I said well I know I've got Dukes IV and I've read in the library book that they dunnae last any longer than six months and she said "well we think you've got two year"... but is that set in stone two years? See I need to find out cos I just think to myself I'm going to ask questions again. It's only my life and I need to ask they questions again!"  **Interview 4: #18**

**Uncertainty**
Uncertainty was a truly fundamental issue, relevant to the daily life of every patient. The following illustrative exerts were taken from many possible examples:
"Well there’s a ray of sunshine if I respond to that treatment. I might get another couple of months on my life. I don’t know, or it might be more comfortable, but that’s only an “if” and I realise that. It’s an outside chance but I’ll go for it, as much as I hate chemotherapy and that. I keep wondering should I do it cos if it’s going to make me upset and feeling unwell and then after three shots of it, that’s like nine weeks, it’s actually speeded up my death rather than slowed it down; so that’s a concern too." Interview 3: #6

"Uncertainty of not knowing what’s happening to me now. It’s going through my head tonight that I’ve got cancer in the throat. That’s what’s going through my head and they’ve not done anything about it. I am saying to myself is it the lymph glands in my throat, is it in my bowels, is it in my kidneys? They’re not telling me nothing like that.” Interview 1: #17

"I mean how long are they going to give me chemotherapy? Could it last maybe five years? Could they still be giving me chemotherapy in five years or would my body just no take it five years? Or it could be like, maybe they’ll come up with something different next year, or next year there’s some other tablet they can give you that miraculously does something to your body?" Interview 4: #18

**Vulnerability**

Vulnerability and the associated frustration result from uncertainty regarding the future, as well as each day.

"At the start obviously you wondered what it was and why’s this happening. Is this real, is there somebody trying to murder me? But as time has come on...this morning I’ve still got wee bits, wee white frogs. They’re no going to hurt me so, it maybe sounds a bit mad like, but for the first two or three days I never said to anybody about it cos you think to yourself they’re just going to whip me right back into this hospital.” Interview 5 (Discussing Hallucinations): #1
"I am definitely going to keep an open mind because before I accepted everything they said and was geared up to everything they said, and then when they changed it, I found that quite devastating. So now we will go with the flow more I think and it will save me the anguish.” **Interview 2: #12**

"I am always apprehensive. I always feel you can be positive if you like, but somebody comes along and it’s like being a boxer with your hands tied; you know you feel the guys going to punch you and knock you down any time! That’s the way I read my life...knowing quite well you’re not going to win! So you’ve just got to carry on as best you can, try and dodge them, that’s it aye.” **Interview 1 #6**

5.13.4

**Social Themes**

The two fundamental social themes are family and communication. Many social aspects of illness exist, however these two key categories are broad and all encompassing.

**Family**

The concept of family is surprisingly complex when considered in relation to terminal illness. The main sub-themes include the desire to protect the family, together with the associated feelings of guilt and fear of dependence, and the importance of familial communication and support. This category is broad and extensively quoted, therefore each sub-theme is simply illustrated by one example below:

**Family Protection**

"The two of them [husband and daughter] were running about like idiots for weeks and weeks, which was horrible and then we hit a really cold, horrible weekend and that was the weekend that the heating decided to break down in the house! When they had arrived in the hospital to see me, the wee one was there, and they were soaked. Their trousers were soaked and they just looked really bedraggled and I thought and they’re going home to a cold house...and I just felt that it was... I should be at home..."
Family Communication

“I don’t want to make it morbid for them so I jokingly say things about my funeral. It’s all done in fun but at the same time you are putting a message to them and I think they realise that when the time comes, they know what I want. So that’s the way I’m doing it wi’ them and they’re getting the message. I kid on wi’ my wife... It makes it easier for me as well you know. If I’m talking, even jokingly, I feel a wee bit relaxed and that’s a lot off your shoulders. You’ve told them so fair enough. They know the score. I just keep doing it in case they forget you know, I keep repeating it: “Whatever happens remember the funeral”. I just keep hinting at odds and ends but they still say “don’t say that dad”. I says “you’ve got to say it, it’s got to happen”. Again they can maybe laugh at it so I know I am getting through.” Interview 1: #8

Family Appreciation

“We’ve been a good team. We’ve always been a good team but I think when things like this happen you realise just how much you need each other and just how much you depend on each other for stupid things, for daft wee things that you just got on and did.” Interview 2: #1

Communication

The “communication” theme encompasses every aspect of patient communication. As an integral feature of daily life, patients’ communicate both verbally and non-verbally with family, friends and healthcare professionals. Communication serves many purposes, including the sharing of emotions and the exchange of information. Patients use communication as a means to acquire information, in order to improve understanding. In addition, patients require the affirmation associated with the acknowledgment of their opinions and feelings. Despite this need to be heard, the large majority of the patients admitted that they would not voluntarily disclose feelings of distress to their doctor, however they would do so, if they were asked directly.
Clearly, the codes within this category are vast. The concept is illustrated with an example of each component. An example of family communication is given above.

Communication With Healthcare professionals
"So the doctor came in, now there was another five patients sitting in the room, and she comes in with the sheet and she said, sort of in front of everybody, “oh good news your tumour has shrunk, and quite considerably” and I says, “but there was two tumours” she says, “oh” and she looked and said, “yes that one’s shrunk too, good”. So she says, “we’ll carry on with this” and all I could think of was that I wished my husband was here to take in what she was saying and I didn’t want to ask her any questions in front of all the other people. So I was sort of sitting there for three hours wanting to tell [my husband] and nobody speaking to me.” Interview 3: #20

Communication With Friends
"Lots of people cannae cope with it you get folk when you go out there to the shop and they’re diving away down side streets. They dunnae ken how to cope with it. I’ve got to say I was probably guilty in my own life if you’ve got friends that’s ill and you really should have been getting round about and helping them but everybody copes differently...and if they were just speaking and getting that first bit past it wouldn’t matter then ken...Maybe I’ve lost four stone in weight and the hair is shaved off but it’s still the same person that’s standing there like ken. No harder to deal with, no harder to talk to than before this happened.” Interview 3: #1

Addressing Information Needs
“They never told me if I had cancer in the throat, or even about the wee bit that was missing, that they took out. I never knew anything about that until he explained to me on that Friday. I asked him why, if I’ve not got cancer in the throat, why am I still getting it [a lump] lying here and sickness and he explained to me what he had done. He said everybody has got this wee flap that goes over when you swallow and opens when it goes down and he says you’ve not got that and I said “why have I not got it” he said because they had to take it out. I never knew they took it out and he
explained he had to bring my stomach up a bit further with the tube and when I came home I was as happy as Larry. So I've just been positive from then on... “Interview 2: #17

Need To Be Heard
“I've saw [the Consultant] himself and I have spoke to him quite positively and I've told him I want to get something done here you know. I wrote him a letter and gave him a letter and he read it and I was speaking to him while he was reading it but I didn’t think he was taking it on board but when I spoke to the other guy yesterday, the other doctor who was very nice by the way, I realised he had been listening to what I'd been saying because some of the things he was repeating was more or less word for word.” Interview 1: #6

Non-Disclosure
“I wouldn't talk to doctors about anything like that [feeling distressed], I'd talk to my wife about it, I mean what can they do? Well you're going to depress the doctors! I wouldnae tell the doctor nothing like that, that’s private. I might tell him I'm worried about it but he cannae do anything about it, there’s not a thing he can do, he cannae take the worry away from you.” Interview 2: #8

5.13.5
Spiritual Themes
The key spiritual themes relate to Reflection, Hope and Faith.

Reflection
This theme is broad, incorporating patients' reflections on experiences of life and death, as well as their past, present and future. This is a major theme with every one of the patients reflecting on these issues to varying degrees. The first 3 examples illustrate the frequent use of age, as a factor in reflection:
Reflections on Age

Interview 1: #4
“Yes so people say you are too young to die at 46 but no, I’ve actually done a lot, a lot in my 46 years. Some things were mistakes, some things I got into trouble with but I was only a kid at the time and boys will be boys! I got punished for it and regretted the embarrassment that it brought on my family and made good for the mistakes that I made which I think turned me into a better person at the end of the day.”

Interview 1: #5
“I’m 79 so time’s going. I’m not going to be in an old folks home, something you will not have to deal with me in an old folks home. These places depress me when I go in and visit some of the older people and my mother ended up in one for about six months and I thought “oh dear”. Sad as it was, but you look back on the happy times and think, “I’ve been lucky, so lucky”. So quite nice to go out, if I can go out feeling the way I do: Great, without any regrets; regrets that I’m not going to see the family progressing but I’ve seen them grow up into, most of them into their teens and twenties.”

Interview 3: #6
“People go to war and get killed, young men, 48 perturbs me. All my plans never worked out. I worked hard when I was working to get retirement and I got the chance of early retirement and I took it to do all the things I wanted to do with my leisure time and it never materialised plus I’ve had the extra capital, but not to be...I mean you work everything right for your health but this is a thing you can’t control. I done everything right financially and time wise and then my health went down so, let that be a lesson to everyone, in my opinion you can’t retire too young, don’t put it off, go for it. Once you hit 60 you become a radar screen for all illnesses that’s going, it starts to show up then cos your bodies getting...if you’ve had a hard life. They say hard work doesnae kill you but I think it does! It’s when you’re yourself you reflect on your life. I feel once my marriage broke up, it must have taken a lot out of me, I feel that now. I really do. I knew I’d never go back to my wife she married again
anyway so I couldn't, but I suppose I never stopped loving her in a sense, you know. I felt cheated in that direction."

Three further examples are provided of a variety of general reflections:

Reflection on Mistakes in Life:
"I shouldn't think about the things I'm thinking about but when you're no doing anything or there's nothing else to do a lot of thoughts come into your head, like you think back maybe twenty year ago and all the bad times I've had, like going to jail and things like that. I thought a lot about that and at that time, all the time I missed with my kids. Maybe I'd have been a better dad if I hadnae went away. Your kids they think you volunteer for jail! (laughing)"  Interview 5: #8

The following passage has been edited, due to the length. It included great detail about many of the stories in the book.

Reflection on a Happy Childhood:
"I've wrote a story for [my daughter] like when I was wee cos my first memory was when I was three so I've started off with that... I just put down like we used to play on our bikes down at the docks, that's the area I was brought up in...I've done about 20 pages, till I was about 12 so I'll do another book for like my teenage years. So I'll just have to get a nice book and write it out nicely cos I've just scribbled it...I'd be sitting watching the telly and I'd go back to my note pad and write something else in. I've read a wee bit to her just now and she thinks it's quite funny, just stupid things ...it's taen me back and then when one of my pals came in and I said we'll talk about like years ago cos I'm doing this book kind of thing."  Interview 3: 18

Reflections on Death
"I'm in the frame of mind I would rather be buried to give my family somewhere to go, I know we go to Burntisland and we stand and we talk to this bit of barren ground but its no the same, but I don't know how to go about that because I havnae got a plot so I don't even know where I would go. So I don't know, but we do talk
We talk about the service, we talk about I want: ‘That’s Life’ sung at the very end, but first of all I want ‘Blue Spanish Eyes’, you know, and its no to make a laugh about it, its just that’s what I really, truly want; ‘Blue Spanish Eyes’ was my husband’s song to me and we were married for 40 year and that is definitely got to be somewhere in the service.” Interview 1: #9

Hope
Hope was integral to each aspect of illness and expressed by every patient without exception. This theme was also broad, relating to hopes for life past, present and future, hopes for the family, hopes for death, and hopes for leaving a legacy. The first three examples illustrate the most common concept of hope, hope related to the course of the disease itself:

“I am feeling, I don’t feel, well sometimes I say to myself well I have got cancer, I am going to die sooner rather than later. It does not worry me too much but then again I am really in good health I feel. So unless something hits me very suddenly, I should have a wee while longer to go and I feel I have been given time to prepare.” Interview 4: #20

“It’s interesting being faced with your own mortality, straight in front of you. I think it was because I’d been told by the doctor that it [brain metastases] greatly complicates things and obviously reduces my chances by quite a significant amount; they weren’t great before but they’re crap now. He says every individual case is different which is something I’ve held on to because it is true and obviously the biggest kind of famous person is Lance Armstrong.”

KT: “He had tumours in his brain didn’t he?”

“Yes, testicular, lung and brain. That’s what I’ve got with a few wee extra twists as well but at the same time his was a lot more serious than mine. His count was something like four times what mine was, he was in the 400,000s and this was only ten years ago so if he can survive why can’t I?” Interview 4: #3
"I’m obviously hoping the cancer has never got to my throat and it’s just the same problem I had when I went in there and that they can do something about it. That’s what I’m hoping for and that I can start eating solids, maybe not right away but I could start eating solids through time, or if they can take me in, I’d even go back in.”

Interview 1: #17

The following examples illustrate other components of the hope construct:

Regarding Hopes for the Future:
"I hope to see my grandchildren up and making their way in life, a bit, and I hope to be happy, see [my daughter] happy, everybody’s happy. I hope the whole world’s happy that’s about all I just want to do, simple things. No asking for wealth or anything like that, just happiness, to me that’s most important now. Didn’t realise it when I was younger but now I do, if you could turn the clock back, I’d have changed a lot of things but it’s too late now, it’s no use looking back, go with the flow.”

Interview 1: #6

Hopes Regarding Death:
"I mean I know that I’ll die I just hope that when I go I’ll not be in any pain and that it’s done nicely and people react properly but there’s not much I can do about it unless somebody turns up with, maybe this morning they’ll have a fantastic cure for cancer, I don’t know!”

Interview 1: #10

Hopes For The Present and Leaving a Legacy:
"I might have a bit longer to go yet and I certainly hope I do. I sound very brave when I’m saying this but it’s no bravery, that’s what’s folk’ll say, “you’re brave” but I say “it’s no brave, it’s when I wake up in the morning I say I’ve got another day”. I says I am hoping against hope, anything if you want me to trial anything I’ll trial it, I says I’ll got for that, if it doesn’t help me it’s gonnae, hopefully, help somebody else further down the line. I would really, really hope that, ken?”

Interview 2: #1
Faith

Faith has two distinct components, Meaning and Religion. All of the patients were able to relate to and demonstrate their understanding of “meaning”. However, “religion” was more specific. Those who were religious prior to their cancer diagnosis relied heavily on it as a coping strategy and source of hope and strength. Those who had no religion prior to diagnosis relied more upon their own, personal concept of a “greater meaning”. Most of the patients revealed their views on life after death and these were remarkably similar, regardless of religion.

The first three examples illustrate a variety of beliefs regarding the afterlife:

“ I do feel there’s something after death, very much so and I want to be up there and looking down on them and helping them as much as I can, even though I am away, so I am not really frightened of death as such. I just think to myself I’ll miss being in the middle of it but I’ll be there (laughing). I do look on it like that and I sometimes think to myself but where does everybody go? But it’ll just be a wee microchip but you’ll still be on that wee microchip, that’s how I think on it, believe it or not. We all meet up sometimes and I’ll see my mum and dad again and I’ll get comfort from them.” Interview 3: #20

“I am not a church goer but I have my beliefs: This is the hell part, hell on earth, we’re here. You have to go through that before you go to heaven and you go there and there’s everything you ever wanted, 24 hours a day, 7 days a week, 365 days of the year. It’s heaven, we just don’t realise it yet until you find that your time is short you can either handle it the best that you can or you fall apart.” Interview 1: #4

“I believe that we go to something far better than here. I feel we’re here to learn, that’s my own feeling, we’re here to learn and I think the one thing we’re here to learn is how to love cos to me when we go to heaven, love is, that’s what heaven is, it’s just pure intense love and you’re with Him. He is complete love and to live there, you are here to learn to love so that you’ll go to Him and you’ve learned a lot. That’s what I feel it’s about.” Interview 1: #2
Both the meaning and religious aspects of faith are exemplified below:

Seeking Meaning Through Religion: Translated By Patient’s Daughter

“She goes “What’s Gods choice, is God’s choice”, if he had put her in this condition. She was scared but at the same time she goes, “It was my faith that was at fault there”. I said have you ever asked the question to God “Why?” and she goes, “You don’t question God, you just get on with it. He’s put me in this situation now and he will pull me out of that situation as well. He’s got his own reasons, I’ve just got to get on with it.” She’s thrown everything on God, like everything is in God’s hands; it’s up to God what he wants to do with her. She still does her prayers and still reads the Koran in the morning that’s her first priority. If she doesn’t read her Koran first thing in the morning it’s a burden on her, she’s got to get that done.”

Interview 1: #16

Developing a Construct of Faith

“[The Quilting Group] had decided that they would all down tools - needles, thimbles at quarter past 11 on this specific Friday morning and they would all just stop and send me prayers, wishes, good vibrations, whatever they wanted to send me and I had to get my self organised to get all these good vibrations. I sat down with my legs up and just fastened my hands in my lap and I bowed my head and I shut my eyes and then I got this feeling for a few seconds of emotion and then I had a feeling of peace and then I had a feeling of strength. So I then had opened my eyes and I thought that was really quite something, I’ve never experienced anything like that in my life...and I don’t know what happened that morning but I know one or two of the women had a strange feeling. There would be different religions, different beliefs but it was this communal good vibrations thing that was just absolutely out of this world! So powerful cos at this moment in time I don’t, I mean, I am Church of Scotland but I don’t really like the package, I think it’s terribly out-dated and I am not awfully sure where I am there but there’s something working out there.”

Interview 1: #12
Religion as a Coping Strategy

"I find my faith helpful in so many ways and on days where maybe things have been a wee bit mixed up or you feel I've not done this very well, I say to myself, "When Jesus was going on the road to Calvary, he couldn't have managed without Simon there". He was he was God's own son, but in a human body. He couldn't manage to carry that cross without the help of Simon of Cyrene helping him. Well these people are my Simon of Cyrene. They're helping me and at the same time even though he was God's own son and divine, he fell three times. So it doesn't matter how many times we fall. The important thing is back in each time and you don't give in when it falls down, whatever it is, if it's something of an upset and you've a bubble and you say, "Right well, that's that away, that's yesterday" and you get up the next day and you say today's going to be better but the important thing is never to give in. Never give in no matter how many falls there are, get back in and with whatever you've got just keep going and I'm not able to just do that on my own. I am able to do it because of the strength of these people. It's in me but it is diminished to a degree but they're empowering and strengthening me to go at the best I can and I'll never give up." Interview 5: #2

5.13.6

Selective Coding

Selective coding to identify a single core theme proved a very straightforward process. Each of the coding categories and sub-categories clearly related directly to one concept: Control.

Concept Map

Figure 48 illustrates the inter-relationships between each of the themes, as well as each of their relationships with the core concept of control. The dotted lines represent slightly weaker relationships.
5.13.7
Inter-relationships

Physical ↔ Psychological
Patients with marked physical debility and dependence are likely to feel very vulnerable. The level of disease understanding influences patients' realistic expectations, regarding their physical abilities. Uncertainty relates to the physical disease progression.

Translated by Patients Daughter
"She said it's more the physical symptoms they make her worry and when she's worried then it affects her emotionally but if the physical symptoms weren't so bad then she wouldn't have all the rest of it, if the physical symptoms were kind of stable or improving day by day then she's not too bothered by the emotional side of it."

Interview 1: #16

Physical ↔ Social
Physical condition affects the family and role within the family, in terms of dependence. Expectations may be modified accordingly, with appropriate communication of information.
"It's just one of these things, again it keeps your confidence up a wee bit and lets you think you're not just totally useless and that you can wash the dishes and you can go and make your dinner. I've always enjoyed making the dinner...and I still enjoy making the dinner. I still try to, I cannae make it sound like I over-help her [his wife] anywhere but as much as I physically can, I like to be there and gie her a wee bit, I cannae shut that out or anything...imagine a hoover beating you! There’s still plenty of wee bits and pieces that I feel an achievement at doing, boil my eggs or...It just keeps me from feeling totally useless and just sitting there all day watching telly which I never, never ever watched much telly. Aye as much as I can do and even at that there are days where I am just so tired I cannae even help her." Interview 3: #1

**Physical ↔ Spiritual**

The physical aspects of illness are a focal point for reflection in terms of the disease journey. The reason for this is that the physical milestones of deterioration and their impact are often the most obvious and tangible. Possibly for the same reasons, hope is also often expressed in terms of physical health. In addition, hope appears to contribute to the blurring of boundaries of reality in relation to patients’ expectations. Faith (meaning and religion) is an all-encompassing extraneous concept that may be applied to any aspect of illness.

"The whole thing is about normality and just trying to get on with life as close to being normal, doing things normally. We all ken that things aren'ae normal and they're never ever really going to be back to the full normality of life but as close as I can make it and as close as we all can make it." Interview 3: #1

**Psychological ↔ Social**

Communication is the key to developing understanding of disease and thus limiting uncertainty. Patients who understand their situation are more likely to learn how to live with it. In turn, confidence grows thus lessening vulnerability.

"I've got all the information now that I never got before and has helped me an awful lot, even [the Community Clinical Nurse Specialist] coming in explaining things to
me and giving me these things to read and that and showing me exactly what they took away, I mean it was a big boost, it cheers you up. If I am going to be sick I know myself now it's because of this tube filling up that I'm going be sick, I know myself why it's happening now at first I didnae...I'm looking forward to living now but I didnae at first.” Interview 2: #17

**Psychological ↔ Spiritual**

Faith may buffer the negative impact of uncertainty by providing purpose and a dimension of understanding through meaning. Vulnerability may be affected in similar way by faith, with hope as an added mediator.

“You get such a strength and such an encouragement. You know obviously in the Bible there is so many promises and there is so much that you can draw from, you know, that gives you that encouragement and strength thing that you do need. You know, so if you are feeling, you know, upset about something there is always something that you can go to to lift you right out of the way you are feeling and another encouragement that I get is, you know, what Jesus actually went through, you know for us. You know, we can never go through anything, you know, as much as he did.” Interview 2: #17

**Social ↔ Spiritual**

Faith did not necessarily relate to an existential phenomenon, but was often fostered in tangible concepts, particularly family. The family also featured prominently in hopes regarding the future. In terms of reflections, those regarding the onset of illness focussed largely on the time around the diagnosis and the associated communications with healthcare professionals.

“Well as I say I was in the hospital and I had been in quite a bit of pain with my back and that but I took it just as being normal pain, I didnae realise what it was. He come up, the doctor, and he said “you'll die with it but not through it”. I just accepted that.” Interview 1: #13
Core Theme: Control

Each one of these multidimensional concepts relates directly to the construct of “control”.

Physical

For the majority of patients diagnosed with cancer, maintenance of control over physical function is a fundamental issue. Physical control facilitates independence, physical and financial, as well as “normality” of life. The ability to actively modify expectations according to the disease stage reflects a control maintenance strategy. The patient is taking pre-emptive measures, controlling the process of the decline by planning for it rather than succumbing to it.

“Keeping that wee bit of pain gives me the indicator to let me know how much I need to do. It’s something that leaves you with a wee bit control over your condition, it leaves you with a wee bit information of your condition, it leaves you a kind of say in what’s happening or isn’t happening, what you’re going to allow to happen, it leaves you with that we bit of control over it, it could be a funny sort of thing to do but it makes sense to me and in a queer obscure round about way that I do understand why I am here [the Hospice]. It does give an explanation what I’m doing here.”

Interview 2: #19

Psychological

The development of understanding is required, in order to reduce uncertainty and increase control. Knowledge allows the making of informed decisions and therefore facilitates choice, a key component of control. Maintenance of control reduces vulnerability and therefore knowledge is powerful asset in this situation.

Following the Third Cycle of Chemotherapy

“I was lying here and I thought, I wonder if this is... I’m going to be like getting worse cos I didnae ken. Like the first day, and then the next day I got up and felt a wee bit worse than I did the first day and I thought I wonder if this is going to carry
on and I'm going to be like this, maybe I've not got two years left, maybe this is it already cos you just think back it's only a matter of weeks and they're usually lying down, sleeping all the time and never get up and I thought is this what's going to happen to me? Just because I felt sorry for myself, but then after I felt alright...if that's all I'm going to have I'll be quite happy with that, but like not knowing if I was getting worse the next day or the day after was making me panic a wee bit...if I feel like this today and feel worse tomorrow and the next day is it going to get any worse? But it didn't really so it wasn't too bad, I can cope with that next time if it happens again...I'll write down on the calendar, that four days when it kicked in and if it does it the same the next time I'll ken it's going to be happening I'll just have to organise my life round." 

Interview 3: #18

Social
Communication provides the means to gaining understanding and knowledge and therefore the above argument holds true. Information facilitates choice and therefore control. The themes within the “family” component also relate to control. Patients’ desire to protect their family and avoid dependence is associated with determination to maintain their role within the family unit and to control the impact and outcome of their illness upon family members.

“I worried more about my family. One of my daughters feels she's got to look after me and I've not to do anything and I am not that type of person, quite a busy person...but at the same time I feel it's giving her a purpose in life, she is, she's got something to do for me and it makes her feel that bit better and I don't want...it's like walking on egg shells trying to get a happy medium because her sisters feel they're not being allowed to help me...I actually stayed at [that daughter's] after the times when I was coming out of hospital because she's in a flat and I found it difficult to go up and down stairs and I think she really enjoyed me staying there, it was like her mothering me but about three weeks ago I felt enough was enough. I needed to get home to my husband and my younger son is 17, they let me get on and do what I want to do, they'll do what's needed to help but if I want to do it they'll say, “Well just carry on and do it”, which is more normal I think...I know my limitations...it's
heavy but I can stand and iron, I can cook and I can clean out a cupboard which I’ve been doing recently and I’ve thoroughly enjoyed doing that. It’s given me, I feel that’s great, I can carry on as normal, I really feel great that’s something that I’ve done.” Interview 1: #20

Spiritual
Hope is a means of control, in terms of mindset and goal setting. Both the “meaning” and “religion” components of the faith construct relate to control. Discovering meaning results in patients developing their own framework of wider understanding, of “why”. Those who are unable to resolve the issue of meaning may feel burdened inexplicably, and therefore feel that their situation is already beyond their control. In order to avoid this situation, some patients actively choose not to seek meaning, this being an active choice and therefore within their control. Religion relates clearly to control in a different way. Those who have strong religion believe that God is ultimately in control of their destiny and therefore, they are relieved of any need to maintain control themselves.

“I think when you become a Christian it is as if you are giving the reins over to somebody else. You know, and there is somebody else in control. I think that attitude gives you a more peace of mind, you know, when you are not actually, when you realise. I mean a lot of people can still realise that they can be in control and still do your own thing, you know. You do your own thing but you feel there is a guidance there you know, and you feel that it is taken out of your hands you know. Which brings such a peace that you don’t actually have to worry about it because there is somebody else that is doing it for you, which is lovely.” Interview 2: #15
5.14
Longitudinal Analysis

Having established the main themes in physical, psychological, social and spiritual categories, together with the core theme of “control”, further analysis was conducted, in order to establish the change over time in patients’ perspectives, as reflected by the evolution of these themes. This was done according to a framework incorporating the evolution of code contents and the frequency of code use over time, whilst accounting for the relative importance of the codes within the context of the narratives, the other categories, as well as the study as a whole. Interviews were analysed in categories according to their timeframe (month one, month two, etc.). As patients died at varying times throughout the study, the “pre-death” interviews were also analysed as a separate group.

5.14.1
Frequency of Codes
The following tables show the frequency of codes over time in each category. Each category has been re-expanded, in order to ensure that any longitudinally emergent themes were recognised. Isolated analysis of the frequency of the codes in isolation, would not determine the evolution of the themes over time. Frequency was examined as a component of the longitudinal analysis and the data generated was used within this context.

*Physical*

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>%</th>
<th>Month 1</th>
<th>%</th>
<th>Month 2</th>
<th>%</th>
<th>Month 3</th>
<th>%</th>
<th>Month 5</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom Debility</td>
<td>26</td>
<td>28</td>
<td>22</td>
<td>24</td>
<td>18</td>
<td>19</td>
<td>23</td>
<td>23</td>
<td>18</td>
<td>26</td>
</tr>
<tr>
<td>Pain Debility</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>4</td>
<td>4</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>7</td>
<td>7</td>
<td>9</td>
<td>10</td>
<td>8</td>
<td>9</td>
<td>7</td>
<td>7</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Effects Treatment</td>
<td>2</td>
<td>2</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Dependence</td>
<td>17</td>
<td>18</td>
<td>14</td>
<td>15</td>
<td>9</td>
<td>10</td>
<td>16</td>
<td>16</td>
<td>12</td>
<td>18</td>
</tr>
<tr>
<td>Related Psychological</td>
<td>13</td>
<td>14</td>
<td>8</td>
<td>9</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>5</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Embarrassment</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
As shown in Table 44, there are no obvious trends. The psychological issues related to the physical disease may have been mentioned less over time, however the significance of symptoms may have been mentioned more frequently. The other themes were raised variably over time, some consistently.

### Psychological

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>%</th>
<th>Month 1</th>
<th>%</th>
<th>Month 2</th>
<th>%</th>
<th>Month 3</th>
<th>%</th>
<th>Month 5</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptance</td>
<td>25</td>
<td>8</td>
<td>21</td>
<td>8</td>
<td>18</td>
<td>7</td>
<td>14</td>
<td>6</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>30</td>
<td>9</td>
<td>20</td>
<td>7</td>
<td>20</td>
<td>8</td>
<td>27</td>
<td>11</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Enjoying Life</td>
<td>8</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Mindest</td>
<td>20</td>
<td>6</td>
<td>18</td>
<td>7</td>
<td>16</td>
<td>6</td>
<td>23</td>
<td>9</td>
<td>26</td>
<td>13</td>
</tr>
<tr>
<td>Laughter</td>
<td>8</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Experience</td>
<td>5</td>
<td>2</td>
<td>12</td>
<td>4</td>
<td>7</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Turning into positive</td>
<td>7</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Determined</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>15</td>
<td>6</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Understanding Disease</td>
<td>40</td>
<td>12</td>
<td>24</td>
<td>9</td>
<td>18</td>
<td>7</td>
<td>22</td>
<td>9</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Vulnerable</td>
<td>33</td>
<td>10</td>
<td>16</td>
<td>6</td>
<td>23</td>
<td>9</td>
<td>19</td>
<td>8</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Frustration</td>
<td>21</td>
<td>6</td>
<td>15</td>
<td>6</td>
<td>9</td>
<td>4</td>
<td>10</td>
<td>4</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>Planning</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Taking action/Routine</td>
<td>2</td>
<td>1</td>
<td>11</td>
<td>4</td>
<td>11</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Around Illness</td>
<td>13</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>11</td>
<td>4</td>
<td>14</td>
<td>6</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Living/Doing</td>
<td>9</td>
<td>3</td>
<td>14</td>
<td>5</td>
<td>12</td>
<td>5</td>
<td>6</td>
<td>2</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Not Dwelling</td>
<td>14</td>
<td>4</td>
<td>11</td>
<td>4</td>
<td>10</td>
<td>4</td>
<td>13</td>
<td>5</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Distraction</td>
<td>6</td>
<td>2</td>
<td>9</td>
<td>3</td>
<td>11</td>
<td>4</td>
<td>5</td>
<td>2</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Through others</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>6</td>
<td>2</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Setting Goals</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>2</td>
<td>7</td>
<td>3</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 45: Frequency of Occurrence of Each of the Psychological Sub-Category Codes Displayed as Number and Percentage At Each Time Point

As shown in Table 45, there is no obvious trend in the frequency of emergent themes over time. Determination may have been expressed more frequently over time whilst negativity and shock were mentioned less. The frequency of the other themes varied over time, some remaining constant.

Social
Table 46: Frequency of Occurrence of Each of the Social Sub-Category Codes Displayed as Number and Percentage At Each Time Point

Again, as shown in Table 46, no trend is apparent here. Perhaps family protection was mentioned less with time. Generally, the frequency of use of the themes was variable over time.

**Spiritual**

<table>
<thead>
<tr>
<th>Theme</th>
<th>Baseline</th>
<th>%</th>
<th>Month 1</th>
<th>%</th>
<th>Month 2</th>
<th>%</th>
<th>Month 3</th>
<th>%</th>
<th>Month 5</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reflective</td>
<td>72</td>
<td>27</td>
<td>28</td>
<td>14</td>
<td>26</td>
<td>17</td>
<td>35</td>
<td>18</td>
<td>23</td>
<td>17</td>
</tr>
<tr>
<td>Hope</td>
<td>27</td>
<td>10</td>
<td>29</td>
<td>14</td>
<td>14</td>
<td>9</td>
<td>24</td>
<td>13</td>
<td>30</td>
<td>22</td>
</tr>
<tr>
<td>Normality</td>
<td>16</td>
<td>6</td>
<td>16</td>
<td>8</td>
<td>21</td>
<td>14</td>
<td>19</td>
<td>10</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Isolated</td>
<td>25</td>
<td>9</td>
<td>12</td>
<td>6</td>
<td>9</td>
<td>6</td>
<td>10</td>
<td>5</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Purpose</td>
<td>20</td>
<td>8</td>
<td>27</td>
<td>13</td>
<td>11</td>
<td>7</td>
<td>22</td>
<td>11</td>
<td>23</td>
<td>17</td>
</tr>
<tr>
<td>Faith</td>
<td>38</td>
<td>14</td>
<td>27</td>
<td>13</td>
<td>11</td>
<td>7</td>
<td>20</td>
<td>10</td>
<td>11</td>
<td>8</td>
</tr>
<tr>
<td>Dignity</td>
<td>8</td>
<td>3</td>
<td>4</td>
<td>2</td>
<td>6</td>
<td>4</td>
<td>5</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>What if</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>266</td>
<td>100</td>
<td>206</td>
<td>100</td>
<td>150</td>
<td>100</td>
<td>192</td>
<td>100</td>
<td>139</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 47: Frequency of Occurrence of Each of the Spiritual Sub-Category Codes Displayed as Number and Percentage At Each Time Point

As shown in Table 47, the frequency use of the spiritual themes varied over time. Patients were most reflective and most hopeful at the outset and spoke most of their purpose at the end.

**Core Theme: Control**

<table>
<thead>
<tr>
<th>Theme</th>
<th>Baseline</th>
<th>%</th>
<th>Month 1</th>
<th>%</th>
<th>Month 2</th>
<th>%</th>
<th>Month 3</th>
<th>%</th>
<th>Month 5</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>56</td>
<td>21</td>
<td>61</td>
<td>30</td>
<td>48</td>
<td>32</td>
<td>54</td>
<td>28</td>
<td>37</td>
<td>27</td>
</tr>
</tbody>
</table>

Table 48: Frequency of Occurrence of the Direct Codes of “Control” Displayed as Number and Percentage At Each Time Point

The direct theme of control appeared fairly consistently over time, as shown in Table 48.
5.14.2

Longitudinal Themes

Having established the code frequency, further analysis was conducted. Patients were categorised according to those who died and those who survived and each category was analysed separately. Dying or surviving may be considered an important differential, as these two groups of patients may have distinct experiences, according to their point on the disease trajectory and the nearness of death.

For those who died, their first interviews were compared directly with their pre-death interviews. For both groups, each sub-category theme was examined over time and each individual patient’s serial interviews were evaluated. Finally, for a sample of patients, each sub-category theme was evaluated over time in each of their serial interviews. This preliminary analysis was gradually refined and the resultant, final evaluation is presented.

Following this longitudinal analysis, key themes emerged within each of the physical, psychological, social and spiritual domains. The basis of these themes was essentially identical to the emergent themes from the overall data analysis. As patients progressed through the final phase of the cancer disease trajectory, their perspectives evolved.

A trend emerged, identical for both groups (those who died and those who survived), showing adaptation to change and acceptance, in each of the physical, psychological, social and spiritual domains. Despite this overall trend towards adaptation, patients experienced unpredictable, transient exacerbations of distress in any one of these domains.

5.14.3

Physical Distress

The key physical issues for patients in the final phase of the cancer disease trajectory related to debility, dependence and expectation. Initially, patients’ distress related to the progressive physical limitations induced by their symptoms and the associated
increasing dependence. This distress was moderated by patients' expectations.
Initially, expectations related to pre-morbid conditions or age.

"I know if I'm going to walk, I'm no going to get walking a lot or far because I just couldn'ae do it, but as I say I've been living with it for quite a number of years." #13

However, as disease progressed over time, patients readjusted their expectations to reflect their altered physical abilities. This modification of expectations facilitated a considerable degree of reconciliation with their debility and dependence. Therefore, the majority of these patients were able to adapt to their physical deterioration over the end stage of their disease. As a result, distress associated with physical symptoms declined with time.

"The breathlessness, yes but that's something that I'd say has crept up on me, it was on the odd occasion up to maybe a couple of months ago, but now it's becoming quite pronounced. If I get up of the chair even up the stairs, I just go and sit down on top of the stair. I've to make sure I go to the toilet and a couple of times, I have to say, I've had a wee accident cos I've got to the top of the stair and I've been so breathless I've had to sit down and this is quite embarrassing like ken (laughing)...I just cannæe get there, it's running down and I think "how blooming embarrassing this is!" She says "don't worry"... but now I think a wee bit: I'd better just go and no sit and watch the end of the programme you're watching," #1

However, most patients suffered episodic, transient deviations from this trend. These episodes related to acute, unpredictable exacerbations of distress. Acute episodes of distress appeared to be precipitated by sudden, unexpected physical change, disproportionate to the established trend of decline.

"Normally tiredness is something that a good nights sleep will help but this fatigue and also the restlessness I've had with my sore legs during the night as well has... you waken up as tired as when you went to bed and I've had more sore heads and yet I've been on pain killers for my achy limbs but it's not made any difference to my
sore heads; it's just, it's something I hope once I get over this I'll never have again, I would say it is a very, very debilitating thing. It's caused me quite a bit of concern because I can't pace myself and that seems to knock me back a bit and yet you can't have a sleep and recharge your batteries; it doesn't work that way." #12

Illustration of physical trajectory in one participant (Survived): “Robert” #17

Interview 1
“A wee bit more independence but it’s no very nice when you’ve got to depend on other people, I’m 65 but I’m no an old man. I would still feel fit if I could put on a wee bit weight and start eating. I could still make myself fit to a certain extent but the way I’m going just now I am just downhill all the time. That’s the way I feel I am going down, down, down. There’s nothing up and up. Nothing.”

Interview 2
“[The pain] comes and goes aye when it does come sometimes it’s severe but it goes kind of quick as long as I take the tablets it goes, but they only last for a couple of hours, so if the pain is still there I have to take another one which I dunnae want to do but sometimes I have to. Pain is not half as bad as it was.”

Interview 3
“Obviously the pain is going to be there for a while, the doctor says that, the pain is going to be there for a long time but as I say I can control it.”

Interview 4
[Talking about a new severe pain] “…when you know that you still got some of the cancer in there you wonder where has it went: Has it went to the lungs? Has it went to the kidneys or the bowel or anything like that? Then you start to wonder especially when you have pains that you have never had before.”
Interview 5
“A lot of the pain comes after I have eaten. I don’t know what it is, why it is like that, but after I have eaten I get quite a lot of pain. I can handle that.

KT: Does that not bother you now?

“Not to the extent that it did at first.”

Graphical Summary

5.14.4
Psychological Distress
The fundamental psychological issues were inter-related and involved understanding, uncertainty and vulnerability. Patients are distressed by the uncertainty associated with progressive terminal illness. Uncertainty is exacerbated by a limited understanding of the disease process and its implications. As a result, patients feel vulnerable. At the time of referral to palliative care services, patients’ uncertainty and vulnerability appeared to induce negative thoughts regarding illness and the future.

“I’ll be scared in case that [neutropenic sepsis] happened to me again, but according to him [the consultant], if it [the chemotherapy] was halved I think the chances are very, very slight. Even if I did take the full thing its very slight that it would ever happen again but I would be very, very, very scared, em, so it depends on
me: If I don’t want it he’ll respect my wishes, but what happens if I don’t take it? Does it hurry my demise on or what? I really don’t know.” #9

However, the majority of patients became accustomed to living with uncertainty and with time, this facilitated more positive thoughts.

“I dunnae worry about it any more because I cannae. It’s not something that’s inside of us to control, to solve, so there’s no use. As time gets on, I’m realising we’ve got to just get on with what’s been given and try and get on with it, get on with life.” #1

Therefore, on the whole, psychological distress gradually improved over the end stage of the cancer disease trajectory. However, all of the patients suffered transient exacerbations of psychological distress levels at some point along this journey. The majority of these exacerbations were associated with an acute rise uncertainty, disproportionate to the chronic level to which the patients had adapted.

“That was where the original pain was, right down my leg to my ankle, so this is the first time since I’ve been on medication that it’s bothered me, so it’s like am I wishing that, am I thinking that’s it, how can I feel so well and everybody tells me I look so well, how can I be like that and it’s going to be a negative result that I’m going to get, that’s what I keep thinking...I just wish they’d phone and tell me.” #20

Illustration of psychological trajectory in one participant (Survived): “Callum” #3

Interview 1

“My life has changed, if I want to walk to the shop in the morning it takes me ages, to get a paper or something like that. Things like that annoy me. I’d say the hardest bit is not being normal. To be able to just do what I want cos there’s so many things I have to think about before I do anything. Just basically not able to do it nine times out of ten.”
Interview 2
“Sometimes I feel I know a lot more about [the chemotherapy] now; what I’m doing and what it’s doing... a bit more trust in it, before you didn’t know. I think just the not knowing, that’s the most annoying thing. When you find out a bit more about it and talk to doctors and they explain things to you, you feel more at ease I think.”

Interview 3
“It’s not as if [the chemotherapy] kind of gradually stops, it just stops completely. One morning you get up and that’s you, you’re finished. You feel like you are getting treatment and then you are not getting treatment any more, you are worried that as long as the doctors know what they’re doing... but there’s a chance... but what happens if the tumour goes crazy in my stomach and they open me up and they’ll not look at it.”

Interview 4
“I can thoroughly see how easy it would be to give up and just become depressed and curl up in the corner and give up the ghost and that’d be me but there’s too much going on. I’m only 24, I’ve got to try and help myself; if positive thinking is it then that’s what I’ve got to do.”

Interview 5
“It’s just like... I know when I’m in the hospital (and the stem cell thing has kind of bothered me a bit) but besides that it’s just a bit calmer, I know when I’ll be in the hospital and what they’re doing what they hope to achieve from it and all the rest of it, it’s just a lot more settled really.”
5.14.5
Social Distress
Communication was fundamental in all areas of patients’ lives, particularly with and between family members, as well as healthcare professionals. At the time of referral, communication with healthcare professionals was vital, in order to maximise understanding of disease.

“Well it’s like this cancer: How long you’ve got to go and that. Like I says to the doctor, there’s a lot of things you want to do but you don’t know if you’ve got the time to do them. That’s what I’d like them to tell me, come right up front with me; how long I’ve got and things like that because I’ll still maybe be able to do the things I want to do but I don’t want to be away and not done anything. My family know; they all know that I want to know, so they won’t hide it from me either.” #8

Communication with family was also essential in the establishment of understanding and support. With time, information seeking becomes less intense and family discussion less disease focussed. This coincides with patients becoming more accepting of their circumstances.

Initially, family induced significant distress, due to patients trying to protect them from the realities of their disease. However, as time passed and death approached, patients’ acknowledged the ability and need for the family to continue. From this point, family provided the greatest source of comfort.
"Again it's back to the argument "there's no point in worrying about things you cannae do anything about". That's a wee bit of knowledge and experience I've acquired that they [my daughters] will acquire. That's because I am that wee bit older, but I keep on saying it to them, and hopefully they'll take it on board. It makes life easier further down the line if nothing else, but while I love them dearly and am delighted to see them all the time, I'd like to see them spending more time for themselves" #19

Social distress therefore declined over the end stages of the cancer disease trajectory. However, transient exacerbations of distress did occur and were related to a change in condition or circumstances that, either required more information in order to be understood, or resulted in a negative impact on the family situation.

"If things would just sort theirselves out I'd be alright. Before I got that letter from the social I was quite "everything is going fine". I've got everything all done for Christmas and money worries are alright, nothing too much drastic to worry about and then you get that and you think oh no I'm going to lose my money...I'm going to be back to square one again like I was when I first got diagnosed. I was trying to get everything organised, I thought I am going to have to go through all this again." #18

Illustration of social trajectory in one participant (Died): "Harry" #1

Interview 1

"It brings stress with having to go to Glasgow, for my wife that incurred a lot of expense for trains and getting my daughter and all that through. Again that's a different stress, so ken when you are all of a sudden dropped onto fixed income, that bring you different worries like, ken."

Interview 2

"I was telling you there it's my wife's birthday, I was sitting last night trying to write her birthday card for this poor lass for an hour. I was sitting upstairs with tears in my eye, just worried in case it might be the last (upset). Just worried in case it should be the last birthday card. That's daft cos I have no intention of that being true cos my
daughter gets married, she gets married next year and I’m going to be there. Excuse me.”

Interview 3
“After coming out seeing [the trials oncologist] I was in a bigger quandary than I had been in all the time. I knew I’d then be left to make this decision myself, whereas before these things were really done for me. I was guided. The decision all of a sudden... I spent a terrible weekend, I spent four or five days just going over and over and talking about it; to myself lots of time, sitting actually talking to myself about it.”

Interview 4
“That woman through there she’ll never let me gie in. She’ll, when she sees it’s coming to the end she’ll no let me go to hospital and have me hooked up to all these machines and that. But I am quite sure now that she’s here I’m out of hospital and looking forward, that she’ll agree with what I’m saying. You cannae be married to somebody for 35 year and not know each other and not love each other.”

Interview 5
“I ken that for [my wife] there’s all the kids and all her family round about her to support her and likewise for my kids. She’s got that; they’ve got that support. It’ll take a long time when it does eventually come but I understand she’s got a strength, she has I’m no kidding, don’t even! She’s a strong, strong, person. She’ll sit down and have a cry but she’s not long in straightening herself back up.”

Graphical Summary

![Graphical Summary Image]
Spiritual Distress

The most evident spiritual themes are faith, reflection and hope. For those with faith, it is fundamental in the context of cancer, whilst for those without, faith appears to be largely irrelevant. All patients reflected, to varying degrees, on their experiences of life, death and illness. This seems to be a natural part of processing the evolving situation that patients find themselves in. However, for a few, reflections relate to harbouring unresolved issues.

During the initial interviews patients were often highly reflective. However, as disease progressed and patients’ experiences evolved, they became more hopeful in their reflections. Regardless of the individual or situation, all patients had hope. Hope appeared to be essential to living and coping with terminal illness on a daily basis.

"I mean what they’ve said they’re giving me two years but it could be three years, hopefully that’s what I am hoping...just be longer if I can keep good and it keeps shrinking a wee bit and they say miracles happen, so we’ll wait and see...aye, in myself I feel I’ve got longer." #18

Again, as with the other domains of distress, transient exacerbations of spiritual distress may occur, due an acute and unpredictable change of circumstances.

"...started with all this fluid on the lung and that. I passed out and I never realised where I was or what was happening for the first four days: it was nothing, and after that when I came round I still didn’t know where I was but four days after I got out the hospital I’d gied up. I’d really...a big dark hole which was never there before. I think I’d just reached a bit where I thought "I just cannae take any more”. I reckon it was maybe the fifth day I came round and I was sitting there and I says to [my wife] “it makes me think that these two or three days if I’d died it wouldn’t have mattered.”" #1
Illustration of spiritual trajectory in one participant (Survived): “Mary” #2

Interview 1
“I was getting worried the week before my sister passed away because I really wasn’t well, I got up one morning and felt very unwell and she was still in bed so I said “I feel a wee bit sick, I’ll need to go upstairs” and I got to the landing there and then the sickness went but I felt dizzy, so I sat on the second bottom stair and rested the rest of my body against the other stairs and I thought, “Now what are we going to do here.””

Interview 2
“I watched, months ago there was a wee snowdrop came up and the tiny, tiny wee stem of it and I thought now that wee thing can get up through that earth and that is particularly claylike on that side, and I thought if that can do that there is no reason why I can’t get up through this because that tiny wee stem can come up through that ground year after year after year.”

Interview 3
“I mean I am tired now but I am determined that I am going to turn it around because I have no intentions of losing. Both for myself, but for the people that have given me such support. That has gotten to me this month. I feel that in losing the progress, or feeling that I have lost the progress, that they have worked so hard that I feel as though I have let them down and I have let myself down. And I don’t like that because I don’t…I am not in the habit of using or abusing people and they have done so much, and within myself I feel as though I have let them down.”

Interview 4
“I feel there’s a learning process in this and I wouldn’t have thought I could have said it last year but I feel now there’s something very positive in it and we’ll just take it one day at a time.”
Interview 5
“I would say to me the main things now when I go forward is, I should have been doing it from the beginning, but my life circumstances didn’t allow for it, but I think that the important thing is we’ve got to create time for ourselves. We’ve got to make quality time where we lift away from the day to day life, from the pressures of life and I think it’s so important for us all to have time for ourselves to just be. Time for yourselves to just be and lift away from the race of life and to always try and focus on the positive, you know.”

Graphical Summary

5.14.7
Anomalous Cases
As expected, not every patient followed the trends indicated by the majority. Anomalous cases indicate selection of an appropriate sample and rigour of analysis, when compared with the emergent themes. This study comprised 2 obvious anomalous cases. One case involved unresolved anger, and conversely, one involved unwavering contentment.

Anomalous Case 1: Unresolved Anger “Michael” #6
The patient who expressed constant anger was a gentleman of 64 years who was divorced and lived alone. He felt cheated out of the retirement time he had hoped for:
"...looking forward to retiring like everyone else, enjoying life and bang six months later I was in the hospital getting tests and they removed my kidney"

He also had unresolved issues regarding his divorce and subsequent estrangement from his family.

“I did rue the day my marriage split up I think it cancelled a lot of things in my life you know. Mostly when I tell you about like when you have the grandchildren and that; mothers are closer to their daughters than their fathers. It’s not that I don’t see them or anything like that, there’s no animosity or anything like that but I just always feel I am in the background.”

In addition to the separation from his family, he had also become socially isolated, as a result of his illness and body image:

“Same if you go to a dance or meeting or that, you are in and out the toilet all night, frightened it [the urostomy bag] gets full you’ve no control. You don’t know what’s happening, if you think it’s getting full you just go and sometimes it’s Ok and sometimes it’s not but you’re better keeping it empty cos there’s less chance of it leaking obviously. So there’re handicaps, big handicaps, psychologically and it affects my relationships too you know. I just don’t get involved with people, a spare part, as I say...”

Excerpts from his interviews are included below. He died during the study and the last interview took place only 12 days prior to his death.

Anomalous Case (Anger): “Michael” #6

Interview 1
“I am at the stage where I want things to happen, I am frustrated with the lack of speed, decisions. I understand they’ve got to think about things and give nature her... to get a balance, but I feel I am the stage now that it’s got to be done, whether it’s a
minus or a plus I don’t know but I feel I want to know, I want to know the truth. I don’t want to be mucked about, come here, back in a fortnight, back in a week, and I am still in this agony and pain. That’s frustrating, very frustrating Katharine I can assure you. Kind of takes the wind out of your sail.”

**Interview 2**

“...and it really hurts me to think I’ve paid into a system for 45 year and I want something out of it and this is the reply you get; not answering calls and mucking you about. I’ve had this illness since I had my treatment which was finished in the middle of November of last year and I’ve been reporting this since and they keep saying “this is what happens and this doesnae happen” and I think I just came to the end of my tether; can’t take any more from them, fed up listening to them telling me just cock and bull stories. I’ve had enough and I feel the whole system has been a let down, a total let down and that’s sad. The national health system should be good; they should care in my opinion.”

**Interview 3**

“There’s not much future for me is there really? So I just have to try and be brave and face up to it and accept it. It’s a thing I am coming to terms with: I have still have the fear factors, everyone has I would imagine, don’t want to die, but I don’t control these things. I do go back to when I did start complaining about my illness after I had my treatment in October. I do feel that [the oncologist’s] department didn’t listen to me: I kept telling then I was in pain and they never took it on board, never seemed to take me serious until I handed in a letter to him, now I find out I was correct and they were wrong.”

**Interview 4**

“I never thought in my wildest dreams that I’d end up like this, certainly didn’t. I daresay most people get the same kind of treatment, I honestly don’t know. I don’t know what the National Health is all about. The more I think about it, there seems to be a big gap somewhere that’s not adding up you know...I don’t feel there’s any care and attention, I think it’s just in out, in out, like an assembly line. I often feel instead
of doing ten or twenty people a day why not do ten or fifteen and give them quality
time.”

Anomalous Case 2: Unwavering Contentment “Caroline” #15

The patient who remained content and peaceful from the outset of her referral to
palliative care was divorced and lived alone, but on the same small street as her
parents. She was a Born Again Christian and therefore faith was of utmost
importance to her. This features strongly in all of her interviews.

“He [God] holds the future so it’s as if it’s been taken out of my hands. I’m not in
control; somebody else is in control so it’s as if the pressure has been taken off me.”

She died during the course of the study and her final interview was conducted only
11 days prior to her death.

Anomalous Case (Unwavering Peace): “Caroline” #15

Interview 1
“I couldn’t fault it at all and [the Consultant] did work really hard to get results
before Christmas, because it was a time where they’re busy as well. Everybody just
worked so hard so I mean my mum was saying “Are you sure you’re no going
private?” My appointments were just coming up and everything was just slotted into
place and it’s been amazing.”

Interview 2
“Well they are going to do my scan in September and I suppose whatever the result
of that is. See how much fluid is actually there. They spoke about draining it but
they are not sure if that would be, how much long term relief that would give me. Or
they might decide on medication but really that is kind of hanging in the balance at
the moment, as I need to wait for my scan. So we don’t really know much about that
just now.
KT: Are you OK with the uncertainty of that or do you not think about it?

“I don’t really think about it until I am actually going through it and come to the point where...There is no point in thinking about it beforehand. I always think that is pretty pointless. It just gets yourself, you can get yourself all wound up and tied in knots for, that is useless.”

Interview 3

“...just resting and everything that’s there; my faith, just grasping hold of it...I think it’s probably increased, I suppose as each day goes on it increases...it’s just happened, I think the closer that you kind of...I suppose...think about eternal things, the closer these things throw round you. Becomes more of a reality you know...”
DISCUSSION
6.1 Introduction

The discussion is presented in three sections. The first section summarises and discusses the descriptive, quantitative data. The second section provides an evaluation of the qualitative data analysis. The final section compares and contrasts the quantitative and the qualitative data, concluding with a comprehensive summary.

6.2 Quantitative Data

6.2.1 Representation of Study Sample

Study Population

The study sample appeared to be representative in terms of ethnicity. The largely white population of Forth Valley (98.9%) was reflected in the 99% white patients recruited into the study. The sample was also representative of social status, with a median DEPCAT of 4, compared with DEPCATs of the areas comprising Forth Valley (Falkirk 4, Clakmannanshire 3 and Stirling 3). Gender was almost equally represented, with 51 males and 49 females in the study sample. The age range was fairly evenly distributed from 24 to 89 years, with a mean of 65.4 years, median 67 years. In keeping with cancer demographics, the age range of 71-80 years was most highly represented, with 31% of study patients in this category. Over half of the patients were married and only 31% lived alone. The relatively large 24% of widowers potentially reflected the study population age range.

At baseline, “lack of energy” or fatigue, was the most commonly experienced symptom amongst 91% of the study population. This is entirely consistent with the literature. In a large study (Carlson et al. 2004) of 2776 ambulatory cancer patients, fatigue was by far the most common symptom, affecting 48.5% of the patients. The lower prevalence of fatigue in Carlson’s study is likely to reflect Carlson’s fitter
ambulatory population in comparison to the current study population of terminally ill cancer patients.

Another study (McMillan and Small, 2002) of cancer patients found fatigue was both the most prevalent (89%), as well as the most distressing symptom. A review paper (Barnes and Bruera, 2002) suggests that patients with cancer have rated fatigue as the longest lasting and most disruptive symptom, resulting in the greatest impact on quality of life.

**Tumour Site**
A wide range of tumour types was represented. The four most commonly represented tumour types were tumours of the lung (23%), colon (17%), breast (16%) and prostate (10%).

<table>
<thead>
<tr>
<th>Tumour Site</th>
<th>Percentage Scotland</th>
<th>Strathcarron</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>17</td>
<td>25</td>
<td>23</td>
</tr>
<tr>
<td>Breast</td>
<td>15</td>
<td>8</td>
<td>16</td>
</tr>
<tr>
<td>Colorectal</td>
<td>13</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td>Prostate</td>
<td>12</td>
<td>6</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 49: Comparison Of Tumour Site Between Scotland, Strathcarron

**Hospice and The Study Population**
As demonstrated in Table 49 above, the study population was largely representative of the new cancer referrals to the Strathcarron Hospice home care service from 01/07/05 to 30/06/05. The lung cancer figures are higher for Strathcarron and in the study population than in Scotland as a whole. This may reflect the demographics of the Forth Valley area. This area incorporates many old mining towns and areas of deprivation. Due to well-documented lifestyle in such areas, with increased tobacco smoking and exposure to smoke, lung cancer is known to be more prevalent.

Patients with breast cancer in the study were representative of breast cancers in Scotland as a whole, but over-represented when compared to the Strathcarron home care service figures. The over-representation may be the consequence of the disease
trajectory of breast cancer. Patients with known metastatic disease often have a longer prognosis than estimated, and their health often reflects this. Therefore patients with breast cancer may have been more likely to participate in the study, if they were feeling physically able. Many studies have evaluated the specific psychological needs of patients with breast cancer. Their findings suggest that this group would be potentially keen to choose to become involved in a study that offers the opportunity to discuss on a regular basis, all aspects of health.

Colorectal cancers were slightly over-represented in the study population when compared with both, the Strathcarron Hospice home care referrals, as well as the percentages for Scotland as a whole. This is not easily explained and may have just reflected the health status of colorectal cancer patients at their time of referral. The local clinical nurse specialist for colorectal cancer has close links with the Hospice and understands the value of early referral.

Finally, prostate cancers were slightly over-represented when compared to the Strathcarron Hospice home care service referrals, though slightly under-represented when compared with Scotland as a whole. Prostate cancers are often insidious in their growth, even at the end stage, and therefore patients may have felt more physically able to participate in the study.

Non-Participants
The non-participation rate was 47.6%. This would be considered reasonable for a population of terminally ill cancer patients with an estimated prognosis of ≤6 months. The main reason given for not participating was “having no interest in research” (34%). The second most common reason was “unwillingness to discuss illness” (14%). Unfortunately, due to reasonable ethical restrictions, these explanations could not be further explored. Therefore, it is possible that some of the patients who did not participate were in fact feeling too distressed to participate. This is discussed further in the study limitations.
The comparative analysis reveals no significant differences in age or gender between the study sample and those who refused to participate. There were no major differences in tumour types represented in the study population, compared with the non-participation group.

Patients with a diagnosis of mesothelioma were however, notably absent from the study sample. Mesothelioma is not a common tumour type, accounting for <1% (0.96%) of annual referrals to the Strathcarron Hospice home care service. However, mesothelioma was over-represented in the refusal group (4.4%). The potential reasons for this have been previously explained. The non-participation of patients with mesothelioma probably reflects the known, extensive symptom burden associated with the disease, together with the legal implications of the diagnosis, which require significant physical and psychological input. Although these are good reasons to assume a potentially increased risk of distress for these patients, the impact of this on the study findings is minimal, as the sample population remains representative, even without inclusion of any mesothelioma patients (only 0.96% of referrals were for patients with mesothelioma).

Finally, patients with oesophageal carcinomas were perhaps slightly under-represented in the study population (3.7%), compared with 6.3% of patients referred to Strathcarron Hospice home care service and 7.7% of patients who did not participate. The potential reasons for this have also been given previously. These include significant symptom burden, tumour type relation to excessive alcohol use and hence potentially chaotic lifestyle, which together would prohibit regular participation in a longitudinal study. However, such patients were represented in the study sample.

In summary, the study population was therefore, fully socio-demographically representative and inclusive.
6.3
Socio-Demographic Predictors Of Distress

The socio-demographic factors for the study population were categorised prior to analysis. These categories were then evaluated for their relationship with significant global distress, according to Distress Thermometer Scores over 5. Univariate logistic regression revealed that the following factors were significantly associated with significant global distress. Significant social dysfunction (OR 5.51, 95% CI 1.17 to 25.9, p = 0.031), perception of receiving inadequate information from oncology doctors (OR 5.86, 95% CI 1.60 to 21.4, p = 0.008), and oncology nurses (OR 4.59, 95% CI 1.24 to 17.0, p = 0.023). In addition, a history of previous depression was almost statistically significant in its association with significant distress (OR 2.58, 95% CI 0.87 to 9.49, p = 0.083).

Multivariate logistic regression was then conducted and revealed weak evidence, indicating that inadequate information (from oncologist, oncology nurse or GP), and social dysfunction are independent predictors of significant distress (OR 3.10, 95% CI 1.10 to 8.74, p = 0.033) for inadequate information and (OR 4.28, 95% CI 0.88 to 20.9, p = 0.072) for social dysfunction.

**Inadequate Information Independently Predicts Global Distress**

This finding indicates that a lack of information from any healthcare professional exacerbates the distress levels of terminally ill cancer patients, thus increasing their risk of suffering significant distress.

This is consistent with the literature. Lazarus and Folkman (Lazarus and Folkman, 1984), major authors on the subject of coping, suggest that information seeking is the most frequent method used to cope with a stressful event for which information is limited. Hence, if information is considered to be inadequate, then it follows that coping would be more difficult and therefore distress levels more likely to rise.

Another author (van der Molen, 1999) considers "information is conceptualised as a form of cognitive control", as it facilitates participation in decision-making. Again, as information is required for coherent decision-making, and is therefore a
determinant of control, then lack of information would potentially result in reduced control and thus contribute to increased levels of distress.

The findings from this study are also consistent with several other studies reviewed earlier, which indicate the importance of information sharing. This study finding related specifically to lack of information. Clearly ambiguous or dishonest information is also implicated in inducing elements of distress. In their review of the communication literature for palliative care population, Fallowfield and colleagues (Fallowfield et al. 2002) assimilated evidence suggesting that ambiguous information increases fear, anxiety and confusion. Similarly, Gerle et al. (Gerle et al. 1960) found that of 101 patients with inoperable cancers, those patients who had not been given complete, honest information regarding their disease, were the most anxious and depressed and had the greatest medication requirement of the sample.

**Significant Social Dysfunction Independently Predicts Global Distress**

This finding indicates that terminally ill cancer patients experiencing significant social dysfunction are significantly more likely to suffer from significant global distress. Social dysfunction was defined as the significant adverse functioning of relationships within the immediate familial situation or social network. The definition did not extend to incorporate isolated instances of financial deprivation.

This study's finding is consistent with data available from the literature regarding elements of social dysfunction. The finding is comparable with Manne and Glassman's (Manne and Glassman, 2000) finding that amongst 191 married patients enrolled in cancer treatment, unsupportive, negative spousal behaviour significantly mediated psychological distress (p<0.01). Further evidence of consistency is seen in another study (Koopman et al. 1998) that found reduced mood disturbance to be significantly associated with increased social support.
Previous Depression Shows a Trend Towards An Association with Global Distress

Univariate logistic regression analysis reveals an almost statistically significant association between a patient’s history of previous depression, and the experience of global distress at the end of life. This trend is discussed later in relation to the impact of a patient’s previous history of depression upon the various components of global distress.

6.3.1
Predictors of Global Distress Amongst Patients Who Died

Detailed analysis of the sub-group of patients who died during the study was limited by the small numbers involved (n=47). Therefore, the findings of the univariate logistic regression analysis were not statistically significant. However, a trend was apparent towards an association between the perception of receiving inadequate information from oncology doctors and experiencing significant global distress in the final months of life (OR 7.0, 95% CI 0.78 to 63, p = 0.082).

Trend Towards Association Between Inadequate Information From Oncology Doctors and Global Distress at The End of Life

The reasons for this association are likely to relate to those previously explained above, with issues of coping and control of potentially heightened importance in the context of active dying.

Information from oncology doctors, as opposed to oncology nurses or the General Practitioner may be of greater importance to terminally ill patients at the end of life. This would perhaps reflect the key role of the oncologist as the cancer expert. The oncologist essentially holds all of the information regarding the patient’s specific circumstances, the disease itself and any potential treatment.
6.3.2

Predictors Of Global Distress Amongst Patients Who Survived

Again, meaningful analysis of the sub-group of patients who survived the study was limited by the small numbers involved (n=51). Univariate logistic regression analysis revealed a significant association between the perception of receiving inadequate information from oncology doctors and significant global distress (OR 5.14, 95% CI 1.01 to 26.1, p = 0.048). In addition, a significant association was apparent between a history of significant mental or physical illness in the family and significant global distress (OR 3.45, 95% CI 1.08 to 11, p = 0.037). Finally, a trend was seen towards an association between receiving inadequate information from oncology nurse and experiencing significant distress (OR 4.50, 95% CI 0.88 to 23.0, p = 0.071).

Association Between A Family History of Significant Mental or Physical Illness and Global Distress

For patients who survived the study, a family history of significant mental or physical illness was significantly associated with the experience of global distress in the last months of life. There may be several reasons for this. Firstly, any major illness in the family, mental or physical, has the potential to cause disruption of social roles and functioning. As already noted, significant social dysfunction is an independent predictor of global distress amongst patients with terminal illness. In addition, previous experiences of physical illness in particular, may have been negative, thus inducing anticipatory fear of a similar personal experience and heightening distress.

Association Between Inadequate Information and Significant Global Distress Amongst Patients Who Survived The Study

The reasons for the significant association between information from the oncologist and the experience of global distress are likely to be similar to those given above. Oncology nurses are also important in the sharing of information, as patients generally tend to spend more time with the nurses, usually during treatment, than
with the oncologist in clinic appointments. This extra time often facilitates the development of a professional relationship between nurse and patient.

6.3.3
Comparison Between Those Who Died and Those Who Survived

Previous Family History of Mental or Physical Illness
The significant association that was found between a family history of physical or mental illness and global distress amongst patients who survived the study (OR 3.45, 95% CI 1.08 to 11, p = 0.037), was not elicited amongst those who died (OR 0.58, 95% CI 0.18 to 1.89, p = 0.37), or the overall study population (OR 1.51, 95% CI 0.68 to 3.38, p = 0.31).

Study survivors are therefore unique in this association. There is no obvious explanation for this finding. Perhaps those who survived were contemplating living with a prolonged period of debility and therefore were more concerned with their illness-associated morbidity, as opposed to the more rapidly impending mortality affecting those who died. The effect of previous mental or physical illness within the family is discussed above and includes the impact on social roles and the potential anticipatory fear associated with a negative experience. Adapting to living with progressive debilitation would be adversely affected by any existing disruption in social functioning and pre-conceived negative expectations of the experience. This may have not been an issue to consider for those who were dying more imminently, and the lack of association for this group may have negated the effect upon the overall study group.

Inadequate Information
Information was potentially more important, and certainly as important to those who survived the study, as to those who died. The similar needs of the survivors may reflect their estimated prognosis of 6 months or less at the study outset and hence the inevitability of their future.
The association between the perception of receiving inadequate information and global distress was statistically significant amongst survivors (OR 5.14, 95% CI 1.01 to 26.1, p = 0.048), but only a trend towards an association amongst those who died (OR 7.0, 95% CI 0.78 to 63, p = 0.082). Due to the borderline p values in both instances and the imprecise nature of statistics on small numbers, it is unlikely that this statistical difference between the two groups is in fact meaningful. In particular, as inadequate information was found to be a significant, independent predictor of global distress amongst the overall study sample.

Comparative interpretation of these findings is therefore difficult, although if the statistical evidence does reflect a true difference, then an explanation should be considered. Perhaps those who survived for longer had greater expectations in terms of their options and survival duration, and therefore may have had greater information needs during the study period, compared with those who died. Those who died may have been more aware of the inevitability of their impending death. Perhaps, the need for information therefore declines at this time, as the outcome becomes a certainty.

6.3.4 Socio-Demographic Predictors Of Physical Distress

The socio-demographic categories were analysed for their associations with significant physical distress according to the MSAS. Scores over 1.5 on the MSAS physical distress subscale were considered to represent significant physical distress. Univariate logistic regression analysis revealed that factors significantly associated with significant physical distress were previous physical illness (OR 2.95, 95% CI 1.28 to 6.80, p = 0.011) and perception of receiving inadequate information from the GP (OR 2.89, 95% CI 1.05 to 7.92, p = 0.039). A trend was apparent towards an association between significant social dysfunction within the family and significant physical distress (OR 2.75, 95% CI 0.89 to 8.47, p = 0.078).
Previous Physical Illness and Significant Physical Distress

Patients who had experienced a previous physical illness were significantly more likely to suffer from significant physical distress at the end of life. This finding may reflect two situations.

The first situation relates to the debility associated with end stage cancer exacerbating an existing symptom burden. A study of newly diagnosed lung cancer patients confers this theory. Cooley et al. (Cooley et al. 2003) found that the best predictor for symptom distress (according to the Symptom Distress Scale) over time, was symptom distress at baseline. Symptom distress at study entry predicted symptom distress for 9 symptoms at 3 months and 7 symptoms at 6 months. This finding implies that patients who were distressed by their symptoms at diagnosis were more likely to experience on-going symptom distress. The findings from the current study suggest that patients who had experienced significant physical illness prior to diagnosis were more likely to experience symptom distress during the final stages of the cancer disease trajectory. These findings appear to have a similar basis in that symptom distress during the cancer journey seems to reflect prior or initial physical symptom burden, perhaps due to exacerbation of existing symptoms.

Alternatively, the present finding may reflect the distress associated with the insight of those who, having one experienced significant physical illness, have developed pre-conceived expectations regarding the experience of symptoms associated with terminal cancer. This theory is exemplified by the findings of Turk et al. (Turk et al. 1998), who compared patients with cancer-related pain (n=184) to those with chronic non-cancer related pain (n=105). Patients with cancer-related pain were found to have significantly higher levels of perceived pain-related disability (p<0.005), increased fear of pain (p<0.03) and greater somatic symptoms of depression (p<0.007) than those with chronic non-cancer pain. This is consistent with the suggestion that expectations of cancer-related symptoms may increase the perceived symptom burden.
In the current study, the clear and direct association between prior physical illness and symptom distress is encouraging, as it seems to imply that the physical subscale score of the MSAS was likely to be valid and reliable, as the surrogate for physical distress in this study. In addition, the patients' histories were also likely to be accurate.

Inadequate Information From The GP
The patients who perceived that they had received inadequate information from their GP, were significantly more likely to suffer physical distress at the end of life. Interestingly, this association did not exist between physical distress and perception of receiving inadequate information from oncology doctors or nurses. The reasons for this are not clear. The explanations for the importance of information, discussed earlier, equally apply in the cases of physical distress. Symptoms may be perceived to be worse, if coping and control are compromised. The specific importance of the GP, with regard to information sharing in relation to physical distress, is unclear and may in fact reflect the relatively small numbers in each category.

A relevant and comparative example of the relationship between information and physical distress is demonstrated by a small Swedish study (Berglund and Sjödén, 1987) of 40 patients receiving chemotherapy, in which analysis revealed that patients who were experiencing communication problems with medical staff were significantly more anxious regarding medical situations (p<0.01), as well being significantly more likely to experience anticipatory nausea prior to chemotherapy (p<0.05).

Trend Towards An Association Between Social Dysfunction and Physical Distress
Patients who experienced significant social dysfunction within their familial situation, showed a trend towards increased physical distress. Perhaps for patients experiencing adverse functioning of familial or social relationships, physical ability may become more important, in order for role maintenance within a dysfunctional situation, thus resulting in greater distress associated with symptoms or debility. In
addition, physical symptoms may have greater impact upon patients experiencing negative or unsupportive behaviours.

Social support provides clear benefits to patients with cancer and in some respects patients with a cancer diagnosis may tend to elicit increased support. In the previously discussed study by Turk et al. (Turk et al. 1998), patients with cancer-related pain reported higher levels of support (p<0.03) and lower levels of negative responses from significant others (p<0.003) than those with chronic non-cancer pain, indicating that cancer pain is considered “valid” and more likely to evoke support. Hence, the impact of symptoms for those not receiving any support, as opposed to enhanced support, may be perceived as much greater.

The impact of social isolation may be exacerbated by social isolation. Bloom and Spiegel (Bloom and Spiegel, 1984) studied females with metastatic breast carcinoma and their families. They showed that one aspect of social isolation results from declining physical function. This reduces the number of social activities in which the patient can be involved, resulting in an increasingly restricted social network. The authors conclude that ironically, for cancer patients, as their need for social support is at its greatest, this is the time when it becomes less available. This finding may contribute to the explanation of the association between social dysfunction and physical distress. Patients experiencing distressing symptoms may be more likely to become socially isolated, thus compromising any external opportunities for social support.

Similarly, this theory is further supported by Strang’s (Strang, 1992) study of patients with cancer-related pain. He found that ability to perform activities of daily living was impaired in approximately two thirds of patients and cognitive activities, such as reading, were impaired in 48% of the patients. Social activities were reduced and familial role was altered as a result of the impact of pain.
6.3.5
Socio-Demographic Predictors Of Psychological Distress

The socio-demographic categories were analysed for their relationships with psychological distress, as measured by the Edinburgh Depression Scale (EDS). The EDS standard cut off of ≥13 was used to define significant psychological distress.

Univariate logistic regression analysis revealed that the factors associated with significant psychological distress were: Previous depression (OR 3.41, 95% CI 1.19 to 9.74, p = 0.022) and perception of receiving inadequate information from oncology doctors, nurses and General Practitioners. A trend was apparent towards an association between significant social dysfunction and significant psychological distress (OR 2.90, 95% CI 0.95 to 8.89, p = 0.062). In addition, a trend was also evident towards an association between marital status and significant psychological distress, for single status (OR 7.24, 95% CI 0.76 to 69.0, p = 0.08).

*Previous Depression and Significant Psychological Distress*

This finding indicates that patients who had a history of depression prior to their cancer diagnosis were more likely to experience significant psychological distress in the final stages of their cancer disease trajectory. Understandably, it follows that those who have a pre-morbid susceptibility to depression are more likely to suffer psychologically during the final stages of a terminal illness. This finding therefore appears to support the validity and reliability of the patient histories and the use of the EDS as a surrogate for psychological distress.

This finding bears similarities to that described in the available literature. Although no other study appears to have explored the specific association between pre-morbid depression and psychological distress at the end of life, Zabora and colleagues (Zabora et al. 2001) examined the prevalence of psychological distress according to demographic factors. They concluded that the most compelling predictor of psychological distress was in fact, the BSI score in the first 2 weeks after diagnosis. Additionally, in a study of psychological distress amongst patients with advanced non small cell lung carcinoma in Japan by Akechi et al. (Akechi et al. 2006),
multiple regression analysis revealed that mood disturbance (POMS) at diagnosis significantly predicts psychological distress at 6 months.

An apparent consensus exists, suggesting that psychological distress in the final stages of the cancer disease trajectory is affected by earlier psychological difficulties, either at the time of diagnosis, or as shown by the current study, prior to diagnosis.

**Inadequate Information**

Patients who perceived that they had received inadequate information from the oncology doctor, nurse or General Practitioner were significantly more likely to experience psychological distress. This finding is explained by the previously described conceptualisation of information seeking in the context of control (van der Molen, 1999) and coping (Lazarus and Folkman, 1984), in that both control and coping are inherently associated with psychological well being.

Other studies have shown how coping relates to psychological well-being. In an American study (Dukes Holland and Holahan, 2003) of patients with breast cancer, approach coping was significantly related to improved psychological well-being (p<0.001), whilst avoidance coping was significantly associated with reduced psychological well-being (p<0.05). Classen et al. (Classen et al. 1996) also assessed coping styles amongst breast cancer patients and found that emotional control was significantly associated with increased mood disturbance (p<0.001) and that having “fighting spirit” was significantly associated with reduced mood disturbance (p<0.01).

Coping strategy and psychological distress are associated, and information seeking is considered a major aspect of coping in adverse circumstances. These concepts contribute towards the explanation of the current findings that, for patients with advanced cancer, the perception of receiving inadequate information from healthcare professionals was significantly associated with psychological distress.
More directly, Lloyd-Williams and colleague (Lloyd-Williams and Friedman, 2001) found that the perceived need for information amongst patients correlated weakly with depression amongst a very similar population to the current study. One hundred patients receiving palliative care for advanced metastatic cancer. This indicates complete consistency with the current study.

*Trend Towards An Association Between Social Dysfunction and Psychological Distress*

Patients who experienced significant social dysfunction tended towards experiencing increased psychological distress. These findings are explained similarly to the finding that social dysfunction was significantly associated with global distress. The examples of literature given do show comparability of findings. These include those of Manne and Glassman (Manne and Glassman, 2000), who showed that amongst 191 married patients enrolled in cancer treatment, unsupportive, negative spousal behaviour significantly mediated psychological distress (p<0.01), and those of Koopman et al. (Koopman et al. 1998) who found reduced mood disturbance to be significantly associated with increased social support. Both of these examples relate specifically to psychological distress and social dysfunction.

In addition, and more directly comparable, in a study (Wilson et al. 2007) of 381 patients receiving hospice, community or hospital palliative care input for cancer in Canada, showed that according to DSM IV criteria, anxiety or depressive disorders were more common amongst patients who received less social support.

The current study did not show a statistically significant association. This may relate to the smaller numbers involved in the analysis of each individual distress domains, compared with the larger numbers involved in the overall, global distress analysis.

*Trend Towards An Association Between Marital Status and Psychological Distress*

Uniquely, a trend was apparent towards an association between marital status and psychological distress. In particular, single status appeared to be associated with an
increased likelihood of psychological distress. This finding is consistent with the literature.

In Zabora’s (Zabora et al. 2001) study of the prevalence of psychological distress according to demographic factors, patients who were married reported least psychological distress, although the differences between the marital status categories were not significant. Similarly, in Akechi’s (Akechi et al. 1998) Japanese study of demographic factors associated with psychological distress amongst ambulatory lung cancer patients, living alone was one of the predictors of psychological distress. Finally, in their study of cancer patients, using their own Illness Distress Scale, Noyes et al. (Noyes Jr et al. 1990) found a trend towards higher distress levels for those who were not married (p<0.07).

Therefore, the findings of the current study that single patients tend towards an increased likelihood of psychological distress are consistent with the available literature. Perhaps single patients are at greater risk of social isolation, which may contribute to their increased risk of psychological distress.

6.3.6
Socio-Demographic Predictors of Spiritual Distress

The socio-demographic categories for the study population were evaluated for their association with significant spiritual distress. Significant spiritual distress was calculated for this population and taken as the cut off of a score of <20 on the FACIT at any time during the study. Univariate logistic regression analysis revealed that a previous history of depression predicts significant spiritual distress (OR 3.80, 95% CI 1.31 to 11.0, p = 0.014). Unlike global distress and its other components, there does not appear to be any association between significant spiritual distress and significant social dysfunction or perception of receiving inadequate information.
**Previous Depression and Significant Spiritual Distress**

This finding suggests that patients with a history of depression prior to their cancer diagnosis are more likely to experience significant spiritual distress in the final stages of the cancer disease trajectory.

There does not appear to be any directly comparable available literature. However, studies have examined spiritual distress and depression. McClain et al. (McClain et al. 2003) evaluated terminally ill cancer patients during their first week of admission to a palliative care hospital. Findings indicated significant correlations between increased spiritual well being (FACIT-Sp-12), and reduced desire for hastened death, reduced hopelessness and reduced suicidal ideation (all p values <0.0001). In another study (Nelson et al. 2002) of terminally ill cancer patients, the Hamilton Depression Rating Scale correlated moderately with the total FACIT-Sp-12 score (-0.40, p<0.01) and more strongly with the meaning and peace subscale of the FACIT-Sp-12 (-0.51, p<0.01). Although there is no evidence regarding a pre-morbid history of depression and spiritual distress amongst terminally ill cancer patients, active depression during the final stages of terminal illness does appear to be associated with reduced spiritual well being, thus perhaps substantiating this finding.

**6.3.7**

**Socio-Demographic Predictors Of Distress: Further Comparison With Previous Literature**

Comparisons have been made between the findings of the present study and those from similar or relevant studies in each section. The non-statistically significant and inconsistent findings are discussed below.

**Socio-Demographic**

Firstly, the current study is compared to Zabora’s (Zabora et al. 2001) large study of the prevalence of psychological distress according to demographic factors. Marital status has been previously discussed and the findings are similar to those of the present study. Similarly, to this study, Zabora et al. found no significant differences in psychological distress levels according to gender.
Zabora also found that psychological distress was greatest in the young and the very old, reaching a plateau in between these age groups. The current study did not detect this variation according to age group. This may simply reflect the difficulty in achieving statistical significance in the current study, especially within a single category. This is particularly relevant as, despite large numbers (n=4496), few of Zabora’s findings were statistically significant. This leads to the conclusion that predisposition to psychological distress is in fact extremely complex.

The findings are also compared to those of Akechi et al. (Akechi et al. 1998) who conducted a Japanese study of demographic factors associated with psychological distress amongst ambulatory lung cancer patients. In addition to living alone, as previously discussed, multiple regression analysis indicated that psychological distress was predicted by female gender, having no children as confidants, using nurses as confidants and using a helplessness/hopelessness coping strategy.

Interestingly, these findings confer with neither those of the much larger study by Zabora et al., nor those of the current study. Akechi’s findings in Japan may reflect cultural differences, or may be less reliable due to the small, homogenous sample.

**Tumour Site**

The current study did not show tumour type to be a statistically significant predictor of distress. Zabora et al. (Zabora et al. 2001) have produced the major paper on psychological distress in relation to tumour site, with at least 100 patients in each diagnostic category. They found that despite lung cancer patients displaying the highest levels of distress, there was in fact no significant difference, when compared with the distress levels amongst patients with tumours of the brain, pancreas, liver and head and neck.

In Germany, Herschbach et al. (Herschbach et al. 2004) found that patients with breast cancer were the most distressed sub-group followed by patients with soft tissue tumours. However, similarly to both Zabora and colleagues and the current
study, the authors here did not identify any significant risk factors for psychological distress either.

Perhaps the effect of the tumour site was negated by the selection of advanced cancer patients for the current study, particularly with respect to metastatic disease (Morris et al. 1986) (Brescia et al. 1992) (Brescia et al. 1990) (Ahles et al. 1984) (Foley, 1979) (Banning et al. 1991). There is a consensus in the literature regarding the significantly increased prevalence of pain amongst patients with bone metastases. Although not specifically evaluated, many of the advanced cancer patients will have had bone metastases, which may have been more directly relevant to distress levels than primary tumour site.

Symptom Distress
Degner and Sloan (Degner and Sloan, 1995) evaluated 434 consecutive patients with a new diagnosis of cancer, using the Symptom Distress Scale. They found that women reported more distress than men (p=0.041), patients with advanced disease had significantly more distress than those with early disease at the time of diagnosis (p=0.0001). The significant gender difference was neither found by other larger studies, nor by the current study. Importantly, this study was done earlier in the disease trajectory and therefore may not be directly comparable, particularly with respect to distress associated with advanced disease.

In a large Canadian study conducted by Carlson and Bultz (Carlson et al. 2004), 2776 ambulatory cancer patients completed several self-rated questionnaires, including the Brief Symptom Inventory. Patients who had the most symptom distress were from ethnic minorities (p=<0.001), lower income households (p<0.001) and were undergoing active treatment rather than follow up treatment (p<0.05). Patients with prostatic carcinoma were the least distressed when results were analysed by tumour site (p<0.001). In terms of comparison, the current study could not be analysed according to ethnicity, due to the representative 99% white population. The current study did not find any association between financial concerns and distress. This may be related to the analysis of the small numbers of patients who admitted to
having financial concerns. Distress levels according to treatment stage were not relevant to the current study of patients receiving palliative care only. Finally, this study is similar only to the findings of Noyes et al. (below) in finding a statistically significant reduction in distress levels amongst patients with prostatic carcinoma.

Noyes et al. (Noyes Jr et al. 1990) studied 438 patients with cancer using the Illness Distress Scale devised by the authors. Overall, symptom distress was highest amongst patients who were younger (p<0.001) and had a lung cancer diagnosis (as opposed to prostatic carcinoma, which was associated with the least distress) (p<0.05). The statistically significant finding that younger patients suffer more symptom distress is unique to this study and does not confer with the findings of the present study or those of other larger studies.

6.3.8
Summary for Socio-Demographic Risk Factors For Distress
The key findings from this study are that social dysfunction and perception of receiving inadequate information were independent predictors of global distress during the end stages of the cancer disease trajectory. These findings are fully substantiated by the findings and theories presented by other authors in the available literature.

Previous significant physical illness predicted physical distress and previous depression predicted psychological and spiritual distress at the end of life. In addition to conferring with the published literature, these findings suggest the reliability and validity of the research tools chosen and their implementation.

6.4
Patterns of Distress Over Time

The following section discusses the longitudinal patterns of global distress and each individual distress domain, over the end stages of the cancer disease trajectory. The inter-relationships between these domains over this time are also evaluated.
6.4.1
Performance Status Over Time
Karnofsky Performance Status was documented at each assessment. A constant average score of 60-70 (see Appendix L) was maintained throughout the study for those who survived. For patients who died, the KPS was initially constant at an average of 60-70, before falling rapidly, prior to death.

These findings have several implications. Firstly, the patients in the end stages of advanced cancer in this study had a constant average KPS of 60-70. This would be considered a relatively good performance status for patients in the terminal stages of advanced cancer, suggesting they remained generally able to care for themselves with occasional assistance during the study period.

Secondly, patients did not appear to experience a gradual decline in performance status over time. For those who died, performance status fell from the constant average level very rapidly, immediately prior to death. This may be considered consistent with the previously discussed cancer disease trajectory, although a more incremental decline in performance status in the final months is often observed. This is evidenced by an extensive literature reviews into prognostic factors which found KPS to have proven prognostic capacity in clinical prediction of survival (Maltoni and Amadori, 2002). However, admittedly a rapid decline in KPS would in fact, be considered very obvious prognostic indicator.

The relatively persistent level of fitness amongst the study population may partly explain the reason why only 2 patients, for different reasons, withdrew from the study, as attrition tends to be inversely related to performance status.

6.4.2
Physical Distress Over Time
The scores from the Memorial Symptom Assessment Scale were plotted, for each individual at each assessment, in profile plots. Box plots were then used to indicate the trends in the average scores at each time point. The analysis reveals that MSAS
scores were highest at baseline. Scores were then variable for the initial 3 months, before stabilising to an individually determined chronic level, consistently lower than baseline.

These findings suggest that physical distress levels are highest at the time the patients are referred to palliative care services. Levels of distress are then variable for the initial period, before falling to a chronic level that is lower than the initial distress but variable, according to each individual. Hence, all patients reach a stable level of physical “distress”, though for some this is a negligible level whilst more significant for others. Despite the chronic level, patients appeared to experience unpredictable exacerbations of distress levels throughout the end stages of advanced cancer.

Therefore, levels of physical distress levels were highest at the time of referral to palliative care services. Levels of physical distress then fluctuated prior to stabilising with occasional exacerbations. These findings are readily explicable. Patients are in fact often referred to palliative care services for the reasons of pain and symptom control. Therefore, patients are often experiencing significant symptoms at this time, which may understandably cause distress. Symptoms management often takes a period of time for adjustment and control maintenance hence the initial fluctuations in symptom distress levels. Level of symptom control is variable, relative to each individual. Some patients will accept and become resigned to a certain degree of symptom burden, whilst others will become symptom-free. Therefore, the chronic levels of symptom distress will depend on each individual. The periodic, unpredictable exacerbations of distress may reflect a new symptoms or recurrence a previously controlled symptom.

**Amongst Patients Who Died**

The patterns of physical distress for those who died during the study were identical to those of the whole sample. Physical distress levels were highest at the time of referral to palliative care services, with initial fluctuation, followed by stabilisation with exacerbations and finally, reduction prior to death. This implies that physical
distress levels generally remained either unchanged or declined immediately prior to death.

**Amongst Patients Who Survived**
The patterns of physical distress for those who survived the study were identical to those of the whole sample. Physical distress levels were highest at the time of referral to palliative care services, initial fluctuation of levels followed, prior to stabilisation of levels with periodic, unpredictable exacerbations throughout the final months of advanced cancer.

**Comparison With The Literature**
Other studies have similarly shown that pain is not necessarily associated with the terminal phase of advanced cancer and cannot be distinguished amongst survivors and those imminently dying. Oster et al. (Oster et al. 1978) found that approximately one quarter of cancer patients died without pain or analgesic use. Additionally, Spiegel and Bloom (Spiegel and Bloom, 1983) found that pain intensity, duration and frequency did not distinguish patients in the terminal phase of metastatic breast cancer from those with more than 1 year’s survival duration.

This evidence is further substantiated by Coyle et al. (Coyle et al. 1990) who found that, although 100% of the patients surveyed reported pain at some point during the study, the pain was in fact described as mild to moderate (80%) and as moderate to severe by only 20% at 4 weeks prior to death. In addition, the prevalence of pain reported fell from 54% at 4 weeks prior to death to 34% one week before death.

Conversely however, the findings of a study by McKegney et al. (McKegney et al. 1981) do not appear to directly support this evidence. They conducted a longitudinal study of 199 patients with terminal cancer and prognosis of more than 3 months but less than one year. Patients were assigned to either the “intensive group” receiving regular specialist palliative home nursing care, or the “non-intensive group” who did not receive home care. Both groups received the same on-going multidisciplinary care. The analysis was conducted in blocks of days prior to death. Eighty percent of those who died reported pain of varying levels at some point during the study. Pain
increased in frequency and severity as death approached. Initially, both groups had the same mean pain scores but at 90 days prior to death, pain continued to increase amongst the non-intensive group, whilst reaching a plateau amongst the intensive group. This difference reach near significance (p=0.06) in the last 30 days of life.

These findings are interesting in relation to the findings of the current study. All of the patients in the present study were receiving specialist palliative home care nursing input. The findings are in fact remarkably similar amongst the two comparable populations of the current study sample, and McKegeby’s “intensive group”, in which a plateau of pain scores was reached approximately 3 months prior to death. The apparent influence of specialist palliative nursing care input will be considered later in relation to the implications of the study findings.

McCorkle et al. (McCorkle et al. 1989) also examined the influence of specialist home care. They conducted a longitudinal study of homebound patients with Stage II or higher lung carcinoma. The first assessment was a maximum of 10 weeks post diagnosis and following this, patients were randomised into 1 of 3 groups: “Oncology Home Care” (equivalent to Macmillan nurse input), “Standard Home Care” (equivalent to primary care team support) and “Outpatient Clinic Care Only".

All of the patients experienced increasing symptom distress over time but that this was delayed by 1 visit (6 weeks) in the 2 home care groups, compared with those receiving outpatient clinic care only (p=0.03). Although not statistically significant, patients receiving oncology home care support showed trends towards relatively fewer hospital admission for management of symptoms and disease complications. In addition, patients receiving home care remained independent for a longer period of time than those receiving outpatient clinic care only (p=0.02). These findings again substantiate the benefits of specialist home care with regard to reducing symptom distress. However, they do not confer with the findings of the present study in that, although symptom distress was delayed by 6 weeks, the levels increased over time. This may relate to the discrepancy between stages in the disease trajectory between the present study of the final months and McCorkle’s evaluation conducted from 10 weeks post diagnosis.
Also at an earlier stage of the disease trajectory, Cooley et al. (Cooley et al. 2003) conducted a retrospective longitudinal study of newly diagnosed lung cancer patients. The authors found that the best predictor for symptom distress over time was symptom distress at baseline. Symptom distress at study entry predicted symptom distress for 9 symptoms at 3 months and 7 at 6 months (odds ratios from 1.6 (p=0.005) to 3.4 (p=0.000)). However, these findings are unlikely to be directly comparable to those of current study, due to the different stages of the disease trajectory under evaluation. In addition, the relevance of palliative care service input should perhaps also be considered and this aspect was not reported upon in Cooley’s study.

6.4.3 Psychological Distress Over Time

The scores from the Edinburgh Depression Scale were plotted for each individual, at each assessment in profile plots. Box plots were then used to indicate the trends in the average scores at each time point. The analysis reveals that EDS scores were highest at baseline. Over time, scores were either constantly variable or stable, at an individually determined chronic level. From 3 months onwards, average EDS levels remained consistently at their lowest.

These findings suggest that psychological distress levels are highest at the time the patients are referred to palliative care services. Levels of distress then vary according to the individual. For some patients, levels of psychological distress remain variable over time, whilst for others the levels fall to a chronic level that is lower than the initial distress but variable, according to each individual (higher for some patients and lower for others). Even for those who attained a stable level, unpredictable exacerbations of distress levels occurred throughout the end stages of advanced cancer.

Therefore, levels of psychological distress were highest at the time of referral to palliative care services. Levels of psychological distress then either fluctuated or stabilised with occasional exacerbations. The high levels of psychological distress at
the time of referral to palliative care services are perhaps understandable. Many patients are anxious regarding the implications of a palliative care referral and may have only recently been given their non-curative disease status. Hence referral-associated psychological distress levels are likely to fall once the patients are established within the service.

For many patients, psychological distress levels quickly stabilised, remaining negligible for some and higher for others. Unpredictable exacerbations of psychological distress levels did occur, even for these patients. These may have related to a sudden change in disease-related circumstances. For some patients, levels of psychological distress varied constantly over the final months of life. Perhaps this was reflection of personality and coping strategy or perhaps these patients experienced more frequent disease-related changes in circumstances.

From 3 months onwards, average psychological distress levels remained consistently at their lowest. This may reflect the support of the specialist palliative care nurse input or may suggest that patients generally adapt psychologically to their circumstances.

**Amongst Patients Who Died**
The average psychological distress levels were highest at the time of referral to palliative care services, with initial fluctuation, followed by stabilisation with exacerbations and finally reduction prior to death. This implies that psychological distress levels generally remained either unchanged or declined immediately prior to death. The only difference when comparing the overall study group and those who survived is that there was less evidence of individuals with constantly fluctuating psychological distress levels amongst patients who died. The initial fluctuation of psychological distress, followed by stabilisation to chronic, lower levels of distress, may reflect an acceptance of circumstances amongst the population imminently approaching death. Interestingly, amongst those who died, the longitudinal patterns of psychological and physical distress appear to be very similar.
Amongst Patients Who Survived

The patterns of psychological distress amongst patients who survived the study were almost identical to the overall study group. Average psychological distress levels were highest at the time of referral to palliative care services, with levels of distress then subsequently varying, according to the individual. For some patients, levels of psychological distress remained variable over time. Amongst others, the levels fell to a chronic level, lower than the initial distress level but variable according to each individual, with periodic exacerbations of distress levels throughout the end stages of advanced cancer. Constant variability of psychological distress levels appears to be a pattern associated with certain survivors of the study. For these patients, the variable levels of psychological distress may reflect their coping strategies and the challenges faced at an earlier stage in the disease trajectory, with a longer future to contemplate and navigate.

Comparison With The Literature

Akechi et al. (Akechi et al. 2006) conducted a longitudinal study of psychological distress amongst patients with advanced non-small cell lung carcinoma in Japan. Consecutive patients, newly diagnosed with non-resectable, non-small cell lung carcinoma were assessed after diagnosis and prior to treatment, at 2 months and finally at 6 months from diagnosis.

Analysis conducted on the complete longitudinal data for 85 patients indicated that tension-anxiety fell significantly and consistently over time, from diagnosis to 6 months (p<0.001). Depression-Dejection fell significantly from diagnosis to 2 months (p<0.001), although there was no significant difference from diagnosis to 6 months. Multiple regression analysis revealed that mood disturbance at diagnosis significantly predicts psychological distress at 6 months. However, there was no significant change in total mood over time. The authors suggest that these findings indicate that overall psychological distress does not reduce naturally over time.

These findings are perhaps not directly comparable with those of the current study, due to the differences in stage of disease. However, some interesting similarities and discrepancies are evident and justify comment. In terms of similarities, tension-
anxiety and depression-dejection, both fell from the time of diagnosis in Akechi’s study. In the current study, psychological distress levels were also highest at the point of study entry, which here was referral to palliative care services. This may reflect the well-documented phenomenon that certain points of vulnerability and increased distress occur during the cancer disease trajectory. These include both time of diagnosis and end of life (Holland et al. 2004) (Zabora et al. 1997) (Norton et al. 2004) (Carlson and Bultz, 2003b) (Butler et al. 2003).

Akechi found that depression-dejection levels fell initially, but then no difference was found from 2 to 6 months. Similarly, in the current study, levels of psychological distress were variable, though lower than the initial levels. Unlike the trend in tension-anxiety levels in Akechi’s study, psychological distress levels in the current study did not show a consistent decline. Perhaps the tension-anxiety components in Akechi’s study were not reflected by psychological distress, as detected by the EDS in the current study. Nonetheless, Akechi found no overall change in mood over time and suggested that overall psychological distress does not reduce naturally over time. Specific change over time of psychological distress levels was not directly analysed in the current study and cannot therefore be compared. However, average levels of overall psychological distress in the current study were lower at death or completion than at baseline levels.

In another study, Lloyd-Williams and Riddleston (Lloyd-Williams and Riddleston, 2002) screened 50 patients with advanced cancer, receiving palliative day care for depression on a weekly basis for 12 weeks. Those who scored below the cut off threshold score at initial assessment showed a very small mean change of only +/- 0.56 over the 12 weeks. This indicates that depression rates appear to remain stable over time amongst patients with advanced disease. Again, the change over time in psychological distress was not directly analysed in the current study, thus precluding comparison. However, although comment cannot be made on mean change, the average psychological distress levels, in the current study were highest at the time of referral to palliative care services and lower from 3 months onwards or prior to death.
Butler et al. (Butler et al. 2003) studied psychological distress amongst 59 women with metastatic breast cancer participating in a randomized trial of the effects of group psychotherapy on psychosocial outcomes and survival. Mean levels of mood, depression and well-being were examined over three time points: Baseline (T1), the second-to-last assessment before death (T2), and the last assessment before death (T3). Analysis revealed that psychological distress remained relatively constant or declined from T1 to T2, however, averages on all measures significantly increased from T2 to T3. Apparently, participation in group psychotherapy did not have a significant impact on the increase in distress proximal to death. The findings of the current study confer with the initial fall in psychological distress levels, as found by Butler et al. However, in the current study psychological distress levels generally remained either unchanged or declined immediately prior to death, they were not exacerbated. This finding conflicts with Butler's evidence suggesting a significant increase in psychological distress prior to death. This may potentially reflect issues specific to the homogeneous, self-selected, small sample of breast cancer patients analysed in Butler's study. Especially, as other studies (Lloyd-Williams and Friedman, 2001) (Herschbach et al. 2004) have indicated that patients with breast cancer are most susceptible to psychological distress.

6.4.4

Spiritual Distress Over Time

On the whole, average FACIT scores showed very minor variations over time. However, if carefully analysed, scores initially fell slightly from the time of referral, with a subsequent slight consistent increase from 3 months onwards. Despite this, FACIT scores were highest at baseline.

As FACIT scores are inversely related to distress, these findings indicate that average spiritual distress levels were lowest at the time of referral to palliative care services. Average spiritual distress levels then increased slightly initially, prior to showing a persistent slight decrease from 3 months onwards in the end stages of advanced cancer. Average spiritual distress levels remained at their lowest at the time of
referral to palliative care services. It is important to note that the relevance of this detail is questionable in view of the very small incremental score changes over time.

Based on the slight incremental changes, these findings imply that at the time of referral to palliative care services, patients experience the least spiritual distress. The distress levels then increase slightly over the initial months. This pattern differs from that of physical and psychological distress. Perhaps the experience of spiritual distress is associated with a lag effect in timing, with the relevance and impact of a palliative care referral initiating an insidious rather than an immediate response. After 3 months of palliative care input, spiritual distress levels then consistently fell slightly. Perhaps this relates either to patients’ adaptation to circumstances or the benefits of specialist palliative care input, or both.

**Amongst Patients Who Died**
Average spiritual distress levels for patients who died were also largely stable. Similarly to the whole group, average spiritual distress levels initially increased slightly, prior to falling slightly amongst those who survived 3 months or more.

**Amongst Patients Who Survived**
Similarly to the whole group and those who died, average spiritual distress levels were generally stable over time for those who survived. The trends were also similar with an initial slight increase in spiritual distress levels, followed by a slight decrease from 3 months onwards.

**Comparison With The Literature**
As previously discussed, spiritual distress is perhaps the least extensively evidenced component of distress in the literature (Cherny et al. 1994). Therefore, there are only a few longitudinal studies assessing spiritual distress over the end stages of advanced cancer available for comparison.

However, the current findings may be substantiated by other studies that have indicated that spirituality is heightened amongst patients with terminal illness. Reed (Reed, 1987) studied 3 groups of 100 socio-demographically matched patients
(terminally ill adults, hospitalised adults and healthy adults). Analysis revealed that a significantly larger number of terminally ill adults indicated a change toward increased spirituality than was found amongst the non-terminally ill and healthy adults.

This is consistent with the findings of the present study, that patients with terminal illness experience a change towards an increase in spirituality (fall is spiritual distress) during their final months. The current study was longitudinal in nature and chartered the course from the time of referral to palliative care services, thus providing an insight into the initial rebalancing of spirituality, as distress levels rise a little before falling again. Again, as these slight incremental changes in distress level were minimal, the current study also confirms the relative stability of spirituality at a moderate level.

6.4.5
Global Distress Over Time
Profile plots and box plots revealed a constant variation in DT scores over time. There were no apparent trends. The lowest average DT scores were noted at the final assessment. These findings imply that global distress levels were constantly variable and unpredictable during the end stages of advanced cancer. Average global distress levels were at their lowest during the final assessment, at 5 months.

The lowest global distress levels at the final assessment may reflect an acceptance and adaptation to circumstances. Perhaps the variability in global distress levels is reflecting the intermittent, unpredictable exacerbations of distress evident amongst each of the distress components. This will be discussed further later, in the section evaluating the relationships between the global distress and the distress components.

Amongst Patients Who Died
Again, global distress levels varied constantly and unpredictably over time amongst those who died. Average global distress levels were lowest at the time of referral to palliative care services amongst those who died.
Amongst Patients Who Survived
The findings amongst those who survived were very similar to the overall study sample. Global distress levels were variable and unpredictable over time, with lowest average levels at the final assessment.

These findings indicate that although trends and patterns can be detected amongst the global distress components, global distress levels themselves are unpredictable. Interestingly, the average levels were lowest at the final assessment amongst the overall sample and those who survived. However, amongst those who died, average global distress levels were lowest at the time of referral to palliative care services. Further analysis was therefore conducted amongst this group.

Global Distress at the End Of Life
The DT scores at the time of death were evaluated for patients who died during the study. Of the 47 who died, 31 patients had been able to complete a penultimate and final DT score in the immediate period prior to death.

At both of these assessments, the median DT score was 5, with an inter-quartile range of 0-7. The median change between these final two assessments was 0, with an inter-quartile range of –2 to 2. The mean distress score increased at the end of life from 4.0 (SD 3.4) to 4.2 (SD 3.3), a mean change of 0.2 (SD 4.4).

No systematic change was found between penultimate and final distress levels in the period immediately prior to death. Therefore, global distress levels did not appear to be affected by proximity to death.

Although average global distress levels were lowest at the time of referral to palliative care services amongst those who died, there was not a rise in global distress levels prior to death. Global distress levels began at their lowest but then fluctuated constantly and unpredictably until death.
Comparison With The Literature

Longitudinal evidence for global distress amongst patients with advanced cancer in the literature is sparse. The reason for this may be that the components of global distress appear to have generally been evaluated separately, as previously discussed. The reported trends in the distress over time are inconsistent amongst the minimal available literature.

One literature review (Carlson and Bultz, 2003b) reports that distress prevalence remains constant throughout the course of disease, with an increase over the terminal phase. Another, (Zabora et al. 1997) suggests that high initial distress levels remain high over the disease course. Direct comparison between this evidence and the present study is difficult, as this study began at the time of referral to palliative care services only, therefore there is no data available for comparison, regarding the period from diagnosis to the point of palliative care referral. However, the current study does not confer with either of these suggestions, showing persistently variable global distress levels over the final stages of advanced cancer. In particular, the current study found no evidence of an increase in global distress levels prior to death. This may simply reflect the detailed longitudinal analysis of global distress over the end stages of advanced cancer conducted in this study, rather than an estimate of distress prevalence during the end stage of disease in comparison with prevalence earlier in the disease trajectory.

6.5 Inter-Relations Between Distress Components

Associations between the assessment scores for each component of distress were examined. Additionally, each distress component was correlated with global distress, in order to establish which aspects of distress are most influential in the overall experience of distress. This analysis was conducted both for baseline scores and for changes over time for the first 3 months.
6.5.1

**Karnofsky Performance Status: Inter-relationships at Baseline**

The KPS did not correlate significantly with the EDS, FACIT or DT. This indicates that performance status did not relate to psychological, spiritual or global distress at the time of referral to palliative care services. However, KPS was significantly, negatively associated with MSAS ($r = -0.23$, $p = 0.02$). This finding implies that a lower performance status at the time of referral to palliative care services is associated with higher levels of physical distress. Performance status is a measure of functionality, which reflects physical ability, or debility. This explains the specific and significant association between a lower performance status and increased physical distress.

**Karnofsky Performance Status: Inter-relationships Between Changes From 0-3 Months**

The changes in KPS over 0-3 months did not correlate significantly with the changes in EDS or DT over 0-3 months. This implies that over the first 3 months from referral to palliative care services, performance status does not relate to psychological or global distress. However, KPS was significantly, negatively associated with both FACIT ($r = -0.28$, $p = 0.03$) and MSAS ($r = -0.28$, $p = 0.02$). These findings suggest that over the first 3 months from referral to palliative care services, lower performance status is significantly associated with increased physical distress. This is consistent with the findings at baseline. However, contrary to the baseline findings, over the first 3 months from referral to palliative care services, a lower performance status is associated with reduced levels of spiritual distress (FACIT higher). The association with spiritual distress does not appear to affect the relationship with overall global distress.

**Comparison With The Literature**

*Performance Status and Physical Distress*

The association between lower performance and increased physical distress was consistent, both at baseline and over the changes of the first 3 months of the current study. This finding confers fully with the findings of Yates et al. (Yates et al. 1980) in their validation study of the KPS, which was conducted amongst patients with
advanced cancer with an expected prognosis of 3 months to 1 year. The authors found the KPS to be a substantially valid indicator of overall physical status, as well as having a close correlation with deterioration in function. To a certain extent, the finding from the current study is validated by Yates’ evidence, suggesting that that the KPS was completed accurately in the present study and that the MSAS was a reliable and valid measure of physical distress amongst the study population of advanced cancer patients.

Furthermore, the findings from this study are also consistent with more recent evidence from Portenoy et al. (Portenoy et al. 1999) who studied breakthrough pain amongst 164 in-patients with cancer, using a cross-sectional survey of self-rated measures of pain, breakthrough pain, depression, anxiety and functionality. Patients with uncontrolled, breakthrough pain had significantly greater functional impairment on the Pain Interference Scale than those with controlled background pain (p<0.001). Multivariate analysis confirmed that breakthrough pain independently contributed to impaired functioning. Unfortunately, the direction of causation of this relationship cannot be determined from this study, due to the cross-sectional data. Breakthrough pain would certainly reflect physical distress, as functionality would reflect performance status.

**Performance Status and Spiritual Distress**

The association between lower performance status and lower spiritual distress levels was only found over the change from 0-3 months from referral to palliative care services, no association existed at the time of referral. This implies that perhaps some adjustment is involved in this process, potentially resulting from the development of increased spirituality in the context of falling performance status.

This would be consistent with Frankl’s (Frankl, 1963) existential theory that individuals have the ability to find meaning in life when life is threatened. In addition, the findings of the current study confer with those of Reed (Reed, 1987), who studied 3 groups of 100 socio-demographically matched patients (terminally ill adults, hospitalised adults and healthy adults), using the Spiritual Perspective Scale.
and Index of Well-Being. Analysis revealed that a significantly larger number of terminally ill adults indicated a change toward increased spirituality than was found amongst the non-terminally ill and healthy adults.

Performance Status and Global Distress
In a recent study, Ransom et al. (Ransom et al. 2006) evaluated the DT amongst bone marrow transplant patients. Four hundred and ninety one patients completed measures including performance status, together with the DT. Raised DT score was associated with lower performance status. This relationship was not apparent in the current study. The reasons for this are not clear, although the populations are not directly comparable.

6.5.2
Physical, Psychological and Spiritual Distress: Inter-relationships at Baseline
MSAS, EDS and FACIT all correlate significantly (p<0.001) with one another at baseline. The FACIT negatively correlated with the other measures. These findings imply that at the time of referral to palliative care services, physical, psychological and spiritual distress levels were all significantly inter-related, with an increase in one associated with an increase in another.

The correlation coefficients between these measures were relatively similar, although the correlation coefficient between MSAS and FACIT was slightly lower than the rest (r = -0.35, p<0.001). Although still significant, this finding implies perhaps a slightly weaker relationship between physical and spiritual distress, in comparison to the other variables.

Physical, Psychological and Spiritual Distress: Inter-relationships Between Changes From 0-3 Months
Similarly to the baseline findings, the changes in MSAS, EDS and FACIT all correlated significantly (p<0.001) with one another over 0-3 months. The FACIT negatively correlated with the other measures. These findings imply that over the
first 3 months from referral to palliative care services, physical, psychological and spiritual distress levels were all significantly inter-related, with an increase in one associated with an increase in another.

Over the first 3 months from referral to palliative care services, the correlation coefficients between all of these measures were relatively similar and slightly higher than correlations at baseline. The highest correlation existed between the spiritual and psychological components \((r = -0.62)\) of distress. Unlike at baseline, there was no difference in the correlation coefficient between the changes in the physical and spiritual distress levels over the first 3 months from referral to palliative care services \((r = -0.55)\).

**Comparison With The Literature**

The findings from the present study indicate that both, at the time of referral to palliative care services and in the subsequent 3 months, the components of global distress are all significantly inter-related. Each of these relationships are evidenced in the literature.

**Relationship Between Physical and Psychological Distress**

This is potentially the most researched relationship between components of distress in the literature. An entire section of the literature review is dedicated to the well-recognised reciprocal relationship between physical and psychological distress. Key papers are summarised below.

Most importantly, scientific evidence indicates that physical injury, pain pathways and the emotional processing of this information is interlinked within the nervous system (Fallon et al. 2006) (Bair et al. 2003). Anxiety, fear and lack of sleep feed into the limbic system. In response to this, the brain modifies pain input at the spinal level, via the spinal cord. This information then feeds back to the brain, establishing a loop (Fallon et al. 2006) (Fallon and McConnell, 2006). Additionally, depression specifically affects levels of serotonin and noradrenaline neurotransmitters, these dampen peripheral pain signals in the complex central pain modulation system. Therefore, the depression associated decrease in levels of these neurotransmitters
may result in an increase in peripheral pain messages, thus contributing to persistent pain (Bair et al. 2003).

Additionally, Chapman and Gavrin (Chapman and Gavrin, 1999) suggest that patients with depression and chronic pain have common behavioural markers of a maladaptive sustained stress response which include fatigue, myalgia, disrupted or non-restorative sleep, reduced appetite, impaired physical functioning and concentration.

Sutton et al. (Sutton et al. 2002) provide an extensive review in which the authors collate the extensive empirical evidence for the contribution of psychological factors to pain. This includes findings that pain intensity relates to increased mood disturbance, maladaptive coping responses, belief that pain relates to disease progression, greater life stress, feelings of anger, frustration and exhaustion, helplessness and hopelessness.

A study of 40 consecutive, matched patients with cancer-related pain of organic aetiology and 37 pain-free cancer patients, conducted by Ahles et al. (Ahles et al. 1983) substantiates this.

Patients were assessed using interviews and pain diaries, involving numerical and visual pain ratings, together with a log of medications and activities. Analysis revealed that patients with pain scored more highly for depression on the BDI (p<0.05) and the VAS-Depression (p<0.004) and also higher for anxiety on the VAS-Anxiety (p<0.05). The interview data also showed that an increased number of the patients with pain admitted to depression (p<0.007) and irritability (p<0.001). The patients who believed pain was secondary to disease progression were compared with those who didn’t using one-tailed t tests. Those who did believe their pain resulted from disease progression had significantly higher scores on the Depression-SCL-90, BDI and Anxiety-SCL-90 (p<0.05). The authors conclude therefore, that pain is in fact multi-dimensional and relationships between the physical and psychological are reciprocal.

300
Spiegel and Bloom (Spiegel and Bloom, 1983) conducted a cross-sectional study of 86 patients with metastatic breast carcinoma, recruited from out patient oncology clinics. Patients completed a battery of self-rated questionnaires relating to psychosocial variables, as well as pain assessment. Multiple regression analysis showed that 50% of the variance in pain experience was accounted for by the level of mood disturbance as measured by the POMS and including depression, anxiety, fatigue, confusion, patient’s belief that pain signified disease progression and the use of analgesia.

In their review article, Bair et al. (Bair et al. 2003) summarise this concept very concisely, “the prevalence of pain in a depressed sample and the prevalence of depression in a pain sample are higher than the prevalence rates when the conditions are individually examined”.

The findings of the current, longitudinal study, that a significant relationship existed between physical and psychological distress both at baseline and over time, confers entirely with all of the available, consistent evidence. Therefore, the findings from the current study are essentially reassuring, in that they again confirm the reliability and validity of the choice of assessment tools used to reflect physical (MSAS) and psychological (EDS) distress amongst this population.

Moreover, these findings contribute significantly to the current literature in which the evidence is largely cross-sectional and relating to the experience of patients earlier in the disease trajectory. This study provides direct evidence of the existence of this reciprocal relationship between physical and psychological distress, amongst patients in the final stages of advanced cancer, both at the time of referral to palliative care services and for the subsequent months.

**Relationship Between Physical and Spiritual Distress**

Strang et al. (Strang et al. 2004) studied the concept of “existential pain”, implying a continuum exists between the existential and physical. The concept proved difficult to define with chaplains suggesting existential pain relates to guilt, isolation and
resignation, whereas palliative medicine physicians suggesting the concept reflects death anxiety, whilst the pain physicians suggesting that existential pain results from “painful living”. Despite the difficulties in defining the existential and physical as a single concept, it is clear that a relationship exists between these two domains.

The current study provides evidence that increased physical distress is significantly associated with increased spiritual distress at the time of referral to palliative care services and over the subsequent 3 months. Interestingly, this is not entirely consistent with the earlier finding that spirituality appears to increase as performance status, a measure of functionality, falls. This difference may reflect the specific concept of physical distress, as opposed to physical and functional decline. Physical decline per se, is not necessarily distressing, perhaps enabling the fostering of spirituality. However, physical distress itself evidently exerts an adverse influence on this process.

One study that highlights this conflict is that of Meraviglia (Meraviglia, 2004). The author studied 60 ambulatory patients with varying stages of lung cancer, using measures of existential meaning, symptom distress (SDS) and psychological distress. Multiple regression analysis revealed that increased functional status was associated with increased existential transcendence (meaning in life) and that increased meaning in life was associated with reduced psychological distress, together this significantly predicted symptom distress, explaining 9% variance.

This evidence confers the findings from the current study that increased physical distress is associated with increased spiritual distress. However, the evidence also conflicts with the earlier finding of the current study that spirituality increases with falling performance status. An explanation has been proffered for the study findings. Perhaps Meraviglia’s finding suggesting that increased functionality is associated with increased meaning in life is a reflection of the experience of patients at an earlier stage in the disease trajectory, when life may not appear to be imminently under threat. Unfortunately, there is no further evidence available in the literature for
comparison, to assist in either substantiating or negating this perhaps slightly controversial study finding.

The significant relationship between physical and spiritual distress in this study is further substantiated by Strang’s (Strang, 1997) study of 78 patients with cancer who were being treated for pain related problems. They were assessed using visual analogue scales and semi-structured interviews. Analysis revealed that patients with greater overall mean pain scores or mean worst pain scores were significantly more fearful regarding the future (p<0.01).

Direct comparison between the limited literature and the current study findings is difficult, due to the timing and methodology. Previous studies were conducted at an earlier stage of the disease trajectory and the majority are cross-sectional. Hence neither the populations, nor the relationships are easily comparable. This study therefore adds directly to the literature, providing evidence for a direct relationship between physical and spiritual distress amongst patients in the final stages of advanced cancer, at the time of their referral to palliative care services and subsequently for 3 months.

**Relationship Between Psychological and Spiritual Distress**

The findings from the current study indicate that increased psychological distress is associated with increased spiritual distress both at the time of referral to palliative care services and over the subsequent 3 months. These findings are consistent with main body of literature.

McClain et al. (McClain et al. 2003) evaluated 160 terminally ill cancer patients (prognosis <3 months) during the first week of their admission to a palliative care hospital using the FACIT-Sp-12, Beck Hopelessness Scale and Schedule of Attitudes Towards Hastened Death. Analysis revealed significant correlations between increased overall spiritual well being (FACIT-Sp-12) and reduced desire for hastened death, reduced hopelessness and reduced suicidal ideation (all p values <0.0001). Multiple regression analysis indicated that spiritual well-being (SWB) was the
strongest predictor of each of the outcome variables. In addition, depression was significantly associated with an increased desire to hasten death, if SWB was low (p<0.001), but not associated if SWB was high (p=0.06). Therefore, SWB appears to provide some protection against end of life despair amongst terminally ill patients. The findings are consistent with those of the current study, although McClain furthermore suggests that spirituality in fact, mediates end of life despair.

In another study (Nelson et al. 2002) of 84 terminally ill cancer patients with a prognosis < 6 months who were receiving palliative care, patients completed measures including the FACIT-Sp-12 and the Hamilton Depression Rating Scale (HDRS). Analysis revealed that the HDRS correlated moderately with the total FACIT-Sp-12 score (-0.40, p<0.01). However, the HDRS correlated more strongly with the meaning and peace subscale of the FACIT-Sp-12 (-0.51, p<0.01), whilst there was no correlation with the faith subscale of the FACIT-Sp-12. These findings suggest that patients with increased meaning and peace are significantly less depressed, whilst the religiosity component of spirituality does not appear to influence levels of depression amongst terminally ill. This study is the most directly comparable to the current study in terms of the population and tools used. However, analysis of the current study did not involve separately evaluating the 2 subscales of the FACIT. Despite this, the findings of the current study, using the overall FACIT score, remain consistent with those of Nelson et al. Both studies indicate that amongst terminally ill cancer patients with a prognosis of <6 months, improved spiritual well-being is associated with reduced psychological distress.

The findings of the current study are therefore consistent with current literature. Moreover, the current study adds to the available literature by providing longitudinal evidence of the direct relationship between spiritual and psychological distress amongst patients in the final stages of advanced cancer at the time of referral to palliative care services and for the subsequent 3 months.
Global Distress: Inter-relationships

The DT correlated strongly and significantly with each of the EDS, MSAS and FACIT, both at baseline and for the change from baseline to the three-month assessment. The FACIT negatively correlated with the DT. The highest Spearman rank correlations were between DT and EDS at both baseline ($r = 0.682$) and for the change from baseline to 3 months ($r = 0.710$).

These relationships were further analysed. The worst scores (highest distress) over the entire study, for each of these measures, were also compared with the worst DT scores. A strong, significant association was found. The likelihood of experiencing significant global distress was significantly higher if EDS was above its cut off level at anytime during the study (OR 12.2, 95% CI 3.40 to 44.1, $p <0.001$), similarly, the risk of experiencing significant global distress was significantly greater if MSAS was above its cut off level (OR 9.79, 95% CI 3.36 to 28.5, $p <0.001$), and the same relationship was found if FACIT was below its cut off level (OR 2.80, 95% CI 1.14 to 6.89, $p <0.025$).

Together, these findings suggest that global distress is directly and significantly associated with physical, psychological and spiritual distress. Significant distress in any one of these 3 domains predicts significant global distress. Psychological distress appears to have the strongest relationship with global distress.

These relationships are reassuring in that physical, psychological and spiritual distress are considered to be components of global distress. The interesting feature of these findings is that the DT as a tool is evidently sensitive in detecting physical, psychological or spiritual distress. In particular, this is still evident despite the course of the erratic, unpredictable course of the DT over time.

Comparison With The Literature

The available evidence for global distress is mainly in the form of validation studies of the NCCN Distress Thermometer. These studies have used various tools and
found the DT to correlate well with them. Roth et al. (Roth et al. 1998) found the DT compared favourably with the validated HADS amongst patients with prostate carcinoma. Jacobsen et al. (Jacobsen et al. 2005) found that the DT compared favourably with both the HADS and the Brief Symptom Inventory used at their established cut offs. Although the patients were earlier in their disease trajectory, the implication of this evidence is consistent with that of the present study; that global distress (DT) is associated with psychological distress (HADS and BSI).

Similarly in Japan (Akizuki et al. 2003), 275 patients with cancer completed the DT and HADS. Psychiatrists used the DSM IV criteria to diagnose adjustment disorders and major depression amongst these patients. The DT correlated significantly with the HADS ($r=0.71$, $p<0.01$) and was also found to be 84% sensitive and 61% specific for the detection of adjustment disorders and major depression, according to DSM IV criteria. Again, this is consistent with the findings of the current study, indicating that psychological distress was most strongly associated with global distress and that the DT is sensitive in detecting this.

In a recent study, Ransom et al. (Ransom et al. 2006) evaluated the DT amongst bone marrow transplant patients. Four hundred and ninety one patients completed measures of depression, anxiety and performance status, together with the DT. Raised DT scores were associated with increased depression, anxiety and lower performance status. The performance status has been discussed previously. Although the study populations are not directly comparable, again, the findings regarding the association between global distress and aspects of psychological distress further substantiate the evidence from the current study.

Trask et al. (Trask et al. 2002) studied 50 patients at a consultation, to determine whether or not Bone Marrow Transplant would be appropriate. The anxiety subscale of the HADS correlated significantly with the DT ($r=0.415$, $p<0.05$), although the HADS depression subscale did not. Regression analysis revealed that 17.4% of the variability in the DT was accounted for by the HADS. Most of this was attributed to the anxiety component, with depression contributing a negligible amount. The
authors therefore suggest that the distress detected by the DT is related more to anxiety than depression. Conversely, Hoffman and colleagues (Hoffman et al. 2004) studied 68 ambulatory patients with cancer using the DT, the BSI and the BSI-18. In contrast to the previous study by Trask et al., in this study, the DT correlated significantly with the depression subscale of the BSI (r=0.54, p<0.001), as well as the anxiety subscale (r=0.68, p<0.001) and the hostility subscale (r=0.50, p<0.001). ROC curves analyses revealed that the DT has a moderate ability to detect distress, as identified by the BSI and the BSI-18 (area under curve = 0.74 and 0.80 respectively, and p<0.001 and p<0.01 respectively.

These studies were both conducted amongst different populations, which were also different to that of the current study. Therefore, direct comparison must be considered with caution. However, both studies reiterate the significant relationship between psychological and global distress found in the current study. These studies discuss the components of psychological distress responsible for the contribution to global distress, which was beyond the scope of the current study. Importantly however, none of the validation studies have evaluated the EDS in relation to the DT. Although the current study was not designed as a validation study, and no implications regarding validity are derived, the evidence does appear to suggest that the EDS is strongly and significantly associated with the DT.

Another important consideration is that none of the validation studies have considered the other potential components of global distress; they have all focussed on psychological distress at one time point. The current longitudinal study therefore adds to the evidence for the DT, indicating its ability to also detect physical (MSAS) and spiritual (FACIT) distress over time. Furthermore, in this study, the DT has been shown to have significant and strong associations with measures of social distress, which is discussed elsewhere in Chapter 6.3.
6.5.4

Summary Of Longitudinal Distress Patterns and Inter-Relationships

In keeping with the available literature, whilst adding to the evidence, the findings of this study indicate that physical, psychological, spiritual and global distress are all inter-related amongst patients in the end stages of advanced cancer at the time of referral to palliative care services and for the subsequent 3 months.

Whilst the MSAS, EDS and FACIT all showed initial variation in levels prior to stabilising to a chronic, lower level with occasional exacerbations, the DT was unpredictably variable over time.

Together, these findings suggest that at the time of referral to palliative care services, levels of physical and psychological distress are at their highest, whilst spiritual distress is lowest. The levels of all 3 components then fluctuate over the initial months, prior to stabilising to a chronic, lower individual-dependent level. Despite this stability, occasional exacerbations occur in physical, psychological and spiritual distress levels.

Due to strong, significant correlations, the evidence suggests that the NCCN Distress Thermometer appears to be sensitive in the detection of these exacerbations in physical, psychological or spiritual distress levels amongst patients at the end stage of advanced cancer at the time of referral to palliative care services and in the subsequent months. However, the NCCN Distress Thermometer is not predictive of impending distress.

Therefore, the NCCN Distress Thermometer would be very useful in screening for distress amongst terminally ill cancer patients receiving palliative care. The tool would detect distress due to a physical, psychological, spiritual or multi-dimensional cause. The underlying cause of the distress would require to be elicited.
6.6 Medication Use And Healthcare Service Input

6.6.1 Medication Requirement

Opioid requirement amongst the current study population of terminally ill patients with advanced cancer was in fact low. Many of the patients were either not using opioid (n = 30) at all, or using low doses. Only 9 patients were using extreme doses of opioid.

Sedative requirement was also very low during the course of the study. Only 8 patients required palliative sedation at the end of life. This was achieved with small to standard doses of sedative drugs, except in one case in which an extreme dose was required. The small numbers of sedated patients may reflect the adverse effect of sedation on conscious level. Data were not available from those who were fully sedated.

Thirty patients required neither opioid nor sedative. Of the 9 patients using extreme opioid doses, 2 were also sedated. The single patient requiring extreme sedation was using a low opioid dose.

These findings provide no clear evidence of an association between opioid and sedative use amongst the current study population. Detailed literature regarding medication use in the terminal stages of advanced cancer has not been reviewed for comparison. The reason for this is that the study of medication use is an extensive, separate area of research, beyond the scope of this study. These findings regarding medication requirement are included purely, in order to provide background information for the study of medication use, in the context of distress.

Medication Dose and Social Status

Both opioid and sedative requirements were compared with social status, according to DEPCAT. There was no apparent relationship between either opioid or sedative
dose and DEPCAT amongst the whole study sample, or both those who died, or survived.

Again, the research regarding healthcare and socio-economic status is vast, and far beyond the scope of this study. For this reason, specific literature regarding medication use and socio-economic status has not been evaluated for comparison.

A study by Macleod (Macleod et al. 2004) found that deprived women with breast cancer had more financial and family concerns, along with increased co-morbidity and depression than their more affluent counterparts. Medication use was not analysed, although an assumption may be made that increased anxiety, depression and co-morbidity may result in increased use of analgesia, sedation and anti-depressants. However, the present study of a heterogeneous advanced cancer population did not find any evidence to substantiate this theory.

Relationship Between Medication and Significant Global Distress
The associations between significant global distress, (defined as worst thermometer score over 5) and opioid dose, were evaluated. Analysis revealed a significant association between opioid dose and significant global distress. Greater opioid doses were associated with an increased likelihood of significant global distress, for a morphine equivalent dose of >100mg, (OR 3.66, 95% CI 0.99 to 13.5, p = 0.022). However, no association was found between sedative dosage and significant global distress.

These findings imply that the experience of significant global distress amongst terminally ill patients with advanced cancer is associated with a higher opioid requirement, but not with sedation.

A significant positive relationship was also found between physical symptoms and opioid dose: Spearman rank correlation between maximum physical score and maximum opiate dose was 0.29 (p=0.004).
Therefore, the relationship between significant global distress and increased opioid requirement could imply that the distress reflects pain levels and hence the requirement to treat with analgesia. This theory would certainly confer with the finding that increased physical symptoms are directly and significantly associated with increased opioid requirement. Nonetheless, the DT has been shown in this study, to detect psychological, social and spiritual distress, as well as physical distress. In addition, this study has indicated that physical, psychological, social and spiritual distress levels are all inter-related and impact upon one another. Therefore, the precise underlying cause of the significant global distress associated with increased opioid requirement is not entirely clear. The important implication however, is that distressed patients appear to use increased doses of opioids which may not be the appropriate treatment for the underlying cause of the distress, unless it is pain related. Unfortunately, the extensive, systematic literature search revealed no similar studies available for comparison.

The lack of association between global distress and sedative use may be related to the small amount of data available for analysis, relating to sedated patients. As previously explained, the numbers of sedated patients at the end of life may have been greater, however, as sedation compromises conscious level, completion of assessment amongst this group of patients would have been impossible. Therefore, this finding should be interpreted with caution.

6.6.2 Contacts

Out-of-Hours Contacts
The frequency of out-of-hours home visits was greater amongst those who died during the study than those who survived. This is likely to reflect differing health status of these groups. Healthcare needs change rapidly as death becomes imminent, and the increased requirement for unscheduled visits amongst the patients who died during the study appears to reflect this.
Relationship Between Out-of-Hours Contacts And Distress Levels

Although the frequency of unscheduled visits differed according to survival or death, the numbers in each category were too small to analyse separately. Analysis of the whole study sample however, revealed a significant association between significant global distress and out-of-hours home visits. Increased numbers of out-of-hours home visits were associated with an increased likelihood of significant global distress; for ≥2 out-of-hours home visits during the study (OR 4.52, 95% CI 1.18 to 17.3, p = 0.036).

These findings suggest that terminally ill patients with advanced cancer, who were significantly distressed, were significantly more likely to require out-of-hours home visits. This is consistent with observations of Holland et al. (Holland et al. 2004) who suggest that distressed patients with cancer attend for consultations more frequently and require increased consultation time.

The implication of the finding from the current study is important with respect to healthcare planning and cost, as it implies perhaps that if the underlying cause of distress was identified and treated, the requirement for unscheduled healthcare contact may decrease.

With regard to identification of the underlying cause, Ashbury and colleagues (Ashbury et al. 1998) conducted a review of 913 patients treated for cancer in the previous 2 years. Patients were recruited through local advertisement and comprised mainly females (66%) and in terms of cancer sites, breast and prostate cancers. Seventy eight percent of patients reported fatigue and this was associated with increased healthcare utilisation, particularly visits to the primary care team, pharmacist, hospital accident and emergency departments and out patient clinics. This study was limited by the recruitment bias and the population is not directly comparable to the current study. However, the evidence is included due to the findings regarding the effects of fatigue upon healthcare contacts and hence the importance in considering fatigue as a potential underlying cause of the global distress experienced by the study patients.
With respect to treatment, this should be specific to the underlying cause. The effectiveness of an intervention in reducing healthcare contacts has been demonstrated in a small pilot study (Rosenberg et al. 2002), amongst 30 men with prostate cancer. Patients were randomly assigned to intervention (written expressive emotional disclosure regarding personal cancer experience on 4 occasions) or control (normal treatment). Patients in the intervention group reported less physical symptoms, particularly pain and less healthcare contact, falling from 10 to 4.4 at 6 months. This compares with a stable average of 8 healthcare contacts over the 6 months for patient in the control group.

**Medication Use and Out-Of-Hours Visits**

Analysis revealed a significant, direct association between opioid dose and the number of out-of-hours home visits. An increased requirement for unscheduled home visits was significantly associated with an increased opioid requirement ($\chi^2 = 4.23, 1$ df, $p=0.04$). Similarly, a direct significant association was also found between sedative dose and the number of out-of-hours home visits. Increased sedation was also significantly associated with increased unscheduled visits ($\chi^2 = 10.9, 1$ df, $p<0.001$).

These findings indicate that amongst terminally ill patients with advanced cancer, unscheduled, out-of-hours home visits are significantly associated with the use of higher doses of opioids and sedatives. This may reflect deteriorating physical health status, with those requiring more home visits also requiring increased medication. Additionally, distress may be the mediator in this relationship, with significant association proven between the experience of distress and both increased home visits, as well as increased opioid dose. Although relationships are not defined, Rosenberg’s pilot study (Rosenberg et al. 2002) may be eluding to a similar concept, as those patients who received intervention reported less physical symptoms, particularly pain and less healthcare contact, falling from 10 to 4.4 at 6 months.
Unscheduled Admissions

A greater proportion of survivors did not require any unscheduled admissions over the study duration when compared with those who died. Again, this probably reflects the rapidly changing healthcare needs of patients, as death approaches imminently.

Relationship Between Unscheduled Admissions And Distress Levels

Although the frequency of unscheduled admissions differed according to survival or death, the numbers in each category were too small to analyse separately. Nonetheless, analysis of the whole study sample revealed a significant association between significant global distress and unscheduled admissions. An increased number of unscheduled admissions was significantly associated with an increased likelihood of experiencing significant global distress, for ≥4 admissions over the study duration (OR 6.37, 95% CI 1.65 to 24.6, p = 0.004).

This finding implies that amongst terminally patients with advanced cancer, who were significantly distressed, these were significantly more likely to require unscheduled admissions. Again this is consistent with observations of Holland et al. (Holland et al. 2004) who suggest that distressed patients with cancer attend consultations more frequently and require increased consultation time.

Similarly to home visits, the implication of this finding is important with respect to healthcare planning and cost, as perhaps identification and treatment of the underlying cause of distress may potentially reduce the requirement for unscheduled admissions. The available literature regarding potential underlying cause and treatment has been discussed above.

Medication Use and Unscheduled Admissions

Analysis revealed a significant direct association between opioid dose and the number of unscheduled admissions. An increased requirement for unscheduled admissions was significantly associated with an increased opioid requirement ($\chi^2 = 15.5, 1 \text{ df, } p<0.001$). Similarly, a direct significant association was also found between sedative dose and the number of unscheduled admissions. Increased
sedation was also significantly associated with increased unscheduled admissions ($\chi^2 = 14.5, 1 \text{ df}, p<0.001$).

These findings indicate that amongst terminally ill patients with advanced cancer, increased unscheduled admissions are significantly associated with the use of higher doses of opioids and sedatives. This may reflect deteriorating physical health status, as patients who require more admissions may also require increased medication. Additionally, distress may be the mediator in this relationship with significant association proven between the experience of distress and both increased unscheduled admissions as well as increased opioid dose.

Bruera et al. (Bruera et al. 2000) evaluated the nature of referrals to the centres in the Edmonton Regional Palliative Care programme. These consist of a Tertiary Palliative Care Unit (TPCU), 3 hospices and 2 acute hospital teams. The analysis revealed that when compared with the other settings, patients referred to the TPCU were more likely to be younger, ($p<0.0001$), have alcohol dependence ($p<0.0001$), have a poorer pain prognosis ($p<0.0001$) and have more frequent and severe symptoms, particularly pain, anxiety and depression ($p<0.0001$). This study is highly specific to the Edmonton Regional Palliative Care programme and not directly comparable with the findings of the current study. However, the literature is provided as an illustration of the characteristics predictive of patient admission to their TPCU. These include patients with more frequent and severe symptoms, particularly pain, anxiety and depression, as well as a poorer pain prognosis.

The current study has provided evidence for the significant association between global distress and the physical, psychological, social and spiritual distress domains. Bruera’s findings, although not directly comparable, do confer the findings of the current study that increased distress appears to be associated with increased unscheduled admissions.
6.6.3

Place of Death

Analysis revealed that for those who died during the study, the most frequent place of death was the Hospice. This was followed by similar numbers of deaths in acute hospitals and at home. This may reflect the nature of the study population who had already accepted referral to community palliative care services. Once patients have accepted community palliative care input, they are also more likely to die in a hospice. Many of these patients were not only familiar with the hospice home nursing input, but also with the hospice itself, as some had spent a period as an in-patient in the hospice prior to death and some had also previously attended the hospice day care centre. Therefore, perhaps dying in the hospice was an active choice for many, although potentially, a necessity for others.

Relationship Between Place of Death and Distress

Unfortunately, this could not be ascertained, as the numbers were too small for formal analysis.

Relationship Between Place of Death and Medication Use

Unfortunately, this could not be ascertained, as the numbers were too small for formal analysis.

6.6.4

Summary of Healthcare Service Input and Medication Use

Amongst terminally ill patients with advanced cancer at the end of life, significant global distress was associated with higher doses of opioids, increased out-of-hours home visits, as well as increased unscheduled admissions. The majority of the patients, all of who were receiving community palliative care, died in the hospice.
6.7
Qualitative Data

6.7.1
Study Population
The qualitative study sample of 20 patients was purposively selected from the overall study population of 100 patients. As previously explained, the sample is not required to be representative of the population as a whole, but should represent diversity and depth. This appears to have been achieved successfully: The single Pakistani patient was included, reflecting the ethnic diversity of the whole population. Patients with a range of religious backgrounds were included, although there were no patients without religion. This omission was probably balanced by the slight over-representation of atheists. Patients of varying social status were included from DEPCAT 1-5 and the only categories not represented were DEPCAT 2 and 6. Gender was equally represented with 10 male and 10 female patients. The full age range of the overall study population was represented from under 51 to over 81, as were a diversity of tumour types.

The qualitative sample was recruited from patients who had already agreed to participate in the larger study. All of the patients who were then asked to consider also participating in the qualitative study agreed, effectively a 100% participation rate. In total, 71 interviews were completed (range 1 to 6 per patient). Fifty percent (n = 10) of this population died during the course of the study, 40% (n = 8) survived the study and 10% (n = 2) withdrew.

Summary of Population
The qualitative sub-group was largely representative of the diversity and depth of the overall quantitative study group and hence, the wider Hospice Home Care population. Generalisation of the findings from this sample to this wider community palliative care patient population should be considered appropriate.
6.8 Domain Themes

From the outset of analysis, it was evident that each of the codes naturally fitted into physical, psychological, social and spiritual categories. As analysis progressed, the emergent themes within each of these individual categories were refined to the point of definition. Despite their definition, none of the concepts were mutually exclusive, evidence of inter-relationships between themes emerged both within and between the four categories. Concept mapping together with evaluation of the meaning of the individual themes and their inter-relationships clearly revealed an evident underlying core theme.

Taken at any cross-sectional time point, these domain concepts were evident.

6.8.1 Physical Themes

The key physical themes were debility, dependence and expectations. These were inter-related.

Debility
Debility related to the effects of physical symptoms and progressive physical deterioration. Patients described the impact of physical debility upon daily living not only in terms of practicalities, but also in relation to perceived quality of life. Fatigue was most frequently cited as the underlying cause of debility.

Dependence
Patients expressed determination to maintain physical independence. Patients described, at best reluctance and at worst fear, of becoming reliant upon family or carers for basic needs associated with daily living.

Expectation
Patients’ expectations regarding their physical abilities and daily functioning were often related to age, pre-morbid physical health status and lifestyle. On the whole,
patients with lower expectations regarding their physical ability were in general older, already living with pre-morbid physical limitations or had a sedentary lifestyle.

Inter-Relationships Between Physical Concepts
Debility, dependence and expectations were all inter-related. Dependence was considered the result of progressive debility and these themes were often discussed within the same context. Patient expectation moderated the impact of debility and dependence upon perceived quality of life. Patients with lower expectations regarding their physical abilities, either prior to or as a result of illness, experienced lesser adversity due to progressive debility.

Comparison With The Literature
Throughout the literature, fatigue appears to be consistently the most distressing symptom of cancer and its treatment. The summary of an extensive review article (Barnes and Bruera, 2002) regarding fatigue suggests that patients with cancer have rated fatigue as the longest lasting and most disruptive symptom, resulting in the greatest impact on quality of life. This is certainly in keeping with the patients’ perspectives in the current study, in which fatigue is cited most frequently as the underlying cause of debility.

In another qualitative study, Holley (Holley, 2000) examined fatigue from the patient’s perspective, using content analysis of 23 in-depth interviews with 17 patients. The author found that patients considered “cancer related fatigue” to be unique and different to the typical fatigue, as experienced by healthy individuals. As a result, the fatigue was unfamiliar and regarded as a negative consequence of illness and a sign that health was declining. Despite the ability to perform essential tasks, as indicted by an average Karnofsky Performance Status (KPS) of 75, fatigue impacted on every aspect of life (physical, psychological, social and spiritual) and induced distress. The findings of the current study are entirely consistent with this evidence. Similarly, amongst the current study population, the average KPS was 60-70, and yet fatigue was perceived to impact significantly and adversely on daily life. The unfamiliarity aspect of fatigue will be discussed later.
Psychological Themes
The key themes were uncertainty, understanding and vulnerability. These themes were all inter-related.

Understanding
Irrespective of social status or apparent intellectual ability, all of the patients needed to understand their situation at their own level. Understanding of every aspect of disease, from the process to the prognosis, was essential for psychological well-being. Understanding was also important for establishing realistic expectations.

Uncertainty
Living a life constantly under threat is associated with immeasurable uncertainty. This was strongly expressed through the patients’ perspectives as a fundamental aspect of the experience of terminal illness. The most frequently described coping strategies involved the minimising of uncertainty through very short term planning, information seeking and not dwelling on the uncertainties.

Vulnerability
Patients described feelings of vulnerability. This was exacerbated by the uncertainty of daily life, as well as the timescale for the future. Vulnerability also resulted from physical debility and dependence.

Inter-Relationships Between Psychological Concepts
Understanding, uncertainty and vulnerability were all inter-related. Uncertainty was the fundamental and pivotal theme. Understanding at the patient’s level was essential to reduce uncertainty. Vulnerability was exacerbated by uncertainty and lack of understanding.

Comparison With The Literature
A study (Dukes Holland and Holahan, 2003) of coping strategies amongst 56 patients with Stage I or II breast cancer revealed that approach-coping was significantly
related to improved psychological well-being \( (p<0.001) \), whilst avoidance coping was significantly associated with reduced psychological well-being \( (p<0.05) \). These findings appear to confirm the current qualitative evidence that uncertainty fundamentally contributed to psychological distress and hence limitation of uncertainty appeared to be a preferred, targeted approach to coping.

Furthermore, the hypothesised connections in the current study between the role of understanding in reducing uncertainty, and the development of coping strategies to limit uncertainty, are both substantiated in the literature. Lazarus and Folkman (Lazarus and Folkman, 1984), the major authors regarding coping, consider information seeking as the most frequent method used to cope with a stressful event for which information is limited. Additionally, in a review paper, van der Molen (van der Molen, 1999) suggests that “information is conceptualised as a form of cognitive control”, as it facilitates participation in decision-making.

6.8.3
Social Themes
The two fundamental social themes are broad and all encompassing. They relate to family and communication. Family and Communication are inter-related.

Family
The concept of family is broad and remarkably complex when considered in relation to terminal illness. The main sub-themes in this broad category include the desire to protect the family, together with the associated feelings of guilt and fear of dependence, and the importance of familial communication and support.

Family Protection
Regardless of age, marital or social status, all of patients expressed an inherent desire to protect their family from their disease and its effects. Patients did not want to expose relatives to the realities of their physical deterioration, which encompassed fear of becoming a burden to loved ones, due to disease induced physical and financial dependence. This concept had two aspects, firstly, patients did not want relatives to be burdened by their needs and this was associated with guilt. Secondly,
patients themselves did not want to be reliant upon family members for physical and financial assistance, as this was considered demeaning or undignified.

**Family Communication**
Patients found that open discussion with family members regarding their disease and prognosis was greatly beneficial. Most importantly, effective communication enabled patients to solicit support from relatives, which in turn brought reassurance and comfort. Additionally, effective communication gave patients autonomy and input into decisions, such as funeral planning and ordering affairs, which would otherwise ultimately require to be made by the family on the patient’s behalf. All of the patients’ narratives included passages regarding family communication. Those who managed this successfully generally appeared to benefit significantly.

**Family Support**
Family support was the ultimate source of comfort and reassurance. Familial support was included in the narratives of every patient, regardless of their family situation. Those who lacked family support were clearly adversely affected by the associated isolation through their illness.

**Communication**
Effective communication with healthcare professionals and family members was essential. This was a fundamental theme amongst all of the patients, together with familial communication, as discussed above. Effective communication with healthcare professionals facilitated information seeking and was essential for developing an understanding of the disease, the process, symptoms and prognosis. The importance of understanding has also been discussed above. Patients who communicated effectively with those involved in their health care benefitted immensely in terms of their increased ability to cope with daily living with terminal illness.
Inter-Relationships Between Social Concepts

Certain inter-relationships between family and communication have already been discussed above. Familial protection is also facilitated through effective communication. Patients who understand their illness are better equipped to protect their family who also benefit from understanding and developing realistic expectation and making plans accordingly.

Comparison With The Literature

Family

Spousal interaction in particular, is of proven importance, as adjustment and distress are directly related amongst couples. A longitudinal study (Fang and Manne, 2001) of 197 ambulatory patients with varying stages of cancer, together with their spouses, revealed that patient distress is negatively correlated with marital quality (p<0.05). Confirmatory factor analysis resulted in a model suggesting that increased functional impairment increased patient distress, which in turn reduced marital satisfaction. Patient and spousal distress were significantly associated over time (p<0.001). This evidence indicates that patient distress mediated by functional impairment, impacts negatively upon spousal relationships. The findings of the current study suggest that this distress may reflect patients’ feelings of fear and guilt regarding burdening their relatives with their physical and financial needs and is evidently experienced by both patient and spouse.

Manne and Glassman (Manne and Glassman, 2000) studied 191 married patients enrolled in cancer treatment. They found that negative, unsupportive spousal behaviours were significantly associated with reduced coping efficacy (p<0.01), perceived control (p<0.01) and increased use of avoidance coping (p<0.01). As these factors have been shown to increase psychological distress, further analysis was conducted and revealed that unsupportive, negative spousal behaviour did in fact significantly mediate psychological distress (p<0.01). This evidence substantiates the patients’ perspectives in the current study, that familial support provides the ultimate
reassurance and comfort. It would therefore follow that stability and support would facilitate ability to cope.

Another study (Northouse et al. 1995) of spousal support evaluated 81 ambulatory females with recurrent breast carcinoma and 74 husbands. Analysis found that females who received increased support were less emotionally distressed. Significant correlations were found between patient and spousal emotional distress (p<0.05) and adjustment difficulties (p<0.01). The authors suggest that partners therefore, have a mutual influence on adjustment. Although the population studied was heterogeneous, the findings indicate that increased spousal support reduces emotional distress, and that partners, together with patients determine adjustment to disease. This evidence confers with the patients' perspectives from the current study, that familial support is fundamental in living with terminal illness.

Norton and colleagues (Norton et al. 2005) studied 143 ambulatory females with varying stages of ovarian carcinoma. They used structural equation modelling to determine that higher perceived levels of unsupportive behaviours from family and friends were associated with lower self-esteem (p<0.001), lower self-esteem correlated with increased psychological distress (p<0.001), and that the indirect impact of unsupportive behaviours, as mediated by low self-esteem upon psychological distress was significant (p<0.001). Although this was a heterogeneous population, the study provides further evidence for the importance of social support.

**Communication**

The purpose of communication has been discussed and is considered to relate to understanding. Again, this is best explained by the work of Lazarus and Folkman (Lazarus and Folkman, 1984), who consider information seeking as the most frequent method used to cope with a stressful event for which information is limited.

In a small Swedish study (Berglund and Sjödén, 1987) of 40 patients, analysis revealed that patients who were experiencing communication problems with medical staff were significantly more anxious regarding medical situations (p<0.01). This
relationship was even stronger when examined for those scoring above the median communication problem score (p<0.001). In addition, experience of communication difficulties with healthcare professionals was strongly and significantly associated with anticipatory nausea prior to chemotherapy (p<0.05). This study provides descriptive data evidence of the importance of communication, as described in the narratives of the patients in the current study.

6.8.4
Spiritual Themes
These were reflection, hope and faith. All of these themes were inter-related.

Reflection
Reflection emerged as a major concept within the patients’ narratives. Each of the patients expressed reflective thoughts, which related to their own experiences of life and death. Patients reflected on their past, present and future, both positively and negatively. Living with terminal illness appeared to heighten the sense of life experience and meaning within it.

Hope
Hope was universally described by every patient but often in varying contexts. Hope related to life past, present and future, hopes for the family, hopes for death, and hopes for leaving a legacy. Patients retained hope despite the most adverse circumstances.

Faith
Faith has two distinct components, Meaning and Religion. Meaning was a universal concept adopted by every patient, regardless of background, religion or disease. The concept of meaning was individually determined and developed, according to the patient’s personal theoretical stance and empirical experience. Despite the individuality, the concept was easily identifiable amongst each of the narratives.
Religion however, was not universal. Those who practised religion prior to their diagnosis became dependent upon it as a coping strategy and source of hope and strength during their terminal illness. Patients who had no pre-morbid religion did not seek religion, but relied more upon their own, personal concept of a wider meaning, as well as other resources, such as social support. Most of the patients revealed their views on life after death and these were remarkably similar, regardless of religion.

**Inter-Relationships Between Spiritual Concepts**

Reflection, hope and faith were inter-related. Reflections often related to hope, and narratives expressing hope often began through reflection. Faith was a fundamental source of hope for patients, regardless of whether source was religion or meaning.

**Comparison With The Literature**

Frankl’s (Frankl, 1963) well-known existential theory implies that individuals have the ability to find meaning in life when life is threatened. Terminal illness may be regarded as that threat. The findings of the current study are consistent with Frankl’s theory; as meaning was a universally expressed, albeit individually determined concept, amongst the advanced cancer patients in the final stages of illness.

For the same reason, the current study findings also confer with those of Reed (Reed, 1987) who studied 3 groups of 100 socio-demographically matched patients (terminally ill adults, hospitalised adults and healthy adults). Analysis revealed that a significantly larger number of terminally ill adults indicated a change toward increased spirituality than was found amongst the non-terminally ill and healthy adults.

Spirituality has also been described as a coping strategy. Laubmeier (Laubmeier et al. 2004) suggests that in facilitating acceptance through discovery of meaning and purpose in adverse circumstances, spirituality may be regarded as coping mechanism. Many of the patients in the current study appeared to use either meaning or strong religious beliefs, as another resource for enhancement of understanding and
hope. Understanding in particular, was a major contributor to coping ability, as previously discussed. Hence perhaps spirituality influenced coping mechanism through understanding and hope.

Morita et al. (Morita et al. 2000) in Japan carried out an exploratory factor analysis of existential distress amongst 162 consecutive patients, admitted to a palliative care unit. Physicians noted any spontaneous expressions of existential distress made by patients on a pre-designed checklist. The most common expressions of existential needs related to dependency (39%), meaninglessness (37%), hopelessness (37%) and burden (34%). Further analysis revealed that existential distress appeared to be a multidimensional phenomenon and that meaninglessness was the underlying theme, significantly associated (p<0.01) with each aspect (dependency, loss of social role, burden on others and hopelessness). These findings are considered in relation to the above theory, that meaning fosters hope and understanding and hence ability to cope. Therefore, conversely and consistently with Morita’s findings, meaninglessness would perhaps reduce hope, understanding and overall coping ability.

Hope was studied qualitatively amongst 16 terminally ill patients in a hospice palliative care team (Buckley and Herth, 2004). Four patients completed a second assessment. The mean HHI scores were high at 39 (maximum 48), for the initial assessments. The main themes from the interviews were categorised as “Hope Fostering” (love of family and friends, spirituality, setting goals and maintaining independence, positive relationships with professional carers, humour, personal characteristics and uplifting memories) and “Hope Hindering” (isolation, uncontrolled pain, devaluation of personhood). The second interviews revealed similar findings, indicating maintenance of hope. Of the 4 patients with a second interview, the HHI score fell amongst two patients, improved in one patient (who had since been admitted to hospice) and stayed the same in the other (who died within 8 hours of the interview). All 4 patients died within 23 days of the second interview. This study evidences the resilience of hope. The patients in the current study universally expressed hopeful thoughts, despite the most adverse circumstances. The
domains predicts significant global distress. Psychological distress appears to have the strongest relationship with global distress.

6.14.2

Qualitative

Detailed analysis of the patients’ perspectives indicates that the global experience of distress arises from a loss of control. Control was the core emergent theme, with each of the major study themes relating directly to this concept, as shown in Figure 51.

![Figure 51: Concept Map](image)

Physical control enhances independence and reduces vulnerability. Maintenance of realistic expectations regarding abilities facilitates control through planning and setting achievable goals, which when attained, provide positive reinforcement. Psychological control over daily uncertainty ultimately facilitates the management of life with terminal illness. Using understanding as a coping strategy limits the uncertainties, whilst knowledge informs decision-making, facilitates choice and enhances control. Socially, effective communication is the key to understanding and hence to control. Maintenance of family role and social support network enhance patient control. Spiritually, those with a strong faith are unique in their belief that control is not required, as destiny is determined by a greater power. Reflection is a means of thought processing which develops understanding and hence facilitates control. Hope is a means of control, through mindset and goal setting.
facilitates the development of realistic expectations regarding physical abilities, again mediating improved coping. Vulnerability results not only from uncertainty, but also and more directly from physical debility and limitations.

**Comparison With The Literature**

In Holley’s study (Holley, 2000) of fatigue from the patient’s perspective, the author analysed 23 in-depth interviews with 17 patients for their content. Patients considered “cancer related fatigue” to be unique and different to the typical fatigue, experienced by healthy individuals. As a result, the fatigue was unfamiliar and regarded as a negative consequence of illness and a sign that health was declining. Despite the ability to perform essential tasks, as indicted by an average Karnofsky Performance Status (KPS) of 75, fatigue impacted on every aspect of life (physical, psychological, social and spiritual) and induced distress. This study substantiates the relationship described above between the physical and psychological components of distress, indicating that the unfamiliarity associated with debility, induces uncertainty.

In a study (Ahles et al. 1983) of 40 consecutive patients with cancer-related pain of organic aetiology and 37 matched pain-free cancer patients, patients were evaluated using interviews, pain diaries and pain rating scales. Patients with pain scored significantly more highly for depression and anxiety on various rating scales than those who were pain-free. The interview data were also analysed and showed that an increased number of the patients with pain admitted to depression (p<0.007) and irritability (p<0.001). The 61% of patients who believed their pain was related to disease progression scored significantly more highly for depression and anxiety than those who did not. These findings, that cancer-related pain is associated with anxiety and depression, particularly if the patient believes the pain reflects disease progression, confer with those of the qualitative study. Together, the evidence demonstrates that cancer-related pain induces fear and uncertainty, which diminishes coping and exacerbates vulnerability.
Similarly, in another study (Spiegel and Bloom, 1983) of 86 patients with metastatic breast carcinoma, patients completed self-rated questionnaires relating to psychosocial variables, as well as pain assessment. Multiple regression analysis showed that 50% of the variance in pain experience was accounted for by the level of mood disturbance, including depression, anxiety, fatigue, confusion, patient's belief that pain signified disease progression. Again, this confers the current explanation of the relationship between physical and psychological perspectives.

A Japanese study (Hirai et al. 2002) assessed 85 patients with advanced cancer receiving palliative care. Patients completed the Self-efficacy scale for Advanced Cancer, HADS and Karnofsky Performance Status. Complex structural equation modelling showed that self-efficacy accounted for 71% of the variance in emotional distress and that physical condition accounted for 8% of the variance in self-efficacy, indicating close relationships between physical condition, self-efficacy and emotional distress. Therefore, patients with advanced cancer in good physical condition had a higher self-efficacy, and this was associated with reduced emotional distress. Self-efficacy, which encompasses the perception of control and active coping, may therefore be a mediator within the relationship between physical and psychological components. This finding also confers with the implications of the current study, that control is in fact the ultimate mediator of all complex relationships.

6.9.2
Physical ↔ Social
Physical ability is of major social importance. Firstly, physical deterioration may result in dependence upon others for practical and financial assistance with daily living. This may be depersonalising for patients who may lose their role with their familial and social network. Social isolation is also the result of physical deterioration and loss of function, as patients become physically limited in their ability to participate in many social activities. Communication is an information seeking strategy, in order to facilitate understanding of physical symptoms and
develop realistic expectations. In certain circumstances, physical disease progression may have an adverse impact upon ability to communicate.

**Comparison With The Literature**

In their study of females with metastatic breast carcinoma and their families, Bloom and Spiegel (Bloom and Spiegel, 1984) showed that one aspect of social isolation results from declining physical function. This reduces the number of social activities in which the patient can be involved, resulting in an increasingly restricted social network. This finding is entirely consistent with the implications of the current study, regarding the relationship between physical and social perspectives.

Fallowfield and colleagues (Fallowfield et al. 2002) gathered evidence suggesting that ambiguous information increases fear, anxiety and confusion amongst the palliative care population. The authors thus urge healthcare professionals to provide honest information regarding diagnosis and prognosis, in order to assist patients in appropriate planning and decision-making. This is consistent with the suggestion that effective communication facilitates the development of realistic expectations regarding physical abilities.

**6.9.3**

**Physical ↔ Spiritual**

Physical losses become milestones of deterioration, each of which is often individually mourned. The grief involves a period of reflection regarding the past, taking stock of the present and finally gives way to renewed hope for the future. Expectations regarding disease are deflected onto the religious and spiritual construct of faith, amongst those who have strong belief.

**Comparison With The Literature**

Strang (Strang, 1997) studied 78 patients with cancer-related pain using visual analogue scales for pain intensity, as well as semi-structured interviews. Analysis revealed that patients with greater overall mean pain scores or mean worst pain scores were significantly more fearful regarding the future (p<0.01), had greater
worries about pain progression (p<0.05), and had more fear and general anxiety that resulted in impaired daily living (p<0.05). This implies that physical pain is associated with an adverse impact upon spirituality. This confers with the findings of the current study that a relationship exists between physical and spiritual perspectives.

Morita et al. (Morita et al. 2000) in Japan carried out an exploratory factor analysis of existential distress amongst 162 consecutive patients admitted to a palliative care unit. Physicians noted any spontaneous expressions of existential distress made by patients on a pre-designed checklist. The frequency of expression of each category was documented. The most common expressions of existential needs related to dependency (39%), meaninglessness (37%), hopelessness (37%) and burden (34%). Despite the limitations of this study, which include cultural differences as well as using a pre-designed checklist, dependency was considered the most common existential need. This further substantiates the findings of the current study that physical losses impact adversely upon spirituality.

6.9.4

Psychological <-> Social

Family were considered the most fundamental providers of psychological support. Communication was used as an information seeking strategy, in order to develop an understanding of the disease. Understanding mediated coping through limiting uncertainty and as a result, confidence increased, this lessening vulnerability.

Comparison With The Literature

In a study (Fang and Manne, 2001) of 197 ambulatory patients with varying stages of cancer, together with their spouses, patient distress was negatively correlated with marital quality (p<0.05). These findings confer the importance familial support.

Manne and Glassman (Manne and Glassman, 2000) studied 191 married patients enrolled in cancer treatment. They considered the marital relationship with respect to negative, unsupportive spousal behaviours and found that this was significantly
associated with reduced coping efficacy (p<0.01), perceived control (p<0.01) and increased use of avoidance coping (p<0.01). As these factors had been shown to increase psychological distress, further analysis was conducted and revealed that unsupportive, negative spousal behaviour were significantly associated with psychological distress (p<0.01). These findings suggest the relationship between social support and psychological distress is mediated by reduced coping efficacy and poorer control. This is entirely consistent with the findings of the current study.

In a study (Northouse et al. 1995) of 81 ambulatory females with recurrent breast carcinoma and 74 husbands, females who received increased support were less emotionally distressed. Significant correlations were found between patient and spousal emotional distress (p<0.05) and adjustment difficulties (p<0.01). The authors suggest that partners therefore, have a mutual influence on adjustment. These findings imply that distress is reflected and experienced mutually between partners, again implying the importance of support.

Lazarus and Folkman (Lazarus and Folkman, 1984) consider information seeking as the most frequent method used to cope with a stressful event for which information is limited and van der Molen (van der Molen, 1999) suggests that, “information is conceptualised as a form of cognitive control”, as it facilitates participation in decision-making. The current study patients are entirely consistent with these hypotheses.

Furthermore, following an extensive review, Fallowfield and colleagues (Fallowfield et al. 2002) suggested that ambiguous information increases fear, anxiety and confusion amongst the palliative care population and hence providing honest information regarding diagnosis and prognosis, will assist patients in appropriate planning and decision-making. Thus the relationships between patients' psychological and social perspectives in the current study are consistent with the wider literature.
6.9.5

Psychological ↔ Spiritual

The importance of understanding and certainty diminishes in the context of faith. Patients with faith rely upon certainty in their belief in a greater meaning and purpose, which by definition is unquestionable. Understanding is therefore not required for this effective coping strategy and hope is fostered by belief.

Comparison With The Literature

Spirituality is considered to be a coping mechanism through the discovery of meaning and purpose in adverse circumstances (Laubmeier et al. 2004). An active-coping cognitive style has been defined as an acceptance of illness and an attempt to view its effects in a positive and meaningful way (Fawzy et al. 1990). This may be mediated by spirituality. The Dealing with Illness-Coping Inventory is based on a modification of the Lazarus-Folkman Coping With Illness Scale which includes a subscale relating to existential and religious belief (Lazarus and Folkman, 1984). Hence spirituality may be considered an integral part of the active-coping style. The study findings are consistent with this evidence.

McClain et al. (McClain et al. 2003) in America evaluated 160 terminally ill cancer patients (prognosis <3 months) during the first week of their admission to a palliative care hospital. Patients completed the FACIT-Sp-12, Beck Hopelessness Scale and Schedule of Attitudes Towards Hastened Death. Analysis revealed significant correlations between increased overall spiritual well being (FACIT-Sp-12) and reduced desire for hastened death, reduced hopelessness and reduced suicidal ideation (all p values <0.0001). Multiple regression analysis indicated that spiritual well being (SWB) was the strongest predictor of each of the outcome variables. Increased spirituality is associated with reduced psychological distress. This may be mediated by improved coping efficacy, due to meaning and purpose in adverse circumstances.

In another study (Nelson et al. 2002), 84 terminally ill cancer patients completed the FACIT-Sp-12 and the Hamilton Depression Rating Scale (HDRS). The HDRS
correlated moderately with the total FACIT-Sp-12 score (-0.40, p<0.01) and more strongly with the meaning and peace subscale of the FACIT-Sp-12 (-0.51, p<0.01). These findings further confer the relationships derived from the patients’ perspectives in the current study.

6.9.6
Social ↔ Spiritual
The importance of communication for information seeking is diminished amongst patients with faith, who have developed their own understanding of the meaning and purpose of their illness. The concept of family featured centrally in the patients’ reflections and hopes. Every one of the patients reflected, generally negatively, on the communication associated with receiving the diagnosis.

Comparison With The Literature
The literature regarding social and spiritual relationships is minimal, with no helpful evidence to allow comparison with the study findings.

6.9.7
Core Theme: Control
Each one of these multidimensional concepts relates directly to the construct of “control”. These conceptual constructs were developed from the theoretical and empirical evidence.

Physical
Control over the physical aspects of functionality is fundamental. Physical control mediates maintenance of independence and reduces vulnerability. Maintaining realistic expectations facilitates control through planning and setting achievable goals which when attained, provide positive reinforcement.

Psychological
Control over thought process is the ultimate goal in the achievement of managing life with terminal illness. Coping is an aspect of control and the preferred strategy was to
limit the daily uncertainties in life with terminal illness. Fundamentally, knowledge informs decision-making, thus facilitating choice and hence control.

**Social**

Control is gained through knowledge, which is derived from information obtained through effective communication. Patients’ desire to protect the family from the realities of illness reflects their determination to maintain control of their role within the family. Social support empowers patients, thus enhancing control.

**Spiritual**

The fundamental concept of control is not an issue for individual with a strong faith. Those with faith believe that their destiny is not self-determined, as it is under the control of greater power in which they have complete trust, or “faith”. Reflections are a means of processing thoughts and experiences, facilitating clarity of thought and therefore enhanced control. Hope is a means of control through mindset and goal setting.

6.9.8

**Summary of Emergent Themes**

Amongst this population of terminally ill cancer patients receiving community palliative care input, patients’ perspectives were easily categorised into physical, psychological, social and spiritual contexts. The fundamental, underlying concept for these patients was control. The key themes were all inter-related, and all directly related to the concept of control.

6.10

**Longitudinal Themes**

The emergent longitudinal themes were similar for patients who died and those who survived. The physical, psychological, social and spiritual categories remained central over the end stages of advanced cancer and control persisted as the core
theme. However, the perspectives within each of these categories evolved, as patients progressed through the final phase of the cancer disease trajectory.

6.10.1
Physical Distress
The issues of debility, dependence and expectation remained fundamental during the final months of life. However, a significant change occurred within the context of expectation. Expectations were initially related to pre-morbid physical condition and age. As disease progressed, patients appeared gradually able to modify their expectations in accordance with their disease imposed limitations. The readjustment of expectations subsequently facilitated acceptance of physical deterioration and to a degree, of dependence. Hence, patients appeared to adapt to their progressive physical deterioration over the end stages of disease. However, unexpected change that was disproportionate to the established rate of decline caused an exacerbation of distress.

Comparison With The Literature
A study (Coyle et al. 1990) of 90 cancer patients found that 100% of the patients surveyed reported pain at some point, although at 4 weeks prior to death, the pain was described as mild to moderate by 80% and as moderate to severe by only 20%. In addition, the prevalence of pain reported fell from 54% at 4 weeks prior to death, to 34% one week before death. This confers with the current findings that patients adapt to physical symptoms as death approaches.

Another study (McKegney et al. 1981) of 199 patients with terminal cancer and prognosis of more than 3 months but less than one year compared an “intensive group” (n=98), receiving regular specialist palliative home nursing care, with a “non-intensive group” (n=101) who did not receive home care. Patients completed self-rated questionnaires on entry into the study and regularly thereafter. Pain increased in frequency and severity as death approached. Initially, both groups had the same mean pain scores but at 90 days prior to death, pain continued to increase amongst the non-intensive group, whilst reaching a plateau amongst the intensive group. This
difference reached near significance (p=0.06) in the last 30 days of life. These findings reflect those of the current study conducted amongst patients receiving home nursing care input.

6.10.2
Psychological Distress
Understanding, uncertainty, vulnerability and their inter-relationships remained the fundamental psychological issues throughout the end of life. Terminal illness was the cause of great uncertainty, which subsequently induced feelings of vulnerability, although this effect was moderated by understanding of the disease. Over time, patients appeared develop a greater understanding of their situation through experience, thus minimising the impact of the daily uncertainty and reducing vulnerability. On the whole, therefore, the patients appeared to develop psychological stability over the end stages of the cancer disease trajectory. However, transient, unpredictable exacerbations of psychological distress did occur, as the result of any acute rise in uncertainty, associated with an unexpected change in circumstances that was different to the experiences for which patients had developed an understanding.

Comparison With The Literature
In a longitudinal study (Akechi et al. 2006) of psychological distress amongst 85 newly diagnosed patients with advanced non-small cell lung carcinoma in Japan, patients were assessed after diagnosis and prior to treatment, again at 2 months and finally at 6 months from diagnosis. Tension-anxiety fell significantly and consistently over time, from diagnosis to 6 months (p<0.001). Depression-Dejection fell significantly from diagnosis to 2 months (p<0.001), although there was no significant difference from diagnosis to 6 months. Multiple regression analysis revealed that mood disturbance at diagnosis significantly predicted psychological distress at 6 months. However, there was no significant change in total mood over time. The authors suggest that these findings indicate that overall psychological distress does not reduce naturally over time. The current study population of terminally ill cancer patients is not directly comparable with the population of newly
diagnosed lung cancer patients in Akechi’s study. The findings from the current study indicate that psychological distress appears to naturally decline, with occasional transient exacerbations. The different trends in psychological distress found in these studies may reflect the different points in the disease trajectory.

6.10.3 Social Distress

The two social aspects of communication and family remained the fundamental issues during the final months of life. The purpose of communication with healthcare professionals and family evolved over time, becoming less intensely focussed on information and support seeking. The family focus also evolved from the urge to protect family members from the realities of their disease, towards acceptance of the family’s support and ability to continue beyond their death. Therefore, the patients on the whole appeared to adapt to the social aspects of their disease over the end stages of disease. However, transient exacerbations of distress were related to unexpected change in circumstances that either required more information, in order to be understood, or resulted in a negative impact on the family situation.

Comparison With The Literature

In a large, multi-national study (Higginson and Costantini, 2002) involving approximately equal numbers of patients across England, Ireland and Italy, 1326 patients receiving community or hospital palliative care were recruited. Within 1-5 days of the patients’ death, the multidisciplinary palliative care team met and completed the Support Team Assessment Schedule (STAS) for the last week of the patient’s life. In all 3 countries, most of the communication difficulties existed between the patient and family at the end of life (<30-40%) with least problems in communication between professionals and the patient and family (10-20%).

Both univariate and multivariate analysis revealed (consistently in all 3 countries), significantly less communication difficulties amongst participants who had received palliative care for longer and those who died at home. When the relationship between communication problems and other quality of life domains was analysed, greater
communication problems were significantly associated with reduced patient and family insight.

Caution must be exercised when considering these findings, in which patient-related issues were derived from the retrospective scoring of healthcare professionals. The findings imply that familial communication becomes more difficult at the end of life and that such difficulties were associated with reduced patient and family insight and were less problematic amongst patients who had been receiving palliative care for longer.

The findings of the current study relate to a population who had all been receiving palliative care for similar time periods, in that all of the patients were recruited at the time of referral to palliative care and were studied for a maximum of only six months, or until they died. The emergent concept of communication was evaluated in the current study, although no formal assessment of specific elements relating to communication with individuals over time was made. Therefore, although we can conclude from the current study that distress surrounding the concept of communication appeared to generally decline over the end stages of cancer with occasional exacerbations, comment cannot be made on the specific aspects of communication between individuals over this time. In the current study, physical communication may have become impaired at the very end of life, particularly amongst sedated patients and therefore this aspect may compare with the findings of Higginson & Costantini.

The only relevant longitudinal study found, regarding familial issues, was a study (Fang and Manne, 2001) in America, which evaluated a heterogeneous population of 197 ambulatory patients with varying stages of cancer, together with their spouses. Patients and their spouses were evaluated at 3 time points (0, 3 and 6 months) and analysis revealed that patient distress correlated negatively with marital quality (p<0.05). Confirmatory factor analysis resulted in a model suggesting that increased functional impairment increased patient distress, which in turn reduced marital satisfaction. Patient and spousal distress were significantly associated over time.
As functional impairment tends to increase with time, the findings of this study imply that spousal distress increase with time. This does not confer the findings of the current study, which imply that spousal, or familial distress levels generally improve with time, even though occasional exacerbations of distress occur. The differences may reflect the methods by which the data were assessed and findings were deduced. Fang and Manne used confirmatory factor analysis, whilst the current study evaluated emergent themes in monthly serial interviews.

6.10.4

Spiritual Distress
The emergent spiritual themes of faith, reflection and hope remained persistent throughout the end stages of cancer. As disease progressed and experiences evolved, patients became more hopeful in their reflections. All of the patients demonstrated their capacity for hope, which was essential to coping with the daily challenges of living with terminal illness. For those with a faith, this became greater with time, providing greater reassurance. Non-religious patients did not develop a faith over time. The narrative of only one patient described loss of faith at the time of diagnosis, which was regained through the progression of disease, resulting in reconciliation with God, prior to death. Spirituality therefore increased as death approached, although transient exacerbations of spiritual distress occurred in relation to acute and unpredictable change in circumstances.

Comparison With The Literature
A study (Reed, 1987) of 3 groups of 100 socio-demographically matched patients (terminally ill adults, hospitalised adults and healthy adults) found that a significantly larger number of terminally ill adults indicated a change toward increased spirituality than was found amongst the non-terminally ill and healthy adults. These findings are consistent with the findings of the current study, which provide further extrapolation indicating that spirituality increased as death approached.

In a qualitative study (Thomas and Retsas, 1999) of 19 patients with terminal cancer, patients participated in semi-structured, in-depth interviews regarding aspects of
spirituality and meaning. Constant comparative technique and grounded theory analysis established a core theme of “transacting self-preservation” which has 3 components, “taking it in, getting on with things and putting it all together”. Development of these spiritual perspectives strengthened the patients’ approach to life and death through reaching a deeper understanding of self. Although these concepts are not identical to the emergent themes of the current study, the fundamental issue is similar; spirituality develops through increased self-understanding and patients adapt to dying.

A qualitative study (Buckley and Herth, 2004) of hope analysed 16 terminally ill hospice patients with a prognosis of months using the Herth Hope Index (HHI) and a semi-structured interview. Four patients completed a second assessment. The interviews were analysed using a data reduction technique and content analysis. The mean HHI scores were high at 39 (maximum 48) for the initial assessments. The main themes from the interviews were categorised as “Hope Fostering” (love of family and friends, spirituality, setting goals and maintaining independence, positive relationships with professional carers, humour, personal characteristics and uplifting memories) and “Hope Hindering” (isolation, uncontrolled pain, devaluation of personhood). The second interviews revealed similar findings, indicating maintenance of hope. Of the 4 patients with a second interview, the HHI score fell amongst two patients, improved in one patient (who had since been admitted to hospice) and stayed the same in the other (who died within 8 hours of the interview). All 4 patients died within 23 days of the second interview. This study provides a more detailed analysis of the concept of hope than the current study does, although the findings of both studies confer that hope appears to remain persistent amongst terminally ill patients as death approaches.

6.10.5

Control

The core theme of control remained the central concept throughout the end stages of the cancer disease trajectory. The transient exacerbations of distress that occurred in
each of the physical, psychological, social and spiritual domains unpredictably over the final months of life related directly to control.

In any one of the four domains, exacerbations of distress were induced by a sudden, unexpected change that was disproportionate to the established trend. Having not previously experienced such a change, patients had not developed an understanding and acceptance of its consequences. Therefore, patients transiently lost their fragile control over their situation and became distressed. Once patients had absorbed, processed or at best resolved this situation, control resumed and the general process of adaptation continued.

6.10.6
Anomalous Cases
The emergent evolution of perspectives was demonstrable in the majority of patients, however, as expected, anomalous cases did exist. These substantiated the findings with validity, as anomalous cases indicate that an appropriately varied sample was selected and that analysis was rigorous, when compared with the emergent themes.

The narratives of two patients were obviously anomalous for different reasons, which were entirely consistent with their personal circumstances. One patient demonstrated persistent anger, which did not resolve as his death approached. In the context of his life situation, this was understandable. He was living alone, following an acrimonious divorce and felt very isolated from his family. He was struggling to develop new relationships, due to his negative body image associated with his urostomy bag. In addition, he had worked very hard his entire life, in order to provide for his wife and family and blamed this for the divorce. Having finally reached retirement age, his health failed him and he felt cheated out of all that he had worked for and resented the sacrifice he had made.

The other patient was a Born Again Christian and demonstrated the epitomy of faith. She had developed her faith over several years and fully engaged with the concept. From the time of referral to palliative care services until the time of her death, she
showed no evidence of distress at all. She was completely unburdened by giving total control of her situation to God and she made no attempt to influence it. Throughout the final months of her life she maintained a palpable serenity, calmness and peace.

Anomalous cases within a small sample population reflect the diversity of human life experiences.

6.10.7
Summary
Patients receiving community palliative care nurse input appeared to adapt physically, psychologically, socially and spiritually to their situation of terminal illness and approaching death. The process of adaptation was facilitated through the development of a fragile control, which was derived from the understanding gained through experience.

Despite this general trend towards acceptance and adaptation, patients experienced episodic exacerbations of distress in any one of the physical, psychological, social or spiritual domains, due to transient loss of control. An unexpected change in circumstances, having never been previously experienced, and therefore inconsistent with the established pattern, caused a sudden loss of control. However, once the alteration in circumstances had been absorbed, processed or even resolved, control was regained and the adaptation process continued.
6.11 Qualitative and Quantitative Data

The findings of the quantitative and qualitative aspects of the study have been reported separately so far, for the purpose of clarity. However, the mixed methodology design was chosen in order to ensure depth and diversity, in answering the overall research question:

*How do global distress and its components evolve over the final phase of the cancer disease trajectory, from the time patients are referred to palliative home care services to time of death?*

The findings from both, the quantitative and qualitative studies are compared and contrasted, in order to provide a multidimensional perspective regarding each of the research questions.

The study aims were to:

- Define the risk factors for distress in the terminal phase of advanced cancer
- To examine the relationship between distress and time
- To evaluate the contribution of each domain of distress to global distress over this time

6.12 Aim 1: Risk Factors for Distress

6.12.1 Risk Factors for Global Distress

*Quantitative*

Multivariate logistic regression revealed inadequate information (from oncologist, oncology nurse or GP) and social dysfunction to be independent predictors of significant distress. In addition, univariate logistic regression indicated that a history
of previous depression showed a trend towards an association with significant distress.

Those who died and those who survived were also analysed separately. Amongst those who died, a trend was evident towards an association between significant global distress and both, perception of receiving inadequate information and significant social dysfunction. Amongst those who survived, associations were revealed between perception of receiving inadequate information and significant global distress. A statistically significant association was apparent between significant global distress and history of significant mental or physical illness in the family.

Qualitative
Qualitative analysis revealed that the experience of distress was related to loss of control. Control was the central concept, fundamental to living with terminal illness. Control was achieved through the development of a personal understanding of the disease process and hence, appropriate and realistic expectations regarding disease progression and the future. Control maintenance required stability of disease progression consistent with the individual's understanding and expectations, together with stability within the context of other aspects of daily life, such as the family situation. Due to the inherent inconsistency in these factors, control maintenance was derived from a fragile balance of variables, with an unexpected or disproportionate change in circumstances disturbing the balance and resulting in loss of control and hence the associated experience of distress.

Quantitative and Qualitative
The quantitative and qualitative analyses provide fundamentally dichotomous perspectives on the same issue. The quantitative data analysis derives socio-demographic predictors of distress, whilst the qualitative analysis provides a perspective-derived concept for underlying cause of the lived experience of distress. Together, the analyses provide a multi dimensional, in-depth insight into the risk factors relating to the experience of distress.
Perception of receiving inadequate information was an independent predictor of distress. As previously discussed, information seeking is essential to understanding disease. Control is achieved through the development of understanding and therefore compromised by a deficiency in information received. This appears to be consistent with qualitative theory that loss of control induces distress. Furthermore, the combined findings confer with the theory of van der Molen (van der Molen, 1999) who suggests that “information is conceptualised as a form of cognitive control”, as it facilitates participation in decision-making.

Significant social dysfunction was found to be an independent predictor of distress. A dysfunctional social situation infers lack of conformity, lack of predictability and stability. Again, in the wider context of living with disease, patients require stability for control maintenance. As a result, patients experiencing significant social dysfunction are more likely to struggle to maintain control of their situation and hence are more likely to become distressed.

Quantitatively, a trend was seen towards an association between a previous history of depression and distress. Depression directly compromises the ability to maintain psychological control over the personal situation, hence increasing the risk of experiencing distress.

Amongst patients who survived the study, quantitative analysis revealed an association between distress and a family history of physical or mental illness. Familial illness impacts adversely upon social roles and functioning, resulting in a similar effect described for social dysfunction.

6.12.2 Risk Factors for Physical Distress

Quantitative

Univariate logistic regression analysis revealed that factors significantly associated with significant physical distress, were previous physical illness and perception of
receiving inadequate information from the GP. A trend was apparent towards an association between significant social dysfunction and significant physical distress.

**Qualitative**

The fundamental physical issues for patients were debility, dependence and expectations. Debility and dependence induced distress, although this effect was moderated by expectation. Patients gained an understanding of an established trend of deterioration and demonstrated an ability to develop realistic expectations accordingly, in order to maintain control. Therefore qualitatively, physical distress related to the loss of control directly associated with debility and dependence and indirectly associated with compromise to the ability to develop realistic expectations.

**Quantitative and Qualitative**

Previous physical illness was associated with physical distress. This is consistent with qualitative concept of debility and dependence inducing distress through loss of control. Amongst patients with a previous physical illness, the debility and dependence may occur more rapidly, magnified by the symptom burden associated with co-morbidity. In addition, such patients may have developed preconceived expectations regarding the debility associated with significant disease, having had previous experience of significant physical illness. Therefore, patients who have previously suffered significant physical illness are exposed to both, the direct risk of control loss, secondary to the more rapid impact of deterioration upon physical abilities and dependence, as well as the indirect risk, secondary to the compromise in ability to develop realistic expectations regarding the effects of deterioration with disease progression.

Perception of receiving inadequate information from the GP was also associated with physical distress. Qualitatively, this again relates to the loss of control associated with the compromised ability to develop realistic expectations, due to an understanding limited by lack of information. The reasons for information from only the General Practitioner being implicated have been discussed previously.
A quantitative trend was evident towards an association between significant social dysfunction and physical distress. Once again, the qualitative concept of control illustrates this association. Patients who are living in a dysfunctional situation are more likely to have difficulties in gaining and maintaining control of their overall situation. This may impact adversely upon distress in any domain. In addition, patients within a dysfunctional familial situation are likely to have a greater requirement for independence, in order to maintain their options for managing it and hence retaining their control.

6.12.3
Risk Factors for Psychological Distress

Quantitative
Univariate logistic regression analysis revealed that the factors associated with significant psychological distress were previous depression and perception of receiving inadequate information. Trends were apparent towards an association between significant social dysfunction and significant psychological distress, as well as marital status and significant psychological distress.

Qualitative
The key psychological issues related to understanding, uncertainty and vulnerability. Understanding at the patient’s level was essential to reducing the uncertainty of living with terminal illness and hence vulnerability, and to facilitate control through the development of realistic expectations regarding the progression of disease. Knowledge informs decision-making, facilitates choice and therefore control. Control over thought process is the ultimate goal, in achieving living comfortably with terminal illness.

Quantitative and Qualitative
Previous depression was associated with psychological distress. This is consistent with the qualitatively derived theory that control over thought process is fundamental
to living with terminal illness; by definition, depression would compromise this ability.

The perception of receiving inadequate information was also associated with psychological distress. The qualitative findings illustrate this evidence through the perspective-based theory that understanding gained from information reduces uncertainty and maximises control. Hence control maintenance is compromised by inadequate information.

Quantitative analysis revealed a trend towards an association between social dysfunction and psychological distress. Patients living within a dysfunctional family situation may be more vulnerable, as a result of the lack of stability in their situation. Qualitatively, vulnerability was a direct cause of psychological distress, by definition, feelings of vulnerability to do not co-exist with feeling in control.

A trend was apparent towards an association between marital status and psychological distress, with single patients more likely to experience distress. Lack of close social support may exacerbate feelings of isolation relating to the experience of terminal illness. Processing and understanding of experience is facilitated thorough discussion and communication, which is limited amongst patients who are single. This indirectly impacts upon control maintenance, whilst the vulnerability associated with a degree of social isolation impacts directly upon control.

6.12.4
Risk Factors for Spiritual Distress

Quantitative
Quantitatively, univariate logistic regression analysis revealed that a previous history of depression predicts significant spiritual distress. Unlike global distress and its other components, there does not appear to be any association between significant spiritual distress and significant social dysfunction or perception of receiving inadequate information.
Qualitative
The spiritual themes were reflection, hope and faith. Those with faith believe that their destiny is under the control of greater power and hence they do not require personal control. Reflections are a means of processing thoughts and experiences, facilitating clarity of thought and therefore enhanced control. Hope is a means of control, through mindset and goal setting.

Quantitative and Qualitative
A previous history of depression was associated with spiritual distress. This may relate to the qualitatively derived spiritual concept of reflection as a means of processing thought in order to provide clarity and enhance control. Depression impacts adversely upon the thought process, perhaps tarnishing reflections with a negative perspective. As a result, the processing of thought and experience would be less direct and clear, resulting in a hindrance to the attainment of control.

The perception of receiving inadequate information did not appear to affect spiritual distress. The concept of spirituality relates to discovery of a greater meaning. Therefore, the conventional understanding of disease and situation may not exert an influence within this existential context. Similarly, social dysfunction was not related to spiritual distress. This may relate to the autonomy associated with the personal discovery of an existential meaning, in the context of which the influence of others is irrelevant.

6.12.5
Summary
With regard to the risk factors for distress, the quantitative and qualitative findings are complementary. The quantitatively derived socio-demographic predictors of distress are illustrated and illuminated through the qualitatively derived perspective-based concepts of the distress experience. Ultimately, socio-demographic factors which relate to a compromise in control, result in an increased risk to patients experiencing distress.
6.13
Aim 2: The Relationship Between Distress and Time

6.13.1 Physical Distress

*Quantitative*
According to the profile plots and box plots of the MSAS scores over time, physical distress levels were highest at the time of referral to palliative care services. Levels of distress were then variable for the initial period, prior to falling to a chronic level, this being lower than the initial distress but variable, specific to each individual. Patients all reached a stable level of physical “distress”, whereas for some this was negligible, for others it was more significant. Despite the chronic level, patients appeared to experience unpredictable exacerbations of physical distress levels throughout the end stages of advanced cancer. The findings were similar for those who died and those who survived.

*Qualitative*
The issues of debility, dependence and expectation remained fundamental during the final months of life. However, a significant change occurred within the context of expectation. Expectations were initially related to pre-morbid physical condition and age. As disease progressed, patients appeared gradually able to modify their expectations in accordance with their disease imposed limitations. Patients appeared able to adapt to their progressive physical deterioration over the end stages of disease. However, unexpected change that was disproportionate to the established rate of decline caused an exacerbation of distress. There was no difference in qualitative findings amongst those who died or those who survived.

*Quantitative and Qualitative*
The quantitative findings suggest the physical distress levels are initially at their highest at the time of referral to palliative care services and fluctuate prior to settling to lower, chronic level with occasional exacerbations. The qualitative findings are entirely consistent, providing a perception-based explanation for the patient
experience of these trends in physical distress over time. Through the development of understanding through experience, with time patients modified their physical expectations, thus regaining control and adapting to their situation. Despite this chronic stability, any unexpected change that was inconsistent with the established trend of decline and was therefore not accounted for, resulting in a transient loss of control, which related directly to an exacerbation in distress. These exacerbations were quantitatively recorded as rises in MSAS scores. The effect was transient, as patients demonstrated the ability to absorb, process or resolve the acute situation and continue at similar stable state.

6.13.2
Psychological Distress

Quantitative

Box plots and profile plots of the EDS over time revealed that levels of psychological distress were highest at the time of referral to palliative care services. Levels of psychological distress then either fluctuated over time for some patients or stabilised, with occasional exacerbations, for others. From 3 months onwards, average psychological distress levels remained consistently at their lowest.

Qualitative

Understanding, uncertainty and vulnerability remained the fundamental psychological issues throughout the end of life. Terminal illness was the cause of great uncertainty, which subsequently induced feelings of vulnerability although this effect was moderated by understanding of the disease. Over time, patients appeared to develop a greater understanding of their situation through experience, thus minimising the impact of the daily uncertainty and reducing vulnerability. On the whole, the patients therefore appeared to develop psychological stability over the end stages of the cancer disease trajectory. However, transient, unpredictable exacerbations of psychological distress did occur. These episodes resulted from any acute rise in uncertainty associated with an unexpected change in circumstances that was distinct from the experiences for which patients had developed an understanding. The unexpected change was associated with transient loss of control,
which subsequently exacerbated the levels of psychological distress. Once the new situation had been understood and therefore processed and resolved, control was regained and the distress levels normalised.

**Quantitative and Qualitative**
The quantitative analysis revealed that psychological distress levels were highest at the time of referral to palliative care services. Levels then either fluctuated over time, or stabilised with time at a lower level, with intermittent, unpredictable exacerbations of distress. This evidence is essentially mirrored by the patients’ perspectives which illustrate and verify the quantitative findings. Patients, with time and experience, appeared to develop an understanding of their situation and subsequently uncertainty was minimised to manageable level and patients regained control. The unpredictable exacerbations of distress, quantitatively evidenced by spikes in the EDS scores, were qualitatively related to the transient loss of control, experienced due to the acute uncertainty associated with an unexpected, disproportionate change in circumstances. The episode of distress resolved once the change had been absorbed and processed and control regained.

Psychological distress fluctuated constantly amongst some patients. These patients were perhaps struggling to gain and maintain control of their situation. Many reasons may have existed for this, but very rapidly progressive disease may have been a contributory factor, amongst patients who did not reach a period of stability of disease and hence understanding.

**6.13.3 Spiritual Distress**

**Quantitative**
Profile and box plots of the FACIT revealed that average scores varied only slightly over time. Spiritual distress was lowest at the time of referral and levels appeared to increase slightly initially, prior to consistently decreasing slightly from 3 months onwards. This detail must be considered with caution, in view of the very small incremental score changes over time.
Qualitative

The key spiritual themes of faith, reflection and hope persisted over time. With time, experiences evolved and patients became more hopeful in their reflections. Hope was universally described and persistent, perhaps increasing with time. Faith became greater amongst the faithful, whilst faith did not develop amongst the non-religious. Spirituality therefore increased as death approached. However, transient exacerbations of spiritual distress did occur, secondary to the loss of control associated with acute and unpredictable change in circumstances.

Quantitative and Qualitative

The FACIT scores over time indicate that spiritual distress is essentially stable over time with small incremental changes. The levels initially increase prior to falling again from 3 months onwards. Spiritual distress is lowest at the time of referral. The qualitative findings provide some insight into the stability of the spiritual distress levels: Two of the three major themes, hope and faith, are in fact consistent over time, perhaps increasing only slightly. However, there is some diversity in the quantitative and qualitative findings regarding the small incremental changes over time. The FACIT scores indicate a rise with subsequent fall in spiritual distress levels over time, whilst the qualitative analysis indicates that patients' spirituality became heightened over time, with occasional exacerbations of distress. The enhanced spirituality may have developed insidiously over time, becoming evident from 3 months onwards. The qualitative analysis provides a general trend over time, as opposed to the accurate monthly average of the quantitative data. The initial rise in spiritual distress is not well illustrated by the qualitative findings. The patients' perceptions demonstrate that spirituality increases with time, despite transient exacerbations of spiritual distress, due to the loss of control associated with acute change in circumstances. Fundamentally, these observed diverse quantitative and qualitative trends must be treated speculatively, due to the apparent overall stability of spiritual distress.
6.13.4

Global Distress

Quantitative
Profile plots and box plots revealed a constant variation in DT scores over time. The only apparent trend was that of inconsistency. These findings imply that global distress levels were constantly variable and unpredictable during the end stages of advanced cancer.

Qualitative
The overall experience of distress was considered to comprise the physical, psychological, social and spiritual themes. A consistent pattern emerged in each of these domains towards a reconciliation with, and acceptance of the inevitable progress of terminal illness. Despite this process, unpredictable exacerbations of distress occurred in any one of the domains as a result of the transient loss of control associated with an unexpected change, disproportionate to the established trend. Patients had the capacity to absorb and resolve the unexpected change, regain control and resume the process of adaptation. This is illustrated in Figure 50 below:

Figure 50: Graph Superimposing Each of the Qualitatively Observed Physical, Psychological, Social and Spiritual Trajectories

Quantitative and Qualitative
The quantitative and qualitative data analyses of global distress complement one another, the patients’ perceptions providing insight into the quantitative data. The
findings together imply that the experience of distress is unpredictable and results from an exacerbation in any one of the physical, psychological, social or spiritual domains. Loss of control is the key stimulus for distress and this relates to an unexpected, unexplained, and hence poorly understood change in circumstances which is disproportionate to the established and accepted trend. The exacerbations of distress are transient due to the patients’ ability to absorb and resolve changes and hence regain control.

6.14
Aim 3: The Contribution of Each Distress Domain to Global Distress over Time

6.14.1
Quantitative
The DT correlated strongly and significantly with each of the EDS, MSAS and FACIT, both at baseline and for the change from baseline to the three-month assessment. The FACIT negatively correlated with the DT. The highest Spearman rank correlations were between DT and EDS at both baseline \( r = 0.682 \) and for the change from baseline to 3 months \( r = 0.710 \). In addition, for each of these measures, the worst scores (highest distress) over the entire study, were compared with the worst DT scores. Again, strong, significant associations were found. The likelihood of experiencing significant global distress was significantly higher, if psychological distress (EDS above cut off) occurred at anytime during the study (OR 12.2, 95% CI 3.40 to 44.1, \( p < 0.001 \)), similarly, the risk of experiencing significant global distress was significantly greater if physical distress (MSAS above cut off) was present at any stage (OR 9.79, 95% CI 3.36 to 28.5, \( p < 0.001 \)), and the same relationship was found with spiritual distress (FACIT below cut off) and global distress (OR 2.80, 95% CI 1.14 to 6.89, \( p < 0.025 \)).

Global distress appears to be directly and significantly associated with physical, psychological and spiritual distress and significant distress in any one of these
domains predicts significant global distress. Psychological distress appears to have the strongest relationship with global distress.

6.14.2 Qualitative

Detailed analysis of the patients’ perspectives indicates that the global experience of distress arises from a loss of control. Control was the core emergent theme, with each of the major study themes relating directly to this concept, as shown in Figure 51.

![Concept Map](image)

**Figure 51: Concept Map**

Physical control enhances independence and reduces vulnerability. Maintenance of realistic expectations regarding abilities facilitates control through planning and setting achievable goals, which when attained, provide positive reinforcement. Psychological control over daily uncertainty ultimately facilitates the management of life with terminal illness. Using understanding as a coping strategy limits the uncertainties, whilst knowledge informs decision-making, facilitates choice and enhances control. Socially, effective communication is the key to understanding and hence to control. Maintenance of family role and social support network enhance patient control. Spiritually, those with a strong faith are unique in their belief that control is not required, as destiny is determined by a greater power. Reflection is a means of thought processing which develops understanding and hence facilitates control. Hope is a means of control, through mindset and goal setting.
6.14.3

Qualitative and Quantitative

The qualitative and quantitative findings fully complement one another. The descriptive data is enriched by the insight provided by the patients’ perspectives. Quantitatively, each one of the physical, psychological and spiritual domains correlates strongly and significantly with global distress. This is qualified through the analysis of the patients’ narratives, which indicate that distress relates directly to loss of control. Each one of the key physical, psychological, social and spiritual themes is a component of the underlying concept of control. The strongest correlation existed between psychological distress and the global experience of distress. This is substantiated by the qualitative implication that manipulation of thought, in order to manage uncertainty through coping strategy, is the ultimate objective in control maintenance. The psychological impact upon control is therefore potentially the greatest of all the domains.

6.14.4

Summary

The combination of quantitative and qualitative findings do indeed provide an in-depth, insightful answer to the question:

_How do global distress and its components evolve over the final phase of the cancer disease trajectory, from the time patients are referred to palliative home care services to time of death?_
6.15
Ethical Implications of the Study

Perceptions of Research Participation
The commitment to participation in this study was evidently acceptable to the majority of the patients involved.

In order to accurately reproduce patients’ sentiments, the following section is illustrated with examples taken from the patients included in the qualitative study. These examples may be considered as a representative reflection of the total study sample.

6.15.1 Completion Rate
The completion rate alone provides a good indication of the level of the acceptability to participants. Only 2 patients withdrew, both at an early stage of the study.

Withdrawn: Patient #9
This was a female patient of 65 years with a diagnosis of lung cancer. She was widowed and was living with her daughter and son-in-law. She was referred to palliative care services following a prolonged hospital admission, due to severe neutropenic sepsis as a result of palliative chemotherapy. She had only recently returned home and remained physically very frail. In addition, she was struggling to come to terms with her diagnosis and in fact, appeared to be in denial:

KT: And just to kind of finish off because you’ve been very kind in talking through all of this difficult stuff, in all this what has been the kind of most positive thing for you, like the thing that you couldn’t have done without or the best thing or the thing that’s come out of it for you?

"Being told I’ve got lung cancer?"
KT: Or just having this illness in general.

"I’m finding this one hard hen, because it’s no happening to me, at the moment it’s still no happening to me. Em, I cannae answer that, I mean I’m getting all this love but I’ve always had all this love, that’s positive, I just didn’t realise I had it as much as what I’ve got, no I really cannae answer that because as I say its, its no happening to me at the moment. It probably will hit home some time that it is, as I say sometimes I look in the mirror and I think aye, aye OK you’ve got lung cancer and then I just flip to something else, no I cannae answer that question darling, sorry."

For this particular patient still coming to terms with the reality of her illness, the interview questions may have been too intrusive. This is a concern raised by Wilkie (Wilkie, 1997) in a paper regarding the ethical considerations of research amongst the vulnerable palliative care population.

In addition to the denial and possible related intrusion, this patient also had some issues of anger and guilt relating to the nature of her diagnosis:

"I stopped [smoking] and I never looked back. Although I do get angry with that, I think, “My God I’ve stopped smoking and noo I’ve got lung cancer”, that annoys me."

When I contacted this patient to arrange my second visit, she was very polite and thanked me for coming the first time but felt she did not wish to continue further. I then discovered she had withdrawn from all palliative care services she had been involved in (home care and day care).

Withdrawn: Patient # 16
This patient was a Pakistani female of 58 years with lung cancer. She lived with her husband who was unaware of her diagnosis. Two of her children were colluding with her to keep the diagnosis from all of her relatives and friends including her husband.
and remaining children. The patients did not speak any English and was therefore relying completely on her daughter to translate. Her daughter was struggling to cope, trying to attend clinic appointments, general practice appointments and keeping her own full time job, whilst also making alternative childcare arrangements (her mother had previously done this) and physically caring for her mother without giving any indication of her mother’s diagnosis to her remaining family.

KT: Do you feel the pressure of it?

"Me? Definitely. I can have really down days and today was one of them. I don’t know whether it’s because of everything I went through with her yesterday but today I just could not get into my work. I just phoned and said that to my manager, just apologised and said “I’m sorry” and I gave him the work I’d done on the memory stick and I said read it at the weekend and tell me what you think on Monday cos I’m just not interested. So it does have an impact."

The interviews were difficult, as they required to be conducted after her working day, at her mother’s house where her infant son would be playing and her father, who did not know the diagnosis, would be in the adjacent room. This was further complicated by the length of time taken for the assessment and interview, as everything required to be translated and was then often discussed. In view of her culture, she also found some of the questions too intrusive or inappropriate to ask her mother and therefore either declined to do so, or had to find a way to rephrase. This may have been in keeping with the findings of Emanuel et al. (Emanuel et al. 2004) who assessed the levels of stress induced by interviews with terminally ill patients and their relatives, discussing the impact of terminal illness. The authors found that ethnic minorities were more likely to report stress, were less comfortable talking about the end of life and were also more anxious about it.

On the day I contacted the patient’s daughter to arrange a third interview, they had earlier received news of disease progression and they were struggling to accept this. With the inherent complexities of the study for this family, the addition of this
unexpected setback resulted in the daughter feeling she herself would be unable to physically and psychologically cope with the added on-going commitment of the study and its associated difficulties. With regret, she withdrew on her mother’s behalf.

Therefore both patients that withdrew did so for understandable external reasons that were not directly related to the study itself. The other 98 patients completed the study.

6.15.2
Affirmation

Many of the participants were affirmed by the study, as they hoped that their input had the potential to help others in the future, as has been postulated by (Kristjanson and Coyle, 2004) (Dobratz, 2003) (Terry et al. 2006) (Barnett, 2001). Some patients were more specific, using the study to convey their message more directly and leave their legacy in this way.

“\textit{I know I was putting you off to begin with because it was something I couldn’t be bothered with at that time but there’s still a bit of me thinks any research that’s carried out now that can benefit somebody later on is good research and who am I to say I can’t be bothered? You know, and [my husband] said, “but you don’t have to do it” and I said, “I know I don’t have to do it but I still think if it’s going on and things can be learned from it then it’s worthwhile taking time to do” but I said, “I’ll need to be stronger before I can do it”}”. \textbf{Interview 1: #12}

“I do hope for myself that this’ll help somebody else in the future cos I’ve been given so much help and blessings by people coming round about me and you coming in and out. I’ve gained so much that I would hope that some of this might help somebody else.” \textbf{Interview 5: #2}

“Just to let people know that even although they’re terminally ill, I said it earlier on, try and laugh, because it does make you feel better and don’t be afraid to talk to
family about cancer, and if they meet with any resistance just tell them straight, “I need to talk about this”. Their pain starts when your pain finishes but if you talk about it now, it does make things easier even for them, yeah there’ll be crying, yeah there’ll be tears but it doesn’t have to be all doom and gloom.” Interview 1: #4

6.15.3
Appreciation
No matter how close to death, almost all of the patients expressed some appreciation for the opportunity to talk openly, without judgement to an impartial, empathic healthcare professional. Despite some patients’ perceptions, no medical advice was in fact offered although where required, suggestions were made for an appropriate alternative contact. The appreciation was often mentioned at the close of an interview, often following emotionally difficult and sometimes intense discussions. These findings are in keeping with the literature suggesting that qualitative research interviews may be a therapeutic experience for patients, providing often the first opportunity for the expression and reflection of their feelings (Wilkie, 1997) (Kristjanson and Coyle, 2004) (Barnett, 2001) (Emanuel et al. 2004).

KT: Thank you so much for speaking to me again

“You’re very welcome, you’re a pleasure to talk to”

KT: That’s very kind of you to say I’ve really enjoyed your…

“Do you realise, to talk to you is a great help, the questions help to bring things out, it does help.” Interview 2: #1

KT: Thank you very much for talking to me, I really appreciate it.

“You’ve helped a bit in the sense that you’ve made it quite simple talking.” Interview 1: #13
"Whereas [my GP], I can’t talk to and have a personal conversation with, the way I do with you and say things that are going on in my life..." Interview 3: #14

KT: Well, listen thank you so much for speaking to me, I really appreciate it, your time, it’s been...

"No problem lass I enjoyed it myself, I enjoyed it." Interview 1: #8

KT: Thank you very much for taking the time to do this.

"You are more than welcome." Interview 2: #19

"Thank you for your patience Katharine cos you’ve not even just helped from the medical aspect you’ve been helping with the emotional things and the day to day things so it’s been tremendous to me. I look forward to your visits very, very much, you are very patient, very, very patient but it’s an uplift when you come. It’s an uplift when you come." Interview 5: #2

6.15.4 Findings In Relation To Other Studies Regarding Ethical Research

The previously discussed article by Hopkinson et al. (Hopkinson et al. 2005) raises issues regarding the ethics of qualitative research. The authors suggest that exploring patients’ perspectives may result in greater self-awareness and that discussion may include potentially distressing issues, generally avoided by healthcare professionals, as little practical help can be offered.

This comprehensive study of distress inherently required the discussion of difficult issues. Moreover, the position of the interviewer was clearly explained to patients at the outset. The Research Doctor’s role was purely to listen impartially, no medical advice would be offered. This study therefore inadvertently encompassed all of the concerns raised by Hopkinson et al. Despite this, patients did not appear to become increasingly distressed as a result of their participation. The previous examples in
fact indicate the occurrence of an opposite effect; that of affirmation and therapeutic benefit derived from talking through difficult issues. As a medical research doctor, avoiding the clinical route in discussion was initially difficult, but was strictly maintained in the interests of research ethics and rigour. With time, this became significantly easier as it became apparent that patients were not looking for answers. The empathy, acknowledgment and impartiality in listening were sufficient to provide a therapeutic benefit.

The following example illustrates the attitude to the difficult questions asked in the quantitative assessment aspect the study.

"When you ask these questions, “Have you anything to live for?” “Do you feel like you could kill yourself?” I’d never get into that, have you anything to live for, I think that’s a different question but oh no there’d never be anything cos I love my wife and I love they kids and my son and daughter, I’ve too much in my life to even think about these things.” Interview 6: #1

In terms of the ethical debate regarding qualitative research in terminally ill patients, the skills and role of the researcher are influential in the outcome and effect. Barnett (Barnett, 2001) suggests that an interviewer with a clinical background is beneficial in this situation.

The relevance of the researcher’s background became evident at an early stage, during the recruitment phase. Initially, the “researcher” was described as such and not as a doctor, due to the study role involving listening without offering medical advice. After 3 weeks without any recruitment success, this title was reconsidered as part of a review of the recruitment process. The decision was made to inform patients both verbally, and on the written literature that a “Research Doctor” was conducting the study. Immediately, following the implementation of this change, recruitment began steadily and consistently gaining momentum and no further changes to the process were required.
This phenomenon may have related to an often ingrained and inherent trust that patients’ place in doctors. This basic level of confidence provided a strong foundation for the development of a trusting research doctor-patient relationship over the course of the serial interviews and assessments. This relationship was likely to have been influenced additionally, by factors other than trust alone, for example, personality and communication skills.

Therefore, in keeping with Barnett’s suggestion, the details of the study findings were very likely to have been enhanced, due to my medical background. The following exert from a narrative, in which a gentleman of 55 years discusses his concerns regarding his sex life openly with me, illustrates this point.

“Aye, I never ever thought I could see myself sit and talk to a lassie about it but I hope you....”

KT: I don’t mind at all

“...but I feel quite comfortable talking to you about it, but as I say I’ve went, I’ve got Viagra...so maybe quite soon, if I can convince her if it’s the last thing I do in my life, it’s no her fault! (laughing)” Interview 2: #1

Wilkie (Wilkie, 1997) raises the potential issue of inexperienced researchers inappropriately raising expectations in their answers to the questions of this vulnerable population. In keeping with Barnett’s suggestion regarding the benefits of a clinical interviewer, the process of the study was certainly also facilitated by my medical knowledge and experience. The following example illustrates this point, with the patient looking for medical information.

This example also demonstrates the potential for the blurring of boundaries between research and medical roles and the responsibility for addressing this, which has been raised by Kristjanson and Wilkie (Kristjanson and Coyle, 2004) (Wilkie, 1997). As exemplified, this issue was generally resolved through the use of communication
skills and provision of an appropriate alternative source of advice. The patient in this example was essentially seeking reassurance.

"My daughter wants to come again and I really would prefer to go on my own this time because I want to know, I am probably expecting the worst. Do you know this type of chemotherapy does it spread quite quickly?"

KT: The chemotherapy?

"The type of cancer I have?"

KT: I honestly don’t know exactly. Each cell type of any cancer is slightly different and has a different kind of progression within itself...the best people to ask are the oncologists because it really is totally dependent on that kind of thing, so I genuinely would be guessing because I haven’t looked at the science part of your actual cell type, which is all very complicated, trying to work these things out.

"I’ll take it as it comes. I keep saying that."

KT: Do you think, what’s inside making you expect bad news?

"I don’t know. I don’t know why because as I say I do feel so well. I just think it’s like everything else they say, the big C, people I haven’t seen for a while are expecting me to look really sick and to have lost weight and to have lost my hair and they’re really genuinely, I mean you can see it in their face...."

KT: Surprised?

"Surprised that I am just me, do you know what I mean? So I don’t know why I am expecting it to be sad news."
KT: Sometimes I think we try and protect ourselves don’t we. Maybe think the worst and hope for the best?

“That’s probably what it is.” (laughing) Interview 2: #20
6.16
Study Limitations

Quantitative

6.16.1.
Sample Size
The sample size of 100 patients may be considered substantial for a longitudinal study amongst a palliative care population. However, due to the large numbers of socio-demographic and clinical variables within this study, the numbers relating to each one are relatively small. In order to maintain quality and rigour, the sample size for the single researcher could not be expanded. The analysis of small numbers is more difficult to interpret and less likely to produce statistically significant results. Therefore, in order to minimise this effect, the categories were condensed although this may have compromised the detail and specificity of the results.

Importantly, the robust analysis, demonstrated strong correlations and highly statistically significant results. This implies that the findings are likely to be replicable and not spurious.

6.16.2
Participation Rate
The participation rate was 52%, which is less than optimal. However, the rate remains acceptable for this particularly frail population with a life expectancy of less than 6 months.

6.16.3
Attrition
As with any study of terminally ill patients, and particularly one in which the inclusion criteria specify a prognosis of less than 6 months, attrition rates were high. Forty seven percent of the patients died but only two withdrew from the study. The
death rates were expected and therefore the analysis accounted for the varying number of assessments for each patient.

6.16.4

Non-Participation

Non-participation was accepted without debate, in keeping with the principals of ethical research. Reasons were noted where possible, although those given may not have been entirely accurate, particularly that of not being interested in research, the most common reason given (34%). The potential that some of the most distressed patients chose not to participate must be considered. The second most common reason given for non-participation was unwillingness to discuss disease (14%). The true figure for this may have been even greater, as anecdotally, the Community Clinical Nurse Specialists were aware of instances in which patients had chosen not to participate for varying reasons, when in their view the true reason was that they were in fact distressed.

Alternatively, however, patients may have chosen to participate for the opportunity it offered to discuss their feelings, due to greater distress. Unfortunately, self-selection is unavoidable. Importantly, the 40% distress rate at baseline is in keeping with suggested prevalence rates for distress (Zabora et al. 1997) (Fulton, 1997) (Farber et al. 1984) (Zabora et al. 2001) (Stefanek et al. 1987), and the longitudinal analysis incorporating distress was statistically and clinically meaningful, thus indicating that refusals due to distress, were unlikely to have significantly affected the outcome.

6.16.5

Effect of Sedation

Sedation reduces conscious level. Therefore, patients who required palliative sedation were often unable to complete assessment measures. As a result, the analysis directly relating to sedative use amongst patients may have been affected. In particular, no relationship was found between sedative use and global distress. As sedation is the treatment of refractory distress, this finding is unexpected. The likely explanation is that the finding is not a true reflection, but a result of the negative
impact of significant sedation upon patient’s conscious level and hence the associated lack of data. Unfortunately, it is likely that the most distressed patients would have been sedated at the end of life, although their evaluation in particular would have been especially revealing. This was an unavoidable limitation.

6.16.6

Use of Self-Report Measures

The quantitative data were derived from scoring patients self-reports. This can never be regarded as completely accurate, due to the reliance upon purely subjective measures for evaluation. Self-reporting has dubious inter and intra-patient reliability. Therefore the results derived from these measures must be interpreted with caution. For example, patients will calibrate themselves upon the scales according to their understanding of the question, whilst also taking into account their own circumstances within the context of their perception of those of others. As a result, some patients may always select a very low score, despite objectively appearing to score higher and vice versa.

Therefore in individual analysis, the scores over time must be considered within the context of all of the scores collected for that patient and interpreted according to the changes seen. For example, in a patient who always scores low, an “average” score for this patient would indicate a significant change. This individual effect is unavoidable however it is absorbed to some degree in the overall analysis of the whole study sample.

Another consideration in the use of self-report measures is that patients are asked to quantify the last 7 days. This can be complicated if one or two days were significantly different to the rest. Often patients asked for advice on how to quantify such a week. In order to maximise the standardisation of the reports, patients were encouraged to factor the significantly different days into the quantification for the week, by averaging out their estimate for each day. The lack of precision is unfortunately an inherent limitation associated with self-reporting.
In addition, repetition of the same self-report measures regularly over time may have resulted in specific issues unique to this methodology. For example, patients may have become used to the questions and therefore pre-planned answers. This was apparent in one patient, but she in fact did this to ensure that her answers were fully considered and meticulous. In addition, she found the questions helped her to formulate her thoughts and appeared to use the self-administration therapeutically. Alternatively, patients may lose interest and answer with less thought or care. Patients may have tried to orchestrate a trend of improvement over time, either for their own benefit or perhaps in their perspective, for the purposes of the study. Patients may have also tried to ensure their answers remained consistent. To my knowledge, this was only apparent in one patient who wished to see the scores each month, in order to evaluate any improvement. However, monthly assessments minimised the potential for learning and manipulating the results.

6.16.7

Social Distress

As discussed in the methods, none of the measures of social distress appeared to be appropriate for use in this study of dying patients, due to their length and detail. The Deprivation Category was used as an indication of affluence. Therefore social distress has not been formally assessed and quantified through self-report. As a result, the longitudinal trends in social distress and associated relationships with other measures and socio-demographic factors cannot be quantitatively assessed. In a comprehensive study of physical, psychological, spiritual and social distress, this is a limitation. However, the balance between completeness and ethics favours patient acceptability and therefore the omission of a social distress measure could not be avoided. Although social distress has not been directly quantified, this domain has been formally evaluated through the examination of the socio-demographic survey, together with the qualitative patient perspectives.
Social Dysfunction

One of the socio-demographic variables was “significant social dysfunction”. There were no formal, documented criteria to define inclusion into this category. Each patient’s specific circumstances were considered individually, according to the familial and social situation. Therefore, this category was defined subjectively and was not standardised, suggesting the specific findings relating to this category may not be directly reproducible. Nonetheless, as there was little dubiety in categorising the current study patients, the reproducibility rates would perhaps be acceptable.

Perception of Receiving Inadequate Information

Patients were asked whether they felt they had received adequate information from the oncology doctor, nurse and their General Practitioner. Patients answered according to their own perception. Unfortunately it was far beyond the capacity of the study to pre-emptively analyse consultations with these healthcare professionals prior to referral to palliative care services. This limitation is well recognised in the literature where the majority of available information relates to patients perception only, as observer-based studies are scarce, most of the actual communication itself, remains unseen (de Haes and Teunissen, 2005).

A standard phrasing of the question was used for all of the patients, in order to minimise diverse interpretations. However, no reference was made in the questioning to timing within the disease trajectory. Therefore, some patients for example, may have considered the information giving specifically at the time of diagnosis only, whereas others may have considered the overall experience of information giving since the time of diagnosis. Therefore, the context of the variable “perception of receiving inadequate information” is somewhat nebulous. Perhaps, specifically asking patients for their perceptions regarding information giving from the time of diagnosis to date would have induced more standardised responses.
Qualitative

Biases are inherent in any qualitative research methodology, due to the reliance upon the interactions of individuals to generate the raw data in the form of perspectives.

6.16.10

Generation of Perspectives

The patients' views were elicited through conversation and questioning during in-depth interviews. These perspectives were therefore inherently influenced by the nature of the relationship with the researcher, as well as the context of the conversation and the environment within which they were expressed.

The relationship with the researcher has been previously discussed. The relationship between two individuals is unique, as is any discussion generated between them. This is dependent upon many factors ranging from personality to the emotional status of either individual. Therefore the perspectives generated from these interviews are likely to be a reflection of these factors and unique to each patient-researcher dichotomy. This is inherent in the generation of any qualitative data and must be considered in the interpretation of the results. The effect was minimised through constancy in using the same researcher in serial interviews.

The use of serial interviews appeared to strengthen the trust within the patient-researcher relationship over time. This was evidenced firstly, by the fact that only two patients withdrew from the study (both with extenuating circumstances) and secondly, even though the majority of patients asked for their carer to be present for the first interview, this was rarely the case for subsequent interviews.

The presence or absence of the carers was also likely to have influenced the content and context of the discussion. This potential component of bias could not be eliminated or standardised, as, in order to comply with the ethical requirements for this vulnerable population, patients were offered the option of having a carer present. Some patients used the research situation as a safe environment in which to raise new
concerns in the presence of their carer, whilst others used the absence of their carer to speak more openly about their fears, particularly for their family and the future.

Additionally, participation in the study may have been therapeutic for patients. Although I was very mindful of my role as the Researcher, I am also aware of my empathic and intuitive nature. At times of evident patient distress, I was unable to simply listen without comment and am aware that I used my communication skills to explore patients' feelings, acknowledge their concerns and provide reassurance or an alternative perspective, where appropriate. Social scientists would argue that the qualitative researcher's role is to simply listen, however, in this vulnerable study population, reality and humanity had to supersede purity.

The evidence for the study patients' feelings of affirmation and appreciation has been previously discussed. As a result, patients may have appeared more positive in their views. This effect may have been transitory lasting only for the duration of each interview, or may have been cumulative over the course of the study. Although the therapeutic benefit was not intentional and thus not purposefully nurtured, this potentially positive effect associated with participation in this study is inextricable from the analysis and must therefore be accounted for, when considering the results. Importantly, a similar positive effect may have also influenced the quantitative findings. Patients who were completing the assessment measures only, also engaged in discussion around the answers to the assessment questions, and therefore the researcher-patient relationship developed equally with these patients.

6.16.11

*Perspectives on perspectives*

As the researcher, my own understanding of the patients' perspectives will have been inherently influenced by my own experiences; within the context and environment of the interviews, as well as more broadly, by my empirical and theoretical frameworks. To some degree, this effect may be considered to have been standardised, as I was the only researcher involved in the interviewing and subsequent analysis.
Nonetheless, I have naturally incorporated the subtle nuances of patients’ non-verbal communication, for example body language, pauses and emotional expression into my interpretation of the transcribed interviews. Qualitative research analysis relies upon the personal interpretation of the researcher and therefore this bias is an unavoidable limitation that must be accounted for in the consideration of the findings.

This effect was minimised firstly, by the validation of my analysis by a second, experienced and independent qualitative researcher. Secondly, I used my field notes, written immediately after the interview, in order to assist the process of accurately reflecting on each specific interview experience. This method of analysis minimised the potential for variation that may have resulted from reliance upon my memories at a later stage, which by then may have been more strongly influenced by my subsequent experiences with each individual, as well as the study as a whole.

Despite this, my empirical framework (initially based upon four years of general medical and six months of specific palliative medicine experience) would have naturally evolved over the course of the study. Therefore, my empirical framework was not consistent over time. My theoretical framework, based upon the documented literature review, was however consistent and comprehensive.

6.16.12

Generalisation

Due to the methods of data generation and interpretation in any qualitative research, findings cannot be generalised or extrapolated to other populations. The evidence generated from this study is accurate for this particular study sample of patients with advanced cancer from the Forth Valley region of Scotland who were referred to and were receiving palliative home care services.
Qualitative and Quantitative

6.16.13
Order of Assessment

A limitation in the methodology related to the order of assessment. Patients interviewed in the qualitative study were also required to complete the quantitative self-report measures. These two components may have influenced each other either positively or negatively. In order to minimise the potential bias, the format of assessment was standardised. In each case patients were assessed with quantitative self-report measures, prior to completing the in-depth interview. The answers to the self-report measures were generally used as a framework for the in-depth interview. During the interviews patients often were reminded of specific issues that they had eluded to or raised during the self-report assessment, thus facilitating discussion.

Completing the formal measures prior to the interview may have helped patients’ to focus their thoughts and formulate their perspectives. However, purist qualitative researchers may argue that this effect may contaminate the clarity of perspectives elicited directly from the in-depth interviews. From this study it is not possible to evaluate the impact that the completion of the self-report assessments had upon the patients’ perspectives, which were subsequently elicited from interviews. In order to establish this, a controlled study of the order of assessment would be required; this is however, beyond the scope of the current study.

6.16.14
Study Population

The participants in this study were at the interface between primary and tertiary care. At the time of study entry, all of the patients had accepted referral to community palliative care services. We must acknowledge the implications of this acceptance in the context of the study findings. Such patients may already be in a position to become more amenable to adaptation to the process of dying.
A regional study of care for the dying in England (Addington-Hall and Altmann, 2000) explored the characteristics of patients who were more likely to receive Community Clinical Nurse Specialist (CSPCN) input. These patients were younger, married, living with their main carer, the carer was their spouse, they were living with children, owned their house and were dependent in their activities of daily living (p<0.01). They were less likely to receive CSPCN input if they had been dependent for over a year, lived alone, or in a nursing home (p<0.01), or if they had a haematological malignancy (p<0.0001). Although these findings may not be directly comparable to Scotland, they provide an indication of the potential biases within the study population. The findings imply that perhaps patients who have better familial support are more likely to receive CSPCN input. The majority of study patients were married (53%), although widows were also well represented (24%) and one patient from a nursing home was included in the sample. Patients with haematological malignancy were also appropriately represented in the current study (2%). Therefore, despite the apparent inherent biases within the CSPCN referred population, the study sample appears to remain well balanced and representative.

Another study (McKegney et al. 1981) compared patients with terminal cancer, with a prognosis of more than 3 months but less than one year who were receiving regular specialist palliative home nursing care (n=98), with those who were not receiving home care (n=101). The nurses visited monthly until prognosis was considered to be less than 3 months, at which point they visited bi-weekly. The analysis was conducted in blocks of days prior to death. Initially, both groups had the same mean pain scores but at 90 days prior to death, pain continued to increase amongst the non-intensive group, whilst reaching a plateau amongst the intensive group: This difference reach near significance (p=0.06) in the last 30 days of life. These findings were considered to advocate strong support for palliative home nursing care, at least in terms of pain control. The level of community nurse input for all of the current study patients was similar. McKegney’s study again highlights the potential beneficial influences of community nurse input, indicating that the current study findings can only be generalised to a population receiving community specialist palliative care nurse input.
McCorkle et al. (McCorkle et al. 1989) studied the impact of homecare support amongst 166 homebound patients with Stage II or higher lung carcinoma. The patients were assessed every 6 weeks for 6 months (total of 5 assessments). Patients were randomised into “Oncology Home Care” (equivalent to Macmillan nurse input), “Standard Home Care” (equivalent to primary care team support) and “Outpatient Clinic Care Only”. The home care started within 2 weeks of the first assessment. The analysis was based on the 78 patients who completed 4 interviews. The authors found that despite randomisation, the Oncology Home Care group did better on most variables on the first visit, which was done prior to the intervention commencing. Analysis was therefore adjusted for this. Patients experienced increasing symptom distress over time but that this was delayed by 1 visit (6 weeks) in the 2 home care groups, compared with those receiving outpatient clinic care only (p=0.03). Although not statistically significant, patients receiving oncology home care support showed trends of relatively fewer hospital admission for management of symptoms and disease complications and they remained independent for a longer than those receiving outpatient clinic care only (p=0.02). Interestingly, and despite this, the patients receiving outpatient clinic only reported improving health perceptions over time, whilst the two home nursing groups reported declining health perceptions. Once again, this study confers the positive influence of specialist homecare nursing input in delaying onset of symptom distress, maintaining independence and reducing admissions for symptom control. Nonetheless, these benefits did not appear to influence the patients’ own health related perceptions in a similar way.

Palliative care offers specialist assistance in relieving physical, psychological, social and spiritual symptoms. The influence of the availability of palliative care on patients’ ability to become reconciled to death is an important consideration. All of the patients in this study were receiving support at home from the hospice Clinical Community Nurse Specialists. This generally involved a weekly or fortnightly visit (according to perceived need) for support and advice, along with the co-ordination of management between the primary care team and hospice. Therefore, hospice admission was more likely and the majority of those who died during this study did die in the hospice.
This study was not comparative. Therefore the findings that patients receiving palliative care input become reconciled with death, cannot be conclusively considered as evidence for the benefits of palliative care. Neither can we assume these findings apply to all dying patients with a cancer diagnosis. The findings of this study may only be considered applicable to patients receiving community specialist palliative care nurse support.
6.17

Study Implications

The study findings have implications for current and future practice.

6.17.1

Predictors of Distress

Social dysfunction and perception of receiving inadequate information were independent predictors of global distress during the end stages of the cancer disease trajectory. Previous significant physical illness predicted physical distress and previous depression predicted psychological and spiritual distress at the end of life. Initial patient review should potentially routinely include assessment of social circumstances, in order to establish evidence of dysfunction, as well as exploration of current patient understanding and perception of information received. Past medical history is already included as part of routine assessment, though psychiatric history is not necessarily always discussed.

Initial comprehensive assessment of the predictors for distress would raise awareness of those patients who are at risk of becoming distressed at the end of life. Targeted measures may then be taken in order to assist such patients in maintaining their control, thus preventing or minimising their risk of becoming distressed.

6.17.2

Screening for Distress

Whilst the physical (MSAS), psychological (EDS) and spiritual (FACIT) measures all showed initial variation in distress levels, prior to stabilising at a lower level with occasional exacerbations, global distress (DT) varied unpredictably over time. Despite the difference in patterns, the significant correlations (p<0.001) between the MSAS, EDS, FACIT and the DT imply that the DT is sensitive in detecting exacerbations of distress in any one of these domains, over the end stages of advanced cancer.
The NCCN Distress Thermometer has been well validated amongst patients with advanced cancer (Roth et al. 1998) (Jacobsen et al. 2005) (Ransom et al. 2006) and may be very useful in screening for distress amongst this population, particularly, as it appears to detect, in this study, distress due to physical, psychological, social, spiritual or multi-dimensional cause. Unlike many of the numerous, extensive self-report measures, the DT consists of a single, all encompassing question. Having detected an exacerbation of distress, further assessment would then be required, in order to elicit the underlying cause of the distress. The DT has an associated checklist of potential physical, psychological, social and spiritual issues, which may assist this process.

The NCCN Distress Thermometer does not predict exacerbations of distress. Therefore, regular screening would be required, in order to detect the unpredictable exacerbations of distress during the final stages of advanced cancer.

The tool is a single, simple question: “On a scale of 0-10, how distressed have you felt in the last week”. The tool should therefore be used as a catalyst for opening discussion and exploring issues raised. This is particularly important, as patients were not keen to disclose feelings of distress.

Interviewer: Do you think, if you’ve had a time when you’ve been feeling worried or anxious or, you know, distressed, is that something that’s difficult to talk to doctors about or not really?

“I wouldn’t talk to doctors about anything like that, I’d talk to my wife about it, I mean what can they do, well you’re going to depress the doctors, no I wouldnae talk to the doctors about anything like that, I wouldnae tell the doctor nothing like that, that’s private, I might tell him I’m worried about it but he cannae do anything about it, there’s not a thing he can do, he cannae take the worry away from you.”

Although the DT question is simple to ask, to manage the answer however may require time and skills and therefore screening should be conducted by an
appropriately skilled professional, in a private setting, with an adequate allocation of time. The management may simply involve the immediate discussion of the issue, if reassurance or information was all that was required. Alternatively, further follow up may be necessary or referral to another colleague may be considered beneficial. Patients scoring below 5 are unlikely to require any management input, although caution should be considered in relation to those with routinely low scores (0-1), who suddenly submit a higher score, even if it is below the cut-off.

According to the study findings that distress exacerbations are unpredictable, distress management must be reactive and responsive at the end of life. Fundamentally, regular, routine screening would enable healthcare professionals to detect the episodic exacerbations of distress. Establishment of the underlying cause for the distress would then enable healthcare professionals to provide appropriate management, facilitating the patient to regain control and resume their stable state.

6.17.3
Healthcare Burden of Distress
Amongst terminally ill patients with advanced cancer at the end of life, global distress was significantly associated with increased requirements for opioids, out-of-hours home visits and unscheduled admissions.

These findings suggest that service input is greater amongst patients who are distressed. The healthcare burden of patient distress at the end of life therefore has potentially significant socio-economic implications.

6.17.4
Summary
Prevention of distress through the identification of patients with risk factors, together with the detection of distress through the use of routine, regular distress screening and the subsequent reactive and responsive distress management, may improve current management, thus enhancing patient experience at the end of life, whilst additionally having the potential to reduce the burden on healthcare service input.
The incorporation of this evidence into current practice may therefore have potentially beneficial implications for advanced cancer patients and healthcare services alike.

6.18 Future Research

In addition to providing numerous answers, this study has also raised some further questions. There is significant scope for expansion of this work and areas of particular interest are discussed below.

The current study has resulted in the development of a rich database of the contributory elements to the distress over time amongst the one hundred participants. Due to the completeness of the data, further interrogation of the database would be straightforward and efficient.

The current study has explored the natural evolution of distress in a clinical setting providing evidence for a fundamental aspect of palliative care. One aspect for further study development, which is currently the subject of a grant application, is a longitudinal intervention study, exploring in detail, the predominant contributors to patient distress, for example pain and anxiety within the context of distress over time. The issue of the predominant problem currently presents a clinical predicament, as each member of the multi-disciplinary team providing holistic patient care has an inherently biased view. As a result, current management is often based upon anecdotal evidence and influenced by local culture and practice. The current database provides a true reflection of patient’s experience of distress over time and would be fundamental in the design of a clinical meaningful, follow-up longitudinal intervention study in order to provide a detailed understanding of the predominant contributors to distress over time and their interactions. This would potentially eliminate the variability in patient management through the provision of evidence upon which to base best practice.
An important and prominent finding of the current study was that the perception of receiving inadequate information was an independent predictor of distress. A logistically difficult, but immensely interesting prospective study would involve the recording of all healthcare consultations from, and including the time of diagnosis for a patient cohort. However, requesting that the patients themselves do not listen to the recordings. Upon referral to palliative care services, a comparative study of the patients’ perceptions regarding the information they were given, juxtaposed with the actual information given in the recordings, would be enlightening. This would provide important insight into whether inadequate information giving is a direct risk factor for distress, or whether distressed patients in fact have an altered perception of their experience.

The current study was conducted amongst a specific population of patients with advanced cancer who had accepted regular palliative care input from community clinical nurse specialists. The debate has been raised, as to whether this input assisted in the patients’ adaptation and reconciliation with death, as found in this study, or whether these findings could be generalised to include all terminally ill cancer patients. Therefore, conducting a similar longitudinal study comparing matched advanced cancer patients who receive, with those who do not receive palliative care, may provide some insight into to the degree of influence that specialist palliative care input has over any innate human ability to face death. Of further interest would be a similar comparative study between patients with terminal illness due to any underlying progressive disease. Currently this would be difficult due to the disproportionate numbers of cancer patients receiving palliative care. However, as the healthcare agenda shifts towards providing palliative care according to need rather than diagnosis, such a study would be highly relevant.

Finally, an intervention study of the implementation of routine distress screening with NCCN Distress Thermometer amongst patients with advanced cancer, regardless of any palliative care input, would provide valuable information. The benefits and feasibility of distress screening would be considered, using outcome measures focusing on patient quality of life and experience. In addition, a
comprehensive healthcare economic study into the cost-benefit ratio would be included. Taken further a similar study of distress screening amongst patients with any progressive disease would provide valuable information. The implications of the findings of such studies may be highly significant, particularly with respect to the distribution of limited resources. For example, patients may be regularly screened within the community and the information used to prioritise, anticipate and direct the intensity of workload of healthcare practitioners. The importance of efficient and effective patient management is increasing as palliative care negotiates an adaptation, without expansion, in order to encompass the needs of any patient with any chronic, progressive disease.

Beyond, and dependent upon the outcome of these studies, would be the development and study of interventions, such as, for example Cognitive Behaviour Therapy, which relate to control enhancement and facilitation. The aim would be to establish effective strategies to minimise and dissipate detected exacerbations of distress. The cost-benefit ratio of any such intervention would certainly require careful analysis.

Abstracts related to this research, accepted to date, are included in Appendix O.
SUMMARY
Study Summary

This longitudinal, end of life study has explored the evolution of distress amongst patients with advanced cancer, from the time of referral to palliative care services to death. The carefully considered, mixed methods design, together with the ethically appropriate conduct, have facilitated the achievement of the study, in overcoming many of the numerous, well-documented challenges presented by end of life research.

Despite separate analyses, the quantitative and qualitative findings complement one another, thus providing a self-validated, multidimensional evaluation of the evolution of distress amongst patients with advanced cancer at the end of life.

Independent predictors of global distress were established as the patient’s perception of receiving inadequate information from healthcare professionals (oncologist, oncology nurse and General Practitioner) and significantly dysfunctional social circumstances. Previous history of physical illness was significantly associated with physical distress and a previous history of depression was significantly associated with psychological and spiritual distress. Qualitatively, “control” emerged as the core concept in relation to distress, amongst patients with advanced cancer at the end of life. Each of the key physical, psychological, social and spiritual themes related directly to control. Thus, through their association with the concept of control, each of the quantitatively determined risk factors for distress was qualified.

Despite minor variations in the specific patterns of each, physical, psychological and spiritual distress levels essentially fluctuated over the initial months, from the time of referral to palliative care services, prior to stabilising at a lower, individual-dependent level. Unpredictable, episodic exacerbations of distress levels occurred in each of these domains throughout the period of stability. The patients’ perspectives evolved over time in a positive direction, indicating their ability to adapt to their circumstances and become reconciled to death. Nonetheless, exacerbations of distress also occurred in any one of the physical, psychological, social and spiritual domains during this final journey. Distress exacerbations related to any sudden and
unexpected change in circumstances that was inconsistent with the familiar trend. The unexpected changes induced transient loss of control and hence, distress was experienced. Patients had the capacity to absorb, process or resolve the change, thus regain control, dissipating distress and resuming the stable state.

Global distress, according to the NCCN Distress Thermometer, varied constantly and unpredictably over time. Despite displaying a different pattern over time, the measures of physical, psychological and spiritual distress all correlated significantly (p<0.001) with global distress at baseline and over time. This suggests that the NCCN Distress Thermometer detects but does not predict distress in any one domain. The direct relationship, determined between each of the key physical, psychological, social and spiritual qualitative themes with the core concept of control, qualifies these findings.

Patient distress appeared to have wider implications for healthcare service. Significant global distress was associated with increased patient requirement for opioids, out-of-hours home visits and unscheduled admissions.

These detailed findings provide some reassurance, by indicating that terminally ill cancer patients receiving community palliative care input appear to have the ability to adapt with time and become reconciled to death. Despite this, any stimulus resulting in loss of control induces distress transiently, until the stimulus is removed, absorbed or processed. The section regarding study limitations discusses in full the various cautions required to be considered in the interpretation of these findings. Importantly, the findings may only be related to terminally ill cancer patients receiving regular palliative care input.

The findings have potential implications for the management of terminally ill cancer patients receiving palliative care services. The inclusion within the patient review, of a routine risk assessment for distress, together with regular screening for distress using the NCCN distress thermometer, may assist in the prevention and early
management of distress, thus enhancing patient experience and reducing the burden upon healthcare services.

Future research should extend to patients with terminal illness, due to progressive disease of any nature, to those who are not receiving palliative care services and subsequently lead to the study of the implementation of a distress assessment, screening and management programme for these patients.
APPENDIX
APPENDIX A

SYSTEMATIC LITERATURE REVIEW

Each combination of the following words:
*Includes any ending of the word in the search

**Distress**
- Stress
- Suffering
- Anguish
- Upset
- Fear
- Worry

**Symptom**
- Pain
- Physical
- Fatigue

**Psychological**
- Emotion*
- Coping
- Adaptation
- Depression
- Anxiety

**Social**
- Psychosocial
- Communication
- Information
- Family
- Culture
- Financial
- Affluence
- Gender
- Relationship
- Marriage
- Spouse
- Couples
- Partner
- Carer

**Spiritual**
- Existential
- Religio*
- Meaning
- Psycho-spiritual
- Psycho-existential
Palliative Care
Palliative
Terminal*
Supportive
End Stage Cancer
Advanced Cancer
Incurable Cancer
Metastatic Cancer
Terminal Cancer
End of life
Death
Dying

Authors
Breitbart, W.
Bruera, E.
Butler, L.
Carlson, L.
Cherny, N.
Chochinov, H.
Derogatis, L.
Fallowfield, L.
Holland, J.
Kissane, D.
Lloyd-Williams, M.
Morita, T.
Portenoy, R.
Spiegel, D.
Zabora, J.

Publications
NCCN publications
NICE guidelines supportive/palliative care

Grey Literature
Professional contacts
Index of research/ Unpublished theses

Databases
CINAHL
MEDLINE
PSYCHINFO
EMBASE
ONCOLINK
CANCERLIT
COCHRANE
EXPLORING DISTRESS IN NEW HOSPICE PATIENTS

You are being invited to take part in a research study that is taking place in the Home Care Service of Strathcarron Hospice. Before you decide whether you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your family or friends if you wish. Please take time to decide whether or not you wish to take part. I will phone you in the next couple of days to answer any questions you may have. If you decide that you do not wish to take part and would rather I did not phone you, please could you let your Macmillan nurse know.

Thank you for reading this

What is the purpose of this study?
Distress can affect all of us at some time in our lives and may happen to us for lots of different reasons. Feelings of distress may be due to physical symptoms such as pain, psychological problems such as anxiety, social worries such as family concerns, and spiritual difficulties such as trying to make sense of our situation. Often, the overall feeling of distress is due to a combination of these concerns so it is quite difficult to understand. Everyone has different levels of distress, some people have very little and some people’s lives are very severely affected by it. These levels of distress do not always stay the same, they constantly change over time as our situations change.

This study aims to understand more about how new hospice patients are affected by distress. The study will explore how distress is made worse and how it is made better as well as looking at how distress levels change over time. This information will help us to understand more about distress so that we can learn how to target and treat distress more effectively in the future.

The study will take place amongst patients who are referred to the Strathcarron Hospice Home Care Service over the next 9 months.

Why have I been chosen?
All patients who are new to the Hospice Home Care service are being asked if they are willing to be involved in this study.
Do I have to take part?
It is entirely up to you to decide whether or not you wish to take part. If you decide that you do not wish to take part, the standard of care you receive from the Hospice will not be affected in any way. If you do decide to take part then you will be asked to sign a consent form and you will be given a copy of it to keep together with this information sheet. If you do decide to take part you are free to change your mind and withdraw from the study at any time, without giving a reason.

What will happen to me if I take part?
If you decide to take part, I will arrange a suitable time to meet with you when I speak to you on the telephone in the next couple of days. I will meet you at a time and place convenient for you. At this meeting I will give you any further information you may need. After this I will ask you to sign the consent form and will give a copy to you. If you would like a family member or friend to be present and contribute, they will be welcome to. They will also be asked to sign a consent form.

I will ask you some straightforward questions about your employment, your family and your current medication. I will then ask you some specific questions from 3 standard questionnaires that are used by health professionals to assess the different types of distress I mentioned earlier (physical, psychological and spiritual). These are very short and will take no more than 20 minutes. I will then finally ask you to rate your overall feeling of distress (on that day) on a simple scale. The whole meeting should take no more than 30 minutes. A few selected patients will be asked to talk more generally about their experiences in an interview done after the standard questions. If you are one of these patients you will be told on the telephone so that you can ask questions and decide whether this affects your decision to take part.

I would meet you once a month for another 2 months and then one final time after that to ask exactly the same questions if you are still willing to take part. Those who had the additional interview would also be interviewed again each time. It is important to try and understand how changes in circumstances affect distress. I would therefore want to repeat the questions if you experienced a time of change during the study, such as an admission into hospital for example.

With your permission the meetings will be tape-recorded. A typed transcription of the full recording will be produced. You will be welcome to read the transcript and make comments so that you can be sure your views have been recorded accurately.

What are the possible benefits of taking part?
Some people find that it is helpful to talk about their experiences. It is hoped that talking about the different types of distress will help us to understand it better so that we can find ways to prevent or treat distress in the future.

What are the possible disadvantages of taking part?
You may find that talking about your physical, psychological and spiritual health is stressful. If you do become upset, then I will try to identify ways to help, otherwise, we will stop the interview. You may find that talking, even for short periods of time, is tiring for you. The interview will be done at a pace that is comfortable for you. However, if you become tired then we will pause or stop altogether if need be.
What if new information becomes available during the study?
You will be told of any new information about distress that becomes available during the study. This may affect your decision to continue taking part. You will be free to withdraw from the study if you wish. The standard of your care would not be affected.

Will my taking part in this study be kept confidential?
Any information about you will have your name and identifiable details removed so that you cannot be recognised. These details will be replaced by a pseudonym that only I know. With your permission, quotations from your interviews may be used in the final report of this study. You would only be quoted under your unidentifiable pseudonym.

All material (written notes, tapes etc.) will be kept strictly confidential and securely locked away. The tapes will be destroyed immediately after the transcription has been typed. Once the research has been reported, all of the study material will be locked in a box and stored in the locked room where all hospice records are kept. This box will be destroyed after 5 years.

The Macmillan nurses know that research is taking place in the hospice home care department and that all new patients are being asked if they would like to take part. They will not know if you decide not to participate. Your Macmillan Nurse, General Practitioner and Hospice Consultant will only be informed with your permission.

What will happen to the results of the research study?
The research is being undertaken as part of a postgraduate degree course: The complete study report will be submitted as the thesis for a Medical Doctorate degree at Edinburgh University. It is hoped that the findings of the study will also be published in medical journals and presented at healthcare conferences. You will not be identifiable in any way in these reports. Please let me know if you would like copies of any publications related to the study, you are very welcome to have them.

Who is organising and funding the research?
Strathcarron Hospice obtained money specifically for this research and is therefore funding the study in full.

Who has reviewed the study?
The study has been reviewed and approved by the Fife and Forth Valley Research of Ethics Committee.

Thank you for reading this
If you have any queries, or would like clarification on any of the above information, then please do not hesitate to contact me. My contact details are on the top of the first page. Alternatively you can ask your Macmillan Nurse to contact me.

Dr Katharine Hubscher
Medical Research Fellow
EXPLORING DISTRESS IN NEW HOSPICE PATIENTS

You are being invited to take part in a research study that is taking place in the Home Care Service of Strathcarron Hospice. Before you decide whether you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your family or friends if you wish. Please take time to decide whether or not you wish to take part.

Thank you for reading this

What is the purpose of this study?
Distress can affect all of us at some time in our lives and may happen to us for lots of different reasons. Feelings of distress may be due to physical symptoms such as pain, psychological problems such as anxiety, social worries such as family concerns, and spiritual difficulties such as trying to make sense of our situation. Often, the overall feeling of distress is due to a combination of these concerns so it is quite difficult to understand. Everyone has different levels of distress, some people have very little and some people's lives are very severely affected by it. These levels of distress do not always stay the same; they constantly change over time as our situations change.

This study aims to understand more about how new hospice patients are affected by distress. The study will explore how distress is made worse and how it is made better as well as looking at how distress levels change over time. This information will help us to understand more about distress so that we can learn how to target and treat distress more effectively in the future.

The study will take place amongst patients who are referred to the Strathcarron Hospice Home Care Service over the next 9 months.

Why have I been chosen?
All patients who are new to the Hospice Home Care service are being asked if they are willing to be involved in this study. As a friend or relative of a patient, you are being asked if you would also be willing to contribute to the study.
Do I have to take part?
It is entirely up to you to decide whether or not you wish to take part. If you decide that you do not wish to take part, the standard of care your friend/relative will receive from the Hospice will not be affected in any way. If you do decide to take part then you will be asked to sign a consent form and you will be given a copy of it to keep together with this information sheet. If you do decide to take part you are free to change your mind and withdraw from the study at any time, without giving a reason.

What will happen to me if I take part?
If you decide to take part, I will meet you with your friend/relative at a time and place convenient for both of you. I will arrange this with your friend/relative on the telephone. At this meeting I will give you any further information you may need. After this I will ask you to sign the consent form and will give a copy to you.

I will ask your friend/relative some straightforward questions about their employment, family and current medication. I will then ask them some specific questions from 3 standard questionnaires that are used by health professionals to assess the different types of distress I mentioned earlier (physical, psychological and spiritual). These are very short and will take no more than 20 minutes. I will then finally ask them to rate their overall feeling of distress (on that day) on a simple scale. The whole meeting should take no more than 30 minutes. A few selected patients will be asked to talk more generally about their experiences in an interview done after the standard questions. You will be welcome to contribute to the interview.

I would meet your friend/relative once a month for another 2 months and then one final time after that to ask exactly the same questions if they are still willing to take part. Those who had the additional interview would also be interviewed again each time. It is important to try and understand how changes in circumstances affect distress. I would therefore want to repeat the questions if they experienced a time of change during the study, such as an admission into hospital for example.

With your permission the meetings will be tape-recorded. A typed transcription of the full recording will be produced. You will be welcome to read the transcript and make comments so that you can be sure your views have been recorded accurately.

What are the possible benefits of taking part?
Some people find that it is helpful to talk about their experiences. It is hoped that talking about the different types of distress will help us to understand it better so that we can find ways to prevent or treat distress in the future.

What are the possible disadvantages of taking part?
You may find that talking about your friend/relative's physical, psychological and spiritual health is stressful. If you do become upset, then I will try to identify ways to help, otherwise, we will stop the interview. The interview will be done at a pace that is comfortable for both you and your friend/relative.

What if new information becomes available during the study?
You will be told of any new information about distress that becomes available during the study. This may affect your decision to continue taking part. You will be free to
withdraw from the study if you wish. The standard of care for your friend/relative would not be affected.

**Will my taking part in this study be kept confidential?**
Any information about you will have your name and identifiable details removed so that you cannot be recognised. Those details will be replaced by a pseudonym that only I know. With your permission, quotations from the interviews may be used in the final report of this study. You would only be quoted under your unidentifiable pseudonym.

All material (written notes, tapes etc.) will be kept strictly confidential and securely locked away. The tapes will be destroyed immediately after the transcription has been typed. Once the research has been reported, all of the study material will be locked in a box and stored in the locked room where all hospice records are kept. This box will be destroyed after 5 years.

**What will happen to the results of the research study?**
The research is being undertaken as part of a postgraduate degree course: The complete study report will be submitted as the thesis for a Medical Doctorate degree at Edinburgh University. It is hoped that the findings of the study will also be published in medical journals and presented at healthcare conferences. You will not be identifiable in any way in these reports. Please let me know if you would like copies of any publications related to the study, you are very welcome to have them.

**Who is organising and funding the research?**
Strathcarron Hospice obtained money specifically for this research and is therefore funding the study in full.

**Who has reviewed the study?**
The study has been reviewed and approved by the Fife and Forth Valley Research of Ethics Committee.

Thank you for reading this

If you have any queries, or would like clarification on any of the above information, then please do not hesitate to contact me. My contact details are on the top of the first page. Alternatively you can ask your friend/relative’s Macmillan Nurse to contact me.

Dr Katharine Ilsescher
Medical Research Fellow
PATIENT CONSENT FORM

EXPLORING DISTRESS IN NEW HOSPICE PATIENTS

Katharine Hubscher
Researcher
Tel: 01324 826222 ext 253
Email: kathhubscher@yahoo.co.uk

Please initial boxes

- I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.

- I confirm that my participation is voluntary and that I am free to withdraw at any time without giving any reason. This will not affect my care or legal rights.

- I agree that any words I say during interviews can be used, anonymously, presentation of this research.

- I agree to the interviews being tape-recorded.

- I agree to the Researcher looking at my case notes.

- I agree to take part in the above study.

Name ____________________ Date __________ Signature __________

Researcher ____________________ Date __________ Signature __________
“SIGNIFICANT OTHER” CONSENT FORM

EXPLORING DISTRESS IN NEW HOSPICE PATIENTS

Katharine Hubbscher
Researcher
Tel: 01324 826222 ext 253
Email: kathhubbscher@yahoo.co.uk

Please initial boxes:

- I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. 
- I confirm that my participation is voluntary and that I am free to withdraw at any time without giving any reason. This will not affect my rights.
- I agree that any words I say during interviews can be used, anonymously, presentation of this research.
- I agree to the interviews being tape-recorded.
- I agree to take part in the above study.

Name __________________________ Date __________ Signature ________________

Researcher __________________________ Date __________ Signature ________________
**Dear Dr,**

I am writing to inform you that your patient, has agreed to participate in the above study taking place in the Strathcarron Hospice Home Care Department. I hope the following information regarding the study is helpful; if you have any queries or would like more details please do not hesitate to contact me. My contact details are above.

**The purpose of the study**

The purpose of this study is to examine the natural course of distress over the end stages (last months) of advanced, incurable cancer and to define factors that are influential in the process. Total distress comprises physical, psychological, social and spiritual domains.

Management of distress is one of the greatest challenges for professionals in Palliative Care. Current literature reveals that distress is costly in terms of service provision, quality of life for patients and quantity of life with regard to both the use of terminal sedation for refractory distress, and direct effect of distress on survival duration. Understanding the components comprising the experience of total distress may enable us to minimise the costs of distress in advanced cancer. To date, the majority of the literature focuses on only one aspect of distress at one point in the disease trajectory.

This study is unique in that it is longitudinal and aims to follow the dynamic process of total distress from the time of involvement of palliative services to patient death. All new referrals to the Strathcarron Hospice Home Care Department are being recruited with the aim to recruit 100 patients in total. Your patient has provided written consent to participation in the study and has given permission for you to be informed of this.

**Study Procedure**

Your patient will be assessed monthly for a total of 3 months and then 2 monthly for a maximum of 6 months. On each occasion the assessment will involve a review of their Hospice case notes, current medication and social circumstances. They will then be asked to answer questions to complete the Memorial Symptom Distress Scale, the
Edinburgh Postnatal Depression Scale, the FACIT-Sp-12 (spiritual distress scale), and then to rate their overall distress level on the NCCN Distress Thermometer. The whole assessment should take no more than 30 minutes. A sub-sample of 20 patients are being purposively selected and consented for in-depth interviews. These interviews will take place in addition to the assessment described above. Assessment will be repeated at the time of any significant event such as admission to hospital or Hospice.

**Reporting of Results**

The complete study report will be submitted as the thesis for a Medical Doctorate degree at Edinburgh University. This will be available in the University of Edinburgh library. It is hoped that the findings of the study will also be published in medical journals and presented at healthcare conferences. Please let me know if you would like copies of any publications related to the study.

**Funding**

Strathcarron Hospice obtained money specifically for this research and is therefore funding the study in full.

**Ethics Approval**

The study has been reviewed and approved by the Fife and Forth Valley Research of Ethics Committee.

Thank you for reading this

Yours sincerely,

Dr Katharine Hubscher
Medical Research Fellow
Dear

I am writing to inform you that your patient, , has agreed to participate in the above study taking place in the Stratcarron Hospice Home Care Department. I hope the following information regarding the study is helpful: if you have any queries or would like more details please do not hesitate to contact me. My contact details are above.

The purpose of the study
The purpose of this study is to examine the natural course of distress over the end stages (last months) of advanced, incurable cancer and to define factors that are influential in the process. Total distress comprises physical, psychological, social and spiritual domains.

Management of distress is one of the greatest challenges for professionals in Palliative Care. Current literature reveals that distress is costly in terms of service provision, quality of life for patients and quantity of life with regard to both the use of terminal sedation for refractory distress, and direct effect of distress on survival duration. Understanding the components comprising the experience of total distress may enable us to minimise the costs of distress in advanced cancer. To date, the majority of the literature focuses on only one aspect of distress at one point in the disease trajectory.

This study is unique in that it is longitudinal and aims to follow the dynamic process of total distress from the time of involvement of palliative care services to patient death. All new referrals to the Stratcarron Hospice Home Care Department are being recruited with the aim to recruit 100 patients in total. Your patient has provided written consent to participation in the study and has given permission for you to be informed of this.

Study Procedure
Your patient will be assessed monthly for a total of 3 months and then 2 monthly for a maximum of 6 months. On each occasion their assessment will involve a review of their Hospice case notes, current medication and social circumstances. They will then be asked to answer questions to complete the Memorial Symptom Distress Scale, the
Edinburgh Postnatal Depression Scale, the FACIT-Sp-12 (spiritual distress scale), and then to rate their overall distress level on the NCCN Distress Thermometer. The whole assessment should take no more than 30 minutes. A sub-sample of 20 patients are being purposively selected and consented for in-depth interviews. These interviews will take place in addition to the assessment described above. Assessment will be repeated at the time of any significant event such as admission to hospital or hospice.

**Reporting of Results**

The complete study report will be submitted as the thesis for a Medical Doctorate degree at Edinburgh University. This will be available in the University of Edinburgh library. It is hoped that the findings of the study will also be published in medical journals and presented at healthcare conferences. Please let me know if you would like copies of any publications related to the study.

**Funding**

Strathcarron Hospice obtained money specifically for this research and is therefore funding the study in full.

**Ethics Approval**

The study has been reviewed and approved by the Fife and Forth Valley Research of Ethics Committee.

*Thank you for reading this*

Yours sincerely,

Dr Katharine Hubseher
Medical Research Fellow
CONSULTANT INFORMATION SHEET

EXPLORING DISTRESS IN NEW HOSPICE PATIENTS

Katharine Hubscher
Medical Research Fellow
Tel: 01324 826222 ext 253
Email: kathhubscher@yahoo.co.uk

Dear Dr,

I am writing to inform you that your patient, has agreed to participate in the above study taking place in the Strathcarron Hospice Home Care Department. I hope the following information regarding the study is helpful; if you have any queries or would like more details please do not hesitate to contact me. My contact details are above.

The purpose of the study
The purpose of this study is to examine the natural course of distress over the end stages (last months) of advanced, incurable cancer and to define factors that are influential in the process. Total distress comprises physical, psychological, social and spiritual domains.

Management of distress is one of the greatest challenges for professionals in Palliative Care. Current literature reveals that distress is costly in terms of service provision, quality of life for patients and quantity of life with regard to both the use of terminal sedation for refractory distress, and direct effect of distress on survival duration. Understanding the components comprising the experience of total distress may enable us to minimise the costs of distress in advanced cancer. To date, the majority of the literature focuses on only one aspect of distress at one point in the disease trajectory.

This study is unique in that it is longitudinal and aims to follow the dynamic process of total distress from the time of involvement of palliative services to patient death. All new referrals to the Strathcarron Hospice Home Care Department are being recruited with the aim to recruit 100 patients in total. Your patient has provided written consent to participation in the study and has given permission for you to be informed of this.

Study Procedure
Your patient will be assessed monthly for a total of 3 months and then 2 monthly for a maximum of 6 months. On each occasion the assessment will involve a review of their Hospice case notes, current medication and social circumstances. They will then be asked to answer questions to complete the Memorial Symptom Distress Scale, the
Edinburgh Postnatal Depression Scale, the FACT-Sp-12 (spiritual distress scale), and then to rate their overall distress level on the NCCN Distress Thermometer. The whole assessment should take no more than 30 minutes. A sub-sample of 20 patients are being purposively selected and consented for in-depth interviews. These interviews will take place in addition to the assessment described above. Assessment will be repeated at the time of any significant event such as admission to hospital or Hospice.

**Reporting of Results**
The complete study report will be submitted as the thesis for a Medical Doctorate degree at Edinburgh University. This will be available in the University of Edinburgh library. It is hoped that the findings of the study will also be published in medical journals and presented at healthcare conferences. Please let me know if you would like copies of any publications related to the study.

**Funding**
Strathcarron Hospice obtained money specifically for this research and is therefore funding the study in full.

**Ethics Approval**
The study has been reviewed and approved by the Fife and Forth Valley Research of Ethics Committee.

Thank you for reading this.

Yours sincerely,

Katharine Hubscher
Medical Research Fellow
### MEMORIAL SYMPTOM ASSESSMENT SCALE

<table>
<thead>
<tr>
<th>Symptom</th>
<th>IF YES</th>
<th>IF YES</th>
<th>IF YES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rarely</td>
<td>Occasionally</td>
<td>Frequently</td>
</tr>
<tr>
<td>Difficulty concentrating</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Pain</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Lack of energy</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Cough</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Feeling nervous</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Nausea</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Feeling drowsy</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Numbness/tingling in hands/feet</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Difficulty sleeping</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Feeling bloated</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Problems with urination</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Feeling sad</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Sweats</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Worrying</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Problems with sexual interest</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Itching</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Lack of appetite</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Dizziness</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Difficulty swallowing</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
<tr>
<td>Feeling irritable</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>0 1 2 3 4</td>
</tr>
</tbody>
</table>

Instructions: We have listed 24 symptoms below. Read each one carefully. If you have had the symptom during this past week, let us know how often you had it, how severe it was usually and how much it distressed or bothered you by circling the appropriate number. If you did not have the symptom, make an "X" in the box marked "DID NOT HAVE."
INSTRUCTIONS: We have listed 8 symptoms below. Read each one carefully. If you have had the symptom during this past week, let us know how severe it was usually and how much it disturbed or bothered you by circling the appropriate number. If you did not have the symptom make an "X" in the box marked "DID NOT HAVE."

| Symptoms                        | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF YES | IF Y
THE EDINBURGH DEPRESSION SCALE

Name

Please UNDERLINE the answer which comes closes to how you have felt IN
THE PAST 7 DAYS, not just how you feel today

I have been able to laugh and see the
funny side of things
As much as I always could
Not quite so much now
Definitely not so much now
Not at all

I have looked forward with enjoyment
to things
As much as I ever did
Rather less than I used to
Definitely less than I used to
Hardly at all

I have blamed myself unnecessarily
when things went wrong:-
Yes, most of the time
Yes, some of the time
Not very often
No, never

I have been anxious or worried for no
good reason:-
No, not at all
Hardly ever
Yes, sometimes
Yes, very often

I get a sort of frightened feeling as if
something awful is about to happen
Very definitely and quite badly
Yes, but not too badly
A little, but it doesn’t worry me
Not at all

Things have been getting on top of me
Most of the time and I haven’t been able
to cope at all
Yes, sometimes I haven’t been coping as
well as usual
No, most of the time I have coped quite
well
No, I have been coping as well as ever

I have been so unhappy that I have had
difficulty sleeping
Yes, most of the time
Yes, quite often
Not very often
No, not at all

I have felt sad or miserable
Yes most of the time
Yes, quite often
Not very often
No, not at all

I have been so unhappy, I have been
crying
Yes, most of the time
Yes, quite often
Only occasionally
No, never

The thought of harming myself has
occurred to me
Yes, quite often
Sometimes
Hardly ever
Never
APPENDIX K

FACIT-Sp-12 (Version 4)

Below is a list of statements that other people with your illness have said are important. By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

Not at all       A little bit       Somewhat     Quite a bit     Very much

1. I feel peaceful...
2. I have a reason for living...
3. My life has been productive...
4. I have trouble feeling peace of mind...
5. I feel a sense of purpose in my life...
6. I am able to reach down deep into myself for comfort...
7. I feel a sense of harmony within myself...
8. My life lacks meaning and purpose...
9. I find comfort in my faith or spiritual beliefs...
10. I find strength in my faith or spiritual beliefs...
11. My illness has strengthened my faith or spiritual beliefs...
12. I know that whatever happens with my illness, things will be okay...
# KARNOFSKY PERFORMANCE STATUS SCALE

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Normal no complaints; no evidence of disease.</td>
</tr>
<tr>
<td>90</td>
<td>Able to carry on normal activity; minor signs or symptoms of disease.</td>
</tr>
<tr>
<td>80</td>
<td>Normal activity with effort; some signs or symptoms of disease.</td>
</tr>
<tr>
<td>70</td>
<td>Cares for self; unable to carry on normal activity or to do active work.</td>
</tr>
<tr>
<td>60</td>
<td>Requires occasional assistance, but is able to care for most of his personal needs.</td>
</tr>
<tr>
<td>50</td>
<td>Requires considerable assistance and frequent medical care.</td>
</tr>
<tr>
<td>40</td>
<td>Disabled; requires special care and assistance.</td>
</tr>
<tr>
<td>30</td>
<td>Severely disabled; hospital admission is indicated although death not imminent.</td>
</tr>
<tr>
<td>20</td>
<td>Very sick; hospital admission necessary; active supportive treatment necessary.</td>
</tr>
<tr>
<td>10</td>
<td>Moribund; fatal processes progressing rapidly.</td>
</tr>
<tr>
<td>0</td>
<td>Dead</td>
</tr>
</tbody>
</table>
Screening Tools for Measuring Distress

Instructions: First please circle the number (0-10) that best describes how much distress you have been experiencing in the past week including today.

Extreme distress

No distress

Second, please indicate if any of the following has been a problem for you in the past week including today. Be sure to check YES or NO for each.

YES NO Practical Problems
- Child care
- Housing
- Insurance/finances
- Transportation
- Work/school

YES NO Family Problems
- Dealing with children
- Dealing with partner

YES NO Emotional Problems
- Depression
- Fears
- Nervousness
- Sadness
- Worry
- Loss of interest in usual activities

YES NO Physical Problems
- Appearance
- Bathing/dressing
- Breathing
- Changes in urination
- Constipation
- Diarrhea
- Eating
- Fatigue
- Feeling Swollen
- Fevers
- Getting around
- Indigestion
- Memory/concentration
- Mouth sores
- Nausea
- Nose dry/congested
- Pain
- Sexual
- Skin dry/itchy
- Sleep
- Tingling in hands/feet

Other Problems:

Version 1.2008, November 15, 2007 National Comprehensive Cancer Network, Inc. All rights reserved. These guidelines and this illustration may not be reproduced in any form without the express written permission of NCCN.
27 January 2005

Doctor Katharine Hubscher
Medical Research Fellow in Palliative Medicine
Strathcarron Hospice
2F1
110 East Claremont Street
Edinburgh
EH7 4JZ

Dear Doctor Hubscher

Full title of study: Evolution of Total Distress In Patients With Advanced Cancer From Referral To Palliative Care Services To Death
REC reference number: 05/S0501/4
Protocol number:

Thank you for your letter of 21 January 2005, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair on 26 January 2005.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised. The favourable opinion applies to the research site listed on the attached form.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as listed overleaf:

..... cont'd/2
Management approval

The study should not commence at the site until you have obtained final management approval from the R&D Department for the relevant care organisation.

Notification of other bodies

The Committee Administrator will notify the research sponsor that the study has a favourable ethical opinion.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

[05/S0501/4] Please quote this number on all correspondence

With the Committee's best wishes for the success of this project,

Yours sincerely.

Enclosures  Site approval form (SF1)
Standard approval conditions SL-AC2

cc: Mr Frank Clark, Strathcarron Hospice, Randolph Hill, Denny Stirlingshire FK6 5HJ
**LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION**

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

<table>
<thead>
<tr>
<th>REC reference number:</th>
<th>05/S0501/4</th>
<th>Issue number:</th>
<th>1</th>
<th>Date of issue:</th>
<th>27 January 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chief Investigator:</td>
<td>Doctor Katharine Hubscher</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full title of study:</td>
<td>Evolution of Total Distress In Patients With Advanced Cancer From Referral To Palliative Care Services To Death</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This study was given a favourable ethical opinion by Fife Local Research Ethics Committee on 26 January 2005. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Post</th>
<th>Research site</th>
<th>Site assessor</th>
<th>Date of favourable opinion for this site</th>
<th>Notes (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Katharine Hubscher</td>
<td>Medical Fellow in Palliative Medicine</td>
<td>Strathcarron Hospice Home Care Service of Strathcarron Hospice</td>
<td>Forth Valley Local Ethics Research Committee</td>
<td>27/01/2005</td>
<td>Approved by the Chair on behalf of the REC:</td>
</tr>
</tbody>
</table>

(Delete as applicable) (Signature of Chair/Administrator*)

(Name)

(1) The notes column may be used by the main REC to record the early closure or withdrawal of a site (where notified by the Chief Investigator or sponsor), the suspension of termination of the favourable opinion for an individual site, or any other relevant development. The date should be recorded.
Dear Catherine,

Re: Evolution of total distress in patients with advanced cancer from referral to palliative care services to death

Thank you very much for supplying the information for the above study. I can now confirm that data collection may commence in Strathcarron Hospice and in Forth Valley Primary Care Operating Division. While undertaking the data collection you must comply with the following:

- The standards detailed in the Research Governance Framework for Health and Community Care. I enclose a copy.
- Ensure compliance with the Data Protection Act and the Caldicott requirements (I have enclosed a brief guide). Should you wish further guidance, please contact Donald Robertson on 01324 826222 or e-mail donald.robertson@strathcarronhospice.org
- Ensure that you are aware of the Health and Safety procedures, I have enclosed a copy of the Hospice policy. If you wish further guidance, please contact donald.robertson@strathcarronhospice.org
- The Hospice Complaints procedure must be accessed if any complaints arise relating to the project and the R&D Office must also be informed. A copy of the Hospice’s policy is also enclosed.
- If any intellectual property is created while undertaking this project or after its completion, you must contact the R&D Office, as arrangements will need to be put in place to exploit it.
- I am also enclosing a document on Freedom of Information developed for Forth Valley staff, which will be essential reading.

If there are any problems or significant changes to the project, you must inform me.
I wish you every success with the project. If I can be of any further help, please do not hesitate to contact me.

Yours sincerely,

Dr Mary Fraser (PhD),
Head of Research and Development

c.c.  Donald Robertson
     Marjory Mackay
TO: KATHARINE HUBSCHER
FROM: FRANK CLARK, DIRECTOR
DATE: 17TH FEBRUARY 2005

RESEARCH PROJECT – EXPLORING DISTRESS IN NEW HOSPICE PATIENTS

I would like to confirm for record purposes that David Gordon, Research & Development Manager of Lanarkshire NHS Board has confirmed that they are content to accept the approval from Fife and Forth Valley Local Research Ethics Committee in relation to the involvement of Cumbernauld/Kilsyth patients in your research.

It will be helpful for you to make this point when you attend the forthcoming meeting of the LHCC Executive.
Accepted Abstracts


**Background:** Distress is derived from interactions of physical, psychological, social and spiritual domains: There has been no longitudinal study of distress.

**Aim:** To explore distress over the terminal phases of cancer determining pattern, predictors and the contribution of each distress domain to global distress.

**Method:** Mixed methods longitudinal study: 100 newly referred patients were assessed monthly until death or for 6 months maximum through documentation of socio-demographics, medical factors and: Memorial Symptom Assessment Scale (physical), Edinburgh Depression Scale (psychological), FACIT-Sp-12 (spiritual), NCCN Distress Thermometer (DT) and in-depth interview (sub-sample of 20 only).

**Results:** Lack of information (p<=0.008) and social dysfunction (p=0.031) were significantly associated with global distress. Over time all domains correlated significantly with: Global distress, in particular psychological (p=0.000), and with each other. Key emerging themes were: Family, communication, physical debility, control and reticence in disclosing distress.

**Conclusion:** The 4 domains are strongly inter-related but psychological contributes most to global distress. Patients become reconciled to death with time. Acute episodes of change may induce distress, transiently altering adaptation to dying. These episodes are detected but not predicted by the DT. The Distress Thermometer could be a very useful screening tool in clinical practice.
Thompson K L, Murray S A, Murray G, Fallon M T. Longitudinal Study Into Total Distress in Patients With Advanced Cancer From Referral To Palliative Care Services to Death. Psycho-Oncology: Abstract: Supplement 2007 Jan

**Purpose:** Global distress is derived from interactions between physical, psychological, social and spiritual domains: These dynamics have not been studied over time. Study aims: To explore distress over the terminal phases of cancer; determining predictors and patterns of distress and the contribution of each distress domain to global distress.

**Methods:** Longitudinal study combining quantitative (100 patients) and qualitative (sub-sample of 20) methods: 100 newly referred advanced cancer patients were assessed monthly until death or for 6 months maximum. Assessment involved documentation of socio-demographics, medical factors and: Memorial Symptom Assessment Scale (MSAS) (physical), Edinburgh Depression Scale (EDS) (psychological), FACIT-Sp-12 (spiritual), NCCN Global Distress Thermometer (GD) (primary end point) and an in-depth interview (sub-sample only).

**Results:** 51% male. 40% distressed at baseline. Significant associations with distress: Depression (p= 0.08); poor information communication from oncology doctors (p<0.001), nurses (p<0.001) and GPs (p= 0.003). EDS, MSAS, FACIT-Sp-12 correlate strongly with GD over time: r=0.691, 0.469 and -0.339 respectively. Key qualitative distress themes: Social; communication and family: Physical; interrelations between fatigue, debility and dependence: Psychological; relate to debility, coping strategies involve limiting uncertainty: Spiritual; control and normality. Patients would not raise feelings of distress with doctors.

**Conclusions:** Psychosocial factors may be most influential in determining global distress. The Global Distress Thermometer is a useful screening tool, particularly as patients are unlikely to report distress. Further analysis will determine predictors, patterns and domain contribution to global distress over time, together with associated drug and service use: This data will be available for presentation.

Hubscher, K L, Murray S A, Fallon M T. Longitudinal study into the evolution of total distress in patients with advanced cancer from referral to palliative care service to death. Palliative Medicine 20(3): 266 Abstract number: 141, 2006 April

**Background:** The experience of distress is derived from the interaction of physical, psychological, social and spiritual domains. The dynamics of these interactions have not been studied over time.

**Aims:** To explore distress in the terminal phases of cancer: To examine influential factors, the relationship between distress and time, and the contribution of each domain of distress to global distress over this time.
Methods: Longitudinal study combining quantitative (100 consecutive patients) and qualitative methods: 20 purposively selected new community cancer patients (sub sample) are being assessed monthly until death or for 6 months maximum. Assessment involves documentation of socio-demographic factors, medication, performance status and: The Memorial Symptom Assessment Scale (physical), Edinburgh Postnatal Depression Scale (EPDS) (psychological), FACIT-Sp-12 (spiritual), NCCN Global Distress Thermometer (GD) (primary end point) and an in-depth interview.

Analysis: Exploration of risk factors for global distress at baseline and death is in progress with univariate analysis. Distress patterns are being examined by plotting distress measures over time. The contribution of each distress measure to global distress is being analysed graphically and via the correlation coefficient at baseline and pre-death. Interview analysis is with grounded theory.

Results: M: F 1:1. At baseline: 80% were fatigued, 20% depressed, 25% distressed (80% of whom had no partner). Correlation coefficients: between EPDS and GD 0.84; FACIT and GD 0.79. Preliminary analysis indicates a trend of increasing psychological, spiritual and global distress over the first 3 months. Qualitatively, frustration with debilitation, importance of control and concerns for family persist over time.

Conclusions: Key qualitative concept: Debilitation impacts directly on each distress domain. This will be explored and the quantitative relations between distress domains clarified, as full analysis to death will be presented.


Background: The experience of distress is derived from the interactions of physical, psychological, social and spiritual domains. The dynamics of these interactions have not yet been studied over time.

Aims: To explore the natural course and management of distress in the terminal phases of cancer: To examine influential factors, the relationship between distress and time, and the contribution of each domain of distress to global distress over this time.

Methods: A longitudinal study combining quantitative and qualitative methodology: Cancer referrals to the hospice community team are recruited consecutively. 100 patients in total will be assessed monthly until death or for 6 months maximum. 100 patients are required to detect an absolute difference of 28% in global distress for risk factors at baseline (80% power, $\alpha = 5\%$). Each assessment includes documentation of socio-demographic factors, medication and Karnofsky Performance Status together with completion of the Memorial Symptom Assessment
Scale (physical), Edinburgh Postnatal Depression Scale (psychological), FACIT-Sp-12 (spiritual) and the NCCN Global Distress Thermometer (primary end point). For a subgroup of 20 in total (19 to date), assessment includes an in-depth interview.

**Analysis:** 65 patients are currently recruited. Risk factors for global distress will be explored at baseline and death with univariate analysis. Distress patterns will be examined by plotting distress measures over time. The change between baseline and pre-terminal distress will be assessed using continuous and discrete variables. The contribution of each distress measure to global distress will be analysed graphically and via the correlation coefficient at baseline and pre-death. Interviews will be analysed using grounded theory assisted by NVIVO.

**Results:** Initial qualitative data analysis will be complete and presentable within 2 months. Quantitative data analysis will begin in January.

**Conclusions:** Data analysis, illustrated by patients’ perspectives, will provide insight into distress in the terminal phases of cancer.
REFERENCES
REFERENCES


recent literature. *Current Opinion in Oncology* 17, 345-50.


well-being of women with breast cancer: The influence of disease phase. 
*Psycho-oncology* 9, 221-231.


National Cancer Research Institute Strategic Planning Group on Supportive and Palliative Care National Cancer Research Institute, (Ed.) (2004) Supportive
and Palliative Care. http://www.ncri.org.uk/


Thorne, S.E., Bultz, B.D., Baile, W.F. and SCRN Communication Team. (2005) Is
there a cost to poor communication in cancer care?: a critical review of the literature. *Psycho-oncology* **14**, 875-84.


