An exploration into the culture of blood transfusion practice in oncology

by

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PART ONE

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Statement of Originality

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ABSTRACT

Background: Clinically defined cancer-related anaemia is common in cancer patients but the impact of mild/moderate anaemia is undetermined, when combined with cancer symptoms and/or the side effects of therapy. Blood transfusion is the standard treatment; however there are significant risks and costs. It is important that the decision to give blood is carefully considered but it is not clear how these decisions are made.

Purpose: To explore the cultural practices which shape the culture of transfusion; and to identify the key elements, which influence clinical decision making in blood transfusion in haemato-oncology and lung cancer patients.

Method: The assessment and decision making processes for blood transfusion were explored using six patient and nine clinician interviews; and observation based on ethnographic methodology. Data were analyzed using thematic analysis.

Findings: The findings fell into four main areas. First, the findings suggested that anaemia and transfusion are commonplace in the clinical setting; and because many patients live with anaemia and it may not be viewed as an illness (The ubiquity of anaemia and transfusion). Second, there is a great deal of uncertainty surrounding the diagnosis and management of this clinical problem; but this uncertainty was acknowledged by both patients and clinicians (Acknowledgement of uncertainty). Third, clinicians and to some extent patients, are socialized into the practice of the sub-discipline (Socialization of practice); and fourth that the haemoglobin level was used as a distinct fragment of information on which to assess for the presence of anaemia and base the decision to treat with blood transfusion (Disaggregation of the body).

Conclusion: By understanding the complexity of factors for variation in practice in the clinical context, new models for learning transfusion skills can be developed. Furthermore, different collaborative groups could be organized to develop optimal
transfusion practices, for example to include nurse-prescribing of blood components.

(299 words)

**Key words:**

Blood transfusion/transfusion practice
Clinical decision making
Haemoglobin
Ethnography
Oncology

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Glossary of terms

**Actigraphy:** A non invasive method of monitoring sleep and activity patterns. The patient continuously wears a device like a wrist watch on their non-dominant arm which monitors activity which can be later analyzed using software.

**Acute Myeloid Leukaemia (AML):** An acute onset cancer of the white blood cells, where the cancer arises in the bone marrow. The most common acute leukaemia in adults.

**ADE:** Combination chemotherapy for the treatment of AML; a combination of cytarabine, daunorubicin and etoposide.

**Allogeneic blood:** Blood donated from another individual, which is typically stored and then provided through a transfusion.

**Alloimmunization:** The process of making an antibody against a foreign antigen.

**Anaemia:** A condition in which the blood is deficient in red blood cells, in haemoglobin or total volume.

**Angiogenesis:** Blood vessel formation. Angiogenesis that forms in cancer is the growth of blood vessels from surrounding tissue to a solid tumour. This is caused by the release of chemicals from the tumour, which activates normal angiogenic pathways.

**Blood components:** Red blood cells; white blood cells, plasma and platelets are components that can be removed from a donor and transferred to a recipient or returned to a donor.

**Clinicians:** Healthcare professionals including physicians and nurses.

**COPDM:** Combination chemotherapy for aggressive lymphoma includes the combination: cyclophosphamide; vincristine; prednisolone; doxorubicin; high dose methotrexate.
Cytokines: Extracellular hormones or messengers, secreted mainly by macrophages and T cells, that interact with the immune, nervous and endocrine system

DHAP: Treatment for relapsed non-Hodgkin’s lymphoma including combination chemotherapy; dexamethasone; cytarabine and cisplatin

Diffuse Large B cell Non-Hodgkin’s Lymphoma: The most common sub-type of non-Hodgkin’s lymphoma (NHL); comprising about 30% of all NHL’s

Endogenous: Originating or arising within the body

Erythroid hypoplasia: Decreased production of red blood cells by the bone marrow

Erythropoiesis: The process of making red blood cells

Erythropoietin: A chemical normally produced by the kidney; stimulates the bone marrow to make red blood cells

Ethnography: Aspect of cultural anthropology concerned with the descriptive documentation of a living culture

FACT-An: Functional Assessment of Cancer Therapy-Anaemia quality of life questionnaire

Ferritin: An iron carrying protein which is a more accurate monitor of long term iron body status than the blood iron level

Functionality: The ability of a patient to undertake activities of daily living

Haemato-oncology: The study and treatment of cancers affecting the blood and bone marrow and lymphatic systems; leukaemia, myeloma and lymphoma

Haemoglobin: The oxygen carrying protein of the blood

Haematologist: A doctor in the branch of medical science that studies blood and blood forming tissues

Function: A description of performance status of a patient

Immunomodulation: Modification or alteration or disruption of the immune system
Interleukin: A chemical messenger secreted by cells of the immune system that act by affecting other parts of the immune system

Leucocyte depletion: Blood components which have had most of the leucocytes (white blood cells) removed

Lymphoblastic Lymphoma: A very aggressive form of non Hodgkin's lymphoma, which requires aggressive therapy

Myelodysplastic syndrome (MDS): Disease in which the bone marrow does not function normally; can transform into acute leukaemia

Myelosuppression: A fall in blood counts caused by radiotherapy or chemotherapy

Normochromic: Normal in colour; when the blood has normal haemoglobin levels

Normocytic: Red blood cell of normal size and shape

Nucleic acid testing: Technology for amplifying genetic material in order to test for the presence of blood contaminants

Oncology: The study of cancer

Precautionary principle: When information about the potential risks is incomplete, basing decisions about the best ways to manage or reduce risk

Prions: Protein segments that may cause infection that leads to some forms of dementia

Quality of life: An evaluation of health status, relative to the patient's age, expectations and physical and mental capabilities

RCHOP: A combination of five drugs to treat non-Hodgkin's lymphoma. It consists of Rituximab; cyclophosphamide; doxorubicin; vincristine and prednisolone

Social construction: relates to any phenomena which is invented or constructed by the participants in a particular culture or society, existing because people agree to behave as if it exists or follow the rules.
**Stage:** Refers to the “stage of the cancer” e.g. advanced or early stage

**Supportive care:** Care given to improve the quality of life of patients who have a serious or life threatening disease

**Tradition:** Custom or belief; a long established action or pattern of behavior in a community or group of people, often one that has been handed down from generation to generation; a body of long established customs and beliefs viewed as a set of precedents

**Transfusion trigger:** The critical point at which a decision is made to give a blood transfusion

**Variant Creutzfeldt Jacob disease:** A transmissible, rapidly progressing, fatal neurodegenerative disorder called a spongiform degeneration that seems to be related to “mad cow disease”

**Venous Thromboembolic Events (VTE’s):** A clinical event caused by a thrombosis (attached or fixed clot) and/or embolus (mobile clots)
CHAPTER 1
Introduction

In this chapter, some background information is provided on the subjects of cancer related anaemia and blood transfusion. The researcher's clinical background and the development of the research problem, in the clinical context are explained. The outline of the study is described, and how it evolved from observations in practice; followed by an introduction to the literature review and evolution of the methodology. It concludes by providing a summary of the findings.

1.1 An introduction to cancer-related anaemia

Clinically defined cancer-related anaemia (haemoglobin of less than 12g/dl) is a common clinical problem for patients and occurs as a consequence of either the disease process or as a side effect of the anti-cancer therapy. The direct effects on the patient vary, ranging from negligible effect to debilitating symptoms and it may be difficult for the patient and the healthcare professional to establish the symptoms of anaemia as distinct from symptoms of disease or therapy. Cancer frequently causes fatigue, and also breathlessness, which are both symptoms of anaemia. These symptoms can worsen or improve with therapy depending on disease and stage. The degree of anaemia can also fluctuate and it can be difficult to determine the impact of anaemia in the patient assessment when the other variables of disease and treatment effects are taken into account.

Many quality of life studies have been undertaken in attempts to demonstrate that anaemia has deleterious effects on cancer patients particularly in relation to fatigue, and that by increasing the haemoglobin, the patients' function and quality of life improves.
However, many of these have been in the erythropoietin studies which results in an intrinsic rise in haemoglobin. It may be that allogeneic blood does not have the same impact or that the effects are unpredictable. More recent evidence now reveals that increasing the patients’ haemoglobin, through the use of erythropoietin agents can have a negative effect on outcomes, (Leyland-Jones 2003; Henke et al 2003; Overgaard 2006; Leyland-Jones et al 2005); therefore, the decision to treat the anaemia requires careful consideration. The perception may be that anaemia is common in cancer patients and that it is important to treat. This may have been largely due to the attention given to erythropoietin therapy evidence as well as the historical approach of treating anaemia with blood transfusion, or it may be other influences such as the culture or practices within the clinical setting or individual behaviors. Alternatively, although cancer related anaemia is described as a common clinical problem it may be that it is only moderate to severe anaemia which impacts on the patient, therefore it is only in these circumstances that the risk of transfusion is justifiable. Less severe anaemia may be inconsequential, and therefore unnecessary to treat; it may be the side effects of disease and treatment take priority over the symptoms of anaemia, which may influence the decision to treat. It may be that when less severe anaemia is placed in the context of the life threatening nature of cancer that it becomes less of a clinical priority in some clinical settings. Together all of these factors imply that managing cancer related anaemia is complex and it is unclear how the decisions are made to treat anaemia with blood transfusion, therefore, substantiating the need for this research.

1.2 An introduction to blood transfusion

It is routine practice to correct anaemia in the UK by using red blood cell transfusions. Around 2.5 million units of blood are transfused every year in the UK; a figure which
increases every year (RCN 2006; Soldan et al 1999) and approximately 20% of this donated blood in the UK is used in cancer patients (Wallis 2006). Blood transfusion is therefore ubiquitous in the acute healthcare settings yet there is relatively limited evidence of its efficacy in improving outcomes when compared with the practice of other treatments, for example, drug therapy. It is accepted that by increasing the haemoglobin, it can increase function, but studies have not been undertaken in individual tumour groups, which will be evidenced in the literature review; it may be that different tumours have different responses in terms of benefit and/or outcome.

There are also potential complications of transfusion, including transmission of infectious diseases, transfusion reactions, alloimmunization, lung injury, over-transfusion and immune modulation with possible adverse effects on tumour growth (Goodnough et al 2005; Toy et al 2005). The safety of blood transfusion has improved significantly over the past 20 years, primarily due to improvements in donor-blood screening and stringent quality-control measures. In spite of these improvements risks remain with blood transfusion (Williamson et al 1999). The history of transfusion-associated infection with human immuno-deficiency virus (HIV) and variant Creutzfeldt Jakob Disease (vCJD), and the fear of future unknown pathogens, for example other harmful prions or microorganisms not yet identified or developed by mutation, are partly responsible for increasingly conservative allogeneic red blood cell transfusion practices (Goodnough et al 1999). Increasing costs and complexity such as leucocyte depletion and nucleic acid testing in producing the end product also contribute to this conservative approach. Historically patients were routinely transfused to maintain a haemoglobin level of around 10g/dl but over the years there has been a gradual reluctance to transfuse for the reasons mentioned earlier. It has been suggested that this growing tendency for the
lowering of the transfusion threshold has gone too far and patients may be under-transfused (Valeri et al. 1998) with mild to moderate anaemia being left untreated (Cella and Bron 1999; Glaspy et al. 1997; Henry 1992; Koeller 1998). This has been strongly emphasized in the erythropoietin literature, which will be described in section 2.3.

It may be that transfusions are so commonplace and historical that traditional practices exist; transfusion behaviours may be habitual rather than focusing on individual patient needs. Blood transfusion is a well established mode of treatment and the education and learning in clinical practice has not been previously explored, for example, how transfusion behaviours are learned. Mandatory transfusion training exists in acute settings but much of the focus relating to transfusion practice revolves around safety aspects, such as correct identification and checking procedures, rather than at the point of decision to treat, to explore if the blood transfusion is actually necessary. Within cancer care it may be low priority consideration when compared to other aspects of care. It is largely a traditional approach whereby two units of blood are ordered in response to the haemoglobin value.

It is unclear at present if the benefits outweigh the risks of transfusion in the treatment of mild or moderate anaemia and how much consideration is given to this uncertainty when making clinical decisions. In summary, the process of assessment of anaemia and the subsequent decision to treat anaemia using blood transfusion requires further exploration. The interactions between patients and clinician and/or nurse require further examination to explore the reality of transfusion practice; that is an exploration into the culture of transfusion practice within the cancer care setting.
1.3 The researcher's background

The researcher's clinical background is haemato-oncology and her interest in cancer related anaemia began when in the clinical role as nurse manager of a haemato-oncology day unit and out-patient department. Approximately 40-50 patients attended the department every day with a variety of haemato-oncology malignancies. Many patients were transfusion-dependent, and multiple transfusion episodes, in different patients, occurred every day. The decisions to transfuse were based on a combination of the haemoglobin and conversation with the patient, which usually included questions about fatigue and breathlessness on exertion. The day unit nurses made the assessments whilst taking the blood samples and sometimes made the decision to send a cross match sample and cannulate the patient because they anticipated the patient would require a blood transfusion. The norm was for the nurse to make the decision to transfuse; cross match and order the blood and later have it legitimized and legalized by the medical staff who would prescribe the blood components. An additional driving force, for speed of assessment, was the need for timely ordering otherwise the patient would be unable to complete their transfusion during the visit to the day unit. In other words, behaviours developed in a pragmatic way to ensure the practicalities of completing the transfusion episode, within the day unit hours of operation and also to circumvent restrictive professional practices.

During the four year period as manager, three interesting reflections shaped the researcher's thinking and, ultimately the development of this research project. Firstly, observing junior haematologists' behaviour and the change in their blood prescribing behaviors following the completion of their transfusion medicine course at National Blood Transfusion Service. Pre-course the haematologists would happily be guided by the day
unit nurses. Post course, they would be more challenging and less likely to want to transfuse patients. This implied a relationship to skills and knowledge but may also be related to attitudes; in summary the intervention (transfusion course) resulted in more questioning behaviours. Secondly, sometime during the four year period there was a period of financial difficulty; up to that time it had been common practice to use a transfusion trigger of 10g/dl and the hospital guidelines were amended to use a new trigger of 8g/dl in an effort to reduce the blood transfusion component spend. There was reluctance by the clinical teams to do this initially, however the researcher observed this change in clinical practice appeared to have minimal impact on the patients. Thirdly, the researcher observed that an individual patient could present with a low haemoglobin level and symptoms and multiple clinicians (nurse or medical) could make different transfusion decisions. There appeared to be little consistency and the reason for this was unclear; the decisions were negotiated between the clinicians, or occasionally one clinician would over-rule another, but frequently the nurses made the ultimate decision because of the practicalities of completing a transfusion episode within the hours of operation of the day unit.

In summary, these reflections contributed to the development of a Master's degree research project (Bishop 2004). This was a quasi-experimental design to determine the impact of transfusion on the functional status of blood transfusion-dependent haematology patients; it was a crossover-design study whereby six patients were transfused for four weeks using a trigger of 8g/dl (low trigger) then crossed over to a transfusion trigger of 10g/dl (high trigger), with a two week washout period. Actigraphy and quality of life questionnaires were used to measure any differences on functionality of patients when maintained at low or high haemoglobin. Actigraphy is a non-invasive technique.
whereby the patient wears a device like a wristwatch on their non-dominant arm and it continuously monitors sleep, wake and activity patterns, by using sophisticated software to capture movement. The study had some methodological flaws; for example, maintenance at either trigger was only for a four week period and this study period may have been too short to determine any impact or changes of the haemoglobin level on functional status. Furthermore, the data analysis was limited by the numbers of patients who completed the study and because of the problems of reliably integrating the actigraphy and questionnaire data. The patients who appeared to benefit the most from blood transfusion were those who had not previously received chemotherapy. The emphasis of the study was on the patient functional status, however, it could not explain the variation in transfusion decision making and therefore ultimately the variation in clinical practice.

A change in clinical position to Nurse Consultant in a different institution resulted in further questions. At the new institution, guidelines were well established and present in every clinical area, however, there was an impression that blood component guidelines were not adhered to. Different practices occurred, in that the clinics were dislocated from the day units and the medical and nursing assessments were separate. For example, a patient may attend clinic for medical review where the decision to transfuse is agreed; however, at the point of care delivery, or during the booking procedure the decision may change, following discussion or review by the nurse. A clinical audit was undertaken which revealed a variation in practice in terms of transfusion triggers in haemato-oncology and oncology (see Service Development Project; Part 2). The oncology unit appeared to use a higher trigger, which may have been because of the
effects of radiotherapy guidelines which specify a higher trigger, but limitations of the audit meant this information was not available.

It emerged that transfusion practice varied but the reasons for this were unclear; it could be related to the:

- Indeterminacy of anaemia and treatment
- The knowledge skills and experience of clinicians or nurses
- Available clinical evidence
- Situational factors such as the environment or financial constraints
- The presence or absence of guidelines
- Individual patient/clinician factors or other factors

Further research was required to explore these factors and place cancer related anaemia and transfusion practice in the context of the clinical setting. If the complexity of factors for variation in practice in the context of the clinical setting could be understood, new models of care, or different collaborative groups could be organized to develop optimal transfusion practices. In addition, by exploring the culture of transfusion practice, further research questions may emerge, for example, what skills and knowledge are required to practice optimal transfusion practice?

Initially, the early ideas for the research project could be summarized into two distinct areas; firstly, the effect of anaemia on the patient and the response to an increase in the haemoglobin following a transfusion; how did the patients feel when they were anaemic and did they experience improvement post transfusion, and did this influence the
decision to treat cancer related anaemia? Secondly, what individual, social, situational and cultural factors influenced the decision to transfuse and was the patient involved in the assessment and decision to transfuse? The challenge was to develop a research project that would answer these questions and the evolution of the research is described in Section 1.5 and in more detail in Chapter 3.

1.4 Developing the literature review

The literature review needed to be extensive and broadened beyond the simplistic starting point of cancer related anaemia and blood transfusion to include some of the influencing factors, for example, the culture and clinical decision making. The literature review expanded as the research project developed. It was difficult to establish what aspects of transfusion practice were important to explore therefore a novel approach, using a relationship diagram, was developed and the researcher found this assisted with the organisation of the literature review and ensured all relevant aspects were covered (Figure 1.4). This was an iterative process and the literature review needed to be re-defined as the project evolved, as new information emerged. Relationship diagrams are a useful and effective way of organising and identifying links between concepts, topics and variables (Finn 2005). They are also helpful in maintaining an overview of the different components of a complex topic and help to convey information that would be difficult to achieve in a written piece of work, allowing the complexity to be appreciated, but still allowing the individual components and their connections to be viewed. A relationship diagram was devised to facilitate the literature review and guide the researcher to develop general themes to explore the literature. In summary, the relationship diagram was used not only to reflect the initial understanding of the subject but also helped to actively promote understanding and give rise to new insights, for
example, the deeply entrenched traditional practice of blood transfusion. This was particularly useful when re-visiting the literature review following the data collection and during the data analysis period.

Figure 1.4: Relationship diagram

(CRA: Cancer related anaemia; DTT: Decision to Treat)

1.5 Summary of the research project

Developing the research project, like the literature review, was an iterative process. The purpose of this study was to explore the culture of transfusion practice and provide more in depth knowledge and understanding of the impact and assessment of cancer related anaemia and its treatment with blood transfusion. The objectives were:

- To explore the cultural practices which shape the culture of transfusion
To identify the key elements, which influence clinical decision making in blood transfusion

The study was limited to haemato-oncology and lung cancer patients as cancer-related anaemia is common in these patient groups (52% and 38% respectively, Ludwig et al 2004); and the clinical teams who cared for these patients were the subjects for interview. The incidence of anaemia in the different types of cancer patients is described in more detail in section 2.2. The initial study design had included a quasi experimental component whereby a combination of actigraphy and quality of life questionnaires would be used to establish the impact of the anaemia on the patient. The patients were to be followed throughout their treatment trajectory and the effects of transfusion monitored longitudinally using FACT-An (Functional Assessment of Cancer Therapy-Anaemia subscale, Cella 1997) and actigraphy for 90 days. The original research therefore had two distinct parts; the first part was designed to focus on the patient and the impact of anaemia and transfusion and the second part to focus on transfusion decision making and behaviours. The effect of the anaemia on the ability of the patient to physically function was to be measured by using a combination of questionnaires and actigraphy; actigraphy is a non-invasive means of measuring activity, sleep and rest patterns (see glossary). The clinical decision making was to be explored by using a combination of observation and interviews, using an ethnographic methodology. However, the design was subsequently altered to include patient interviews, and the actigraphy and questionnaires abandoned, not only to answer the research questions, but also because of methodological flaws in the original design and difficulty in recruiting patients to the 90 day study period. The actigraphy and questionnaire may not have captured the patient experience of anaemia and transfusion and also it became apparent following some of the clinician interviews that patients were
involved in the decision making. It emerged that by interviewing patients, more detail of the experience and their involvement would be possible. Therefore the final research design was a combination of observation and patient and clinician interviews using an ethnographic methodology. This evolutionary process of the final research methodology and design will be described in more detail in Chapter 3.

The change in research design, that is the abandoned quasi-experimental components of the study (actigraphy and questionnaires) and substitution with patient interviews, was discussed and agreed with the research supervisors. The project required a substantial amendment to be submitted to the ethics committee and the patients were subsequently interviewed. This added information about the culture of anaemia and the management with blood transfusion from the patient perspective that otherwise would not have been available. The assessment process and patient-clinician interaction was explored using interviews and observation based on ethnographic methodology; but the change in study design included patient interviews to establish their views on the impact of the anaemia and give insight into their involvement in the decision to transfuse. This provided data to explore the clinical decision making process to determine the influencing factors on the decision to treat the anaemia with blood transfusion.

Data on the clinics and environment were collected to provide information on the frequency of anaemia in this clinical setting and how the clinics functioned because this may influence behaviours. Eight clinical staff and six patients were interviewed and the interviews transcribed over a nine month period. Observations were undertaken in the clinics and day units and field notes transcribed. The researcher's influence and her interpretation was considered and reflected in the researcher's diary and is described in
the ethical issues section 4.5 and conclusion chapter (Chapter 7). Preliminary data analysis began at the point of data collection and a modified thematic analysis using Spradley (1980). Early themes emerged, for example, uncertainty, and these provided the foundations of further data collection and analysis.

The findings fell into four main areas. First, the findings suggested that anaemia and transfusion are commonplace in the clinical setting; and because many patients live with anaemia and it may not be viewed as an illness (*The ubiquity of anaemia and transfusion*). Second, the findings suggest that there is a great deal of uncertainty surrounding the diagnosis and management of this clinical problem; but this uncertainty was acknowledged by both patients and clinicians (*Acknowledgement of uncertainty*). Third, the findings suggest that clinicians and to some extent patients are socialized into the practice of the sub-discipline (*Socialization of practice*); and fourth that the haemoglobin level was used as a distinct fragment of information on which to assess for the presence of anaemia and base the decision to treat with blood transfusion (*Disaggregation of the body*).

The implications of the findings are discussed in Chapters 6 and 7 with particular reference as to how the transfusion culture influences decision making and how cancer related anaemia is managed in the clinical setting; with recommendations for clinical practice and further research.

1.6 Summary

In summary the researcher's background, history, clinical experience and skills and knowledge and attitudes shaped the evolution of this research project. From the early
belief that anaemia and blood transfusion practice was an important clinical issue came
the understanding that cancer related anaemia may not be viewed as an illness, by
clinicians or patients that warranted discussion and debate in the clinical setting. The
reasons for this were multiple, interconnected and complex. The researcher used the
multiple data sets (demographic data; clinic data; interview data; observation of practice
data) to create a version of the reality, but it should be remembered this is the
researcher's version of reality and others' interpretations may differ. However, the
different data sets added rigor to the results of this study, by demonstrating the recurrent
themes within the different data sets.

This chapter has provided some initial background to the study and a brief overview.
The first step was to explore the literature using the categories described in section 1.4.
It has been explained briefly how the use of an ethnographic approach would provide a
way to explore the research question, but a greater understanding of ethnographic
methodology was required and advice sought on how to undertake ethnographic
observation and interviews. This is outlined in more detail in Chapter 3. Data collection
was undertaken over a 9 month period and data analysis took a further four months.
The data analysis and findings are described in detail in Chapter 5. The discussion and
implications for practice and future research evolved; and these are described in
Chapters 6 and 7 respectively. In summary, it was a case of protracted but fluid
evolution with continued refinement and re-definition to produce the final ethnography
and thesis.
CHAPTER 2

Literature Review

This chapter summarises a review of the relevant literature. First, the literature was reviewed to establish the incidence and pathophysiology of cancer related anaemia; this helped to clinically define the anaemia and explore the biological basis for the indeterminacy of anaemia. Second, the literature was reviewed to explore the current evidence for the impact of the anaemia and to establish the importance of managing anaemia appropriately. The review included the extensive erythropoietin literature as much of the recent research into cancer related anaemia management has attempted to determine the benefits of increasing the haemoglobin by using erythropoietin therapy. Third, the literature was explored to determine the symptoms and assessment of anaemia and what assessment strategies are used by clinicians; the rationale for including this is that one of the challenges of managing this type of anaemia lies in distinguishing the symptoms of anaemia from symptoms of the cancer, particularly the more subjective symptom of fatigue. Fourth, the transfusion literature was reviewed to describe the current evidence for transfusion thresholds and the risks and benefits of blood transfusion; this would provide a basis of understanding of any factors which may influence transfusion decision making or attitudes to blood transfusion. Finally, it is unknown what factors influence how blood transfusion behaviours are learned and practiced therefore the clinical decision making literature was explored in addition to the literature focussing on social interactions and the development of cultural knowledge in clinical settings.
In summary, the literature review was undertaken to understand current knowledge about cancer related anaemia and treatment with blood transfusion. The decision to treat cancer related anaemia is complicated because of individual patient adaptations to anaemia; the range of symptoms cancer patients experience, and because haemoglobin levels fluctuate according to disease status and therapy; and it is unclear if clinicians observe trends in haemoglobin or if they assess the haemoglobin level in isolation. It is also unclear how the patient is involved and if the patient is in concordance with the clinician when making the clinical decision to transfuse and this justified an exploration into the literature of patient factors, which may influence the decision making. In summary, like any literature review, the overall aim was to determine the gaps in the literature and guide the researcher in developing the design of the study. This chapter concludes with a summary of the literature and the purpose of this research.

2.1 Search Methods

The following search strategy was utilised for this review, using text and keyword and MESH terms in each database:

- Anemia/anaemia
- Blood transfusion
- Blood transfusion guidelines
- Cancer related anaemia/anemia
- Cancer related fatigue
- Fatigue/lethargy/tiredness/asthenia/breathlessness
- Erythropoletin/erythropoletin/Erythroid Stimulating Agents/ESA’s
- Lung cancer/breathlessness
The following databases were used to obtain relevant studies for this review.

- The Cochrane Controlled Trials Register (Central/CCTR)
- MEDLINE (1966 to July 2008)
- EMBASE (1980 to July 2008)
- CINAHL (1982 to July 2008)
- British Nursing Index (January 1984 to July 2008)
- AMED (1985 to July 2008)
- SIGLE (1980 to July 2008)
- Dissertation Abstracts International (1861 to July 2008)

Reference lists of all articles obtained were checked for additional studies. In addition textbooks were acquired on ethnography, clinical judgement and decision making.

2.2 Incidence and pathophysiology of anaemia in cancer

Clinically defined cancer-related anaemia is reported as a common problem in cancer patients, and even more so in patients with haematological and lung malignancies, with an incidence of 52% and 38% respectively (Ludwig et al. 2004). The consequences of anaemia, namely fatigue, and cardiovascular and respiratory symptoms, can adversely affect patients' quality of life and may even alter their response to treatment (Ludwig and Fritz 1998; Ludwig and Strasser 2001). Moreover anaemia is often associated with the
presence of several adverse prognostic parameters and is itself a predictor of poor prognosis (Caro et al 2001).

2.2.1. Clinical definition and incidence

The pathogenesis of cancer-related anaemia is variable, but may involve bleeding, erythroid hypoplasia, reduced red cell survival, nutritional deficiencies, decreased erythropoietin levels, haemolysis and poor iron re-utilisation by bone marrow (Bokemeyer 2005; Estrin et al 1999). Furthermore, cancer-related anaemia is exacerbated by myelosuppressive chemotherapy and may be aggravated by radiotherapy (Barrett-Lee et al 2000).

Anaemia can be defined as a deficiency in the concentration of haemoglobin (Hb) containing red blood cells, and is a widely prevalent complication amongst cancer patients, but the incidence and severity varies according to the type of malignancy (Groopman and Itti et al 1999). A large European study, the "ECAS" survey (n=15,367) was conducted to prospectively evaluate the prevalence, incidence and treatment of anaemia in European cancer patients (Ludwig et al 2004). Thirty-nine per cent of patients were diagnosed with an Hb of less than 12g/dl at enrolment, 10% had an Hb of less than 10g/dl and 1% had an Hb of less than 8g/dl (see Table 2.2.1 for classification of anaemia; Groopman and Itti 1999). The ECAS survey was undertaken to inform clinicians of the frequency of cancer related anaemia and may have been used as a drive for using erythropoietin. The conflict here is although the ECAS survey reports the frequency of anaemia as high the actual number of patients that would need transfusion according to current guidelines is greatly reduced (10% with Hb less than 10g/dl and 1% with an Hb of less than 8g/dl). Therefore there may be a large number of patients who
are technically anaemic at diagnosis, however, only a very small proportion would be eligible for treatment according to transfusion recommendations.

The ECAS study also demonstrated rates of anaemia were shown, not surprisingly, to rise during treatment, especially with chemotherapy. They also varied by tumour type, for example, patients who had haematological and lung cancers had substantially higher rates of anaemia than other types of cancer. Patients with breast, head and neck and uro-genital cancers had rates below the average at enrolment (30%, 25% and 29% respectively). It is most common in haematological malignancies where 52-64% of patients had haemoglobin values between 8 and 10g/dl and 19-23% had haemoglobin values less than 8g/dl (Nowrousian et al 1996).

Table 2.2.1: The National Cancer Institute Anaemia classification (Groopman and Itti 1999)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Classification</th>
<th>Haemoglobin level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>Within Normal Limits (WNL)</td>
<td>12-16g/dl (women)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14-18g/dl (men)</td>
</tr>
<tr>
<td>Grade 1</td>
<td>Mild</td>
<td>10g/dl-WNL</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Moderate</td>
<td>8.0-10.0g/dl</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Serious/severe</td>
<td>6.5-7.9g/dl</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Life threatening</td>
<td>&lt;6.5g/dl</td>
</tr>
</tbody>
</table>

This classification of anaemia is universally accepted and will be used during this thesis to describe levels of anaemia.

2.2.2 Pathophysiology of cancer related anaemia

The pathophysiology of cancer related anaemia is multi-factorial (Mercadante et al 2000; Spivak et al 2005). There are numerous causes that could have produced the anaemia
in cancer but in a considerable number of cases there is no bone marrow infiltration, blood loss, haemolysis, renal, hepatic or endocrine disorders or nutritional deficiencies that could explain the anaemia (Nouwrouslan 2005). This cancer-related anaemia, has many haematological and biochemical similarities with anaemias that occur in chronic inflammatory diseases, such as rheumatoid arthritis and chronic infectious diseases, such as tuberculosis, systemic fungal infections and acquired immunodeficiency syndrome (Nouwrouslan 2005).

Tumour-associated factors such as tumour bleeding, haemolysis, deficiency in folic acid and vitamin B12, can be acute or chronic. In the advanced stages of haematological malignancies, bone marrow involvement often leads to progressive anaemia and in clinical practice this causes ethical dilemmas when to stop transfusing. In addition, interaction between tumour-cell populations and the immune system can lead to the release of cytokines, especially interferon-alpha, interleukin-1 and tumour necrosis factor. This disrupts endogenous erythropoietin synthesis in the kidney and suppresses differentiation of erythroid precursor cells in the bone marrow. As a result, patients with tumour anaemia may have relatively low levels of erythropoietin for the grade of anaemia observed (Spivak et al. 2005). In most cases the anaemia is hyporegenerative (slow to recover), normocytic and normochromic characterised by a normal or reduced serum iron and transferring saturation despite a normal or elevated ferritin (form of iron; see glossary) level (Nouwrouslan 2005).

Recent investigations show that the anaemia may be the result of an activation of the immune and inflammatory system and certain cytokines such as Interferon (IFNs), Tumour Necrosis Factor (TNF) or Interleukins (IL) could potentially be involved in its
development (Diagram 2.2.2). The concentrations of these cytokines are found to be increased in cancer patients and in other patients with chronic disease and their levels correlate with the degree of anaemia (Nouwrousian 2005). In cancer related anaemia the red blood cell survival is shortened to 60-90 days (normal is 120 days) (Zucker 1985), but the more important factor contributing to the development of anaemia appears to be a relative failure of erythropoiesis to compensate for this shortened survival. The pathogenic mechanisms postulated to be involved in this process are impaired iron utilisation (Lee 1983, Zucker 1985), suppression and shortened survival of erythroid progenitor cells and inadequate erythropoietin production.

Diagram 2.2.2: Pathophysiology of anaemia (Supplied by courtesy of Amgen with permission)
Administration of erythropoietin has been shown to correct the anaemia in a proportion of patients and it has also been demonstrated that not only does this therapy increase serum levels of erythropoietin but it may also overcome the suppression of erythroid progenitors and improve iron mobilisation. Erythropoietin therapy and related literature will be described in more detail in the following section (section 2.3). Alternatively the anaemia could be corrected by administering blood transfusion and this would essentially increase the numbers of circulating red blood cells transiently and therefore it could be expected the benefits would be short-lived as the underlying causes of the anaemia would not be affected. It may even be that the transfusion could have a negative feedback mechanism and suppress the production of erythropoisis further thereby inhibiting the production of endogenous red blood cells.

2.2.3 Treatment effects

As stated cancer therapy can increase the incidence and intensity of the anaemia. The pathophysiological effects are multiple, but at the most simplistic level it is a direct effect of the therapy on the bone marrow, resulting in temporary myelosuppression. Some agents have other effects, for example, it is believed platinum-based chemotherapy regimens may diminish endogenous erythropoietin production by damaging renal tubular cells (Wood 1995) and myelotoxic chemotherapy can compromise erythroid precursor cells. As a consequence, dose-intensified treatment regimens or shortened treatment intervals as well as multimodal therapies can increase the degree of anaemia further (Groopman and Itri 1999). For example, severe (grade 3) anaemia in elderly patients with haematological malignancies may occur in up to 74% in patients with Non-Hodgkin Lymphoma after standard CHOP treatment (Groopman and Itri 1999). In addition, some of the newer chemotherapeutic agents such as taxanes or vinorelbine are strongly
myelosuppressive and frequently cause severe anaemia (Groopman and Itri 1999). The highly variable response to cancer therapy, which is dose and therapy dependent, and further complicated by individual patient factors could be a criticism of cancer related anaemia studies in that frequently it is researched as a collective when in fact it is more complex and unpredictable due to individual therapy and patient responses.

2.2.4 Effects of anaemia on the tumour
An important aspect of anaemia in patients with malignant disease is the effect of the anaemia on the tumour itself. For several cancers, including cervical carcinoma, head and neck, prostate, bladder and lung cancer as well as lymphoma; anaemia is known to be an independent factor associated with a worse prognosis (Caro et al 2001). Other studies have shown Hodgkin’s disease, chronic lymphocytic leukaemia, cervical carcinoma and cancer of the head and neck, anaemia has been reported as an independent prognostic factor (Hasenclever 1998; Nowrouslan 2002). This is partly due to confounding factors because advanced cancers usually present with lower haemoglobin levels at diagnosis compared with early-stage cancers and also have poorer survival outcomes. Besides this, one causal explanation might be the improved oxygenation of tumour tissue at higher haemoglobin levels. Since tumour cells become resistant by tumour hypoxia, improved oxygenation may prevent hypoxia maintaining tumour cells sensitive to radiation and most chemotherapy drugs. Early studies suggested that anaemia, with the consequence of increased tumour hypoxia, might result in a poorer response to chemo or radiotherapy as described previously (Hockel et al 1993; Nordsmark et al 1996; Vaupel and Hockel 2000; Vaupel et al 2002). More recently, hypoxia may be more prevalent in anaemic patients than in patients with normal Hb levels (Vaupel and Mayer 2005) and tumour hypoxia may impair the effectiveness of
radiotherapy and oxygen-dependent chemotherapies (Hockel et al. 1993; Schrijvers 1999; Vaupel and Mayer 2005).

Anaemia is associated with a poor outcome in patients treated with radiotherapy, because anaemia results in poor tumour oxygenation and tumour hypoxia reduces ionisation sensitivity (Vaupel et al. 2001). Radio-biological studies have shown that tumour hypoxia leads to less radiation induced cytotoxic-free radicals resulting in less radiation-induced DNA damage and tumour cell kill. Tumour oxygenation is also impaired by haemoglobin levels of more than 14 g/dl in women and more than 15 g/dl in men which result in increased viscosity and a drop in effective perfusion (Vaupel et al. 2002). It was therefore suggested to keep the haemoglobin levels during radiotherapy within a potentially optimal range of 12-14 g/dl for women and 13-15 g/dl for men in order to achieve maximum tumour oxygenation (Vaupel et al. 2002). These observations generated the hypothesis that strategies to diminish cancer-related anaemia might not only alleviate anaemia-related symptoms but also improve tumour response and overall survival. It is unknown what the impact of this evidence and hypothesis has in that it may result in a tendency to over-transfuse as the healthcare professional may feel that transfusion will benefit outcome. Furthermore, in the practice of clinical oncology (clinicians who prescribe radiotherapy and chemotherapy) it would be common practice to maintain higher haemoglobin levels in patients who are receiving radiotherapy. Medical and nursing teams may be accustomed to this practice and not be discerning of this when making clinical decisions, resulting in a tendency to over-transfuse.
2.3 Erythropoietin literature

The erythropoietin literature is extensive and is therefore important to review to give insight to the benefits and risks of maintaining a higher haemoglobin level. More recent literature suggests a reduction in confidence in erythropoietin therapy which may have an impact on the decision to transfuse. The erythropoietin literature will be described in relation to the impact of erythropoietin's effect on the tumour and the results of the erythropoietin trials and the possible impact of the literature on clinical practice, for example NICE guidelines.

2.3.1 Definition of erythropoietin and impact on tumour growth

Human erythropoietin is a 166 amino acid glycoprotein hormone and it is the principle regulator of red cell production, stimulating the proliferation and differentiation of erythroid precursors in the bone marrow. Recombinant erythropoietin and epoletin beta are commercially available erythropoietins with almost identical sequences to the native protein and Darbopoiitin Alfa is a synthetic form of erythropoietin with a similar action but is longer acting (Minton et al 2008).

Erythropoietin receptors have been detected in numerous cancers (Arcasoy et al 2003; Arcasoy et al 2005; Dagnon et al 2006; McBroom et al 2005; Leo et al 2006) and it is also possible that endogenously produced or exogenously administered erythropoietin promotes the proliferation and survival of erythropoietin receptor expressing cancer cells (Feldman et al 2006; Yasuda et al 2003; Mohyeldin et al 2005; Henke et al 2006). There is an ongoing debate about the validity of those studies, because the antibodies used most often lacked erythropoietin receptor specificity (Elliot et al 2006; Osterborg et al 2007). Thus, the interpretation of the observations made in many of those studies is
questionable. Besides this, other researchers have postulated a anti-apoptotic effect of erythropoietins on other tissues including neural (Brines et al 2000; Brines et al 2004) and cancer cells (Um et al 2007). In addition, it has been proposed that there is link between endogenous erythropoietin and angiogenesis in vivo (Hardee et al 2007; Ribatti et al 2007a; Ribatti et al 2007b). It has been suggested that endogenous erythropoietin is needed to promote tumor angiogenesis and to maintain the viability of endothelial cells (Bohlius et al 2008). This seems a logical proposal, in that erythropoietin could enhance tumour growth, however, the clinical implications of these findings have not been clarified to date.

Correction of anaemia by the use of erythropoietin may have a positive impact on treatment outcomes (Blohmer et al 2002; Grogan et al 1999; Glaser et al 2001; Littlewood et al 2001), however, these studies have improved intrinsic haemoglobin levels by erythropoietin, not by transfusion and there has been conflicting results (Bohlius et al 2006). Furthermore, it could be that if the haemoglobin is maintained there may be less treatment dose reductions. More recent investigation suggests that outcomes are worse following correction of anaemia (Leyland-Jones et al 2003; Henke et al 2003; Overgaard et al 2006; Leyland-Jones et al 2005) and it could be hypothesised that anaemia may be a natural response to tumour control. It is unclear the mechanisms involved as these studies were using erythropoietin and it may be the endocrine function that is important as opposed to the increase in haemoglobin that led to the worse outcomes.

Overall, the evidence from both in vitro and in vivo studies as well as clinical trials is insufficient to draw firm conclusions whether erythropoietins promote tumor proliferation.
or not (Bohlius et al 2008). In summary, a direct relationship between the presence of erythropoietin receptors on tumor cells and tumor proliferation in response to exogenous erythropoietins has not been established to date. The impact of the erythropoietin data on blood transfusion practice has not been evaluated and although data is not conclusive the information that erythropoietins may have a negative effect on outcome may shift the balance from erythropoietin therapy in favour of blood transfusion once more.

2.3.2 Erythropoietin therapy trials
Randomized placebo-controlled studies have shown that treatment with erythropoietin raises haemoglobin levels, reduces transfusion needs and improves quality of life in anaemic patients with cancer (Boogaerts et al 2003; Osterborg et al 2002), however, erythropoietin responses in patients with cancer related anaemia appears to differ considerably depending on the type of underlying malignancy (Jacobs et al 1989; Ludwig and Fritz 1998; Miller et al 1990; Nowrousian 2005). Studies have shown that as haemoglobin increased with erythropoietin therapy, functional capacity parameters improved significantly and it is important to note that where there was no increase in haemoglobin there was no improvement in energy level, activity level and overall quality of life (Demetri et al 1998; Glaspy et al 1997; Littlewood et al 2001). For the average increase in haemoglobin (2g/dl), there was a statistically and clinically significant improvement in each quality of life parameter (Littlewood et al 2001). An equivalent rise in haemoglobin can be achieved by a two-unit blood transfusion but it may be that increasing intrinsic haemoglobin via erythropoietin therapy may have more functional benefits, than by increasing haemoglobin via allogeneic blood, particularly as the effects of transfusion are probably transient and difficult to sustain longer term (Osterborg et al 1998). This would make erythropoietin therapy the preferable treatment for anaemia.
Furthermore, a more recent Cochrane review showed that there was only a small but significant improvement in cancer related fatigue in chemotherapy patients receiving erythropoietin or darbopoietin (Minton et al 2008).

Early erythropoietin therapy trials showed a trend towards improved survival in patients treated with erythropoietin (Antonadou et al 2001; Littlewood et al 2001; Vansteenkiste et al 2002). However more recent published trials have raised the concern regarding the impact of erythropoietin agents on survival in oncology and hematology patients and these have reported increased mortality in patients treated with erythropoietins (Henke et al 2003; Leyland-Jones et al 2003; Overgaard et al 2006; Wright et al 2007). Three clinical studies reported increased tumor progression or death due to tumor progression in patients receiving erythropoietin (Henke et al 2003; Leyland-Jones et al 2003; Leyland-Jones et al 2005; Overgaard et al 2005). The Henke et al (2003) and Leyland–Jones et al (2003) studies had survival as a primary endpoint, although the robustness of these data has been questioned because of the methodological limitations of these studies (Aapro et al 2004); this meta-analysis of nine randomized controlled trials examining the effects of erythropoietin on tumour progression and survival in cancer patients. They concluded that treatment with erythropoietin has no impact on survival in anaemic patients but may be associated with a reduced risk of tumour progression (Aapro et al 2004), however, this has since been shown to not be the case in more recent studies as described above. The conflicting evidence was summarized in a recent Cochrane review assessing the effects of erythropoietin (erythropoietin or darbopoietin) to either prevent or treat anaemia in cancer patients (Bohlius et al 2006). This was a systematic review of 57 trials with 9353 patients. Not surprisingly, the use of erythropoietin significantly reduced the relative risk of red blood cell transfusions (RR
On average participants in the erythropoietin group received one unit of blood less than the control group. There was suggestive evidence that erythropoietin may improve the quality of life but the relative risk for Thrombo-Embolic Events (VTE's) was increased in patients receiving erythropoietin compared to the control group (RR 1.67, 95% CI 1.35 to 2.06; 35 trials, n = 6796). Studies have implicated the tumor-mediated activation of the haemostatic system in both the formation of tumour stroma and in tumor metastasis hence the tendency for VTE's in some patients, (Francis et al 1998; Levine et al 2003), however it appears that erythropoietin therapy can increase this risk further.

The Bohlius et al (2006) Cochrane Review also concluded that uncertainties remain on how erythropoietin affects tumour response or overall survival as described earlier. In summary, the evidence in favour for and against erythropoietin has alternated as data has emerged over the years. Although erythropoietin therapy is not currently recommended for use in the NHS by NICE (with the exception of ovarian cancer) the evidence for and against for erythropoietin and has received significant interest by clinicians as overall it has appeared to improve quality of life. This is now balanced against significant risks but even the improvements in quality of life have to be reviewed with caution as allogenic blood transfusion is unlikely to have the same beneficial effects as intrinsic blood.

2.3.3 Impact of the erythropoietin literature

As mentioned, the research of management of cancer related anaemia has been dominated by the erythropoietin studies in recent years. Personal experience demonstrated clinicians' frustrations when erythropoietin was not approved by NICE and
many use erythropoietin for their private patients in preference over blood transfusion, probably because the pharmaceutical support of the multiple erythropoietin studies. It is not clear what the impact of this has been and how much this has influenced practice. In contrast there has been a dearth of research in the use of transfusion for the management of cancer related anaemia, perhaps because of the initial hopes that erythropoietin would solve this clinical problem. Blood transfusion is a costly treatment and yet is not subject to the same scrutiny as erythropoietin and the reasons for this are not clear.

Over the years the nature of clinical research funding has undergone a dramatic change, shifting away from public funding and resulting in the pharmaceutical industry being the largest sponsor of medical based research (Freemantle et al 2005). Although this has beneficial effects and has provided the needed support for research, resulting in medical advances this has also caused concern over conflicts of interest (Bodenheimer 2000). Furthermore, several studies and systematic reviews have shown an association between industry sponsorship and pro-industry conclusions (Bekelman et al 2003; Kjaergard and Als-Nielson 2002). The conflicting results in the randomized controlled trials (RCTs) of erythropoietin use may be an example of the powerful influences and conflicts of interests involved in pharmaceutical sponsored studies and from a personal perspective have been influential in the researcher’s scrutiny of RCT’s. In summary, there are probably many reasons for the conflicting results in the erythropoietin studies, for example, there may be biased interpretation of results or selective reporting; for example many are reporting improved survival however, these studies were not designed to evaluate survival and therefore may not have been powered sufficiently to make such conclusions.
2.3.4 Summary of erythropoietin literature

In conclusion, a few points should be considered before accepting the hypothesis that the role of erythropoietin in cancer is already defined. Biological pre-clinical studies have identified at least two opposite actions of erythropoietin on cancer cells, one favoring the growth and the other enhancing the cell's sensitivity to treatment. The proof that patients benefit from correction of mild or moderate anaemia is not definitive. It may be that translational research projects may be the most appropriate type of study before any further clinical trials are developed (Apolone 2004). Furthermore, the two patient groups in which adverse events were demonstrated were head and neck cancers (Henke et al 2003) and breast cancer (Leyland-Jones et al 2003) and it may be more basic science investigations have to be undertaken in different tumour types to assess the effects of erythropoietin on different tissues. This demonstrates the problem whereby in a proportion of the studies cancer patients tend to be grouped in studies of cancer-related anaemia as a homogenous group. It may be improving the haemoglobin by either erythropoietin or transfusion may be of more benefit in some tumour types and not others and in fact may be detrimental in some tumour types if tumour hypoxia is the means by which tumour growth is reduced or the presence/lack of erythropoietin receptors is significant. A further consequence of the large volume of erythropoietin studies may be that although not transferable to transfusion practice, they may influence clinician perceptions about increasing the haemoglobin. Furthermore, even if erythropoietin may result in an improvement in fatigue and other quality of life parameters it may not offset the risk to outcome. Patients' perceptions of the management of their anaemia have not been explored in a qualitative study previously, either in transfusion or erythropoietin studies.
2.4 The impact of anaemia on symptoms and Quality of Life (QoL)

The clinical manifestation and severity of anaemia can vary considerably among individual patients. Moderate to severe anaemia can cause signs and symptoms such as headache, palpitations, tachycardia and shortness of breath. Fatigue, depression and impaired cognitive function account for most of the symptoms that diminish quality of life as a result of anaemia (Maxwell 1984; Pecorelli 2000; Winningham et al 1994). Chronic anaemia can result in severe organ damage affecting the cardiovascular system, immune system, lungs, kidneys and the central nervous system (Ludwig and Strasser 2001). This section will describe the literature relating to the symptoms of anaemia and its relationship with fatigue, followed by a summary of the impact of anaemia on the patient.

2.4.1 The symptoms of anaemia

In addition to physical symptoms, the subjective impact of cancer-related anaemia on quality of life, mental health and social activities may be substantial but there may be an assumption that all of these are the direct impact of the anaemia. However, one could argue that a cancer diagnosis and consequences of treatment would have the same impact without the presence of anaemia. There is evidence this is not the case as clinical studies have reported correlations between haemoglobin levels and quality of life (Cella 1997; Holzner et al 2002; Lind et al 2002). One of the common anaemia-related problems is fatigue, which impairs the patient's ability to perform normal daily activities (Ludwig and Strasser 2001; Vogelzang et al 1997), but again, it could be argued fatigue, occurs independently of anaemia and persists long after the anaemia has resolved, although it can worsen with anaemia.
Anaemia in cancer is associated with debilitating symptoms and poorer health-related quality of life (Smith and Tchekmedyian 2001; Tchekmedyian 2002). Severe symptoms may also result in dose reductions or delays of chemotherapy; a combination of these factors may lead to higher tumour burden and a decreased overall survival (Glaser et al 2001; Grau and Overgaard 2000; Knocke et al 1999). More recent evidence of these factors is described in the previous section. As mentioned previously, these observations generated the hypothesis that strategies to diminish cancer-related anaemia may alleviate fatigue and improve quality of life. When faced with a patient with fatigue and other debilitating symptoms it is not clear if clinicians and nurses respond to these somewhat subjective symptoms or if their decision making is based on a response to the haemoglobin level. This will be explored further in the section on clinical decision making (Section 2.7).

2.4.2 Anaemia and fatigue

Anaemia and its relationship to fatigue warrants further exploration because it has been demonstrated anaemia is associated with greater fatigue (Ahlberg et al 2003; Glaus 1998; Stone et al 2000a). Cancer-related fatigue is described as an abstract, multidimensional subjective experience, affecting 70 to 100% of the cancer patient population (Mock 2001). It has a profound effect on the whole person, physically, emotionally and mentally (Ahlberg et al 2003), and can persist for months or even years following completion of treatment. If fatigue is chronic it implies that transfusion may not be the ideal therapy as it only has transitory effect. Fatigue can have a phenomenal impact on a patient's life, interfering with daily activities (Curt et al 2000) and also may potentially have devastating social and economic consequences (Flechtnier and Bottomly 2002). Fatigue can hinder a patient's chance of remission or even cure, owing to the
effect it can have on the desire to continue with treatment (Morrow et al 2001). Indeed, fatigue is frequently reported to be the most bothersome symptom to the patient with cancer and is certainly a major quality of life issue (Bruera et al 1989; Cella 1997; 1998; Littlewood et al 2001; Morant 1996; Portenoy and Itri 1999; Sobrero et al 2001; Yellen et al 1997).

The reported prevalence of fatigue among cancer patients varies between 60-100% (Groopman and Itri 2000; Irvine et al 1994). The Stone et al study (2000) compared four groups of patients recently diagnosed with breast, prostate or inoperable non-small cell lung cancer or receiving inpatient palliative care, the two latter groups had a higher degree of fatigue than did the former two groups, suggesting factors other than anaemia are important. A significant correlation between disease burden and fatigue was also noted. Furthermore in a study of elderly patients with a new diagnosis of cancer (early vs. late stage), late stage was associated with greater fatigue and pain (Given et al 2001). Thus overall the results of these studies support the notion that tumour stage is associated with degree of fatigue but not necessarily with anaemia because of the large differences in incidence. In summary, fatigue may be a reflection of tumour bulk and disease progression and can be difficult to separate from symptoms of anaemia.

In addition, many patients who are not anaemic also report high levels of fatigue (Wang et al 2001) and there are many studies that report fatigue increases during radiotherapy (Hickok et al 1999; Janda et al 2000) and chemotherapy (Groopman and Itri 1999; Littlewood et al 2001; Richardson et al 1998) and long after therapy is complete (Wang et al 2001). The worsening fatigue scores as chemotherapy progressed were in the presence of stable haemoglobin scores in a phase III erythropoietin study (Littlewood et
suggesting that the chemotherapeutic effects were a stronger influence in the development of fatigue.

Cancer related fatigue is multifactorial with physical and psychological components (Ream and Richardson 1996) and the aetiology is not well understood (Cella et al 1997; Yellen et al 1997). Due to the complex nature of fatigue there is an ongoing debate on how to measure fatigue (Cella et al 1997; Groopman and Itri 2000). Most importantly, fatigue appears to be a symptom underestimated by oncologists. In a survey designed to characterize the epidemiology of cancer related fatigue from the patients', oncologists' and caregivers' perspective, 61% of the patients reported fatigue affected their daily life more than pain (Vogelzang et al 1997). Conversely, 37% of the oncologists reported that fatigue was a more prominent problem than pain. It may be further study is warranted because for some tumour types, for example, lymphoma and leukaemia, pain is generally not an issue. The assessment of fatigue would be an integral component of assessment of anaemia but other contributing factors such as disease stage and/or therapy should be considered and it is not clear if this is taken into account when making the decision to treat the anaemia.

Several studies have examined the impact of fatigue on daytime functioning, daytime sleepiness and altered circadian rhythms in the haematology population. Fatigue has been associated with sleep disturbances in patients with the following haematological malignancies; leukaemia, lymphoma and multiple myeloma (Lee et al 2004). Wang and colleagues (2002) studied a convenience sample of 246 patients with leukaemia or lymphoma. Single item scales were used to rate symptom severity from 0-10 and the most common complaint was “waking up during the night” (77%) followed by “not feeling
rested" (60%) and "waking up too early" (59%). Fatigue was related to sleep disturbances, pain, opioid use and gastrointestinal symptoms. Analysis of anaemia was not included in this study. Most interesting was the finding that fatigue was related to changes in sleep patterns rather than duration of the night's sleep; a finding that supports prior studies of persons with other types of cancer before, during and after radiation therapy (Smets et al 1998a; Smets et al 1998b). Bishop (2004) demonstrated increasing sleep disturbance and declining activity on an actigraph of a patient who was dying; this was progressive and independent of anaemia. Berger et al (2007) demonstrated sleep maintenance problems that contributed to fatigue prior to chemotherapy and moderate to severe fatigue after chemotherapy in 130 breast cancer patients using actigraphy. Andrykowski et al (1997) followed a heterogeneous population of 138 adults for 18 months post-transplant and found that fatigue and sleep problems did not greatly diminish over time. This is suggestive that disease status, treatment effects and sleep disturbance may be a more powerful influence on fatigue than anaemia; although blood laboratory values are not described in this latter study, it would be expected that blood counts would have normalized 18 months post therapy.

At the clinical level, however it appears the relationship between fatigue and anaemia is universally accepted and the majority of patients with a malignancy experience anaemia at some stage throughout the course of treatment or as a consequence of the disease itself (Sadler et al 2002). Although this relationship is accepted it is often not until haemoglobin levels are considerably low before fatigue becomes an issue because the body adapts to the lower concentration of haemoglobin and it may not be until the anaemia becomes severe that it impacts on fatigue. In fact, some studies failed to find any correlation between anaemia and fatigue (Bruera et al 1989) or poor association
only (Morant 1996). But because anaemia is one of the few contributing factors, which can be controlled by healthcare professionals it can become the main focus of concern and therefore it could be hypothesized that this would contribute to a tendency to over-transfuse. The Bruera study was of patients with advanced breast cancer and it may be other factors were more significant in this population; as described earlier. Although anaemia is involved in the pathogenesis of cancer-related fatigue perhaps its importance should not be overestimated. For example, a study of the correlates of fatigue amongst 227 assorted cancer patients an 98 controls revealed that although there was as significant association between fatigue severity and haematocrit the magnitude of the correlation was quite weak (R= -0.22, p<0.05, Stone et al 2000a). Equally weak correlations have been found between haematocrit and quality of life (Crawford et al 2002) and in another study of a mixed cancer population it was reported that anaemia could explain only 8% of the variation of fatigue scores (Lind et al 2002). In view of these studies perhaps anaemia may be a modest contributor to fatigue and a different approach to assessment is required to establish the impact of anaemia.

2.4.3 Summary of impact of anaemia
In summary, the presence of cancer-related anaemia probably decreases patients' quality of life, and may impact on fatigue (Demetri 2001; Glaspy 2001; Ludwig and Strasser 2001) and is associated with shorter survival times in some cancer patients (Caro et al 2001). It is difficult to separate the anaemia related fatigue and quality of life factors from cancer-related fatigue and the impact the cancer has on the quality of life, and this may explain in part why some of the studies have failed to show a correlation between anaemia (or haematocrit) and fatigue. This has implications for the assessment of anaemia which will be discussed in the following section. It would be
useful to replicate some of the erythropoietin studies to determine if using blood transfusion to increase the haemoglobin level to 12g/dl makes an impact in quality of life and function, however, the ethics involved would be difficult to resolve, for example to justify exposing patients to additional transfusion.

2.5 Assessment of cancer-related anaemia

It is reported that in order to establish the impact of anaemia, clinical evaluation should include history taking, physical examination and laboratory testing (Loney and Chernecky 2000; Smith and Tchekmedyian 2002); however, the significance of anaemia and fatigue to the patient are often overlooked in routine assessments and optimal methods for assessing and treating this remain unclear (Gillespie 2002). One of the contributing factors in this variation of assessment of anaemia could be that it is dependent on the patient's symptoms, however there is wide variation in the presentation of anaemia, and the clinical symptoms do not always correlate with haemoglobin concentration. It is not clear what the actual practice of assessment is within the clinical setting and although laboratory evidence is recommended it may be that this is not available at the time of consultation in some settings. It is also not clear who makes the final decisions or what the patients' involvement is in the decision making process. In summary, the manifestation and severity of anaemia vary considerably among individual patients and the patient - healthcare professional interactions and processes are not known which culminate in the final decision to treat with blood transfusion. There appears to be a lack of literature available exploring this process in depth, therefore the literature will be described in relation to assessment, the patients' assessments and the context of the assessment.
2.5.1 Assessing the impact of anaemia

It was demonstrated in section 2.2.1 the haemoglobin level is used to define anaemia and the degree of anaemia (mild, moderate, severe and life threatening). Many patients with chronic anaemia are apparently asymptomatic with a haemoglobin concentration of 8g/dl but when patients' symptoms have been formally evaluated using functional assessment, those with haemoglobin concentrations of 12g/dl reported less fatigue and a better quality of life (Cella 1997). However, chemotherapy and radiotherapy may confound the situation and the impact of anaemia in cancer patients may not be as clearly defined as this; for example, some chemotherapy regimens are known to induce more fatigue as described in section 2.2.3. Some would argue that if symptoms are searched for properly, they are present when the haemoglobin levels are less than 12g/dl (Smith and Tchekmedyian 2002), others would argue it is not until the levels are much lower and treatment is not indicated until the level falls below 8g/dl (Hill et al 2002). However it may not be this simple; it may be that symptoms of disease and side effects of therapy mimic the symptoms of anaemia and the Hill et al (2002) was a study of non-cancer patients. The level of haemoglobin at which the patient becomes symptomatic varies between individuals and reports in the literature are not consistent, therefore it may be that haemoglobin level is not a good indicator of the impact of the anaemia and therefore should not be the main influence in deciding to treat the anaemia, until low levels are reached or predicted, i.e. severe anaemia.

Identification of risk groups may also be important. The patients who are most at risk are those who present with anaemia at the point of diagnosis as well as those who are scheduled to receive platinum containing regimens (Bokemeyer 2005). Co-morbid conditions such as nutritional deficiencies and infection require identification and risk
factors and treatment history have also been identified (Gillespie 2003). For example cachexia has been identified as a cause of fatigue (Ahlberg et al 2003; Inui 1999; Kuzrock 2001) and may be induced by loss of nutrients as a result of anorexia, nausea and vomiting or hypermetabolism. The age of the patient, that is, older patients, and those who have a degree of cardiovascular or respiratory compromise may be more at risk of being unable to tolerate anaemia and the prevalence of both cancer and anaemia increases with age (Balducci 2007)

Although it has been demonstrated that cancer anaemia can lead to tissue hypoxia and can impact on virtually all organs of the body (Bokemeyer 2005; Ludwig and Strasser 2001) it is likely the awareness of the impact of anaemia (like fatigue) remains inconsistent among healthcare-providers and patients or it may be that in actual practice, these consequences of anaemia are not measurable or evident. The main reported clinical manifestations include fatigue, exertional dyspnoea, palpitations, dizziness, vertigo, depression, impaired cognitive function, nausea, anorexia, sleeping disorders and loss of libido (Foubert and Wujcik 2005; Ludwig and Fritz 1998). It could be argued that many of these symptoms could be directly attributed to the cancer and/or therapy, and do not occur until the anemia is severe. Of these signs and symptoms, fatigue is the most commonly reported symptom of cancer-related anaemia (Glaspy et al 1997) and symptom of cancer and cancer treatment with prevalence estimates ranging from 60-96% (Vogelzang et al 1997). In clinical practice it is likely that it is the mild (10g/dl-WNL) to moderate (8.0-10.0g/dl) anaemia which are therefore the most difficult to assess and the treatment decisions more variable. It could be argued that a more discerning assessment should be applied for this group of patients; or the patients themselves are involved in the decision making as they may be more likely to gauge the impact of the
anaemia. To a lesser degree it may be that patients with severe anaemia (6.5-7.9g/dl) may tolerate low levels of haemoglobin depending on other factors such as age, speed of onset and the presence of cardiovascular disease, but this is not always predictable. Patients with more life-threatening anaemia (<6.5g/dl) would likely require blood transfusion as a life-saving intervention in order to stabilize the cardiovascular and respiratory symptoms and unless for terminal care this decision is usually more easily defined. In summary, the assessment of the anaemia is inextricably linked to balancing the risks and benefits of blood transfusion and the clinical decision to treat the anaemia; this will be incorporated into the following sections.

2.5.2 The patients' assessment

Patients' subjective perceptions of how recent symptoms or changes have affected their lifestyle are important, especially as anaemia may present with gradual or vague complaints (Loney and Chernecky 2000). Changes in a patient's ability to carry out daily activities, to perform family and work roles and social activities can profoundly affect their quality of life, and these could potentially be assessed in the clinic setting. Many quality of life assessment tools are available but many can be burdensome for patients to complete (Foubert and Wujcik 2005). Of the many measures available only one is designed specifically for cancer anaemic patients, the Functional Assessment of Cancer Therapy-Anaemia (Appendix 1) or FACT-An (Cella 1997). The FACT-An subscale comprises the FACT-F subscale incorporating the FACT-General questionnaire (27 questions on four QOL dimensions: physical, functional, emotional and social well-being) with 13 additional fatigue-specific items and seven non-fatigue items (Cella 1997). The FACT-F subscale used alone or as part of the FACT-An questionnaire is a brief, validated and reliable assessment. These subscales successfully demonstrated an
association between fatigue and anaemia in a large survey of cancer patients in a community setting (Cella 1998). For this reason, FACT-An has been widely used in the anaemia literature examining quality of life. However, Oliva et al (2002) questioned the reliability and internal validity of FACT-An. They studied quality of life in 17 adult patients with anaemia secondary to myelodysplastic syndrome (MDS). Only the physical, functional and fatigue components of the questionnaire showed acceptable levels of internal consistency (Cronbach's standardized reliability coefficient alpha of 0.74, 0.9 and 0.83 respectively). Most importantly, the seven-item non-fatigue component of the anaemia subscale was not reliable in this group (alpha=0.57). It could be related to the fact this group of patients may not have undergone any chemotherapy for their MDS; however this was not clear in the paper. Olivo et al (2002) suggest the reported relationship between haemoglobin and quality of life may have stemmed from a change in transfusion use. This is also justified because the supportive care of transfusion itself acts on the self-perception of well being in a multi-dimensional context (e.g. understanding of the severity of anaemia, frequent day care admissions, an association with a worsening prognosis or fear of transfusion adverse events) and in such patients it may actually introduce confounding answers to each of the quality of life measurements. In other words it is possible that patients who reported increased quality of life simply because they received fewer, if any, transfusions.

Gabrilove et al (2001), in response to this criticism of the FACT-An, did a multivariate analysis comparing haemoglobin, QOL and visits to the hospital that resulted in either no transfusion or transfusion. Patients overall QOL scores during each visit were regressed with age, sex and haemoglobin as covariates. If transfusion was the mechanism through which haemoglobin affected QOL it should have been observed that a significant and
large coefficient on the haemoglobin variable among patients who received transfusion and a small and insignificant coefficient among patients who did not receive transfusion. However, this was not the case; the coefficients on the haemoglobin variables were similar in size and not statistically significantly different from each other. Similar results were observed for the activity and energy quality of life parameters. This suggests that either the FACT-An may not be a reliable and valid tool or more importantly suggests the minimal impact of transfusion on the quality of life parameters.

2.5.3 The context of the assessment

It is recommended in the literature that a full comprehensive assessment is important, however, the clinical context may be an important factor, as discussed more comprehensively later in section 2.7. In the clinical setting where time may be limited, Portenoy and Itri (1999) recommend asking three simple questions to assess the impact of fatigue severity over time, which includes asking the patient to rate their fatigue on a scale of one to ten and if it interferes with their ability to function. Changes over time are important because it has been demonstrated that symptoms can fluctuate during the course of chemotherapy (Richardson et al 1998). Payne (2002) indicated that fatigue fluctuated during the course for chemotherapy and continued after treatment ended. There have been similar findings in radiotherapy studies (Magnan and Mood 2003). The negative consequences of over-simplifying the clinical problem by asking questions only about fatigue may result in over-transfusion, because as described earlier the presence of anaemia is not the only factor resulting in fatigue. Other clinical contributing factors are relevant, for example, the stage of disease and where the patient is on their treatment pathway.
In summary, it has been suggested in the literature that a thorough assessment of anaemia should include laboratory parameters, physical symptoms and quality of life parameters (Foubert and Wujcik 2005) in addition to consideration where the patient is in their disease and treatment trajectory, but the reality may not reflect this. A number of assessment tools are available for the assessment of cancer-related anaemia but a number of these multi-dimensional tools are time consuming and burdensome for the patient to complete. In addition, there has been conflicting evidence of their reliability and validity. It may be that patient-clinician interaction should form the basis of the decision to treat, as long as the clinician has the appropriate skills and knowledge on which to base the decision. Time and resources are generally limited in busy oncology clinics and the patient-healthcare professional interaction may be the only activity, which will reliably continue. It could be suggested that current clinical practice may require a quick and easy to use, evidence based screening tool that can be properly evaluated and incorporated into the patient-healthcare professional consultation, however, it is unlikely such a tool could be developed, because of the variable and subjective nature of the impact of cancer related anaemia, therefore the focus should perhaps shift to the quality of patient-clinician interaction and relationship, the skills and knowledge of the workforce and changes in systems and behaviors. This has not been previously explored in anaemia research.

2.6 Risks and benefits of blood transfusion

Blood transfusion is the standard approach to the correction of anaemia, but carries significant risks including transfusion reactions, serious infections, iron overload and reduced immuno-competence (Littlewood et al 2001). Donor selection is becoming more stringent therefore should a real shortage of donors develop, patients receiving
blood for less certain indications, such as mild or moderate cancer related anaemia may be the first to be rationed. However, more importantly, any unnecessary risks to patients should be avoided, particularly if there is little proven benefit. Alternatively, if some patients benefit from blood transfusion then it is equally important that these patients should not be rationed. The level at which the benefits of blood transfusion outweigh the risks is a matter of continued debate and uncertainty which warranted exploration of the current literature review.

If a patient has no obvious symptoms of anaemia he/she is usually transfused when their haemoglobin is less than 8.0g/dl. This is a “pragmatic” guideline suggested by the British Society of Haematology (BCSH 2001); however, as stated previously, the BSCH state that randomised controlled trials for evidence-based guidelines for the transfusion of blood have yet to be undertaken (BCSH 2001). In addition, there is considerable variation in transfusion practice between different countries and even within different departments, (Foubert and Wujcik 2005) in spite of the presence of clinical guidelines (Barrett-Lee et al 2000). The NHS transfusion guidelines recommend that if the haemoglobin is between 7-10g/dl the decision to transfuse should be based on the clinical condition of the patient (NHS Executive 2006) and this may account for some of the variation in practice. Blood transfusion guidelines and mandatory transfusion education are available in all hospital settings, but optimal transfusion practices may not exist and the reasons for this are complex. Healthcare professionals may weigh the levels of evidence and symptoms differently, for example, and patients may be transfused on the basis of laboratory values rather than full assessment of the impact of cancer-related anaemia balanced against the risks of transfusion. This decision to treat may be related to their levels of skills and knowledge regarding the assessment of
cancer-related anaemia and transfusion practice; or it may be influenced by the availability of resources or patient pressure. Ritualistic practices may exist for example, a national audit revealed 88% of transfusions were two-unit transfusions (Barrett-Lee et al. 2000), which suggests the treatment is not tailored to the individual.

This section will explore the literature in relation to the risks and costs of blood transfusion, studies that have examined the effects of different transfusion thresholds and the benefits of transfusion.

### 2.6.1 The risks and cost of blood transfusion

As stated previously, new pathogens, such as vCJD, may result in the shrinking of the donor pool and if the supply reduces further, it may result in more scarce resources (i.e. blood components) having to be used more carefully (Thomas 2005). Costs are escalating as collection, testing, processing and administration and safety systems become more complex in preparing the final blood transfusion component (Varney and Guest 2003); the NHS cost for an adult transfusion is estimated at £185 but estimated to be £635 for red blood cells, when hospital stay, management of complications and cost to society were included (Varney and Guest 2003). Using this cost as a guide within cancer care this equates to approximately £320 million per annum spend on blood transfusion within the UK. Drug costs are subject to scrutiny in healthcare settings yet it is unclear if cost is a consideration when deciding to treat anaemia with blood transfusion.

Potential complications associated with blood transfusion are transmission of infectious diseases, transfusion reactions and allo-immunisation, over transfusion and immune
modulation with possible adverse effects on tumour growth (Landers 1996). Other complications such as allergic reactions and death due to major incompatibilities are also of concern. The risks of transfusion-related transmissions are 1:180,000 per units of blood transfused for hepatitis B virus, 1:1,600,000 for hepatitis C virus and 1:1,900,000 for HIV in the US (Goodnough 2003). The development of intensified anti-cancer therapies has increased the risk of blood transfusion (Bohlius et al 2006) and the use of growth factors such as GCSF (Granulocyte Colony Stimulating Factor) means that dose reductions due to neutropenia can be avoided because red cells and platelets can be supported with transfusion. Moreover, with improved survival and the use of more intensive chemotherapy regimes, the requirement for blood transfusions has increased while the donor supply has diminished (Williamson et al 1999).

Historically, there has been a fascination with blood (Thomas 2005), and a number of beliefs about the nature and function of blood have been described in Helman (1990); for example it provides lay theories about a variety of illnesses including "thin blood" causing anaemia (p26). Helman describes how the clinician should be aware of the "possible hidden symbolism in any lay conceptualizations about blood" (p26); in today's western world it is associated with transmission of infection and it is not clear what the impact of this is. Conversely blood transfusion may historically be perceived as life saving as it is a well established therapy, for example it was in 1946 that the National Blood Transfusion Service was founded and blood was routinely used as a life saving therapy. These represent opposing views; firstly that blood may cause harm in the form of a transfusion transmitted infection and secondly it may be life saving. It is not clear how individual clinicians and patients perceive the risks balanced against the benefit.
Unlike many other countries, the donation of blood in the UK is entirely voluntary and for this reason it may be viewed as an inexpensive resource. Furthermore, because of the historical use of blood it may also be seen as a natural product, a good product that saves lives, and it may be that many healthcare professionals are unaware of the amount of processing that the final product has been subjected to, and the real cost of blood transfusion.

It is only in more recent years that blood transfusion has been recognised as carrying significant risk. For example, the advent of Serious Hazards of Transfusion (SHOT) reporting and mandatory training highlight the risks; however, neither of these systems emphasise the need to avoid the transfusion in the first instance. In addition, the transference of life threatening viruses, such as HIV and more recently vCJD, via transfusion has also increased the awareness that transfusion is not without risk and perhaps patients, clinicians and nurses are more reluctant to want to transfuse because of this. Since the high profile infection risks, the price of blood transfusion has risen and new regulations have been introduced. Actions against negligence and consumer protection legislation have led to implementation of further safety initiatives such as mandatory training. Furthermore the number of people willing to donate is declining and is compounded by increasingly strict donor eligibility criteria (Ferriman 1998; Simon 2003; Sullivan et al 2007). This could all result in a tendency to under-transfuse to minimise risk and exposure to unknown pathogens. Patients and the public may perceive transfusion as a risky medical procedure (Lowe and Ferguson 2003) and not surprisingly, there is a negative association between perceived risk and acceptability (Ferguson et al 2005). Conversely Ferguson et al (2005) demonstrated in a questionnaire survey of the general public that blood substitutes are also perceived as
risky and in fact have more risks than donor blood which implies that patients still perceive blood to be a relatively safe product. It is not known how cancer patients perceive blood transfusion and if they perceive it is essential or if they believe there are alternatives to transfusion. Lee (2006) describes how surveys of lay people over the last decade indicate that public concern about transfusion safety has remained prevalent, dominated by the fear of contracting HIV. It may be that patients do not offer a true reflection of symptoms in an effort to avoid transfusion or believe blood transfusion is desirable in an effort to reduce symptoms, especially fatigue.

2.6.2 Transfusion thresholds

Transfusion thresholds (or triggers) have reduced over the years with the drive to conserve blood and reduce costs. This has been successful in some clinical areas for example the use of per-operative blood transfusion. There has been little evidence to support the growing trend for the conservative approach in the management of anaemia however there have been some studies in the acute setting. A pilot study of 84 patients with hip fractures used physical activity as a measure of the adequacy of post-operative haemoglobin concentration (Carson et al 1998). No difference was found between patients who received transfusions to maintain the haemoglobin above 10g/dl and patients who received transfusions when they were symptomatic or when their haemoglobin concentration fell below 8g/dl. However, it is difficult to transfer these findings to a cancer population for several reasons because the pathophysiology of cancer-related anaemia is more complex and the treatment may require more than simple replacement. The erythropoiesis in this surgical cohort would be normal therefore the body’s natural replacement of red cells would be normal. Furthermore, the study was on carried out whilst these patients were inpatients where activity is limited,
whilst the oncology outpatient population are attempting to have a "normal" life and undertake some activities of living.

The Carson study was one of the ten randomized controlled trials summarized in a Cochrane review of studies examining transfusion thresholds and the effects on clinical outcomes (Hill et al. 2002). All of the studies examined surgical, trauma or intensive care patients and no study had been carried out during the outpatient period. Johnson et al. (1992) found no difference in exercise endurance in liberally transfused Coronary Artery Bypass Graft (CABG) patients and in those who had been conservatively managed. Bracey et al. (1999) applied a self-assessment tool to determine if similar patients who followed a restrictive transfusion protocol, felt fatigued and therefore were less willing to undergo rehabilitation; they found no difference in vigor in these patients compared with those who followed a liberal transfusion protocol. The review concluded that the limited published evidence supports the use of restrictive transfusion triggers in patients who are free of cardiac disease; however, they recommended that future trials should be carried out to discover the effects of conservative transfusion triggers on functional status. They concluded that the trials were of poor quality but also recommended research should be carried out in different patient populations.

2.6.3 Benefits of transfusion

The management of anaemia in cancer is frequently aimed at improving fatigue levels and this could technically be described as a main benefit of the transfusion. Despite the prevalence and impact of cancer related fatigue there is limited data available with regards to the precise aetiology, pattern over time and exacerbating and relieving factors for fatigue (Fletchner and Bottomly 2002). This complicates the development of effective
management interventions, including blood transfusion (Dimeo 2002). The aetiology of the fatigue pathway remains to be fully established and a number of causes have been suggested, such as, the effect of tumour and cancer treatment, co-morbid medical conditions including anaemia, hypothyroidism, cytokines, sleep problems, psychological factors such as anxiety and depression and loss of functional status (Lucia et al. 2003; Mustian et al. 2007; Wagner and Cella 2004). The cause of fatigue may also differ between individuals as well as according to the phase of the disease and the type of treatment received (Ryan et al. 2007) and in summary is highly individualized and multifactorial as described in section 2.4.2. In an attempt to improve management of cancer related fatigue the National Comprehensive Cancer Network (NCCN 2005) has developed guidelines. Initially any treatable factors that may cause fatigue should be identified and treated. The panel identified seven factors; pain, emotional distress, sleep disturbance, anaemia, nutrition, activity level and co-morbidities. If the patient does not have any treatable contributing factors or cancer related fatigue persists, then additional treatment is recommended depending on the patient's clinical status. This incorporates education and counseling, general strategies for the management of fatigue, pharmacological and non-pharmacological interventions. In line with these guidelines the role of non-pharmacological interventions in the management of fatigue is supported by Mustian et al. (2007) and colleagues who have identified psychosocial therapies, physical exercise, and a range of other interventions as potentially beneficial. These factors make it difficult for the clinical teams to manage fatigue and the presence of anaemia may offer to the clinician a potential solution of management; in that the clinician may offer a transfusion when faced with a fatigued patient. This would have a perceived benefit of relieving fatigue and of some importance may be the fact that it is a relatively quick and simple solution as opposed to other fatigue management strategies.
described. Equally, as there are not many solutions to fatigue and the symptom is exacerbated by chemotherapy and radiotherapy; it may be tempting to offer transfusion as a strategy. Again, this may result in over-transfusion practices and is related to the process of clinical decision making. It is not clear from the current research available if clinicians transfuse patients in an attempt to lessen fatigue and other symptoms.

2.6.4 Consequences of withholding transfusion

Over the years the threshold has gradually declined form 10g/dl to 8 g/dl with little evidence and no risk reports, as described earlier in the researcher's own clinical practice. The reality may be that the restrictive guideline is only adhered to in selected clinical settings or situations. This rigid numerical trigger ignores individual patient factors and the underlying pathophysiological consequences determining each patient's individual tissue oxygen demands as described in section 2.2. Some of the literature relating to non-malignant anaemia reports that a thorough knowledge of oxygen transport and the physiology of anaemia are still considered to be the most important factor in guiding decisions on transfusion (Hébert et al 2004; Madjdpour and Spahn 2005) but this is difficult to assess in this clinical setting. Adaptive responses to a decrease in haemoglobin concentration include blood flow alterations to central organs and a shift in the oxy-haemoglobin dissociation curve thereby allowing more oxygen to be released to the tissues (Morisaki and Slbbald 2004). The body is therefore capable of adapting and some patients can function to near normal levels with haemoglobin levels of 7g/dl. “Whole body oxygen delivery (DO₂) is the product of blood flow or cardiac output and arterial oxygen content” (Madjdpour and Spahn 2005; p33). The rationale for giving blood should be to increase arterial oxygen content as well as volume thereby increasing DO₂ which essentially restores adequate tissue oxygenation.
Hébert et al (2004) identified 18 studies examining blood transfusion on oxygenation variables. All studies showed a significant increase in haemoglobin but four of them showed no increase in DO\textsuperscript{a} and of the fourteen that did show an increase in DO\textsuperscript{a}, only five showed a parallel increase in physically dissolved oxygen. The lack of increase in oxygen consumption could be explained by lack of oxygen debt (lack of oxygen in the tissues) prior to transfusion (Madjdpour and Spahn 2005). Earlier studies showed that in the presence of oxygen debt and tissue hypoxia there was a concomitant increase in oxygen uptake following blood transfusion (Fitzgerald et al 1997). Madjdpour and Spahn (2005) surmise that there are factors that are likely to predict if a patient will respond to blood transfusion, but it would appear that in clinical practice it would be impossible to know which patients had adapted to the anaemia and which of those had oxygen debt.

Casutt et al (1999) examined 170 blood transfusions in 67 anaemic cardiac patients and took measurements five hours before and after transfusion. They found pre-transfusion haemoglobin; preoperative ejection fraction and age were unrelated to individual responses in cardiac index, DO\textsuperscript{a} and increase in physically dissolved oxygen. Spahn (1999) argues that impaired functionality of stored blood could be a cause of the lack of increase in dissolved oxygen. Earlier studies suggested that “old blood” (blood stored for more than 25 days) may be less effective transporters of oxygen (Offner 2004), and some studies have shown that “old blood” has a negative effect on incidence of infection (Marik and Sibbald 1993; Vamvakis 2002) however, more recent reviews have concluded that current evidence on the effect of storage duration of red cells is insufficient and that additional trials are necessary to define the role of age of cells on outcome (Ho et al 2003; Napolitano and Corwin 2004).
A more recent study tested the hypothesis that serious complications and mortality after cardiac surgery are increased when transfused red cells are stored for more than 2 weeks (Koch et al 2008). Data was examined from patients given blood transfusions during heart surgery. A total of 2,872 patients received 8,802 units of blood that had been stored for 14 days or less ("newer blood") and 3,130 patients received 10,782 units of blood that had been stored for more than 14 days ("older blood"). The median duration of storage was 11 days for newer blood and 20 days for older blood. They found that patients who were given older units had higher rates of in-hospital mortality (2.8% vs. 1.7%, P=0.003), incubation beyond 72 hours (7% vs. 5.6%, P=0.001), kidney failure (2.7% vs.1.6%, P=0.003), and sepsis or septicemia (4.0% vs. 2.8%, P=0.01). The composite of complications was more common in patients given older blood (25.9% vs. 22.4%, P=0.001) and "older" blood was associated with an increase in the risk-adjusted rate of the composite outcomes (P=0.03). At one year, mortality was significantly less in the patients given newer blood (7.4% vs. 11.0% P<0.001). These studies have yet to be replicated in the oncology setting but imply there may be further risks of transfusion, particularly if "old blood" is transfused.

In summary, what these studies may imply is that there is a unique response to transfusion, which may have a physiological basis and is dependent on a degree of oxygen debt or may be related to factors in the donated blood itself. There would be no way of predicting this in the clinical setting therefore other factors would have to be relied on to make an assessment of the impact of anaemia and the decision that blood would be safe to administer in balancing the benefits over the risk. It may also be that unique factors in the blood product itself may determine the degree of benefit (i.e. the response)
to blood and that again this would not be possible to predict or more importantly in the later studies that there may be deleterious effects of the "older" blood transfusion and these are not currently considered in practice. The age of the blood product is not considered when issued for a cancer patient; many of whom may be severely immuno-compromised whilst having a transfusion.

2.6.5 Summary
There may be an assumption that transfusion will improve quality of life, similar to what has been shown by erythropoietin administration. Allogeneic blood transfusion may not give the benefits of intrinsic haemoglobin and carries additional risk, but currently erythropoietin is only recommended in selected situations (e.g. ovarian cancer with Hb 8-10g/dl receiving platinum based therapy) by NICE; therefore transfusion remains the option for NHS patients for the treatment of cancer-related anaemia (NICE 2008). The prevalence of mild to moderate anaemia and the potential clinical and functional impact on patients make it important to have a systematic approach to the diagnosis and treatment of anaemia. However there is widespread variation of transfusion practice and limited understanding of the decision to treat cancer-related anaemia.

In summary, many of the assumed benefits of allogeneic blood transfusion therapy are questioned and the potential hazards of transfusion may have been underestimated. Recent evidence suggests that in many clinical settings there are significant under-recognised hazards of transfusion and it may be detrimental to the patient to support higher haemoglobin levels. Blood transfusion should perhaps not be the default therapeutic decision when evidence for efficacy is lacking and there is clinical uncertainty as in the case of moderate or mild anaemia. It should be a carefully considered decision
with the risks and benefits considered in each unique clinical episode. Isbister (2007, p10) donated allogeneic blood should only be used as therapy when:

- There is evidence of potential benefit
- There are no alternatives
- A quality product is available
- The risks are appropriately considered and balanced against the benefits

It is clear that in NHS settings there is no alternative to blood transfusion (except for NICE criteria 2008) but it is unlikely that there is assurance of complete safety, absolute benefit and consideration of risks and benefits in blood transfusion practice. In this context the clinical decision to give blood appears to be complicated, but the practice may not reflect this complexity. For example, it is not known in the clinical setting if healthcare professionals consider the risks of transfusion when making the clinical decision to transfuse. It also begins to raise questions about what skills and knowledge are required to make these decisions; how are these learned in practice, and who is best placed to make the decisions?

2.7 Clinical Decision Making

It is difficult to know which healthcare professional group is best placed to assess the impact of anaemia. Nurses' roles have been extended to include prescribing and the next step would be for nurses to prescribe blood (Piri and Green 2008); in addition as blood transfusion is not a drug it is not subjected to the same prescribing controls as medicines (Blood Safety and Quality Regulations 1995). It could be argued oncology and/or haematology nurses can play a key role in the assessment of cancer related
anaemia through their frequency of contact with patients during clinic, day care visits, telephone conversations and the ensuing relationship. The day unit nurses may have a wealth of experience through repeated exposure to patients receiving transfusions in the day care units. Alternatively, the healthcare professional with the greatest skills and knowledge of cancer related anaemia may be the most appropriate to assess anaemia and it could be assumed this is physicians; however it may also be important the healthcare professional has expert decision making skills. It has been previously described in the literature review that it may be difficult to assess cancer related anaemia and that some uncertainty may exist; therefore expert clinical decision making skills may be necessary to reduce the uncertainty. This section explores the literature to see how clinical decisions are made; what influences thought processes (cognition) and therefore decision making and finally a summary of relevant cognitive theories. The last section is important because this study is an attempt to understand this process in the clinical setting.

2.7.1 Making a diagnosis; expertise and decision making

Experienced clinicians use a variety of methods of arriving at a diagnosis, depending on their familiarity with the clinical problem (Table 2.7.2). Difficult and unfamiliar problems require the slower full systematic history and examination methods, while the familiar well-encountered problems are quickly diagnosed with pattern recognition. Novices soon discover that more information is derived from the history than the examination (Del Mar et al. 2006). This implies familiarity with the patient may improve outcome in addition to improving "pattern recognition" assessment and decision making. It is sometimes described as a subconscious or intuitive process (Norman et al. 1992) and can be difficult for clinicians to articulate how the diagnosis is achieved. According to Del Mar et al.
(2006) investigations should be used to confirm or exclude a diagnosis, however, it is not clear in the assessment and treatment of cancer related anaemia if this is the case.

Table 2.7.1 Different cognitive models to arrive at a diagnosis (Del Mar et al 2006, p14)

<table>
<thead>
<tr>
<th>Type of cognitive process</th>
<th>Characteristics</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full systematic history and examination</td>
<td>Slow: exhaustive-minimizes the forgetting of important possibilities</td>
<td>New patient with suspected cancer</td>
</tr>
<tr>
<td>Hypothetico-deductive reasoning</td>
<td>Faster: concentrates the gathering of information into provisional diagnoses generated very early, raising new possibilities readily</td>
<td>Surgeons’ diagnosis of acute abdominal pain</td>
</tr>
<tr>
<td>Pattern recognition</td>
<td>Fastest: relies on experience. Less helpful for problems not encountered before, or remembered</td>
<td>Spot diagnosis of mumps</td>
</tr>
</tbody>
</table>

Hypothetico-deductive reasoning (analytical thinking) is used when faced with a more challenging diagnosis. Anaemia may be more difficult to diagnose when complicated by symptoms of disease and/or treatment. Each piece of information gathered either increases or decreases the hypothesized diagnosis as the clinician considers several
possible diagnoses. Clinicians attempt to match the presentation within their internal “schema” (Coderre et al 2003). Information gathering is an important part of achieving an accurate diagnosis but there is a risk that too much emphasis is placed on pieces of evidence, for example, laboratory values or if the patient has too many problems at once (Del Mar et al 2006). Evidence also shows that there can be an error in the clinicians’ knowledge base which can cause them to focus on a sign or symptom that is not able to accurately validate a diagnosis (Gruppen et al 1999).

Typically, arriving at a diagnosis involves taking a history, physical examination and then using investigations to confirm or exclude a diagnosis. Generally, evidence has shown the more experienced clinicians use the history as a means to diagnose with the examination and systems review to confirm the diagnosis, i.e. it is the conversations that reveal the most information (Del Mar et al 2006; Hampton et al 1975; Hoffbrand 1989). This process however is poorly understood and has not been explored in the clinical assessment and decision making in the cancer related anaemia and if there are other influences in the clinical setting.

2.7.2 Context of the decision

Studies evaluating relationships between physician background characteristics (e.g. years of practice and medical training) and quality of care have found few consistent associations in decision making (Wigton et al 1999). One possibility is the task is too complex or there is too much uncertainty, therefore different decisions are made. Clinical judgments and decisions are not isolated cognitive events and they can only be meaningfully conceptualized in relation to the task; and that task will occur within a unique clinical context (Dowie and Elstein 1999). Clinical cognitive theory acknowledges
this to some extent but clinicians (nurses and doctors) operate in particular clinical settings and wider social contexts and these influence to varying degrees, depending on the unique culture or the nature of the task. Dowie and Elstein (1999) develop the argument further to explore the effects of the economic context and the scarcity of resources; the ethical and legal context which is the influence of the ethical codes of consideration of the "social" or "common good"(p34) and the professional context which is about the risk of errors and accusations of negligence. In other words, the clinicians' decisions may be influenced by resource availability, or for example, in the palliative care setting a clinician may continue to transfuse a patient because of the ethical dilemma of withdrawing supportive blood transfusion. Decision-making therefore can be affected by the severity of the potential outcomes in comparison to the anticipated regret for different pathways not taken (Col et al 1997) e.g. a healthcare professional might be more likely to transfuse a patient because he/she considers the risks of anaemia to be greater and more worrying than the risks of transfusion. The ethical issues are also powerful influences in blood transfusion for example, it is difficult to withdraw blood transfusion in the palliative care setting if the patient has had blood transfusion support throughout active therapy period (Stone et al 2000b); and as mentioned previously the availability of resources may influence the decision to transfuse.

Site of practice (area of clinical practice; the institution; place of work) variables have been better predictors of quality than have characteristics of individual physicians. A study by Salem-Schatz et al (1999) explored the relationship between physicians' knowledge and attitudes regarding the use of blood products, and the quality of their transfusion practice, based on in depth physician interviews and medical record reviews. The sample included 296 transfusion episodes ordered by 17 physicians in 2 teaching
hospitals. The quality of transfusion practice was defined as the proportion of a physician's transfusion episodes scored as justified, as determined by explicit chart audit plus implicit physician review. Large baseline differences were observed between the two hospitals; 48% of transfusions in Hospital A were justified compared with 81% in Hospital B. At the physician level, knowledge of transfusion indications and receptivity to input from colleagues were significantly associated with higher quality transfusion practice (p = 0.01 and p = 0.02 respectively). These findings suggest that in addition to organizational context, physician characteristics may be associated with the quality of care related to a specific clinical practice and the degree to which others are involved in the final decision to transfuse. This was a quantitative study using questionnaires and retrospective casenote analysis but did not explore the detail of the processes and discussions that occurred culminating in the diagnosis of cancer related anaemia and the decision to transfuse.

When there is uncertainty about the management of a problem, or when it appears there is variation of practice, generally evidence based guidelines are employed to facilitate management and improve the skills and knowledge of the healthcare professionals, with other drivers being to reduce costs and improve safety. Most of the safety initiatives about transfusion are driven by national policy and mandatory “Serious Hazards of Transfusion (SHOT) reporting Williamson et al (1999). The practice of transfusion fulfills all of these criteria. The best form of these guidelines incorporates all the current evidence and explicitly states the potential harms and benefits of treatments. Some evidence is available on the management of cancer related anaemia but it is a naïve assumption that when research evidence is made available it is accessed by practitioners, appraised and then applied in practice via clinical practice guidelines (NHS
Executive 1996). In addition, despite the growth of clinical practice guidelines, their actual value is infrequently assessed through formal evaluation procedures (Carter 1996).

Control of transfusion practice is attempted by the production and implementation of transfusion protocols and/or guidelines and mandatory transfusion education; these are practiced in all hospital settings, but optimal transfusion practices may not exist and the reasons for this may be more complex than anticipated (Brunskill et al 2008). Brunskill et al (2008) summarise by stating:

"A better understanding of and more investment in implementation research should be a priority for transfusion given the background of the high costs of blood, the scarcity of blood as a resource and the risks associated with transfusion. Initial work on improving our knowledge on the different influences on transfusion prescribing behaviour is important and would feed directly into any studies designed to explore different interventions for practice change" (p15).

In summary, guidelines cannot incorporate all the factors that may be important to a patient or clinician in making a decision, such as the clinical context of that decision, the social interactions between the patients and the clinicians or how transfusion practice is learned within the organization; and this may be why guidelines do not always result in the desired outcome which is control of the practice. The first steps may be to explore further the influences on the decision and from there develop any change required to develop future practice.
In summary there are a multitude of influences on clinical decision making in the clinical setting; increased workload, lack of time, poor communication and traditional working practices may all contribute to less than optimal decision making practices (Firth-Cozens 1997) and it may be the context of the decision that is paramount. More subtle influences are the effects of resource availability; ethical considerations and professional codes of conduct. The following section describes some theories of cognition from the literature that attempt to incorporate the context of the decision.

2.7.3 Cognitive theory

Section 2.7.1 introduced some of the types of thinking that are used, describing intuition and analysis in relation to experience of the clinician; section 2.7.2 showed there are both external and internal influences on how decisions are made. This section describes how some researchers have developed theories of cognition to explain how the real world influences decision making. Hammond et al (1980) defined intuitive thought as rapid, unconscious data processing achieved by combining available information and averaging it; he describes intuitive thought as having low consistency and only moderately accurate. Analysis is at the other end of what he describes as the cognitive continuum and has the opposite features in being slow, conscious and consistent. He describes intuitive and analytical thinking as poles of a continuum because most thinking is a combination of both. However, the task is also on a continuum; in cognitive continuum theory, tasks are considered to occupy a position ranging from analysis inducing to intuition inducing, indicated by task features that influence the model of cognition that the thinker will adopt. These include:

- The complexity of the task (e.g. number of pertinent cues will increase use of intuitive thinking)
- The ambiguity of the content of the task (e.g. unfamiliarity induces intuition; high accuracy requirement induces analysis)
- The form of task presentation (e.g. if sub-tasks are required analysis is induced; time constraints will induce intuition) (Hammond et al. 1980; 1986)

Hamm (1999) also describes how the ability of a task feature to induce a mode of cognition also depends on what the thinker knows; therefore the knowledge of the decision maker influences the final decision. Dreyfus and Dreyfus (1986) took this further and developed a theory of expert cognition and described five stages that one must go through to be an expert (novice; advanced beginner; competent; proficient and expert). The novice must think analytically to perform; the advanced beginner has learned to perceive intuitively but must still apply rules; the competent person exercises both perception and action components of the skill intuitively but the proficient person perceives the whole situation intuitively but makes decisions analytically and finally the expert makes these decisions intuitively as well. The Dreyfus theory emphasises the relationship of thinking with experience and the Hammond Cognitive Continuum Theory emphasis that the task dictates the type of thinking used. Hamm (1999) describes how performance is likely to be the most accurate when the clinician's mode is appropriate to his/her level of experience, for each level of task. "Together the two theories provide an explanation for variations in cognition on different tasks at different stages in career" (Hamm 1999; p101); these may prove useful when analyzing how clinicians make their decisions regarding blood transfusion as the nature and context of the task may be as important as the experience of the clinician (nurse/doctor).
2.8 Social interactionism and the development of culture

The previous section described the influences on clinical decision making but described how the decisions are not made in isolation, therefore the interactions and relationships between clinicians and patients warrant further investigation. It is the behaviours in a setting that shape the clinical culture. Culture refers to "the shared patterns of group behaviour acquired through intergenerational learning; knowledge and behaviour shared by a group" (Winkelman 2009, p430) and in the context of this study it refers to the transfusion behaviours in the different clinical settings. All societies, including clinical settings, have characteristics that endure over time despite the individuals changing within that society; and it was of interest to the researcher if transfusion practices endured because of characteristics of the clinical setting to determine if this was an influence on clinical practice. The sections that follow will describe the literature in relation to the development of clinical cultures and how the interactions between individuals within the culture are significant in shaping behaviours. The importance of the social interactionism justifies the argument for using an interpretive ethnographic methodology, whereby meaning is interpreted from the social interactions between the individuals; the methodology of the study will be described in more detail in Chapter 3.

2.8.1 Social interactionism

Earlier in the literature review it was described how clinical decisions can be made (2.7); it was also described how the task and the experience of the clinician can influence the decisions but learning and thinking does not occur in isolation. Atkinson (1995) describes how decision making can be a collective organisational activity and is frequently undertaken in complex organisational settings (not just clinics or hospitals). Decisions may be subject to debate and question, therefore the individual characteristics...
as described in the earlier section on clinical decision making is by no means the whole story. Atkinson describes this as "Clinical decision making is not the outcome of individual minds, operating in a social vacuum" (p54). This implies clinical practice and the quality of decision making as discussed in section 2.7 may be related to more social, interactional and situational factors.

Giddens (2008) describes the process whereby societies have "structural continuity over time" (p163), which perpetuates values, norms and social practices. He describes how socialization is the process whereby an individual gradually becomes knowledgeable and skilled in the ways of the culture in which they exist. If this is translated to the clinical setting, it may be that some of the traditional transfusion behaviours are a result of socialization in practice; the clinician may become knowledgeable and skilled in transfusion because of what is learned through interactions with others, and not merely by undertaking education and training. Equally the patient may become socialized into the behaviours of being a patient within the unique clinical setting.

The interactions therefore between individuals are important and it was described in section 2.7 how decision making is not made in isolation; interactions between individuals take place through symbols and the interpretation of meanings and is described as "symbolic interactionism" (Giddens 2008; p107). Giddens further states:

"Symbolic interactionism stresses the exchange of symbols between individuals in social interaction. Unlike other theories, symbolic interactionism emphasizes the small-scale interactions of individuals, not society as a whole" (p26).
The basic principles of symbolic interactionism can therefore be summarised as follows:

- Human beings possess the capacity for thought which is shaped by the social interaction
- People learn meanings and symbols through social interaction
- People are able to modify or alter the meanings and symbols they use in interactions by interpreting the situations they are in (Baert 2004)

Symbolic interactionism, especially the work of George Herbert Mead (1863-1931) traces its roots back to pragmatism in philosophy with other influences from Georg Simmel (1858-1918) and GHF Hegel (1770-1831) (Baert 2004). Mead developed three important themes: firstly a focus on the interaction between actors and the social world; secondly view that the actors and the social world are dynamic and thirdly the centrality of actors to interpret the social world. Mead recognised the importance of observable behaviours but also stressed the importance of covert behaviours. Alternatively, Erving Goffman (1922-1982) described this as “dramaturgy”, which is a view of social life as a series of dramatic performances, but like Mead implies that the self is not always revealed. Goffman also described how the self is shaped by the dramatic interactions between social actors and their audiences. The basic unit of analysis in Goffman’s work is “the team” and how the members of the team use impression management to maintain a particular image of themselves when interacting with others. According to Goffman these “fronts” tend to become institutionalised and are therefore selected rather than created; he was interested in “encounters” that is face to face interactions where people are constantly in the presence of others. In summary, both Mead and Goffman portray a dynamic self, actively intervening in the world and like Mead, Goffman emphasised the
extent to which people are reflexive beings, by being able to monitor their actions and therefore having the ability to manipulate their surroundings.

In this context, it is the "clinician-clinician" and "patient – clinician" interactions which form part of the area of study, for example, how is anaemia explained and what does it mean or how is the haemoglobin used to define anaemia. To the members of all societies, the human body is more than just a physical being; it is also the focus of a set of beliefs about its social and psychological significance, its structure and function. Therefore anaemia may have different meanings for individuals and transfusion practice may be influenced by individual and group beliefs. Although social behaviour is guided to some extent by the forces such as roles, norms or shared expectation, individuals perceive reality differently according to their backgrounds, interests and motivations. Giddens describes how individuals shape reality through the decisions and actions they take, in other words, "reality is not fixed or static, it is created through human interactions [ ] it is a social construction of reality" (p130). Studying social interaction in everyday life by using ethnographic methodology sheds light on larger social systems and institutions, justifying its use in this study, as this is a study and analysis of everyday behaviour in situations of face to face interaction; it is described as a form of study of micro-sociology (a study of face to face interactions). Therefore the interactionist theorist views individuals as active and creative participants who construct their social world, not as passive conforming objects of socialization.

2.8.2 Cultural knowledge

Cultural knowledge plays a key role in most work based practices and activities (Eraut and Hirsh 2007). Much of the discrete cultural knowledge is acquired informally through
participation in working practices and much of this is unconscious and clinicians may be unaware of the influence on their behaviour; "It is implicit learning normally associated with the concept of socialization" (Eraut and Hirsh 2007; p5). Eraut (1997; 1998) describes this socialized knowledge as "personal knowledge and capability" and is defined as "what individual persons bring to situations that enable them to think, interact and perform" (p128). It incorporates knowledge; skills and practices; personal understanding of people and situations; accumulated memories and episodic events (Eraut 2000; 2004) and other aspects of expertise; practical wisdom and self knowledge, attitudes, values and emotions. The evidence of personal knowledge mainly comes from observations and this implies a holistic rather than fragmented approach to knowledge and links to symbolic interactionism in that the individual is active in the learning. It also implies the influence of the culture on learning and behaviours; it is currently not clear if these cultural factors influence cancer related anaemia practice and if these influence transfusion behaviours. By using an ethnographic methodology to study the social interactions and processes and individual characteristics such as knowledge, skills and attitudes a social construction of transfusion practice could be developed; a creation of the social interaction of individuals and the group. It could be argued that transfusion practice is common sense knowledge and Luckman and Berger (1966) in their study of the social construction of reality, describe this type of knowledge as those things that individuals take for granted. They emphasize that "obvious" facts of social reality may differ among different people, even when in the same culture. It was described earlier how transfusion is a well established therapy which has existed in many clinical settings for many years and transfusion practice may represent an "obvious" social construct. To study transfusion practice in more detail may illuminate the ways in which transfusion
behaviours are learned and create a construction of transfusion practices in the clinical context.

2.8.3 Patient factors

It was described in section 2.8.2 how patients may be active in the social interactions that culminate in them receiving a blood transfusion, however, it is not clear from the literature if patients are concerned about anaemia or how involved they are in the assessment and decision to treat. It is known that patients now rate fatigue as their most common and debilitating side effect (Bruera et al 1989; Morant 1996; Portenoy and Itri 1999; Sobrero et al 2001 Cella 1997; 1998; Littlewood et al 2001; Yellen et al 1997) but the fatigue experienced may not actually be a reflection of the anaemia as previously discussed in section 2.4. Patient websites for example, Cancer Bacup Fatigue Management, recommend blood transfusion as a treatment for fatigue and also list anaemia second to cancer treatment as the cause and the NHS website for breathlessness lists anaemia as a common cause of fatigue (Cancer Bacup 2008). Patients, who seek information about fatigue management, particularly if it is recommended in the patient literature, may also seek transfusion in an effort to combat fatigue, but this is unknown. It may be assumed that patients are actively involved in the assessment and decision making of their anaemia management and that they are included in the social constructs of transfusion practice, but this is not known.

Conversely it has been described how patients can be distant from the point of care and decision making; the patient may also be read and interpreted "in absentia" for example in the Multi-Disciplinary Team (MDT) meetings (Atkinson 1995; 62). Atkinson describes the latter as being where the body is transformed into a series of signs and
representations by means of a “complex array of technologies of inspection” (Atkinson 1995; 63), e.g. the Computerised Tomography (CT) scan; the laboratory results; the histopathology and so forth and this is not uncommon. These items of information are combined by individual clinicians or groups of clinicians to create an assessment and/or decision. It is not known if this occurs in the management of cancer related anaemia, for example, if anaemia is managed from a distance; or if the patient is involved or if the management of anaemia is by individuals or groups of clinicians.

In general, patient participation in medical decisions appears to be increasing; possibly as a result of dissatisfaction or due to basic questioning of physician expertise. One review concluded that because of uncertainties associated with most medical decisions, clinicians who assume complete autonomy for decisions put themselves in a difficult ethical position (Brody 1980). As medical decisions become more complex and are associated with greater costs to the patient, clinicians have been increasingly motivated to incorporate patient preferences in critical decisions (Zook and Moore 1980). The question of how value judgments should be incorporated into decisions is difficult; although it is the patient who lives with the decision, many patients believe that the clinician who regularly treats the conditions is best able to understand the outcomes and ascertain what risks are worth taking (Eraker and Politser 1999). A patient survey of 51 patients receiving transfusion revealed that patients would like more information about transfusion, mainly because of concerns about viral transmission and nearly 40% thought written consent should be obtained prior to transfusion (Murphy et al 1997). A study of nurses and patient preference for involvement in their care, revealed nurses over-estimated patients’ preferences to be actively involved in their care (Florin et al 2006). It is suggested that patients should be assessed for their preference, for
example, a passive role, a collaborative role or active role (Florin et al 2006). In summary, it is not clear what impact or involvement the patient has on the decision to treat anaemia, if any; or if the patient is influenced by the culture of the clinical setting. It may be that increasingly patients will be more involved in their care as balancing risks and benefits may be more important where patients increasingly seek claims for clinical errors, as this would result in more ownership of the decision by the patient, and less with the clinician.

2.8.4 Summary
This section has described the literature of social interactionism and cultural learning and gives some insight into the development of the research design and the rationale for using an ethnographic methodology. To study the social interactions that occur in blood transfusion practice, some participant observation would be justified as some understanding of the everyday lives of the participants would be necessary to understand the context of the actions and behaviours of individuals; and the process by which the clinicians and patients construct the situation through their interaction. Further insight is gained by interviewing the participants. By combining the data sets a construction of transfusion practice could be created by interpreting meaning from what behaviours and interactions are observed or described. This justifies the use of ethnography, but given the close contact required, the researcher would have to consider her own values and strive to be objective in the conduct of the research. As described earlier this is achieved by using the different data sets to validate the interpretations developed by the researcher and by using reflexivity to self-critique and self appraise and continually re-visit the data. This will be described in more detail in the
development of the methodology chapter (Chapter 3), and the analysis will be described in more detail in Chapter 5.

2.9 Literature review summary

At a basic physiological level it could be argued that reliable monitors of tissue oxygenation and haemostasis are required to study the benefits (or lack thereof) of blood transfusion. This is unlikely in the near future, therefore, pragmatic guidelines defining transfusion triggers have been developed in an effort to control practice, and prevent over-use of blood products. The quest for a universal transfusion trigger i.e. one that would be applicable to patients of all ages under all circumstances should probably be abandoned (Hardy 2004); and therefore most guidelines define a range, e.g. 7-10g/dl for chronic management. In simplistic terms, transfusions should be tailored to the patients needs at the moment the need arises, but it is not clear if this happens in clinical practice or how the decision is made. Future research and development should perhaps focus on the determination of optimal transfusion strategies in various patient populations and on reliable monitors to guide transfusion therapy (Hardy 2004); but it could be arguable that should disease specific guidelines and monitoring be developed, practice may still vary because of other more powerful influences, which may initially not be obvious.

In summary, the assessment and decision to treat cancer related anaemia is a complex one and the details of the process are relatively unclear. It may be that the laboratory value is the greatest influence or it may be patient or resource issues also impact on the assessment and decision to treat. If the behaviours and practice can be examined in greater detail, and how they are learned, then it may give some insight as to how to
Improve the assessment and management of cancer related anaemia and guide what changes may be required to change transfusion prescribing behaviours.

2.9.1 Implications for practice

As described earlier the anaemia experienced by the oncology patients is usually more chronic in nature and has a physiological cause and therefore differs from patients who suffer blood loss. It is seldom life threatening unless a patient has experienced an acute bleed. Therefore, in principle red cell transfusions for patients with chronic anaemia should be given at intervals to maintain the haemoglobin just above the lowest concentration that is not associated with symptoms of anaemia, but as previously discussed it may be difficult to determine what this concentration is for individual patients. Many patients do not receive any treatment for mild anaemia and it is not until the patient becomes moderately or severely anaemic that treatment is initiated. It is not clear what are the determining factors for the decision to treat, for example, is it particular symptoms or is it primarily the haemoglobin level or is there other cultural or social influences? Most clinical practice guidelines recommend restrictive red cell transfusion practice with the goal of minimizing exposure to allogeneic blood (from an unrelated donor) as well as reducing healthcare costs. They tend to set a transfusion trigger of 8g/dl in the absence of cardiovascular disease. However, in cancer related anaemia most patients would be transfused with haemoglobin of less than 8g/dl and very few people if more than 12g/dl. (NICE 2004).

The volume of transfusion any given patient receives varies according to diagnosis, complexity and tumour type (Bokemeyer 2005; Estrin et al 1999; Ludwig et al 2004). As mentioned previously eighty-eight per cent of transfusion episodes in the cancer
population are two-unit transfusions (Barrett-Lee et al. 2000). This suggests there may be ritualistic practice in transfusion with a tendency to treat laboratory values rather than make a clinical decision to treat and aim for a specific transfusion target (Foubert and Wujcik 2005) or to treat symptoms of anaemia. Again, the rationale for this decision is not clear; it could be argued that unless it is clear of the reasons for these decisions, it would be difficult to improve practice.

Cost and resources may influence the decision to treat anaemia. As mentioned, the cost of the actual blood product is increasing but in addition to this there are the added costs of the administration of the blood transfusion (for example, nursing and laboratory time, beds, management of adverse events). The actual number of blood donations increased by 2% in 2000-2001 but the cost of transfusion increased by 256% to £898 million (Varney and Guest 2003) with the direct cost of the blood product accounting for only 19% of the total cost of transfusion (Crimieux et al. 2000). This could be an influence on the haematologists whose transfusion prescribing behaviours changed following the transfusion course at the blood transfusion centres, which was an observation in practice described earlier.

It may be that a clinician faced with an anaemic patient in clinic may want to order a blood transfusion; however, limited resources may result in a delay or no transfusion at all. Furthermore, a lack of day care beds may result in unnecessary patient admissions for blood transfusion and the Barrett-Lee audit demonstrated 25% of transfused cancer patients were admitted as inpatients for their blood transfusion (Barrett-Lee et al. 2000). This is difficult to interpret as it may be patients were admitted for other co-morbidities. The NICE (2008) guidance on the use of erythropoietin was based on the assumption
that 25% of patients require overnight stay for blood transfusion, which again could be argued that this was not a decision that considered patients may have been admitted because of a co-morbidity. From personal experience it is very rare to admit an ambulatory patient solely for transfusion. These patients would normally be deferred until there is an available time in the day unit rather than being booked as an in-patient, however, this will vary according to clinical setting. At present it is unclear as to how much resource availability influences the decision to treat patients with blood transfusion.

Anecdotal data has revealed that transfusion practice varies widely between different institutions and clinical settings, even within the same institution and the reasons for this are unclear. In summary, the amelioration of cancer-related anaemia with blood transfusion should be considered a priority in the presence of confirmed symptoms and when there is evidence that the patient responds to blood transfusion. The aim should be to provide best supportive care in this population, with the emphasis on neither, over- or, under-transfusing of blood and a more discerning approach may be required. If there is inappropriate resource or environment to support this practice, then service development or adjustment may be required. Furthermore, if a deeper understanding of how decisions are made in the clinical setting it will inform as to what interventions or change in behaviours that needs to be developed to improve practice.

2.9.2 Implications for research

The presence of cancer related anaemia reportedly decreases quality of life and increases fatigue levels but it may be difficult to differentiate between symptoms of anaemia from disease and treatment influences, and there could be a risk that patients
are unnecessarily exposed to treatment of anemia. Some patients appear to benefit more from blood transfusion than others and it is not uncommon for patients to express that they feel no benefits following a blood transfusion. It may be that attempts to provide best supportive care of anaemia are unpredictable but blood conservation strategies should be maximized, or blood transfusion should be at a minimum clinically justifiable. This would justify a study attempting to explore if discerning transfusion decision making was practiced in a variety of clinical settings and if not, what are the influences on the reasons for non discriminatory prescribing of blood.

A further criticism of many of the anaemia and erythropoietin studies is that tumour types are frequently grouped together and the impact of anaemia and effects of erythropoietin and haemoglobin level may be different for different tumour groups. It may be useful to explore any differences in practice in different tumour groups, and the reasons for this; as this may explain some of the differences in practice. This would justify the rationale for examining haemato-oncology and lung cancer as symptomology may have different impact on patients and there may be behavioural differences between the subspecialisms.

In the clinical setting the traditional approach to treating cancer related anaemia is “the two-unit transfusion”; this is probably a response to haemoglobin levels but this is not clear. The haemoglobin level may not be a good indicator of the impact of the anaemia and therefore should not be the main influence in deciding to treat the anaemia, unless low levels are reached or predicted. The literature describes the importance of a full assessment of anemia but this may or may not be important and the actual practices of assessment and treatment of cancer related anaemia have not been explored. Exploring
the actual practices within healthcare settings necessitates a qualitative approach which would capture the reality of practice. It is argued here that a qualitative research methodology, such as ethnography, with some participant observation in clinics and day units where the assessments or decisions are made is an appropriate approach to studying this clinical issue. Participant observation could give some insights into the culture of the management of anaemia, which is thought to be based on traditional practices. By using a combination of observation and interviews an interpretation of the social constructs involved in the management of anaemia could be developed; the management of anaemia may not be merely a response to a biomedical fact (e.g. a decision based on a response to the haemoglobin level), but may be influenced by a range of social, situational or institutional processes or factors.

An attempt to establish why there is variation in transfusion decisions would require more detailed qualitative approaches of enquiry, for example, with interview techniques with healthcare professionals to explore what decision making criteria is used in deciding whether to transfuse a patient or not. The literature review revealed there may be some uncertainty in the treatment of cancer related anaemia, and further uncertainty with variable responses to transfusion, therefore the decision to treat is complex. The Medical Research Council (MRC 2000; 2008) have produced a framework for evaluating complex interventions and suggest if a particular intervention is already widely practiced, it may be useful to establish the theoretical basis that suggests the intervention has the desired outcomes or "it may be formal theory of individual or organisational behaviour, organisational constraints or types of behaviours that promote or inhibit change" (MRC 2000, p4). The MRC concludes that qualitative research is important in understanding why something happens and that it may be valuable in ascertaining whether
inappropriate beliefs and assumptions may be leading to the wrong interventions (MRC 2000, p9). The updated MRC guidance (MRC 2008) also describes how research into the context of the intervention can be valuable in determining how an intervention works or how it can be optimised and "can identify contextual factors associated with variation in outcomes" (p12); and describes how the context of an intervention can be crucial to treatment success or failure. By combining fieldwork observation and interviewing key healthcare professionals it would be anticipated a picture of the reality of transfusion practice would emerge. More accurate and detailed assessment of cancer related anaemia may result in more, not less, use of blood if the current literature is to be believed; but it may be the overall aim should be to use blood appropriately, thereby only exposing the risk of transfusion to those who will have direct benefit from the blood transfusion.

In summary, the arguments described (the complex decision; the social interactions; the context of the interactions and decision) provide rationale for further research in the assessment and treatment of cancer related anaemia. The need to develop more efficient services, or services which are at the least clinically justifiable, is not only a response to government policy initiatives for greater economic and professional accountability but it has ethical implications; the aim of any improvements in transfusion practice would be to optimise the patient's quality and quantity of life without exposing him/her to unnecessary risks and ensuring that any transfusions are at a minimum clinically justifiable. This research project was, therefore designed to both inform and influence the management of cancer-related anaemia and transfusion practice, by contributing to the body of knowledge about decision making in the clinical setting and the cultural influences at play.
2.9.3 The purpose of the research

This chapter described the literature review which laid the foundations for the development of the research by identifying gaps in knowledge and explored the influence of cultural and social factors to ultimately inform the research methodology. The purpose of this study was therefore:

- To explore the cultural practices which shape the culture of transfusion
- To identify the key elements, which influence clinical decision making in blood transfusion in haemato-oncology and lung cancer patients.

Mixed data collection methods were used within an ethnographic methodology for the reasons described in section 2.9.2. The evolution of the research and ethnographic methodology will be described in more detail in Chapter 3.
CHAPTER 3
Methodology

This chapter begins by reflecting on the purpose of the study and incorporating the important elements of the literature review. It is followed by a brief description of the original research design and the deficiencies of that design; followed by a description of the evolution of the final research design based on interpretive ethnographic methodology. Ethnography is described in more detail, with reference to the literature and includes sections on the influence of the researcher, the methodological framework and ethnographic observation and interviews. It concludes with a summary of the chapter.

The literature review assisted the researcher to develop the purpose of the research and similarly the purpose of the research informed the evolution of the methodological foundations of the project; and proved to be a creative and iterative process. The original research design was briefly described in Chapter 1 (section 1.5); this included a quasi experimental component (actigraphy and FACT-An questionnaire) and an ethnographic methods component (clinician interviews and observation). From the outset it was recognized combining these data sets would be difficult and the risk would be that the research would result in large volumes of data that could not reliably be integrated. This was highlighted by the ethics committee. Furthermore, as described in Chapter 1, the actigraphy and questionnaire may not have captured the patient experience of anaemia and transfusion. Following commencement of the study, and completion of some of the observation fieldwork, and clinician interviews, it became
apparent that patients' involvement in the decision making may be important; it emerged that by interviewing patients more detail of the experience and their involvement would be possible. In other words patients formed part of the social functioning of the group involved in the management of cancer related anaemia and transfusion practice. Furthermore some of the staff interviewed suggested that patients should also be interviewed and some doubt emerged at the outset of the study that the original design using actigraphy and questionnaires would fail to meet the objectives of the research project. It is argued here that ethnography was valuable because it offered a way of holistically exploring the relationships and behaviours within the clinical setting and this is described in more detail in the following section. Therefore the final research design was a combination of observation and patient and clinician interviews using an ethnographic methodology and patient interviews were included with the aim of exploring the culture of transfusion practice.

3.1 Reflections on the purpose of the research

The researcher reflected on the purpose of the research, which was to explore the cultural practices which shape the culture of transfusion; and to identify the key elements, which influence clinical decision making in blood transfusion in haematology and lung cancer patients. The risk was that the questionnaire and actigraphy data would provide simplistic and reductionist data that would not provide the whole story, for example, the patient interpretations of what anaemia and transfusion meant for them. This change of researcher thinking is more succinctly described in the "Integration of knowledge, research and practice" paper and later in this thesis in Chapter 7, but resulted in a transition from a positivist approach to an interpretive approach. It was not a simple case of measuring the problem, for example, how many patients were fatigued
or how much activity and rest they had; it was more about listening to what patients had
to say, observing behaviors and exploring the ideas and concerns which the subjects
themselves described and interpreting meaning from these descriptions. Add her about
symbolic interactionism. In summary, researchers who use qualitative methods aim to
use “a holistic perspective which preserves the complexities of human behaviour” (Black
1994; 425) and therefore seek to find closeness to the reality rather than just skimming
the surface.

With the purpose of exploring the transfusion culture in mind, different elements needed
to be examined. Diagram 3.1 demonstrates the possible elements which may influence
the culture of transfusion practice; this was developed from the literature review and
personal experiences. In general terms, individual characteristics such as experience,
skills and knowledge were considered (both of patients and clinicians); the interactions
between the individuals and their behaviours; the practices that existed within the
organization, for example, the opportunities to learn; the meaning of cancer related
anaemia and blood transfusion for the individuals; the difficulty or simplicity of the task
(i.e. the clinical decision) and various artifacts that may influence the behaviours for
example resource, the clinic sizes and laboratory results.

All of these factors could potentially shape the culture and therefore needed to be
considered at the design stage and throughout the research journey. It shaped the
design evolution in the sense that the methodology should be able to explore all of the
elements above and provided rationale for the change from the original research design,
to include patient interviews in addition to staff interviews in an attempt to explore the
elements that contribute to the culture of transfusion practice. This transition is described in more detail in the following section.

Diagram 3.1 Possible elements for exploration of the transfusion culture

3.2 Quasi-experimental design to understand the impact of transfusion on the patient

The original research design as described earlier, was a quasi-experimental approach to assess the impact of cancer related anaemia and the impact of transfusion on a cohort of anaemic cancer patients. It was limited to haemato-oncology and lung cancer patients. The rationale at this stage for choosing these two groups was because the incidence of cancer related anaemia is high in these two groups (Estrin et al. 1999; Ludwig et al. 2004). The original aim was to establish if there was a relationship between haemoglobin levels and blood transfusion with their levels of activity and fatigue. A
repeated-measures design obviated the need for a meaningful control group as subjects serve as their own control group. The original study design included following ten patients (five haemato-oncology and five lung patients) with actigraphy for 90 days and FACT-An applied at two weekly intervals for the 90 day period. The transfusion culture and the elements that influenced clinical decision making was to be explored by using ethnographic clinician interviews and observation in the haemato-oncology and lung cancer clinical settings.

The FACT-An scale questionnaire was chosen in the original research design to measure the functional status of participants (Appendix 1) (Cella 1997). The FACT-An has been used widely in studies measuring the impact of anaemia, for example in CABG patients (Bracey et al 1999) and erythropoietin studies (Demetri et al 1998; Glaspy et al 1997). It was also in the original design to use actigraphy. Actigraphy is a technique, which uses a simple, non-invasive instrument worn like a wristwatch (actiwatch) that is capable of measuring performance levels in and around the home, as patients go about their normal day-to-day activities. It’s usefulness in evaluating functional performance is based on the premise that day-to-day activities require varying degrees of physical movement. It was believed that this small study would determine if this technique were useful in examining cancer-related fatigue and the effects of anaemia on activity and functional status. The justification of using FACT-An, and actigraphy was that a pattern of fatigue and activity would be established in relation to transfusion. The aim of this quasi-experimental component of the study was to present the data in a descriptive, diagrammatic and pictorial manner and initially it was felt that this would allow a large amount of empirical data to be handled in an unbiased and objective manner, particularly
as the actigraphy data would be objective. It was hoped that this would provide data that could bring some certainty to the uncertain world of managing cancer related anaemia.

Descriptive statistics constitute the clearest and most straightforward means of expressing mathematical relationships between variables (Hallett 1997) but the limitations are that a simplified reductionist picture emerges. However, the literature review had revealed the indeterminacy of anaemia and transfusion practice and if the original design had been adhered to, the detail of all the patients' contributing factors to the transfusion culture described in the previous section could not be explored; all that may be revealed is what is already known in that the physiological basis of anaemia and response to transfusion is unpredictable. It was described earlier in section 2.9.2 the MRC (2000; 2006) research guidelines for complex interventions also recommends including exploration of behaviours, parameters of behaviours and methods of organising and delivering those behaviours (e.g. type of practitioner, setting and location). This adds weight to the decision to change the research design to explore the context of the anaemia and decision to transfuse. Furthermore, the positivist perspective would be to assume experiment and science can solve this uncertainty, however the interpretive approach would be to accept this uncertainty and try to understand the meaning of anaemia and the human response (either patient or clinician) to the anaemia and transfusion behaviours in the clinical setting.

At the outset the aim was the mixed methodology of combining quasi experiment using actigraphy and FACT-An would offer an element of qualification and even interpretation to the qualitative work (staff interviews) by providing a set of methods by which complex meanings and relationships within a set of data can be clarified and understood, for
example, linking activity levels with the date of blood transfusion and haemoglobin levels. But it was not clear what data sets e.g. actigraphy data would illuminate the interview or observation data or vice versa; this was a major methodological flaw in the early design in that there would be a risk data could not be combined in a reliable way or that data could be redundant or over-simplified because the process of data analysis did not have reliable foundations. For example, there was no precedent for ethnographic data (from interviews and observation) being combined with questionnaire data and actigraphy data. It was one of the informal comments from the local ethics committee that a large amount of data would be produced and how reliably could the data be analysed and linked. Furthermore, by not including patient interviews from the outset, not all of the components that may influence the transfusion culture and behaviours would be included, for example, the patient experience and interactions with clinicians.

In summary, the aim of quasi-experimental phase of the study was to establish the impact of anaemia and transfusion on the patient using four data collection methods (actigraphy, questionnaires and ethnographic interviews and observation) over a period of time on a cohort of haemato-oncology and lung cancer patients. The rationale for using both questionnaire and actigraphy was to capture subjective and objective data respectively. However, as data emerged from some of the staff interviews and observations in the clinic it was felt that patient interviews would yield important information. Some of the research questions could not be answered by actigraphy and FACT-An data; for example the questions concerning patient attitudes about receiving a blood transfusion and their involvement in the process. The FACT-An would not reveal any information on how patients feel following a transfusion and any subjective improvement in function as FACT-An was to be applied at 2 week intervals and not timed
to coordinate with blood transfusions. This would have been logistically impossible. Following some of the staff interviews it was clear the patient was involved in the assessment and decision making process therefore it was a logical progression to include patient investigation within the same methodological framework as staff. In addition, several of the staff who were interviewed presumed that patients would also be interviewed, particularly to establish the patient involvement in the assessment of the anaemia and any decisions made regarding treatment.

One haemato-oncology patient was initially recruited in the original design phase; however, she was admitted to hospital with a severe neutropenic episode therefore she was taken off the study. Following discussion with the research supervisors and further consideration of the design a substantial amendment was submitted for approval. The amendment was to abandon the original quasi experimental design (FACT-An and actigraphy) in order to undertake some patient interviews using an ethnographic methodology similar to the staff interviews. This would have the following advantage of not being dependent on patients surviving the 90 day study period and without hospital admission but more importantly allow for exploration into the elements that possibly shape transfusion culture as described in section 3.1 as well as give insight into how patients actually feel when they are anaemic (their experience); what interactions they have with clinicians, the benefits they feel following a transfusion as well as their attitudes to blood. The substantial amendment was approved and the patient interviews were undertaken.
3.3 The Blood Transfusion Audit

Prior to the development of this research proposal an audit was undertaken to establish the transfusion trigger and compliance with blood transfusion guidelines. This revealed a difference in transfusion triggers between haematology and oncology, the haematology trigger was 7.6g/dl and the oncology trigger was 9.2g/dl (Appendix 2: Table 3.3a). This provided further rationale to exploring transfusion practice in haemato-oncology and lung cancer in order to explore why there was variation in transfusion triggers in the two disciplines. It also revealed that the majority of transfusions were two unit transfusions (Appendix 2: Table 3.3b). The results of this audit stimulated the development of this research project, as further understanding of anaemia and transfusion practice was required. Details of the audit are in the "Service Development Project" (Part 2). The audit demonstrated the volume of blood usage within oncology and haemato-oncology over a three month period. Initially, the service development project outcomes were that more education and training may be required in an effort to improve compliance to guidelines. The audit also stimulated more questions about why the transfusion practice may differ between oncology and haemato-oncology and the possibility of other influential patient or staff behaviours.

There were constraints to this audit as the oncology diagnosis data was not accurate so it could not be established which tumour types or radiotherapy/ chemotherapy treatment sub-groups received more/less blood transfusion. There were also missing data in haemato-oncology, which made comparison between transfusion practice in terms of single/multiple transfusions and timing of transfusions impossible. Time constraints meant only 202 oncology blood transfusion patient episodes were examined.
3.4 The evolution of the study’s methodology

In summary, by combining the researcher’s personal experience, the literature review findings and the service development project (blood transfusion audit), the final research project and methodology emerged. The ethnographic interviews and observations were undertaken but in no fixed order, as the project developed, and adaptations were made. The order was related to subject and researcher availability. It was an iterative process, for example, as knowledge and insight was gained into the assessment of cancer-related anaemia and transfusion practice, the content of the interviews changed and different personnel were approached in the clinics for more information.

As described in the Chapter 1, personal experience and observation contributed to the early evolution of the research, but the researcher experience influenced the project throughout all phases and cannot be separated. Assumptions were made in the service development project that by merely improving the skills and knowledge of the clinical teams that transfusion practice would improve, however the literature review (Section 2.8) showed that tacit knowledge, social interactions and the culture could influence behaviours (Eraut and Hirsh 2007). Earlier in this chapter it was described how the reality of transfusion practice was to be explored therefore the underpinning methodology was questioned and the purpose of the research revisited. In summary, it was this final process; and a combination of the experience and interpretation of the literature and audit; and preliminary reflection of the purpose of the study and early analytic reflection (clinician interview and observation data) with the supervisors that culminated in the final design and underpinning methodology (Diagram 3.4). This amendment resulted in a difficult change of attitude and philosophical and ontological
perspective of the principal researcher, but was necessary to achieve the aim and objectives of the study.

Diagram 3.4: The evolution of the study's methodology

The original design had a partly positivist methodological basis and was partly quantitative and partly qualitative and the new design was underpinned only by qualitative methodology. There can be conflict between qualitative and quantitative methodologies as they are based on competing philosophical positions of positivism and naturalism and this was personally experienced by the researcher, and is described in more detail in chapter 7 (7.5: The reflexive ethnographic journal) and the paper "Overview of integration of knowledge, research and practice" (Part 1). It also contributed to the
potential difficulty of reliably integrating numerical and graphical data (from the actigraph and questionnaire) with interview and observation data.

Naturalistic research strategies pay attention to what humans feel, perceive and do in natural settings that are not experimentally contrived or controlled (Atkinson et al 2001). A number of qualitative research paradigms derive from naturalism and can involve long investigative processes in order for the researcher to make sense of a social phenomenon by contrasting, comparing, replicating and classifying the object of study (Cresswell 2002). Naturalism emerged as a challenge to positivism in the 1990’s; up to this point the latter dominated in the health and human sciences (Hammersley 1992). Naturalism proposes that as far as possible the social world should be studied in its “natural state” and not disturbed by the researcher (Hammersley and Atkinson 1997; p7). Naturalism draws on a wide range of philosophical and sociological ideas, but especially on symbolic interactionism (described in section 2.8.1), phenomenology and hermeneutics (collectively called ‘interpretivism’), (Hammersley and Atkinson 1997; p7). Alternatively, positivism argues there is a real world which is independent of people’s perceptions.

However, despite the differences between positivism and naturalism they are both committed to realism (Atkinson et al 2001). Both are underpinned by the belief that there is an objective reality and that the task of social research is to represent social phenomena in a literal way, documenting their features and explaining their occurrences (Hammersley 1992). They fail to take into account that social researchers are part of the world that the study. Thus the process of understanding inevitably reflects the prejudices of the researcher. Naturalist and social researchers and logical positivism researchers
assume that the distance from the data ensures validity; that is, it reduces researcher
effect (Spencer 2001). The world is revealed to people, not constructed by them and
dependence causal relationships can be created and for positivists the most important
feature of scientific theory can be confirmed or rejected with certainty. Interpretivism
refers to epistemologies or theories about how knowledge of the world is obtained;
interpretivism loosely relies on interpreting or understanding the meanings that people
attatch to their actions and ethnography is often described as interpretivist or at least anti-
positivist (O’Reilly 2009). In summary, neither positivism nor naturalism provides an
adequate framework as both neglect the fact the researcher is part of the social world of
study. It is argued here that ethnography is particularly valuable not only because of the
attention to context and synthesis of findings from different methods (interviews and
observation) but also because it offers a holistic way of exploring the relationships that
underpin clinical practice (Savage 2006a).

In the mid 1980s anti-realism and post-modernism were developed to challenge the
assumption of an objective reality (Hammersley 1992). In its place, subtle realism
(Hammersley 1990), analytical realism (Altheide & Johnson 1998) and critical realism
were suggested. Even though these approaches have their differences, they all share a
common theme, that knowledge is based on assumptions and human constructions and
the concept of reflexivity was introduced. Post modernists accept the real world is
complex, ambiguous and at times messy and contemporary social researchers argue
that human behavior can only be understood within the context it occurs. The social
world cannot be understood in terms of simple causal relationships, because human
actions are based on or influences by social and cultural meanings through motives,
beliefs, rules, discourse and values. Behavior is linked to the meaning of a situation
has for a person (Bloor 2001), which by nature would make it complicated and perhaps
difficult to understand all the nuances involved, but ethnography provides a
methodological foundation to explore this.

Qualitative research can be subject to criticism as lacking scientific rigor, however,
qualitative research aims to make sense of or interpret phenomena in terms of the
meaning people bring to phenomena. However, if the culture of transfusion practice was
to be reliably explored it is argued here that after a thorough consideration of the
available theoretical approaches within the qualitative paradigm, ethnography was
chosen as the most appropriate strategy of inquiry to address the aim of the study. One
could argue in this case that the reality of anaemia and transfusion practice within the
cancer care setting was the aim of the study; therefore the ethnographic approach may
be more likely to represent the reality. Denzin (1997) describes how by using an
ethnographic methodology:

*The ethnographer discovers the multiple truths that operate in the social word;
these stories move people to action and they rest on a distinction between fact
and truth [ ]. Truth and facts are socially constructed, and people build stories
around the meanings of facts. Ethnographers collect and tell these multiple
versions of the truth (pxv)*

The clinical practice occurs in the clinical setting and all that it encompasses, including
feelings and subjectivity, hence the final methodological design of ethnographic
interviews and observation of all parties, including the patients, seemed logical. The
researcher’s instinctive approach to this research was to try to make a quasi
experimental (positivist) methodology “fit” with the purpose of the study. It was therefore
a convoluted journey to arrive at the final research design but it felt more comfortable,
and helped to “complete the picture” in a way that the quasi experimental methodology may not have fulfilled. It could be argued that this journey may have been necessary for the researcher to change epistemological stance; or that natural tendencies meant that the researcher’s ability to undertake an ethnographic study would be limited. This will be discussed in more detail later when summarizing the reflective journal in section 7.6. It has been demonstrated in this section that the dominant critical element for the author was a return to the original research question and purpose of study, to reach a conclusion as to what methodology and design could fulfill all elements of the study.

3.5 Ethnographic methodology

From the literature review and the clinical audit results it is clear there are many facts known about the incidence of cancer-related anaemia and the volume and practice of blood transfusion. However, as mentioned there is limited understanding of how a patient presents with anaemia in the clinical setting and the interactions that follow with the healthcare professionals that culminates in the decision to treat the anaemia with a blood transfusion. To gain more insight into the process, an examination of the “culture of transfusion practice” would be required. Ethnography is “the work of describing a culture” and typically uses observation techniques to both study and learn from people (Spradley 1980; p3). The ethnographic researcher may use many approaches to explore a social group or cultural tradition but the ultimate aim is to conduct the research in the “natural context” and takes into account the flaws, restrictions and opportunities that encompass the lives of the participants in a given social situation (Serrant-Green 2007; p4). There is an attempt to interpret the culture by eliciting meaning from observation and interviews of the participants. Given that there was so much variation in the clinical practice of the management of cancer related anaemia it was the obvious
methodological basis for this research and one could argue that patient interviews should have been included in the original research design. This ethnographic approach would allow for exploration into the factors that underlie variation in practice and explore the impact of the individual patient and staff factors. Furthermore, by taking an interpretive stance within ethnography offers a holistic way of exploring the relationships between the different behaviours and interactions that underpin the clinical practice of transfusion; it is the small scale interactions between individuals that required exploration and the exchange of symbols in social interaction, that is the “symbolic interactionism” described in section 2.8.1 that is being explored in this study. For example, drawing on the work of Mead it is the covert as well as the overt behaviours which are of interest to the researcher and the interactions that occur between individuals. Goffman referred to “the team” as a group of people who cooperate to maintain a particular definition of a situation; he describes this as “situational propriety” (Goffman 1963) which refers to the way in which the meaning of actions or concepts is dependent on the context in which they emerge. This notion ties in with the earlier point in section 2.7 in that as human beings we gradually learn practical and tacit knowledge which enables us to understand the meaning of actions within a particular context. Goffman provided insights into the complex interrelationship between self-presentation and others, and social theorists such as Giddens developed this further to describe how this notion is central to the production of social order and predictability in daily social interaction. It may be that blood transfusion practice for example can be explained by this symbolic order because it is dependent on the coordination of everyday social interaction. It is the social interactions in “the teams” which are examined in this study using an ethnographic methodology.
3.5.1 The researcher's influence

The researcher is integral to the success of ethnographic research and is intimately bound in the research pathway as described earlier, from the project's inception the researcher's experience, attitudes and epistemological stance shaped this project. One way of making the researcher's influence transparent is by keeping a reflexive diary; in this way the diary can be analysed at project completion to describe this journey of learning, thinking and reflection. Brewer (2000) describes the researcher involvement in ethnography:

"Ethnography is the study of people in naturally occurring settings or field by methods of data collection which capture their social meanings and ordinary activities, involving the researcher participating directly in the setting if not also the activities, in order to collect data in a systematic manner" (p6).

Delamont (2004) describes further:

"Participant observation, ethnography and fieldwork are all used interchangeably...they can all mean spending long periods watching people, coupled with talking to them about what they are doing, thinking and saying, designed to see how they understand their world" (p218)

The researcher spent periods of time interviewing and observing and although they may not be technically described as "long periods", the research design was developed to try to "understand their world" of transfusion. There is "no escape" for the researcher and she had to first acknowledge her own attitudes, behaviours and persuasions and how
they impact on the way in which the research is undertaken; a level of reflexivity was required to attempt to establish the reality of practice. The reflexive diary was essential for data analysis and insight into changing attitudes as the research progressed. In summary, ethnography as a study approach requires the researcher to become partially immersed in the field by making careful records of observations and asking participants for an explanation. The methodology of this phase of the study is strongly "emic", an approach that involves eliciting meaning and perceptions from the informant's viewpoint (Morse 1994), rather than the researcher's viewpoint, which is known as "etic", although the researcher should be aware of their own personal attitudes and experiences as this may influence the interpretation of what is being observed. This is an important consideration in study design when determining the level of participation by the researcher.

The style of writing of the ethnography is worth a mention. Critics of ethnography note the tendency of ethnographers to write in the first person as if their account was the one true voice of authority (Hammersley and Atkinson 1995; O'Reilly 2009). Whilst it is important to place oneself in the research and in context, there is no prescriptive method for writing the ethnography but the "legacy of the reflexive turn is the demand to think consciously about writing styles and the nature of the argument" (O'Reilly 2009, 190); for example, it has to be decided if it is written in past or present tense; first person or an authoritative voice. In summary, the researcher used the advice of O'Reilly (2009):

"...whatever is decided about the writing, our responsibility is to those we study. Studies can be rich, evocative, colourful, and a pleasure to read, but should retain an authoritative status as a piece of scholarly research if this is what we
have told our participants. Similarly, we cannot forget there is a real world out there that we studied, social actors who allowed us into their lives to do so and maybe gatekeepers who permitted access to the group." (190)

In conclusion, the researcher decided to write in the authoritative voice and attempt to locate herself in the different cultures of haemato-oncology and lung cancer (Clifford and Marcus 1986) through descriptions of her clinical observations and interview transcriptions within the clinical arena of cancer related anaemia. It could be argued a true ethnography does not necessarily fit the order of a doctorate thesis and the prescriptive chapters that are required, but this is a scholarly document that has a predetermined construction; it was therefore important to write an account that was neither overtly subjective nor lacking in methodological detail (Bennett 2002).

3.5.2 The methodological framework of ethnography

Ethnography is concerned with people's behaviours in everyday contexts rather than under unnatural or experimental circumstances. Data is usually collected by observation and interviews and tends to be flexible and unstructured to avoid pre-fixed assumptions that impose on what people say or do. Bloor (2001) encompasses all the previous points asserting that ethnography is the product of engagement with a group of people, the observer's understanding and a reflexive concern with the relationship between the researcher and participants. Rather than ignoring the influence of the researcher as described in the previous section, ethnographers show the nature of the relationship and how they use reflexivity to tease out the participants' experience and their own. For example, the researcher's background was in haemato-oncology with less experience in
oncology and therefore it was important not to make assumptions about the practices within oncology but use the data as the evidence.

One way of addressing the differences and commonalities in perspectives is through the approach of analytic realism (Altheide and Johnson 1998). This is based on the view that the social world is an interpreted world, not a literal one, but one which is always constructed by the ethnographers who study them. While the ethnographer's commitment is to obtain people's perspectives on social reality, analytic realism recognises that most fields have multiple participants and multiple perspectives. This means the ethnographer must attempt to report this multiplicity and demonstrate where her voice is in relation to the others. Because of the researcher's background it is therefore appropriate to frame this study within analytic realism; in this way feelings, perceptions, behaviours and actions of the staff and patient participants will be included and reflect the multiple voices and perspectives that influence the assessment and decision to treat cancer related anaemia. In summary, ethnography seeks to explain both specific aspects of a culture (what all members are aware of and take for granted, e.g. blood is donated and readily available and no questions are asked about it's use) and tacit elements, which are outside one's awareness, (e.g. attitude to blood transfusion, intuitive decision making).

3.5.3 Ethnographic observation and interview

Observation can be a useful tool for exploring and uncovering the knowledge base and clinical practice in a chosen setting (Kennedy 1999). Observation helps us to make sense of the world around us and guides our decisions and actions. It has been suggested that there is a need to distinguish between the technical/rational type of
knowledge (knowing that) based on empirics and the “know how” based on professional artistry (McIntosh 1996, p320). The healthcare professional may have the knowledge and skills to rationalize the decision to transfuse but may use tacit knowledge to aid the decision or it may be due to personal characteristics, for example, confidence to withhold transfusion until stronger evidence is available. In addition, groups of health professionals may make different decisions to those of individuals. Although a group may agree for example to not transfuse unless the haemoglobin is less than 8g/dl as per hospital guideline, a healthcare professional faced with an individual patient may tend to err on the side of caution or rely on personal experience or it may be more strongly influenced by how well they know the individual patient. Therefore exploration of the knowledge underpinning the decision-making surrounding the decision to treat cancer related anaemia requires a research approach that could account for the complexity of the activity, give consideration to the personal characteristics of those involved and the context of the care setting where these decisions are made.

Participant observation combined with in depth interviewing has the potential to illuminate previously covert patterns of behavior and decision-making and would yield richer data (Hammersley and Atkinson 1995). In this research, the "participant as the observer " was the model adopted whereby the specialist nurse (the researcher) observed in the clinic and took field-notes; she was an occasional participant in these clinics, and had experience in assessing and managing anaemia. It has been suggested there is a spectrum of participation, where the researcher is either a complete observer, or at the other extreme a complete participant whereby the data is collected covertly (Figure 3.5.4). The extreme forms may be unethical because they violate either the right to autonomy or hide the fact that the researched are being observed (Hammersley
and Atkinson 1995) although the ESRC guidelines (2007) approve extreme forms for some social research. The reality is that the researcher was somewhere between these two extremes and combined overt and covert observations but gained consent when necessary. Moderate participation occurs when the researcher seeks to maintain a balance between being an insider and an outsider, between participation and observation. The active participant seeks to do what other people are doing and the ethnographer tries to learn the cultural rules of behavior. A degree of involvement in the clinic was inevitable as the researcher was a known clinical figure but fortunately not routinely involved in any of the clinics.

Figure 3.5.4: Spectrum of participation and observation

Participant observation was chosen because transfusion practice is heavily influenced by experience and it was thought to be an advantage if the researcher shared the same professional experience to decide what questions to ask. However, the known observer can disturb the natural environment, and may cause a change in normal behavior and consequently the researcher can record unreliable data; this should be taken into account during data analysis. Silverman (2006) describes the aims of observational research (p68):

1. Seeing through the eyes of: viewing events, actions, norms, values etc. from the perspective of people being studied
2. Description: attending to mundane detail and to help understand what is going on in a particular context and to provide clues and pointers to other layers of reality

3. Contextualism: can understand events only when situated in the wider social and historical context

4. Process: viewing social life as involving interlocking series of events

5. Flexible research designs: open and unstructured research design which increases the possibility of coming across unexpected issues

6. Avoiding early use of theories and concepts (p68)

A qualitative approach using both observation and interviews and taking interpretivist ethnography as the philosophical and theoretical context allowed the researcher to explore the traditional practices of transfusion and clinicians' and patients' attitudes to transfusion. Dialogue between the researcher and the researched was essential (Murphy 2005); for example, the ethnographic interview would require identification of appropriate informants, which may follow on from the observations or may be part of the same process, but in this case the clinicians were approached either during the clinics or during separate conversations when opportunities arose. Spradley (1979) describes the ethnographic interview as a "speech event, which shares many similarities with the friendly conversation" (p58). He further describes how many ethnographers gather much of their data through conversations during participant observation, slowly introducing new elements to assist informants to yield more information. Both explicit and tacit cultural knowledge are revealed through speech, whether in casual comments or lengthy interviews and every ethnographer makes use of what people say, in seeking to describe his or her culture. Because language is the primary means of transmitting culture from
one generation to the next, much of the culture is encoded in linguistic form; therefore the combination of interviews and participant observation was justified in this study. Inferences can be made from what people do, for example, in clinic, (cultural behavior) and by listening to the language, therefore consideration must be given as to what language will be used, for example, verbatim or concrete language or use of generalizations. Exclusive use of the ethnographic elements, or introducing them too quickly, would make the interviews too formal and more like an interrogation. This would threaten the aim of the interview, which was to find out what processes, skills and knowledge are used to influence the clinical decision to transfuse. Rapport would evaporate and cooperation may discontinue. The informants would probably perceive the aim of the study to reduce blood usage therefore this would influence their responses therefore the ethnographer had to be aware of their own influence on informants' behaviour and responses. Furthermore, earlier nursing ethnographic study has revealed that discrepancies can occur between narratives during interviews and the reality of practice (Allan 2006) and therefore this adds weight to the use of ethnographic observation to determine the social behaviours, which culminate in a blood transfusion episode. In this case, the researcher did all of the observations and interviews; the researcher was a senior nurse in the clinical areas therefore this had to be considered in analysis if the interviewees described behaviours that was not observed in clinical practice, particularly if any behaviours were contrary to guidelines or policy. The relationships between the interview and observation data will be described in more detail in Chapter 5 (section 5.1) and how the data were integrated.

In summary, ethnographic research can help healthcare professionals to solve problems beyond the reach of many other research approaches, particularly in the understanding
of patients' and clinicians' worlds. The ethnographic phase of this study attempted to make sense of transfusion practice by not only presenting the findings from the viewpoint of the individuals involved, but also by embedding the social context of that experience in the research process. The context in which experiences occur are a key strength of ethnography in enabling service providers, healthcare professionals and policy makers to use the results of research in initiating, developing or evaluating healthcare and social care practice or by developing further study.

3.6 Summary

The initial study design of combining qualitative and quantitative methodologies can be tempting because this approach would seem to give a “fuller picture” (Silverman 2006, p51), however, multiple sources of data may require more advanced data analysis skills. The temptation is to move between data sets and focus on one more than other when difficulties arise. This provided further weight to the decision to amend the original design, as this had not been thought through in robust way.

In summary, this research project harnessed a variety of different ethnographic methods to qualitatively interpret clinical practice, rather than seeking to quantify and measure its effects by quantitative methods. Therefore it was not value free and acknowledges the human contribution to the process, which would not be acceptable to the positivist researcher. It is these features, which make it suited to the research of the diagnosis and treatment of cancer-related anaemia as it has already been stated there is subjectivity involved in the assessment and management of this type of anaemia and wide variation in practice. It was an interpretivist approach whereby the researcher explored the symbolic interactionism in the function of the group involved in transfusion
practice to construct an account of the transfusion culture in cancer related anaemia; with emphasis on the key elements involved in the clinical decision to transfuse. If there is to be an improvement in the understanding of clinical practice, the individual and social contributions, needs to be acknowledged. It is not merely treatment of a laboratory value but a complex decision, which is influenced by a multitude of factors, and the degree of influence of these factors is unknown; or alternatively, it may be a complex decision, which has been simplified, by focusing on laboratory values, but the fact remains the reality of cancer related anaemia diagnosis and treatment is relatively unknown. This methodology fits with this project because it was not clear at the outset what factors were involved in the assessment and management of cancer related anaemia. This methodology may also be used to help practitioners critically reflect on and examine their work practices and social interactions, to arrive at some sort of consensus of what kind of services could be provided and why they need to be provided in a particular way. It could be described as a critically reflexive model of research, being both practice-based and patient-centered in its philosophical methods. It is only following an analysis of the diagnostic processes and decision to transfuse that an understanding of the influencing factors will be ascertained and optimal transfusion strategies may be developed for patients.
CHAPTER 4
Method

This chapter begins by describing the participants in this research, including exclusion and inclusion criteria, and how entry was gained to the field. It includes a description of how the data was collected followed by the relevant ethical concerns in social and ethnographical research. The data collection proceeded in no fixed order and was subject to participant and researcher availability (Diagram 4).

Diagram 4: Chart demonstrating data collection

4.1 Patient Participants and data collection

The criteria for patient selection was agreed and decided on following consultation with Consultant Haematologists and Oncologists; advice was also sought from the transfusion lead Consultant and Transfusion Practitioners and the nursing teams.

4.1.1 Patient participants

Potential participants were identified by, either the Haematology or Oncology day care unit staff, or medical staff in the clinics as they were in frequent contact with out-patients
who regularly attend for blood transfusion. See Table 4.1.1a for initial inclusion and exclusion criteria for patients to be considered for study.

Table 4.1.1a: Inclusion and exclusion criteria (patients)

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Male or female lung cancer out-patients or haemato-oncology outpatients who have cancer-related anaemia and who are supported with regular blood transfusion therapy. This was defined as patients who have received blood transfusion at least once every two weeks for the previous month or in whom it is anticipated blood transfusion support will be required.</td>
</tr>
<tr>
<td>2. Patients must be willing and able to complete the Functional Assessment of Cancer Therapy-Anaemia (FACT-An) questionnaire</td>
</tr>
<tr>
<td>3. Patients must be willing to wear the actiwatch</td>
</tr>
<tr>
<td>4. Subjects must be able to and understand and have signed the written, informed consent form and the written information provided therein. Appropriate time should be allowed for consideration and questions.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patients who are on erythropoietin therapy</td>
</tr>
<tr>
<td>2. Patients who are in any other investigational trial or therapy relating to anaemia</td>
</tr>
<tr>
<td>3. Patients who cannot read and write English because of problems of interpreting and completing the questionnaire</td>
</tr>
</tbody>
</table>

The aim for the quasi-experimental component of the study was to recruit five haematology and oncology and five lung cancer patients to study. Potential participants were approached by the researcher during a routine visit to the Haematology or Oncology Day Care and/or Outpatients in a South East England NHS Acute Trust, and invited to take part in the study. Patients were provided with the information sheet (version 2) (Appendix 3) and actiwatch information sheet (version 2) (Appendix 4). The researcher provided an explanation for the study at this stage and gave opportunity for any questions.
patients were asked to return to their next clinic appointment with a decision to enter the study and, if agreed, asked to complete the consent form (Appendix 5). Contact details for the researcher were provided. Once the consent form was completed a letter was sent to the patient’s GP (Appendix 6) and hospital Consultant. A copy of the consent and GP letter was filed in the patient’s case-note and with details of the research and start date documented in the patients’ medical records. Each patient was assigned a unique identification number (e.g. PH1, PH2 etc for haematology patients and PL1, PL2 etc for lung cancer patients) to assure anonymity.

Initially one haematology patient was recruited to the original design. Unfortunately she was admitted to hospital during the second 45 day period of observation and therefore data collection was discontinued. A second haemato-oncology patient was approached and he declined due to his concerns about further responsibility in addition to his concerns about his health and treatments. A lung cancer patient also declined for similar reasons. These factors contributed to the decision for the substantial amendment and change of research design as described in Chapter 3.

Substantial amendments were made following the closure of the quasi experimental component of the study, which were approved by the local research ethics committee. The inclusion and exclusion criteria were revised (Table 4.1.1b). The details of the data collection for the ethnographic interviews are described in section 4.1.3.
Table 4.1.1b: Revised inclusion and exclusion criteria (patients)

**Inclusion criteria**

1. Male or female lung cancer out-patients or haemato-oncology outpatients who have cancer-related anaemia and who are being supported with regular blood transfusion therapy. This was defined as patients who have received blood transfusion at least once every two weeks for the previous month or in whom it is anticipated blood transfusion support will be required.

2. Patients must be willing to be interviewed

3. Subjects must be able to and understand and have signed the written, informed consent form and the written information provided therein. Appropriate time should be allowed for consideration and questions.

**Exclusion criteria**

1. Patients who are on erythropoietin therapy

2. Patients who are in any other investigational trial or therapy relating to anaemia

3. Patients who cannot read and write English because problems of interpreting and completing the information sheet and consent form

4.1.2 Patient demographic data

Patients were interviewed in no fixed order and dependent on availability and consent (Appendix 7: Table 4.1.2a). Following consent of the patient participants, demographic data was collected on the age, sex and diagnosis and current therapy of the patient at entry, and whether they were working, family details as well as the timing and volume of blood transfusions. Demographic data was available on Electronic Patient Record and casenote record. Detailed information about family and work was obtained prior to interview. This data is shown in Appendix 7 (Table 4.1.2b; Table 4.1.2c and Table 4.1.2d).
4.1.3 The ethnographic interview

Potential patient participants were identified by, either the Haematology or Oncology day care unit staff, or medical staff in the clinics as they were in frequent contact with out-patients who regularly attend for blood transfusion. The aim for the patient ethnographic interview component of the study was to recruit three haemato-oncology and three lung cancer patients to study. Potential participants were approached by the researcher during a routine visit to the Haematology or Oncology Day Care and/or Outpatients Department or day care units in a South East England Acute NHS Trust, and invited to take part in the study. Patients were provided with version 4 of the patient information sheet (Appendix 8) and an opportunity to ask questions. All the patients who were approached agreed to be interviewed. They signed a consent form (Appendix 5) on their next scheduled visit and were subsequently interviewed using a digital tape recorder in either the "Quiet Room" or a single room in the ward area. Patients were assigned a unique identifiable number (ID number) and were identifiable thereafter by their unique ID number only. Some interview questions were formulated in advance (Appendix 9), however, other questions evolved as a reaction to the patients' responses.

All interviews were subsequently transcribed by the principal investigator and the digital recording removed. A sample of transcribed data is shown in Appendix 10.

4.2 Staff participants and data collection

Prior to undertaking this research, there had to be some insight and understanding of the processes and environments where the assessment and clinical decision making activities were undertaken. The potential participants needed to be considered. The
researcher had prior experience in the management of cancer related anaemia and had prior knowledge that day care unit nurses, Clinical Nurse Specialists and medical staff were involved at various stages of the processes.

This research project required gaining consent from the multi-professional team. Key personnel involved included:

- Nurse Consultant (Haemato-oncology)-research project lead
- Consultant Haematologist- Transfusion and haematology lead
- Consultant Haematologists
- Consultant Medical Oncologists (Lung Cancer)
- Haematology and Oncology Specialist Registrars
- Clinical Nurse Specialists
- Haemato-oncology and oncology nurses
- Haemato-oncology and lung cancer patients

4.2.1 Staff participants

Clinicians (nurses and doctors) were interviewed in no fixed order and dependent on availability and consent (Appendix 7: Table 4.2.1). The researcher approached the directorate team via e-mail or by directly approaching clinicians for volunteers who were involved with patients with cancer related anaemia. All clinicians were invited to participate via letter and received an Information Sheet (Appendix 11). Each interviewee assigned a unique number so the primary researcher could only identify them (e.g. SH1 -staff haematology 1; SL1-staff lung 1 etc). The random numbering was due to staff being approached and assigned an ID number but subsequent difficulty in arranging an
interview time. They were given an opportunity to have questions answered and were only interviewed following signed consent to participate in this study (Appendix 12).

4.2.2 The ethnographic interview (clinicians)
The interviews were undertaken in a private facility, for example, a pre-booked seminar room, clinic room or single office. The interview was recorded using a digital recorder. Some pre-determined questions (Appendix 13) were used to attempt to ensure aspects of assessment and transfusion practice were discussed however the interviewer had to be flexible and respond to answers in an instinctive way. Nine interviews were undertaken and included healthcare professionals from each group: Consultant, Specialist Registrar, Day Unit nurses, Clinical Nurse Specialists and Anaemia Clinical Nurse Specialist; the latter primarily cares for patients with non-malignant disorders although has experience of cancer related anaemia. The ethnographic interview was more like a conversation, whereby the interviewer slowly introduced new elements to assist informants because if the interview is too formal rapport may disintegrate and cooperation will cease (Spradley 1980, p59). All of the interviewees were previously known to the researcher and the implications of this will be discussed in the sections on ethical considerations (sections 4.4 and 4.5) and reflexive ethnographic journal (section 7.6). All interviews were subsequently transcribed by the principal investigator and the digital recording removed. A sample of transcribed data is shown in Appendix 14.

4.3 Observation fieldwork
The researcher had the advantage of knowing all of the clinical areas, including clinics and day care units. Access was not a problem with this research, as the relevant clinicians had been approached at the early design stage of the research.
4.3.1 Gaining entry to the field

Gaining entry into clinics was via the Consultant in charge of the clinic. The lung medical oncology/haemato-oncology Consultant was informed by letter and e-mail of the intention to commence the study and the primary investigator gained consent to undertake observation in their clinic (Appendix 15), although informal discussion had previously taken place during project design phase. Assurances of unobtrusiveness was described as the observer was making field notes only and was not involved in any assessment or decision-making behaviors. The clinics and day care units are all in a single centre acute Trust. The level of participation in these clinics varied as some of the patients and personnel were more intimately known to the investigator. Generally, gaining entry was not an issue as the primary investigator was known in all areas to varying degrees. This was perceived as an advantage in this study.

4.3.2 Observation fieldwork data collection

Initially the researcher attempted to use the pre-designed data collection form (Appendix 16) however this was soon abandoned in preference for a small notebook as this was pragmatically easier to collect the data. Direct quotes and descriptions of body language were included as observed. The field notes differentiated between pure observations e.g. “the patient looked pale” from the primary researcher’s opinions, e.g. “I felt the clinician brushed aside the patient’s complaints of tiredness”. Plans were made of the clinic areas in an attempt to demonstrate the complexities of the physical environment.

Data collection was undertaken according to researcher and participant availability. There was no pre-determined sequence of data collection as described. Observation in
the clinical field was determined by researcher availability to coincide with clinics and day care activity in progress. Six clinic/day care episodes were observed (three haematology clinics/day care units; three lung clinics/oncology day units) in total. The haematology clinic and day care units are separate from the oncology clinics and day care units. Plans of the out-patient clinic are shown in Appendix 17 to demonstrate the number of clinic rooms in each area and more specifically to demonstrate the complexity of the oncology out-patient clinic design.

Each clinic is approximately 3-4 hours duration but the actual time spent in the clinical areas was variable and dependent on activity particularly as more focused data collection was the aim in later observations. See Appendix 7 (Table 4.3.2a) for observation fieldwork schedule.

Clinic and day care activity lists were obtained and the patient haemoglobin recorded. Following each clinic data collection episode, any gaps were filled immediately following the clinic to attain as accurate a field record as possible. In some clinic situations it was easy to record data verbatim, for example, during consultations. Other observations had to be completed immediately following the period of observation and attempts to transcribe as faithfully and accurately as possible. All filed data were transcribed into Word document and data on patient haemoglobin and transfusion data recorded on a spreadsheet. The sample of fieldnotes is in Appendix 18 and the haemoglobin and transfusion data is shown in Appendix 7. Table 4.3.2b demonstrates the differences in the size of lung and haematology clinics. Table 4.3.2c demonstrates the number of anaemic patients in the clinics, using the NCI criteria as described in section 2.2.1 (Table 2.2.1)
4.3.3 Managing the disruptive effect of the researcher

The role adopted by the researcher during periods of observation was clearly defined from the outset. It can be difficult not to volunteer opinions and a balance has to be achieved between establishing trust and rapport while retaining enough distance for the purposes of data collection. The researcher wore her clinical uniform (as is standard practice for this level of nurse in this Trust) and collected data in an unobtrusive way and avoided questions, which may have influenced the assessment and decision to treat anaemia; it would have been unusual to have been in the clinical areas in civilian clothes. Inevitably she was drawn into patient and staff conversations. There were some ethical issues here as the researcher was known to some participants as a manager and to others as a nurse consultant. This will be discussed in more detail in section 4.5 (ethical issues).

4.4 Managing multiple data sets

The data were managed as a continuous process during data transcription. Some analysis and synthesis of results of ethnographic data as it was collected revealed the emergence of new information, for example, the involvement of multiple people in the decision making process. It was not a simple interaction between a clinician and or nurse and a patient but a process, involving multiple players, therefore the plan changed slightly to include observation in the day care units as it was revealed some of the important patient and staff interactions occurred in this healthcare setting as well as the out-patient clinics. This influenced subsequent observations and interviews and the data collection phase merged into the analysis as the principle investigator’s knowledge and understanding changed. Both ethnographic interviewing and participant observation, whether done separately or in combination, involve a series of tasks best carried out in
some kind of sequence. The ethnographer for example, must locate a social situation and informants before doing interviews and participant observation. Some questions are best asked before others and observation and interviews must precede analysis of interview data (Spradley 1980), however, slight modifications to order of data collection were necessary as dependent on availability of participants and researcher. Combining the data will be described in more detail in the data analysis in section 5.1.

4.5 Ethical issues
Ethics will be discussed in relation to social research and more specifically the issues within ethnography.

4.5.1 Ethical issues in social research
Research ethics is usually concerned with issues such as the need for voluntary (not coerced) participation, with the right to withdraw from the study or retract consent, and this is stated in the patient and staff information leaflets. Participants must have informed consent and be protected from becoming psychologically or physically harmed by the research project or exploited in any way. Less obvious ethical issues include accurate recording and safe management of data produced by the project with adequate feedback and reporting of progress. Therefore both staff and patients only participated in the study following informed consent and were provided with a photocopy of their consent form. All participants were allowed time to consider their participation in the study. This was always more than 24 hours. All patient and staff data was anonymized at the point of data collection and in any subsequent presentation or publications including this doctorate thesis. Patient consent forms were filed in the patient case notes with copies held in the site file.
All documentation, i.e. copies of consent forms, and data were kept in site files in a locked room within the principal investigator's office during the active phase and later stored in the research office (Haemato-oncology) for ease of any subsequent Medicines and Healthcare Products Regulatory Agency inspections and to comply with Good Clinical Practice (GCP) guidance. The researcher completed local GCP training in March 2007.

Issues of confidentiality and anonymity in clinical research can be contentious because projects and results are often made public in order to gain support and thus participants and their setting is relatively easy to identify once a report is published. Therefore, there was careful consideration when writing up this research project to ensure any staff and patients were anonymized. In summary, ethical issues had to be considered throughout all stages of this research project including respect of privacy if patients objected to the presence of the researcher.

4.5.2 Ethical concerns in ethnography
Sensitivity during the observation phase of the project was required because although it does not involve the patient being asked any questions directly, patients may object to the presence of the observer in clinic. Baillie (1995) highlights the problems of obtaining consent in ethnographic studies. She identifies a number of nursing studies in which the researchers have not explained if or how they obtained consent where the observations involved patients. Moore and Savage (2002) also outline more specific dilemmas in gaining consent in observation studies such as marginal participants and the problem of not being able to control who enters the field of observation. Even when the aims of the
research have been made explicit, it is not uncommon for participants to forget this (Hammersley & Atkinson 2003) and this is probably more likely in this case when the ethnographer is known to the staff and patients in the clinical areas. It is probably further compounded by the fact the researcher is trying to build a rapport in an attempt to gain the confidence and minimise reactivity. Hammersley & Atkinson (2003) describe how ethnographers rarely inform all "participants" during observation and this was the case in this research. Anonymity would be the key to ensuring ethical principles are maintained particularly if controversial or poor practices are revealed. Sensitivity was required in this project; some of the staff participants for example, described what they believed to be poor practice. This was not necessarily the case as it was part of the discovery process and will be described in greater detail in the findings and discussion sections (section 5 and 6).

In the introduction, the researcher described her own observations and experience of the management of cancer related anaemia. Awareness of this was required throughout the project and the researcher's own changing attitudes and opinions as the data and information emerged. Openness and frankness was required at the supervision sessions and feedback from the supervisors was used as a way of validating the findings. Notes were taken and the reflexive diary used. There needed to be an appreciation that the subsequent analysis was the researcher's version of the reality and an acceptance that others may view the data differently. Furthermore, the researcher's clinical background was in haemato-oncology and not lung cancer; clinical knowledge was greater in this area and may influence the behaviours of the researcher and the interpretation of the data. It is important therefore the researcher does not pre-judge, force interpretations of the data to fit with their beliefs but instead the researcher acts as
a resource to make sense of the data; otherwise the risk would be unreliable findings. As Hammersley and Atkinson (2007) state:

"This requires the exercise of some analytic nerve, tolerating uncertainty and ambiguity in one's interpretations and resisting the temptation to rush to determinate conclusions." (163)

In a sense, the foundations of the analysis lies deep within the data; this necessitates rechecking and re-visiting the data to ensure the emerging findings are an interpretation of the reality, and this is often not immediately apparent.

Moore and Savage (2002) summarise by stating that rather than being very prescriptive, researchers need to be able to respond to any changing circumstances in the field and deal with them in a pragmatic way. This was a problem in one of the haematology clinics when a patient known to the researcher became distressed following information of a relapse in her disease and the researcher had to terminate the fieldwork observation temporarily to offer support to the patient and seek assistance. To avoid any ethical concerns, any patients who may be involved in the observation phase of the study were asked by the researcher for consent to undertake observations in clinic or sit in during consultations. This is recommended to clarify or avoid concerns, which may later emerge (Kennedy 1999) therefore an explanation to the reason for the researcher's presence was explained prior to any consultations observed. The difficulty arose however during general observations of environment and behaviours in open areas when overhearing conversations in an attempt to create an image of the space and culture of the clinic or day unit areas. This is more significant if there is potential to
cause harm, distress or embarrassment to the people who have been studied. In summary, it is the responsibility of the ethnographer to try to act in ways that are ethically appropriate, remembering the aims of the research whilst balancing any problems that are encountered and respecting the values and interests of the people involved. The researcher should be able to support their actions and judgments if challenged and recognise that others may disagree with the arguments presented.

4.6 Conclusion
This chapter described the data collection and the ethical considerations in undertaking this type of research. The data are displayed in the appendices and some reference will be made to the demographic data in the following chapter. The data collection and analysis were not discrete activities; during the data collection period early ideas and a "sense of what was going on" was emerging. Some of the content of the interviews and observations were surprising and therefore required the researcher to think it through and discuss the emerging themes with the supervisors. The following chapter describes the findings and the process of data analysis to demonstrate to the reader how the final themes emerged from the different data sets.
CHAPTER 5
Data Analysis and findings

This chapter describes the process of analysis; how the different data sets were integrated to produce the findings of the study. All the data collected were organized and transcribed by the researcher. The demographic data of the clinics (e.g. size of the clinics, frequency of anaemia) and patients (number of previous transfusions and haemoglobin data) are referred to in this section, as this data contributed to the overall analysis. The data were therefore comprised of:

- Demographic patient data (Appendix 7)
- Demographic clinic data (Appendix 7)
- Patient interview data (Appendix 10)
- Staff interview data (Appendix 14)
- Observation fieldwork data (Appendix 18)

Every effort was made to transcribe the interview and observation data contemporaneously as memory was not an adequate substitute for subsequent analysis. The volume of data is typically large in ethnographic studies. The raw data refers to the mass of information that was gathered throughout the different phases of the project and will be referred to and excerpts used throughout the analysis, findings and discussion chapters.

The aim of the analysis was to allow the researcher to attain a clearer understanding of the way in which the subjects construct or views their world. Morse (1994) suggested
four stages of data analysis including: comprehending, synthesizing, theorizing and re-contextualizing. Through this process the researcher built up a picture gradually of how the various stories fitted together and what the most important themes were within the clinical context. In practice, these four processes tended to occur in an iterative or repetitive loop, with the researcher returning to earlier stages when any new questions were raised by the analysis. Repeatedly the researcher visited her original thoughts and ideas in her reflexive diary in an attempt to make sense of what was emerging. Themes changed and merged; and new ones emerged throughout; and it was a process or activity of refinement and restructuring therefore the description of an "activity" is apt. It is important to recognize there is no formula for the simple analysis of ethnographic data and no guarantees for success hence the acceptance that others may disagree with the interpretation of the data. It required "thinking it through" rather than mere management and manipulation of the data and revisiting the data and literature review with others; talking and thinking about it and visiting it again.

5.1 Integrating the data sets

Different data sets were analyzed to create a version of the reality. In Chapter 3 it was described how meaning can be interpreted from analysis of the context, and synthesis of findings, from different methods (interviews and observation). This data analysis offered a means of holistically exploring the relationships that underpin the clinical practice of transfusion. The researcher had to interpret or understand the meanings attached to the social behaviours, by examination of the different behaviours and small scale interactions between individuals that underpinned the clinical practice of transfusion. It is these small scale interactions between individuals that required exploration and the exchange of symbols in social interaction, informed by the "symbolic interactionism"
described in section 2.8.1. In summary, the aim of the analysis was to attribute meanings to the social interactions in order to describe the culture of transfusion practice.

This raised the question of how to combine these data sets (demographic data; observation and interview data) and previous knowledge, to ensure the relationships between the data sets are explored, meanings elicited and brought together to make sense of the reality. Sometimes it involved "picking up a thread" for example, the commonality of anaemia and seeing if it was within the other data sets (Moran-Ellis et al 2004; p6). For example, threads picked up in one data set (e.g. interviews), for example, the "importance of the haemoglobin value" may be picked up in another data set (e.g. observations). Triangulation of data in the true sense means combining different research methods and Moran-Ellis et al (2006) describe how combining different data sets may be a form of "integration" and not necessarily triangulation; and concludes:

"we came to the conclusion that integration described a relationship between methods brought about by decisions to operationalise and implement the research whilst triangulation described an epistemological claim" (p45)

By this, they mean that integration is a form of reaching an outcome of using mixed methodology to reach a new epistemological claim; in this ethnography, different data sets and interpretations are combined in a way to form a whole (i.e. it is not triangulation). The data sets are inter-dependent but retain their own paradigms and are not translated into one another; each equally contributing to the final analysis; and used to corroborate or substantiate the emergent themes. Initially, each data set was
analyzed, for example, to contribute to the analysis, for example, to develop the beginnings of early themes. These were then “integrated” to form an early theme or sub-theme; from there the sub-themes were explored again for common over-arching themes or in some cases contrasting sub-themes to interpret meaning from the sub-themes to create the final themes. This will be described in more detail in the following sections.

5.2 Aims of the analysis

The goal in ethnography is to discover the cultural patterns that influence peoples’ behaviours and to make sense out of their experience; the first step was to select social situations (the outpatient clinics and day units) and make observations and collect samples of behaviors, situations, events and feelings. Patterns and relationships emerged from the early observations and interviews. Cultural meaning not only comes from the patterns based on similarity but also from contrasts, for example the contrast between the more and less experienced and knowledgeable staff and the differences in haematology and oncology.

In ethnography the analysis of data is not a distinct stage as described previously; including the “integration phase” as the researcher moved back and forth between the data sets. Previously Morton-Cooper (1980) described the aim of data analysis is that it “tells the story” accurately, faithfully and intelligently (p89). It started to take shape in the reflexive diary and in diagrammatic form as the researcher tried to make sense of the information as it came in from a variety of sources, for example the observations, interviews and discussions with supervisors and colleagues. This was an iterative process and is central to the “grounded theorizing” promoted by Glaser and Strauss in which theory is developed out of data analysis and subsequent data collection is
strategically guided by emergent theory. Some describe this "theorizing" as an activity as opposed to a procedure (Hammersley & Atkinson 2007; p158) and involves using the data to illuminate ideas and then linking those ideas to other research findings and then bringing the ideas back to "test their fit" with further data (p158). The ideas are emergent from one's experience in the field, personal experience, literature review findings and preliminary analytical reflections of the data as described in section 3.4.

Not all ethnography is rooted in grounded theorizing as some ethnography is directed more towards description and/or explanation. Analysis of routine practices such as transfusion practice, can lead to the analysis of rituals and a focus on routine actions and behaviours (Hammersley & Atkinson 2007; p169). Understanding the patterns of action and behaviours can also involve trying to understand the rules; this does not just mean the official bureaucratic rules but also the informal rules or norms that guide everyday conduct and behavior. This understanding of rules as guides implies the importance of decisions; the practicalities of decision-making are important in many organizational and professional contexts. In healthcare, decision making is vital to the everyday performance therefore a description and/or explanation of the process of decision making within the cultural context was an outcome from the analysis. In other words, a description and possible explanation for why and how the decisions are made to give a blood transfusion to a cancer patient in a specific culture was an outcome of this analysis. Embedded in this, of course, is the influence of that culture on the decision making behaviours. In summary, therefore this research was not aimed at developing a theory of transfusion culture and behaviours but to understand the culture of transfusion informed by the symbolic interactionism to create a holistic picture of the reality of transfusion practice in cancer related anaemia. From there a rational and objectively
defined model can be developed and applied which aids the exploration and understanding of the social world. Further ground breaking questions may be developed that can be explored through other methodologies (Greenhalgh and Taylor 1997) and this will be explored further in section 7.3 when discussing the implications for further research.

Ethnographic research typically has a classic “funnel structure” where the focus narrows as the research progresses (Hammersley & Atkinson 2007; p160); as the project and analysis progresses separate themes are examined in more detail. During this process, they describe how frequently, even well into the inquiry how new themes emerge, and not uncommonly it is completely different from what may have been expected at the outset. It required an openness and flexibility and acceptance that ideas can change throughout the ethnographic journey. In other words, instead of coming to the field with specific questions the ethnographer analyzes the field data compiled from participant observation and ethnographic interviews to discover questions. The field notes required some preliminary analysis after each period of fieldwork, as did some of the early interviews, in order to know what to look for during the next period or from further interviews and this is part of the “funneling” process that Hammersley & Atkinson (2007) describe. In this way the focus narrowed from observations and discussion about clinical practice to details of how the different clinical areas are organized and from there a further analysis on how the different cultures are organized; for example, how the cultures impact on activities and behaviours.

Initially demographic data were used to describe the clinical setting and the incidence of the clinical problem of anaemia and patterns of blood transfusion administration. The
purpose of this was to provide a description of the clinical setting for anaemia and its management within the sub-specialisms of oncology and haemato-oncology. Componential analysis was used as a distinct technique, for example, to map out the different components within the early themes (Appendix 17) using excerpts from the data. From there, a taxonomic analysis (a thought process to start grouping together similar themes and separating out contrasting themes) was used to explore relationships and contrasts in the early themes (Spradley 1980). These processes will be described and mapped out in detail, using the data to demonstrate their emergence. In summary, this section will begin by describing the final themes and demonstrate how these final themes were arrived at by describing the clinical areas and practice; and thereafter early themes and their relationships. By “mapping out” the early themes and describing the components of these themes (componential analysis), relationships and contrasts emerged to “funnel” the early ideas into the final themes. Examples are described throughout the following sections of how themes merged together to create the final themes (sections 5.6, 5.7, 5.8 and 5.9). Therefore this research methodology and subsequent analysis demanded reflexivity and flexibility and a degree of creativity, which in was an enlightening experience for the researcher.

5.3 The clinical setting and patient demographics
Analysis of the incidence of anaemia and transfusion practice in the clinical setting was necessary to determine the incidence of anaemia and transfusion in the clinics and day units. Patient demographic data is also represented in Appendix 7 to show the patients clinical background and transfusion episodes. Descriptive techniques were used to analyze and present this data.
5.3.1 Activity and incidence of anaemia in the clinics and day units

The literature review had revealed that anaemia is a common and important clinical problem in cancer. It was therefore necessary to establish the reality of this problem in these clinical settings if the impact was to be understood. The haemato-oncology and oncology lung clinics and day units differed in physical size, (Appendix 7) staffing and levels of activity (Appendix 7: Table 4.3.2b and Table 4.3.2c).

The clinics and day units were all spatially distinct clinical areas (different wings and different floors within the same hospital) with separate staff. Appendix 17 for example maps out the clinic areas and demonstrates the different size and complexity of the environments. The haemato-oncology day unit was smaller and essentially one physical space, with a separate staff and clinical preparation area, whereas the oncology day unit had different zones for different types of activity (e.g. a zone for supportive care; a zone for chemotherapy administration). In summary the oncology areas were larger; with more staff and more clinical activity. This may have an impact on decision making and behaviours in the clinical setting therefore it was important to capture this data. This proved to be important when it comes to the discussing and analyzing different practices within the sub-cultures of haemato-oncology and oncology, as the environment, activity and people within the physical spaces influence the behaviours and culture of the sub-specialisms, which is discussed later.

The data collected on clinic activity required organization, in order to demonstrate the incidence of anaemia in the clinical setting as this may have influenced clinical behaviors. It was discovered that many patients attending the clinics could be clinically defined as anaemic (Hb < 12g/dl), however, only a few patients, had blood ordered and
prescribed in clinic. This was similar in the day unit areas. (See Appendix 7: Table 4.3.2c). The fieldnotes had not captured this data, and this was obtained retrospectively from the clinic lists and the Electronic Patient Record (EPR). The demographic clinic data demonstrates that clinically defined anaemia was a common clinical issue in clinic. Only 22% of patients overall had a normal haemoglobin level. 22.5% in haematology and 22.3% in the lung clinics (Appendix 7, Table 4.3.2c). This data demonstrated the commonality of clinically defined anaemia in the clinical areas and how few patients had normal haemoglobin values.

5.3.2 Demographic patient data

All of the subjects were either having chemotherapy or had been exposed to several cycles of chemotherapy. See Appendix 7: Table 4.1.2b for details of diagnosis and stage and treatment details, for example PH1 and PH3 had stage IV disease which means they had advanced, bulky disease (descriptions of diagnosis and treatment can be found in the glossary of terms). None of the patients were working at the time of the interview due to ill health. Their work and family details are shown in Appendix 7: Table 4.1.2c. All of the patients had been exposed to multiple blood transfusions.

The incidence of anaemia and transfusion varied between the sub-specialisms. The data described mirrors the literature review in that the anaemia experienced by these haematology patients is more frequent and severe. Therefore not surprisingly, the haematology patients had also experienced more transfusions. Again this may have an impact on the behaviours in the clinical setting, therefore provides a rationale for collecting and analyzing the data; and these data were integrated with the ethnographic observation and interview data sets as described earlier.
5.4 Overview of themes

By undertaking this process of analysis the final themes emerged (Diagram 5.4). Final thematic analysis revealed that the haemoglobin was the only determinant that was perceived by participants to be certain, when compared to other patient factors including the symptoms of anaemia. The impact of the haemoglobin often meant that it was "separated out" from the rest of the patient factors; or assessment occurred in isolation from the patient and this is described as "disaggregation of the body" in this study (Diagram 5.4). The haemoglobin value was perceived as the only constant in an uncertain world and therefore was a powerful influence on the clinical decision to transfuse. There appeared to be "acknowledgement of uncertainty" by all levels of clinicians (doctor and nurse) where symptoms were described as vague and the response to transfusion could not be predicted, however, there seemed to be a point at which there was less uncertainty and that was in the presence of more severe or life threatening anaemia and some of the transfusions fitted this category of patient. In other words uncertainty decreased as the severity of the illness increased.

The figure below provides a summary of the final themes however it was a complex and lengthy process to arrive at the concluding themes. The aim was to narrow the scope of enquiry to the most significant issues and this is referred to as the iterative – inductive approach to ethnographic analysis (O'Reilly 2005). The data description, and process of analysis, will be discussed in more detail to demonstrate how the early themes emerged from the data and were combined to produce the final themes described above.
5.5 Thematic analysis and early themes

Undertaking thematic analysis is not a discrete phase but is "tangled up with every stage of the research process" (O'Reilley 2009, p15); the data collection and analysis occur simultaneously. The researcher has to determine any meanings to the social behaviours and seek to understand the underlying motivations, thinking and ideas that have resulted in those behaviours developing. Secondly, the researcher has to identify and comprehend some of the recurrent patterns that emerge; therefore structured routines and relationships are used to provide a framework that might be relevant to understanding similar settings, which in some cases may be generalisable.
Data analysis did not proceed in a linear fashion and analysis and the writing up was constantly interspersed with periods where steps were re-traced (Ezzy 2002). It began by "working through" the large volume of data, to develop early themes and then work out how they were related or contrasted to each other. The researcher looked for surprises, concerns, inconsistencies, contradictions or information that were puzzling or demonstrated differences in opinions and in this case particularly those that related to anaemia and transfusion.

The early themes were established (Diagram 5.5) from the data; the researcher mapped these early themes out in a table and these were derived from the different components of each theme using the data (Appendix 19). This required re-visiting the data and trying to make sense of all the relationships and components as well as inter-relatedness and contrasts of the early themes as described in section 5.1 on integrating the data sets. The relationship diagram was devised in an attempt to piece together the various relationships that emerged. The relationship diagram assisted this process and this was changed on multiple occasions, and was an iterative-inductive process as described earlier. This was very much "a live document" for the researcher, who prefers to use visual representation to demonstrate process, systems or theory. This document was used to map out all the components and determine where overlaps and contrasts existed.

These sub-themes started to emerge and it was important to start to draw them together to create an early description of what may be going on. In addition to these sub themes, there were data from the clinics, for example, the incidence of anaemia. These sub
themes have been evidenced below using excerpts from the data; these have been described under the sub-headings of the final themes in an attempt to map the process of analysis out for the reader.

Diagram 5.5: Relationship diagram demonstrating sub-themes

5.6 The ubiquity of anaemia and blood transfusion

From the literature review it was evident that clinically defined anaemia is common in this population; blood transfusion is used in a variety of clinical situations and clinicians encounter transfusion early on in training. It is not a new or novel form of therapy, the public are aware of it, and many patients and staff have been previous blood donors (up to 3 million donations per annum in the UK). The literature review revealed that anaemia is common but that patients adapt and learn to live with anaemia, which can diminish its impact. Anaemia may be present but may be of minimal clinical consequence because it
does not require an action or treatment and therefore a contrasting theme developed in
that "anaemia and blood are not important", in spite of the frequency one encounters this
in clinical practice. Diagram 5.6 demonstrates the bringing together of these components
or early themes, to demonstrate the emergence of the final theme of "The ubiquity of
anaemia and blood transfusion" by diagrammatically demonstrating the relationships
between the components.

Diagram 5.6: Taxonomic analysis: relationship of components and early themes-Ubiquity
of anaemia and blood transfusion

This is a form of taxonomic analysis (Spradley 1980) whereby the components or
themes are grouped together by resemblance or related criteria or contrasting criteria.
Some of these components arise from the demographic clinic and patient data; others
from audit data and the literature review (high incidence of anaemia and frequency of blood transfusion) and others are early themes from the ethnographic data. The researcher's experience and interpretation of the data is also an influence. Each component will be described separately demonstrating how the data contributed to the development of the "ubiquity of anaemia and blood transfusion".

5.6.1 The frequency of anaemia and blood transfusion therapy

It was demonstrated in the literature review that anaemia and transfusion were common in the oncology setting and was further substantiated in the audit data. The demographic patient data showed that clinically defined anaemia was frequent in the clinic setting but that in contrast the number of patients who were transfused were minimal. Thematic analysis of the staff interview data revealed that they viewed anaemia and transfusion as common and familiar:

"People will always be anaemic and we are always going to need blood transfusions no matter what great inventions they come up with...in our acute setting..." (SH4; 251)

"Oncologists use a lot of blood [ ] I bet most of our registrars don't have a single day of the week without transfusing a patient, you know I bet most of our registrars prescribe blood every day of the week at least once if not more than once and so I think a lot of oncologists use a lot of blood" (SL1; 196)

The patient demographic data revealed the patients on study had been exposed to multiple transfusion episodes, more so in the haematology-oncology population. To clarify, it is a small proportion of patients who receive multiple transfusions, but given the large numbers of patients who attend oncology out-patient departments every week, the exposure to transfusion episodes is multiple. Similarly the interview data revealed that patients were very familiar with being anaemic and having blood transfusions; they were also familiar with the processes involved which is demonstrated in the second extract:
"You could get the outside parameters because you know I need blood probably about once a week or once every 8 days and sometimes you need it twice" (PH3; 148)

"You come into the clinic and they take your bloods, take it away and analyse, you might need platelets or blood and you know that you won’t get them before 3pm anyway, because that is the delivery time. By then because you have been sitting there, its getting up to 3 o’clock, then you have your blood 1 unit, usually 2 and that could last an hour and a half maybe two hours a bag and they’ll find a vein. They will put in a cannula in at the beginning. If they think you need blood rather than just take drugs they will put a cannula in at the beginning." (PH3; 166)

By combining the data sets in this way one starts getting the sense that within this culture anaemia and blood transfusion are a given; they are embedded in day to day practice, routinized and can be found in any oncological setting.

5.6.2 Living with anaemia

It was revealed in the literature review that the human body can adapt to anaemia; and section 5.3.1 revealed the majority of patients in this clinical setting had a degree of anaemia, however, only a few were actually treated. Importantly, even when patients are treated with blood transfusion, it will often be the case that they remain anaemic. It was revealed in the interview data that clinicians do not use the textbook definitions (NCI definition in literature review; Table 2.2.1) and although many cited some definitions, there was an acknowledgement that it was only when the haemoglobin reached a critical level (and this varied) that treatment would be initiated, for example:

"...but if they have a haemoglobin of less than 10g/dl I would refer to them as anaemic but I would not necessarily treat them for that" (SL1; 11)

"I suppose technically anaemia is haemoglobin lower than the...the normal so it would be less than 11.5 in a female, less than 12.5 in a male, but we don’t act on these values, we only act when it is symptomatic or if the haemoglobin drops below eight" (SH2; 3)

There was also an implied awareness of the adaptability to anaemia, or expectation of some tolerance to the anaemia, prior to initiating any therapy and it was also described by the patients:
"you get used to feeling rough anyway and you usually just put that to one side"  
(PH3;71)

The staff also acknowledged patients' tolerance and that perhaps the other experiences of cancer and treatment may overshadow the problem of being anaemic, for example:

"So with these patients it is not ideal, it is very difficult I think for them and I think that is probably why a lot of them don't shout out about their symptoms because they know that they are going to have to go through all of that on top of this"  
(SL;508)

At a fundamental level there seemed to be an acceptance by patient and staff that cancer patients live with their anaemia and symptoms, particularly fatigue. It was only when there was a "critical trigger" for patients or clinicians that treatment was initiated, for example, the patient may experience an escalation of symptoms or the haemoglobin may have decreased to a critical point.

"It is just that, when people put things in an order of importance that they could shift anaemia a little bit down their priority list, because they are coping with it until they come up to a point that they can no longer shift it down the priority list"  
(SH9;90)

"She has to work, she has to go to college, and it came to a point that she could no longer do her college work and that is when she decided to come in..."(SH9;58)

The decision to treat the anaemia was unpredictable and variable but nonetheless there appeared to be a point at which it switched to a clear decision to treat. This is discussed in more detail in section 5.7 in the discussion about uncertainty.

At a more subtle or analytical level, the "cancer-related anaemia" may have had a different meaning for different clinicians and patients or it may have a different meaning than when "anaemia" is used isolation. For example one of the patient extracts demonstrates that in spite of multiple blood transfusions he did not consider himself to have anaemia:

"You use the word anaemic. I don't use the word anaemic, because I don't perceive myself as anaemic. But maybe I should." (PH3; 39)
This was also reflected in the different definitions in the interview data. The meaning of a diagnosis is an important factor in how a disease is managed, and may be an influence on the culture of transfusion practice, and will be explored in more detail in Chapter 6.

5.6.3 Anaemia and blood transfusion in the hierarchy of clinical issues

Despite the frequency of anaemia it emerged from the data to be unimportant in terms of continuing education of the management of anaemia; this was evidenced by statements in the interviews, for example, one of the Consultants when asked about his transfusion training stated:

“Well nobody has trained me since I was at medical school. I probably should have been” (SH1; 312)

And he commented further:

“I know that medical students get an appalling lack of education about blood transfusion these days” (SH1; 326)

The management of anaemia did not appear to be discussed in clinical practice; it did not pose a clinical issue that warranted discussion between colleagues; for example where one of the Consultants described how anaemia the management of anaemia is learned in the clinical setting “I am treating it as a given, it is something they (the doctors) learn by osmosis,” (SH1; 336). The following excerpt by the other consultant similarly demonstrates the low priority of transfusion decisions in clinic, but alternatively it may be due to the prioritizing of other issues in the clinic:

“I guess what it comes down to is that most of our clinics are very busy and who gets a blood transfusion and who doesn’t is not something that is necessarily discussed with the consultant ...whereas any chemotherapy change has to be discussed with the consultant we don’t mandate that for blood transfusions...and so therefore I guess the message that gives out is that this is a less important decision and so therefore the registrars or clinical fellows don’t feel that they have to come and talk to us about it they will make the decision and because they are not talking to us about it and because we are not talking to them we are probably not educating on the job about blood transfusion” (SL1; 28)
The lack of discussion about anaemia and transfusion was also evident in the fieldwork data, whereby a long consultation with a known anaemic patient was largely based around the disease and plan, and the anemia was not discussed until the end of the consultation and the patient described how he received his blood results as an outpatient:

"The patient explains that he gets the blood results from the nurse anyway...and he doesn't think the GP even looks at it". (H.11.3.08;91)

This demonstrated the patient's awareness of the professional's priorities of care and links to the clinician's description of priorities in the clinic described in the earlier excerpt; the primary disease and therapy is the focus and not the anaemia or the quality of life issues. In summary, the important decision making discussions focused on the disease and treatment and the management of anaemia seemed to be given low status or priority; at most a brief discussion around the technical/logistics of the transfusion as demonstrated in one of the fieldnotes:

"They discuss her need for blood first—your Hb is 7.2—how are you feeling—it was 8.5 last week—shall we transfuse you?" [They discuss the plan for today—maybe she could fit in blood today—go up to the day unit to discuss with them first "If you think you can have blood today then do it"—"sounds good—let’s do it" (HC1;35)

The low priority or status of anaemia and transfusion decisions was demonstrated elsewhere, for example, one of the Specialist Registrars described how she could not remember if her decision making had been overruled by another healthcare professional and she described this as "none scar me so much" (SH2;479). In addition, it may be linked to the "meaning of cancer related anaemia", whereby although anaemia was common it was not until it reached a critical level that it warranted a diagnostic label and treatment. In summary, the management of mild or moderate cancer related anaemia sits relatively low in the hierarchy of clinical issues for cancer patients and this is reflected by the lack of discourse and education. The hierarchy of the clinical issues will
be discussed in more detail in section 6.2.1 where the relationships between the hierarchies of clinical task and knowledge will be explored in more detail.

The important elements of transfusion practice seemed to be primarily related to safety, and process issues to avoid making transfusion errors, rather than decision making as demonstrated in the following extract:

"my main recollection of mandatory training was about labeling the bottles correctly and storing them in the right place and getting the blood from the right place as opposed to when to transfuse and why" (SL1:256)
"we were taught how to check a patients ..you know, when you are taking a sample and also when you are putting a sample up how to check the patients details and check the blood group and the expiry date and that sort of thing, so apart from that I can't think of any." (SH2:306)

Therefore, the safety aspects of transfusion sit high in the hierarchy of training and education. This may be related to national mandates about transfusion safety and the financial risks to the Trusts for not complying with mandatory training measures. In summary, the education systems in place, in the form of mandatory training were not focused on clinical decision making, but on the processes involved once the decision to transfuse had been made and this may be related to the institutional priorities of ensuring safety and compliance.

5.6.4 Summary
This section (5.6) demonstrated how the different components and emerging themes, derived from the different data sets were combined and integrated to produce the theme of "The ubiquity of anaemia and blood transfusion" (shown in Diagram 5.6). It is an interpretation of the reality; for example, the researcher had to acknowledge her interest in transfusion and that the participants appeared to find this a new experience to be asked about their transfusion practice. For example, one of the Consultants commented,
during the interview: "you are being very challenging.... it is very interesting" (SH1:337).
However, by continually re-visiting the data and questioning the content of the data it emerged that there was an acceptance of the commonality of anaemia and transfusion, that patients lived with anaemia and transfusion, but that in contrast to the cancer and therapy it did not warrant education; debate and careful decision making. The multiple facets of this theme will be discussed in more detail in Chapter 7, because it has implications for the sharing of knowledge; decision making and transfusion training and practice.

5.7 Acknowledging Uncertainty
As described in the literature review, there was an acknowledgment that the symptoms of anaemia were unpredictable. The haemoglobin was an absolute value that all participants referred to as defining anaemia, however, it was universally acknowledged that uncertainty exists, particularly if the anaemia was moderate or mild, and the haemoglobin levels that were used to define anaemia varied among patients and professionals. This may be related to the indeterminacy of the anaemia; or alternatively related to the difficulty of separating out the symptoms of disease and side effects of treatment from the symptoms of anaemia.

The literature review also revealed there were unpredictable responses to transfusion and the benefits of transfusion may not be clear; therefore the professional has to decide how to balance the benefits against the risks. It was felt that some of this uncertainty could be relieved if the anaemia was contextualized or assessment and treatment decisions could be improved if the professionals who "knew" the patient were the key decision makers. It was implied that the quality of that decision could be improved if the
decision was contextualized and therefore was a contrast to the other themes or components that resulted in the uncertainty. Therefore although uncertainty existed; by contrast the uncertainty could be reduced if the decision was placed in context for if the patient was known to the clinician. Diagram 5.7 demonstrates how individual early themes or components were combined to produce the overarching theme. As in the previous section, each early theme will be described in detail using extracts from the data sets to demonstrate the researcher’s thematic analyses.

Diagram 5.7: Taxonomic analysis: relationship of components and early themes - Acknowledging uncertainty
5.7.1 Uncertainty

It was demonstrated in the literature that a wide variation in practice exists in spite of clinical guidelines. It was described how symptoms could be attributed to anaemia but fatigue levels in particular did not always correlate with anaemia. This uncertainty was revealed in the data and related to assessment and diagnosis of anaemia, for example the Specialist Registrar acknowledged the uncertainty of anaemia:

“It's an individual thing, definitely. I don't think there is a level for anyone” (SH2;42)

Another level of uncertainty existed in relation to the uncertainty of response to the transfusion, for example:

“.I just can't remember a time when I was saying“ I definitely think this person needs a transfusion “ (SH2;515)

(when asked about response to transfusion) “most of the time..they are very vague..very vague descriptions really..just feeling more energy or just feeling a bit better but is that a change due to transfusion or due to something else that is going on otherwise with them..it is very difficult to say” (SH4; 156)

“.you will feel so much better after two units of blood..and often they don’t…”(SH4;244)

The patient data revealed similar findings in that they acknowledged the uncertainty of confirmation of anaemia as well as the uncertainty of response to transfusion. Patient PH3 described this eloquently early in his interview:

“At times you couldn't tell whether you felt awful because you were low in the blood states or you felt awful because you ... because of the chemotherapy . And even when you had the blood you were obviously better because you're going about ..but you could still feel awful...but that was no reflection on the blood going in. Sometimes for example, about 3 or 4 weeks ago, I had blood on the Friday and I had the best weekend I had had for about 5 months. I had a good period of for three days and then I went downhill and for that one weekend I felt really brilliant and that was down to the blood”. (PH3;5)

PH1 described her tiredness but this was unpredictable and not necessarily related to the haemoglobin level, for example early in the interview when asked what she thinks she feels like when she is anaemic she stated:
"I feel fatigue....I just want to like...erm... get some rest, everything that I do, I do very slowly. Simple things like washing the dishes take longer for me, because I feel very fatigued".(PH1;4)

But conversely when asked about her haemoglobin level when she comes to the hospital and being able to predict the anaemia she responded:

"Yes very surprised...actually last time it was 7.6 and I wasn't feeling so tired....like I think it was yesterday....yes Thursday... yes... and I wasn't feeling so tired. I was feeling tired but as normal as I had been before but this was the lowest level that I had been."(PH1:45)

The patients were therefore uncertain about the relationship between how they were feeling with the presence of anaemia and described in their interviews how they used the haemoglobin value about confirming or rejecting the presence of anaemia, for example:

"It is sometimes the other way around because sometimes you just feel awful because of just the mixture of what is happening to you and you can just feel awful and in fact your bloods are all right. You know they could be 9.4 or whatever it is."(PH3;45)

In summary, "uncertainty" was described by both clinicians and patients; to some degree this had been expected, however, it is interesting that patients themselves could not "read their bodies" and their symptoms did not always correlate with the haemoglobin level. When this happened the haemoglobin level was frequently used as the deciding factor whether to transfuse or not. This demonstrates the importance of the haemoglobin result in the decision making which will be discussed in further detail in section 5.9.1.

5.7.2 Separating the symptoms

This theme started to emerge early in the patient interviews where it was described how difficult it was to define the anaemia and separate the symptoms of anaemia from symptoms of disease or side effects of treatment; and is closely linked to the previous theme. Without being able to clarify the symptoms of anaemia, it is difficult to treat;
treatment can easily result in either over or under-transfusion. Examples from the data that demonstrate this difficulty of separating out the symptoms; include the following:

"I suppose the most common things are, the tiredness, the fatigue which again is a tricky one because it could be cancer-related fatigue and chemo-related fatigue that we talk about...again it may not be associated with the anaemia" (SH5:65)

"...I would normally say ...are you any more tired than normal...are you any more breathless than normal and if I think they might be then I would perhaps go into some more detail about that to try to determine if they had a symptomatic anaemia as opposed to symptoms of their disease....and of course symptoms of disease can be very much overlapping with symptoms of anaemia." (SL1:27)

To combat the uncertainty, it appeared the haemoglobin was used to define and diagnose the anaemia. For example:

"We know they are anaemic already, because we have got a blood count in front of them" (SH2:133)

It may be the clinicians did not therefore feel the need to confirm the symptoms of anaemia, particularly as there was uncertainty about the symptoms; the symptoms may then become inconsequential and may not even be pursued with the patient. For example when asked about symptoms of anaemia one of the clinicians stated:

The questions I am asking myself is ...do I need to? ...and by that I mean if the haemoglobin has fallen (SH1:417)

In summary, at the early stages of analysis this was described as "separating the symptoms" whereby there seemed to be attempts to ask about symptoms but the questions to patients were also vague and non-specific for example, questions about being tired or breathless, which may have been related to the uncertainty as described earlier. Conversely, there appeared to be faith in the haemoglobin value as described in the last two excerpts; further analysis was required to unpick the detail of how the haemoglobin value was interpreted by the clinician as it appeared the symptoms were not able to be interpreted in a robust way.
5.7.3 Risks vs Benefits

As described earlier, the uncertainty also existed as to whether the patient would benefit from the transfusion and whether all the risks and benefits could be applied in cancer related anaemia. The benefits might be that one may expect some symptomatic improvement or improvement in quality of life parameters but from the earlier analysis this was perceived to be unpredictable by the patients themselves. It also implies there may be difficulty in assessing response (i.e. measuring the benefit) by clinical staff and this was acknowledged in the interviews, for example:

"...in fact so there is not very good continuity in assessment of response to blood transfusions I think something in which we should and could improve but we don't robustly assess response [ ]...we have no robust mechanism of assessing response of a transfusion which means that there is a risk and I am sure it happens that people do get repeat transfusions who are not necessarily benefiting from them". (SL1;130)

This has implications for practice in that there may be a tendency to over-transfuse, thereby increasing or causing unnecessary risk. The risks of transfusion are part of mandatory training (as described earlier) but surprisingly, this did not seem to be of a concern to the medical team who tended to view it as no harm or minimal harm of administering blood transfusion. For example:

"...because when I do transfuse people at that level some of them feel better and I rarely don't, ...I don't see people being worse" (SL1;424)

I am thinking we can and probably do transfuse people who don't need to have it or who maybe don't need to have a transfusion, the consequences of that seem potentially less catastrophic than giving the wrong chemo or the wrong chemo dosage to the wrong person (SL1;299)

It could be that the medical clinicians do not have the "hands-on" experience to balance the risks with the benefits because they are not present at the point of care delivery, i.e. at the point of transfusion. This may be related to earlier discussions about the hierarchy of clinical issues or concerns in that a transfusion decisions are of less clinical consequence than other decisions in the clinicians “hierarchy of concerns”.

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It was also revealed that decisions to transfuse had been made in clinic or later when blood results became available or that a nurse had asked for a prescription to be written or for a decision to be changed, which will be explored in the section on "shared responsibility" in section 5.8.3. The nurses are the actual administrators of the blood however, and this may result in the nurses being more cognisant of the risks of transfusion, for example:

“Possibly, whether they (doctors) are just not thinking about it or think they are doing the nurse a favour by just prescribing the blood, yes.. it could be any of those things but they haven’t thought enough about it ...they haven’t had a scare..." (SH5;355)

“...yes so people being made aware if you have never seen a reaction or you know a bad transfusion related event you are not really going to think twice about prescribing .....you know for any drug;....if you see a bad effect or side effect it really scares you and you think ...god and you think twice” (SH6;381)

“and in fact transfusing them is putting them at risk and you don’t want to over-...transfuse...”(SH4;116)

Patients may also consider the risks and some may wish to avoid transfusion but the patients described how they had to receive blood in order to survive therefore in relation to this the risks seemed inconsequential, for example PH1 describes:

PH1: “I just sometimes get scared because I know that sometimes I can get some illness, even knowing that they do tests for all kinds....there is always the possibility that something goes wrong...so of course I have had lots of blood and I think “oh my god” how many chances of getting something, some illness, so of course I am really scared...it just keeps in my mind”

Pt: "Do you worry about it?"

PH1: “Yes of course, I do worry about it you think about in the future I could develop another kind of illness like...erm...hepatitis so obviously I do worry.”

Pt: “And how do you see blood transfusion now?”

PH1: “In my situation right now because of the leukemia and because of the chemo and how it reacts for me and for me and how it makes me feel..I need the blood..for me now it's very good” (PH1;69)

In summary, the benefits appear to be unpredictable and the risks do not seem to be considered at the point of decision making; the reasons for this may be complex and will
be discussed further in subsequent sections. Furthermore there may be something about the immediacy of blood transfusion; it is a transient treatment with a transient effect and can have a limited impact, therefore the long term risks are not important. This can influence decision making particularly if the patient has poor prognostic disease where the short term benefits outweigh the long term risks; therefore the risks may be inconsequential. This was implied in SH1 interview where he described a reluctance to transfuse children because of the long term risk. The patients also seemed to accept the risks as the blood is a life saving treatment for them at that moment in time; but recognised the benefits were not sustainable as in PH3 comments in 8.8.2 where he felt good following a transfusion for one weekend only.

5.7.4 Contextualizing the anaemia

The uncertainties have been described; however, it was revealed in the data that some strategies are employed in an effort to reduce the uncertainty. This is about contextualizing anaemia; it involves thoughts about the speed of onset of the anaemia; the type and intensity of therapy; stage and type of disease and previous response to transfusion and individual patient characteristics. Therefore the context of anaemia and the ability to have some degree of prediction had an influence on assessment and decision making. For example, the day unit sister described how she contextualized the anaemia trying to take into account their disease and treatment and whether the patient's blood counts were recovering or not:

"(you) take into account where they are in their treatment, their disease status, their age..."(SH4;89)

"If you have got someone who you know is recovering their counts from chemotherapy but their haemoglobin is maybe lagging a little bit behind...I would often try and not transfuse them because you know that the bone marrow is beginning to work again" (SH4; 187)
Similarly, one of the Consultants described this behaviour as an attempt to contextualize the anaemia and relate it to the pathway:

...but often you can...sometimes you can tie it to what's happened to the haemoglobin over time...and see in fact they've been tired for ages and they've only become anaemic since you started chemotherapy and they're no more tired than before...so that's not the anaemia (SL1;72)

Therefore there is a suggestion here that some of the uncertainty can be reduced by linking the anaemia more closely with the other patient factors such as disease and treatment detail, and timing of anaemia in relation to treatment pathway. This may have implications for clinical decision making in practice as it implies that the clinical staff who have most knowledge about the individual patient may be best placed to assess, diagnose and treat cancer related anaemia.

5.7.5 Summary
The section has demonstrated how the sub-themes are linked together, for example, uncertainty is related to the difficulty of separating the symptoms of anaemia from the symptoms of cancer. The risks and benefits of transfusion are also uncertain and it was described how patients did not always improve post-transfusion. This uncertainty was acknowledged and various strategies were described that could improve the decision making, for example, previous knowledge of the patient. The final contrasting theme of contextualizing the anaemia may give some insight into how improvement into the management of anaemia can be made and this has implications for practice which will be explored further in the discussion chapter (Chapter 6) and the implications for practice section (Section 7.2).
5.8 Socialization in practice

It was not clear at the outset of the study how transfusion practice is learned, but it was recognized in the literature review that despite clinical guidelines, transfusion practice varied. Some of this may be due to the uncertainty in diagnosis and treatment as described, however, as the data analysis progressed other themes emerged which may provide some further explanation of variation in practice. Furthermore, there was evidence from the data that traditional practices existed in different clinical settings; that practice varied according to institution and sub-specialty; that shared or collective decision making was acceptable practice and therefore all of these may be described as forms of socializing the various players (doctor, nurse or patient) into the accepted behaviors of that culture (Diagram 5.8). It appeared that clinicians are socialized into anaemia practice depending on where they are and in what institution. For example, it was evident that clinicians changed their practice because that was acceptable in the new department or institution and that was the traditional practice in that particular clinical setting. It was demonstrated in the previous section that uncertainty existed therefore institutions use transfusion guidelines in an effort to control the practice and prevent over or under-use of blood products. This research demonstrated how small communities of practice actually controlled the use of blood more so than by implementation of guidelines. This was further substantiated by the evidence that showed multiple clinicians may be involved in making the decision to transfuse; the decision sometimes appeared to be shared or mutually agreed, or changed at the point of care delivery (the day units) and therefore the decision making could be described as a social behaviour.
The behaviours seemed to be different for the different sub-specialisms of haematology-oncology and lung cancer and this gave further evidence for the socialization in practice. However, individuals bring their own experiences, knowledge and attitudes to the different social communities and these are influenced by the environment and these have been collectively referred to here as "internal and external influences". As for the previous sections, each theme will be discussed separately to explain how these were derived from the different data sets.

Diagram 5.8: Taxonomic analysis: relationship of components and early themes--Socialization of practice
5.8.1 Traditional practice

Traditional practices were implied in many of the interviews in relation to blood transfusion practice. These were described as “habits” or reference to the fact that blood has been a long standing form of therapy and that “old evidence” was used to dictate practice. For example one of the Consultants commented:

“The reason that we tend to give two at a time I am sure is affected by practicalities and habits as it is by logic” (SH1;171)
“because other therapies you get updated in but bloods been around a long time you know you just use it ...”(SH1;318)
“so.. there is clearly a body of very old scientific evidence to show that getting your haemoglobin level above ten doesn't really help you terribly very much” . (SH1;113)

Similarly the Oncology Consultant acknowledged the existence of traditional practice in the following extract, and more specifically in relation to the two unit transfusion:

“Obviously we give two unit transfusions far more often than any other amount for I have no idea what reason. I do know and this is historic when I was a medical SHO both general medical and in oncology which I was in the same place we were told that we should never give a one unit transfusion to anybody ever because there was never an indication for that ...people needed two or three units or they didn't need it at all...”(SL1;445)

Conversely, it was acknowledged that practice had changed over time, with acknowledgment that a lower trigger was now used:

I haven't a clue ..I would suspect that they are better at that now than they were, you know in the olden days you used to throw blood around... (SH1;269)
“...and I think also doctors are more reluctant to prescribe whereby initially when I think back years ago when your haemoglobin was 9...9.5 you know you could have a couple of units of blood and it was prescribed willy-nilly... “ so yes there has been a huge change in practice” (SH5;154)

It was demonstrated in the literature review that medical behaviours and clinical decision making can be entrenched (Firth-Cozens 1997) and these data demonstrated that perhaps this is the case in relation to transfusion prescribing practice.
5.8.2 Internal and external influences

This broad term was used to describe the early theme of what influenced the clinician in making decisions about transfusion; these could be practitioner attitudes or external influences on their behaviours such as practices within the institution or clinical setting.

For example, the Specialist Registrar described her experiences in other hospitals:

“while I have been here no patient has ever commented that they feel that they are not being transfused often enough or that they feel tired at home and that maybe just that they haven't communicated that to me, but...erm...I would certainly...in X hospital it was commented..oh it's a bit cruel to let them go til its below 8 before transfusing them but I've certainly...its never been communicated that patients feel we are being cruel to them not to transfuse them before...I don't know (SH2;97)

“Erm...I don't think we are meant to but certainly at my last hospital we would, if somebody was about to be discharged we would transfuse them up to a higher haemoglobin” (SH2;55)

The second extract demonstrates how the doctor followed the routine practice in that area in spite of it being against those hospitals guidelines; in other words, clinicians may tend to be influenced by the “transfusion culture” in the particular clinical setting rather than practice independently and this may contribute to the variation in practice described earlier. For example, she also described the practice on the wards:

“All the things you are saying about what the triggers to transfusion and when you should...transfusing are...I don't think that is clear I don't think we have particular training...all we know is on the ward is when someone's haemoglobin drops below 8 you should transfuse and that's what the SHO's know but more formal training we haven't had.”(SH2;423)

Similarly the Clinical Nurse Specialists explained their experiences of this setting in comparison to other clinical settings:

Yeh... I suppose that is what they are used to...just different trusts they have different ways of doing things (SH4;106)
I mean I was taught here to look at the 10, but whereas before I probably wouldn't have worried til about 9 (SL4;356)
It was also related to what education they had experienced; some of the participants made reference to the erythropoietin literature, as demonstrated in the following excerpts:

"... I know because the manufacturers of erythropoietin have banged this into us over the years that patients feel better if they are on erythropoietin and they have got high haemoglobins and that's very good. erm..." (SH1;92)

"Well... up until a couple of weeks ago or ten days ago then you would say there is good evidence to use to use erythropoietin to maintain haemoglobin in those circumstances and..erm..with clinical benefit but now in the last week to ten days you can say erythropoietin might be harmful..erm..and may impair survival outcome from malignancy so I think the jury is still out on erythropoietin and ESA's (SL1;220)

As described earlier where the clinics were busy and there was no time to dedicate to decision making (section 5.6.3), the practicalities of transfusion influenced the transfusion decision making, for example, resource availability, as demonstrated in the following excerpt:

"a lot of this has got to do with space, we can't just transfuse everyone who's haemoglobin is below 10. We haven't got the bed space or the staffing to do it. It depends what it is, if it is below 9 and we are giving them chemotherapy, we know it is going to be lower again next week...If they are really feeling quite rough, tired and short of breath and things, before we give them treatment we will still give them the chemotherapy, but probably give them the blood transfusion the next week, if we can" (SL4;96)

"I think the resources are considered with the ....where are they going to have this blood, where can we fit them in and how can they have it in a timely fashion before or after chemotherapy so from a resource point of view that is at the forefront of my mind how and where am I going to give them this blood...ehm..."(SH5;211)

One of the nurses described how medical clinicians do not think the decision through because they may not have witnessed transfusion reactions:

"... it could be any of those things but they haven't thought enough about it ...they haven't had a scare..."(SH5;355)

The nurses are at the point of care delivery and therefore witnessed transfusion reactions may negatively influence their decision to transfuse. Also, as they are the
administrators of blood they may associate transfusions with additional workload and the 
day unit nurses are responsible for managing the resources within the day unit. This 
may mean nurses would be less likely to want to transfuse patients than medical staff 
and therefore challenge the medical decision as was evident in the day unit sister 
interviews, where they prioritized treatments or changed medical decisions:

"but I have just said we just can't do it, we have got a list on the board now of 
people, prioritising them and we look at their symptoms more, it is a bit 
harsh." (Si4; 115)

Alternatively, medical clinicians may not be giving transfusion decisions much thought as 
described earlier and this may be related to the hierarchy of the task (the decision to 
transfuse). From a junior doctor perspective it may be acceptable for nurses to make the 
transfusion decisions because they do not consider this to be an important decision, as 
they do not discuss their decision making with the Consultant as described in section 
5.6.3. In summary, this section demonstrates the complexity of influences on the 
individual clinicians in making clinical decisions and begins to describe how the culture of 
the organization and other internal factors may influence decision making.

5.8.3 Shared responsibility

This sub-theme is related to the previous theme where it was emerging that multiple 
clinicians may be involved in the ultimate decision to transfuse. It seemed that no single 
professional group owned this clinical issue; and the patient was also involved in the 
decision therefore this sub-theme was described as "shared responsibility". For 
example, one of the Specialist Registrars described how this shared responsibility 
worked in practice:

".. I mean certainly if the consultant said "actually I don't think they need blood " 
they are perfectly within their rights to say, no they don't need blood it is their 
patient and as long as they explained why then that would be fine I think...and
normally when I worked on the day unit, the nursing staff would tell me...because they knew the patients a lot better than me and they knew how likely they were to be symptomatic...how quickly they would come back, whether they could wait, in their opinion for another day and manage without blood..." (SH2;479)

The Consultant Haematologist also described the shared responsibility and like the Registrar viewed this as a positive experience:

"I get questioned you know...does someone really need that transfusion? I mean I can't think of specific instances but you know I would not be put out if I had a phone call saying somebody has come up for their transfusion and actually their haemoglobin is not that low or actually maybe they should have three units rather than two and I would take that as being good teamwork' (SH1;364)

Conversely some perceived this behaviour as negative, although it was fully acknowledged this practice also occurred:

"Yep em if the doctor that saw the patient is around, if the consultant is around they will come back to the person that saw the patient, otherwise they may not and they may go to the Reg and...I'm trying to think when I was that Reg, and if somebody came to me em.......then. I don't know, its sounds too horrific for words...I'm trying to imagine if it could possibly happen....that the person who prescribes the blood never sets eyes on the patient. em...I think that does happen....I think it does" (SL1;383)

"just blood being prescribed by a registrar as a favour to a nurse for a patient that they have never seen and they know nothing about and it is quite frightening and it happens and I see it happening most weeks, and that is something that needs to be addressed" (SH5;397)

"but you would hope when someone is taking responsibility for prescribing the drug they would see them, but I see it in clinics most weeks where random registrars have been asked to prescribe blood for patients they have rarely or never seen and I think it is wrong and perhaps it needs to be brought to their attention. But if there is no-one chasing it and if people aren't taking responsibility for it then it is difficult...it does happen, in clinics especially..."(SH5;346)

In these latter excerpts the shared responsibility is not viewed as teamwork but more lack of responsibility or ownership of the prescribing. Perhaps at a deeper analytic level the key word is “prescribing”; as was demonstrated in the literature, blood components are not subject to the same rules as medicines yet the word “prescribing” is used
routinely when referring to transfusion; it may also be related to the status of the task as described earlier in that it is not perceived as of high importance therefore not subject to the same rules as prescribing medications. It may be the principles of prescribing medications may not need to be applied to the principles of prescribing blood therefore this would have implications for practice which will be discussed in Chapter 7.

5.8.4 The influence of the sub-specialist culture
Of further interest was the way in which the sub-specialisms of haematology and oncology differed, which may give insight into how anaemia is managed in the clinical setting. Haemato-oncology cancers are rare, treatments can be intense and relationships between individual patients and clinicians form along the way. This was evident in the observations, whereby patients and medical nursing staff used first name terms to address each other. Conversely, lung cancer is a common cancer with typically short survival and poor prognosis. This is perhaps an observation that is not typically acknowledged but may be important in determining the culture of the sub-specialty. The differences in sub-specialisms may be related to the nature of disease and treatment or the volume of patients or patients having poor prognosis disease within the lung clinics. This will require further discussion in Chapter 7 as to how this influenced the differences in behaviours and management of anaemia between the two sub-specialisms.

The environment seemed to also have an impact on the behaviors, for example, the oncology clinic was larger and more complex and appeared more chaotic, for example there were larger numbers of patients (see Table 4.3.2b). The haemato-oncology clinic
was more self contained and quiet. This was an important feature as it may have affected the time available for patients-clinician consultations. Appendix 17 shows the layout of the clinics. One of the registrars described the oncology out-patient clinics as a "warren" and many of the conversations were concerned with the functionality of the clinic rather than discussions about patients or educational discussions. For example, see LC1 fieldwork notes (Appendix 18) where much of the energy in clinic was consumed in process of how the clinic was functioning, for example, were the computers working and how difficult it was to secure a clinic room as evidenced in the following excerpt:

Another SpR comes in "I haven't a hope in hell"...she is talking about finding a clinic room. What is more important is finding a room with a computer that is working. The Consultants walk in...he introduces the new Consultant and then she is escorted to a room. There is also a visiting doctor with the senior Consultant. The senior Consultant starts complaining about the room with the broken computer..."the computer department need to come and apologise to the patients" (LC1;34)

These clinics were busy, with more patients and less time. The junior doctor aspired to be like the Consultant because he complained he had taken an hour to explain a diagnosis. This implied the culture of the clinic was about efficiency and speed. Another important feature may be the poor prognosis of these patients and the emphasis being to improve symptoms rather than cure, for example the Lung Consultant was efficient when explains the prognosis to the patient and it was over in a matter of a few minutes, for example:

"we cannot cure this disease...you haven't got a lot of cancer but it can't be surgery". Again the patient asks how long she has got. He explains he cannot be definite but approximately a year-he explains some people go on for a lot longer and others do not. He explains that in some people it can prolong life...by 3 months...it is designed to improve symptoms and make you feel better. They repeat again the conversation around what she can do...can she leave the house...
and again she mentions her pain. He states there are “no prizes for grinning and bearing it” (LC1; 169)

This may impact on the management of anaemia. It may be that the team overcompensates treatment of symptoms in an effort to improve quality of life if quantity of life is not optional. This was implied in some of the interviews, for example, SL1 explained:

“I treat a lot of lung cancer where it’s very difficult because lung cancer patients do get breathless because of their disease and often because of other co-morbidities they have associated with their malignancy... such as chronic airways disease and sometimes they have a degree of cardiac disease as well... Having said that in some ways in a lung cancer patient... if their breathlessness is a significant feature and they almost have a lower threshold... even though I know that anaemia may not be the sole or maybe even the most important reason for their breathlessness and their breathlessness often to my mind... their breathlessness is multifactorial in aetiology I would almost perhaps have a lower threshold for transfusing such a patient because if it happens to help they can be patients who symptomatically can be very difficult to treat... so I would...”(SL1;44)

Conversely the haemato-oncology clinic was calm; it was a smaller more contained environment. The relationships between the patient and the team seemed closer and there was a familiarity between the patient and clinician. A further example which demonstrated the differences in the sub-specialisms was the observation of how patients were informed of diagnosis and treatment plans. For example, when taking notes during a patient consultation, one of the Consultants’ asked what the observations had to do with anaemia. This was the first period of observation, where the researcher was attempting to get a feel of the clinic culture as opposed to focusing on anaemia. The researcher explained that perhaps not directly but the way in which he managed that patient did, for example, he explained her laboratory results and showed her them in graph form on the computer. This was an example of the general impression of that clinic in that the medical staff may have had more time to “educate” the patient about their disease and progress, than in the oncology clinic. This was further substantiated
during the more focused patient interviews, where the haemato-oncology patients appeared more knowledgeable about their disease and treatment and frequently used the same language as the professionals for example:

...if my neutrophils are low,... like....In two days or three days I have to have more blood .... if my neutrophils are coming up..yes if my neutrophils are coming up and I don’t feel tired anymore (PH1;100)
Well I know because I am allergic to platelets in that I have developed antibodies because I have had so many different platelets..(PH3;418)

Conversely, the lung patients did not use medical terminology or seem so informed for example:

"I don't know..I don't know really. I just see the doctor and he says I need blood. He then books it on the phone....(PL1;122)

The reasons for this are probably multiple as described but have implications for how the sub-cultures may influence transfusion practice, in that if the patient is informed they may be more involved in the decision making process. However, it also implies that the nature of the clinics and the pressures within the clinical setting may mean that is some clinical settings this "education of the patient" may not be possible, either due to time constraints or the way in which the clinics are organized and structured. It may also mean the patients are socialized into the practice of that sub-culture.

Another significant difference in the sub-cultures was the different haemoglobin levels used to describe anaemia and frequently referred to in the interview data. The oncology clinicians described anaemia by using a higher haemoglobin level, for example in the following excerpts. The first excerpt is the haemato-oncology example; the second excerpt is the oncology example:

"anaemia is anything that's abnormal but in our patients we would probably have a lower threshold than some sectors would....and of course you have to assess
each patient individually...em...in our case...some patients with a haemoglobin of 8 [...]...Again...its very difficult to say...it's usually around 8 or 8'ish”. (SH4;4)

"If I'm honest...I don't separate particularly for males and females so I would say a haemoglobin of less than 10g/dl is anaemic or is anaemic as far as I am concerned although that on it's own would not be my trigger for transfusion..." (SL1;3)

This higher trigger used in oncology was revealed in the audit data, but not in the actual transfusion triggers used in the oncology patients in this study. This may be a reflection of the impact of radiotherapy, whereby there is clinical evidence for use of a higher trigger. Oncology departments have radiotherapy and chemotherapy patients and this may influence the oncologists when describing what they define as anaemia, however, there was no evidence in this study that in the lung oncology setting that higher triggers are actually used either in how the clinicians described when they would transfuse or in the lung clinic data. The second excerpt is revealing in that it describes a definition of anaemia, but they would not transfuse at this level. This will be discussed in more detail in Chapter 7.

5.8.5 Summary

Some sub-themes within the "socialization in practice" may help to explain the wide variation in practice described in the literature review; this contribution to knowledge about transfusion practice has not been previously acknowledged. The variation in practice has been described but not the influences on behavior within the clinical setting of haemato-oncology and oncology, which can be summarized as:

- The influence of the local community of practice
- The low priority and status of anaemia management
- The shared responsibility
- Habitual behaviours which in this research has been described as traditional behaviours

Optimal transfusion behaviours may be developed if the cultural influences on transfusion are acknowledged and different strategies are developed. Furthermore, socialization of practice may have implications for how training and education in transfusion practice is to be developed; more emphasis needs to be placed on evidence and efficacy of transfusion rather than merely the safety aspects.

5.9 Disaggregation of the body

The haemoglobin value, widely and frequently referred to by participants, seemed to be the trigger for action but there was a great deal of discussion about the symptoms in the interviews (perhaps because the researcher asked about symptoms); yet the reality was many of the actual behaviours were a response to the haemoglobin, and very little assessment seemed to occur in practice, other than a few brief questions. It was also demonstrated in previous sections how assessment may not be necessary if the haemoglobin result was available. This implies the haemoglobin is used in isolation, and decisions may be made when all the information is not available. The ease and universality of the haemoglobin test (virtually every patient who attends the outpatient areas has their Hb tested) relates to availability heuristics described in the literature review, whereby a clinician will base a decision on the ease of availability of information. The shared decision making described earlier, sometimes meant that decisions were changed or made in absence of the patient, therefore not all the information would be readily available, for example, the patient would be unable to contribute to the assessment and provide the subjective information. For example, when the doctors
wrote on the charts to give blood if the haemoglobin was less than 10g/dl as described in
the following excerpt:

...because that when it (prescription chart) normally comes to us is when it has
been circled and a note put at the bottom of the page to give them a blood
transfusion whereas they may not have been assessing for that before, they have
just got the result (SL4:222)

The overarching general theme is that sometimes the assessment and decision making
are made either without knowing the patient or having all of the information available.
Conversely, it was acknowledged that the assessment and decisions were improved if
the patient has a relationship with the clinician, or the low haemoglobin was
contextualized as described in section 5.7.4.

Diagram 5.9: Taxonomic analysis: relationship of components and early themes -
Disaggregation of the body
5.9.1 Importance of the haemoglobin

It was described earlier how the symptoms cause uncertainty when assessed in isolation. This was further consolidated in the interview with SL4 (Oncology Day Unit Sister) who stated when asked what would prompt them to ask the patient questions about the presence of the symptoms of anaemia:

"...and you have got the results in front of you or if you notice that they looking really pale and they are just not quite themselves. I think it is because we have got the results in front of us...it doesn't happen that often unless it is really low that you actually look at someone and go...your anaemic...it is more that we have got the results first and then we see them, if you know what I mean" (SL4; 79)

The idea started to form for the researcher that the impact of the haemoglobin level has profound effect; a low haemoglobin level would stimulate the clinician to ask about symptoms or how the patient was feeling. In an uncertain world perhaps the haemoglobin value is the only constant and therefore the major influence on the decision. Alternatively it may be that the influence of the culture is another "certainty" and therefore this drives the clinical behaviour to conform to what is the usual practice in these clinical settings. The level of haemoglobin was important, so for example, clinically defined mild anaemia (10-12g/dl), was tolerable, however, it appeared the haemoglobin was the primary determinant for the ultimate diagnosis therefore the holistic assessment did not seem of importance:

"Ok I think we are quite spoilt because we get full blood counts on everyone, so if I am sitting in a leukaemia clinic I won't actually bring the patient in until they have had a full blood count so that I know that they are anaemic" (SH2; 128)

"...but again you would still have to have the blood count in front of you so you wouldn't have to do anything clever...in order to ...you would just have to assess how the anaemia was affecting them symptomatically...and so again you would ask for oedema, chest pain shortness of breath, how it impacted on their walking distance, whether they got chest pain going up hills, that sort of thing" (SH2; 161)
The literature revealed that generally when making a diagnosis, one uses the history and symptoms followed by laboratory investigations to confirm or refute a diagnosis. In the case of cancer related anaemia it appears to be the opposite in that the laboratory value implies a diagnosis and the presence of symptoms may be used some of the time to confirm or refute the diagnosis; sometimes the laboratory value was used in isolation. This phenomenon has not been previously described in relation to cancer related anaemia and may be related to the culture of organization and/or of resources, for example, there may not be the time to explore the other effects of the cancer related anaemia.

In this study, there was no evidence that systematic or holistic assessment was undertaken to confirm the diagnosis, other than the anaemia nurse specialist who acknowledges that diagnosis and management of non-malignant associated anaemia differs from cancer patients because “they (cancer patients) are a different group in the sense that some of them have got problems with their bone marrow and that is the factory” (SH9;320), which means the production of red blood cells is affected. There was also evidence that in non-malignant cases holistic assessment was undertaken:

When those patients come in they are put through a full assessment. The full assessment will be ...first get the full story from the patient when they come and let them tell their story. From that you could actually start to make sense. From what they are telling you their story. [...] That compromises the oxygen circulation that is happening in their body. So putting all of that together, all of that information from asking the patients questions, doing a physical assessments and then taking vital signs. (SH9;125)

This was a more thorough approach, however, in a sense this is making a primary diagnosis with an attempt to find out the cause of the anemia, for example, iron-deficiency or vitamin B12 or folate deficiency. One could argue that the management of
cancer related anaemia is different because the underlying cause is known; it is secondary to the cancer or therapy, and is an accepted consequence of disease and treatment. It may be related to the hierarchy of the task in that if the management of anaemia is perceived as a low status decision because it is regarded as a symptom of the cancer as opposed to a disease entity in its own right. It is not a primary diagnosis, but merely a consequence of the disease and therapy; therefore the clinical attitude and approach may differ for these reasons and this will be discussed in more detail in section 7 in relation to assumptions that can be made about making a diagnosis.

5.9.2 Knowing the patient; knowing anaemia

This theme initially emerged as "knowing the patient", because it emerged that the relationship with the patient was important in transfusion decision making and it was described how knowledge of the patient improved the quality of decision making. However, not surprisingly it also emerged the more experienced clinicians seemed to be more discerning in their assessment and decision making. Therefore this theme was developed from the data that demonstrated or described how improvements could be made when assessing anaemia.

Earlier it was described how it was acknowledged by the clinicians that by contextualizing the anaemia (the low haemoglobin level), assessment and decision making could improve. Similarly the sub-theme of "knowing the patient" emerged; and that by not reviewing the haemoglobin value in isolation, assessment and decision making could improve. It may appear obvious, but direct interaction with the patient is an important part of the process and may actually improve practice. The patient-clinician
interaction was described in the interviews frequently as a series of questions about tiredness and shortness of breath. Appearance included how the patient walked and their colour. Both patients and clinicians acknowledged that knowing the patient was an advantage in the assessment process and was the preference for assessment. For example the Specialist Registrar described her experience of working in the day unit:

...and normally when I worked on the day unit, the nursing staff would tell me because they knew the patients a lot better than me and they knew how likely they were to be symptomatic...how quickly they would come back, whether they could wait, in their opinion for another day and manage without blood...(SH2;479)

But when you have a key person liaising with the patient and working with the patient, it is quite easy to put "your finger on the pulse" and decide whether to transfuse or not because you know your patient better and you can get the facts for your assessment quite easily (SH9;479)

This knowledge of the patient may prevent the disaggregation of the body whereby the haemoglobin is used in isolation and relates to the patient being involved in the decision to treat the anaemia, for example, patients described how the team interacts with them:

Yes some take more part, some get more involved in how I feel when... erm...do I feel symptomatic more..what do I think...they listen and we talk [ ], some get involved and some doesn't, some prefer not to get involved as much with the patient" (PH1;186)

Or based on their experience based on a whole print out and see what it looks like. I would think that it is their decision. I have never ever said " I want blood " and they said " no you don't " and I said " I do! " I've always felt very comfortable with how we work it out (PH3;301)

However, it was also likely that clinical decisions were improved by more exposure over time. It may because of the uncertainty of diagnosis and treatment that experiential or tacit knowledge may improve decision making. For example, in the following excerpt by a Consultant:

"my response to that as junior registrar would have been, they are telling me they need a blood transfusion, somebody who has been doing this job for years is telling me that this person needs a blood transfusion, they probably do so I will just prescribe it... whereas now I might challenge that I would not have
challenged that 6, 7 or 8 years ago so I know myself it is not a conversation that I have had with any of the registrars and so I have to say I don't know what my response would be but I suspect it would be, like mine, initially you would do it and then maybe over time you sort of work out that not everybody needs a blood transfusion” (SL1;171)

However, it was also observed that it has taken many years to become more discerning, and this may be hampered by the reality that within the culture of blood transfusion; there is limited discussion and discourse about this clinical issue and one could argue that because of this; tacit knowledge may take longer to accumulate. In summary, "knowing the patient and knowing anaemia" may have a positive impact on transfusion practice, but this will be discussed in greater detail in Chapter 6.

5.9.3 Summary

The haemoglobin value was a powerful influence on assessment and decision making behaviours; both patients and healthcare professionals made reference to it. It may be related to availability heuristics as described in the literature review, whereby the haemoglobin is accessible and reliable. The NCI classification of anaemia also uses the haemoglobin value to define anaemia but in contrast the symptoms and holistic assessment are described as important in the literature, with many studies focusing on quality of life. The relative unimportance of the task of deciding to transfuse and the balance between the factual evidence (the haemoglobin level) and the tacit knowledge (knowing the patient) demonstrates the complexity of the decision; this will be described in more detail in Chapter 6 where the relationship between hierarchy of task and disaggregation will be explored. The reality is that holistic assessment did not seem to occur in practice; the haemoglobin was obtained to diagnose the anaemia although conversely it was recognized knowing the patient and discussing the anaemia with the patient was the preferred option; with decision making improving with experience.
5.10 Summary of analysis and findings

The ethnographic cycle has been described by Spradley (1980; p 29), however, the primary researcher did not technically adhere to this. She adapted the original to include "asking questions" not only of oneself but supervisors and colleagues as well as the participants themselves. There seemed to be a point where the same issues and themes were recurring and no new themes or data was emerging (Diagram 5.10) and the researcher described this as "saturation".

Diagram 5.10: The ethnographic cycle (author version of cycle)
This analysis process may not adhere to true ethnographic methodology as one could argue that saturation is never reached and cultures could be observed *ad infinitum* and new themes would emerge. The researcher would argue that this research explored a specific aspect of decision making within the wider culture and therefore there came a point that saturation was reached.

From the early themes, the data was re-visited on multiple occasions. Further analysis, resulted in appreciation that some of the initial themes had the same meaning or underpinning behaviors as described during the componential analysis. In this way, new categories or sub categories emerge and there was a considerable amount of reassignment of data among the categories (Boeije 2002). Final analysis revealed fewer themes, although it was essentially an extension of the analysis as opposed to separate discovery. The aim was to search for universal cultural themes, and a description of the larger relationships among the early themes. The overall analysis phase was lengthy, iterative and could be described as a fluid process, constantly moving and changing until the researcher was satisfied that all elements of the data had been interpreted and organized into some sort of meaning that would underpin the clinical practice in the broadest sense. The different data sets were utilized to substantiate common threads of thoughts and ideas. In other words there was an attempt to bring generality to the findings in order for the possibility of transferability to other transfusion cultures. The four different influencing themes emerged, following working through and thinking about the data:

- Ubiquity of anaemia and blood transfusion
• Acknowledging uncertainty
• Socialization of practice
• Disaggregation of the body

These phenomena have not been described previously in the management of cancer related anaemia with blood transfusion. The findings suggest that anaemia and transfusion are commonplace; but the management of cancer related anaemia may differ from other types of anaemia. It was complicated by the fact that presenting symptoms could not be attributed to anaemia as confounded by symptoms of cancer and side effects of therapy; which made confirmation of diagnosis uncertain. The haemoglobin was used almost universally, (and sometimes in isolation) to diagnose the presence of cancer related anaemia, but it was described how the assessment and management of this type of anaemia could be improved if the anaemia and treatment was contextualized and if the professional had prior knowledge or was familiar with the patient. Treatment decisions were heavily influenced by the clinical culture through socialization into the cultural practices, probably more so than by guidelines, knowledge and even experience. The culture of anaemia and transfusion practice, and clinical decision making in the wider sense, in relation to the literature will be discussed in more detail in the following chapter (Chapter 6).
This chapter discusses the findings and follows a similar structure to Chapter 5 as each major theme is discussed in further detail and in relation to existing knowledge and the literature review. This exploration of the culture of anaemia management used a variety of ethnographic methods to illuminate how this clinical problem is managed in the clinical setting. Blood transfusion is the traditional approach to treating anaemia but, despite guidelines and mandatory training, in all clinical settings wide variation of practice is reported (Salem-Schatz et al 1993). It was a combination of this variation in practice, and observation that many patients did not appear to improve post-transfusion, which motivated the researcher to explore this subject further. Exploring actual practice using ethnographic methods has provided an explanation for why uncertainty and variation exists in clinical settings.

The analysis and findings section described the culture and the chronicle of events in the clinical settings, however, ethnographic methodology takes this a step further and there was an attempt to interpret what was happening in reality; to make sense of it and explain it as a form of "constructing an account". To do this the researcher employed analytic categories that presumed general patterns but with the recognition this does not "fix" the phenomenon under study; by this it is meant there may be deeper understanding of the clinical problem but it may require further research, education or service developments to begin to tackle any issues that emerged from the findings.
It should be remembered, however, that cultures are not homogenous; one cannot make broad generalizations without taking into account differences amongst the group members. However, this "construction" although it may not be validated or generalisable, does not mean elements cannot be used elsewhere in other clinical settings to make sense of what is happening; otherwise the research would only have value for the culture that was explored. Rigor has been applied to this research by integrating the data sets and using the evidence from the data sets to validate the findings. Therefore from the findings, tentative associations can be inferred and by close examination of the detail of the processes involved in decision making, some causal mechanisms may be developed. Schofield (1990) elaborates how by this means, ethnographers can make reasonable judgments and assumptions about the transferability of findings that can be applied to other settings. The clinical usefulness of this construction lies in the ability to use it to change practice or increase awareness in the social world of medical care, and in this case, of cancer related anaemia, where complexity in its management has been demonstrated; with the recognition that barriers exist, which prevent insight by clinicians. Therefore, the following is a discussion of the findings and is a product of the ethnography; the primary researcher's interpretation and use the literature to understand of the process of assessment and management of cancer related anaemia and blood transfusion.

6.1 The ubiquity of anaemia and blood transfusion

This study suggested the reality is that clinically defined anaemia is ubiquitous in the cancer care setting. The important issue here is "clinically defined", in that this term encompasses all patients who have a haemoglobin of "less than within normal limits" (NCI criteria; Groopman & Itri 1999). The clinic data revealed it was not until the
anaemia became moderate or severe by NCI criteria that treatment was initiated. The implication here is that cancer patients live with their anaemia; and healthcare professionals and patients seem to accept this as a normal consequence of disease and therapy; treatment is not initiated until a critical point is reached. Although a small proportion of patients are transfused, the large numbers of patients and the increased frequency of anaemia in some patient groups mean that healthcare professionals are frequently involved in blood transfusion decisions and this was revealed in this study. Transfusion is a common therapy for cancer related therapy and frequently delivered form of treatment in cancer day unit settings; there was familiarity with this subject and all participants could tell their "stories". Blood transfusion is also used in the treatment of non-malignant anaemia (e.g. peri-operative anaemia; sickle cell anaemia etc) but it may be that cancer related anaemia differs in some way from other types of anaemia, because of the context of the anaemia and the inextricable relationship with the cancer and treatment. The patients learn to live with the symptoms of cancer and anaemia and the side effects of treatment and it is only when the haemoglobin level falls to a critical level, or symptoms reach a critical point that treatment is initiated. This difference will be explored by discussing the meaning of cancer related anaemia and how patients live with their anaemia.

6.1.1 Biomedical assumptions about cancer related anaemia

Anaemia is defined as having a lower than normal haemoglobin; and it fits a classical biomedical definition. Winkelman (2009) describes how western society and scientific medicine, views illness primarily as disease, which is understood as biological abnormalities in the body’s structure, chemistry or function. This assumption of biological disease is so deeply engrained in the thinking of most health professionals that
they may make assumptions. For example, in making a diagnosis and assigning a biomedical labels provide a universal valid system of classification but the assumption is that medical practice is culture free and scientifically neutral and objective (Winkelman 2009). The findings of this study supported this claim in that the haemoglobin value (biomedical value) was used to define the presence of anaemia but the participants acknowledged that sometimes the degree of anaemia did not correlate with the symptoms or patient experience. In defining disease, the biomedical approach is to focus on the results of laboratory results; but may neglect the patient experiences, therefore the haemoglobin level was used to define and treat the anaemia however, this had different meanings and experiences for the participants, which will be explained in more detail below.

The processes whereby particular disease labels are attributed can be ambiguous in some cases, and they may not be determined solely by naturally occurring categories and phenomena. For instance in the literature review it was described how Hunt (1985) uses the example of hypoglycaemia to show a degree of indeterminacy in the attribution of that biomedical term. She argues that contrary to a commonsense view of a diagnosis as a description of facts, a term such as hypoglycaemia expresses the physicians' concepts of "anomaly" or "dysfunction". Furthermore, Winkelman (2009) describes how he has been with clinicians measuring blood glucose levels and some levels were so low that the patient should have been unconscious, but was functioning normally; he summarized by stating "the biological condition is not the sole determinant of a disease, but, rather, how the condition relates to the social context" (p42). In summary, the attribution of the disease label is highly variable among clinicians, and Hunt concludes
that one must regard such diagnostic labels as cognitive constructs and as such are subject to the influence of culture and context.

This approach could be applied to the concept of anaemia. It is not simply a biomedical term; it has different meanings for different healthcare professionals, which are subject to culture and context. For example anaemia was frequently described in the classical sense as haemoglobin of less than 12g/dl by the participants, yet the definition of anaemia requiring treatment in the clinical setting was much lower than this, and varied between individuals. Furthermore this differed between haemato-oncology and oncology clinicians. Haematology clinicians frequently talked about a haemoglobin of less than 8g/dl however, oncology clinicians tended to use a higher trigger in discussion, usually 10g/dl. The higher trigger used for describing anaemia in the oncology setting did not necessarily translate into treatment (as demonstrated in the clinic data where only those with haemoglobins of less than 8.5g/dl were treated), it may be this is the description used in that sub-culture to describe anaemia, but not necessarily the trigger to treat the anaemia.

A vivid demonstration of the variety of meaning of cancer related anaemia was the statement by PH3 (in section 8.7.3) who stated that he did not see himself as having anaemia, despite multiple transfusion episodes. The label of anaemia, however, may be necessary for the clinicians in order to describe a clinical situation. Lave and Wegner 1991 (in Atkinson 2005) describe how this "is as much a matter of apprenticeship as any other culture specific way of knowing and telling" (p47); there needs to be a production of reliable (that is reproducible) clinical descriptions otherwise there would be no organizational control. However, this study demonstrated that despite the universality
and ubiquity of anaemia in the cancer setting; and the use of the biomedical diagnostic label of anaemia, cancer related anaemia had a different meaning for different subcultures and even for different individuals within the sub-cultures. If the definition was variable, this could contribute to the indeterminacy and uncertainty of treatment as individuals are socialized into the meaning of anaemia for their particular sub-culture. The definition of anaemia also relates to the disaggregation of the body; as the defining criteria is the haemoglobin level and not necessarily what the patient feels or experiences. Finally, this also demonstrates how the ubiquity of anaemia and blood transfusion relates to the other themes (acknowledging uncertainty; socialization of practice; disaggregation of the body) as they are all inextricably linked to each other as part of the wider culture of cancer related anaemia practice. In other words it is about the context of the anaemia, how it presents in clinic, what it means for patients and clinicians, and how it is diagnosed and treated in the individual clinical setting.

6.1.2 Adapting to anaemia

In the preceding section it was described how in defining the disease, normal values are used, but this can be problematic, because the concept of "normal" can be variable. For example, many cancer patients could have been anaemic prior to their cancer diagnosis and this would be their norm. Furthermore, many cancer patients remain anaemic for many months or even years despite transfusion; and the degree of anaemia may fluctuate. Therefore, the patient may continually be anaemic throughout therapy, by biomedical criteria; however they adapt or learn to live with their anaemia.

The literature review described the physiological adaptation to anaemia and how it may not be until there is a degree of oxygen debt that the patient becomes symptomatic. This
physiological trigger is undetermined and therefore many patients adapt to a degree of anaemia; some to a trigger as low as a haemoglobin of 7g/dl (Hébert et al 2004; Morisaki and Sibbald 2004; Madjdpour and Spahn 2005). This is why clinically defined anaemia may be common, but why it is not always evidenced in behaviours or symptoms in patients. This study demonstrated how staff participants could all remember patients who had surprised them by adapting to their anaemia; and more interestingly the patients themselves could not predict their fluctuations in haemoglobin to correlate with how they were feeling. This study replicates the physiological findings demonstrating the unpredictability of cancer related anaemia and of the finding in the patients' poor predictions of their symptoms, which implies the level of oxygen debt trigger may be variable within individuals at different times on the treatment pathway. However, this has already been demonstrated in the literature review that patients' symptoms and side effects of chemotherapy fluctuate during the treatment pathway (Richardson et al 1998) and it may be these symptoms overwhelm and confound both patient and clinician as to what are cancer-related symptoms and what are anaemia-related symptoms. This may have been the reason for the situation where patients received blood despite having relatively high haemoglobin (PH2 received two unit transfusion when his haemoglobin was 9.8g/dl). This will be discussed in more detail in the discussion about symptoms (section 6.2.1); but the difficulty in separating the symptoms may be further confounded by this adaptability. In summary, the degree of adaptability appears to be highly variable and unpredictable and as ubiquitous as the anaemia itself.

6.1.3 Conclusion

It has been demonstrated that the dividing line between "normal" and abnormal is not nearly as sharp as one would assume at first glance; even when using distinct
biomedical markers. The meaning of the haemoglobin level appears to be different in different sub-cultures and even within individuals. It is a subjective assessment of anaemia; even in the presence of the haemoglobin, and therefore may be influenced by all the experiences and knowledge and culture of the clinical setting. The ubiquity of the anaemia may also mean that it is not viewed as an illness. If a disease at the time of diagnosis causes no pain or suffering or disability, even if it precedes or accompanies a more serious ("real") disease such as cancer; especially if it is frequently encountered, it will not be viewed as an illness (Eddy 1999). This may contribute to why participants in this study did not always perceive the anaemia to be important.

6.2 Acknowledging uncertainty

This section develops further some of the uncertainties described in the previous sections. The literature demonstrated the definition of anaemia using the NCI criteria (Groopman & Itri 1999) and the pragmatic transfusion trigger guideline developed by the BCSH (1999) of 8g/dl; both of which are used in clinical settings. However, given the uncertainties about what constitutes a disease, it appears these definitions and guidelines may be arbitrary. Similarly, the literature review described the classical symptoms of anaemia, (Ludwig and Strasser 2001; Vogelzang et al. 1997) but it was not always demonstrated in this study that assessments or decisions fitted all the criteria. Correlations between haemoglobin levels and quality of life were also reported (Cella 1997; Holzner et al 2002; Lind et al 2002) but these studies fail to describe the reality in that this may be unpredictable, and for this reason cancer related anaemia may not always be easy to clinically manage. Despite many studies on cancer related anaemia, the reasons for this variation in practice has not been clearly defined. There are descriptions of the difficulty in managing this clinical problem but limited explanation.
other than recommendations that more comprehensive assessment of the patient is required. This section will discuss uncertainty further in relation to making assumptions about the symptoms as well as making assumptions about response to transfusion.

6.2.1 Assumptions about assessing the symptoms of cancer related anaemia

The findings of this study demonstrated that the symptoms did not always mean the patient was suffering from their anaemia. This study showed the symptoms of disease and side effects of treatment may create such a degree of indeterminacy that there would be no rationale in trying to assess the haemoglobin with the symptoms in a robust way. For example, this study revealed that patients themselves were frequently "wrong" when they assessed how they were feeling with their haemoglobin. They could be feeling well, with no symptoms and have a clinically defined severe anaemia (Hb 6.5-7.9g/dl); or the reverse where they were feeling extremely fatigued yet their haemoglobin level could be 9-10g/dl. This is an important feature of cancer related anaemia. The literature describes how a full systems review assessment is required to assess anaemia (Foubert & Wujcik 2005), however, this study's findings suggests that the uncertainty should be acknowledged as it may be that even if a full assessment was undertaken, the outcomes may be no different. This study revealed the actual practice of diagnosing anaemia, that required treatment, was usually a response to the haemoglobin; and the trigger for treatment was culturally influenced.

It is known from the literature that few clinicians make use of the complete history and systems review (Hoffbrand 1989). In the assessment of anaemia the literature stresses the importance of systems assessment however; actual practice in this study reveals this was not undertaken. The reasons for this are unclear from this study and warrant further
discussion. The assessment appears to be based primarily on the laboratory values with or without conversation with the patient. It was described in the findings how the clinician described a lack of time in the clinic, which suggests if clinicians had more time perhaps their assessment and decision making may be more thorough. A Cochrane Review of the effects of interventions aimed at changing the length of time for consultations revealed that longer consultations did not necessarily have benefits or resulted in change of clinician behaviours, but did result in patients’ taking more responsibility for their problems (Wilson and Childs 2006). The assessment may be brief or non-existent, and the decision to transfuse made in response to the haemoglobin level however, the physicians’ priority in clinic may be to focus on the cancer in the hierarchy of clinical concerns as described in section 5.6.3. This hierarchy of task and knowledge can be summarized in diagram 6.2.1.

Diagram 6.2.1: Hierarchy of knowledge and task
The physicians focus of concern on the task of treating the cancer may not need to change or indeed should it change because clearly the cancer should be the clinicians focus, however, it has implications for how anaemia could be managed. If the responsibility were to shift to the nurses for example, because their clinical priorities may differ from the physicians' priorities, they may place greater emphasis on quality of life issues and therefore give the treatment of anaemia more consideration. This will be discussed in more detail in Chapter 7.

The literature demonstrated frequently encountered, low risk clinical conditions are frequently assessed using pattern recognition (Del Mar et al 2006). Clinicians attempt to match the presentation within their internal “schema” (Coderre et al 2003) but there is a risk that too much emphasis is placed on pieces of evidence, for example, laboratory values or if the patient has too many problems at once (Del Mar et al 2006). This study has revealed the latter may occur when the haemoglobin is the evidence and the patient has not only multiple symptoms but unpredictable symptoms further confounded by the fact the symptoms may not be attributable to the anaemia. It was also revealed in the literature review that more experienced clinicians gain more information from the history rather than systems review i.e. it is the conversations that reveal the most information (Del Mar et al 2006; Hampton et al 1975; Hoffbrand 1989) and the more difficult decisions require a full history (Del Mar et al 2006). It may be that the assessment and treatment of cancer related anaemia is over-simplified because of its frequency and complexity or because it is not a primary diagnosis but a consequence of cancer and treatment; it is likely in the out-patient setting that parsimonious behaviors ensue because of the lack of time to dedicate to this common but complex problem and
therefore limited time is dedicated to questioning patients. The time factor may also be related to the priorities of the different professional groups as described earlier.

The literature review described how learning in the social world incorporates knowledge; skills and practices; personal understanding of people and situations; accumulated memories and episodic events (Eraut 2000;2004). In summary, personal knowledge mainly comes from observations and this implies a holistic rather than fragmented approach to knowledge. It may be the day unit nurses are in the best position to learn the skills of anaemia and transfusion practice as they will have "accumulated memories" of patients who attend for blood transfusion; they are more likely to be in a position to observe changes over time and may be related to the findings of the importance of "knowing the patient", particularly if the clinic process remains unchanged where patients are reviewed by different physicians.

In summary, it would be easy to be critical of the behaviours in clinic however, in a sense it can be understood how these behaviours have evolved. The behaviours may have developed because of the clinical priorities of physicians and this has implications for practice, which will be discussed in more detail in Chapter 7.

6.2.2 Assumptions about response to transfusion

Despite the frequency of cancer related anaemia and blood transfusion to treat it in the UK, there has been limited research in this area. The bulk of research activity in cancer related anaemia as described in the literature review has been the erythropoietin studies. Multiple erythropoietin studies have demonstrated improved quality of life with an increase in haemoglobin (Boogaerts et al 2003; Osterborg et al 2002) and the earlier
studies showed improved survival outcomes (Antonadou et al 2001; Littlewood et al 2001; Vansteenkiste et al 2002). However more recent published trials have raised the concern regarding the impact of erythropoietin agents on survival in oncology patients and these have reported increased mortality in patients treated with erythropoietins in some tumour groups (Leyland-Jones 2003; Henke et al 2003; Overgaard et al 2006; Wright et al 2007). These studies may be a powerful influence on perceptions about cancer related anaemia and transfusion practice; and the influence of the pharmaceutical industry was described in the literature review (Bekelman et al 2003; Kjaergard and Als-Nielson 2002). The findings in this study demonstrated clinicians were aware of the early positive impact of erythropoietin and there may be assumptions that a concomitant increase in haemoglobin by transfusion, may improve quality of life. There are two criticisms of this assumption. Firstly, the rise in haemoglobin with erythropoietin is sustained, constant and generally, patients’ haemoglobin rises up to within or near normal limits (Demetri et al 1998; Glaspy et al 1997; Littlewood et al 2001); treatment with blood transfusion results in peaks and troughs of haemoglobin. Secondly, the benefits of erythropoietin may be greater because it results in a rise in homologous haemoglobin; as opposed to allogenic blood in the form of a blood transfusion. There is risk in transference of findings from erythropoietin studies. Blood transfusion and erythropoietin are different forms of treatment therefore outcomes cannot be comparable; this study revealed the clinicians were knowledgeable about the erythropoietin literature, perhaps because there was no comparable blood transfusion literature in this clinical setting. The clinicians may assume patients’ quality of life will improve post-transfusion, yet this study revealed patients and clinicians could not consistently describe benefit following a blood transfusion, and the risk would be a tendency to over-transfuse.
This study revealed the response to transfusion was described by participants as unpredictable. Some other specialties have started to research outcomes from blood transfusion in more robust ways; presumably derived from a similar hunch to this researcher that sometimes patients seem to have no benefit from transfusion whatsoever, in terms of improved quality of life or that blood transfusion can adversely affect outcome. If one thinks about what a blood component contains; it contains not only red blood cells but white blood cells and foreign proteins and this may have immunomodulatory effects (Landers 1996); and it was described in Chapter 2 how properties of the transfusion itself may contribute to variable responses. The Koch (2008) study in the literature review revealed how cardiac patients did significantly worse following transfusion of "old blood". It may be that the age of the blood, patients receive in oncology, has the same negative effect; or result in the patient feeling no benefit following transfusion as red blood cells only have a finite life span. This study revealed how in this clinical setting participants (patients and professionals) described unpredictable responses to transfusion, but it was beyond the scope of this study to explore the age of the transfused blood. The age of blood is not considered in oncology and haematology and this may have implications for future research which will be discussed in Chapter 7.

A further uncertainty exists; Wigton et al (1999) described how physicians and medical students use and interpret evidence in individual ways; and this does not seem to change even amongst the most experienced physicians. This was observed in this study where evidence was cited from the erythropoietin studies and different interpretations used. Furthermore, when a clinician is unable to turn to a definitive body
of clinical research, they use a variety of bodies of evidence including clinical observations. The individual nurse or clinician may be most impressed by observations made in his or her own individual practice. This source of evidence is notoriously vulnerable to bias and error (Eddy 1999), who states:

"What a clinician sees and remember is biased by the types of patients who come in; by the decisions of a patient to accept a particular treatment and return for follow up; by a natural desire to see good things; and by a whole series of emotions that charge one's memory" (p52).

In this study, the nurses described "scare" associated with transfusion and in the analysis chapter it described how this may be related to the fact that nurses were at the point of care delivery and hence more likely to have witnessed transfusion errors or adverse reactions. The physician may not have these vivid memories and therefore may perceive blood transfusion as being a form of low risk therapy; for example, it was described how frequently they would prescribe blood without having any contact with the patient. The way in which the clinics were set up also meant that different clinicians would be assessing the response to the blood transfusion; which may add further inconsistency. Alternatively, this casual approach to transfusion could be related to the "shared responsibility" theme and the physician may be trusting of the nurses decision making as in SH1 statement where he described this as "good teamwork" (Section 5.8.3). This will be discussed in more detail in section 7.3.

6.2.3 Conclusion
In summary, there is indeterminacy in the definition of the diagnosis of cancer related anaemia and the treatment with blood transfusion. It is difficult to know what the most powerful influences on the responses to uncertainty are and although they are most
likely to be a combination of the multiple phenomena described. Typically, the final decision about how to manage a patient requires synthesizing all the information about a disease, the patient, signs and symptoms and the effectiveness of tests, outcomes of treatment and values. In the management of cancer related anaemia decisions may be undertaken without actually knowing the impact on the patient; with uncertainty about signs and symptoms, risks or benefits and with incomplete and biased information about outcomes and this seems to be acceptable in the culture of transfusion practice in oncology. Furthermore there may be inadequate communication due to lack of time in the clinics and inconsistency of review as patients are reviewed by different clinicians. In summary, it may result in a tendency to oversimplify and use the haemoglobin value as a basis to treat the patient.

Another influencing factor is the available evidence, which demonstrates that different tumour groups may respond differently or have different treatment needs. Yet cancer related anaemia was researched in the early years as a disease entity rather than within context of the tumour type; as demonstrated by the fact that it can be a prognostic indicator in some disease groups (Hasenclever et al 1998). It may be the benefits of transfusion differ between patients with different tumour types for multiple reasons for example; the oncologist described how perhaps a more liberal approach to transfusion may be required in lung cancer patients because of their breathlessness (Section 5.8.4).

It is likely that variation in practice is inevitable and in fact may be desirable. Eddy (1999) describes how some variation in practice is appropriate; "the differences in patient’s risks, signs and symptoms, responses to treatment and values are real" (p59). There are also differences in clinician talents and different facilities, resources and
environment. Alternatively, Eddy (1999) also describes how uncertainty can harm the quality and cost of medical practice; and most of the simplification of uncertainty pushes in the direction of overutilization. If this is the case, the amount of uncertainty which exists in this clinical area would tend to explain the over-utilization of blood components as described by participant SL1 in section 5.7.3. This has implications for practice and again raises the question as to who is best placed to create individualized and holistic assessment and treatment of cancer related anaemia and this will be discussed further in section 7.2.

6.3 Socialization in practice
This section will focus on the influence of the culture on the assessment and decision making processes. In the end given all the uncertainties, incentives and heuristics described in the previous sections, the clinician may do what is most comfortable, i.e. treat rather than not treat. If there is no way to identify what is best for certain, or prove that blood transfusion has no benefit or have a deleterious outcome, then the safest and most comfortable position is to do what others are doing. A physician or nurse who follows the practice of others is safe from criticism, and free from having to defend oneself, as defended by the concurrence of colleagues. This tendency to succumb to the cultural and environmental influences is likely to be the most single important explanation of regional variation in practice and even within the same institution. This has not been described previously in relation to the management of cancer related anaemia.
6.3.1 The ethics of resource availability

The impact of the resources in the day care unit to administer blood was shown in this study to change the decisions to transfuse. This is likely to be a component of "socialization in practice" but the findings related to use of resource and lack of impact of the implications of cost warrant more detailed consideration. The day unit staff influenced the decision to transfuse by working within the constraints of the available transfusion slots; if they had time the transfusion would take place and if not the decision was deferred or changed. The cost of transfusion was shown in the literature review to be massive and yet in this clinical setting it was given minimal consideration; when clinicians were questioned about resource and cost, the financial implications were not a consideration.

It may be resource availability is a powerful influence on the final decision and why clinicians do not object to a change in plan of care. There may be an acceptance that if there are finite resources then there is reduced questioning behaviours leading to an increase in acquiescing behaviours. This may contribute to the socialisation in practice as it is accepted that decisions may be changed by others. It may be new clinicians adapt to new departmental or institutional behaviours depending on resource availability as this would be outside their sphere of influence, particularly for the junior clinician, especially if there is limited resource. It could explain why the day unit nurses are in a powerful position to question decision making as they control the resource. It was not clear from this study if there were unlimited day unit resources that this would lead to a more liberal transfusion practice, but it may be a factor for national variation in transfusion practice, for example, the experience of SH2 who described a more liberal transfusion strategy at her previous hospital, as they had capacity to transfuse patients.
prior to discharge. It is perhaps morally repellent to acknowledge that resource availability, influences decisions but this may be a consideration in the clinical setting and needs to be acknowledged.

In a wider sense there is an acceptance that resources for the provision of healthcare are scarce, in that it is likely there “never will be enough resources to satisfy human wants completely” (Drummond 1999, p436). This was described in the literature review with reference to the donated blood supply and the future risk of new pathogens impact on supply. Blood components do not appear to be subject to the same cost scrutiny as drugs; it has the potential to become scarce, and a scarce resource should be used carefully, therefore it was surprising this was not an influence. In this study, local day unit facilities were however viewed as a limiting resource and this may require future examination, for example, how frequently are decisions changed and what is the impact on outcomes, if there is a limited resource in a clinical setting and what is the cost of ensuring adequate resources are available.

6.3.2 Clinical intuition and the cognitive continuum

It has been shown in the literature review the kind of task the clinician is working on influences their thinking (Hamm 1999); and when an expert clinician reviews a patient sometimes it can appear that no reasoning has been used at all. In the literature review (section 2.7) Hammond (1980; 1981;1986) described the concept of the cognitive continuum and how clinicians use different ways of thinking when faced with different problems; ranging from analysis through to intuition inducing decision making; these features included: the complexity of the task; the ambiguity of the task and the form of task presentation. If the diagnosis and management of cancer related anaemia is
applied to Hammond's cognitive continuum, by the nature of the clinical problem (pertinent cue of haemoglobin; relationship between the cues; linear principle; limited response time) it leans towards intuitive thinking. However, these are not isolated thoughts as it has been shown the social and institutional context can also be expected to have a role in determining the mode of cognition a clinician uses (Hamm et al 1984). Much medical reasoning for example, takes place in discussion, with different clinicians and skill mixes; and such groups will accept some kinds of thinking, that which seems familiar, competent and eliminates uncertainty, (Bursztajn et al 1981); hence as demonstrated in this study the faith of the biomedical value of the haemoglobin.

The institution also affects the prevailing mode of cognition used through the kind of staff training and the amount of time it allows for reasoning about each patient and the rewards or outcomes (Hamm 1999); for example if efficiency in clinic is highly valued this will push towards intuitive thinking. This was evident in the oncology clinics where the Specialist Registrar aspired to be as efficient as the Consultant, because of limited time availability. Intuitive thinking can lead to error if the practitioner is a novice as described in the literature review (Dreyfus and Dreyfus 1986: theory of expert cognition); as the novice must think more analytically, or at a minimum obey the rules (in this case the transfusion guidelines). This may relate to the observation by the Consultant that the day unit nurses are in a sense the "gatekeepers of transfusion" in that he described how they are more likely to adhere to guidelines. Alternatively, it may be the day unit nurse is an expert as described in chapter 2 and uses his/her intuitive knowledge to make discerning decisions. In summary, it is probably a combination of the cognitive theories that explain the practice of transfusion; some of the decision making is influenced by the nature of the task, some by the experience, knowledge and skills of the clinician and
some by the institutional and cultural factors that influence the cognitive mode used in the clinical setting.

6.3.3 Learning the skills: storytelling and rhetoric

There is an implication in the findings that even if research evidence should be available much of what was learnt in actual practice about transfusion practice was by experience or by working in the particular culture. Mandatory training had little impact and was about process not the decision making. Therefore it could be argued the most experienced clinicians, in terms of repeated exposure to cancer related anaemia and treatment with blood transfusion, may have superior decision making skills; as discussed in the previous section. However, the everyday accomplishment of medical work is dependent on a wide range of skills and in large part they are gained through tacit acquisition as part of an apprenticeship into the specialism. “These tacit skills are often indeterminate and are rarely explicit but are largely rhetorical” (Atkinson 1995, p91) therefore it requires more than just exposure to the task in hand; it requires consideration and discussion. The competent practitioner translates the skillful work of clinical investigation and laboratory tests, into plausible and persuasive accounts that justify past actions, current understandings and future plans as evidenced in some of the professional participants’ stories about transfusion. Medical knowledge is grounded in a great deal of talk and enacted within an oral culture, however, this study revealed the management of anemia escaped the rhetoric in clinical practice and the consequences of this was that there was lack of these informal systems for learning the craft of managing cancer related anaemia. The experienced Consultant for example, described how she did not discuss transfusion decisions with her junior teams. It may be that one learns their skills by being exposed to the clinical scenarios as it was described the skills
were “learned by osmosis”, therefore it may be assumed the more experienced or those who have had the most exposure to cancer related anaemia, would have the more finely tuned skills to assessment and decision making skills; as described in the previous section when discussing “experts”. It may be that some of the discussion and learning would be with the patients themselves, rather than with colleagues; for example the day unit nurses who frequently treat all cancer patients with blood transfusion. The quality of their pattern recognition as described in the literature review (Del Mar et al 2006), should be greater and as a consequence their decision making more discerning, but this would require further testing in future research.

The problem with tacit knowledge is that it is not easily shared, and it was evident from the interviews that the clinicians found it difficult to express their knowledge and rationale for decision making; which makes it difficult to share expertise. This may because of the tacit nature of their knowledge, however, it may have implications for who is best placed to assess and treat cancer related anaemia and this will be discussed in implications for practice in Chapter 7.

6.3.4 Teamwork and shared decision making

There is a tendency to focus on the patient and clinician interaction as a determinant of quality of care (Atkinson 1995), and therefore this was initial reason responsible for the research to focus on the clinic as it was assumed that this was where all the assessment and decision making was undertaken. However, it became apparent as the data was collected the decision making could occur anywhere, for example, in the day units or via telephone conversations or at the end of clinic or when laboratory results became available. This study revealed that an analysis of the doctor-patient interaction in clinic
cannot capture the full extent of care systems in place in the case of this clinical problem. The consultation if viewed sociologically is a very complex social construct but is only a partial view, and the author would argue, only a miniscule part of medical work (Atkinson 1995). This study demonstrated the management of cancer related anaemia is a collective problem which is socially managed and whether this can be transferred to management of other clinical problems could be debated. This team-working was implied by the Consultant Hematologist who fully supported the contribution by the day unit nurses in their assessment and decision making skills:

"...once they (day unit nurses) have been trained up they are not only extremely competent and motivated but there is an atmosphere where they are encouraged to question what the doctors are doing" (SH1:361)

The practice of assessment of cancer related anaemia and decision to treat with blood transfusion has been shown in this study to be a collective, organizational activity; the decisions may be subject to negotiation and revision, based on the talk within and between groups or teams of practitioners. This demonstrates that medical decisions may not involve just one nurse or doctor but may also bring into play more than one group of professionals, members of which contribute different views of expertise and different organizational interests. The silent isolated single handed decision-making is, therefore, is probably not the model for the assessment and treatment of cancer related anaemia with blood transfusion; there may be many actors and the social setting in the organization of the clinic will generate its own information. The quality of decision making may therefore be dependent on the communication within the team rather than the individuals within the team; or the degree and quality of communication with the patient. This will be discussed in more detail in section 6.4.
6.3.5 Organizational sub-cultures
The findings demonstrated differences between the sub-cultures of haematology and oncology; for example, although both disciplines gave weight to the haemoglobin, there was a tendency for them to differ in their description of the definitions of anaemia. This is substantiated in the literature where there may be different discourse and language used in different settings and Atkinson (1995) makes a distinction between “information” and “decisions” (p53). All too often information (such as laboratory results) is treated as given, while the exercise of judgment or decision-making is applied to that information; so for example, although the definitions of anaemia were different in the sub-cultures the point at which they initiated treatment was similar.

The management of the distressing symptom of breathlessness for the lung team was particularly problematic and they described this in their interviews. Breathlessness whether due to anaemia or disease appeared to be the most problematic symptom to manage for clinicians and patients, therefore, this may lower the threshold to treat the anaemia, in an effort to do something to relieve it. This was alluded to in SL1’s interview when she described how blood transfusion would be unlikely to make her patients feel worse but may help improve their breathlessness, although there was a recognition and acceptance that it may not. Conversely, this was not an issue for haematology-oncology.

Atkinson’s work on the culture of the haematology clinic demonstrated that medical students are progressively socialized into the culture of the clinic (Atkinson 1995). This study demonstrated the different cultures of the haematology and oncology clinics. The haematology clinics provided a focused learning and education environment for staff and patients. Patients were shown their results in graphical form for example on the
computer and complex disease parameters such as cytogenetics were discussed. Although the culture of the clinics in haematology oncology was educational and academic, this was not translated into the management of anaemia and the reasons for this are likely to be multiple as described in previous chapters. However, there did seem to be more patient involvement and the "knowledgeable patient" was evident. This was further evidenced by the patient interviews where patients frequently described their blood results, including differential counts and genetic changes. This could have been attributed to increased exposure to clinical situations and blood transfusions; but is likely to be a product of the culture of the clinic in that it was usual for patients to have complex issues explained to them.

6.3.6 Conclusion

Clinical decisions are not isolated cognitive events; the significance of making decisions in the context of the clinical settings is emerging as important. In this study it was demonstrated that the assessment and decision making in cancer related anaemia can be socially and spatially disparate, meaning that transfusion decisions are influenced by the different social interactions in different clinical settings therefore this inevitably results in variation in practice. This was described in section 2.8 whereby decision making is not made in isolation but through interactions between individuals which take place through symbols and the interpretation of meanings and events (Giddens 2008). He described how it is the small scale interactions that can influence behaviours and by trying to understand these interactions in this study, it became increasingly evident as this thesis progressed that the context of the assessment and decision is important; whether in relation to resource or the unique qualities of the culture or how knowledge and skills develop in the culture. If improvements are to be made in transfusion practice,
it may be prudent to reflect on elements within this section regarding exposure to transfusion; controlling the resource and how expertise can be developed. This will be discussed with implications for practice in Chapter 7.

6.4 Disaggregation of the body

Analysis revealed that the haemoglobin was frequently the only determinant that was expressed by the participants as reliable and typifies the biomedical model as described earlier. The impact of the haemoglobin often meant that it was "separated out" from the rest of the patient factors or assessment occurred in isolation from the patient and this was collectively described as "disaggregation of the body". Atkinson (1995) used this term in his ethnography of haematologists whereby a diagnosis was made using various samples and evidence, for example:

"with each of these techniques and others like them – the haematologist helps to disaggregate the body into finer and finer discriminations" (p65).

He was referring to the diagnostic material including various biopsies, morphology and other test to make a conclusion about diagnosis and stage of disease. In the context of this research finding, the haemoglobin is separated out perhaps because of the unreliability of symptoms and signs or because the patient was not always available to confirm the presence of symptoms in the presence of the haemoglobin. The haemoglobin value may have been perceived as the only constant in an uncertain world and therefore was a powerful influence; and there was evidence that the laboratory values were used in isolation to diagnose and treat the anaemia, in the absence of the patient, therefore this terminology is being adapted to adopt a different meaning.
6.4.1 Disaggregation of practice

The separation of medical knowledge from the social setting warrants further discussion. Berg (1992) cited in Atkinson (1995, p.46) describes how medical sociologists have too often separated out the medical and social in order to explain particular aspects of medical knowledge. He described how in such sociological work:

"it is simply biomedical knowledge that directs the physician, through logical steps, from individual findings towards the right diagnostic and therapeutic decisions. The "cognitive" domain of medical action was thus regarded as self explanatory, not needing and defying sociological scrutiny" (Berg 1992, p.153).

The view that Berg criticizes fails to do justice to the social organization of everyday knowledge production and reproduction. For example, anaemia and blood transfusion practice can be seen as routine knowledge but this research has demonstrated it is not managed merely as a biomedical event but is influenced by the social world. In Atkinson's work it was not uncommon for haematologists to request an action in a patients chart (1995, p.56), only for the request to be ignored or not perfectly complied with. This behavior was evident in this study whereby the oncologist would write on the chart to give blood if the haemoglobin was less than 10g/dl and expected the nurse to act accordingly. The social and technical division of labour in hospital often results in teams or individuals working at cross purposes; therefore the term "disaggregation" could be used more widely to describe the various pockets of activity and decision making in the clinics and day units. Action and knowledge do not necessarily dovetail smoothly together to produce a seamless web of decision-making, especially if agendas are different. For example, the quick action in clinic in response to a haemoglobin may
be to decide to give a transfusion, however, to those in the day unit it could mean organizing another blood sample; patient transport; a phone call to Blood Bank; a phone call to the patient; cannulation of the patient; collecting the blood; finding a doctor to prescribe the blood and so on. SL4's interview (Day Unit Nurse) demonstrated this perfectly, whereby requests for transfusion were changed at the point of care delivery, in the day unit, and it may be related to the volume of work a single transfusion episode entails.

Similarly, although not evidenced in this study, it is not uncommon practice for the blood bank department to question and challenge a transfusion decision depending on a haemoglobin level, which is the only clinical information they would have available; further reinforcing the importance of the haemoglobin in the clinical setting but also demonstrating it is a significant amount of work for them that may be influenced by the same resource pressures as the day units (e.g. short staffing levels). In summary, different specialists define their work and their interests in quite contrasting ways, and hence may define the clinical problem (anaemia) differently and they may also be working with different competing timetables in the wider clinical setting.

6.4.2 Knowing the patient

Another use of the theoretical concept of “disaggregation” could be in the context of the growing sub-specialism in medicine; the body is not stable, nor whole. Each professional group fragments the body into their specialty; laying claim to a distinctive knowledge to that part, e.g. haematologists claims the blood, bone marrow and lymph nodes, the lung oncologist to the lungs and breathing. The body is represented in various departments, divisions and laboratories and the body may be discussed without
actually "knowing the patient". In other words, the modern body has been appropriated and reconstituted by a diverse group of experts and healthcare professionals. In this system of medical inspection and surveillance, the integrity of the body is dissolved into a series of more or less discrete domains of knowledge (Atkinson 1995). Important clinical decisions can be made in the absence of the patient; and this is may be a frequent and acceptable occurrence. This has been recognized as a feature of medical practice in that a considerable volume of medical work is away from the patient and the consultation (Atkinson 1995). Medical staff are familiar with the concept that decisions are made about patients following consultation with other professionals; the Multidisciplinary Team decision making is a perfect example whereby the clinician and/or nurse relays the patient history. The pathologist displays the histology and provides a summary and the radiologist provides a summary of the imaging. The diagnosis is confirmed and treatment planned based on a summary of histology and imaging and resultant staging. The Consultant treating the patient has the final responsibility but he/she must trust the pathologist/radiologist and other professionals for example, cytogenetisist; immunophenotyping scientist. They seem to do this unwittingly. This is an example of shared decision making and demonstrates the complexity and social behaviors involved. It also demonstrates the "disaggregation of the body" (Atkinson 1995) into various parts which then come together again in the MDT to form a cohesive summary of what is going on for that patient. It may be the only way medical work can function in that clinicians have to trust other's decisions on a regular basis; therefore there may be acceptance of change of decisions as demonstrated in this study.

This is further substantiated in this study when the Consultant Oncologist was "horrified" when she described how decisions were made by staff when they had not "laid eyes" on
the patient; however, one could argue far more important decisions are made in absentia of the patient and this is culturally acceptable. In fact the shared decision making is preferred and is borne out of the “Improving Outcomes Guidance” for all tumours (DoH 1995). The other Haematology Consultant in contrast welcomed the shared decision making and liked the fact that transfusion was being controlled by experienced nurses as described earlier, who he described as “Gatekeepers”. The literature review, reported Salem-Schatz et al (1993) study that demonstrated improved transfusion practice (81% vs 48%); the former group having more knowledge but also more receptive to input from colleagues. In summary, it could be argued that it should be a shared responsibility with opportunities for those to challenge and question the original decision based on either their own skills or knowledge or their knowledge of that particular patient. Conversely, as most of the symptoms are subjective and unpredictable it could be argued improved decision making could be made by the clinician with the most intimate knowledge of the patient as they would be the best equipped to recontextualize the haemoglobin value with the person standing before them. Atkinson (1995) describes how the clinical gaze is no longer “anchored to the bedside itself” (p61), however, it could be argued as this study shows that decision making is thought to be improved if the clinical gaze encompasses the patient and all the available information about that patient to enable a bedside decision, which would have the advantage of involving the patient in the decision.

6.4.3 Conclusion

Improved decision making requires knowledge of the patient and preferably the assessment and decision making is in conjunction with the patient to avoid the “disaggregation of the body” that occurs if the haemoglobin is evaluated in isolation.
Reconstitution and recontextualization of the haemoglobin either with symptoms e.g. breathlessness, or signs, such as fatigue or patient dialogue could improve decision making; and involving the patient in the decision may be helpful. In this sense the phenomena of haemoglobin and signs and symptoms are constructed together to make sense of what is going on, and a patient-centered decision can ensue. Patient centered care is a term used to “describe the therapeutic relationships between care providers and service users, and between the care providers themselves” (Manley and McCormack 2008; p12). The preferred option is for the team to work with the patient to make the most appropriate decision. In summary, whilst some decisions may be possible in absentia of the patient; it may be advantageous if there is more patient involvement in the clinical decision to administer blood, because off the vast amount of uncertainty, and cultural influences; and this decision should certainly not be made on the basis of the haemoglobin in isolation.

6.5 Summary
This chapter discussed the findings in relation to the literature and the reality of clinical practice in cancer related anaemia and its management with blood transfusion. The management of this problem has been over-simplified for a multitude of reasons described. Firstly there is a lack of evidence and education (both formal and discourse in practice) and assumptions have developed based on the belief that cancer-related anaemia may be the same as other types of anaemia; which may be related in part to the commonality of anaemia. Secondly, assumptions have developed about transfusion practice; for example that by increasing the haemoglobin patients will benefit, but be at no more risk. Thirdly, faith in the biomedical value of the haemoglobin level is highly valued and clinical decisions are frequently made on the basis of this knowledge alone.
The reasons for this are complex and based on a multitude of unpredictable measures or application of generic anaemia and transfusion and/or erythropoietin study evidence. However, the overwhelming influence of the culture was unexpected and was evidenced in the starkest way by seemingly automatic and unquestioning change of decision making behaviours depending on where the participants worked. These elements will be brought together in the conclusion to suggest implications for practice and further research; in addition to making recommendations for the future.
CHAPTER 7

Conclusion

This chapter concludes the thesis and presents a summary of the findings of the ethnography of the culture of anaemia and blood transfusion practice in the haematology and oncology settings. The strengths and limitations of the study are discussed together with suggestions for research into cancer related anaemia and blood transfusion practice. Whilst this study was concerned specifically with anaemia in haematology and oncology and lung cancer, the relevance of findings may have broader implications for patients with different tumours and therefore most of the discussion and conclusions are generic to patients with cancer related anaemia.

This chapter will summarize the analysis, findings and discussion chapters and recapitulate the key issues and their implications for practice and future research. It should be clear from the data that variation in professional or clinical practice in this area is real and the differences in patients' risks, signs and symptoms, responses to treatment and values are real. Differences in nurses or clinician skills, knowledge and area of expertise are real, as are the availability of resources. Therefore it could be argued variations in clinical decisions are inevitable, and desirable in many instances, if treatment is tailored to the individual. However, it is not clear if the variations in practice are appropriate. The problem is that uncertainty clouds every aspect of cancer related anaemia that many of the appropriate variations may not occur and many of the variations in the management of anaemia do not appear to be motivated by logic but rather because it is the common practice in the particular clinical setting. More
importantly perhaps there appears to be lack of the involvement of the patient in the decision. Much of the practice of transfusion appears to be based on tradition and practices within the specific culture and this is further confounded by the difficulty in being transparent and accepting of uncertainty in that it goes against the values placed on evidence based practice and the certainty of medical knowledge. It should be accepted that it may not be easy to be precise about defining the clinical problem and that “one size fits all” approach may need to be abandoned, for example, the use of definitive transfusion triggers. The decision making should be tailored to the unique individual and perhaps the only way to do this is by involving the patient in that decision.

7.1 Summary of the study
The aims of the study were to explore the impact of cancer related anaemia and how decisions were made to treat the patient with blood transfusion, using an ethnographic methodology (Chapter 3). Data were collected over a nine month period using fieldwork observation and interviews with clinical staff and patients. Thematic analysis was used to analyze the data (Chapter 5) based on an adaptation of Spradley’s framework (1980).

The findings fall into four main areas. First, they suggest that anaemia and transfusion are commonplace in the clinical setting; and this is related to fact that many patients live with anaemia and it may not be viewed as an illness. Second, the findings suggest that there is a great deal of uncertainty surrounding the diagnosis and management of this clinical problem; but this uncertainty is acknowledged by both patients and clinicians. Third, the findings suggest that clinicians, and to some extent patients, are socialized into the practice of the culture of transfusion practice; and fourth that the haemoglobin
level is used as a distinct fragment of information on which to assess for the presence of anaemia and base the decision to treat with blood transfusion.

7.2 Implications for practice
This section brings together the literature, the findings and the discussion points to make recommendations for clinical practice in the management of cancer related anaemia and offer suggestions to potentially influence the culture of practice.

7.2.1 Managing cancer related anaemia
This study has shown cancer related anaemia may differ from other types of anaemia and is therefore not a distinct disease entity; it should probably be assessed, treated and researched in context of the cancer and the treatment, by making transparent what is invisible in clinical practice for example, the transfer of knowledge, uncertainty and socialization of practice. Managing cancer related anaemia may be improved if likened to monitoring a chronic condition. The essence of monitoring a chronic or recurrent condition is periodic measurement; followed by adjustment of the management. Factors that should be considered include what needs to be monitored, (for example Hb, fatigue and breathlessness); the frequency of measurements and how to adjust treatment. For example, the subjective opinion of the patient could be monitored in a self report tool and represented in graph form not dissimilar to the fatigue diary (Richardson 1994). This may give more control over to the patient resulting in more patient-centered decision making. However there are also several common errors of monitoring to avoid: rechecking to soon, over-reacting to chance fluctuations and over adjusting therapy, for example, the clinician response to fluctuating haemoglobin levels may result in over-responsiveness to the low haemoglobin. In this way trends rather than one off
assessments and responses to transfusion could be monitored. Monitoring (and adjustment of treatment) can be then thought of as a form of external homeostasis: bringing the average level and fluctuations back to more tolerable levels.

This study demonstrated how patients live with anaemia, and from the insights the aim of transfusion would be to maintain a haemoglobin to a level at which symptoms can be tolerated. Graphical representations may be helpful in monitoring levels of fatigue and the haemoglobin; and breathlessness in the lung patient population. Chronic care can potentially be improved (and at reduced costs) if for each chronic disease patients were more involved in their care (Del Mar et al 2006: p98) and more patient centred models of care were developed. In summary, some chronic diseases are effectively self-managed by patients, e.g. blood pressure, asthma and anticoagulation. It may be this model could be applied to the management of cancer related anaemia or at least involve the patient to a greater extent in the assessment and decision making processes, with the acceptance that there has been a tendency to over compensate and treat the anaemia unnecessarily.

Finally, it was also demonstrated in the literature review that the ability of the task feature to influence the mode of cognition is influenced by the knowledge of the practitioner on the task (Hamm 1999). Generally the greater the knowledge; the more analysis occurs; this has implications for practice in that the staff participants described how they had no further education on transfusion making decisions. At a basic level, mandatory training could be changed for cancer clinicians to incorporate some of the elements in this study; for example, to increase awareness of the influences on decision making; to achieve patient concordance and to encourage more discussion in practice about this subject. In
addition to formal education the functions of the clinic need to be considered as these influence learning and practice; for example how to change the clinics to facilitate patient and clinician learning through discussion and rhetoric. This may need consideration of the physical environment as well as process, for example, how to facilitate communication between the professionals and how to ensure patients are reviewed with all the information available.

7.2.2 Changing the culture
In healthcare today in the UK, using evidence based practice is considered to be best practice and traditional practice is not viewed as legitimate. However, this study demonstrated practice was entrenched because of the cultural influences, including the processes and structures of the clinical settings, professional relationships and the ways in which transfusion practice is learned. Traditional practices existed because of the tacit knowledge and intuitive behaviours demonstrated and described by practitioners. For a change to occur in the transfusion culture may take a radical shift in work practices which may be disruptive as transfusion has always been done in a certain way. If there is to be a change in practice; it would require a continuous development rather than a series of one off changes and involvement of everyone involved. Successive reforms typically focus too closely on changing structures and processes, and too little on changing patterns of behaviour and relationships in care settings (Manley and McCormack 2008). Reform of the culture of care would be necessary if the patient-centered approach to the management of anaemia is to be implemented.

The literature review, findings and discussion chapter described the theoretical basis for recommending a change of practice. Firstly, the literature review described the
importance of the small interactions; the exchange of different symbolic meanings in the form of "symbolic interactionism". Secondly, this provided the basis for exploring transfusion practice using ethnography to study the social interactions that influenced transfusion behaviour. Third, the findings demonstrated that transfusion behaviours were influenced by the culture and relationships and interactions in the clinical setting; the decisions were not made in isolation.

The findings have implications for change of practice. It will therefore require a long term plan and a series of changes and strategies to engage the whole clinical team. One cannot be too prescriptive at this stage as it probably requires a flexible approach as each change may inform or influence another; it would be an iterative process. Examples could include focused education for the clinical teams as described in the previous section but this alone may not be influential if most of intuitive knowledge is passed on by rhetoric. Therefore, the clinical environments and processes would need to be considered as described earlier, to facilitate a learning environment for improved decision making. Another radical approach would be to formalize the nurses' responsibility for transfusion decisions; legalize and legitimate their involvement in the process in the same way as non-medical prescribing of medication. It could be argued that nurses would be more discerning in their transfusion decision making than physicians as they would be a clinical priority as opposed to the physicians whose priority is to diagnose and treat the cancer; this is related to the hierarchy of clinical priorities as described in the findings in section 5.6.3 and discussed further in section 6.2.1. Unlike non-medical prescribing there is legally no barrier to this change and in theory an institution could manage this change independently, however, it would be advantageous to changing the culture if a national change occurred; otherwise,
traditional practices may persist is if it did not become a widely practiced behavior. This does not mean exclusively a nurse decision but just empowering the decision-makers and hopefully formalizing and improving the teamwork. Furthermore it would allow the clinical group (the nurses) who has the problem of the management of anaemia as high priority of their clinical issues, as they directly deliver the treatment and control the resource. It could also facilitate the patients and the day unit nurses to make patient-centered decisions based on the patient held diary as above, in the clinical environment that is the point of care delivery.

These are merely the researcher’s opinion on how the culture could begin to change; but with the understanding of the much wider involvement of all the players including laboratory staff; all the clinical teams; the transfusion practitioners and transfusion committee and the Trust as a whole. Success or failure of change will be dependent on the researcher’s ability to persuade others of the value of this study as a starting point.

In summary, the assessment and decision to treat should be put into context; the conversations between patient and clinician should be in relation to where the patient is on their treatment pathway and perhaps the decision to transfuse not be solely based on what is culturally acceptable. Ideally, there should be discussion and concordance between the patient and the clinician. However, one has to consider the cultural barriers to this; consider the time allowed to make the decision in the clinical setting and the low priority of anemia and its’ management. The clinics are busy and many of the patients are on treatment; this study has shown anaemia is low on the list of priorities for clinicians and patients. The researcher has produced an ethnography of transfusion practice and has provided a foundation on which to base change in clinical practice and
one of these changes may be to legitimize nurse prescribing of blood components. Of course, equally nurses do not work in isolation and would be subject to the cultural influences on practice, however, by legalizing prescribing of blood components, decision making would be a clinical priority in this professional group, which by virtue of contextualizing the task; the meaning of the decision for the nurse; and the influence of their experience implies that prescribing behaviours would improve.

7.3 Implications for further research
Discussion and progressive focusing of this research also resulted in a shift from concern with describing social events and behaviors towards starting to test any explanations of behaviour and/or theories that have been developed; with the aim of recommending future research activity. In summary the aims of the research were to explore the culture of transfusion practice and determine the influences on clinical decision making. This was congruent with the MRC (2008) guidance to explore the influences on interventions in an effort to determine what could optimize the outcomes of well established interventions, in this case, blood transfusion. It was discovered was that uncertainty was acknowledged and decision making was based on the culture of transfusion practice in the organization. The next steps would be to test interventions that could tolerate uncertainty for individual patients but within that is the understanding that variation exists because of the nature of cancer related anaemia. For example, to explore the benefits of nurse prescribing and patient centered decision making as described in 7.2. Expanding this research methodology into other clinical settings with patients with other cancers may be useful to determine if any other types of cancer patients have different issues with cancer related anaemia and symptoms. In summary, the uncertainty of the benefits of transfusion in the population with mild or moderate
anaemia surely warrants further research, for example, longitudinal research to
determine if maintaining low or high haemoglobin, using blood transfusion impacts on
tumour growth, outcomes or infections. The unpredictability of response to blood
depthusion may also warrant further research for example to determine if patients have
less response when "old" blood product is used, although it is acknowledged this did not
form part of this study.

The effects of the culture on transfusion practice were surprising. This research has not
fully answered the impact of the transfusion guidelines and if different strategies can be
used to implement guidelines or measure the impact of different education strategies,
other than mandatory training; the latter has been shown to be futile in terms of making
an impact on the clinicians decision making. The lack of consideration of cost of blood
transfusion was an intriguing finding for the researcher; this is probably not a unique
attitude and belief that blood is of minimum cost for example a recent excerpt from a
journal demonstrates:

"Speaking about the standard use of transfusions, Mr Foubert says:

"Transfusions rapidly raise the blood cell count and haemoglobin concentration
and are effective in virtually all patients at limited cost" (Davis 2008; p12)

A robust cost analysis of the real cost of blood transfusion in cancer related anaemia
may be useful. The real world is such that resource has to be considered and it should
only be those patients with clinical need and benefit who should receive transfusion. A
transfusion episode requires a great deal of resource as well as the cost of the product
itself and if 2.5 million units are used per anum in the UK; the lack of consideration of
cost may push towards over-utilization of blood and this would have massive financial
implications. Other clinical specialties are already exploring alternative strategies to
transfusion successfully and perhaps oncology and haematology are behind in this area of research with the exception of the erythropoietin research.

Finally, and perhaps most importantly, there was the assumption the patient's haemoglobin may be representative of the degree of suffering by the patient; the haemoglobin was used in isolation to influence the decision to treat. However, it may be that a low haemoglobin value is not representative of the impact of anaemia on the patient. A unique finding of this study was that even the patient's "got it wrong" in that they were surprised by the haemoglobin result as it did not always correspond with how they were feeling, for example, they may be asymptomatic (e.g. no shortness of breath or fatigue) with a low haemoglobin, but they would be treated with blood transfusion. This may result in the tendency to over-transfuse. Is the hypothesis that the management of anaemia is classic case of disaggregation of the body? It is proposed here that the unique difference of cancer related anaemia (as opposed to other types of anaemia) is that the classical signs and symptoms of anaemia are not applicable in the assessment of this type of anaemia. A future study could include a longitudinal study mapping the symptoms of this type of anaemia and quality of life with haemoglobin levels. It is suggested here this may be useful to undertake in patients with different tumour types as the impact of anaemia may vary between cancers, for example, the lung cancer patients may have a lower tolerance of the symptoms of anaemia because of the impact of their breathlessness.

7.4 Summary of recommendations for practice and research

The preceding sections have described implications for practice and suggestions for changing practice in addition to describing possible future research studies. This study
has contributed to the knowledge of cancer related anaemia and transfusion practice however this requires translation into improving practice. It also poses further questions and these should also be translated into action, by generating further research studies.

These are summarized below in Table 7.4.

Table 7.4: Recommendations for practice and research

<table>
<thead>
<tr>
<th>Recommendations for practice</th>
<th>Issue</th>
<th>Recommendation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer related anaemia is not a primary diagnosis</td>
<td>Manage cancer related anaemia like a chronic condition</td>
<td>Develop self management tools (patient information, patient diary, patient held record)</td>
<td></td>
</tr>
<tr>
<td>Patients live with their anaemia</td>
<td>Patient centred decision making</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncertainty in determining impact of anaemia</td>
<td>Manage cancer related anaemia like a chronic condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaemia management is low priority in the clinics</td>
<td>Shift the professional decision making</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Legitimize nurse prescribing of blood components to allow decision making to occur at point of care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learning the skills of anaemia management are not facilitated in the clinical or educational environment</td>
<td>The learning environment should facilitate tacit learning</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinic remodeling to create environment conducive to learning</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Redesign mandatory training</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recommendations for research</th>
<th>Issue/hypothesis</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of research in different tumour groups</td>
<td>Expanding this methodology into other cancer populations</td>
<td></td>
</tr>
<tr>
<td>Lack of research into the benefits of transfusion for patients with mild/moderate anaemia</td>
<td>Longitudinal research to determine if maintain a low or high haemoglobin with blood transfusion has an impact on tumour growth, infections or outcomes</td>
<td></td>
</tr>
<tr>
<td>The classical symptoms of anaemia (breathlessness/fatigue etc) or haemoglobin are not useful in assessing cancer related anaemia</td>
<td>Longitudinal study mapping the symptoms of this type of anaemia and quality of life with haemoglobin levels.</td>
<td></td>
</tr>
<tr>
<td>Lack of cost benefit analysis of blood transfusion</td>
<td>Cost analysis of blood transfusion in cancer practice</td>
<td></td>
</tr>
<tr>
<td>Lack of research into the unpredictability of response to transfusion</td>
<td>Physiological studies to determine if the age of blood transfused has an impact on infections and outcomes in the cancer population</td>
<td></td>
</tr>
</tbody>
</table>
7.5 Strengths and limitations of the study

The strengths of this study include its original contribution to the understanding of cancer related anaemia and its management with blood transfusion; and the use of this methodology to explore the culture of transfusion practice. Whilst the findings cannot be generalized because of the nature of the methodology (Chapter 3), they undoubtedly offer a range of insights into the practice of blood transfusion in the oncology setting. This contributes to the understanding of why there is variation in clinical practice in different clinical settings. Much previous research concerning cancer related anaemia was quantitative, where the researcher(s) would typically isolate symptoms of anaemia and use different quality of life tools to measure it; which offered some objectivity but failed to perhaps tease out the uncertainties of the assessment and management of this type of anaemia. The weaknesses of those studies is that certain generalizations have been made about cancer related anaemia that fail to take into account the unique individuals' unpredictability of their anaemia in terms of it's impact as well as unique responses to individual blood transfusion episodes. This ethnographic approach to the study of this clinical problem has enabled a deeper understanding of how anaemia impacts on cancer patients, from the patients' perspectives and indicated ways in which different aspects of anaemia and transfusion relate to each other. The findings demonstrate the intricacies that exist in cancer related anaemia management, and how different sub-cultures within institutions influence decisions. In this way this study has enabled a more holistic understanding of this clinical problem, which in turn will inform on possible ways to improve the management of cancer related anaemia.

The study contributes to knowledge about how clinical teams function (Atkinson 1995) and demonstrates clinical decision making theory in practice. The findings suggest that
clinical knowledge about anaemia and transfusion develops in accordance with theories about tacit knowledge and intuitive knowledge. The study shows that by contextualizing the anaemia and by having the patient at the centre of decision making, it may improve the management of cancer related anaemia. It has demonstrated the power of the cultural influences; and if the desired outcome is to change practice then it may require a huge cultural shift for this to occur. This is perhaps unrealistic considering the deeply entrenched transfusion practices that exist, but would go beyond mere manipulation of processes and systems.

A further strength of the study was the use of different data sets to develop the ethnography; the findings emerged by finding threads or ideas in one data set then use a different data set to corroborate or verify the emerging theme. This added robustness to the findings, rather than if a single data source had been used.

A limitation of the study is that, as an ethnographic study, it represents the researcher's interpretation of reality and that there may be other possible interpretations of reality, although the participants' voices are represented in the final thesis. Furthermore, it could be argued that a limitation of this study was that there were not extensive periods of time spent in the field; this study was limited to fieldwork observation in six clinics. Therefore this study could not be considered to be an in-depth ethnography but rather an exploratory study adopting an ethnographic approach. It could also be argued the researcher was an experienced nurse in the sub-specialism of haematology and less so in the sub-specialism of lung cancer; this may have influenced the researcher's interpretations of the observations during the fieldwork and therefore may have influenced the findings. The familiarity of the researcher within the organization is
acknowledged here and this will be discussed in greater depth in the following section, which reflects on the researcher's journey.

Finally the study was based in two cancer sub-specialisms therefore there may be limits to transferability of findings to other tumour group patients and staff populations or different types of anaemia and their management. Furthermore, this study was confined to relatively small samples within two sub-specialisms and this may have skewed the data, and it is acknowledged this is a limitation of this study. Equally, it may not be transferable to paediatric settings, whereby there is a greater reluctance to expose children to transfusion, because of the long term risks of transfusion combined with their better outcomes from cancer, which would influence the culture of transfusion practice.

7.6 The reflexive ethnographic journal

It was described in Chapter 1 and in the previous section how the researcher is integral to interpretive ethnographic methodology and combines the perspectives of both the researcher and the researched (Savage 2000). The essence of this was captured in my reflexive ethnographic journal and used throughout the research from inception to completion. This is described as "ethnographic reflexivity" (Allan 2006; p404) and the final thesis therefore could be described as my interpretation of the truth, in that I have contributed to the final product. My experiences, imagination, inspiration, motivation and intellect influenced this research and without it I would argue that an original contribution to knowledge would have been unlikely. I have worked in haematology and cancer for many years and have cared for many "anaemic patients"; I have made thousands of "transfusion decisions" and therefore have formed attitudes about clinical practice, which influenced my interpretation of the data and this is acknowledged here.
My journal formed the foundations of the reflexivity in this research and I used it throughout the data collection and data analysis phases where I would write myself notes and further questions. For example, early excerpts described visits to the lung clinic “very busy, packed waiting room, people afraid to get up from seats in case they lose their slot” and observations from the day care unit “a patient wants a newspaper to read whilst he is waiting for his cannula to be put in and his blood to start”. Both of these observations were from December 2007 prior to formal observation and interview work but formed part of the ethnography in that I was beginning to formulate a picture of what was happening. Also interspersed throughout the journal were notes I had taken during supervision, in addition to thoughts and questions to myself; these included sudden and random thought processes whilst writing or following some of the observations and interviews. I also took notes when I met with key people who informed or assisted with this project (these are identified in the research log, Part 2). For example, I wrote the following when I met with an experienced ethnographer:

- What do I want to observe in the clinic?
- Are all the patients relevant?
- What is the structure of the consultations?
- Who is present in the Consultations?
- What are the things that are shaping the clinic and how it functions?
- Where do they (patients and clinicians) sit?
- What took place?
- What were the behaviours?”
These notes assisted me during the subsequent observations in clinic and helped me to understand that it was not possible to record every consultation and every aspect of the clinic, but learn to focus on the important elements of the behaviours and environment within the clinical settings.

Looking back through the annotations it could be demonstrated how my thoughts changed and evolved as the project developed, for example, "uncertainty" was noted early on in the journal as was "the educated patient". These early notes taken following some of the interviews and observation fieldwork revealed the beginnings of the sub-themes within the final research findings. These are described here as "analytic memos" and included notes made on the "role of uncertainty" and "knowing the patient: are relationships important?". Such notes demonstrated my formulation of ideas and during the analysis the reflexive journal helped me to bring these ideas together and develop themes; notes were taken when re-reading the data and diagrams sketched to try to start making sense from the large volume of data. It was an iterative process whereby I would move between the data and take notes then repeatedly re-visit other data to verify my thoughts and ideas.

The content of the reflexive diary demonstrated the shift in my understanding; firstly was my realization that the management of this clinical problem was influenced by the cultural practices, which were in turn dependent on the social interactions in that culture. Secondly, I had an increased understanding that uncertainty clouds all assessments and decisions from an early belief that the haemoglobin was infallible. Thirdly, I recognized the importance of contextualizing the anaemia in the presence of the patient, in an attempt to prevent the disaggregation of the body and that this, in combination with the
other cultural practices, may result in less than optimum transfusion practice. Finally, I recognized that different professional groups (physicians and nurses) may have different clinical priorities and this may influence the decision making behaviours and interactions.

Finally, this project took me four years to complete, although undoubtedly the last six months were the most intense. However, during this four year period not only had my understanding of cancer related anaemia and transfusion practice developed but the change of research design represented a personal ontological struggle for me. Originally it could be described that I had a natural leaning towards a positivist ontological perspective but that I shifted to an interpretive perspective with a determined attempt to see the world through the eyes of others and I attempted to represent this truthfully and faithfully by using reflexivity and the data. I found this a difficult but rewarding process especially as new information emerged from the data. Having gone through this ontological shift I would argue, based on my personal experience of undertaking this research, that any researcher could undertake ethnography, if it is the most appropriate methodology to explore the reality of practice. There is no robust argument that any individual's version of reality is not valuable even if it requires a paradigm shift, if one keeps true to the data. I would argue that if one is dismissive of any standpoint epistemology, not only could it be perceived as disrespectful but there would be a tendency to not appreciate, understand or assimilate different types of research evidence, whether qualitative or quantitative. In summary, this ethnographic study not only acknowledged my personal contribution but also required me to use reflexivity throughout the research from the early ideas through to study completion to create the final thesis.
7.7 Summary

This study has shown that the culture of a specialism is a powerful influence on behaviours, which may result in less than optimal blood transfusion for a multitude of complex reasons which have been outlined in chapters 6 and 7. Some recommendations from this study relate to the practical aspects of how transfusion decisions should be made in clinical practice; others relate to how patients could be empowered to take control of their “symptoms of anaemia”. There may be no reason why patients cannot begin to manage their chronic condition in the same way as other patient groups manage their diabetes or heart disease; with the appropriate support and information. They are in the best position to know what level of anaemia is tolerable.

There has been recent debate about nurses prescribing blood components and this study supports and endorses nurse prescribing of blood in this clinical context. This study showed that nurses already make decisions about transfusion; are experienced and exposed to transfusions; and therefore a recommendation of this study would be to legitimize this and develop training and education to support to nurses to undertake this extended role; not dissimilar to non medical prescribing. This is further supported by the evidence that nurses may be in an ideal position for the social learning in that they are frequently exposed to anaemic patients who are undergoing blood transfusion and quality of life issues may be their clinical priority. This would be a radical shift in practice and would potentially disrupt the culture of transfusion practice; the decision making base would be shifted away from the medical team and would be shared with the group who control the resource and more importantly, who have more opportunity to negotiate with the patients as they attend the day units for therapy. Although some transfusion nurses have proposed this (Pirie & Green 2008), this is the first research evidence which
has suggested there is a rationale and theoretical basis for supporting this radical change and this is a unique contribution to the study of transfusion practice.

Local systems change is recommended to change the responsibility of assessing cancer related anaemia and the "prescribing" of blood components by the day unit nurses, for reasons described earlier (quality of life priorities; point of care delivery). For this innovation to be successful, it is acknowledged that such change is most effective when it involves the key stakeholders (Kitson 2009). Healthcare organizations do not work in a logical organized manner and therefore the "systems" involved in blood transfusion practice need to be understood first. This study has provided some insight into the systems and it is recognized that the "purposeful integration of systems theory with knowledge translation theories and models may enable the application of research and new knowledge to practice be speeded up" (Kitson 2009 ,p225). In other words it may take more than a change in responsibilities, but engagement of the teams in understanding the interactions and behaviours, and additional knowledge, engaging the whole team in the process, may facilitate change.

By combining the empowerment of patient and nurses in this way, the shift towards a nurse-patient partnership in anaemia management may provide a way forward to reducing the uncertainty, although it is acknowledged that uncertainty may continue to exist and indeed may be desirable. However, another strategy to improve decision making would be recontextualization of the anaemia. Anaemia should be put back into the body, and treated accordingly. It should not be viewed as a separate symptom and should be re-contextualized into the rest of the disease and treatment pathway. This would bring robustness to those indications where blood is absolutely necessary, and
when not to transfuse, for example, when there is only mild or moderate anaemia and the blood counts are recovering. It would also mean that any research or practice should be related to the patients with different cancers. The problem is that much of the research is related to anemia and transfusion as a clinical entity whereas it may be more prudent to undertake research in specific tumour populations as outcomes related to anaemia and transfusion may vary between patients with different tumour types; and the patient's transfusion needs may vary in relation to quality of life. What may be best practice for one type of cancer patient may not be for another; therefore any guidance would need to reflect this and perhaps tumour specific guidelines need to be developed; with the flexibility of patient partnership working reflected in those guidelines. If these factors were considered the decision to administer a blood transfusion is more likely to be discerning and there may be less likely tendency to over-transfuse. If the decision makers were the key clinical staff in the best position to do this; it is likely the socialization of practice would remain a powerful influence over the behaviors, however the outcome would be closer to optimal transfusion practice as the patient would be at the centre of the decision to transfuse, which should surely be the ultimate aim.
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Appendix

Appendix 1: FACT-An anaemia and fatigue subscale (version4)

By circling one number per line, please indicate how true each statement has been true for you during the past 7 days.

### Additional concerns

<table>
<thead>
<tr>
<th>Statement</th>
<th>Not at all</th>
<th>A little</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel fatigued</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I feel weak all over</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I feel listless (&quot;washed out&quot;)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I feel tired</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have trouble starting things because I am tired</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have trouble finishing things because I am tired</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have trouble walking</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am able to do my usual activities</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I need to sleep during the day</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I feel lightheaded (dizzy)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I get headaches</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have been short of breath</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have pain in my chest</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am too tired to eat</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am interested in sex</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am motivated to do my usual activities</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I need help doing my usual activities</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am frustrated by being too tired to do the things I want to do</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have to limit my social activity because I am tired</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Below is a list of statements that other people with your illness have said are important. By circling one number per line, please indicate how true each statement has been for you during the past 7 days.
## Functional Well-Being

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>I am able to work (include work at home)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>My work (include work at home) is fulfilling</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am able to enjoy life</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have accepted my illness</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am sleeping well</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am enjoying the things I usually do for fun</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I am content with the quality of my life right now</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix 2: Blood transfusion audit

Table 3.3a: Transfusion triggers (Haemato-oncology and oncology)

<table>
<thead>
<tr>
<th></th>
<th>Number of transfusion episodes</th>
<th>Mean Hb transfusion trigger</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haemato-oncology</td>
<td>54</td>
<td>7.8 g/dl</td>
<td>5.1-10.3 g/dl</td>
</tr>
<tr>
<td>Oncology</td>
<td>202</td>
<td>9.1 g/dl</td>
<td>5.8-12.8 g/dl</td>
</tr>
</tbody>
</table>

Table 3.3b: Single vs. Multiple Unit Transfusions (Oncology only)

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single unit</td>
<td>14</td>
<td>6.9</td>
</tr>
<tr>
<td>2 unit transfusion</td>
<td>162</td>
<td>80.2</td>
</tr>
<tr>
<td>3 unit transfusion</td>
<td>21</td>
<td>10.3</td>
</tr>
<tr>
<td>&gt; 4 unit transfusion</td>
<td>5</td>
<td>2.5</td>
</tr>
<tr>
<td>Total</td>
<td>202</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 3: Patient information Sheet (version 2) (on headed notepaper)

REC Number: 07/H0802/96
Principal Investigator: Liz Bishop

Introduction
You are being invited to take part in a research study, which is part of a Doctorate study being undertaken at Surrey University by the Haematology Nurse Consultant, Liz Bishop, and <name of acute trust>. Before you decide, 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 friends, relatives and your GP if you wish. Ask us if there is anything you do not understand or if you would like more information. Take time to decide whether or not you wish to take part. Should you decide to take part in the study, you should keep this document in a safe place in case you need to look at it again.

Thank you for reading this

1. What is the purpose of this study?
The main purpose of this study is to find out if blood transfusion has an impact on your quality of life and fatigue and activity levels.

Haemoglobin, which carries oxygen from the air that we breathe, is found in the red blood cells in your bloodstream. The red blood cells are responsible for carrying this oxygen to your tissues. As a result of your condition, or treatment, you may develop a low red blood cell count and consequently a low haemoglobin level. Together, these may cause anaemia. Common symptoms of anaemia are fatigue (tiredness), lack of energy and shortness of breath. In some cases these symptoms can also interfere with your ability to perform daily activities, such as bathing, shopping, working or hobbies so it is important for us to understand the impact of anaemia on your activity levels.

Blood transfusion is routinely used to correct anaemia, but it is not known how it impacts on fatigue and activity and quality of life in the outpatient setting. We would like to do further research to measure quality of life and activity over a period of 90 days whilst maintaining your haemoglobin with blood transfusion. We may observe your consultation in clinic but we do not interfere with the decision as to whether to give you blood transfusion or not. In a separate part of the study we are also interviewing doctors and nurses to examine in more depth how they assess and treat anaemia and observing their behavior in clinic.

2. Why am I being invited to take part?
You have been invited to join this research study because you have anaemia and you sometimes receive blood transfusion to maintain your haemoglobin levels. You would, if you decided to take part, be 1 of 10 patients to enter the study in this hospital.

3. Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you
decide to take part you are still free to change your mind or withdraw at any time and without giving a reason. This will not affect the standard of treatment or care you receive.

4. What will happen to me if I take part?
The study lasts for a total of 90 days. If you decide to take part in this study you will have to attend clinic at the beginning of the study but this can be co-ordinated with one of your usual visits to clinic. Your fatigue levels will be measured at visits at the clinic every four weeks (4 times in all) by completing a brief questionnaire. This takes approximately 10 minutes and you will be asked to complete it before your blood results are available. The study nurse will explain how to complete the questionnaire. If the timing of the questionnaire does not coincide with your clinic appointment you will be posted your questionnaire and asked to return it by post in the Stamped Addressed Envelope provided.

Activity levels will be recorded by a technique known as actigraphy. This involves wearing a device called an actiwatch (worn like a wristwatch) and this records your movement and sleep. It is waterproof but it is best to take it off whilst bathing, showering or swimming. The actiwatch is worn throughout the 90-day study period. See the attached sheet “Instructions for wearing the Actiwatch”

5. What do I have to do?
For this study to be successful, it is important you complete the questionnaire and wear the actiwatch continually (apart from when bathing). Throughout the study period you can take your medications as usual. Throughout the 90-day period you will attend the hospital as dictated by your doctor. We will also record how often and how much blood transfusions you receive.

6. What is the procedure that is being tested?
Blood transfusion is routinely used to increase patients’ haemoglobin levels. It is necessary to maintain the haemoglobin to enable oxygen to reach the tissues and for this reason we tend to transfuse patients when the haemoglobin level fall to 8.0g/dl or below or when you have symptoms of anaemia. However, there is some uncertainty as to the benefits of blood transfusion in terms of patients’ quality of life, namely fatigue and activity levels.

Throughout the study period you will be given blood transfusion according to standard practice, i.e. when your haemoglobin falls. The blood will be dripped into your arm via a cannula (a fine tube inserted into a vein) during your out-patient visit. This study will examine how often you have blood transfusions and if this impacts on your quality of life, specifically your fatigue and activity levels. The researchers will not influence the decision to give you blood. This will remain the decision of the doctor looking after you.

7. Are there other ways of treating my condition?
Sometimes patients who are anaemic are treated with a drug called erythropoietin but it is not routinely available. Not all patients respond to this drug and your doctor may decide it is not an appropriate way to manage your anaemia.
8. What are the possible side-effects?
There are risks of receiving blood transfusion. The main risks are infection and
transfusion reactions but this study is not influencing the decision to treat the anaemia.
This is the decision of your doctor.

9. What are the possible disadvantages and risks of taking part?
There are no disadvantages or risks to you directly because we do not interfere with your
treatment. The only inconvenience of this study is having to wear the actiwatch
throughout the study period and complete the questionnaire.

Before agreeing to take part in the study you should check that any private medical
insurance you have will not be affected by you taking part.

10. What are the possible benefits of taking part?
There are no direct benefits of this study to you. The information we get from this study
may benefit future patients who have anaemia.

11. What if new information becomes available?
Sometimes during the course of a research project, new information becomes available
about the treatment/drug that is being studied. If this happens, your doctor or nurse will
tell you about it and discuss with you whether you want to continue in the study. If you
decide to withdraw, your treatment will continue as before. If you decide to continue in
the study you will be asked to sign an updated consent form and the new information
would be explained to you. Also, on receiving new information your research nurse or
doctor might consider it to be in your best interests to withdraw you from the study.
He/she will explain the reasons and arrange for your care to continue.

12. What happens when the research study stops?
When you have completed the 90-day study period you will continue with routine care
and attendance at the hospital as before. This means you will have blood transfusions
dependent on your symptoms and haemoglobin level at each visit as before.

13. What if something goes wrong?
If you have any complaints about treatment you have received you should inform your
study nurse or doctor. If there are complaints about something serious happening during
or after your participation in the study you should inform your study doctor/nurse
immediately. The research supervisors at Surrey University may also be contacted <
insert supervisors name and telephone numbers>. Any transfusion reactions will be
recorded and followed-up as usual practice. Your legal rights are not affected by giving
your consent to take part in this study. Your right at law to claim compensation for injury
where you can prove negligence is not affected. This should not affect any private
medical insurance you have.

14. Will my taking part in this study be kept confidential?
Yes—all information, which is collected about you during the course of the research, will
be kept strictly confidential. Any information about you, which leaves the hospital for
data analysis, will have your name and address removed. A letter will be sent to inform
your GP that you are participating in this study. The questionnaires that you complete
will be kept confidential within the study.
15. What will happen to the results of the research study?
The results of the study when completed, will be analysed, reviewed by the study team, and published in a research journal in due course. The results will also be published as a Doctorate study at Surrey University. Neither you, nor anybody else who see the results from the study will be able to identify anyone from the study. The results of this study are likely to be available December 2008. If you would like a summary of the results when available please inform the research nurse.

16. Who is organising and funding the research?
This study is organised and funded by the <name of acute trust>.

17. Who has reviewed the study?
This study has been reviewed and approved by the National Ethics Committee, Surrey University ethics committee and the local ethics committee of <name of acute trust>.
Appendix 4-Actiwash Information Sheet (version 2)
Instructions for wearing the Actiwash

Please put on the Actiwash and wear it as you would a wristwatch. The webbing strap can be pierced at any point according to your personal fit. The Actiwash is a device used to measure movement and determine your sleep-wake cycle.

The Actiwash must be worn continuously, on your non-dominant wrist. (i.e. the one that you don't write with).

It is essential that you do not remove it when you go to bed.

Although the Actiwash is waterproof, please remove it when washing-up and showering and if you are going swimming or taking a bath.

Remember to attach the Actiwash immediately afterwards.

To press the event button, press in the circle on the top of the Actiwash, you will hear a click.

Press the event button at night when you go to bed and turn the lights out to go to sleep.

Press the event button when you wake up in the morning to start getting up.

Please call me if you have any queries
Appendix 5: Patient Consent form (version 1) (on headed notepaper)

Date given to patient: ___________________________

Ethics protocol number: 07/H0802/96

Patient identification No: P

Name of principal investigator: Liz Bishop

<table>
<thead>
<tr>
<th>Please tick box</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I confirm that I have read and understand the information sheet dated .......... (version......) for the above study and that I have had an opportunity to ask questions</td>
</tr>
<tr>
<td>2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, and my medical care and legal rights will not be affected.</td>
</tr>
<tr>
<td>3. I am willing to allow access to my medical records to check that the study is being carried out correctly. I have been assured that strict confidentiality will be maintained.</td>
</tr>
<tr>
<td>4. I agree for my GP to be notified of my participation in this study</td>
</tr>
<tr>
<td>5. I agree to participate in the above study</td>
</tr>
<tr>
<td>6. I would / would not like to be informed of the results of this study (please delete as appropriate)</td>
</tr>
</tbody>
</table>

Name of patient: Date: Signature:

Name of person obtaining consent: Date: Signature:

(If different from principal investigator)

Principal investigator: Date: Signature:

(1 copy for patient, 1 copy for principal investigator, 1 copy for hospital notes)
Appendix 6-GP letter (version 2) (on headed notepaper)

Patient name:
Hospital Number:
DOB:
Address:

Telephone number:
Date:
Study Title: A study to determine the impact and assessment of cancer-related anaemia in lung and haematology cancer patients and the decision to treat with blood transfusion

REC Number: 07/H0802/96
Principal Investigator: Liz Bishop
Anticipated study start date:

Dear Doctor ..............,

The above patient has agreed to participate in a study at <insert acute NHS Trust> It is a study examining the impact of blood transfusion on the fatigue and activity levels of patients with cancer-related anaemia. The study period is 90 days. Their fatigue and quality of life will be measured at baseline and 4-weekly intervals using a questionnaire, which takes approximately 10 minutes to complete (Functional Assessment of Cancer Therapy-Anaemia Questionnaire). Activity will be measured continuously by wearing an actiwatch on their non-dominant wrist—a technique known as actigraphy. Patients will receive blood transfusion as directed by their doctor. Patients will attend the hospital as directed by their team throughout the study period.

If you require more information regarding this study please do not hesitate to contact me, in the department of haematology.

Yours sincerely,
Appendix 7: Demographic Data

Patient Data

Table 4.1.1a: Patient interview schedule

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Date of interview</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH1</td>
<td>20.8.08</td>
</tr>
<tr>
<td>PH2</td>
<td>22.8.08</td>
</tr>
<tr>
<td>PH3</td>
<td>27.8.08</td>
</tr>
<tr>
<td>PL1</td>
<td>18.8.08</td>
</tr>
<tr>
<td>PL2</td>
<td>25.8.08</td>
</tr>
<tr>
<td>PL3</td>
<td>1.9.08</td>
</tr>
</tbody>
</table>

Table 4.1.2b: Demographic, diagnosis and treatment details

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Age</th>
<th>Sex</th>
<th>Diagnosis and stage</th>
<th>Treatment to date</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH1</td>
<td>32</td>
<td>Female</td>
<td>Stage IV lymphoblastic lymphoma</td>
<td>3 cycles COPDM chemotherapy</td>
</tr>
<tr>
<td>PH2</td>
<td>62</td>
<td>Male</td>
<td>Acute Myeloid Leukaemia</td>
<td>3 cycles of ADE chemotherapy followed by cord blood stem cell transplant</td>
</tr>
<tr>
<td>PH3</td>
<td>28</td>
<td>Male</td>
<td>Stage IV Diffuse Large B cell Non Hodgkin's Lymphoma</td>
<td>6 cycles CHOP chemotherapy; relapsed and underwent 2 cycles DHAP chemotherapy followed by autologous stem cell transplant</td>
</tr>
<tr>
<td>PL1</td>
<td>67</td>
<td>Male</td>
<td>Squamous cell carcinoma left lung (T4 N2 M0)</td>
<td>Radical chemoradiotherapy to left lung, 3 cycles of vinorelbine and cisplatin. Completed 64Gy in 32Gy</td>
</tr>
<tr>
<td>PL2</td>
<td>59</td>
<td>Female</td>
<td>Non small cell lung cancer left lower lobe (T2 N2 M0)</td>
<td>Completed chemoradiotherapy, 4 cycles vinorelbine and cisplatin. Completed 64Gy in 32Gy</td>
</tr>
<tr>
<td>PL3</td>
<td>52</td>
<td>Male</td>
<td>Adenocarcinoma right lung (T3 N2 M0)</td>
<td>3 cycles of vinorelbine and cisplatin</td>
</tr>
</tbody>
</table>
Table 4.1.2c: Patient family and employment details

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Marital status</th>
<th>Dependents</th>
<th>Previous employment</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH1</td>
<td>Married</td>
<td>2 children; aged 5 and 8</td>
<td>None; housewife</td>
</tr>
<tr>
<td>PH2</td>
<td>Married</td>
<td>2 children; independent adults</td>
<td>Engineer</td>
</tr>
<tr>
<td>PH3</td>
<td>Single but long term partner</td>
<td>None</td>
<td>Graphic designer</td>
</tr>
<tr>
<td>PL1</td>
<td>Divorced</td>
<td>3 children; independent adults</td>
<td>Retired</td>
</tr>
<tr>
<td>PL2</td>
<td>Married</td>
<td>1 child; independent</td>
<td>Office clerk</td>
</tr>
<tr>
<td>PL3</td>
<td>Single</td>
<td>None</td>
<td>Unemployed</td>
</tr>
</tbody>
</table>

Table 4.2.1: Clinician interview schedule

<table>
<thead>
<tr>
<th>Staff ID</th>
<th>Designation</th>
<th>Date of Interview</th>
</tr>
</thead>
<tbody>
<tr>
<td>SH1</td>
<td>Consultant Haematologist</td>
<td>4.2.08</td>
</tr>
<tr>
<td>SH2</td>
<td>Specialist Registrar (Haematology)</td>
<td>28.2.08</td>
</tr>
<tr>
<td>SH4</td>
<td>Day Care Unit Sister (Haematology)</td>
<td>6.12.07</td>
</tr>
<tr>
<td>SH5</td>
<td>Clinical Nurse Specialist (Haematology)</td>
<td>28.1.08</td>
</tr>
<tr>
<td>SH6</td>
<td>Clinical Nurse Specialist (Anaemia)</td>
<td>6.6.08</td>
</tr>
<tr>
<td>SL1</td>
<td>Consultant Oncologist (Lung)</td>
<td>19.12.07</td>
</tr>
<tr>
<td>SL4</td>
<td>Day Care Unit Sister (Lung)</td>
<td>17.3.08</td>
</tr>
<tr>
<td>SL5</td>
<td>Clinical Nurse Specialist (Lung)</td>
<td>28.1.08</td>
</tr>
<tr>
<td>SH9</td>
<td>Anaemia Clinical Nurse Specialist</td>
<td>12.4.08</td>
</tr>
</tbody>
</table>

Table 4.3.2a: Observation and fieldwork schedule

<table>
<thead>
<tr>
<th>Clinic/Day Unit ID</th>
<th>Care</th>
<th>Date of fieldwork</th>
<th>Time spent in clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>HC1</td>
<td></td>
<td>28.2.08</td>
<td>4 hours</td>
</tr>
<tr>
<td>HC2</td>
<td></td>
<td>11.3.08</td>
<td>3.5 hours</td>
</tr>
<tr>
<td>HC3</td>
<td></td>
<td>23.5.08</td>
<td>4 hours</td>
</tr>
<tr>
<td>LC1</td>
<td></td>
<td>1.2.08</td>
<td>5 hours</td>
</tr>
<tr>
<td>LC2</td>
<td></td>
<td>28.3.08</td>
<td>4.5 hours</td>
</tr>
<tr>
<td>LC3</td>
<td></td>
<td>22.5.08</td>
<td>4 hours</td>
</tr>
</tbody>
</table>
Table 4.3.2b: Clinic size contrasts: Oncology and haematology

<table>
<thead>
<tr>
<th></th>
<th>Oncology</th>
<th>Haemato-oncology</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OPD</td>
<td>Day Unit Bed or chair spaces</td>
</tr>
<tr>
<td>Size-number of rooms/bed spaces</td>
<td>18</td>
<td>35</td>
</tr>
<tr>
<td>Patient numbers</td>
<td>25-65</td>
<td>45-55</td>
</tr>
<tr>
<td>Nurse numbers</td>
<td>3</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 4.3.2c: Haemoglobin values of patients in clinical areas and transfusions administered from clinic/day care decisions (anaemia is defined using the NCI criteria; Table 2.2.1; p34)

<table>
<thead>
<tr>
<th>No./% of patients with Hb</th>
<th>HC1</th>
<th>HC2</th>
<th>HC3</th>
<th>LC1</th>
<th>LC2</th>
<th>LC3</th>
</tr>
</thead>
<tbody>
<tr>
<td>WNL (&gt;12g/dl)</td>
<td>7</td>
<td>7</td>
<td>2</td>
<td>6</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Mild (10g/dl-12g/dl)</td>
<td>11</td>
<td>12</td>
<td>10</td>
<td>22</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>Moderate (8g/dl-10g/dl)</td>
<td>6</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Severe (6.5-7.9g/dl)</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Life threatening (&lt;6.5g/dl)</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>24</td>
<td>19</td>
<td>33</td>
<td>26</td>
<td>37</td>
</tr>
<tr>
<td>Number of patients treated with blood transfusion</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>% of patients WNL</td>
<td>28%</td>
<td>29%</td>
<td>10.5%</td>
<td>18.8%</td>
<td>18.5%</td>
<td>29.7%</td>
</tr>
<tr>
<td>% of anaemic patients</td>
<td>72%</td>
<td>71%</td>
<td>89.5%</td>
<td>81.2%</td>
<td>81.5%</td>
<td>70.3%</td>
</tr>
</tbody>
</table>
Appendix 8: Patient Information Leaflet (version 4)

Version Number: 4; 9.8.08

Research Ethics Committee Number: 07/H0802/96

Principal Investigator: Liz Bishop

Introduction
You are being invited to take part in a research study, which is part of a Doctorate study being undertaken at Surrey University by the Haematology Nurse Consultant, Liz Bishop, and <insert name of acute NHS trust>. Before you decide, 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 friends, relatives and your GP if you wish. Ask us if there is anything you do not understand of if you would like more information. Take time to decide whether or not you wish to take part. Should you decide to take part in the study, you should keep this document in a safe place in case you need to look at it again.

Thank you for reading this

1. What is the purpose of this study?
The main purpose of this study is to find out if blood transfusion has an impact on your quality of life and fatigue and activity levels.

Haemoglobin, which carries oxygen from the air that we breathe, is found in the red blood cells in your bloodstream. The red blood cells are responsible for carrying this oxygen to your tissues. As a result of your condition, or treatment, you may develop a low red blood cell count and consequently a low haemoglobin level. Together, these may cause anaemia. Common symptoms of anaemia are fatigue (tiredness), lack of energy and shortness of breath. In some cases these symptoms can also interfere with your ability to perform daily activities, such as bathing, shopping, working or hobbies so it is important for us to understand the impact of anaemia on your activity levels.

Blood transfusion is routinely used to correct anaemia, but it is not known how it impacts on fatigue and activity and quality of life in the outpatient setting. We would like to do further research to measure quality of life whilst maintaining your haemoglobin with blood transfusion. We may observe your consultation in clinic but we do not interfere with the decision as to whether to give you blood transfusion or not. In a separate part of the study we are also interviewing doctors and nurses to examine in more depth how they assess and treat anaemia and observing their behavior in clinic.

2. Why am I being invited to take part?
You have been invited to join this research study because you have anaemia and you sometimes receive blood transfusion to maintain your haemoglobin levels. You would, if you decided to take part, be 1 of 10 patients to enter the study in this hospital.

3. Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to change your mind or withdraw at any time and without giving a reason. This will not affect the standard of treatment or care you receive.

4. What will happen to me if I take part?
The study involves being interviewed by the principal investigator, Liz Bishop. She will arrange a convenient time to interview you, which coincides with a routine hospital visit to the hospital. In a quiet and private location she will ask you a series of questions about anaemia and blood transfusions. The questions will be about how you are feeling and about your symptoms. Other questions will be about the blood transfusions. The interview will be tape recorded, but your identity will not be revealed. The interview will last no longer than 1 hour. The tape recording will be transcribed by the principal investigator and anonymised. In other words, the copy of your transcript will be named PH1, PH2 and so on and not be identifiable other than by the principal investigator. No-one other than the principal investigator will have access. You can have a copy of the transcript at your request. The recording will be removed from the digital recorder following transcription.

5. What do I have to do?
The only requirement for you is to have the interview. It is very informal.

6. What is the procedure that is being tested?
Blood transfusion is routinely used to increase patients' haemoglobin levels. It is necessary to maintain the haemoglobin to enable oxygen to reach the tissues and for this reason we tend to transfuse patients when the haemoglobin level falls to 8.0g/dl or below or when you have symptoms of anaemia. However, there is some uncertainty as to the benefits of blood transfusion in terms of patients' quality of life, namely fatigue and activity levels.

Throughout your treatment period you will be given blood transfusion according to standard practice, i.e. when your haemoglobin falls. The blood will be dripped into your arm via a cannula (a fine tube inserted into a vein) during your out-patient visit. This study will examine how often you have blood transfusions and if this impacts on your quality of life, specifically your fatigue and activity levels. The researchers will not influence the decision to give you blood. This will remain the decision of the doctor looking after you.

7. What are the possible disadvantages and risks of taking part?
There are no disadvantages or risks to you directly because we do not interfere with your treatment. The only inconvenience of this study is having to be interviewed. Before agreeing to take part in the study you should check that any private medical insurance you have will not be affected by you taking part.

8. What are the possible benefits of taking part?
There are no direct benefits of this study to you. The information we get from this study may benefit future patients who have anaemia.

9. What if new information becomes available?
Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your doctor or nurse will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your treatment will continue as before. If you decide to continue in the study you will be asked to sign an updated consent form and the new information would be explained to you. Also, on receiving new information your research nurse or doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

10. What happens when the research study stops?
When you have completed the interview you will continue with routine care and attendance at the hospital as before. This means you will have blood transfusions dependent on your symptoms and haemoglobin level at each visit as before.

11. What if something goes wrong?
If you have any complaints about treatment you have received you should inform your study nurse or doctor. If there are complaints about something serious happening during or after your participation in the study you should inform your study doctor/nurse immediately. The research supervisors at <insert name of university> may also be contacted <insert supervisor names/telephone numbers>. Any transfusion reactions will be recorded and followed-up as usual practice. Your legal rights are not affected by giving your consent to take part in this study. Your right at law to claim compensation for injury where you can prove negligence is not affected. This should not affect any private medical insurance you have.

12. Will my taking part in this study be kept confidential?
Yes—all information, which is collected about you during the course of the research, will be kept strictly confidential. Any information about you, which leaves the hospital for data analysis, will have your name and address removed. A letter will be sent to inform your GP, that you are participating in this study. No-one other than the principle investigator will have access to the data. You can have a copy of the transcript at your request. The recording will be removed from the digital recorder following transcription.

13. What will happen to the results of the research study?
The results of the study when completed, will be analysed, reviewed by the study team, and published in a research journal in due course. The results will also be published as a Doctorate study at Surrey University. Neither you, nor anybody else who see the results from the study will be able to identify anyone from the study. The results of this study are likely to be available December 2008. If you would like a summary of the results when available please inform the research nurse.

14. Who is organising and funding the research?
This study is organised and funded by the <insert name of acute NHS trust>.

15. Who has reviewed the study?
This study has been reviewed and approved by the National Ethics Committee, Surrey University ethics committee and the local ethics committee of <insert acute NHS Trust>.
Contact for further information
If you need any further information or have any questions regarding the study, or your participation, please contact

Thank you for considering to take part in this study; you will be given a copy of this information leaflet and signed copy of the consent form to keep.
Appendix 9: Sample Patient Questions

1. What do you feel like when you are anaemic
2. When do you think you feel anaemic?
3. What are your sleep patterns?
4. How do you think you can tell you are anaemic?
5. Why do you think you are so tired?
6. Can you predict when you might be anaemic?
7. Do you have any concerns about having blood transfusion?
8. How do you feel once you have had a blood transfusion?
9. If there is any benefit how long does this last?
10. How are you involved in the decision to have blood?
11. How much do you know about your other blood counts and results?
12. Do the nurses and doctors ask you enough about how you are feeling-can you describe some times?
13. What do you think we could do better?
14. What do you know about blood transfusions?
If perhaps, first of all can you think back to a time when you were anaemic and tell me what it felt like?

The difficulty I have... is with the kind of chemotherapy I had. At times you couldn't tell whether you felt awful because you were low in the blood states or you felt awful because of the chemotherapy. And even when you had the blood you were obviously better because you're going about but you could still feel awful... but that was no reflection on the blood going in. Sometimes for example, about 3 or 4 weeks ago, I had blood on the Friday and I had the best weekend I had had for about 5 months. I had a good period of for three days and then I went downhill and for that one weekend I felt really brilliant and that was down to the blood.

But sometimes it didn't make you feel brilliant?

No

And were there times when it didn't have any impact at all?

I had blood yesterday, two bags and I couldn't tell the difference afterwards. But the difficulty I have here is you are on treatment... and then you are on this and that and you are lying in bed or sitting in a chair like your level is low now... but if I go back 5 weeks ago prior to all, you know, in between treatment and starting this one I can obviously feel the difference.

And so, what sort of things do you feel when you feel low? What are your main symptoms?

Tired... I don't get breathless. I just feel tired, actually I can sometimes tell when I am getting low on blood.

You can? If your haemoglobin level is low yes? How can you tell?

You start to slow down and I can remember sitting at home thinking I am beginning to feel really draggy and you come in and you go to the day unit and you say I think I am going to need blood today, and they go and check and they say yes. So you get quite a good idea when you think back to your question at the beginning, when do you feel anaemic? You use the word anaemic. I don't use the word anaemic, because I don't perceive myself as anaemic. But maybe I should. I could say yes I do need a top up.

So you would generally know that yourself and say or sometimes would it be the other way around?

It is sometimes the other way around because sometimes you just feel awful because of just the mixture of what is happening to you and you can just feel awful and in fact your bloods are all right. You know they could be 8.4 or whatever it is.

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Do you know what levels it gets to when you start to feel really washed out?

Well I think it gets about ....well it's not below 8 but it is very difficult to judge, because it is not just that. I am sure the platelets I get, infections, so it is a combination of things...but there are instances when I can say, yep I have had blood and I feel really great.

Like that weekend?

Like that weekend.

So sometimes you feel good after blood, sometimes it doesn't make an impact. What ratios is that roughly, what do you think? Out of the times that the benefits are there and not there?

Obviously the benefits are there...but sometimes I still feel bad

At a physiological level?

Yes because obviously without it I would feel worse than I did erm.. I think probably it perks me up in a sense that I can walk more upright, you know what I mean? I can trot along and you...you get used to feeling rough anyway and you usually just put that to one side...erm ratio....the thing is I can remember when I feel really, really bad and I have blood, it does me good and I can remember like that weekend when I had it and I was surprised how perky I was . and like all the other periods like I had blood last night, actually I feel quite good today but I actually felt quite good yesterday, but that may be is because I am just lying in bed, not doing anything because if I am up I am walking and straining and kind of pushing myself along .

And if you were to describe how much better it makes you feel, you know percentage wise, what would you say?

Oh sometimes I can think 200% better..but other times nothing. I was in XX hospital and I had three bags of blood, I don't know why they just did go on with the bloods. I was really feeling awful .you know I was thinking I just don't know what is going wrong with me. I had about 6 hours in blood transfusion and I perked up . yes I can really remember it.

Can you remember how low you were then?

Yes really low I was really feeling ....

And can you remember how low your haemoglobin was?

No but it must have been pretty low to have 3 pints of blood. I shouldn't say this but I think they cocked up the ordering actually

Do you think so?
Well you see XX is different from here. If you order blood you get it today. In XX if you order blood today you get it tomorrow.

All right then you have got to come back?

Because it is not an emergency I mean obviously if it was an emergency you would get it straight away. But mine wasn't an emergency. I think I just got totally out of kilter. I should have had blood earlier at that weekend.

So you can remember when it does you really good, it perks you up. It's a kind of tonic

And the times when you have felt really good about it can you remember if any significance in time or a relationship to your chemotherapy. Was it when you were recovering or immediately afterwards...do you think that is linked?

The weekend that I hadn't had any chemotherapy I was just coming up to the day unit to have blood when necessary, and I just needed to be monitored until they found another donor. The blood I had last yesterday could well be related because I don't...there is no obvious...erm no obvious ginormous pick up but I think that is related because I am having chemotherapy which I am finding very difficult to handle. So you are having other things pushed in at the side when you are feeling slightly ill and therefore your perky level actually doesn't go up, if I can put it like that.

Levels of perkiness vary?

Obviously you are better because you have had blood. You must do, but it is not noticeable. When I am away from all the chemotherapy and I have blood I can feel the difference. As soon as you start putting other influences into the mix the difference becomes less marked.

Do you think you can predict when you are anaemic or is that related to just the tiredness?

It is quite interesting because when I was coming up to the day centre during the week... I came in on a Thursday and then I didn't come in again until the Tuesday. So you actually had to worry over the weekend whether you were going to run out of platelets and whether you were going to run out of blood. So you would actually watch your results quite closely to see if you could actually predict them. Platelets were easier to predict than blood interestingly. You could say like I am sure I will need platelets, its down and you track back and you know you need platelets? Therefore I can calculate that I need them before the weekend and he would say something stupid like I should...and therefore say no..it was more difficult because you couldn't work out. There seemed to be no correlation between what was happening before and what is happening now..

So there is no pattern is there?

You could say with the... I mean within a certain period I am going to need blood anyway but within that period it was very difficult to work out. You could get the outside parameters because you know I need blood probably about one a week or
once every 8 days and sometimes you need it twice and sometimes you would go 
out like that and much to my annoyance I couldn't work out why that happened/
That's ok I think that is a recurrent theme. And do you have any worries about having 
blood, does that bother you?
No no
You don't have any concerns or thoughts about it?
No
When you make that decision or when that decision is made to have blood, you 
touched on it briefly, so you are in the clinic or the day unit. Describe that process, 
you come into the unit or you come into the clinic and what is it that, how do you get 
to the outcome that you are having blood?
You come into the clinic and they take your bloods, take it away analyse, you might 
need platelets or blood and you know that you won't get them before 3pm anyway, 
because that is the delivery time. By then because you have been sitting there, its 
getting up to 3 o'clock, then you have your bloods, unit, usually 2 and that could 
last an hour and a half maybe two hours a bag and they'll find a vein. They will put in 
a cannula in at the beginning. If they think you need blood rather than just take drugs 
they will put a cannula in at the beginning.
So is that because you have had a discussion, is it, with somebody?
Yes because I was feeling really tired today.
So you say that?
Yes they say, how are you and I say I feel really tired, I need to have some blood. So 
he puts in a cannula which is sensible then they can take the bloods. So they are 
very efficient, you know I lie on a bed or sit in a chair.
And have there been times when you have gone in and said I think I need blood and 
then it turns out you don't, or do they always do what you ask?
No no no I think what they don't want to do is to keep putting needles into you...and I 
have had a cannula put in then they have done their thing then taken it out and that 
is fine. You try and make an assessment, they make an assessment and it is all very 
fair and logical and they take it out because actually you don't need blood or 
platelets.
And is that ok. When you have come in and said you feel tired?
Yes I am quite happy with that because I might feel tired for other reasons, because 
this is the difficulty with, and that is when I was neutropenic. It is difficult because you 
can be tired anyway.
Do you think your tiredness is related to your neutropenia?

I think it must be related to blood as well, not to platelets erm I mean I suppose when one is low, I think the difficulty you have is I can operate quite a long time without feeling tired and then because I have gone through all the chemotherapy and I have gone through all the transplant thing, then back here again, you are actually quite tired. Your life is "being tired".

You live with it?

You live with it erm

Has that been cumulative?

I think it has, but if you ask me do you feel tired now, I don't feel too tired.

So it fluctuates?

Yes

So how does it feel?

I find I get tired in the evening. I am tired earlier if you know what I mean and I can have bad days, like last week I had a really bad week and I just felt tired and awful all the time. This week I actually don't feel ....I feel tired but ...

Do you sleep all right?

I doze really because I have this on my mind...lots going on I guess..

What about since your diagnosis?

Not bad but I haven't slept particularly brilliantly. I mean in hospital it doesn't really matter quite honestly because you doze during the day. At home I will get up, get dressed have breakfast and go and do something and if you are tired, you just go to bed early because what you don't want to do is just sit in a chair feeling tired, because you feel even worse.

So one of your strategies is to get up and do things?

Yes, I always get up and get dressed, eat wander around the house, sometimes go out sometimes don't. I don't like lying in bed, I can't cope with that.

And when you have blood and you say you are a bit more perkier does it help you do more?

It makes the quality of what you are doing better. That weekend, we had people in for coffee and tea. You could for a moment, you were actually having a normal life, you know you were discussing politics, you were discussing financial things with friends and talk about anything but cancer. And all of a sudden you felt this is you know, it
just makes things normal for a moment.

How sustainable is it?

It had gone by Monday afternoon

And is that something you generally find with blood transfusions...sustainability?

I think it wears off ...yes ...the difficulty is to judge that, though I have never thought about it in those terms because if you go downhill, I am not quite sure if you go downhill gently or all of a sudden you go like that then level off. Or you just feel, just "I'm feeling a little bit grotty today because I haven't got any blood, you know I need blood. You might just say I feel grotty today because you do...you don't always relate it to, I need something. You are likely to think about it when you come up to the out patients.

How do you think the doctors and nurses decide when you need blood? What do you think makes them think that you do?

Well I presume they look at your print out, which I get a copy of as well, and from that they decide whether to do it or not

Just from that lab result?

Or do you think they look at you, or talk to you?

There were two instances when I felt really tired and I needed to have blood. And there have been instances when I felt ooh I might need blood, but I didn't need blood but that didn't worry me. You know you come in and I feel tired and your blood is something like 9.8 or something and you think..oh 9.8 is all right.

And did you think that or did they think that?

They thought that. But when you see 9.7 you could see. You know people ask why and they are very good at explaining ...but if you see 9.8 you think oh that's all right. That is a level that I am sustainable at quite happily.

So what level do you want, if I was to say to you, what level do you want your blood at?

I would judge it by how I feel

Right

I mean if I walk in without seeing these results I can't say I am 9.9 today or I am whatever. I can just say I am feeling really tired and I think I will probably need blood.

So is it just a mutual agreement, how would you describe it?

No I don't think it is a mutual agreement at all. I think it is the doctors who decide.
Based on the labs?

Or based on their experience based on a whole print out and see what it looks like. I
would think that it is their decision. I have never ever said "I want blood" and they
said "no you don't J" and I said "I do!" I've always felt very comfortable with how we
work it out.

And thinking about your relationship with them, how would you describe your
relationship with the team members and is there some relationships that are different
or better or..?

I think within any team within any organisation, there are some you relate to more
quickly, more easier than others and some you find easier to talk too. They might find
it easier to talk to you because they have to form a relationship as well...so you can
see it. I mean it is quite fascinating to sit and watch as part of my job at work, but it
doesn't worry me. If I had somebody who I really didn't like, but they were good, I
would just say that they were good. I would rather have somebody who had no
bedside manners and was brilliant, than someone who had brilliant bedside manners
but was awful. I would rather go for the medicine than be brilliant and I am quite
happy with that. I mean I can accept that quite happily but that doesn't happen. But
there is a difference between people? Yes there has to be, that is the nature of the
beast.

What's good then, what's good sort of interaction, what do you think that is?

I think some people you just relate to more easier than others. I think they are all
good. I can actually say we get on with them all, but the pure nature of the beast, in
that some people you feel more relaxed with, maybe that is the wrong word erm...but
if I come in ...in the morning to the outpatients on the ground floor we don't know
exactly who we are going to see and actually I don't care who we see.

Do you think it is better to see the same person?

I don't know

How well do you know the team?

We know them all now, it is something we have talked about, wondering that, but the
feeling that I get is that it is a team effort, so by seeing everyone on the team you are
actually broadening their knowledge of you and that could well be to my advantage
and anything that comes to my advantage is fine by me.

Do you think it is anything to do with how the team functions then?

I haven't got any experience about how other teams in the hospital work. If you asked
me before I came in I would have thought I was seeing one person. Obviously not the
same person what with leave and all that. But I thought the people you see the
numbers would have been slightly narrower, but they are slightly narrower
anyway...1....2...3...4...5.......5 different we see maybe 6. So it's not a great number
erm no J (wife) and I have discussed this and wondered. We feel the advantages
outweigh the disadvantages. And they are actually all nice, they are all concerned
and in that sense I have no worries

Thinking about the nurses now, do you think, have they been involved in discussions
to give you blood do you think?

I don’t know, because when you go into the day unit, it disappears into the office and
then one of the nurses will come out and say yes you have to have blood today J. So
you don’t know who is making the decision. I assume it is the doctor.

Do you feel involved in it?

Not particularly but I don’t think it is something I need to be...its not my expertise so ..

And if, thinking about the discussions you have had with your wife and whatever is
there things you think we could do better in terms of managing your period as an out-
patient particularly I am thinking?

No I don’t think so erm ..

You said you sometimes worried over the weekend or there was a gap, you know
...will I get through to the next period when I am back or... was that an issue, or I
wonder if I can last until then ?

No I don’t think so. It is something I thought because obviously ..my wife worries
because when you are at home you can’t get it and we are actually quite a long way
from the hospital. Because last time I got an infection we had to go to X hospital and
that is the nearest hospital I can get to quickly so you are only worried about distance
so you are really trying to see if you can get everything topped up. It is just so it
means you won’t get an infection over the weekend. It is usually my platelets
because you.. I can last quite long on blood cant you. But I have been down really,
really low on platelets and you don’t want those too low because you start to bleed.
So only in that sense really I don’t spend my time worrying at home otherwise I’d be
a nervous wreck.

Is there anything else you want to ask or say?

I think since we have been here I think everyone has looked after me beautifully. Yes
if I take it as a 95% level and my biggest contact is opposite in the S ward and they
have been really good. But everywhere you go, I mean I went down for a CAT scan
yesterday and they were lovely there, I have been surprised how lovely people are.
So I think we were very lucky to come to X hospital.

Because it is not easy being a patient is it?

No it is rotten

Do you think you learn how to be a patient? Is it difficult to learn or is there a way you
have to be?
No I think you have to be yourself. I think you certainly get institutionalised by the very nature of the beast, how long I have been here, but you know the nurses don't treat you as an institutionalised person. They treat you as a human being, they are very courteous and they try really, really hard (talks about last Christmas) they went out of their way to help.

Anything else you want to say about blood?

Just that I have had alot...and I get resistant.

How do you know that?

They told me.

So you know all about antibodies and things?

Well I know because I am allergic to platelets in that I have developed antibodies because I have had so many different platelets...you know if I was to have a bad lot...when my face has gone up like a football.

Just going back to what you said..do you think the haematologists want to avoid giving you the blood or platelets..is that the sense you get?

I think quite correctly they want to give you the right medicine at the right time. They don't want to over prescribe and they don't want to under prescribe it.. they want to give you blood at the appropriate moment rather than just give you blood because you are 8.9. I think the process is thought about... it is certainly done with care. I think that everything they do they think about it, it is approached with the patients best interests at heart.

Do you think what they are doing is balancing the risks and the benefits?

Yes but I think if you are needing blood then you would get it. If I need platelets I get it, if I need blood I get it. But if there is a question...is it necessary today? Maybe there thinking is maybe we can leave can leave it for another couple of days and then over a period of time the number of transfusions you will have to have is less and therefore that must be better for him. So overall you would get slightly less transfusions. So if they were having 10 you would be having 9 therefore you have saved one transfusion which could help you and obviously blood is a resource you don't want to waste but you don't want to be too liberal with it.

And is that the sense you get?

That is the sense I get...

Anything else?

No (interview terminated)
Appendix 11: Staff Information Sheet (version 1) (on headed notepaper)

REC Number: 07/H0802/96

Principal Investigator: Liz Bishop

Introduction
You are being invited to take part in a research study, which is part of a Doctorate study being undertaken at Surrey University by the Haemato-oncology Nurse Consultant, Liz Bishop, and <insert acute NHS Trust>. Before you decide, 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 colleagues if you wish. Ask us if there is anything you do not understand or if you would like more information. Take time to decide whether or not you wish to take part. Should you decide to take part in the study, you should keep this document in a safe place in case you need to look at it again.

Thank you for reading this

1. What is the purpose of this study?
The main purpose of this study is to examine the culture and practice of assessment of cancer-related anaemia and the key elements you use when deciding to treat the anaemia with blood transfusion. There is also a patient component to this study to examine if blood transfusion has an impact on patient's quality of life and fatigue and activity levels. Following exploration of these elements it is hoped that we can determine the most appropriate strategies to ensure optimal transfusion prescribing behaviours in the treatment of cancer-related anaemia.

Blood transfusion is routinely used to correct anaemia, but it is not known how it impacts on fatigue and activity and quality of life in the outpatient setting. It is known that different clinicians/nurses make different decisions in the assessment and treatment of cancer related anaemia in spite of the presence of clinical guidelines. The reasons behind this are unclear. One way of establishing the influences on the decision to treat cancer-related anaemia is to interview a variety of grades and type of clinical staff in an attempt to discover what factors are involved. In a separate part of the study we are also observing the behaviors of clinical staff how they assess and treat anaemia because there may be other factors involved, e.g. lack of availability of beds or it may be the patient-clinician interaction is an important feature.

2. Why am I being invited to take part?
You have been invited to join this research study because you are a clinician/ nurse who cares for patients with cancer-related anaemia and are frequently involved in treating patients with blood transfusion. The aim is to interview 8-10 staff and undertake observation in six clinics (three haemato-oncology and three lung clinics).

3. Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you
decide to take part you are still free to change your mind or withdraw at any time and without giving a reason. This will not affect your post.

4. What will happen to me if I take part?
You will be interviewed by the primary investigator of the study (Liz Bishop, Nurse Consultant, Haematology). The interview will be tape-recorded. It will take place in a private office/location of your choice. The tape recording will be transcribed and subsequently analyzed by the primary investigator. Your identity will not be revealed.

5. What do I have to do?
You will be interviewed by the primary investigator. It is not clear at this stage how long this interview will be but it will be no longer than one hour. It will be very informal and there will be no fixed questions.

6. What is the procedure that is being tested?
There is no procedure as such being tested, however, it is an exploratory study examining what signs and symptoms (if any) you feel are important in diagnosing cancer-related anaemia. In addition, it is an attempt to also define what factors influence you in your decision to order a blood transfusion to correct the anaemia.

7. What are the possible disadvantages and risks of taking part?
The main disadvantage is the impact on your time.

8. What are the possible benefits of taking part?
There are no direct benefits of this study to you. The information we get from this study may benefit future patients who have anaemia and inform clinical practice.

9. What happens when the research study stops?
When you have completed the interview the recording will be transcribed. Your details will not be revealed to the transcriber as you will be assigned a unique study number. The primary investigator will analyze your transcription. The study will be reported as part of a doctorate study at Surrey University and subsequently as a published original paper. It may also be presented at Trust wide meetings or national or international conferences, however, your identity will not be revealed.

10. What if something goes wrong?
Your legal rights are not affected by giving your consent to take part in this study. Your right at law to claim compensation for injury where you can prove negligence is not affected. This should not affect any private medical insurance you have.

11. Will my taking part in this study be kept confidential?
Yes-all information, which is collected about you during the course of the research, will be kept strictly confidential. Any information about you, which leaves the hospital for data analysis, will have your name and address removed.

12. What will happen to the results of the research study?
The results of the study when completed, will be analyzed, reviewed by the study team, and published in a research journal in due course. The results will also be published as a Doctorate study at Surrey University. Neither you, nor anybody else who see the results from the study will be able to identify anyone from the study. The results of this
study are likely to be available December 2008. If you would like a summary of the results when available please inform your research nurse.

14. Who is organising and funding the research?
This study is organised and funded by the <insert acute NHS Trust>.

18. Who has reviewed the study?
This study has been reviewed and approved by the National Research Ethics Committee, Surrey University ethics committee and the local ethics committee of <insert acute NHS Trust>.

Contact for further information
If you need any further information or have any questions regarding the study, or your participation, please contact

Thank you for considering to take part in this study; you will be given a copy of this information leaflet and signed copy of the consent form to keep.
Appendix 12: Staff Consent Form (version 1) (on headed notepaper)

Date given to staff volunteer: ____________________________

Ethics protocol number: 07/H0802/96

Staff identification No: S

Principal Investigator: Liz Bishop

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Please tick box

1. I confirm that I have read and understand the information sheet dated .......... (version ......) for the above study and that I have had an opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, and my legal rights will not be affected.

3. I have been assured that strict confidentiality will be maintained.

4. I agree to participate in the above study.

5. I would / would not like to be informed of the results of this study (please delete as appropriate).

Name of staff: Date: Signature:

Name of person obtaining consent: Date: Signature:

(If different from principal investigator)

Principal investigator: Date: Signature:

(1 copy for patient, original copy for principal investigator)
Appendix 13: Sample clinician participant questions

Questions about anaemia and cancer

1. How would you define anaemia?
2. What are the main symptoms of anaemia?
3. At what level of haemoglobin do you think your patients develop symptoms of anaemia—can you give examples?
4. What are the main symptoms/signs that patients with cancer have?
5. What are the main symptoms of cancer-related anaemia—are there any differences form other types/causes of anaemia?
6. Why are your patients anaemic?
7. What do you think is the clinical course of anaemia?
8. What strategies can be used to improve a patient's anaemia?

Questions about the assessment of anaemia

1. Describe to me how you assess anaemia?
2. Can you give me examples of questions you ask patients?
3. Have you ever decided to treat the anaemia without asking the patient any questions or doing any physical assessment—if yes—can you describe?
4. What physical or objective signs/symptoms do you use in your assessment?
5. What subjective or patient reports do you use?
6. Does your assessment of anaemia change dependent on where you think the patient is on their disease or treatment pathway?
7. Who do you think should assess anaemia and what skills and knowledge do they need?
8. What do you think are the main contributing factors to a cancer patient's symptoms?
9. How can you separate the symptoms of disease/side effects of chemotherapy from symptoms due to anaemia—what techniques/strategies do you use?
10. What do you think contributes to a patient's fatigue levels—start with the most influential?

Questions about blood transfusion

1. What are the risks of blood transfusion?
2. Do you think patients are aware of the risks—if yes which ones are they most aware of?
3. What do you think is the main risk?
4. What are the benefits of blood transfusion?
5. What benefits do patients describe to you—think what they actually say?
6. What proportion of patients describe a benefit to you?
7. What do you think is a reasonable transfusion trigger?
8. What is the Trust's transfusion trigger?
9. How many units of blood do you mostly order—Why and in what situations do you use different numbers of units?
10. Do you ever order single unit transfusions—If yes—when and why?
11. Do you think single unit transfusion would be good—describe pros and cons?
12. How much is a unit of blood?
13. Do you ever consider the cost of the transfusion?
14. Do you ever consider the resources required—does this influence your decision to treat—if yes—can you describe?
15. How would you like to treat a patient with anaemia—e.g., more blood transfusion

Questions about attitudes towards anaemia and blood transfusion

1. Do you ever feel any pressure to treat a patient's anaemia?
2. Do patients ever request a blood transfusion?
3. Can you think of situations when a patient has received a blood transfusion because they wanted it but you would have withheld blood transfusion?
4. Do you think patients see blood as an expensive or scarce resource—describe?
5. Do you think staff see blood as an expensive or scarce resource—describe?
6. Have you observed any changes in the treatment of anaemia with blood transfusion over the years?
7. Who do you think should request blood transfusion—e.g., any doctor, level of doctor, experience etc
Appendix 14: Sample of clinician interview transcription data

1. **PI** So how would you define anaemia in one of your patients?

2. **SL1** I think there are different definitions of anaemia... em...I think with a ..if I'm honest..I don't separate particularly for males and females so I would say a haemoglobin of less than 10g/dl is anaemic or is anaemic as far as I am concerned although that on its own would not be my trigger for transfusion...clearly there are laboratory definitions of anaemia with laboratory normal variables.. em..I think treating solid tumour oncology patients..many of whom are receiving cytotoxic chemotherapy.. em... I guess practically speaking because the vast majority of them have a haemoglobin lower than the lower limit of normal on laboratory variables that in itself is not sufficient for me in my head to determine them as being anaemic...so.. but if they have a haemoglobin of less than 10g/dl I would refer to them as anaemic but I would not necessarily treat them for that.

3. **PI** How would you explain that to a patient?

4. **SL1** Em...I will say your blood tests show you are mildly anaemic and that's probably partly because of your cancer and partly because of the treatment we are giving you but its only very mild and we don't need to do anything about it now..having said that whatever somebody's haemoglobin is I would look back at the first haemoglobin we have recorded for them for example before we have given them chemotherapy or if we are giving them chemotherapy..em... or the earliest date which I have known them so I have some idea of what the change has been for that person over their disease course ..I mean obviously if they have been a long standing patient for many years I might look back at their haemoglobin 6 months or a year ago..so I can see whether I think that represents a change or if it has been a dramatic change or a recent change..em..and em..if somebody is anaemic in my mind then I will also ask them.. I would normally say ...are you any more tired than normal..are you any more breathless than normal and if I think they might be then I would perhaps go into some more detail about that to try to determine if they had a symptomatic anaemia as opposed to symptoms of their disease....and of course symptoms of disease can be very much overlapping with symptoms of anaemia..say if somebody to my mind..em..has a haemoglobin of say 9.8g/dl I would probably tell them that they were mildly anaemic and that we would keep an eye on that and ask them about symptoms that could develop that we didn't necessarily need to do anything about that now other than watch it...em...I suppose remembering that most of my patients will be returning to clinic at least every three weeks so we have ample opportunity to watch that..to look at that and watch it.

5. **PI** What sort of things do patients tell you about their symptoms and how can you separate that out?

6. **SL1** Em..It's..there are differences depending on which disease type I am treating..and I treat alot of lung cancer where its very difficult because lung cancer patients do get breathless because of their disease and often because of other co-morbidities they have associated with their malignancy....such as chronic airways disease and...
sometimes they have a degree of cardiac disease as well. Having said that in some ways in a lung cancer patient if their breathlessness is a significant feature and they almost have a lower threshold...even though I know that anaemia may not be the sole or maybe even the most important reason for their breathlessness and their breathlessness often to my mind...their breathlessness is multifactorial in aetiology I would almost perhaps have a lower threshold for transfusing such a patient because if it happens to help they can be patients who symptomatically can be very difficult to treat...so what I would...What I would say...I haven't quite answered your question yet...I will do that in a minute...what I would say to a patient is...If I do feel we need to intervene with a blood transfusion...then I would say to the patient it may help your breathlessness...this may help with your tiredness and fatigue...but it may not and I'll need you to monitor and think yourself...three days after the transfusion, a week after the transfusion, ten days after the transfusion...is my breathlessness any different than normal...is my tiredness any different than normal...to try and decide whether anaemia was the cause of their symptoms and whether transfusion actually alleviated them or whether it didn't...because otherwise in the lung cancer population you could be transfusing repeatedly and regularly without actually any symptomatic gain on behalf of the patient because actually the anaemia is not the reason that they are feeling unwell.

In terms of what patients say to me...if you ask most patients are you tired...the answers yes because they've got cancer and maybe because they're anaemic...so I am sure if I was to ask most of the non-anaemic patients if they are tired...the answers yes...if you say are you a little bit anaemic...are you tired...are you breathless...usually the answer is yes...I am a bit tired...but often you can...sometimes you can tie it to what's happened to the haemoglobin over time...and see in fact they've been tired for ages and they've only become anaemic since you started chemotherapy and they are no more tired than before...so that's not the anaemia...sometimes you don't know...quite often you have a patient with a malignancy who is or not having chemotherapy who is anaemic and if you ask them directly...is a bit tired...sometimes feels a bit breathless...and it can be very difficult to determine whether anaemia is one of or the cause for that.

Do you think patients expect transfusions and do you ever feel any pressure to give a blood transfusion?

I think patients...there are patients who expect treatment...whatever that may be but there are also patients who...particularly if they haven't had transfusions in the past...are quite scared of transfusion so they are not necessarily looking for you to transfuse them...some are and some are not and some are looking for an intervention and they talk about iron tablets...and so...will iron tablets they make me feel better but we don't usually give them iron tablets.

Do you routinely check for other causes of anaemia?

Iron, transferrin...no we don't...so clearly you don't know whether someone has an iron deficiency anaemia or whether...most typically...obviously we do have a full blood count profile we can see whether it is normocytic anaemia or whether it is normochromic anaemia and most frequently it is and it's not a sudden drop in.
haemoglobin with an iron deficiency picture...em.. and certainly if I was going to give somebody an iron supplementation I would want to check a ferritin level but just because somebody is anaemic...no I don't typically check their ferritin routinely...but I also don't give them iron-no I don't ever...I don't think I ever do...and not in the patient cohort I treat currently anyway-I don't treat them with iron- at all.

PI If you can describe the patients who do get benefit and those who don't—is there anything distinguishable between them?

SL1 I would say some patients who are more profoundly anaemic feel better...usually get some benefit...it is less obvious and predictable...so if someone has a haemoglobin level of 6/7 per decilitre I think they universally feel pretty shocking...em... and usually feel better because most of my patients are not actually bleeding...em... and although I rarely see patients with anaemia that profound, when I do and it usually a disease related phenomenon, I think they almost universally feel terrible and blood transfusion does make them feel better, whereas if someone has a haemoglobin between 9 and 10 grammes per decilitre, I rarely transfuse, I'm not saying never but I rarely transfuse these people. Or if you do have a haemoglobin between 8 and 9 I do think there are some patients who... I know there are patients who feel very little difference having had a blood transfusion and I personally don't find I can predict who they are.

PI But say if somebody has had a haemoglobin of between 8 which is our guideline and you have transfused them because they are giving you a report and they don't have a significant benefit would you automatically stop transfusing them?

SL1 I think our response to that...em...my response and I think myself as part of a team, our response to that is...em...is not ideal and is not robust...because what I know is that there is...I guess in clinical practice what will happen is I might tell someone that I am going to arrange a blood transfusion and see what happens in terms of their symptoms but actually the way actually the way that our clinics are set up if what we rarely I may not see them next or I may see somebody that someone else has transfused and so...em...I rarely will see them next time in fact so there is not very good continuity in assessment of response to blood transfusions I think something in which we should and could improve but we don't robustly assess response so although if I am going to give someone a blood transfusion or considering ordering a blood transfusion to someone who has previously been transfused I will ask them if it helped last time...em...I don't robustly...we have no robust mechanism of assessing response of a transfusion which means that there is a risk and I am sure it happens that people do get repeat transfusions who are not necessarily benefiting from them.

PI Could you argue that that might impact on you how you assess anaemia in the first place?

SL1 Yes it does because...

PI You've not been able to see a change in time?

SL1 Eh...yes...there is that and also I do think that I am aware, now that I work more closely with haematologists that the process most haematologists go through...
they transfuse is quite different than the process that I think a lot of oncologists go through in that...em..if the haem...what I grew up with is the haemoglobin is less than 10g think about transfusing them if the haemoglobin is less than 10g they are having chemotherapy they definitely should have a transfusion without...and that was that...that was that without any additional consideration of what was how chronic was the anaemia what was the patients symptoms, would they benefit erm and although my approach to that has changed over time that is certainly the approach I started with pretty much everyone with a haemoglobin of less than 10 grammes should have a conversation about blood transfusion and if they were on chemotherapy they definitely needed the blood transfusion with a haemoglobin of that level.

PI Is that for all solid tumours or just lung cancers
SL1 That was all solid tumours, now
PI Do you think that is still the case for juniors...doctors
SL1 I think...em...I think it can be the case for some definitely and I think it is also the case for...I think it is I don’t know whether it is in protocols actually or I don’t know any protocols where it is written but...em...pharmacy and chemotherapy nursing where a lot of them come back saying "don’t we need to transfuse them first, the haemoglobin is 9.8 and so what I suspect happens is...my response to that is, if I have an oncology pharmacist or senior oncology chemotherapy nurse coming to me with that request, my response to that as junior registrar would have been ,they are telling me they need a blood transfusion ,somebody who has been doing this job for years is telling me that this person needs a blood transfusion, they probably do so I will just prescribe it. whereas now I might challenge that I would not have challenged that 6, 7 or 8 years ago so I know myself it is not a conversation that I have had with any of the registrars and so I have to say I don’t know what my response would be but I suspect it would be, like mine, initially you would do it and then maybe over time you sort of work out that not everybody needs a blood transfusion

PI Why do you think that that is the case?
SL1 Why do I think that not everybody need it?
PI No why do you think that it is different in oncology than haematology?
SL1 We have no transfusion teaching, we have a lot of anaemic patients we have a lot of patients who’s treatment makes them anaemic
PI But you could argue that haematology does as well
SL1 Yeh ...I know to a greater extent...absolutely, but...em...but transfusion medicine is a branch of haematology it is where I think haematologists know more about transfusion medicine than oncologists and therefore know more about actually know more about the risks and resource limitations and the appropriateness of selecting for blood transfusion. Oncologists use a lot of blood but have no training in when to transfuse, when not and why not, and yet I bet most of our registrars don’t have a
single day of the week without transfusing a patient, you know I bet most of our
registrars prescribe blood every day of the week at least once if not more than once
and so I think a lot of oncologists use a lot of blood but have no training in it …and
there has been, I suppose to be fair there are situations in oncology for example in
radiotherapy brain cell cancers where there is evidence that maintaining an adequate
haemoglobin helps tissue oxygenation and therefore improves delivery of treatment
and therefore improves outcome and …em… anecdotally I saw someone today who
was going to have their next cycle of chemotherapy and their haemoglobin was 9.7.
He obviously wasn't particularly symptomatic from it…em… I told him he was mildly
anaemic but I wasn't going to do anything about it…we will just keep an eye on it and
if it got much worse or we got a lot of symptoms he might need a blood transfusion
later but nothing to worry about now, it is a normal part of cancer and cancer
treatment. He then went off to see the radiotherapists who says we are going to give
him radical radiotherapy he can't have a haemoglobin level of 9.7 we better get that
up by giving him 2 litres of blood. Try and get his haemoglobin to 12, and of
course…em… there is evidence now in a number of cancers now that outcome is
better if you maintain the haemoglobin level around 12 grammes per decilitre
throughout treatment particularly with squamous cell cancers. I think that is fine I
think that is a research driven rational for transfusion which I think..

PI As opposed to a …?

SL1 Well… up until a couple of weeks ago or ten days ago then you would say there is
good evidence to use to use erythropoietin to maintain haemoglobin in those
circumstances and …em..with clinical benefit but now in the last week to ten days you
can say erythropoietin might be harmful..em and may impair survival outcome from
malignancy so I think the jury is still out on erythropoietin and ESA's…em… but I think
that blood transfusion in order to maintain haemoglobin at a given level because
research has showed that treatment is more likely to be successful in cancers it is
going to be better to maintain a haemoglobin. I think in that situation clearly you may
want to discuss costs and resources and like you do with any new drug intervention
where needs improve survival but at least that has a rational behind it whereas I
know myself and I really do think throughout a lot of oncology that the rational for
prescribing a blood transfusion is that the haemoglobin is a bit low on paper
and…em… you know and there is a wide held belief that the trigger is less than ten… I
think that is a wide held belief.

PI What about the impact on clinical guidelines?

SL1 Minimal

PI Why do you think that?

SL1 Because people don't read them or don't realise that they are there and they have
entrenched practice and so they work according to their habit and entrenched
practice and unless a new guideline or new rational is widely, well not widely
publicised but repeatedly told so someone is aware of it I don't think that will lead to a
change of practice I think maybe if a new guideline is emailed to everybody and
everyone is told it is available on the intranet these are the guidelines
Oh course you could argue that every hospital has transfusion guidelines as we do and with that we all do mandatory training so our guidelines are currently or is it because they are not evidence based or is there any other reasons why?

I am assuming that they are evidence based I don't know that they are not. I suppose I am aware of the guidelines because I go to mandatory training...but actually mandatory training which you can rattle off in ten minutes on line doesn't...doesn't really address what you do now and is that correct and how could it be different and...er...its better than nothing but I have to be honest my main recollection of mandatory training was about labelling the bottles correctly and storing them in the right place and getting the blood from the right place as opposed to when to transfuse and why.

Going back to the culture of the clinic and the assessment of anaemia in clinic, do you think there is things that could be changed or improved that might make you think...

Yes I do. I think that we could...if I talk about the non lung cancer patients as opposed to...I think actually it would not be difficult to have a basic anaemia symptoms of anaemia assessment that maybe you had yourself, maybe you even give it to the patient and ask them to monitor symptomatic response, which of these symptoms do you have, comment 48 hours...5 days a week, 10 days...I don’t know I don’t think it would be that hard to do because we are all used to assessing toxicity from and clinical benefit from chemotherapy so we give a clinical, we give a therapeutic intervention, we see the patient a couple of weeks later and we assess the benefit they have had from that both clinically and also the toxicity they have had from that but yet we don’t do that with blood transfusions and actually it wouldn’t be difficult to do....you’d have a set list of possible symptoms that someone might get from anaemia and assess the clinical benefit from that and document in that in a robust and rigorous way....if there is a paper proforma trigger these are the questions, this is the date of the transfusion, what is the assessment, then you might actually look at this and use it as a tool I can quite easily imagine tools that might help I think lung cancer patients that is needed but what is a also needed for lung cancer patients is a more robust assessment of breathlessness as a whole...em... when lung cancer patients are breathless a segment of anaemia comes in to what is required but it is not the whole thing. I think it would be easy to do but I think it could be...I guess what it comes down to is that most of our clinics are very busy and who gets a blood transfusion and who doesn’t is not something that is necessarily discussed with the consultant...whereas any chemotherapy change has to be discussed with the consultant we don’t mandate that for blood transfusions...and so therefore I guess the message that gives out is that this is a less important decision and so therefore the registrars or clinical fellows don’t feel that they have to come and talk to us about it they will make the decision and because they are not talking to us about it and because we are not talking to them we are probably not educating on the job about blood transfusion and I say that in as far as an oncology consultant can educate about blood transfusion but I expect most of us have learnt some thing about over the time and what I have said to you is that my use of blood has changed over the years that I have been in oncology and it has reduced...em...in that I am less likely to transfuse now than I was before but actually I rarely have that conversation with my juniors.
Do you think it is seen as not important then?
I think it is seen as less dangerous than chemotherapy, and...yes I think it is seen as less dangerous than chemotherapy so although talking now I am thinking we can and probably do transfuse people who don't need to have it or who maybe don't need to have a transfusion, the consequences of that seem potentially less catastrophic than giving the wrong chemo or the wrong chemo dosage to the wrong person, and I am not taking it lightly...but I guess we, on the wards allow SHO's to decide who needs a transfusion and not where we have never let a SHO decide who gets chemotherapy or not...I think a lot of the transfusing happens without even my knowing i.e. I see a patient I don't have their blood results with me...the blood results are not back when I see the patient so...they go on a list to be checked later and that never comes back to the consultant, that goes from the clinic nurse/chemotherapy nurse directly to the clinical registrar who decides whether to transfuse or not

Oh I didn't know that

And so I will sometimes know that the patient I see is anaemic but I maybe won't even know that and some of that will go direct to the registrar

Going back to the assessor you mentioned males and females and that you didn't think that you looked at that particular area are there any other....

Ok that's fine in terms of skills and knowledge...I think that the person who is making the decision first of all needs to understand what are the potential causes of anaemia and not to assume in outpatient care cohort that it is all because they have got cancer and make sure that they have not had an acute drop in haemoglobin, that they are not bleeding so we need to know what the causes are of anaemia and how to assess for acute changes in haemoglobin and symptoms and signs of blood loss.

They need to have an understanding of what is likely to happen to that patient in the future with or without a blood transfusion in terms of cancelling their treatment because that may impact on the appropriateness of transfusion or not and I think you should always have an understanding that blood is a limited resource and not everyone with low haemoglobin needs to have a blood transfusion so I think we should have some understanding of the symptoms of anaemia are and actually have a written assessment and documentation of what those are so that if...so that when so that there is the possibility of assessing whether or not that the patient has symptomatic benefit from it. Although before I had any mandatory training...
last did mandatory training it's the first training in blood transfusion that I recollect although it can't actually be the first training I've ever had in blood transfusion but I don't remember ever having had any other, but of course people need to understand the risks of blood transfusion but you wouldn't prescribe any other treatment without considering the side effects of that treatment might be or what the risks might be.

PI You'd look up the BNF to see what the risks are

SL1 Yes you would

PI But do you think junior doctors could rattle off all the risks of transfusion?

SL1 Probably not I doubt it

PI And what the risks are?

SL1 I don't think they'd be able to do that with any precision...I am not sure I can do that with precision...em...I think they would be able to, I think they would understand that the reasons for needing, to provide matched blood..em..to match blood and I think they would know... maybe an infection risk. I would assume they would know that blood donors are screened..em..I don't know exactly.

PI Do you think they would know about the other things like TRALI?

SL1 No... no, I don't because I don't know if it forms a regular part of general education particularly.

PI Just going back, so ideally in an ideal world somebody would have all that knowledge, but going back to your clinic, what you are describing to me is that actually the person who makes that ultimate decision might not have even seen that patient.

SL1 Yes that's true, I think that probably is the case......

PI In some of the cases you don't have the blood results that the chemo nurse goes back and asks the Reg..?

SL1 Yep em if the doctor that saw the patient is around ,if the consultant is around they will come back to the person that saw the patient, otherwise they may not and they may go to the Reg and...I'm trying to think when I was that Reg, and if somebody came to me em....then.. I don't know, its sounds too horrific for words...I'm trying to imagine if it could possibly happen....that the person who prescribes the blood never sets eyes on the patient..em..I think that does happen....I think it does.

PI Going back to what you described blood as a limited resource..what do you mean by that?

SL1 I suppose what I mean by that is..em.... Well that blood is available through donation, and whilst there maybe blood banks but actually it is possible for them to run out of blood..em..you know blood is not manufactured in pharmacy....or you
know by some pharma company it's a donated product, and although there are a lot of donors and there is and... er... there is actually... hospital units only have a certain amount of blood in store and the country has a certain amount of blood available and if it's overused there is a possibility for resources to become more limited or stretched or for the blood to run out completely, so that is what I mean that it's....

Do you think people think about that when prescribing blood or do they think about it in the same way as you might think about an expensive drug?

I don't know, I think it is... I do know that for example when I was a surgical house officer and you have to cross match blood and it is your responsibility to match sure blood is cross matched for patient X before they turn up for their operation and is it a group and save? Do you cross match and how many units do you cross match? I really remember then being made aware not to over cross match all the patients who were going for surgery because it wasn't necessary and because blood was limited and it was a waste for example you would never cross match 8 units for everybody..em..you wouldn't cross match blood for some people at all and so I was definitely aware that as a surgical trainee that blood was limited and that has stayed with me a bit...em.. in oncology if I think, why do I sometimes not transfuse people?

So I have got someone who's haemoglobin is 8.9 and they are a bit under the weather, why do I not transfuse them? Is it because that is not the policy, is it because the blood scarce and that is the policy, or is it because the risks outweigh the potential benefits? I don't think in my mind. I think it is because I am not convinced they need it but I...so I do think that is one reason why I sometimes don't transfuse people, I think you shouldn't transfuse everybody and they don't all need it anyway and but I don't often think, but if someone has a haemoglobin between 8 and 9 I actually don't believe that the risks outweigh the benefits. Now there may be very good medical evidence to tell me that I am wrong but I don't believe the risks outweigh the benefits...em.. and I think the reason I think that is because when I do transfuse people at that level some of them feel better and I rarely don't, ...I don't see people being worse and it maybe that the side effects are rare, but if they are and they get them they can be severe I suppose. But I rarely see people having or knowing that they have had a transfusion reaction with a fever or a rigor but that has been self-limited so I rarely see people having seriously sequelae from having a blood transfusion...almost never... so I suppose in my mind...so therefore I am saying ..I don't not transfuse because of the risk even though I know there can be side effects from risks of transfusion I don't think it is that that stops me...I think the thing that stops me is either I know from that patient from past experience that they are unlikely to get clinical benefit or that I am not convinced that they will get clinical benefit at this stage and they don't meet the guidelines anyway...em.. and built into that there maybe something about resource and the fact that the resource is scarce and I don't want to overuse blood for people who I am not convinced are particularly symptomatic from their anaemia and therefore I think in my mind I wouldn't waste blood on someone who I wasn't convinced was symptomatic so that would be an issue more than the risk I think.

And do you have any thoughts about two unit transfusions

Yes I do my view on two unit transfusions are that....obviously we give two unit
transfusions far more often than any other amount for I have no idea what reason. I
do know and this is historic when I was a medical SHO both general medical and in
oncology which I was in the same place we were told that we should never give a
one unit transfusion to anybody ever because there was never an indication for that
...people needed two or three units or they didn't need it at all...em...and most people
could get away with two because they would feel better enough with two so that was
good amount to give. I remember once wanting to give somebody one unit of
blood and I may have been wrong but the rational had all packed out. The team
rational was, it was a patient who's cardiac failure was very severe but they were
anaemic and we wanted them to have more than one unit of blood but we wanted to
give it very slowly so that we knew that overnight we probably wouldn't give them
more than one unit and we might give a bit more after a bit of time and probably no
evidence for that either but we were told that unless we were giving him more and
more quickly he shouldn't be having blood at all. So that is the teaching I had as a
junior, was there was never any indication for a single unit transfusion. Everybody
was given two units or more and most people felt better with two, so start with two
and see what happened...em...I don't know whether other people had other specific
teaching but I do know that we managed to give two units transfusions. I do
sometimes give 3 units, I only give more than 3 if someone's haemoglobin is 5 say or
less than 5

And why three sometimes?

Erm...erm I guess if someone's haemoglobin is between 6 and 7 I'd probably
prescribe three units, I don't know why I would. Two units wouldn't feel like quite
enough. Desperately unscientific.

Going back to the benefits what do patients describe to you and ...

Some patients are very clear, it was like Lazarus I was resurrected it was amazing, I
felt so much better, everyone told me I looked better. I had so much more colour in
my cheeks...and the partner is sitting there and said they looked so much better it
was brilliant it was a miracle miracle...em...very quickly within a few hours I was a
new man. New woman it was fantastic...em...and sometimes you'd say how did you
feel afterwards? and they'd say dunno really. much the same really or are you
breathless? Yes and it is clear it hasn't made a very big difference. I would say
myself its only probably within the last 18 months- 2 years that I am rigorous about
asking those questions if I know somebody has had a blood transfusion and then
documenting those responses...em... and it is really quite a recent thing, you know
relatively recent thing that I have been rigorous about doing that...em...but yes some
patients I think benefit really well and sometimes people don't and I think at the
moment I cannot predict necessarily in advance who that patient is going to be

And in hindsight can you think....

I sometimes wonder whether ....erm...sometimes in hindsight ok. I mean it might be
different because we are looking at different patient groups for me I would say
sometimes in hindsight they have got terrible CPD and that was going to be such a
large component of their breathlessness that I was never going to make that better
by giving them two units of blood which more often than not would be exactly what
they have had...and two units of blood was not going to take away 60 years of smoking and dreadful emphysema...em..you know.. in some of those patients it does make an incremental difference and it makes there multi factorial breathlessness more manageable

Do you ever think about where they are in their treatment or disease pathway?

Yes I do I was about to say

Or in relation to their cycles of chemotherapy

Err yes..em.. in terms of where they are ...I think that somebody who is symptomatically anaemic with limited season early in their chemotherapy actually is more likely to feel better because the reasons that they are tired and/or breathless are more limited and anaemia is more likely to be a large part of that or a major part of that. Where as some of my patients who are very near to the end of their disease or to the end of their life particularly if ...I think the impact is actually less particularly..if they are only moderately anaemic as opposed to profoundly anaemic I think the people who are profoundly anaemic which for me is few and far betwen .Profoundly anaemic I think it usually does makes some degree of difference. And people who have very advanced disease erm again every symptom of which anaemia is a part is then again multi factorily caused and so I think treating the anaemia is never a miracle or is rarely miraculous

And do you then consciously decide to not transfuse or is that a difficult decision in oncology?

Em...rarely unless somebody is truly terminal or pre terminal so in the very last week or couple of weeks of life but I think of someone in the last three months of life I don't think that on its own would stop me from transfusing I don't know, and I guess it then becomes a balance actually... hmm I think we do quite often say to people, I don't know that we are right. ..for example if we decide that they are not having any more active chemotherapy treatment and so the treatment is supportive care and palliative care measures but we can still do other things such as painkillers and blood transfusion as though it is some kind of panacea you know " don't worry your not having chemo but you can still have blood " and it feels like a sort of...an intervention and I think we sell it to the patients as such a bit ,without necessarily always having much fore thought about whether it will help . and I suppose I wouldn't want to....again I mind be wrong and it may be a lack of knowledge on my part but I am not sure I would want to just decide that patients can have blood transfusions because hopefully I have the knowledge and evidence that it might not palliate them, but again it does come down to .If you do transfuse someone in an attempt to palliate symptoms we ought to be much more robust at assessing a response to that palliative intervention and therefore making a decision whether it is worth repeating in the future or not, and I really don't think we do that

What do you think could improve the treatment of anaemia?
I think what could improve the treatment of anaemia in oncology, is actually erm I am quite sad I won't be there when you come into the clinic. I suppose you are there to observe but I would quite like to have you there to teach almost and to challenge, and to say "are you sure you're going to give this blood transfusion and why" and I think it would improve treatment of anaemia if we did have a .. if we.. all of us in oncology could stand a bit of education from a blood transfusion physician or a haematologist or someone who knows more about it than we do and to let us know how you would approach this in haematology and I guess maybe a lymphoma haematologist or somebody who is not too many miles away from what we do but also knows about transfusion medicine as well and to actually learn that approach or to have someone challenge us and say "but why are you transfusing this person that's against the guidelines" nobody ever challenges us. If any of us prescribes a blood transfusion we are never told that contravenes guidelines ever....em..or at least I never have been...so I think it is ....and I doubt...so...

What sort of information would you want because....?

I'd want...first of all I would want to know is what somebody who knows more about transfusion medicine than I do would do in the same situation. What would they do .. I suppose what I would want to know is what questions do you ask when you are deciding whether to transfuse and how do you monitor response to that and what are your triggers for someone who is anaemic who is on chemo or not on chemo and are those different from each other and does the fact they are on chemotherapy make a difference to the decision to transfuse? And should it or should it not and why or why not? Em.. and what would be the frequency of repeat? I don't know...how would you assess responses is it symptoms alone or is it other laboratory measures or....?

What do you think our differences are the ?

My impression is probably that you transfuse less than we do. At the same level i think the threshold for a haematologist to transfuse is think they would have a higher threshold to transfuse so ie they wouldn't transfuse for all indications that we do...that is what I think is the difference. But I rarely ...rarely spend this much time thinking about it, so in clinic I ask them a few questions very quickly and I'll decide whether to transfuse or not..and I might say to them have you had a transfusion before, and also did it help?

What do you think about educating patients?

Going back to something we said ages ago. You asked whether patients expect a blood transfusion if I tell them they are anaemic I do try and educate patients at that point where I consider education to tell them that they don't necessarily need a transfusion or they don't necessarily need intervention right now. I mean I guess patients need to know what. I also wouldn't like to think that somebody has been struggling at home for weeks on end and is clearly profoundly anaemic and very symptomatic and we didn't know about it and we could have made them better very simply or made them feel better simply with a transfusion if we had known, I think patients need educated in both ways... this is what to look out for and we might need to check your blood count but not everyone with anaemia needs a transfusion all the time. I guess they don't need to know they need a blood transfusion every time.
And what if you had more access to EPO?

Again if we disregard the latest concerning data that EPO may lead to worse to malignancy outcomes possibly...if we disregard that completely..em...if we had more access to EPO I would have used it ...to maintain haemoglobin in patients having undergoing cancer treatment on the basis that there is some evidence that doing that leads to improved cancer outcome...and the other reason that I would use it if I had access to it I mean clearly there are side effects of EPO and if someone does get pure red cell aplasia...then that is a dreadful thing and they become life long transfusion dependant and so that is a very significant risk and catastrophic for the person if it does happen. Clearly it is not common but if it does happen it is catastrophic. Having said that for most patients and chemotherapy units EPO injections are far simpler and quicker than blood transfusions...so Yes.

Is there anything else you wish to add? Are there any burning issues?

No...I don't think so...I can't think of any. Is that OK?
Appendix 15: Request to observe clinic (version 1) (on headed notepaper)

<Insert Consultant details>

<Insert Date>

Dear Dr ..............,

Re: Research study
REC Number: 07/H0802/96
Principal Investigator: Liz Bishop

There are several phases to the above research study. One of the phases is to undertake ethnographic observation study in six cancer clinics (3 lung cancer; 3 haemato-oncology clinic) to identify the key elements, which clinicians and patients use to assess and treat cancer-related anaemia and explore the culture of transfusion practice. Both the observation and field notes will be undertaken by myself. Please see the attached fieldwork data collection sheet. No staff or patients will be identifiable on completion of the study and all data will be anonymised. If you agree to this you will be contacted via e-mail to confirm the date of the proposed observation and which of us will be attending your clinic. Results of this study will be made available to you at your request.

Thank you for consideration in participating in this study. Please do not hesitate to contact me should you require more information.

Yours sincerely,
Appendix 16: Field note data collection sheet (version 1)

<table>
<thead>
<tr>
<th>Date:</th>
<th>Time clinic starts</th>
<th>Time clinic finishes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of clinic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time clinic finishes</td>
<td>Number of clinic rooms</td>
<td></td>
</tr>
<tr>
<td>Doctors present (including grade)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses present (Including grade)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others present</td>
<td>Number of patients</td>
<td></td>
</tr>
<tr>
<td>Hb results of all patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultation times recorded and grade of staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Details of anaemic patients (Hb &lt;8g/dl)</td>
<td>Patient 1</td>
<td></td>
</tr>
<tr>
<td>Patient 2</td>
<td></td>
<td></td>
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<td>Patient 3</td>
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<td>Patient 4</td>
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<td>Patient 5</td>
<td></td>
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<tr>
<td>Details of how patients are booked for Tx</td>
<td>Patient 1</td>
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<td>Patient 2</td>
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<td>Patient 3</td>
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<td>Patient 4</td>
<td></td>
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<tr>
<td>Patient 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Field notes: (Codes: P=patient; D=Doctor; N=Nurse; C=Clerk)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 17: Haemato-oncology Out-patient Department
Oncology outpatient clinic department

Oncology OPD

- Nurse Station
- Photocopy
- Treatment Room
- Staff Changing
- Staff VVC
- Staff room

Reception

- Doctor's room

- Antenatal Care Admin

- Patient VVC
- Child room
- Nurse Station
- Clinic Rm 15
- Clinic Rm 16
- Clinic Rm 17
- Clinic Rm 18
- Clinic Rm 11
- Clinic Rm 10
- Clinic Rm 9

Cupboard storage

- Clinic Rm 1
- Clinic Rm 2
- Clinic Rm 3
- Clinic Rm 4
- Clinic Rm 5
- Clinic Rm 6
- Clinic Rm 7
Appendix 18: Sample of observation fieldwork data

3 clinics running concurrently
- Lung clinic (7 rooms)
- Palliative care clinic (1 room)
- Radiotherapy clinic (2 rooms)

Other clinics (round the corner but shared waiting room and phlebotomy)
- Anticoagulant clinic
- Chest clinic

11 doctors in clinic
- 3 Lung Consultants (2 first day for one of them—one only there for half the clinic)
- 1 PC Consultant
- 1 RT Consultant
- 7 SpR's

Medical Staff for lung clinic
3 Consultants
4 SpR's

Nurses
- 1 staff nurse (to run the clinic)
- 2 HCA (to assist with running the clinic)
- 2 Lung CNS
- 2 Lung research nurses
- 1 RT Nurse

Admin staff (at reception)
- 2 clerks (Lung/PC/RT clinic)
- 1 clerk (Anticoag clinic)

Cancer Information Centre
1 information officer

Patient Numbers Booked
- 9 patients RT (radiotherapy) clinic
- 8 patients PC (palliative care) clinic
- 37 patients for Lung Clinic
I arrive in the clinic at 0945. The clinic is due to start at 0950.
There are windows in the waiting room

The waiting room is already ¾ full-a mixture of patients for the anticoagulant clinic and the lung clinic. There is a lot of noise. It is a mixed population; ethnically diverse and ages vary but first impression is an elderly population. There are 3 patients in the doorway in the big hospital wheelchairs which are bulky and taking up a lot of space in the entrance towards the clinic rooms
There is a ? confused/demented lady talking loudly to herself near the desk
The Cancer Information Office door is open but there is no-one there

Three clinic clerks are sitting at the desk

I go into the communal room
"Poor D" is there-he is the first doctor in clinic. I had been introduced to him when I had a previous visit to the clinic as "Poor D". He is a Medical Oncologist SpR. I said good morning. He said the other doctors were still in the MDT. He said he had seen the first patient already...another SpR came in. He started talking to her about a patient who had not been prescribed GCSF and had become unwell-she should have had GCSF. He asks her "shall we do an audit-it would be good..bet there are lots of patients".

SN comes in and interrupts them-"can one of you see this patient (she is holding the notes)..she is not very well..can she be seen by a doctor soon?" She hands the notes the female SpR and walks out.

The RT nurse is on the phone talking loudly about a patient-describing her symptoms. One of the lung CNS’s comes in with a set of casenotes, picks up the phone and dials someone and starts speaking about a patient. One of the research nurses comes in and sits at one of the PC’s and logs onto the EPR and looks up blood results. The CNS and the Lung RN do not speak-everyone is busy-there is no time for pleasantries-everyone is busy with their problems.

Another SpR comes in "i haven't a hope in hell"..she is talking about finding a clinic room. What is more important is finding a room with a computer that is working
The Consultants walk in....he introduces the new Consultant and then she is escorted to a room. There is also a visiting doctor with the senior Consultant. The senior Consultant sees me and starts complaining about the room with the broken computer.."the computer department need to come and apologise to the patients".
There are other discussions going on "lets see if there is a room here..is Dr X in there?.no good..come on let's go and have a look"

I walk out into the corridor-it is narrow and winding and the scales and height measurement device is in the corridor. Patients and family members are milling about. Some are being escorted to Consulting Rooms-others are being weighed.
One of the doctors is asking a patient in the corridor "Did you get your letter?"

I walk into the waiting room-it is now full and some people are standing-I do a head count-there is now 77 people waiting. The confused noisy patient has gone-there
are still 2 wheelchairs. Some are waiting at the desk-someone is asking the clinic clerk about congestion charges. A doctor comes out into the waiting room and shouts a patient's name. A patient with four family members stand up and follow the doctor towards the consulting rooms. I overhear a person saying "I've not seen it so busy here. Standing room only. I only came up for a blood test." I leave the waiting room and go back down the corridor. I can overhear conversations "not even Carbopetoposide" and another doctor can be heard doing a dictation in the first clinic room. She has scans up on the PC. There are other conversations between another doctor and the staff nurse "can you give someone an inhaler? She has just started chemotherapy... she just needs a quick script.

I then go into a clinic room with a new patient and the SPR and the Lung CNS. The doctor makes the introductions-I explain I am just observing. She is 77 years old and with her daughter in law. She looks very well. The doctor asks her when she saw the surgeons and what did they say to her. She said she had a lot of pain and rubbed across her chest where she had felt the pain... "it is still there-I can't wear my usual bras... I have got to wear my old ones". What did the surgeon explain to you asked the doctor. The patient said "he said he could get rid of the fluid... and the pain would get better but I still have the pain... he wasn't very nice... he said I had the cancer but not much... surgeons are a funny bunch."

The SPR then explained it was lung cancer and it was a solid lump on the right side but it also was on the other lung, which was why there was fluid on her lung. The SPR and CNS then start talking about the CT scan-its not on PACS because it was done elsewhere.

The patient says "I have lots of questions"

The doctor wants to know more

"I have patches for the pain... Were these given by your GP?"

The patient talks continuously... "I wasn't very well and he gave me some painkillers. My doctor said... you shouldn't be in pain... That's what we said... we said we would ask all the questions today because they (the surgeons) didn't say very much... It's cancer they said... It was a shock. So why is the pain still there... that's what I want to know."

The doctor asks about the painkillers and the patient continues talking whilst rummaging in her handbag for the list of tablets she is on... she hands a piece of paper to the SPR. He examines it and asks her if she is still taking the co-dodamol because she shouldn't be if she is also taking the paracetamol because they both have paracetamol in them. The doctor explains to the patient that she shouldn't be in pain and he tells her "we can sort that out today as well". He goes onto explain the reason for her pain that it is pleurisy which just means inflammation and he draws her a picture of her lungs explaining that they are in a casing and every time she breathes in and out they are rubbing and this is why you are getting the pain... He also draws her a picture of where the cancer is-that it has been on both sides of the chest and caused some fluid to accumulate. The CNS and SPR talk about trying to get the scans again..

"This isn't good" says the patient. The SPR states that they have seen the scans in the MDT... and discussed them but that we haven't physically got them or the written report. They return to a discussion about the operation. The SPR states the first part of the operation was to have a look and suck some of the fluid out. The patient interrupt again- "Can't they cut it out?"
The SpR shakes his head..."what we know is that you have a primary lung cancer and it has spread into the pleura-cutting out the primary tumour won't cure the cancer..cancer starts with one abnormal cell then doubles to 2 cells..then 4..then 8.,then 16..but not very quickly..your type is slow growing..but we can treat it with chemotherapy.."

"Why have I still got the pain?..my breathing is alright..that's what I can't understand."

"You still have the whole of one and half of the other...what would you be doing now if you weren't in the clinic..do you go out..do you still go to the shops..do you go out shopping or do you need a lift?"

"Yes..I go out a lot..no..I walk..I do a lot of hoovering"

It sounds like you could cope with chemotherapy..

What does this involve?..will I lose my hair.."

The SpR and CNS explain the chemotherapy regime and how often the patient has to come to hospital..they also stop and talk to each other...confirming the day of treatment and how many courses they think she will have..whilst they are doing this and explaining to the patient the daughter writes the probable dates in her diary. The patient and daughter sometimes get it wrong and appear confused but the SpR reassures them..explaining that it is quite complicated and that they will write it all down for them.

The patient asks "What is the success rate?" and the doctor explains that "we have to hope it takes the pain away and improves your symptoms..we also want to increase your quality of life and for longer..but we won't know what until we have given you your first few doses and check the CT again..we can get good results..and you are fit and well to start with."

The patient asks "would you carry on after 4 lots?" and the response is "most people don't cope with too much..the patient looks disappointed but not tearful. She says that some people have told he they can have tablets.."if I had a tablet I wouldn't need to come up?...I get a lot of indigestion..I get confused..some with food..she gets the list out again and the SpR looks at it..he points at the list and says she can take two of those (for her indigestion).."we're not doctors..we don't know."

The SpR tries to cheer her up..you are still hoovering? You look very well..apart from the glaucoma you have been well..we think you will be able to cope with chemotherapy. The CNS and SpR talk together again-reassuring each other throughout their discussion, muttering in low voices about the stage..T4 and M1..

The SpR tells the patient he is going to get his boss-"the guvner" to come and see her. (all new patients see the Consultant)

Whilst he is out of the room the CNS sits next to the patient and takes her hand.
She also opens the patient booklet she has in her hand and shows it to the patient. (The team use the Roy Castle Charity patient information leaflet because it has space to write the specific diagnosis, stage and team etc.). The patient asks the nurse when the treatment will start-she is told it will be within a fortnight-she also asks if she can have a drink whilst she is having therapy as she likes a "Scotch of an evening". The CNS also informs her she will have another CT scan as it has been some time since her first scan and they will want to repeat it before she has therapy to provide a baseline. The patient didn't look very happy about this and explained that she didn't like the scanner and found it claustrophobic. The patient also asks what will happen if she doesn't have any treatment. The CNS answers honestly and informs the patient it will spread...but turns the conversation into the advantages of chemotherapy...for example it works on the whole body therefore may prevent it spreading. The conversation is interrupted by the Consultant coming back into the room with his visiting doctor and the original SpR..

Introductions are made and the Consultant sits down closely to the patient. He controls the conversation-the overall impression is serious, very polite but confident. It is very controlled and unlike the SpR and CNS conversation he does all the talking and does not allow them to interrupt. If they do he stops them politely and states he will cover that in a minute. He informs them very clearly that "we cannot cure this disease...you haven't got a lot of cancer but it can't be surgery"

Again the patient asks how long she has got. He explains he cannot be definite but approximately a year-he explains some people go on for a lot longer and others do not. He explains that in some people it can prolong life..by 3 months...it is designed to improve symptoms and make you feel better. They repeat again the conversation around what she can do...can she leave the house and again she mentions her pain. He states there are "no prizes for grinning and bearing it" and that the pain relief can be increased...the patient asks about radiotherapy but she is told "lets not go there too much information". He states his goodbyes and shakes their hands and wishes them the best and leaves the room with the other two doctors.

Again the patient looks a bit shocked...she shrugs her shoulders and looks at us and says "You can't live forever.." The CNS reminds the patient that the Consultant was talking about the average patient and that some patients do very well-The patient started asking about hair loss and she is reassured the treatment will not cause hair loss.

The SpR comes back in and yet again there is movement around the desk. It is like musical chairs. The patient is distressed-she is fidgeting and is repeating herself about the hair loss. The SpR sits down again and explains the other side effects-he explains that taking chemotherapy is not like taking penicillin and side effects include things like becoming anaemic and risk of infection. It is explained that she will be given another week to read all of the information and return to clinic the following week to ask any further questions and make a final decision regarding treatment. He also explains that he will give her something else for the pain and he writes another prescription for her. He spends some time explaining that he will not increase the dose of the patch as this would give her a "funny head". Eventually he and myself leave the room as I want to allow the patient sometime with the CNS in
202 case she is upset.

203

204 I return to the communal room-the other CNS is on the phone about another patient
205 -I hear her saying she is worried about him and she wants the palliative care team
206 to see him-she is saying he is non-compliant, he is not well and he has
207 haemoptysis. A research nurse is looking up patient laboratory results on one of
208 the computers. The new Consultant comes in and picks up another set of
209 casenotes-the casenotes are in a note trolley in order to be seen-there are about 8
210 sets of notes waiting. I ask the Consultant if he tries to see the same patients each
211 time. He states they don't. I ask him if he thinks it would be more efficient and
212 improve continuity of care if the patient mostly saw the same doctor at each visit.
213 He disagrees, saying it's probably not possible and the patient benefits from seeing
214 different doctors with different skills. I disagree and explain it may be easier to see
215 the subtle changes in patients and although difficult to ensure seeing the same
216 doctor each time—maybe it would be possible 70% of the time. He shakes his
217 head and he is not keen for this continuity. I wonder if it is related to the size of
218 these massive clinics and/or the poor prognosis of the patients or if it is the culture
219 to see different patients in oncology.

220 The SpR comes into the communal room again. He feels he did not do a good job
221 informing the patient about her lung cancer and treatment. I say I am sure he did.
222 He said he should be able to do it like the Consultant and I get the impression he
223 wanted to be able to deliver the message quicker and more efficiently. He also
224 asks me about giving a patient some platelets. I ask him what the patient's platelet
225 count is. The patient's platelet count is $15 \times 10^9/l$. I explain our guidelines.
226 Patients should have platelets if their count is less than 10 or if the patient is unwell
227 with a fever or actively bleeding then they should be administered if between 10
228 and 20. We establish the patient is not and I ask him when she is due
229 chemotherapy. He explains it is the following week and I suggest that probably her
230 count is on its way up and he will find it recovers on its own. He agrees and
231 decides not to give a platelet transfusion.

232 I observe more communications in the corridor-patients are still being shepherded
233 through to be weighed and then returned to their seats. One of the patients is a bit
234 shaken and doesn't look very well—there are 2 healthcare assistants with her and
235 they are guiding her into one of the Consulting rooms as she appears to have
236 soiled herself in the toilet. I hear the staff nurse saying to them that she will speak
237 to the Site Nurse Practitioner to arrange a bed to be booked. There is also a foul
238 smell throughout the clinic—it is because there is a palliative care patient with
239 fungating lungs and the Palliative Care Consultant has been with him and his family
240 in a room for over an hour and it is pervading the clinic area. One of the HCA's is
241 spraying air freshener.

242 I go into another consulting room with another patient about to be seen. Another
243 SpR is seeing this patient. He has small cell lung cancer with bone metastases.
244 He has had 2 cycles of chemotherapy (Carboplatin/Etoposide). The SpR asks how
245 he has been. He says he is feeling better and states “I guess it's working”. He also
246 informs the doctor he has put on 4 kg and that his appetite is better and that he is
247 eating properly. The doctor asks about his hair—its not falling out. The doctor
confirms what the patient believes in that it is a good sign that the patient is feeling better. They have a discussion about the CT scan that the patient should have had the week before — the patient did not receive an appointment letter but on further examination it is revealed the patient’s address has changed and he had not informed the hospital. The doctor re-books one on the computer and simultaneously calls the CT scanning department to book a scan. She writes the appointment down for him on his appointment card. They confirm the next appointment date for chemotherapy and the patient leaves.

The impression of the clinic is that it is busy and there is a lot of movement and discussions in different places — for example — patients have their first encounter at the booking in desk and then they take a ticket (like a delicatessen ticket) for the blood test queue. They then sit in the crowded waiting room for a long time waiting to be called in by the doctor. The Cancer Information Room is in the corner of the waiting room but no-one seems to want to go in. Maybe they are afraid they will lose their seat. It is not very inviting — its name is on the glass window — but it is not easy to see what it is or what it is there for. Also if you were to go in other patients would see you — and what would that be like if you started to cry and the waiting room full of people could see you. It is a bit like a gold fish bowl.

In addition, there is an anticoagulation clinic running alongside the cancer clinic which probably does not help the patients relax. It is a chaotic environment with several clinics running at the same time — staff coming and going, names being shouted out. Perhaps patients are afraid they will miss their turn. The clinic clerks are busy at their computers, booking patients in and out, occasionally there is a small queue at the desk (3 or 4 people) and how do the patients know which clerk to go to (one is for the anticoagulant clinic) if it is the first time visiting the clinic.

The phlebotomy area is behind the desk — you go in a separate door. There are 3 phlebotomists — two for the anticoagulant clinic — the other is for the lung clinic and chest clinic. There are two systems for calling patients through to phlebotomy — anticoagulant patients have their names called and the other clinic patients take a delicatessen type ticket and wait for their number to be called out. There is no way for the patients to understand this unless they have been there before. I hear the clerks repeating the systems to new patients. There are 2 white boards on display to inform patients. The waiting time is displayed on the oncology board but the anticoagulant board is 3 days out of date. The anticoagulant board is scruffy and has been written with a dry pen so can’t be seen unless quite close. The oncology board is neat.

The doctors and CNSs appear quite stressed — as if they have a lot on their minds. They have to move from one situation or conversation to another quickly — sometimes on the telephone, sometimes in clinic rooms or the corridor. They are all working hard. A lot of time is taken up with process and system management rather than discussing cases or research or discussion about individual patients. Perhaps this clinic has been busier than normal — also the technical issue of one of the precious clinic rooms being unavailable (no computer) seems to be having a very negative impact. There is no lunch break — the clinic runs until 3pm. There is biscuits and drinks and the usual tray of fruit which is provided by the Trust for all oncology areas which is laid out in the communal room. People eat on the hoof but
302 don't seem to expect anything else. However, the atmosphere is good—people are
303 friendly and smiling. There is laughing and joking—withstanding the difficult and
304 complicated environment.
305
306 Clinic finishes at 3.30pm
Appendix 19: Componential analysis

<table>
<thead>
<tr>
<th>Early Themes</th>
<th>Componential analysis</th>
<th>Evidence</th>
</tr>
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<tbody>
<tr>
<td>The impact of the haemoglobin</td>
<td>The Hb was the primary determinant for diagnosis and management of anaemia for patients and clinicians. The Hb seemed to be equally important in haematology and oncology, however, haematology use a lower transfusion trigger of 8g/dl and oncology had a tendency to discuss using a higher trigger of 10g/dl.</td>
<td>We know they are anaemic already, because we have got a blood count in front of them so I am not at all good at assessing for that sort of thing. (SH2;131)</td>
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<td>I suppose obviously you look at the blood results and if someone's haemoglobin is less than 8 and then you are thinking about them being anaemic (SH5;3)</td>
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<td>&quot;Its very mechanical you know its below 10. Its not its not a holistic overview of how outpatient is feeling it was just...Right ok if it is below 10. &quot; (SL5;444)</td>
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<tr>
<td>Separating the symptoms</td>
<td>The problem of separating symptoms of anaemia from symptoms of their disease and side effects of chemotherapy. The impact of breathlessness in lung cancer patients and the difficulty of separating this from symptoms of anaemia. Related to experience, skills and knowledge of the HCP- the day unit nurses see the patient as a whole.</td>
<td>Its not going to be just the fact that they are anaemic...they have so many other symptoms so dealing with that more than just saying your haemoglobin is 8.5...you will feel so much better after two units of blood...and often they don't... (SH4;244)</td>
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<td>non-cancer related anaemia may not be as symptomatic because they are not receiving cytotoxics. (SH5;45)</td>
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<td>I suppose the most common things are, the tiredness, the fatigue which again is a tricky one because it could be cancer-related fatigue and chemo-related fatigue that we talk about. again it may not be associated with the anaemia (SH5;85)</td>
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<td>... I would normally say...are you any more tired than normal...are you any more breathless than normal and if I think they might be then I would perhaps go into some more detail about that to try to determine if they had a symptomatic anaemia as opposed to symptoms of their disease....and of course symptoms of disease can be very much overlapping with symptoms of anaemia... (SL1;27)</td>
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<td>if you ask most patients are you tired...the answers yes because they've got cancer and maybe because they're anaemic...so I am sure if I was to ask most of the non-anaemic patients if they are tired...the answers yes. (SL1;67)</td>
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<td>The disease...in most cases people that are really fatigued it has got a lot to do with the disease and the type of cancer that they have got (SL4;295)</td>
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<td>...and normally when I worked on the day unit, the nursing staff would tell me because they knew the patients a lot better than me and they knew how likely they were to be symptomatic...how quickly they would come</td>
</tr>
<tr>
<td>&quot;Knowing&quot; the patient</td>
<td>Seeing patterns and changes over time; having a relationship with the patient. Related to experience of the clinician and/or nurse and who has the</td>
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326
opportunity or patient contact to make the assessment and decision.

Access to all the information—the haemoglobin and the patient

Decisions made in absence of patient is acceptable, however acknowledges knowledge and relationship with the patient is important.

back, whether they could wait, in their opinion for another day and manage without blood... (SH2; 479)

...obviously nurses can’t prescribe blood so at the end of the day you have to get a doctor, a doctor has to prescribe it but... I think from a time point of view and knowing a patient on an individual basis it’s more of a nurse... in my opinion a nurse could do more effectively perhaps... (SH5; 106)

But when you have a key person liaising with the patient and working with the patient, it is quite easy to put “your finger on the pulse” and decide whether to transfuse or not because you know your patient better and you can get the facts for your assessment quite easily (SH9; 479)

Yes some take more part, some get more involved in how I feel when... erm...do I feel symptomatic more...what do I think... they listen and we talk (FH1; 186)

Contextualizing anaemia

Acknowlegement of the patient treatment and disease pathway

Importance of not assessing the Hb in isolation

Holistic assessment

take into account where they are in their treatment, their disease status, their age... (SH4; 89)

if you have got someone who you know is recovering their counts from chemotherapy but their haemoglobin is maybe lagging a little bit behind... I would often try and not transfuse them because you know that the bone marrow is beginning to work again (SH4; 187)

...but you can usually tell the patients up front who are going to need blood because they are usually the patients with heavy disease bulk or bone marrow infiltration and with those patients I usually say, look it is very likely that you are going to need blood so they are prepared so that it’s not sprung on them (SH5; 225)

I got those patients that are known to me, I know what they were like at diagnosis...and it is kind of, you are wanting to improve their quality of life...erm without... I’d be looking at their performance status... how well they are, how well they would be to come up here, what stage of their disease they are... if they are very palliative, what we are going to achieve by that if they have been feeling that way throughout because of their disease or symptoms arising from their disease... (SL5; 93)

...but often you can... sometimes you can tie it to what’s happened to the haemoglobin over time... and see in fact they’ve been tired for ages and they’ve only become anaemic since you started chemotherapy and they are no more tired than before... so that’s not the anaemia (SL1; 72)

So in my head I don’t have a cut off for males and a cut off for females but I do think about size, sex and comorbidities when I am deciding to transfuse (SL1; 323)

Oh yes definitely... I can predict yes...
| Uncertainty | Lack of clarity in diagnosis; Indeterminacy; Hesitancy; no definitive treatment; lack of clarity in knowing the effectiveness of the treatment (the blood transfusion). The uncertainty exists at a level of haemoglobin (mild or moderate anaemia). Further analysis is required to explore if in the presence of severe anaemia there is less uncertainty. |
| Balancing the risks and the benefits | Recognition that there may be benefits. Knowledge of risks, but benefits outweighing the risks. Not all patients benefited. Immediacy of treatment. Belief that there was no harm in giving blood |

...I just can't remember a time when I was saying "I definitely think this person needs a transfusion." (SH2;515)

So...alot of time the Registrar on the day unit may say their haemoglobin is 8.9 we'll transfuse them. OK...If you ran that sample again it could just as easily be 9.2. (SH4;123)

most of the time...they are very vague...very vague descriptions really...just feeling more energy or just feeling a bit better but is that a change due to transfusion or due to something else that is going on otherwise with them...it is very difficult to say (SH4; 156)

It's an individual thing, definitely. I don't think there is a level for anyone (SH2;42)

...in fact so there is not very good continuity in assessment of response to blood transfusions I think something in which we should and could improve but we don't robustly assess response...we have no robust mechanism of assessing response of a transfusion which means that there is a risk and I am sure it happens that people do get repeat transfusions who are not necessarily benefiting from them. (SL1;130)

If it is end stage and they are dying then if the haemoglobin keeps dropping then there is not going to be any benefits in keep giving them blood transfusions, but on stage, but god if they have still got six months but if they are in the last month or I can't see much point to be honest (SL4;660)

No...I mean unless someone is physically very short of breath in front of you or very pale or whatever, and if they are not really describing their benefit it is often hard to say that there has been a benefit (SH5;143)

because when I do transfuse people at that level some of them feel better and I rarely don't...I don't see people being worse and it maybe that the side effects are rare (SL1;424)

Yes either a third to 50 (benefit from blood transfusion) (SL4; 176)

erm... the ones with the worst performance status it is more difficult to determine, or that is my experience anyway, as to whether it has been a benefit to them. (SL5;219)

Yes of course, I do worry about it you think about in the future I could develop another kind of illness like...erm...haemorrhage so obviously I do worry. (PH1;78)

In my situation right now because of the leukaemia and because of the chemo and how it reacts for me and for me and how it makes...
| Living with anaemia (fatigue and other symptoms) | Patients tolerate symptoms of anaemia. Anaemia is not serious; Healthcare professionals assume patients to tolerate a level of symptomology; not all symptoms or side effects can be treated. Linked to the frequency of mild or moderate anaemia in the clinical setting. | Oh it is low, I think nausea and vomiting and neutropenia and things like that are much higher up the scale...that would be the bottom one...mm.m (SL4:596) So with these patients it is not ideal, it is very difficult I think for them and I think that is probably why a lot of them don’t shout out about their symptoms because they know that they are going to have to go through all of that on top of this (SL5:508). At no point does he ask the patient if he is tired or how he is feeling or any assessment of the impact of his anaemia (H. 11.3.08;47). I feel fatigue...I just want to like...erm... get some rest, everything that I do, I do very slowly. Simple things like washing the dishes take longer for me, because I feel very fatigued. (PH1:4). I don’t sleep well...I don’t sleep very well during the night. I haven’t slept well since I had the leukaemia (PH1:16). It is just that, when people put things in an order of importance that they could shift anaemia a little bit down their priority list, because they are coping with it until they come up to a point that they can no longer shift it down the priority list (SH9;90)....well over a quarter of the human race is suffering from anaemia at any given time. So I think it is a big problem, but because of the way that it affects individuals, people adjust to the symptoms, people adjust to their way of life. That they only come up to seek help for severe health and medical help when it is really very, very severe. (SH9;74). She has to work, she has to go to college, and it came to a point that she could no longer do her college work and that is when she decided to come in... (SH9;59). If one’s got a patient who is on chemotherapy and is one of the regular patients then I am much less searching about their symptoms, partly because there is a sort of set pattern.... (SH1;30). |
| Traditions | The importance of “what has always happened in practice” Anaemia is common. Blood is ubiquitous Change of practice over time as experience is gained—not by evidence or guidelines “Word of mouth” | ...two units of blood is what we always transfuse. I know I always thought earlier in my career...I always thought one unit of blood won’t do anything but it will raise your haemoglobin by a gram... (SH4;199). It was always just automatically two units and no-one really ever you know...I was always told one unit won’t really do anything so what was the point in giving it. (SH4;205). That is what I was told when I came, by the registrar on the ward and so on... (SH2;441) ...and I think also doctors are more reluctant to prescribe whereby initially when I think back years ago when your haemoglobin was 9...9.5... 329 |
| Internal and external influences | Current practice in the clinical setting as a major influence; personal attitudes; impact of unique clinical environment; lack of impact of mandatory training in transfusion; impact of erythropoietin research; lack of |

you know you could have a couple of units of blood and it was prescribed willy-nilly... so yes there has been a huge change in practice (SH1;154)

The reason that we tend to give two at a time I am sure is affected by practicalities and habits as it is by logic (SH1;171)

I am much less enthusiastic about transfusing them up to a target haemoglobin than I used to be if they are comfortable with their lower haemoglobin...that is probably the biggest change. (SH1;183)

I haven’t a clue...I would suspect that they are better at that now than they were, you know in the olden days you used to throw blood around... (SH1;269)

Well nobody has trained me since I was at medical school...I probably should have been (SH1;312)

I would have thought that anyone in a hospital who is using a significant amount of blood should be updated because it is. you know that is actually interesting isn’t it because other therapies you get updated in but bloods been around a long time you know you just use it...

(and I really do think throughout a lot of oncology that the rational for prescribing a blood transfusion is that the haemoglobin is a bit low on paper and...am...you know and there is a wide held belief that the trigger is less than ten...I think that is a wide held belief (SL1;230)

obviously we give two unit transfusions far more often than any other amount for I have no idea what reason. I do know and this is historic when I was a medical SHO both general medical and in oncology which I was in the same place we were told that we should never give a one unit transfusion to anybody ever because there was never an indication for that...people needed two or three units or they didn’t need it at all... (SL1;445)

(Who taught you a trigger of 10 I don’t know. It has just been a standard practice, I don’t know if that is related to the radiotherapy because that is what they come back to look at anything below 10, yes it is not one particular person (SL4;344)

you know that is actually interesting isn’t it because other therapies you get updated in but bloods been around a long time you know you just use it... (SH1;319)

Er...I don’t think we are meant to but certainly at my last hospital we would, if somebody was about to be discharged we would transfuse them up to a higher haemoglobin (SH2:55)

Yeh... I suppose that is what they are used to...just different trusts they have different ways of doing things (SH4:106)
The impact of different institutions-staff base decisions on the practice within the particular institution or department-staff very quickly accepting of local practice. Non questioning.

Socialization of practice

The impact of resource availability

I mean I was taught here to look at the 10, but whereas before I probably wouldn’t have worried till about 9 (SL4:356)

All the things you are saying about what the triggers to transfusion and when you should transfusing are ...I don’t think that is clear I don’t think we have particular training...all we know is on the ward is when someone’s haemoglobin drops below 8 you should transfuse and that’s what the SHO’s know but more formal training we haven’t had I don’t know whether it is... (SH2:423)

... I know because the manufactures of erythropoietin have banged this into us over the years that patients feel better if they are on erythropoietin and they have got high haemoglobins and that’s very good...erm... (SH1:92)

so...there is clearly a body of very old scientific evidence to show that getting your haemoglobin level above ten doesn’t really help you terribly very much. (SH1:113)

Well nobody has trained me since I was at medical school...I probably should have been (SH1:312)

Somebody who has been doing this job for years is telling me that this person needs a blood transfusion, they probably do so I will just prescribe it, whereas now I might challenge that I would not have challenged that 6, 7 or 8 years ago so I know myself it is not a conversation that I have had with any of the registrars and so I have to say I don’t know what my response would be but I suspect it would be, like mine, initially you would do it and then maybe over time you sort of work out that not everybody needs a blood transfusion (SL1:169)

...em...there is evidence now in a number of cancers now that outcome is better if you maintain the haemoglobin level around 12 grammes per decilitre throughout treatment particularly with squamous cell cancers. I think that is fine I think that is a research driven rational for transfusion which I think..(SL1:213)

...em...with clinical benefit but now in the last week to ten days you can say erythropoietin might be harmful...em...and may impair survival outcome from malignancy so I think the jury is still out on erythropoietin and ESA’s..em...but I think that blood transfusion in order to maintain haemoglobin at a given level because research has shown that treatment is more likely to be successful in cancers It is going to be better to maintain a haemoglobin. (SL1:222)

my main recollection of mandatory training was about labelling the bottles correctly and storing them in the right place and getting the blood from the right place as opposed to when to transfuse and why. (SL1:256)
1. Anaemia and blood transfusion is not important

<table>
<thead>
<tr>
<th>I would quite like to have you there to teach almost and to challenge, and to say &quot;are you sure you're going to give this blood transfusion and why&quot; and I think it would improve treatment of anaemia if we did have a... if we... all of us in oncology could stand a bit of education from a blood transfusion physician or a haematologist or someone who knows more about it than we do and to let us know how you would approach this in haematology (SL1:547)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I mean honestly I wouldn't want it, I mean I know it is checked and everything but still the thought of having someone else's blood in your body (SL4:318)</td>
</tr>
</tbody>
</table>

In comparison to the impact of the diagnosis and side effects of cancer therapy; the chemotherapy is more important; decisions made in absentia of patient

Linked to the frequency of mild and moderate anaemia in the clinical setting.

Blood transfusion is ubiquitous

The patient explains that he gets the blood results from the nurse anyway...and he doesn't think the GP even looks at it. (H. 11.3.08:91)

Possibly, whether they are just not thinking about it or think they are doing the nurse a favour by just prescribing the blood, yes... it could be any of those things but they haven't thought enough about it...they haven't had a scare... (SH5:365)

Just blood being prescribed by a registrar as a favour to a nurse for a patient that they have never seen and they know nothing about and it is quite frightening and it happens and I see it happening most weeks, and that is something that needs to be addressed (SH5:397)

I know that medical students get an appalling lack of education about blood transfusion these days (SH1:326)

I am treating it as a given, it is something they learn by osmosis, (SH1:336)

I guess what it comes down to is that most of our clinics are very busy and who gets a blood transfusion and who doesn't is not something that is necessarily discussed with the consultant...whereas any chemotherapy change has to be discussed with the consultant we don't mandate that for blood transfusions...and so therefore I guess the message that gives out is that this is a less important decision and so therefore the registrars or clinical fellows don't feel that they have to come and talk to us about it or they will make the decision and because they are not talking to us about it and because we are not talking to them we are probably not educating on the job about blood transfusion (SL1:281)

...what I have said to you is that my use of blood has changed over the years that I have been in oncology and it has reduced...em... in that I am less likely to transfuse now than I was before but actually I rarely have that conversation with my juniors (SL1:291)

I am thinking we can and probably do transfuse people who don't need to have it or who maybe don't need to have a transfusion, the consequences of that seem potentially less...
### 2. Shared responsibility

No single healthcare professional owns the clinical problem; shared clinical decision making

Linked to who is most experienced and who is best placed to assess and treat cancer related anaemia

Linked to earlier work by Atkinson (1995) - decision making a collective, organizational activity

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"...I am sure there are situations but none stick in my mind, none scar me so much. I don't think I'd mind, I mean certainly if the consultant said "actually I don't think they need blood" they are perfectly within their rights to say, no they don't need blood it is their patient and as long as they explained why then that would be fine I think...and normally when I worked on the day unit, the nursing staff would tell me...because they knew the patients a lot better than me and they knew how likely they were to be symptomatic...how quickly they would come back, whether they could wait, in their opinion for another day and manage without blood..."

"...Yep em if the doctor that saw the patient is around, if the consultant is around they will come back to the person that saw the patient, otherwise they may not and they may go to the Reg and...I'm trying to think when I was that Reg, and if somebody came to me...then...I don't know, it sounds too horrific for words...I'm trying to imagine if it could possibly happen...that the person who prescribes the blood never sets eyes on the patient...em...I think that does happen...I think it does...More than skills and knowledge...Yes absolutely. Experience...yes...I think so...yes and people accepting responsibility for it as well...they just don't seem to do it...people prescribe...yes so people being made aware if you have never seen a reaction or you know a bad transfusion related event you are not really going to think twice about prescribing...you know for any drug...if you see a bad effect or side effect it really scares you and you think...god and you think twice...just blood being prescribed by a registrar as a favour to a nurse for a patient that they have never seen and they know nothing about and it is quite frightening and it happens and I see it happening most weeks, and that is something that needs to be addressed...but you would hope when someone is taking responsibility for prescribing the drug they would see them, but I see it in clinics most weeks where random registrars have been asked to prescribe blood for patients they have rarely or never seen and I think it is wrong and perhaps it needs to be brought to their attention. But if there is no-one chasing it and if people aren't taking responsibility for it then it is difficult...it does happen, in clinics especially...(I get questioned you know...does someone really need that transfusion? I mean I can't think of specific instances but you know..."
would not be put out if I had a phone call
saying somebody has come up for their
transfusion and actually their haemoglobin is
not that low or actually maybe they should
have three units rather than two and I would
take that as being good teamwork (SH1:364)
I think a lot of the transfusing happens without
even my knowing i.e. I see a patient I don't
have their blood results with me ...the blood
results are not back when I see the patient
so...erm...they go on a list to be checked later
and that never comes back to the consultant,
that goes from the clinic nurse/chemotherapy
nurse directly to the clinical registrar who
decides whether to transfuse or not (SL1:305)
The influences on clinical decision making and the culture of blood transfusion practice in cancer related anaemia: an ethnography

by

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University of Surrey

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The influences on clinical decision making and the culture of blood transfusion practice in cancer related anaemia: an ethnography

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Abstract

Background: Clinically defined cancer-related anaemia is common in cancer patients but the impact of mild/moderate anaemia is undetermined, when combined with cancer symptoms and/or the side effects of therapy. Blood transfusion is the standard treatment; however there are significant risks and costs and considerable variation in practice. It is important that the decision to give blood is carefully considered and it is not clear how these decisions are made.

Objectives: To explore the cultural practices which shape the culture of transfusion; and to identify the key elements, which influence clinical decision making in blood transfusion in haemato-oncology and lung cancer patients.

Methods: The assessment and decision making processes for blood transfusion were explored using six patient and nine clinician interviews; and observation based on ethnographic methodology. Data were analyzed using thematic analysis.

Findings: The findings fell into four main areas. First, the findings suggested that anaemia and transfusion are commonplace in the clinical setting; and because many patients live with anaemia and it may not be viewed as an illness (The ubiquity of anaemia and transfusion). Second, there is a great deal of uncertainty surrounding the diagnosis and management of this clinical problem; but this uncertainty was acknowledged by both patients and clinicians (Acknowledgement of uncertainty). Third, clinicians and to some extent patients, are socialized into the practice of the sub-discipline (Socialization of practice); and fourth that the haemoglobin level was used as a distinct fragment of information on which to assess for the presence of anaemia and base the decision to treat with blood transfusion (Disaggregation of the body).

Conclusion: The classical symptoms of anaemia may not be useful in the assessment of this type of anaemia because confounded by symptoms of the cancer and side effects of
therapy. The management of anaemia is not a priority in this setting however by understanding the complexity of factors for variation in practice in the clinical context, new models for learning transfusion skills can be developed. Furthermore, different collaborative groups could be organized to develop optimal transfusion practices, for example to include nurse-prescribing of blood components.

Keywords
Anemia
Blood transfusion
Cancer, neoplasms
Culture
Decision making

What is already known about the topic?
- Anaemia is common in the cancer population and blood transfusion is the standard therapy
- Transfusion practice varies considerably and the reasons for this are unclear
- It is not known how transfusion behaviours are learned or how the decisions to treat with blood transfusion are made in the clinical setting.

What this paper adds?
- This study demonstrates that transfusion practice is heavily influenced by the culture or sub-cultures within an organization
- The classical symptoms of anaemia may not be useful in the assessment of the impact of anaemia but this hypothesis requires further research
• Anaemia is not a priority in the clinical setting and therefore there is a lack of informal systems for learning transfusion decision making.

• New ways of learning and new models of care are suggested to develop optimal transfusion practices, for example introduction of nurse prescribing of blood components and patient centred decision making.
Introduction

Clinically defined cancer related anaemia is reported as a common problem in patients with a incidence of 52% and 38% respectively (Ludwig et al 2004). The pathogenesis of cancer-related anaemia is variable, but may involve bleeding, erythroid hypoplasia, reduced red cell survival, nutritional deficiencies, decreased erythropoietin levels, haemolysis and poor iron re-utilisation by bone marrow (Bokemeyer 2005; Estrin et al 1999). Furthermore, cancer related anaemia is exacerbated by myelosuppressive chemotherapy and may be aggravated by radiotherapy (Barrett-Lee et al 2000). The presence of cancer related anaemia probably decreases patients' quality of life, and may impact on fatigue (Demetri 2001; Glaspy 2001; Ludwig and Strasser 2001) and is associated with shorter survival times in some cancer patients (Caro et al 2001). However, the body is uniquely capable of adapting to anaemia, which allows more oxygen to be released to the tissues (Morisaki and Sibbald 2004) thereby some patients can function to near normal levels with haemoglobin levels of 7g/dl.

Blood transfusion remains the standard therapy for cancer related anaemia for the majority of patients in the UK, but there is considerable variation in transfusion practice. There are risks to transfusion such as transmission of infectious diseases, transfusion reactions and allo-immunisation, over transfusion and immune modulation (Goodnough 2003). However, improved survival, and the use of more intensive chemotherapy regimens supported by growth factors, means the requirement for blood transfusions has increased while the donor supply has diminished (Williamson et al 1999). Most clinical practice guidelines adopt the British Society of Haematology recommendations and use a transfusion trigger of 8g/dl (BCSH 2001), but this numerical trigger ignores individual patient factors and the underlying pathophysiological consequences determining each...
patient's individual tissue oxygen demands. Furthermore, there may be also be a unique physiological response to transfusion, which is dependent on a degree of oxygen debt (Madjdpour and Spahn 2005), therefore the decision to transfuse blood needs to be carefully considered and it is not clear how these decisions are made in the cancer setting.

There are many influences on decision making but studies evaluating relationships between physician background characteristics and quality of care have found few consistent associations in decision making (Wigton et al 1999). Site of practice variables have been better predictors of quality than have characteristics of individual physicians. In addition, tasks occur in unique clinical contexts and clinical judgments and decisions are not isolated cognitive events. A study explored the relationship between physicians' knowledge and attitudes regarding the use of blood products, and the quality of their transfusion practice, based on in depth physician interviews and medical record reviews (Salem-Schatz et al 1993). Large baseline differences were observed between the two hospitals; 48% of transfusions in Hospital A were justified compared with 81% in Hospital B. At the physician level, knowledge of transfusion indications and receptivity to input from colleagues were significantly associated with higher quality transfusion practice (p = 0.01 and p = 0.02 respectively). Decision-making can therefore be a collective organisational activity, subject to debate and question, and therefore may be more related to social, interactional and situational factors.

It was not clear if cultural factors influenced cancer related anaemia practice; therefore an ethnographic methodology was used to study the interactions and individual characteristics using a combination of interviews and observational fieldwork.
Ethnography is concerned with people's behaviours in everyday contexts rather than under unnatural or experimental circumstances and it is argued here that ethnography was particularly valuable not only because of the attention to context; but also because it offered a holistic way of exploring the relationships that support transfusion practice (Savage 2006).

Methods
Ethical approval was obtained and nine medical and nursing clinicians were interviewed and included Consultants, Specialist Registrars, Clinical Nurse Specialist and Day Unit Nurses. Six patients were also interviewed; Table (i) shows patient inclusion and exclusion criteria and Table (ii) shows patient demographic details.

Table (i): Inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
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</thead>
<tbody>
<tr>
<td>4. Male or female lung cancer out-patients or haemato-oncology outpatients who have cancer-related anaemia and who are being supported with regular blood transfusion therapy. This was defined as patients who have received blood transfusion at least once every two weeks for the previous month or in whom it is anticipated blood transfusion support will be required.</td>
</tr>
<tr>
<td>5. Patients must be willing to be interviewed</td>
</tr>
<tr>
<td>6. Subjects must be able to and understand and have signed the written, informed consent form and the written information provided therein. Appropriate time should be allowed for consideration and questions.</td>
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<thead>
<tr>
<th>Exclusion criteria</th>
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<tr>
<td>4. Patients who are on erythropoietin therapy</td>
</tr>
<tr>
<td>5. Patients who are in any other investigational trial or therapy relating to anaemia</td>
</tr>
<tr>
<td>6. Patients who cannot read and write English because of problems of interpreting and completing the information sheet and consent form</td>
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</tbody>
</table>

Table (ii): Patient demographic data
<table>
<thead>
<tr>
<th>Age</th>
<th>Sex</th>
<th>Diagnosis and stage</th>
<th>Treatment to date</th>
</tr>
</thead>
<tbody>
<tr>
<td>32</td>
<td>Female</td>
<td>Stage IV lymphoblastic lymphoma</td>
<td>3 cycles chemotherapy</td>
</tr>
<tr>
<td>62</td>
<td>Male</td>
<td>Acute Myeloid Leukaemia</td>
<td>3 cycles of chemotherapy followed by cord blood stem cell transplant</td>
</tr>
<tr>
<td>28</td>
<td>Male</td>
<td>Stage IV Diffuse Large B cell Non-Hodgkin's Lymphoma</td>
<td>6 cycles chemotherapy; relapsed and underwent 2 cycles salvage chemotherapy followed by autologous stem cell transplant</td>
</tr>
<tr>
<td>67</td>
<td>Male</td>
<td>Squamous cell carcinoma left lung</td>
<td>Radical chemoradiotherapy to left lung, 3 cycles of vinorelbine and cisplatin. Completed 64Gy in 32 fractions</td>
</tr>
<tr>
<td>59</td>
<td>Female</td>
<td>Non small cell lung cancer left lower lobe</td>
<td>Completed chemo-radiotherapy, 4 cycles vinorelbine and cisplatin. Completed 64Gy in 32 fraction</td>
</tr>
<tr>
<td>52</td>
<td>Male</td>
<td>Adenocarcinoma right lung</td>
<td>3 cycles of vinorelbine and cisplatin</td>
</tr>
</tbody>
</table>

All participants gave informed signed consent. All interviews were digitally recorded and later transcribed by the researcher. Six focused fieldwork observations were undertaken in outpatient and day care clinics. The data were analyzed using thematic analysis; initially, each data set was analyzed separately, to develop a sub-theme and then integrated to create the final themes.

**Results**

Early in data analysis, sub-themes started to emerge from the data, which were related to each other (Diagram i); these sub-themes came together to form the main themes. Final thematic analysis revealed there were four main themes (Diagram ii).
Figure (i): Relationship diagram demonstrating sub-themes

Figure (ii): Final generic themes of cancer related anaemia and treatment with blood transfusion
Ubiquity of anaemia and transfusion

The demographic clinic data demonstrated that clinically defined anaemia was a common clinical issue in clinic and day care units; only 22% of patients overall had a normal haemoglobin level, however, only a few patients, had blood ordered and prescribed in clinic and the day unit areas (Table iii). This was also evidenced in the staff interview data which revealed that they viewed anaemia and transfusion as a familiar occurrence:

"Oncologists use a lot of blood [ ] I bet most of our registrars don't have a single day of the week without transfusing a patient"

However, it was recognised that patients tolerated their anaemia, for example:

"So with these patients it is not ideal, it is very difficult I think for them and I think that is probably why a lot of them don't shout out about their symptoms because they know that they are going to have to go through all of that on top of this"

Despite the frequency of anaemia it emerged from the data to be unimportant in terms of education of the management of anaemia; this was evidenced by statements in the interviews, for example, one of the Consultants when asked about his transfusion training stated:

"Well nobody has trained me since I was at medical school...I probably should have been"

Furthermore, the management of anaemia was not discussed between colleagues, for example:

"I guess what it comes down to is that most of our clinics are very busy and who gets a blood transfusion and who doesn't is not something that is necessarily discussed with the consultant ...[ ]...and so therefore I guess the message that gives out is that this is a less important decision and so therefore the registrars or clinical fellows don't feel that they have to come and talk to us about it they will make the decision and because they are not talking to us about it and because we are not talking to them we are probably not educating on the job about blood transfusion"
In summary, the management of mild or moderate cancer related anaemia sits low in the hierarchy of issues for cancer patients and this is reflected by the lack of education and lack of discourse in the clinical settings.

Table (iii): Haemoglobin values of patients in clinical areas and transfusions administered from clinic/day care decisions (HC=Haematology clinic/day unit; LC=Lung clinic/day unit)

<table>
<thead>
<tr>
<th>No./% of patients with Hb</th>
<th>HC1</th>
<th>HC2</th>
<th>HC3</th>
<th>LC1</th>
<th>LC2</th>
<th>LC3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within normal limits (&gt;12g/dl)</td>
<td>7</td>
<td>7</td>
<td>2</td>
<td>6</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Mild (10g/dl-12g/dl)</td>
<td>11</td>
<td>12</td>
<td>10</td>
<td>22</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>Moderate (8g/dl-10g/dl)</td>
<td>6</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Severe (6.5-7.9g/dl)</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Life threatening (&lt;6.5g/dl)</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>24</td>
<td>19</td>
<td>33</td>
<td>26</td>
<td>37</td>
</tr>
</tbody>
</table>

Number of patients treated with blood transfusion

<table>
<thead>
<tr>
<th></th>
<th>HC1</th>
<th>HC2</th>
<th>HC3</th>
<th>LC1</th>
<th>LC2</th>
<th>LC3</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of patients within normal limits</td>
<td>28%</td>
<td>29%</td>
<td>10.5%</td>
<td>18.8%</td>
<td>18.5%</td>
<td>29.7%</td>
</tr>
<tr>
<td>% of anaemic patients</td>
<td>72%</td>
<td>71%</td>
<td>89.5%</td>
<td>81.2%</td>
<td>81.5%</td>
<td>70.3%</td>
</tr>
</tbody>
</table>

Acknowledging Uncertainty

Uncertainty in diagnosis was universally accepted, for example the Specialist Registrar acknowledged the uncertainty of anaemia:

"It's an individual thing, definitely. I don't think there is a level for anyone"

The patient data revealed similar findings in that they acknowledged the uncertainty of anaemia as well as uncertainty of response to transfusion as one patient described in the following excerpt:

"At times you couldn't tell whether you felt awful because you were low in the blood states or you felt awful because you...because of the chemotherapy. And even when you had the blood you were obviously better because you're going about...but you could still feel awful...but that was no reflection on the blood going
in. Sometimes for example, about 3 or 4 weeks ago, I had blood on the Friday and I had the best weekend I had had for about 5 months. I had a good period of for three days and then I went downhill and for that one weekend I felt really brilliant and that was down to the blood"

The clinicians also acknowledged the uncertain response to transfusion:

"...in fact so there is not very good continuity in assessment of response to blood transfusions I think something in which we should and could improve but we don’t robustly assess response [...] I am sure it happens that people do get repeat transfusions who are not necessarily benefiting from them"

However, it was described how uncertainty could be reduced if the anaemia was assessed in the context of the patient pathway for example the day unit sister described how she contextualized the anaemia:

"(you) take into account where they are in their treatment, their disease status, their age...If you have got someone who you know is recovering their counts from chemotherapy but their haemoglobin is maybe lagging a little bit behind...I would often try and not transfuse them because you know that the bone marrow is beginning to work again"

**Socialization in practice**

Traditional practices were described in many of the interviews in relation to blood transfusion practice, for example:

"because other therapies you get updated in but bloods been around a long time you know you just use it"

"The reason that we tend to give two at a time I am sure is affected by practicalities and habits as it is by logic"

It emerged that clinicians are socialized into anaemia practice depending on what institution and department, for example, the Specialist Registrar described her experiences in other hospitals:
“Erm ..I don't think we are meant to but certainly at my last hospital we would, if somebody was about to be discharged we would transfuse them up to a higher haemoglobin”

Yeh... I suppose that is what they are used to...just different trusts they have different ways of doing things

Sometimes the clinics were busy and there was no time to dedicate to decision making, and the practicalities of transfusion influenced the transfusion decision making, for example, resource availability, as demonstrated in the following excerpt:

“I think the resources are considered with the ....where are they going to have this blood, where can we fit them in and how can they have it in a timely fashion before or after chemotherapy so from a resource point of view that is at the forefront of my mind how and where am I going to give them this blood...”

It seemed that no single professional group owned this clinical issue, for example, one of the Specialist Registrars described how this shared responsibility worked in practice:

“.. I mean certainly if the consultant said “actually I don't think they need blood “ they are perfectly within their rights to say, no they don't need blood it is their patient and as long as they explained why then that would be fine I think...and normally when I worked on the day unit, the nursing staff would tell me...because they knew the patients a lot better than me and they knew how likely they were to be symptomatic...how quickly they would come back, whether they could wait, in their opinion for another day and manage without blood...”.

Conversely some perceived this behaviour as negative, although it was fully acknowledged this practice also occurred:

“just blood being prescribed by a registrar as a favour to a nurse for a patient that they have never seen and they know nothing about and it is quite frightening and it happens and I see it happening most weeks, and that is something that needs to be addressed”

A significant difference between oncology and haematology was the variation in haemoglobin levels used to describe anaemia and frequently referred to in the interview data. The oncology clinicians described anaemia by using a higher haemoglobin level,
tending to describe a trigger of 10g/dl, whereas the haematology specialists tended to
describe anaemia in the context of 8g/dl but this did not appear to result in more
transfusions in oncology. However, the sub-specialism influenced the decision making,
for example, the Lung Consultant explained:

"I treat a lot of lung cancer where it's very difficult because lung cancer patients do
get breathless because of their disease and often because of other co-morbidities
they have associated with their malignancy...[ ] I would almost perhaps have a
lower threshold for transfusing such a patient because if it happens to help they
can be patients who symptomatically can be very difficult to treat...so I would..."

In summary, the practice was heavily influenced by the sub-culture, whether this was the
influence of the sub-specialism or the individual department or institution.

Disaggregation of the body

Most of the transfusion decisions were based on the haemoglobin; minimal assessment
seemed to occur in practice, other than a few brief questions to the patient, which were
often prompted by the haemoglobin value, for example:

"... I think it is because we have got the results in front of us...it doesn't happen
that often unless it is really low that you actually look at someone and go...your
anaemic...it is more that we have got the results first and then we see them, if
you know what I mean"

This phenomenon of separating out clinical information has been described by Atkinson
(1995) as "Disaggregation of the body" and can be used to understand this clinical
situation whereby the haemoglobin value was used in isolation to make the transfusion
decision.

Both patients and clinicians acknowledged that knowing the patient was preferred, for
example the Specialist Registrar described her experience of working in the day unit:
"...and normally when I worked on the day unit, the nursing staff would tell me because they knew the patients a lot better than me and they knew how likely they were to be symptomatic...how quickly they would come back, whether they could wait, in their opinion for another day and manage without blood..."

Clinicians were engaged with patients to varying degrees:

“Yes some take more part, some get more involved in how I feel when...erm...do I feel symptomatic more...what do I think...they listen and we talk [ ] some prefer not to get involved as much with the patient”

It may because of the uncertainty of diagnosis and treatment that experiential or tacit knowledge may improve decision making, for example, in the following excerpt by a Consultant:

“my response to that as junior registrar would have been, they are telling me they need a blood transfusion, somebody who has been doing this job for years is telling me that this person needs a blood transfusion, they probably do so I will just prescribe it... whereas now I might challenge that I would not have challenged that 6, 7 or 8 years ago so I know myself it is not a conversation that I have had with any of the registrars and so I have to say I don’t know what my response would be but I suspect it would be, like mine, initially you would do it and then maybe over time you sort of work out that not everybody needs a blood transfusion”

In summary, transfusion decisions were based on the haemoglobin value, but it has been demonstrated here that the haemoglobin value does not always correlate with how the patient is feeling. Uncertainty exists but experiential learning and knowing the patient were acknowledged as improving the decision, however, because transfusion decisions are sometimes made in absence of the patient and because decision making is not debated in practice, sub-optimal transfusion practices exist.

Discussion

This study showed the symptoms of disease and side effects of treatment are indeterminate and there may be no rationale in trying to assess the haemoglobin with the symptoms in a robust way. The literature describes how a full systems review
assessment is recommended to assess anaemia (Foubert and Wujcik 2005), however, this study's findings suggests that it is likely that variation in practice is inevitable and in fact may be desirable, for example, Eddy describes how some variation in practice is appropriate; “the differences in patient’s risks, signs and symptoms, responses to treatment and values are real” (Eddy 1999, p59). However, Eddy also describes how uncertainty can harm the quality and cost of medical practice; and most of the simplification of uncertainty pushes in the direction of overutilization. If this is the case, the amount of uncertainty which exists in cancer related anaemia would tend to result in over-utilization of blood components.

Medical work is dependent on a wide range of skills and the majority are gained through tacit acquisition as part of an apprenticeship into the specialism; “these tacit skills are often indeterminate and are rarely explicit but are largely rhetorical” (Atkinson 1995, p91), and therefore require discussion and debate. Discrete cultural knowledge is acquired informally through participation in working practices and much of this is unconscious; “it is implicit learning normally associated with the concept of socialization” (Eraut and Hirsch 2007, p5). Giddens describes how socialization is the process whereby an individual gradually becomes knowledgeable and skilled in the ways of the culture in which they exist and how societies have “structural continuity over time” (Giddens 2006, p163), which perpetuates values, norms and social practices. The interactions between individuals take place through symbols and the interpretation of meanings and this has been described as “symbolic interactionism” (Giddens 2006, p107), for example the different haemoglobin values that were described between oncology and haematology. Symbolic interactionism emphasizes the small-scale interactions of individuals, not society as a whole, however this study revealed the
management of anaemia escaped the rhetoric in clinical practice and the consequence of this was a lack of informal systems for learning how to manage cancer related anaemia.

The significance of the interactions implies the quality of decision making may be dependent on the communication within the team; or the degree and quality of communication with the patient. The silent isolated single handed decision-making is, therefore, is probably not the model for the assessment and treatment of cancer related anaemia with blood transfusion. Ideally, because of the risks of transfusion the patient should be consulted and together the clinician(s) and patient make sense of what is going on, and patient-centered decisions can ensue. Patient centered care is a term used to "describe the therapeutic relationships between care providers and service users, and between the care providers themselves" (Manley and McCormack 2008, p12). However, this study revealed the importance of the haemoglobin and this may be either a reflection of the uncertainty of symptoms or alternatively it may be related to the limited time to dedicate to cancer related anaemia in the out-patient setting; parsimonious behaviours may ensue whereby a quick decision based on the haemoglobin value is made because of the value placed on the haemoglobin result. Therefore anaemia sits low in the hierarchy of clinical concerns, because the physicians’ priority in clinic is to focus on the cancer and treatment. This lack of priority for anaemia may also be influenced by the meaning of anaemia; if a disease at the time of diagnosis causes no pain or disability, even if it accompanies a more serious ("real") disease such as cancer, it will not be viewed as an illness especially if it is frequently encountered (Eddy 1999) and will therefore be given low status. These elements are summarized in Diagram 3.
Diagram 3: Hierarchy of knowledge and task (cancer related anaemia)

In summary, the unique difference of cancer related anaemia (as opposed to other types of anaemia) may be that the classical signs and symptoms of anaemia are not applicable in traditional assessment because they are confounded by the symptoms of cancer and treatment; this hypothesis would require further investigation. It is likely that socialization of practice will remain a powerful influence over behaviors, however, if nurse-prescribing of blood components were legitimized transfusion decisions could be optimized as day unit nurses may be best placed to prioritize anaemia, through repeated exposure to transfusion and by knowing the patient. Optimal transfusion practice should be the aim and the decision making should be tailored to the unique individual and perhaps the only way to do this is by involving the patient in that decision.
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Overview of the integration of knowledge, research and practice

by

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1.0 Introduction
This paper is a summary of the integration of knowledge; research and practice over the four years of doctorate study; providing the reader with an understanding of the taught elements, the research journey, and the implications for clinical practice for the author. It will begin by describing the development of self; and will be followed by the development of the research project including a description of the change in the ontological position of the researcher. It will conclude by describing any deficiencies in learning, as well as conclusions and recommendations for the future doctorate programmes.

2.0 Development of self
Undertaking the taught elements of the doctorate programme highlighted shortfalls in knowledge and experience; particularly in the critical thinking of designing and undertaking a research project. In addition, professional development and a greater understanding of the wider strategic and political themes continued concurrently in order to fulfill the aims of the course. The taught elements of doctoral studies and advanced research methods provided the foundations for developing and refining the research project; and the communities of practice, leadership and innovations in organizations were the most instructive in contributing to professional development, however all modules contributed to successful completion of the doctorate. The taught elements of the programme were relevant to the professional development as the author moved to a new post in October 2005 as Nurse Consultant in haemato-oncology and in December 2007 moved to Head of Nursing for Oncology and Haematology. The move to a more influential role as Head of Nursing and managing a team of 180 nurses with an annual budget of £7.5 million required advanced leadership skills to manage at a clinical level
but was lacking in some essential skills for a senior nursing management position, the latter of which will be described later in section 5.

Relationship diagrams are a useful and effective way of organising and identifying links between concepts, topics and variables (Finn 2005). They are also helpful in maintaining an overview of the different components of a complex topic and help to convey information that would be difficult to achieve in a written passage alone, allowing the complexity to be appreciated, but still allowing the individual components and their connections to be viewed. Therefore a relationship diagram was developed to demonstrate the links between knowledge, theory and clinical practice both in professional practice and the development of the research question (Appendix 1).

As the research journey progressed, the researcher changed and developed novel thoughts and new ways of thinking at several levels. Firstly, the understanding of the reality of cancer related anaemia and transfusion practice changed, for example, it was the uncertainty and inconsistency surrounding the management of the clinical problem that led to the research however, it emerged the socialization of transfusion behaviours was the major influence in this inconsistency and this had not been anticipated. Secondly, the fundamental ontological and epistemological positions changed as the project evolved, which was a difficult journey for the researcher, who was new to reflexive ethnography, and this will be described in more detail in the following section.

3.0 Knowledge and research development
Throughout the programme it was essential to improve critical thinking and theory development skill through extensive reading and thinking. An aspect of study, which
was crucial to the success of the research project, was the challenge of narrowing down a topic of study in a logical and coherent fashion to produce a realistic and feasible project. In other words, taking an idea from its inception through the various highs and lows and learning and using creative skills to recognize and/or develop originality to develop a project was the key to success. Chapter 1 of the research thesis demonstrates the origins of the research project and describes how the project changed to an ethnographic methodology; however, the shift of ontological position was not an easy journey because the researcher had a positivist approach at the outset of the project. In summary, this ontological shift was difficult to accept and using the ethnographic methodology to explore the messy nature of the social world in depth, including an acceptance that a more positivist approach would not be able to answer the research questions.

Previously a reductionist approach had been taken with regard to the science of method or “methodology”, for example, during the researcher’s MSc project. The development of the methodology in the doctorate research required an open approach, and by using a combination of extensive reading, critical thinking and discussion with supervisors and other experienced researchers, and medical colleagues, a final research methodological approach evolved to underpin the final project design. This was an iterative process and interviews and observations commenced, however, the literature had to be re-explored and advice sought from experienced ethnographers as to how to improve these data collection phases (see Research Log, Part 2). Although the willingness to change the methodology was driven by the need to answer the research questions in a more robust way it was difficult and highlighted the need for flexibility and creativity for successful research.
The data analysis phase was the most time consuming component of the research but it was the most rewarding and creative part of the four years, requiring culmination and integration of all the skills and knowledge gained from undertaking the doctorate. In summary, the research was an attempt to study the reality of the culture of anaemia and transfusion practice in the clinical setting. Denzin (1997) quotes Malinowski (1922) who was a founding father of ethnography summarized the purpose of ethnography:

"Find out the typical ways of thinking and feeling, corresponding to institutions and culture of a given community and formulate the results in the most convincing way" (xv)

The researcher attempted to do this within the sub-specialisms of haemato-oncology and lung cancer. A cultural model (4 main themes; chapter 5) was developed from the findings to bring some meaning to the actual practice and although not generalizable, "they may be relevant to other groups at other times and places" (O'Reilly 2009, 82). In summary, the aim was to inform and influence transfusion practice and the communities of practice module was reflected on as group knowledge and behaviours were important in influencing the decision making.

4.0 Professional Development

The emotional change in the shift of ontological position form a positivist to an interpretive epistemology described in section 3 and in Chapters 3 and 7 of the thesis also resulted in a change of professional behavior. A more open and less reductionist viewpoint and more critical stance has developed although it is acknowledged this was a
fluid change, with some resistance along the way. There are different ways of
developing clinical practice and there has been a recognition that human behaviours and
relationships massively influence the quality of care and this is not solely to do with an
individual's skills and knowledge.

The emotions and leadership module was the most influential in facilitating my
professional development, for example, the Myers-Briggs Personality Type Inventory
(MBTI) assisted examination of personal strengths and weaknesses as a leader and this
was developed further in the clinical setting by applying it to my senior team (Team
MBTI). Subsequently, this was used in staff appraisals (including 360 degree appraisal
methods) which then facilitated the team to improve teamwork, by improving behavior,
individual development and communications. Recognizing that emotions were important
and required to be controlled and/or harnessed to improve functionality and productivity
not only in oneself but in others influenced my leadership and management skills.

Strategic development and the policy review and service development projects
contributed to overall professional development, specifically in relation to the Nurse
Practitioner role and Nurse Consultant role. Research demonstrates that nurses can do
some of what doctors do and often to the greater satisfaction of patients (Shum et al
2000; Venning et al 2000). Whilst undertaking this doctorate I moved from Nurse
Practitioner to Nurse Consultant and finally to Head of Nursing. This was a natural
development from being a medical substitute in the Nurse Practitioner role to leading
clinical aspects of a service, for example the rapid access lymphadenopathy service and
late effects clinics in the role of Nurse Consultant, to leading a team and facilitating team
development and improving nursing services and standards in the Head of Nursing role.
The success of each of these roles was greatly influenced by the doctorate programme, facilitating initially improvement in self but more long-term improving others by influencing on a larger scale, as I moved towards leading a team of 185 nurses. This may not have been achievable or certainly less successful if the Doctorate in Clinical Practice had not been undertaken.

On a broader scale, one of my expectations and needs from undertaking this doctorate was to improve interdisciplinary debating skills to help reduce boundary disputes and work towards capitalizing on the wealth of skill that all the team can bring to bear on solving health problems. As confidence improved throughout the four years, these perceived restrictions to behavior dissolved and the ability to put one’s point across on a convincing and coherent way improved as did critical analysis skills. This not only enhanced my personal strengths but influenced the local and wider nursing workforce.

Therefore in summary, the key components of my professional development were:

- Understanding my personality type and using my strengths to develop myself and other team members; and managing my weaknesses to improve productivity and performance
- Development of verbal communication skills, participate in group-discussion, intervene in meetings and present cases and deal with criticism, demonstrating greater analytical and critical thinking skills
- Improved critical thinking and reasoning skills and using evidence appropriately to persuade organizational teams to explore and develop innovative practice
- Development of strategic knowledge and using this knowledge to enable implementation of novel practice and bring about change.
- Exploration and greater insight of my personal ethical framework and broadening my ontological perspective to apply it both in practice and research
- Development of advanced team working skills in order to implement "the learning organization" (Garside 1999; 211) in practice. Garside (1999) describes the difficulties in challenging the norms so systems and practice can be unlearnt and re-learned. In relation to the research project, this was and continues to be a challenge in changing the management of anaemia, where blood transfusion practice is influenced by the culture of the clinical setting.

5.0 Limitations and recommendations

Healthcare systems and policy is constantly changing and there is the need to measure and be able to eloquently describe what it is that nursing contributes to the healthcare systems to ensure efficiency and efficacy of the nursing workforce. The deliverables and outputs of nursing have to be measurable and quantifiable and in more recent years nursing metrics and Key Performance Indicators are being developed. If the outputs are measurable this empowers nurse leaders, but nurses need to be equipped how to develop these and use these systems to benefit nursing and patient care. How to develop and use these measures as well as how to develop the skills to financially manage a budget were not incorporated into the doctorate programme. The lack of knowledge and skills about the economics of healthcare (e.g. commissioning; drug expenditure etc) weakens the post-doctorate healthcare professional as this information is learned by default and therefore limits the nurse leader, in being able to communicate or challenge other professionals to the required standard. The doctorate programme would be strengthened if the economics of healthcare systems were incorporated into future programmes.
6.0 Conclusion

In summary, undertaking a Doctorate in Clinical Practice was more a process of "adding to" a well established portfolio of knowledge and skills and fine tuning what was already in existence, but more importantly it resulted in a shift of attitudes and critical analytic skills. Undertaking a doctorate program was a continuation therefore, albeit a more intense period, of lifelong learning and development. It required hours of reading and more importantly, hours of creative thinking and reflection, to achieve the end product, but this would not have been achievable in isolation and the contribution of the supervisors and taught elements of the programme are acknowledged (see Research Log, Part 2). Although it included self-direction and motivation as well as self-discipline, resilience and tenacity and the ability to prioritize and juggle a number of tasks at once, to essentially project manage the research; the support and advice of the supervisors was essential.

In summary, fulfillment of learning and development was successful and resulted in an increased confidence to design, undertake and implement high quality research in the field of clinical haematology and the skills to hold one's own in the wider field of oncology. It has also given me the confidence to write and publish more as well as contribute to assisting others with project development and management, and my publication portfolio has increased in the last four years. Furthermore, it has made me more, well-equipped and therefore more powerful to anticipate, influence and lead change in an ever-changing world and more prepared to question one's own practice as well as that of others.
Appendix 1: Development of self: Integration of elements of the program plus learning that has resulted in integration of knowledge, research and practice

**Taught Modules**
- Introduction to doctoral studies
- Professional ethics in a risk society
- Advanced research methods for the reflective practitioner
- Policy, politics and power
- Communities of practice
- Emotions, leadership and innovations in organisations

**Formative and summative projects**
- Review of learning and development needs
- Topic review
- Policy review
- Annual reviews
- Research proposal
- Log book
- Academic paper
- Overview of the integration of knowledge, research and practice
- Portfolio
- Viva voce

**Professional Development**
- Supervision sessions with research supervisors
- 1:1 with nurse manager and clinical lead
- Cancer strategy team
- Operational meetings
- Leading on projects, e.g. developing nurse services
- Developing the clinical team
- Clinical supervision

**Publications**
- Book chapters
- Peer review papers
- Conferences

**Development of self**
- Increased knowledge of policy and strategic planning
- Contemporary practice
- Advanced practice
- Innovative practice

**Personal Relationships**
- The team
References


Policy Review
Service Development Project
Research Log

by

Liz Bishop

THESIS
Submitted for the degree of Doctor of Clinical Practice

PART TWO

Faculty of Health and Medical Sciences
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Introduction

Part two of the thesis incorporates the policy review, service development project and the research log. The policy review describes the NHS Knowledge and Skills Framework (KSF) under the Agenda for Change (2003), followed by an exploration into the evolution of the policy, with reference to the socio-economic and political environment, and workforce influences. The policy review also explored the Knowledge and Skills Framework with reference to advanced nursing practice roles. At the time of undertaking the doctorate in clinical practice the author was an Advanced Nurse Practitioner and moved into a Nurse Consultant post in Haematology and therefore had an interest in how "medical work" undertaken by nurses was integrated into the KSF framework; particularly as the KSF excludes the medical profession. The research project described in Part 1 led to greater understanding of learning skills and knowledge in the clinical setting, and it is now appreciated that the KSF does not easily incorporate the tacit-intuitive learning and shared knowledge between professionals. The KSF is inflexible and does not accommodate easily the assessment of practitioners' holistic skills and knowledge acquisition and therefore it does not solve the problem of blurred professional boundaries, and this is described here. Finally, the policy review concludes with a description of the limitations of this policy implementation.

The second section of Part 2 describes the service development project, which included the audit of blood transfusion practice in oncology and haematology; this demonstrated a difference in practice between these sub-specialisms. The audit was described in the research thesis (Chapter 3, section 3.3) and revealed that variations in transfusion practices existed, but it was assumed at the early stages of the doctorate programme that the variation was due to different levels of skills and knowledge between the oncology and haematology clinicians. The research has demonstrated the
complexity of transfusion practice and argued that the decision making was shaped by the culture of the clinical setting. Therefore, the service development project conclusions that using strategies to increase the skills and knowledge of the clinicians did not reflect the reality of transfusion practice. The four year doctorate journey therefore started with a narrow view of skills and knowledge, reflected in the KSF policy review, which had not explained the complexities of clinical practice; the service development project started to generate some further questions and the research contributed to the understanding of how clinical behaviours develop in the clinical setting, albeit in the narrow field of transfusion practice.

In the third section, the research log maps out the pathway learning for the author of the clinical doctorate. It was a convoluted pathway with substantial amendments to the project and as described earlier from the early view of skills and knowledge it emerged that healthcare behaviours, including the development of expertise, is shaped by the culture and not merely absorption of biomedical knowledge and skill acquisition. The research log demonstrates the time frames for the researcher’s journey and should be read in conjunction with the “Overview of the integration of knowledge, research and practice” paper in Part 1, which brings together all of the elements of the clinical doctorate.

Finally, Part 2 concludes with a conclusion of the integration of the two parts of the final thesis and describes how the different elements of the doctorate programme fit together to provide a unique contribution to the practice of transfusion, and more generally to learning skills and knowledge in the clinical setting.
The NHS Knowledge and Skills Framework

(NHS KSF): A Policy review

1.0 Introduction

In 1999 the government published a paper "Agenda for Change: Pay Modernization in the NHS" and this initiated the largest radical shake up of NHS payment systems since the evolution of the NHS in 1948, applying to over a million NHS staff (DOH 1999a). As part of the process, the NHS Knowledge and Skills Framework (NHS KSF) policy was developed which lies at the heart of the career and pay progression strand of the "Agenda for Change" and applies to all healthcare professionals with the exception of doctors, dentists and some board level and other senior managers (DOH 2004). The NHS KSF attempts to describe the knowledge and skills, which NHS staff need to apply in their work in order to deliver quality services. The challenge is to bring coherence to a chaotic and fragmented healthcare system, maximizing the contribution of all the different professional groups, with the over-arching purpose to facilitate the development of services so that they better meet the needs of the users and the public by investing in the staff. In summary, the KSF was developed with the intent to bring fairness and equality to the education and training and promotional systems within the NHS.

The NHS KSF is designed to support the healthcare workers and facilitate their learning and provide every member of the service with the same developmental framework thereby producing high quality services for the public indirectly. With current concerns of staffing the NHS, the KSF (and Agenda for Change) is an attempt to prepare the future healthcare workforce by providing fairness, equity and a formal structure for staff.
development. Previously, many healthcare institutions have attempted this at local level but there has been a pressing need to develop policy at macro level. This has resulted in the development of national, competency-based assessment systems, culminating in the NHS KSF policy. However, the implementation of this relatively new policy was always going to be contentious, as the different professional groups have historically resisted the notion of cross-professional, competency-based assessment systems (Masterson 2002). The national programme is not yet fully rolled out and it may take some time to establish if implementation has resulted in the aims that it was designed to achieve.

A feature of many health policy documents is the recognition of a pressing need to redesign the workforce. This is not a new phenomenon but until relatively recently, redesign was formulated by single professional disciplines. Little regard was given to the impact of change by one discipline on rest of the healthcare professionals, however, this is starting to change and a range of documents have been published which acknowledge that unless workforce design is undertaken in an integrated manner across all disciplines, it is unlikely that any solutions will provide the highest quality of service with the limited financial and human resources available (Benton 2003). The Wanless review (Wanless 2002) takes this further by stating:

"Changing skill mix and increasing workforce capacity cannot happen quickly: it needs to be planned and actively managed......But before the end of the decade, there needs to be considerable progress on skill mix and pay modernization to avoid capacity constraints" (para 5.57).
While the NHS KSF attempts to unite the workforce, there continues to be a range of policy threads in the form of pay modernization that seem to be inadequately connected, for example the Consultant contract Framework (DOH 2002) and the NHS Plan (DOH 2000). The interdependence of disciplines is real and any action taken by one professional group in terms of role redesign or workload transfer will have an impact on other groups and the reality is that cross-professional knowledge and consideration of these changes is rarely found. For example, do medical colleagues support, or even understand, the changes involving non-medical prescribing? Was the impact of reduction in junior doctors' working hours integrated into the other healthcare workforce plans prior to implementation? The KSF has attempted to unite the workforce and integrate the healthcare professions but in reality how successful will this be? This paper will address how far the KSF has worked towards preparing the future workforce for the effective running of the NHS and undertake a thorough policy analysis of the KSF in an attempt to determine the origins and meaning of this policy in particular relation to redesigning future roles in advanced nursing practice.

2.0 Policy Analysis

Policy analysis involves a detailed process of examination, dissection, evaluation and research of a specific policy and it contains three central ingredients: "the policy making process, its context and the use and development of theory" (Harrison 2001). The NHS requires adaptation and reform if it is to survive the increase in demand therefore a policy analysis framework examining future requirements and preparation of the workforce of the future would be appropriate for detailed examination of the KSF. The Human Resources Development Policy Formulation: A Framework for Analysis (WHO Health systems 1998) will be used to facilitate the in-depth analysis of this policy with detailed study of the political context in which it evolved and the major influences in
shaping this policy (WHO 1998) (Diagram 2.0). The context of policy development in diagram 2.0 refers to the overarching political and socio-economic environment, disease patterns and the involvement and degree of influence of various stakeholders. The policies refer to the macro-economic policies and major government organizational reforms for example, the labour government's intention to modernize the welfare state system when they came into power in 1997, as well as inclusion of the policies themselves. The support systems refer to information technology; human resources and financial planning that are required for planning and implementing workforce planning scenarios.

The relationships between each component within each factor and their individual or cumulative effects on policy development are complex and highly interconnected. Many may have indirect effects, and their influence is mediated through other factors and dynamics, for example the historical power of the medical profession. This makes it difficult to isolate the precise impact of any one of the factors and although the tool provides a basic framework to facilitate policy analysis, it does therefore mean there are limitations. For example, not all of the above have shaped the development of the KSF and some have been more powerful influences than others, for example, future workforce capacity has had a major impact, yet some of the professional bodies have not. In addition, some players have not been considered, for example, the private sector. The wider issues of traditional practice and staff attitude are not incorporated into this model yet this has a major impact on how the KSF policy rhetoric will be translated into practice. The NHS and its various professions have a long history of tradition, particularly medicine and nursing, and this undoubtedly influences policy evolution. Furthermore, the strength of the professional bodies may also hinder implementation of the NHS KSF by contributing to gaps and slippages in the accurate implementation of this new policy. A form of critical or discourse analysis of the KSF policy will reveal the motivation and politics involved, as well as an interpretation of the conditions behind this policy, to allow a comprehensive review of this new policy. In summary, a critical analysis using this framework as a policy analysis tool, recognizing the above shortfalls, and an exploration of the relevant forces, will culminate in a theory of development of the NHS KSF.
3.0 Description of the KSF

Undoubtedly the NHS is a knowledge-based service but despite the critical importance of knowledge and skills, historically there has been a general and persistent failure to provide the NHS with information about, how the service runs and knowledge transfer between the different services sectors, which are central to the effective running of the service. There appears to have been a lack of basic information about “what is going on” and a wide range of technical issues, many of which had been recognized since the early days of the NHS, but which had not been tackled systematically. The need for information and understanding in these areas is growing rather than declining and in addition, there now seems a desire to prepare for the future rather than the traditional NHS approach to change, which tended to be reactive. It could be argued the development of the KSF is required to guide the service in whatever is the chosen direction. The focus of the NHS KSF is not to describe what attributes a worker has, but rather on how they apply their knowledge and skills to meet the demands of the work of the NHS. It seeks to describe what people actually do and focuses on the application of knowledge and skills, rather than individual talents. The KSF is a key tool for describing and redesigning future roles and this framework has been designed especially for the NHS and is capable of describing a wide range of current roles. It is made up of 30 dimensions with six core dimensions which are relevant to every post in the NHS: these are communication, personal and people development, health, safety and security, service improvement, quality and equality and diversity. The other 24 dimensions are specific and apply to some but not all jobs in the NHS. For each dimension the government has provided a brief summary and all dimensions, whether core or specific, have a number of levels. Most dimensions have four levels, but there are a few that extend to five. For every level there is a more detailed description that helps to explain what is required in terms of the knowledge and skills associated with that dimension at
that particular level. In addition, further indicators that help assess whether a particular competence is being met are given alongside examples of their application and how they relate to previously published benchmarks.

The NHS KSF claims several long-term benefits for patients, public and the NHS workforce and can be summarized as follows:

- Improving the quality of care through embedding the principles of good patient care in the development and review of staff and linking the KSF to policy imperatives

- Improving recruitment and retention by embedding good human resource management into the service

- Improving teamwork

- Greater innovation in the deployment of staff by providing a tool for role design

- Improving equality of opportunity and diversity. The NHS KSF introduces for the first time an NHS wide framework applied equally for all staff in development, review and career progression

- Improving career development by providing an integrated service-wide framework that shows progressive levels of application of knowledge and skills that can be used flexibly to careers in the NHS
• Improving morale by providing an open, explicit and fair development

• Improving pay

In summary, for every post in the NHS a post outline based on the NHS KSF will be developed, with the exception of medics and some senior management roles. Outlines must reflect the requirements of the post and not the abilities or preferences of the person who is employed in that post. This describes a rather pragmatic approach, however, a wide range of professional and non-professional groups of workers are involved, which inevitably will lead to conflict when trying to manage such a vast and diverse work population. It is these issues, as well as the context of KSF development, which will be described in the following sections, with particular reference to advanced practice nursing roles.

4.0 The evolution of advanced practice nursing roles

The NHS Plan, published in 2000 (DOH 2000), outlined the government’s strategy to modernize the NHS and set out a programme for reform, identified performance targets for the service and detailed the government’s plan for investment in the NHS. In relation to nursing, it was the aim to enhance the skills of the workforce and remove professional boundaries. Alongside of this policy, healthcare restructuring and increase in demand for some services, for example, patient support and information, has led to substantial increases in different types of advanced practice roles, for example the Clinical Nurse Specialist (CNS), Nurse Practitioner and Nurse Consultant roles. The Nurse Practitioner, typically undertakes some medical tasks and can “diagnose, refer, prescribe and provide complete episodes of care for clients with undifferentiated healthcare problems” (Stillwell 1985). Alternatively, the CNS role has not been regulated and in the past there has
been no specific educational or experiential requirements resulting in wide variation of services offered. The Nurse Consultant, on the other hand, is closely linked to explicit NHS priorities and expected to establish cross-boundary inter-agency creative solutions but may be used inappropriately as some Trusts employ consultants because it may be a more attractive role and thereby aiding recruitment, rather than arising out of clearly defined organizational goals. The lack of consensus on how to define advanced practice and the variety of nursing roles that exist has contributed to the latest policy development with higher levels of practice, (although not finally defined yet), to be registered on a separate section of the NMC register. The competencies will be revised to align them with the KSF, and the nursing committee will develop a registration system and propose a process for accommodating existing practitioners (due September 2005). Despite it being a primary aim, it is unlikely that introducing these new standards will reduce the excess of titles that currently exist, although work will continue with this (Walter 2005). This formal recognition and registration of advanced practice should be welcomed as it has been devised to protect patients from nurses who adopt such titles but without the necessary education, skills and knowledge.

There is general consensus, in several models, that clinical practice is the primary focus of these advanced practice roles (Bryant-Lukosius et al 2004) but the evolution of these advanced practice roles has probably arisen under a variety of circumstances as described earlier. For example, some argue that advanced practice nursing roles have arisen out of an emphasis on reducing costs and is in fact experimentation and nothing more than a stopgap for the shortage of doctors (Castledine 1995). Not surprisingly therefore, role conflicts and role negotiations are a way of life for advanced nurse practitioners (Dowling et al 1996). How role domains are defined varies depending on the model, for example Manley (1997) identified four integrated roles related to direct
and indirect expert practice, education, research and consultation with knowledge and skills related to transformational leadership, collaboration and organizational development. The Synergy Model (Maloney-Harmon 1999) identifies eight domains of practice for clinical nurse specialists and these relate to clinical judgement, clinical inquiry, teaching/learning, collaboration, systems thinking, advocacy/moral agency, caring practices and response to diversity. The Strong Model identifies five domains for the acute care nurse practitioner, including direct comprehensive care, support of systems, education, research, publication and professional leadership (Ackerman et al 1996). Whatever model is applied these are all fairly generic competencies, which can be applied to both medical and nursing domains but do not explore in-depth the concept of specialism. Specialism, and indeed sub-specialism, is increasing as treatment and care becomes increasingly complex; nursing and medicine and some of the other allied healthcare professionals use some generic skills and specialism usually follows thereafter, whereby the professional focuses on either a particular practical or theoretical branch of their profession. Some of these skills are not easily transferable and some skills developed by advanced nurse practitioners have expanded into areas traditionally seen in the medical domain. Equally, however, some doctors have developed particular interest in counselling and support, which would have been traditionally viewed as nursing activities. This “blurring of boundaries” suggests skills and knowledge should not be categorised into nursing or non-nursing or medical activities and the labelling of procedures into “medical” or “nursing” must be considered to be historically dated in the current climate and conflicts with the modernising of the NHS which, has been high on the political agenda for many years now.

Essentially the KSF and Agenda for Change were driven by this need to modernize the healthcare workforce systems and pay systems. One approach to solving this problem
would be to establish "ideal" requirements, for example, appropriate technology and resources with professionals being motivated to change (Harrison 1994). Rushing and Smits (2005) developed a framework analysis for creating the ideal workforce in their work in various countries setting up new workforce systems (see Table 4.0). The KSF incorporates some of these systems, for example, the fundamental principles of lifelong learning and competency based practice. However, one could argue some of the major players have been excluded from the KSF policy, such as the medical professional bodies therefore there is not flow and progression amongst the healthcare workforce. These and other issues will be discussed in more detail when examining the political and social context of policy development of the KSF.

Table 4.0: Criteria for the ideal workforce training and education system (Rushing FW and Smits 2005)

<table>
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<td>Be customer driven-organized around the needs of students, workers and employers</td>
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<td>Be easy to find and enter, and be designed so that people can move easily between programs and the workplace.</td>
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<tr>
<td>Meet the needs of all learners, including those who have under-served in the past because of racial, ethnic or cultural differences, gender, disability or learning style</td>
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<td>Provide support services such as career counseling, childcare and financial aid to those who need them</td>
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<td>Be competency-based so that all students are able to master the skills and knowledge they need in as much or as little time as they need to do so</td>
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<tr>
<td>Be staffed by people who are prepared to teach a diverse student body and who have relationships with employers that help them to stay up-to-date with changes in their own fields</td>
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<tr>
<td>Be co-ordinated with private sector programmes, with social and other services and with economic development strategies</td>
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<tr>
<td>Be based upon full partnerships between business, labour, and training and education</td>
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<tr>
<td>Rely on the best labour market information, so that people acquire skill that local industries need</td>
<td></td>
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<tr>
<td>Provide students and workers with a foundation of basic skills to equip them to be lifelong learners</td>
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<tr>
<td>Be accountable for results and committed to using outcome measures to continuously improve programme</td>
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It may be that advanced nurse practitioners are evolving as a discrete professional group, outside of the traditionally accepted definitions of nursing and medicine (Barton et al 1999) but it may not be ideal to create another separate group if one were to apply the above Rushing and Smits model. It will be interesting to see how these new roles can be integrated into the KSF because medicine is not included.

Clear boundary definition cannot be based on knowledge alone because both medicine and nursing draw from the same core academic disciplines. As Barton et al (1999) states: "preventing or limiting movement of occupational boundaries, by rigidly defining particular skills lacks insight into the very evolution of occupations and professions" (p59). In theory the KSF seeks to unite the professions, however, the exclusion of medicine does not fit with the emerging philosophy of a needs based service irrespective of professional boundaries. For example, how are the competencies of medics assessed? Is there a separate framework for skills assessment or is it still working on the traditional "watch one, do one" principle? In addition, if the Rushing and Smits model is applied, the KSF does not allow easy migration of the workforce: a healthcare professional may have the necessary skills and knowledge but still has to remain within their professional body. This will inevitably lead to conflict and lack of definition for advanced practice roles.

In summary, there is now a driving force to reconfigure healthcare systems, largely driven by the need to provide quality healthcare with limited resources and a situation where the NHS is making the most of what staff it currently has because in the current climate it is unlikely many more staff with the necessary skills and knowledge will be readily available. In the interim period there has been considerable scope for making better use of nursing staff in specialist roles but this has been hindered by rates of
recruitment and retention. There is a need for improved education and training for non-medical staff, who could take on the functions of doctors but the standards are variable and services patchy and some doctors are unwilling to delegate functions when they are unsure of the skills of the staff. In addition some nurses have been trained to perform tasks but are reluctant to continue performing; there may be many reasons for this, for example, they may feel unsupported or have been inadequately prepared. It may be that nurses are struggling to reconcile the tension between advancing their technological skills and retaining their caring role. Perhaps nurses and medical staff should share responsibility for these activities rather than transferring them wholesale to the nurses' domain (Cahill 1996). Cahill further explains one of the criticisms of advanced practice is that it is aimed at conserving the expensive energies of doctors, particularly when one examines the emerging roles of Surgical Assistant and Nurse Practitioner. The National Association of Theatre Nurses is uneasy for example about the way in which the surgical assistant is developing: "(we)... must be clear why these roles are being introduced and ensure they improve the quality of patient care" (NATN 1996, p49). It could be said one of the major driver of KSF was to facilitate nurses and other healthcare professionals to take on the dull and repetitive tasks of doctors but conflict arises over who is responsible for the new service and who is accountable should errors occur and who will accredit such practitioners, even if outcomes can be made explicit? (Manley 1997). Again, it will be interesting to observe if the KSF will help give clarity and definition to extended role development and advanced practice nursing. This combined, with the new legislation for separate registration under the auspices of the NMC should in theory help resolve some of the questions raised, but may not answer all of them.
5.0 Context of development of NHS KSF

This section refers to the political and socio-economic environment that helped to shape the development of the KSF. It then focuses on patient need and how this shaped the evolution of the policy, and describes the major players and the professional influences, and finally describes the KSF and conflict with the private sector.

5.1 Political and socio-economic environment

The labour government elected in May 1997 has set the reform of the welfare state to be one of its major tasks (Powell 2000). The third way has evolved, which is a new and distinctive policy approach, which differs from the old left and the new right (Klein 2001). It is argued that the third way is best summarized by a new acronym "PAP", which is that of Pragmatism And Populism (Lister 2001; Powell 2000) and broadly speaking encapsulates the idea of an alternative to both capitalism and socialism (Heywood 2003). Lister describes this "Populism" as an attempt to "woo rather than lead the electorate" and "Pragmatism" as a "problem solving or what works" approach rather than a direct assault on structural inequalities (Lister 2001, p428). The KSF could be argued to be a populist policy in that it attempts to provide equanimity and as part of Agenda for Change modernize the pay structure. However it already excludes some healthcare professionals therefore it cannot be equal. Certainly it is a pragmatic approach to attempting to define the core competencies, which must exist if one is to provide an equal service and is an attempt to define the reality of healthcare provision and meet the needs of the population.

The new labour seeks to move from a passive to an active preventative welfare state and with the NHS focusing on more pro-active policies such as preventing illness rather than concern with repair or treatment (DOH 1998; DOH 1999b). Health system reform
must balance two systems: in the short term they must utilize existing services to meet the needs of the population and at the same time improve the health of the nation (Black 2002). It is no longer a question of just throwing money at the NHS in a reactive way but focusing on long-term issues in a continuous way. The emphasis is now on devolving responsibility back to the individual and this personal responsibility lies at the heart of the third way. The KSF fits with the principle of the third way in that it is seen as a continual process rather than a once off episode of development and certainly devolves responsibility back to the employee to maintain the necessary skills and knowledge in which to provide a quality service.

Finally, the third way embraces the idea of competition or market state. A competition state is:

“a state whose principal role is to pursue strategies for national prosperity in conditions of intensifying global competition. The state should therefore concentrate upon social investment, which means improving the infrastructure of the economy, and, most importantly, strengthening the skills and knowledge of the country's workforce” (Heywood 2003, p151).

This approach to the economy focuses on supply, aiming to boost production and improve competitiveness, rather than a democratic “demand” approach, which aims to increase consumption and eradicate poverty. Education and personal development is valued in this approach because it promotes employability and benefits the economy in an indirect way. From this perspective the government is merely an enabler, setting the scene by re-shaping the workforce attitudes, values, beliefs, skills and knowledge rather than directly shaping the economy. This has resulted in the UK government having an
increased interest in competence. Essentially healthcare provision relies on the professionals possessing a variety of skills and being competent in those skills. In an increasingly litigious society it is essential there is proof of possession of skills. Furthermore, increasingly patients have rights to complain and there is increased consumer interest in healthcare standards, with media coverage and sometimes hype surrounding poor standards or errors or omissions of care. In theory, the KSF enables this process, legitimizing the knowledge and skills required to provide a service, and thereby is a format for providing evidence for particular skills should complaints arise. It could be seen as a way of protecting patients and the system from unsafe practitioners.

5.2 Demographic and epidemiological environment
Ultimately it is patients who create the demand for health services and trends undoubtedly influence this demand. Non-communicable disease will most likely represent the main burden of mortality and morbidity in the future with respiratory disease and cancer leading the field and increasing health risk related behaviours such as obesity and smoking (Sausman 2003). Furthermore, latest figures from WHO show that global cancer rates could increase by 50 per cent to 15 million new cases by 2020 (WHO 2003). There are several implications for the future workforce from the known trends in the burden of disease. First the prevention and treatment of chronic disease is likely to be a key function of future primary care, for example in the management of obesity and diabetes. Here it is envisaged, as in the Wanless report (Wanless 2002), that nurses will be taking on new roles in the prevention and treatment of chronic disease, in prescribing and in helping patients through treatment programs. Avoidable deaths from cancer and heart disease, suggest a more appropriate mix of services in the future of preventative, curative and community based and hospital based treatment. The emphasis may be on lifestyle adjustment with emphasis on prevention and screening.
This may mean new skills and knowledge development for the healthcare workforce, for example, health education and communication skills. The KSF has gone some way to meeting this new need, for example, by the inclusion of "health and well-being" dimension, focusing on the protection of health, health promotion and prevention of adverse effects. This is the first time they have been formally valued as an aspect of service provision, previously emphasis was largely on effective treatments. Secondly, with the increase in chronic disease burden there is a need to reduce healthcare costs. It was described earlier the economic burden of the NHS continues and health promotion and disease prevention could be potential sources of reducing costs. Costs may be reduced indirectly by investing in staff education and development in health promotion skills and this would be a major driver in shaping the NHS KSF.

The introduction of new policy should be driven by patient needs and the growing concept of "patient centred care" is emerging. Although, widely used, it is a poorly understood concept in practice and in reality it is often doctor centred, hospital centred or diseases centred care, which is provided (Stewart 2001). As the Commission for Health Improvement said in 2003: "too often care is still organized round the convenience of the NHS rather than the people who use the service" (Which 2005). The government believes patient choice will drive up standards and improve efficiency as well as provide more flexible and personalized care for patients. A study by (Little et al 2001) asked patients about patient centred care and it revealed that many doctors do not provide patient-centred care and demonstrated a fixed style. There is evidence of tangible benefit of patient centred communication and it is positively associated with patient satisfaction, adherence and better health outcomes (Stewart 1995). A recent policy report executive summary on patient choice (Which 2005) expects choice to transform healthcare and the NHS, creating "a more personalized NHS that is responsive to
consumers' needs" (p4). This represents a change in culture whereby choices about healthcare are about much more than reducing waiting times and choosing a provider for elective hospital care. The government wants an approach that puts patients at its heart and involves patients and the public in shaping the future of healthcare. Consumers of the healthcare service actually want "better locally provided services that are more flexible and treat them faster" (Which 2005; p11). This flexibility is at the heart of government reform including the philosophy, which underpins the KSF. This flexibility implies new ways of working, with perhaps different healthcare professionals taking on new roles to provide flexible care. This has been driven by patients, who want to see, "fewer faces and more personalized care" (Which 2005, p3). The current medical training does not sit nicely with this need, as rotation is required for training purposes; a possible solution is to use other healthcare professionals with extended roles and KSF may facilitate this development by providing a formal structure for the development of multidisciplinary teams working in new ways to provide this personal service. However, it may be there are opposing forces that prevent the use of alternative healthcare personnel to their full capacity and these will be discussed in more depth in the following section.

5.3 Major players

Contemporary healthcare involves a number of professional groups working together for the benefit of patients, yet professions still remain independent. They are educated separately, have different hierarchy, document care in different notes and even have different language and different priorities, which was demonstrated in the research project. However, there are very few healthcare tasks that are legally restricted to one group yet the professions still remain entrenched in their respective colleges and professional regulating bodies, however, in a number of areas the significant barriers are
being diminished, for example nurses can prescribe although this has been a painfully slow process and is still fairly limited. Nurse Practitioners are taking over work from General Practitioners and the contribution of specialist nurses with advanced skills to clinical teams in acute care is now widely recognised, with nurses providing equal or better care than medical staff (Ford 1997; Horrocks et al 2002; Marchione and Garland 1997). The Primary Care Act 1997 opened up new structures for primary care provision and in a few pilots nurses are taking the lead in providing and managing primary care and even employing GPs. It is clear from these examples that much effort has been put into team building and improving communication skills but attempts at working together continue to be restrained by differences in styles of learning, in career patterns, in models of working and in regulatory mechanisms and these developments have been sporadic and driven by individuals rather than policy. Moreover there is still little or no movement between professions, for example, it is no easier now for a highly experienced and skilled nurse to become a doctor than it was 30 years ago. The KSF still does not address this issue as medics are excluded but if “appropriate human resources are to be available to meet the healthcare needs of the coming decades these structural problems need to be addressed” (Doyal and Cameron 2000, p1023). If the nurse is teaching a medical colleague and providing clinical supervision where is this addressed in KSF therefore the equanimity that it promises to offer is lost. Where nurses take on the work of junior doctors (and in some instances senior doctors), for example in the case of the Nurse Practitioner there has often not been the supporting educational programme and it has been a case of “task drift” (Doyal and Cameron 2000, p1024) and have tended to be formulated locally and unsystematically (Dowie 1999). Under these circumstances the healthcare professionals report considerable stress of being unsupported in “no-man’s land” and the danger may be that patient care could be compromised rather than enhanced.
In assessing the strength of the varying professions and conflict of interests, the powerful position occupied by the medical profession is apparent (May 1992). Department of health policies that challenge the interests of key groups within a profession are likely to be resisted. The Blair government has been able to introduce changes to the regulation of the medical profession because of the accumulation of evidence about failures in clinical performance, for example, the Shipman report. But some of these changes have been painfully slow, for example, the time it has taken for clinical audit to become compulsory and independent review, such as the Cancer Peer Review measures. Such examples, "speak volumes about the ability of the profession to delay or resist policies that threaten clinical autonomy" (Ham 2004, p184). The medical profession is undoubtedly extremely influential as a service provider thus creating an interesting relationship between the profession and the government. Ham (2004) suggests this power results in considerable discretion being accorded to the medical profession because of the strong position of the being them main influence in service provision. It is not surprising, therefore, the medical profession, resisted the pressure to be part of the NHS KSF, protecting the professional autonomy and retaining power. The other professions were more easily wooed, with the promise of improved salary and working lives with the introduction of KSF and Agenda for Change. The Trade Unions of the other professional bodies were consulted and agreed in 2002 and who could resist with promises of "supporting staff to develop" (p5), "treating all individuals fairly and equably" (p4) and "simple and feasible to implement" (p6) (DOH 2004). It will surely take time to evaluate the implementation of KSF and to audit if it truly has fulfilled its promises to all healthcare workers, with the exception of course, of the medics and senior management staff (DOH 2004). What policy measures will be put in place to ensure these latter two groups will have the necessary skills and knowledge to be competent?
5.4 Private sector

Much of the infrastructure to prepare people for success in the world of work is in the public sector and this includes the NHS. The private sector will undoubtedly continue to grow but NHS policy has tended to ignore this growing sector of healthcare, not to mention the voluntary sector. If one returns to the Rushing and Smits model it is clear that all sectors should be included when preparing the ideal workforce. Ideally policy should encompass all healthcare systems if systems are to be seamless and in terms of KSF, if opportunities are to exist to advance knowledge and skills when healthcare professionals move from one system to another.

Patients currently have a choice whether to have treatment in the independent or public sector. Over six million people or around 11 per cent of the population are covered by private medical insurance in the UK (Ham 2004). The number of people with insurance has increased steadily throughout the lifetime of the NHS and expansion was particularly rapid in the early 1980’s, probably due to the influences of the Thatcher government. This trend will probably continue, although in recent years there has been a substantial growth in the numbers of people paying for private hospital treatment out of their own pocket with some estimates suggesting a three-fold increase between 1997 and 2002 (Timmins 2003). It is unclear if KSF will ensure the staff in this private sector will be appropriately competent and rewarded for their work. If one returns to the Rushing and Smits model of the ideal workforce planning consideration should be made to both private and public sectors. Just as patients have a choice about whether to have treatment in the independent sector so the professionals have a choice whether or not to work there. Independent sector employers have for many years attracted staff by implementing the “Improving Working Lives Agenda” (Taber 2002), offering flexible working hours, empowering staff and providing education and training, career
development and a clean working environment. If the KSF and Agenda for Change improves these systems for the NHS staff it may impact on the independent workforce (Kirk 2004). If healthcare professionals return to the NHS and deprive the private sector, how will this influence the choices offered to patients or vice versa? The exclusion of the independent sector from KSF contradicts the flexibility and patient choices outlined in other policy statements (DOH 2004; DOH 2005). It may be that in the current political arena the emphasis is on ensuring the NHS survives even at the cost of the private sector. The KSF is described as the “NHS KSF” and is not designed for knowledge and skills framework for both private and public sector therefore global health and workforce preparation is not being considered.

6.0 Support systems
This section refers to the systems that are required to sustain policy development and implementation. Firstly, the ever changing information and technology systems are described and how this will require flexibility in the workforce; secondly the human resource capacity issues are described, which will influence the degree of success of the KSF implementation. Finally this section concludes with a summary of the financial policies and climates that may contribute to sustainability of the KSF.

6.1 Information and Technology
The popularity of evidence-based medicine has offered the opportunity to challenge traditional medical practice and resulted in the shift of power base (Harrison 1998). “The essential character of a profession is that the members of it have specialized knowledge and skills which the public will wish to use” (Merrison 1979, p3). This traditional concept of a profession is being undermined by development in the volume of knowledge, which now exceeds the abilities of the individual profession to master it (Harrison and Dixon 392
2000). The pace at which new knowledge appears has increased and the emphasis on evidence-based medicine has undermined old practices. In other words it is becoming harder for individual professionals to master all the relevant knowledge and easier for non-professionals to gain access to it. In addition, increasing technology allows for greater ease of dissemination of knowledge, for example, it has been estimated there are 7 million websites, of which 100,000 pertain to health (Sastry and Carroll 2002). The combination of these factors should lead to a new approach to investing in knowledge and skill acquisition in terms of investment in people and providing a quality service. The rapid growth in clinical knowledge has been recognized through the introduction of continuing professional development for all the professions. The public, who are in fact the “ultimate financiers” of the NHS (Harrison and Dixon 2000, p239) are more informed, have access to the internet and are no longer passive users of the service (Cockburn and Pit 1997). The NHS Direct On-line and the “Expert Patient” represent the increasing significance of the role of the user and reflect the increased power of the patient in shaping policy development.

It is difficult to do justice to the current range of medical and technological advances. Web-based or IT based therapy may be offered in the future replacing some of what healthcare professionals do now (Sausman 2003) and information will be at hand on health issues on virtually any dimension. This may mean patients could be as well-informed as the healthcare professional and in some ways it will be easier for the patient to be more knowledgeable about a single aspect of health than the healthcare professional who has to be knowledgeable about many aspects of healthcare. The Technology Foresight Programme in the 1990's predicted that by 2010-2014, 10 per cent of surgical interventions could be carried out by robotic techniques (Robert 1999) and although this sounds fantastical at the current time, who could have predicted the
changes that keyhole surgery and angiography techniques would make? For the workforce such developments require the development of new skills and new knowledge. New surgical techniques, new therapies, on-line health services and electronic health databases will require specific skills in research, data and information management and other highly specific skill development. As well as the demand for new skills from the healthcare workforce, the impact of new and scientific developments will change existing roles from one professional group to another, and will need to influence the education and training of professionals. This need has forced the modernisation of competency-based care and the development of KSF. For example, this need has also included the recognition that information and technology skills must be formally integrated as valuable and necessary skills for the modern healthcare worker.

6.2 Human resources: national capacity
The NHS employs more professionals than any other sector of the economy. The labour force of the UK is projected to increase slowly in the future, reaching 29.8 million by Spring 2011 (Armitage and Scott 1998), with the proportion of women increasing to 46.1% of the overall workforce. The labour force will also be a little older but this is even more marked in the nursing workforce (Buchan and Edwards 2000). The ageing health workforce will require sustained improvements in recruitment and retention but the NHS is traditionally seen as a rigid career, which may not offer the benefits in terms of flexibility and pay that other skilled service sector professions provide, and thereby be a less attractive option for the new workforce entrants. However, security of career may be an advantage if recession and insecurity returns to the UK. In the future it may be labour markets are not only influenced by national trends but also by international trends because of increased in movement and technology. If so, the health sector will be competing with other industries (and countries) for a skilled and educated workforce and
there are some areas where there will be stiff competition (Sausman 2003) and there are ethical as well as supply issues when recruiting from other countries (Buchan 1998). In addition, dissatisfaction with national pay settlements has led many nurses to leave the NHS (Dowie and Langman1999). This means the health sector will need to deliver on making a career in the health service an attractive one in the future. The KSF and Agenda for Change have gone some way in delivering on this. The need for flexibility and increased pay under a modern system will alleviate some of these issues and this is to be welcomed but the decline in nurses and other healthcare workers is a real concern and may impinge on the success of creating a flexible workforce and introduction of new ways of working.

There have also been issues with supply and demand for medical staff. Reasons for shortage include an accelerating trend for consultants to take early retirement, greater demand for consultant delivered (as opposed to consultant led) service and higher numbers of women doctors (more than 50% leaving medical school are women) working in hospital specialties, some of whom may choose to work part-time or take a career break (Allen 2000; Dowie and Langman 1999). The government accepted the Medical Workforce Standing Advisory Committee’s (the Campbell Committee) recommendations in its demand for a 20% increase in the number of medical students; however, it will be a number of years before this has a real impact. In addition, younger doctors are more like their contemporaries outside medicine in terms of education and aspirations. They want flexibility in their careers and they find it absurd to waste their time performing mundane tasks. Portfolio careers will soon be here in medicine and the days of 40 years in one specialty in one place will be over (Allen 2000). The professions are going to have to change, with more flexible training and multidisciplinary working but as stated earlier there is often resistance to change (Allen 2000). As she quotes the Prime Minister
"There is the challenge for the professions to strip out unnecessary demarcations, introduce more flexible training and working practices and ensure that doctors do not use time dealing with patients who could be treated safely by other healthcare staff" (p 1533).

Another factor driving change in acute hospitals was the enforcement of the European working Time Directive which has made it difficult to provide 24 hour medical cover in many specialities and even more so in small hospitals. A government review examining decentralization of services suggested the development of extended roles for nurses and non-medical practitioners are essential to address the challenges of reduced availability of medical staff (DOH 2003). As mentioned previously the KSF supports this legitimising the process of role extension within a formal framework. This trend for frustration due to the time spent performing non-medical or mundane duties is growing in the medical profession. Since the 1980's it has been known that a large proportion of the time of trained clinical staff is used up by documentation, scheduling tasks, meetings and other administrative duties (Black 2002; Lathrop 1993). This places pressure to provide systems and utilisation of non-clinical staff to reduce the non-clinical workload burden. The KSF should facilitate the development of new roles to support medical colleagues as well as non-medical staff and thereby reduce their time spent on non-clinical duties. For example, it may be that “schedulers” are employed to co-ordinate cancer care pathways, scheduling therapies, staging procedures and ensuring all results are available prior to consultation. Skilled Clinical Nurse Specialists, or medical staff, currently perform some of these tasks, but this may not be the best use of their time, and best utilisation of their skills and knowledge. Furthermore the Clinical Governance Agenda demands more time is spent on audit, risk management and other quality issues which places further demands on the clinicians time with medics spending an extra four hours a week on management, administrative and professional activities, compared with 1989 and 2
hours less on clinical work (Dowie and Langman 1999). Some of this demand, however, may be relieved by the employment of clinical audit facilitators and quality assurance managers.

In summary, difficulties in recruitment are becoming so acute and widespread in the UK that they are likely to constrain service delivery and development (DOH 1999; Doyal and Cameron 2002; Masterson 2002). Workforce planning has been high on the agenda since the mid-1990's and the government has indicated that planning should examine how multi-professional teams can provide the best patient-focused services irrespective of professional boundaries (DOH 2000). Although this could be considered as a major driver for the development of KSF and Agenda for Change, the threats to available future labour workforce are a real concern and may not in fact be a driver to change but a resistor to change.

6.3 Macro-economic and financial policies
NHS expenditure has steadily increased over the years (Table 6.3). These increases were necessary to enable the NHS to meet the demands created by changes in demography, technology and society as described earlier. Analysts of the health service pointed out that there was not a fixed quantity of disease but there is potentially infinite demand (Ham 2004). This is because of the greater use of services by older people, opportunities for diagnosis and treatment opened up by developments in medical technology and of course what was alluded to earlier, the emergence of a new generation of service users with high expectation of the standard of care to be provided.
Table 6.3: NHS expenditure in the UK, 1949-2003 (Ham 2004, p74)

<table>
<thead>
<tr>
<th>Calendar year</th>
<th>Total (£m)</th>
<th>Total cost at 1949 prices (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1949</td>
<td>437</td>
<td>437</td>
</tr>
<tr>
<td>1954</td>
<td>539</td>
<td>434</td>
</tr>
<tr>
<td>1959</td>
<td>792</td>
<td>528</td>
</tr>
<tr>
<td>1964</td>
<td>1137</td>
<td>667</td>
</tr>
<tr>
<td>1969</td>
<td>1733</td>
<td>814</td>
</tr>
<tr>
<td>1974</td>
<td>3835</td>
<td>1151</td>
</tr>
<tr>
<td>1979</td>
<td>8855</td>
<td>1255</td>
</tr>
<tr>
<td>1984</td>
<td>16080</td>
<td>1447</td>
</tr>
<tr>
<td>1989</td>
<td>25690</td>
<td>1765</td>
</tr>
<tr>
<td>1994</td>
<td>39715</td>
<td>2200</td>
</tr>
<tr>
<td>1999</td>
<td>52264</td>
<td>2518</td>
</tr>
<tr>
<td>2003</td>
<td>74343</td>
<td>3229</td>
</tr>
</tbody>
</table>

High rates of growth in the 1960s and early 1970s gave way to lower increases in the late 1970s and 1980s in terms of the cost of the NHS as a percentage of gross national product (Ham 2004). The Thatcher government was a major influence in tighter control of public expenditure with emphasis on efficiency, privatization and competition. Social expenditure was subject to close scrutiny. This trend changed with the arrival of the labour government in 1997 and the comprehensive spending review initiated by the government, which from 1999 resulted in a return to higher increases. In 2002 the Wanless report outlined the technological, demographic and medical trends which may affect the NHS in an effort to determine the financial and other resources required to ensure the NHS could continue as a publicly funded, comprehensive high quality service on the basis of clinical need and not on the ability to pay. It was to inform the government on future decision-making on NHS spending. It concluded that tax financing of healthcare should continue and not be replaced by social insurance or private funding as confirmed in the NHS Plan. It also noted that the UK were lagging behind some other countries in health outcomes, partly because of the lower levels spent of expenditure on health in the UK (Irvine et al 2002). It identified a number of factors likely to increase
spending on health care over the next 20-year period including rising patient and public expectation, advances in technology and a recommendation that better use is made of information and computer technology. It also recommended the need for stronger links between health and social care and as stated earlier greater emphasis on disease prevention and health promotion. Although the Wanless review did not necessarily break new ground it was an extremely important influential report for securing the future financial sustainability of the NHS. In summary this government's financial commitment to the NHS is reflected in the development of the KSF designed solely for sustainability of the NHS and protection of the workforce.

7.0 Conclusion

It is clear the NHS is continually being reshaped in response to changing needs and fashions, as well as the struggle for power between different professional groups. If one brings together the driving forces that led to the development of the KSF it has been a process that has evolved over many years. Inevitably tensions exist which may hinder the implementation of this policy, for example, problems already exist when professions work out-with their traditional boundaries in terms of existing advanced practice roles. These forces can be grouped and include drivers and resistors to change (Diagram 2.0). National and global policies and financial stability undoubtedly influence healthcare policy because they inevitably have an impact on the workforce. The purpose of this critical or discourse analysis of course, is not to provide definite answers, but more to reveal the hidden politics as well as reveal possible interpretations of the development and subsequent implementation of the NHS KSF. It may also shed light on any flaws in the policy, for example, the exclusion of non-public sector healthcare workforce issues, or forecast any problems with implementation of the policy. In summary, the development of the NHS KSF was inevitable when the driving forces are examined.
(Diagram 2.0), however, it may be that now the policy is in place the "resistors" will prevent the successful implementation of this policy and there will only be lip service paid to the liberation of the professions.

It has been difficult for the NHS to examine long-term issues, including workforce development and therefore policy formulation has tended to be reactionary rather than visionary. Here the need is to create genuine flexibility between different professional roles, as there is the same ultimate goal of providing excellent service provision for the users of the NHS. Although such flexibility is creeping in there still remains some fundamental errors in the KSF policy. If boundaries are truly blurring why were medical staff not included in the KSF? Are their knowledge and skills any different to the other professions? And how is the UK to address this with its current shortage of doctors, nurses and other professionals? Perhaps the way of the future of the NHS is to provide teams of "Healthcare Professionals" equipped with the necessary knowledge and skills without any other restrictive professional bodies. These artificial barriers have hindered development in the past and there may be a need to become more open-minded at an individual and institutional level. However, if the professional bodies are disbanded, this may impact on the ethical and professional standards as there will be no regulatory systems or alternatively, new systems will have to be devised.

In terms of advanced practice nursing roles the KSF may help provide clarity as nurses struggle to fill gaps in the service and assist with the preparation of more junior colleagues for advanced roles. It may also assist with preparation of non-professionals to develop new knowledge and skills, which will ease the non-clinical burden from the clinical staff. However, it does not cover the multitude of shared responsibilities and shared learning in the workplace. An awareness of the resistors to KSF and the
potential of outside forces to influence the successful implementation of this policy will hopefully prepare nurses in advanced clinical roles be aware of the pitfalls of role development. For example, failure to truly apply cross-professional knowledge and skills will be devastating in terms of service sustainability and will frustrate career pathway redesign, particularly for nurses taking on advanced practice roles. It is important that the individual disciplines understand the longer term cultural, career, service, education and regulatory impact of changes that are relevant to their sphere of practice as well as that of other colleagues who form part of the increasingly complex team.

The NHS KSF has tried to address certain kinds of knowledge, for example, non-clinical and managerial knowledge that have been previously neglected or deemed to be of secondary importance. These gaps have become more evident as the NHS has been increasingly called to account for its performance as a system of care and a user of national funding. This “calling to account” whether it is through more effective external audit or through politically driven measures to improve performance has revealed an organisation short of many of the skills and the knowledge base required to provide an effective system of health care delivery. The KSF and Agenda for Change policy may offer signs of hope but time will tell. It may be the exclusion of medics and senior management staff will hold back the changes that KSF and Agenda for Change may have allowed, because ultimately these personnel form the bulk of the healthcare power base.
References


Buchan J (1998) Ethical recruitment from other countries. Employing Nurses and Midwives. 5, September 6-7


(accessed 4.6.05)


http://www.doh.gov.uk/consultantscontract/framework.pdf (accessed 15.7.05)


http://www.which.net/campaigns/health/qualityandsafety/0508healthchoice-rep.pdf (accessed 2.8.05)

http://www.who.int/hrh/documents/en/right-balance.pdf (accessed 5.6.05)

The service development project provided some of the stimulus and foundations for the research project, which was described in Part 1 (Chapter 3; section 3.3). It was a practice-orientated project to audit transfusion practice in oncology and haematological oncology and to establish the transfusion triggers used in the clinical setting. This provided a baseline measurement of current transfusion practice in the clinical setting and a foundation for a change management programme to improve blood transfusion practice. The service development project was presented as a series of five slides and 1000 words in support of the slides and these are presented below.

1.0 Introduction

Cancer Related Anaemia (CRA) is common in patients with haematological and solid tumours malignancies. The pathogenesis is variable, but may involve bleeding, erythroid hypoplasia, reduced red cell survival, nutritional deficiencies, decreased erythropoietin levels and poor iron re-utilisation by bone marrow (Bokemeyer 2005; Estrin et al 1999). CRA is exacerbated by myelosuppressive chemotherapy and may be aggravated by radiotherapy (Barrett-Lee et al 2000). Cancer patients can experience such severe anaemia that blood transfusions are required for symptomatic palliation. The transfusion trigger is set at a pragmatic level of 8g/dl in this Trust with a few exceptions. The British Society of Haematology also recommends this trigger (BCSH 2001). Blood transfusion guidelines exist in this large acute teaching hospital but there was a perception these were not being adhered to and variation in transfusion practices in the treatment of CRA existed, between the sub-specialisms of haematological oncology and oncology.
The presence of CRA decreases patients' quality of life, impacts on fatigue (Demetri 2001; Glaspy 2001; Ludwig and Strasser 2001) and is associated with shorter survival times in cancer patients (Caro et al 2001). Correction of anaemia may have a positive impact on treatment outcomes (Bloehmer et al 2001; Glaser et al 2001; Grogan et al 1999; Littlewood et al 2001) however these studies have improved intrinsic haemoglobin levels by erythropoietin, not by transfusion.

There may be ritualistic practice in transfusion with a tendency to treat laboratory values rather than do a full assessment of the impact of anaemia (Foubert and Wujcik 2005). It can be difficult to distinguish between symptoms of disease and symptoms of anaemia, resulting in a tendency to over-transfuse, particularly in advanced stage disease. In addition, there is considerable variation in transfusion practice between different
countries and even within different departments (Foubert and Wujcik 2005) in spite of the presence of clinical guidelines (Barrett-Lee et al 2001).

Each unit transfused carries risk (Text Box 2.0). Exposing patients to blood transfusion may not be the best supportive care practice. The mandate from the NBTS and the RCN is to minimize exposure (RCN 2006) and prescribe blood only when it is really needed (McClelland 2002), hence the recommendation for single unit transfusions (Garrioch 2003).

Text Box 2.0: Risks of transfusion (Nowrousian 2002)

- Immunologic reactions including immunosuppression
- Transfusion Transmitted Infection (HIV, CMV, Hepatitis B,C, Bacterial infections, vCJD, malaria)
- Transfusion errors
- Acute haemolytic transfusion reactions
- Fluid overload
- Severe allergic reaction or anaphylaxis
- Transfusion Associated Acute Lung Injury (TRALI)
- Transfusion Associated Graft versus Host disease
- Reactions due to other red cell antibodies other than anti-A and anti-B
- Delayed haemolytic reactions
- Post Transfusion Purpura
- Febrile non-haemolytic reactions
- Iron overload
The ECAS survey (n=15,367) was conducted to prospectively evaluate the prevalence, incidence and treatment of anaemia in European cancer patients (Ludwig et al 2004). A UK audit revealed a trigger of 7.9g/dl (n=103). The volume of transfusion varies according to diagnosis, complexity and tumour type (Appendix 1, Table 3.1a & 3.1b) (Bokemeyer 2005; Estrin et al 1999; Ludwig et al 2004). Eighty-eight per cent of transfusion episodes in the cancer population are 2 unit transfusions (Barrett-Lee et al 2000). An audit was undertaken to examine blood usage in haematology and oncology in this acute Trust (Text Box 3.0). This project integrated well with other Trust-wide projects examining strategies of reducing blood transfusion.
Text Box 3.0: Aims of the audit of blood usage in haematology and oncology

- To audit the blood product usage within haematology and oncology for 3 months and establish the transfusion triggers
- To assess compliance with trust policy on blood product ordering thresholds.
- To assess the clinical decision making process in the assessment and treatment of CRA

3.1 Establishing transfusion triggers

Method
- Obtain data of all blood transfusions in haematology and oncology
- Use EPR to establish haemoglobin level at time of transfusion (< 48 hours)

Results

<table>
<thead>
<tr>
<th></th>
<th>Number of transfusion episodes</th>
<th>Mean Hb transfusion trigger</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haematology</td>
<td>54</td>
<td>7.8g/dl</td>
<td>5.1-10.3g/dl</td>
</tr>
<tr>
<td>Oncology</td>
<td>202</td>
<td>9.1g/dl</td>
<td>5.8-12.8g/dl</td>
</tr>
</tbody>
</table>

3.2 Documentation of rationale for transfusion

Method: Twenty randomly selected case-notes were analyzed.

Results
- Only 2 out of 20 had details of assessment of CRA and reasons for transfusion.
- Reasons included breathlessness and tiredness. One of the patients had bilateral pleural effusions
- Mostly stated “2 units blood” with no assessment or decision-making details
Timing of transfusion

11.8% (n=24) of oncology patients were transfused within 1 month of death. This data was unavailable for haematology oncology.

Table 3.2: Single vs Multiple Unit Transfusions (Oncology only)

<table>
<thead>
<tr>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single unit</td>
<td>14</td>
</tr>
<tr>
<td>2 unit transfusion</td>
<td>162</td>
</tr>
<tr>
<td>3 unit transfusion</td>
<td>21</td>
</tr>
<tr>
<td>&gt; 4 unit transfusion</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>202</strong></td>
</tr>
</tbody>
</table>

3.3 Costs of transfusion

Data was obtained for blood transfusion budgets and whether there was over or under spend on blood (Slide 2), which shows overspend on oncology blood product.

3.4 Audit Constraints

Unfortunately oncology diagnosis data was not accurate so it could not be established which tumour types or radiotherapy/chemotherapy treatment sub-groups received more/less blood transfusion. There was missing data in haematology oncology, which resulted in the inability to compare transfusion practice in terms of single/multiple transfusions and timing of transfusions. Time constraints meant only 202 oncology blood transfusion patient episodes were examined.
3.5 Summary of context analysis

Text box 3.5 shows a summary of the context of the audit and some preliminary ideas.

Text Box 3.5

- Haematology and oncology patients use large amounts of blood products with attached costs.

- Patients may be admitted for transfusion because the Oncology Day Units do not offer a transfusion service → necessitates admission → unlikely to admit for single transfusion alone. This may increase actual costs.

- Haemato-oncology Day Units offer a blood transfusion service → facilitates single unit transfusion but need to establish the ratio of single unit/multiple unit transfusions

- Local and national transfusion policy and guidelines exist but not adhered to

- Blood prescribing behaviours are different between haemato-oncology and oncology
There are a number of theoretical models of change, which describe the processes where organizations successfully alter their practices, structure or climate. A diagnostic analysis identifying factors to influence the proposed change is useful. Lewin developed a three-step model for implementing change (Text Box 4.0) based on the concept of Force Field Analysis (FFA) (Lewin 1951). FFA change theory is based on the premise that driving forces must outweigh resisting forces if change is to be successful, however it assumes that simply introducing change will result in new practices being adopted or being sustained over a long period of time. There is a danger these forces are viewed as opposing but the aim of this FFA was to not create battle lines but to make a realistic all-round assessment of everything that could influence change (Appendix 2).
Text Box 4.0: Three-step model (Lewin 1951)

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Unfreezing”</td>
<td>Getting the need to change to be accepted; involves dismantling processes or behaviours that support or maintain the previous behaviour.</td>
</tr>
<tr>
<td>Change/transition/moving</td>
<td>The new concept is introduced; an alternative; introducing a clear and appealing option or new pattern of behaviour.</td>
</tr>
<tr>
<td>“Re-freezing”</td>
<td>Consolidating the revision so there is no reversion to the old behaviour.</td>
</tr>
</tbody>
</table>
It is a naïve assumption that when research evidence is made available it is accessed by practitioners, appraised and then applied in practice via Clinical Practice Guidelines (CPG) (NHS Executive 1996). Blood transfusion guidelines, including mandatory transfusion education, are practiced in all hospital settings, but optimal transfusion practices may not exist and the reasons for this are complex. A variety of strategies will be required if change is to be successful (slide 4). Barriers to change are summarised in Text Box 5.0. In addition, despite the growth of CPGs their actual value is infrequently assessed through formal evaluation procedures (Babinski 1996; Carter et al 1996).
1. Change models suggest that implementation programmes can be successful if they use interventions and activities that reduce restraining forces (Garside 1998).

2. Increased workload, lack of time, poor communication and traditional working practices may all contribute to resistance to change (Firth-Cozens 1997).

3. Multi-faceted interventions may be more expensive and/or time consuming so additional resources may be required.

4. Health professionals may not believe the evidence: they may have other information, which suggests the contrary (e.g. use evidence from erythropoietin studies which show that patients QoL increases as the Hb increases).

5. Groups of health professionals make different decisions to those of individuals. Although a group may agree for example to not transfuse unless the haemoglobin is less than 8g/dl as per hospital guideline, a healthcare professional faced with an individual patient may tend to err on the side of caution or rely on personal experience.

6. Decision-making is often affected by the severity of the potential outcomes in comparison to the anticipated regret for different pathways not taken (Col et al. 1997) e.g. a healthcare professional might be more likely to transfuse a patients because he/she considers the risks of anaemia to be greater and more worrying than the risks of transfusion.

5.1 Phase 1: "Unfreezing"

The first step is to highlight the need for change and get agreement from the major stakeholders that this project is worth tackling (Text Box 5.1) (Lomas 1993)

Text Box 5.1: Getting agreement that a topic is worth tackling depends on:

- Whether the issue is perceived as a significant problem by those who have to change
- The extent to which it ties in with national policy and whether it will be supported by those charged with implementing national policy
- Whether all the major problems associated with the change can be solved
- Whether there are key individuals or organisations who are strongly opposed to the change
- The nature of the vested interests, either in the proposed change of the status quo
- The resource implications of the change
- Whether there is a significant gap between what people publicly say about the change and what they are prepared to do
- The change delivers a relative advantage, whether it will be compatible with current beliefs or working practices or whether it can be piloted (Stocking 1992)
5.2 Phase 2: Changing, moving and transition

A range of interventions has been shown to be effective in changing professional behaviour in some circumstances (Appendix 1 & 2). These are summarised in Text Box 5.2.

Text Box 5.2: Summary of research findings on professional behaviour change (Appendix 3 & 4)

1. There is little evidence that passive dissemination alone results in behaviour change [32] however, this approach may be useful for raising awareness of research methods
2. Most interventions are effective under some circumstances; none is effective under all circumstances
3. Interventions based on assessment of potential barriers are more likely to be effective
4. Multi-faceted interventions targeting different barriers to change are more likely to be effective than single interventions
5. Educational outreach is generally effective in changing prescribing behaviours
6. Reminder systems are generally effective for a range of behaviours
7. Audit and feedback, opinion leaders and other interventions had mixed effect and should be used selectively

Table 5.2: Action Plan

<table>
<thead>
<tr>
<th>Restraining Forces</th>
<th>Process</th>
<th>Liase with</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited stakeholder engagement</td>
<td>Audit and feedback at Oncology/haematology/cancer clinical audit study day</td>
<td>Haematology and Oncology teams</td>
</tr>
<tr>
<td>Knowledge &amp; Skills in assessment and treatment of CRA in oncology healthcare professionals (Medical &amp; nursing staff)</td>
<td>Initiate and implement &quot;Back-2-Basics-Anaemia&quot; outreach education</td>
<td>Consultant haematologist, Joint Nurse/Medical education sessions</td>
</tr>
<tr>
<td>Knowledge &amp; Skills in blood minimisation strategies</td>
<td>Include in mandatory training</td>
<td>Blood Transfusion Practitioners</td>
</tr>
<tr>
<td>Patient information to address ethical issues</td>
<td>Blood transfusion PIL</td>
<td>Clinical staff in all areas</td>
</tr>
<tr>
<td>Limited oncology day unit capacity</td>
<td>Contribute to Capacity &amp; Demand Analysis of day unit services in the network chemotherapy review of services to ensure capacity includes transfusion</td>
<td>Lead Chemotherapy Nurse, Service Improvement Facilitator</td>
</tr>
<tr>
<td>Complexity of assessment of CRA</td>
<td>Reminder systems in all clinical areas (flow chart/slide 5)</td>
<td>Clinical teams</td>
</tr>
<tr>
<td>Complexity of Clinical Practice Guidelines (CPG)</td>
<td>Add CRA specific section to CPG</td>
<td>Blood Transfusion Practitioners; Consultant Haematologist (Transfusion)</td>
</tr>
</tbody>
</table>
Does your patient need a transfusion?

**Patients at Risk**
- Coronary artery disease
- History of cerebrovascular insult
- Severe pulmonary disease

**Patient with suspected CRA**
- Signs and symptoms of CRA, Hb > 8g/dl
  - Symptoms more likely to be due to therapy/disease or further ↑ in Hb anticipated

**Patients to maintain Hb > 10g/dl**
- Radiotherapy patients
- H&N cancer patients
  - Signs and symptoms of CRA, Hb < 8g/dl
  - Symptoms more likely to be due to anaemia or further ↓ in Hb anticipated

**No Blood Tx**
- If patient is tolerating CRA and due back in clinic < 1-2 weeks with hold blood or give 1 unit only

**Blood Tx 1-2 units**

---

6.1 Phase 3: Refreezing and evaluation

Consolidating a change can be the greatest challenge. It is easy to return to previous practices without constant motivation and reminders (EHC 1994). A further challenge exists in the constantly mobile workforce so any change implementation strategies has to be continuous. Any systematic approach to changing professional practice should include plans to monitor, evaluate, maintain and reinforce any change, e.g. monitored by an annual audit programme or continuous surveillance.
6.2 Discussion

In summary, the amelioration of CRA should be considered a priority in providing best supportive care in this population, with the emphasis on neither, over- or, under-transfusing of blood. Further research is needed to evaluate the role of transfusion in the treatment of CRA for example:

- Do cancer patients who are exposed to transfusion have an increase in comorbidity?
- Can single unit transfusions be used effectively in this population, with scoring of symptoms after each unit transfused?
- Studies to examine healthcare professionals’ CRA assessment skills.

As transfusion costs increase, or if blood becomes more scarce, it may be that erythropoietin will be re-considered by NICE but until this happens research must continue to enable optimal transfusion practice for the treatment of CRA.
Appendix

Appendix 1: Frequency of anaemia and transfusions

Table 3.1a: Frequency of anaemia during cancer treatment and transfusion (Bokemeyer Disease Anaemic patients (%) Patients receiving transfusions (%)

<table>
<thead>
<tr>
<th>Disease</th>
<th>Anaemic patients (%)</th>
<th>Patients receiving transfusions (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple myeloma</td>
<td>47</td>
<td>22</td>
</tr>
<tr>
<td>Cervical cancer</td>
<td>34</td>
<td>16</td>
</tr>
<tr>
<td>Ovarian cancer</td>
<td>34</td>
<td>15</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>34</td>
<td>13</td>
</tr>
<tr>
<td>Non-Hodgkin's lymphoma</td>
<td>32</td>
<td>16</td>
</tr>
<tr>
<td>Testicular cancer</td>
<td>32</td>
<td>14</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>21</td>
<td>12</td>
</tr>
<tr>
<td>Colorectal</td>
<td>13</td>
<td>8</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>12</td>
<td>8</td>
</tr>
</tbody>
</table>

Table 3.1b: Significance of mean number of units transfused (Estrin et al 1999).

<table>
<thead>
<tr>
<th>Overall</th>
<th>No of blood units transfused</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>Adults</td>
<td>5.8</td>
</tr>
<tr>
<td>Children</td>
<td>6.1</td>
</tr>
<tr>
<td>Difference</td>
<td>1.5</td>
</tr>
<tr>
<td>Complex patients</td>
<td>8.0</td>
</tr>
<tr>
<td>Common patients</td>
<td>4.2</td>
</tr>
<tr>
<td>Difference</td>
<td>3.8</td>
</tr>
<tr>
<td>Solid tumours</td>
<td>4.7</td>
</tr>
<tr>
<td>Haematological tumours</td>
<td>7.1</td>
</tr>
<tr>
<td>Difference</td>
<td>2.4</td>
</tr>
<tr>
<td>Males</td>
<td>6.5</td>
</tr>
<tr>
<td>Females</td>
<td>5.2</td>
</tr>
<tr>
<td>Difference</td>
<td>1.3</td>
</tr>
</tbody>
</table>
Appendix 2: Transfusion practice force field analysis summary

**Patient factors:**
Patients may be influencing the decision to transfusion to relieve symptoms due to other causes, e.g. from perception that it will relieve fatigue as stated in Bacup Fatigue booklet.
Do they know the risks of transfusion? Have they consented?

**Knowledge & Skills**
Implication that oncology are over-using blood, which may be due to lack of skills and knowledge in assessment of CRA
Mandatory blood transfusion is in place for 4,500 healthcare professionals in the Trust and includes the management of risk of transfusion and safety issues but not the importance of minimising exposure

**Global Influences**
Around 3.4 million blood components are transfused every year in the UK. This increases every year (RCN 2006)
New pathogens, means the blood donor pool is shrinking and a scarce resource must be used carefully (Thomas 2005)
Costs are escalating as collection, testing, processing and administration systems become more complex (Varney and Guest 2003)

**Prioritising & Rationing**
Audits reveal 25% of cancer patients who require blood are admitted (Barrett-Lee et al 2000) = waste of resources as most transfusions can be undertaken on an out-patient basis if there were not a lack of day beds
The actual number of blood donations increased by 2% in 2000-2001 but the cost of transfusion increased by 256% to £698 million (Varney and Guest 2003) with the direct cost of the blood product accounting for only 19% of the total cost of transfusion (Cremieux et al 2000)
The NHS cost for an adult transfusion was estimated to be £635 for red blood cells, when hospital stay, management of complications and cost to society were included (Varney and Guest 2003)

**Policy**
NICE guidelines did not recommend erythropoietin therapy for routine treatment of CRA therefore blood transfusion remains the primary treatment option for CRA
National policy to reduce blood usage

**Ethical Issues**
Ethical issues are powerful influences. It is difficult to withdraw blood transfusion in the palliative care setting if the patient has had blood transfusion support throughout active therapy period (Stone et al 2000)
Risk of under-transfusing
Appendix 3: Reviews of the effects of broad implementation strategies on professional practice
(CME=Continuing Medical Education; RCT= Randomised Controlled Trial; CCT=Controlled Clinical Trial; CBA=Controlled before/after; XS=Cross Sectional; ITS=Interrupted Time Series)

<table>
<thead>
<tr>
<th>Authors and focus</th>
<th>Inclusion criteria</th>
<th>Main Results</th>
<th>Main Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effectiveness of CME</strong> (Davis et al 1995)</td>
<td>Study design: RCT, CCT Participants: healthcare professionals Intervention: Educational intervention Outcomes: Objective measure of physician performance or healthcare outcomes</td>
<td>99 studies met the inclusion criteria. Improvements in at least one major endpoint in physician performance or patient outcome of care were identified in 66% of comparisons. Single strategies likely to be effective included educational outreach, opinion leaders, patient mediated interventions and reminders. Multi-faceted interventions were more likely to be successful. Studies which undertook a needs analysis to inform the development of the interventions appeared more likely to be positive.</td>
<td>Widely used CME delivery methods such as conferences have little direct impact on improving professional practice. CME provides seldom use more effective methods such as systematic practice-based interventions and outreach visits.</td>
</tr>
<tr>
<td><strong>Effectiveness of continuing education on nursing practice</strong> (Waddell 1991)</td>
<td>Study designs: not explicitly stated Participants: nurses Intervention: Continuing nurse education interventions Outcomes: Practice related behaviours</td>
<td>34 studies met the inclusion criteria. Education positively affects nursing practice. The average number of an intervention group performed as well as or better than 77% of the members of control groups. Findings that related to mediating effects were inconclusive.</td>
<td>The overall effect supports the hypothesis that continuing education positively affects nursing practice. There was a greater likelihood of effect when learners were from the same practice environment and planned their continuing education activities accordingly.</td>
</tr>
<tr>
<td><strong>Relationship between compliance rates and the subject of practice guidelines</strong> (Schwartz et al 1996)</td>
<td>Study design: Not explicitly stated (CBA, XS) Participants: Providers Intervention: Publication or dissemination of guidelines developed by official organisations Other: studies of locally developed guidelines also included</td>
<td>23 studies with 143 recommendations addressing 70 different aspects of medical practice were included. The overall mean compliance rate was 55%. High complexity recommendations had significantly lower compliance rates. There was no significant difference in compliance between recommendations with high versus low observability.</td>
<td>There was a high degree of variation in reported compliance rates and a low average compliance rate. High complexity/low triability recommendations may require more active dissemination activities to predispose practitioners to change their behaviour than low complexity/high triability recommendations where efforts can focus more quickly on enabling change at the local level.</td>
</tr>
<tr>
<td><strong>Effectiveness of strategies for implementing clinical practice guidelines</strong> (EHC 1994)</td>
<td>Study design: RCT, CBA, ITS Participants: Medical staff Intervention: Guideline dissemination and/or implementation strategies Outcomes: Process of care or patient outcome</td>
<td>91 studies met the inclusion criteria. 81 of 87 studies reported significant improvements in adherence to recommendations of practice guidelines. 12 of 17 that reported patient outcome also reported significant improvements</td>
<td>Properly developed guidelines can change clinical practice and may lead to changes in patient outcome. Guidelines are more likely to be effective if they take into account local circumstances, are disseminated by an active educational intervention, and implemented by patient specific reminders.</td>
</tr>
<tr>
<td><strong>Effectiveness of strategies for implementing clinical practice guidelines</strong> (Davis and Taylor Valsey 1997)</td>
<td>Study designs: not clear Participants: Practising clinicians Intervention: Guideline implementation strategies Outcomes: Not clear</td>
<td>Weak interventions included didactic traditional CME and mailings; moderately effective interventions included audit and feedback; relatively strong interventions included reminder systems, academic detailing and multiple interventions</td>
<td>Future implementation strategies should be based on an understanding of the forces and variables influencing practice and through the use of methods that are practice and community based rather than didactic.</td>
</tr>
</tbody>
</table>
Appendix 4: Summary of systematic reviews of the effects of implementation targeting specific behaviours related to prescribing

(CME=Continuing Medical Education; RCT= Randomised Controlled Trial; CCT=Controlled Clinical Trial; CBA=Controlled before/after; XS=Cross Sectional; ITS=Interrupted Time Series)

<table>
<thead>
<tr>
<th>Authors and focus</th>
<th>Inclusion criteria</th>
<th>Main Results</th>
<th>Main Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improving drug prescribing in primary care (Soumerai et al 1989)</td>
<td>Study designs: RCT, CBA, ITS Participants: Physicians Intervention: Non-regulatory, non-commercial programmes to improve drug prescribing Outcomes: Drug prescribing practices</td>
<td>44% studies met inclusion criteria. 85% of inadequately controlled studies reported positive findings, compared to 55% of well controlled studies. Dissemination of printed educational materials alone reported to be ineffective in all adequately controlled studies, whereas every uncontrolled study reported positive effects</td>
<td>Mailed educational materials alone may change knowledge or attitudes, but had little or no effect on actual prescribing behaviour. Few well controlled studies have documented the effectiveness of group education. Ongoing feedback may be effective in improving certain types of prescribing practices, such as generic use of drugs in academic settings. Brief one-to-one educational outreach sessions are effective in substantially reducing prescribing.</td>
</tr>
<tr>
<td>Review of techniques to improve prescribing behaviour (Anderson and Lexchin 1996)</td>
<td>Study designs: RCT Participants: Physicians Interventions: Interventions to improve prescribing behaviour Outcomes: Not explicitly stated</td>
<td>9 studies met the inclusion criteria. Printed educational materials alone do not improve practice. Interventions combining education and feedback were found to be more effective. Educational strategies involving face-to-face contact between the expert and the physician were successful. Feedback including specific recommendations for change in the use of medications were more successful than a description of current practice</td>
<td>Specific educational and feedback strategies can improve quality of care. Results are limited due to the lack of data found on patient outcomes. Need for further research on prescribing and on providing information to patients.</td>
</tr>
<tr>
<td>Effectiveness of interventions to improve prescribing behaviour (Gill 1998)</td>
<td>Study designs: RCT, CBA Participants: Physicians Interventions: Professional interventions Outcomes: not explicitly stated</td>
<td>79 studies met inclusion criteria. 53 were single intervention studies and 22 multi-faceted intervention studies. 51% of interventions changed prescribing behaviour in comparison to the control group. Multi-faceted interventions had some effect on changing prescribing behaviour</td>
<td>No clear differences between approaches. Multi-faceted approaches are most promising.</td>
</tr>
</tbody>
</table>
References


EHC: Effective Health Care (1994) Implementing clinical guidelines can be used to improve clinical practice. University of Leeds Press. www.medicine.ox.ac.uk/bandolier. (accessed 2.4.06)


Ludwig H and Strasser K (2001) Symptomology of anemia. *Seminars in Oncology.* 28:2, suppl.8, 7-14


Research Log

The research log provides an overview of the process and timelines involved in the research project. It describes the initiation, the planning, the literature review and the supervision sessions and concludes with a summary of the research project process.

1.0 Getting started
The quality of research expected at doctoral level is underpinned by the researcher’s imagination, inspiration, motivation and intellect and without it an original contribution to knowledge is unlikely. However, despite having original ideas and questions, it was difficult to know where to start, but the doctorate structure provided guidance by demanding early pieces of written work, for example the policy review and topic review. The topic review was submitted in 2005 and was designed to assist with the literature review. The service development project in 2006 also assisted with focusing the development of the research question and this was described in the previous section, but some questions remained unanswered, for example, why did the variation in practice exist?

Although the researcher did the majority of the work, the project would not be achievable without the assistance of others, particularly the experience and wisdom of the supervisors, but also the clinicians in the workplace and key administrators who would assist with the approval processes. It was important therefore, at the outset of the research to start formulating lists of key people who could assist with the development of the research project and these key individuals are listed in Appendix 1, but their names have been excluded for anonymity purposes. In summary, starting the project was dependent upon speaking to the right people, sharing ideas, generating questions and
starting to plan, which was dependent upon collaboration with the key people and negotiation with the supervisors.

2.0 Current and past research: the literature review

The researcher was fortunate to attend a bi-annual cancer related anaemia conference in Rome in 2005. This was a meeting of experts in cancer related anaemia and a vast summary of the literature was provided as well as an opportunity to meet experts in the field and listen to their presentations, which were inspirational (for example Drs Barrett-Lee, Glaspy, Aapro, Littlewood etc). It is important to note this was a pharmaceutical sponsored event and therefore the focus of the conference was on the erythropoietin literature. This opportunity also provided literature to contribute to the overall literature review.

The literature review is described in the research thesis in Chapter 2 (Part 1) and the researcher had access to multiple libraries for example, The Royal Marsden library, University of Surrey Library and Kings College London. A relationship diagram was developed to focus the literature review and to ensure the different elements were explored. The literature review was an iterative process as the project developed but in summary the aims were:

- To provide a summary of representative literature
- To provide an overview of the knowledge base, including methodology
- To identify gaps in knowledge and develop a specific focus that supported the research being undertaken
In summary, the literature review critically evaluated the literature with the aim of underpinning and justifying the research, clarifying and creating conceptual frameworks (e.g. symbolic interactionism) and helped to clarify areas that were less well understood (e.g. the reasons for variation in transfusion decision making).

3.0 Project management

Researchers are faced with a considerable amount of project management and guidance was needed to plan and co-ordinate the research project. Supervision was an essential component to enable successful completion of the doctorate thesis. Two experienced researchers facilitated this project and helped to:

- Bring together ideas
- Focus the research question
- Develop the methodology
- Direct the researcher to key experts in the field, research papers, theory and literature
- Ensure student achieved work within agreed time frames

The supervision sessions became more focussed as the research project progressed. A summary of supervisory meetings, their content and agreed objectives set at each meeting is demonstrated in Appendix 2. Early delays in submitting the proposal was due to time constraints imposed by work pressures, however, researcher activity increased in 2007 and the research proposal was submitted to NRES, the local ethics committee and subsequently the university ethics committee September 2007. Data collection continued from December 2007 through to October 2008, with substantial amendment to the project in August 2007, which is described in Chapter 1 and Chapter 3 of the thesis.
Supervision continued throughout and increased during the data analysis and writing up stage to ensure the project was managed within the timelines. The first draft of the thesis was submitted in December 2008 and final draft in February 2009. Amendments were made accordingly following feedback from the supervisors. Part 2 was compiled in January and submitted in February 2009 as was the "Overview of the integration of knowledge, research and practice" (Part 1). The clinical academic paper was drafted following the completion of all the other elements, and final feedback received, in order to ensure the academic paper was of the highest quality and there was clarity of the important elements of the research had been checked by the supervisors.

4.0 Reflexive ethnographic journal
The researcher kept an informal reflective diary in the form of the reflexive journal to record thoughts and meetings/discussions with any of the key people described in section 1.0 as well as preliminary analytic thoughts. This was an essential component of ethnography as described in Part 1 (Chapter 7, section 7.5). For example, early excerpts describe visits to the lung clinic "very busy, packed waiting room, people afraid to get up from seats in case they lose their slot" and observations from the day care unit "a patient wants a newspaper to read whilst he is waiting for his cannula to be put in and his blood to start". Both of these observations are from December 2007 prior to formal observation and interview work but formed part of the ethnography in that the researcher was beginning to formulate a picture of what happened and where to ensure more focused observations and interviews could occur at a later stage.

Notes were also taken in the research journal when key meetings took place with key people who informed or assisted with this project and who are identified in Appendix 1.
For example, during a meeting with an experienced ethnographer the following notes were made:

- What do I want to observe in the clinic?
- Are all the patients relevant?
- What is the structure of the consultations?
- Who is present in the Consultations?
- What are the things that are shaping the clinic and how it functions?
- Where do they (patients and clinicians) sit?
- What took place?
- What were the behaviours?

These notes assisted the researcher focus during the subsequent observations in clinic and helped her to understand that it was not possible to record every consultation and every aspect of the clinic, but learn to focus on the important elements of the behaviours and environment within the clinical settings. It was the small interactions and exchanges of meaning (symbolic interactionism) that was important to capture during the fieldwork observation and interviews with key staff and patients. This meeting helped to clarify this for the researcher and therefore it is recommended to meet and discuss how to conduct the research with other experienced ethnographers if ethnography is the methodology of choice.

Early notes taken following some of the interviews and observation fieldwork revealed the beginnings of the sub-themes within the final research findings. These are described here as "analytic memos" and included notes were made on the "role of uncertainty" and "knowing the patient: Are relationships important?" as the researcher started to formulate
ideas. The diary was kept throughout until completion of the thesis. The diary was also used to project manage and keep timelines and activities documented.

5.0 Summary

The project took four years to complete and the writing up was sporadic and dependent on research activity, although the final six months were the most intense. Ideas changed throughout therefore even when the final proposal was passed by the ethics committee in September 2007, it was important not to have fixed ideas about either the flow of the project or the outcomes. Several factors contributed to the successful completion and these included good relationships at work, for example, with the chairman of the ethics committee and face to face communications with the ethics committee and R&D committee administrators, as well as the clinical teams. Relationships with the research supervisors were also perceived to be positive because of their relevant experience, their accessibility and good communication, requests for work, and meticulous and timely feedback, and recommendations for reading.
Appendix

Appendix 1: Key people

<table>
<thead>
<tr>
<th>Identify people who may help</th>
<th>Date contacted</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood transfusion lead clinician</td>
<td>Dec 2005</td>
<td>Meeting 11.12.05 to discuss provisional plan, feasibility and obtain support</td>
</tr>
<tr>
<td>Blood Transfusion Practitioners</td>
<td>January 2006</td>
<td>Meeting 11.12.05 to discuss provisional plan, feasibility and obtain support</td>
</tr>
<tr>
<td>Consultant Haematologists</td>
<td>February 2005</td>
<td>One of the haematologists is also LREC chair</td>
</tr>
<tr>
<td>Lung Oncologists</td>
<td>January 2007</td>
<td>Informal meeting with both to gain approval and seek access to clinics</td>
</tr>
<tr>
<td>Lung CNSs</td>
<td>April 2005</td>
<td>Informal meeting with both to gain approval and assistance with patient and staff recruitment</td>
</tr>
<tr>
<td>Haematology CNSs</td>
<td>April 2005</td>
<td>Informal meeting with both to gain approval and assistance with patient and staff recruitment</td>
</tr>
<tr>
<td>Day Unit Sisters/Charge Nurses</td>
<td>April 2005</td>
<td>Informal meeting with all individually to gain approval and seek access to clinics/assistance with patient recruitment</td>
</tr>
<tr>
<td>Research Supervisor</td>
<td>Feb 2005</td>
<td>Meeting with supervisors 12.6.05 (discuss process of projects for DClinPrac) Meeting with supervisor 3.8.05 (Policy Review and Personal Development)</td>
</tr>
<tr>
<td>Research Supervisor (changed)</td>
<td>October 2006</td>
<td>Changed one of the supervisors because project changed to include ethnography</td>
</tr>
<tr>
<td>Researcher experienced in observation techniques</td>
<td>October 2006</td>
<td>Advice and helpful hints meeting to assist with observation techniques</td>
</tr>
<tr>
<td>R&amp;D Lead</td>
<td>October 2006</td>
<td>Consultant haematologist Informal meet to discuss process and attend R&amp;D meeting</td>
</tr>
<tr>
<td>R&amp;D co-ordinator</td>
<td>July 2007</td>
<td>Meet with R&amp;D coordinator for Oncology &amp; Haematology</td>
</tr>
<tr>
<td>LREC co-ordinator</td>
<td>May 2007</td>
<td>Telephone conversation and email correspondence to ensure LREC submission process smooth</td>
</tr>
</tbody>
</table>
## Appendix 2: Summary of supervision sessions

<table>
<thead>
<tr>
<th>Date</th>
<th>Supervisor</th>
<th>Supervision focus</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.3.07</td>
<td>SF, HA</td>
<td>Changes to study design; send proposal to Consultants for comment.</td>
<td>Widen literature review&lt;br&gt;Remove action research and focus on ethnography literature&lt;br&gt;Make changes to research proposal and re-send to supervisors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reduce scope of study to focus on haemat-oncology and lung cancer using actigraphy/FACT-An</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Focus on literature of traditional practices and culture, explore sociology literature</td>
<td></td>
</tr>
<tr>
<td>22.5.07</td>
<td>SF, HA</td>
<td>Positive feedback from Consultant Haematologists&lt;br&gt;&quot;Stumbling block&quot; of starting NRES application</td>
<td>Refine inclusion and exclusion criteria&lt;br&gt;Seek Oncologist approval&lt;br&gt;Submit to ethics/NRES by end of June 07&lt;br&gt;Clarify funding for actigraphy hire&lt;br&gt;SF to send letter for NRES application&lt;br&gt;LB to e mail summary of supervision</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discussed time frames: short and long term with aim to submit final thesis by August 09</td>
<td></td>
</tr>
<tr>
<td>2.7.07</td>
<td>SF</td>
<td>Checked letters and ethics submissions&lt;br&gt;Discussed process of R&amp;D submission and LREC submission&lt;br&gt;Discussed ethics of permission with observation and to seek clarity at LREC</td>
<td>Submit ethics for 14.9.07&lt;br&gt;Send pdf file of ethics submissions to supervisors&lt;br&gt;University ethics</td>
</tr>
<tr>
<td>7.11.07</td>
<td>SF, HA</td>
<td>Ethics approval with minor amendments only and queries about the volume of data&lt;br&gt;GCP training completed 6.11.07</td>
<td>Submit to University ethics for approval&lt;br&gt;Research triangulation in ethnography&lt;br&gt;Send through transcripts to supervisors for comment</td>
</tr>
<tr>
<td>23.4.07</td>
<td>SF, HA</td>
<td>Interviews going well&lt;br&gt;Observations started&lt;br&gt;Reflective diary (research journal) being kept and used to document key insights, e.g. oncology clinics (process) and haemat-oncology clinics (education of patients)&lt;br&gt;One patient recruited</td>
<td>Start drawing out key themes&lt;br&gt;Complete interviews after identifying themes&lt;br&gt;Observations in day units&lt;br&gt;Recruit patients</td>
</tr>
<tr>
<td>4.6.08</td>
<td>SF, HA</td>
<td>Discussed themes in observation fieldwork&lt;br&gt;(anaemia is not important, shared responsibility)&lt;br&gt;Run further literature search&lt;br&gt;Reflective journal (&quot;analytic memos&quot;)</td>
<td>Continue data collection&lt;br&gt;Update observation notes&lt;br&gt;Continue analytic notes&lt;br&gt;Annual review to complete and submit</td>
</tr>
<tr>
<td>3.7.08</td>
<td>SF, HA</td>
<td>Discussed changing the design to include patient interviews rather than track patients using actigraphy</td>
<td>To submit to NRES for substantial amendment and chase&lt;br&gt;Complete data analysis Oct/Nov 2008&lt;br&gt;Write up and submit December 2008&lt;br&gt;Amend submission date to February 2009</td>
</tr>
<tr>
<td>30.7.08</td>
<td>SF, HA</td>
<td>Feels interview and observation data will emerge easily as good contacts&lt;br&gt;Transcribing own data</td>
<td>Continue data collection&lt;br&gt;Use field diary to &quot;test&quot; hypothesis/thoughts and feelings from the field&lt;br&gt;Consider decision making literature and theoretical framework</td>
</tr>
<tr>
<td>4.10.08</td>
<td>HA, SF</td>
<td>Submitted chapters for review (literature review, methodology)&lt;br&gt;Some areas well developed, others less so&lt;br&gt;Consider knowledge, skills acquisition and Clarify interpretive stance within ethnography</td>
<td>Consider external examiners&lt;br&gt;Agree previous time lines&lt;br&gt;Re-submit integration paper and write log&lt;br&gt;Re-submit first draft of thesis December 2008&lt;br&gt;Meet in January</td>
</tr>
<tr>
<td>12.1.09</td>
<td>HA</td>
<td>Discussed feedback on first draft&lt;br&gt;Academic paper to focus on practice oriented journal of overview paper of four main themes</td>
<td>Second draft of thesis by 9th February 2009&lt;br&gt;Read Giddens &quot;social interactionism/symbolic interactionism&quot;&lt;br&gt;HA, SF to identify external examiners&lt;br&gt;Feedback to Trust to be undertaken following completion of thesis</td>
</tr>
</tbody>
</table>
Conclusion
This section concludes both parts of the thesis and is therefore a summary of all the conclusions and recommendations of the combined elements of the thesis (the research; clinical academic paper; overview of the integration of knowledge, research and practice; policy review; service development project and the research log). The following is a summary of the main conclusions:

- Variation in transfusion practice exists (see service development project)
- The culture of the clinical setting influences learning and clinical decision making in transfusion practice (see Chapter 5 for final themes).
- The hierarchy of skills and knowledge demonstrate different clinical priorities in the different professions. This thesis provides a theoretical framework to describe how different tasks may be apportioned low or high status in the clinical setting (see Chapter 6 and 7).
- Transfusion decisions are shared and "task drift" (see policy review, section 4.0) occurs where nurses are making transfusion decisions without the formal structures in place to support this practice.
- The KSF does not accommodate the tacit skills and intuitive knowledge and this is evident where skills cross professional boundaries, particularly with the medical profession, who are excluded from the KSF (see policy review).

The following is a summary of recommendations for practice and further research:

- Transfusion guidelines may be improved if they are less didactic or designed to incorporate different clinical situations to incorporate the real variations in transfusion need. In other words if they accommodate patient-centred decision making.
- Non-medical teams, for example, nursing teams, can effectively manage chronic conditions as it is manipulation/maintenance/prevention of adverse events rather
than diagnosis and management. This includes the management of cancer related anaemia which could provide a model for the management of other chronic conditions.

- Legitimisation of nurse prescribing of blood components is recommended and this change of clinical responsibilities should be formalised to avoid the "task drift" described above.

- Further research may include longitudinal studies of transfusion and the effects of blood transfusion on outcomes of patients with different tumour types.

- Ethnographic methodology to explore other practices where uncertainty exists is recommended or to repeat this research following implementation of some of the recommendations for clinical practice, e.g. implementation of nurse prescribing of blood components.

Final words of the thesis are important and somehow need to capture the essence of the energies and creativity of the researcher but recognise the contribution of everyone involved in the final product. It will therefore conclude with the words of Winter et al (2000, p35) by stating that this thesis contributed to original knowledge by containing "innovation, speculation, imaginative reconstruction and cognitive excitement and the author has clearly wrestled with the method, trying to shape it to gain new insights" into practice in the clinical setting. The "wrestling" was within the researcher's own ontological perspective and with the supervisors' guidance this was eventually resolved, and undoubtedly the researcher has changed and developed both intellectually and professionally because of this, which surely must be the overall aim of the Doctorate in Clinical Practice.

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