The interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials: A single centre qualitative case study.

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Declaration

This thesis has been accepted for the School of Law and Social Sciences

We hereby certify that this dissertation, submitted by above candidate conforms to acceptable standards and fully fulfils the thesis requirements for the degree of Doctor in Health and Social Care Practice.

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This thesis is dedicated to cancer patients and those who live with them and for them through their hard treatment decisions.

"There are no facts, only interpretations" Friedrich Nietzsche (1844-1900)

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(my Greatest Teacher)

Abstract

Objective. There is an on-going worryingly low patient entry to Cancer Clinical Trials (CCTs) in the UK. The doctor-patient communication difficulties have been highlighted as a significant reason for this low entry. The purpose of this study was to explore the role of interprofessional communication in seeking informed consent (IC) and how this may impact on patient uptake to CCTs. The use of overarching concepts assisted in framing the aims of the study. Research questions focused on the experience of interprofessional responsibility as shaped by time, the experience of gaining trust and its association with the patient's best interest, and the experience of facilitating patient's autonomy.

Methods. The research design encompassed a qualitative phenomenological approach within a case study to ascertain the experiences of 26 clinical and non-clinical professionals who directly or indirectly communicated with CCT adult patients. The research methods used to collect data comprised in-depth semi-structured interviews. Data were complemented by the practitioner researcher's research diary which contributed to the analytical approach.

Results. The findings of the study have shown how interprofessional communication impacts on obtaining IC to CCTs. The medical professionals were primarily positioned for their responsibility for IC, although when explored from an interprofessional and nursing standpoint, the role of time as a process became increasingly significant. Both professionals viewed trust as integral to obtaining IC to CCTs, but there were differences between how trust was initially gained and subsequently maintained. While participants considered facilitating patient autonomy a prerequisite, the possibility of valid consent if relied solely on patient autonomy was questionable.

Conclusion. Above all else, it was found that interprofessional communication over time maintained the professional-patient trusting relationship wherein facilitating the relational component of autonomy defined valid and lasting IC to CCTs.

Key words: Informed consent, Cancer clinical trials, Interprofessional, Responsibility, Trust, Autonomy.

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Glossary of Terms

Equipoise: An ethical basis for the clinician to assign patients to different arms of a study (Freedman, 1887). The clinician does not know the efficacy of the trial treatment choice, which is often blinded.

Haematology: The medical speciality of blood diseases / dyscrasias.

Informed Consent (IC) in Clinical Research: The voluntary patient authorisation of participation in a clinical trial as a result of adequate information disclosure. To ensure IC is valid and real, 3 critical and essential elements are required; voluntarism, information disclosure, and decision-making capacity (Gupta, 2013).

Multi-disciplinary Team (MDT): A multi-professional or interprofessional team referred to as involved in the patient's care and decision-making.

Oncologist: A medical doctor who specialises in cancer care and treatments.

Phase 1 & 2: Earlier phase trials designed to ascertain the drug safety via dose escalation.

Phase 3 & 4: Randomised or Later phase trials designed to ascertain the efficacy of a new drug against a standard treatment.

Randomised Controlled Trials (RCTs): A trial which ascertains the efficacy and safety of a new drug when compared to a standard treatment drug (Sedgwick, 2011). The computer randomly assigns the patient to a study arm. RCTs are considered the 'Gold standard' in study design available (Grossman, 2005).

Relational autonomy: This type of autonomy seeks to take into consideration the social and political structures, and forms of oppression within decision-making, often due to social restrictions on an individual's ability to act autonomously. Relational autonomy challenges the assumptions found in the bioethical literature that views autonomy as an individual endeavour (Mc Leod and Sherwin, 2000).

Research diary: Refers to the reflective journal kept by the researcher which captures the assumptions and the reflectivity between the researcher and the study.

'Therapeutic error': When patients are susceptible to 'therapeutic misconception' (confusing the context of the trial), 'unrealistic optimism', and 'therapeutic mis-estimation' due to their prior research understanding (Jansen, 2014, p.7).

Trust: A psychological contract gained by the interaction between two parties involving a social dimension (Gilson, 2003; Hurd et al., 2017).

Shared decision-making (SDM): A partnership in decision-making between the physician or healthcare professional and the patient (Barton and Eggly, 2009).

Chapter One: The Introduction

1.0 Introduction

The focus of this thesis is the interprofessional experience of obtaining / seeking informed consent to Cancer Clinical Trials (CCTs) and the role of communication within this. The study pertains to the adult cancer patient population assumed to have mental capacity as opposed to children. From my previous practitioner researcher and educator experience within the high-risk cancer treatment and research, I have developed a long-standing interest in finding out why there are on-going difficulties with obtaining informed consent from cancer patients to clinical trials. My particular interest lies in the value of interprofessional communication within a contemporary setting.

CCTs are necessary for the advancement of cancer treatment, yet 'slow accrual to CCTs impedes the progress of effective cancer treatments' (Brown et al., 2011, p. 1). It is estimated internationally that less than 5% of adult cancer patients enter CCTs (Unger et al., 2016). The UK National Cancer Patient Experience Survey (NCPES, 2018) evidenced that CCTs are discussed with less than 30% of cancer patients. However, there has been some advancement in the UK CCT recruitment since improvements to research networks within the National Health Service (Jenkins et al., 2010). Clinical trials have long since been known to cause communication difficulties for clinicians obtaining informed consent from cancer patients arising from the way information is delivered by physicians and understood by patients (Fallowfield et al., 2002; Jenkins et al., 1999). The interprofessional experience of communication difficulties is under researched. It is intimated that there are shortcomings in professional-patient communication in cancer research. Sankar asserts that the social context

of communication is 'overlooked' in relation to "what, how and by whom it is said" (Sankar, 2004, p.1).

To fully understand the communication practices at play the experience of all professionals involved needs exploration. The introduction begins with a brief overview of obtaining informed consent to CCTs from the traditional standpoint. Following on from this, the importance and aims of the study are presented within the context of the chosen research method. The structure of the thesis is outlined indicating the content of the subsequent Chapters 2-9.

1.1 An overview of informed consent to cancer trials

Put simply, informed consent (IC) is the voluntary patient authorisation of participation in a clinical trial as a result of adequate information disclosure. To ensure IC is "valid and real, 3 critical and essential elements are required; voluntarism, information disclosure and decision-making capacity" (Gupta, 2013, p. 1). The medical profession has traditionally held the responsibility for information-disclosure prior to obtaining informed consent and subsequently their quality of communication with patients is paramount. Low recruitment has been attributed to the physician's communication or lack of patient understanding owing to an inability to achieve informed consent in the first instance (Butow et al., 2014; Brown et al., 2004; Jenkins et al., 2010; Brown et al., 2011). The majority of the sociological research pertains to these medical challenges or is aimed at improving communication practices for the medical profession.

There has been uncertainty about how much information doctors ought to provide to patients to enable patient understanding and to achieve informed consent. Despite training programmes to address and improve doctors' communication strategies, Brown et al. (2011)

found shortcomings relating to doctors poorly explaining information. Furthermore, Brown et al. (2011) showed that trust in the physician was a defining factor necessary that enabled patients to follow the physician recommendation, sometimes favouring a paternalistic physician approach to deciding on the clinical trial, potentially negatively on achieving consent.

Where patient understanding is questionable, the validity of informed consent could be undermined owing to a lack of patient autonomy. The practice of obtaining informed consent that encompasses vast quantities of information delivery may be problematic when limited to a single patient encounter, or when limited to one professional encounter. It is speculated that obtaining informed consent is an interprofessional process of interaction with patients (Corrigan, 2003).

1.2 The importance of the thesis

The central purpose of this thesis is to explore the role of interprofessional communication in seeking informed consent and how this may impact on adult patient uptake to CCTs. The role of interprofessional communication was explored through the experiences of the professionals involved. Contributing to the achievement of this purpose, this thesis will detail the interprofessional experience (to include nurses, doctors and clinical managers) of obtaining informed consent to CCTs by exploring aims set out as individual research questions:

1. How professional responsibility is experienced as determined by time spent with patients for its impact on obtaining of informed consent to CCTs.
2. The experience of how trust is gained or lost by professionals within an ongoing process of informed consent, and how perceptions of patients' trust are associated with maintaining the patients' best interest.
3. How professionals experience facilitating diverse patients' autonomy when obtaining 'valid' informed consent to CCTs.

4. Whether an enhanced way of interprofessional working improves the communication difficulties that underlie poor informed consent to CCTs.

It is speculated that this exploration will build on the sociology of professions to gain a better understanding of interprofessional communication practices needed to improve obtaining informed consent to CCTs. In Chapter two, the background to the study is presented.

1.3 The conceptual approach

The key concepts underpinning the focus of this research are outlined and interlinked with each other in Chapter three. The concept of communication as a central focus within professionalism is linked to the trust and autonomy needed to achieve informed consent to CCTs.

1.4 The methodology

The methodological approach was set against the lens of the conceptual framework wherein the key concepts of informed consent, communication, professionalism, trust and autonomy are interlinked. See Glossary of terms on page 10. A qualitative phenomenological approach was used to explore the aims as set out as research questions. Data were collected by undertaking 26 semi-structured interviews with nurses, doctors and clinical managers and by keeping a research diary. As the researcher was also a professional and manager within the setting, a phenomenological approach described by Heidegger (1962) was chosen allowing for the interpretation of more than one truth.

1.5 Data analysis

Data were analysed by categorising into codes and subsequent themes from the language, words and phrases the participants used to relay their experiences with patients. The data were interpreted from the insider researcher's perspective as aligned with the concepts identified.

The practitioner researcher and participants view is later explained as a fusion of one constructing the other (Munhall, 1989).

1.6 The results and discussion of the findings

There are three analysis / discussion chapters spanning Chapters six to eight. In Chapter six there is a focus on how professionals experienced their responsibility. In Chapter seven the professional experience of gaining, and losing trust is explored, and its association with patients' best interest. In chapter eight, the difficulties with facilitating patients' autonomy is explored in relation to specific diverse cancer patient needs. In the final Chapter, a summary of the findings and the conclusions are provided along with the strengths and limitations of the study. Recommendations for professional practice improvement and further research are put forward.

Chapter Two: The Background

2.0 Introduction

Since the early nineties, CCTs have led the way in clinical trial progression in the UK, and it was then that doctors' communication practices first received attention (Fallowfield, 1995). Low recruitment to CCTs has continued to be attributed to difficulties with doctor-patient communication (Brown et al., 2011). Yet the field of clinical trial contemporary practice is advancing to encompass nursing and interprofessional practice. It is necessary to outline the origin of informed consent to clinical trials since its inception. It will be explained how professionals need to meet regulatory and ethical requirements to ascertain informed consent. Furthermore, the significance of clinical trial phases in relation to CCT patient consent is illustrated.

2.1 The origin of informed consent

The doctrine of informed consent as we know it today is based on moral philosophy and law. In the aftermath of the Nazi War crimes in World War 11, the Nuremberg Code was created in 1947 laying down regulations for ethical conduct in research (Jefford and Moore, 2008). The Declaration of Helsinki in 1964 established an ethical set of principles internationally requiring that participants entering research are adequately informed to include research risks and are given the right to refuse or withdraw from the research at any time and to provide written informed consent (World Health Association, 2008).

The 1970's brought about a detailed framework of clinical trial conduct which required all professionals undertaking research to adhere to Good Clinical Practice (GCP) and

International Harmonisation (IHC). This framework of clinical trial conduct was formalised by the Belmont Report (1979), issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. Central to the framework is the emphasis on the responsibilities of researchers to protect and respect individual patients / participants from harm and to ensure transparency for the sharing of research information.

2.2 The components of informed consent to CCTs

Arising from the need to respect and protect patients / participants from harm as a primary goal in clinical practice, four bioethical principles are commonly referred to. These are beneficence, non-maleficence, respect for autonomy and justice (Beauchamp and Childress, 2001). The principle of beneficence holds that the trial benefit is greater than the side-effects, moreover, ensuring against non-maleficence (harm). The provision of information about the trial is necessary for the patient to attain an understanding that is sufficient for him / her to consent to the trial. In order to achieve informed consent, the primary focus is to attain the individual's autonomous and voluntary authorisation to participate in research (del Carmen and Joffe, 2005).

While advocating for individual autonomy according to Beauchamp and Childress (2001), it could be perceived that autonomy trumps other principles, however, in reality there is often a preference among patients for shared decision-making or 'relinquishing autonomy' respectively (Biedrzychki 2011; Sinding, 2010). Furthermore, Corrigan (2003) speculates that the reliance on 'individual autonomy' underestimates the importance of the social dimension when obtaining consent. In more recent years and pertinent to CCTs, the quality of informed consent received attention, possibly due to questions about the lack of quality of informed consent that is achievable or the difficulty in achieving it.

2.3 The progression of informed consent to CCTs

As the field of clinical trial practice has expanded it is possible that professional boundaries are being challenged or even eroded. The nursing profession have sought professional role advancement within clinical research although their responsibility for IC remains often unclearly defined or evaluated, requiring exploration.

2.3.1 The medical and traditional standpoint

Commonly oncologists (cancer specialist doctors) hold a dual responsibility as a researcher and as a clinician, which Barton and Eggly (2009) identified as a central ethical issue due to differing role priorities relating to upholding patient autonomy or using a shared decision-making model. Medical communication was found to be problematic because the way doctors delivered information could be persuasive, for example placing 'value judgements' on the trial (Barton and Eggly, 2009; Weinfurt et al., 2003; Albrecht et al., 2003; and Butow et al., 2014). Even after doctors training in consent, still the language used continued to be arguably persuasive, yet consent improved if more time was given to patients (Brown et al., 2004; Brown et al., 2007, Bergenmar et al., 2011).

2.3.2 The process of informed consent as a social endeavour

Although seeking consent is evidenced by the patient signing the consent form, Corrigan (2003) asserts that in reality consent is unlikely a 'one-time event' and concurs with Brown et al. (2007) that consent is a process over time. Owing to the complexity of information delivery needed, particularly in relation to randomised controlled trials (RCTs), sufficient time is essential to meet consent requirements. Integral to incorporating patient choice, more time afforded patients with an opportunity to express preferences (Brown et al., 2004; Hietanen et al., 2007). In more recent times the notion of shared decision-making (SDM) has been shown

as the preferred approach because it involves patients in decision-making and patients have shown preferences for sharing the responsibility of the decision to enter a trial as opposed to the referred to 'loneliness' of an autonomous patient consent decision (Madsen, 2007).

The problem with obtaining consent over time is that the traditional role of the medical profession may be constrained in the achievement of clinical trial consent. Once informed consent is achieved, the continuation of care must prevail throughout the duration of the clinical trial which can take several months and longer for the follow up, which arguably may span interprofessional practice.

2.3.3 The emergence of the interprofessional role

The doctor-patient relationship holds particular significance because of the power dynamic created where trust is needed before the medical recommendation for the clinical trial is accepted by the patient. Even when informed consent is obtained there is the possibility that it may not be of reliable quality, notwithstanding the possibility that consent can be lost during the duration of the trial. There may be care gaps that doctors are challenged to fulfil. The possibility of the interprofessional social interaction with patients may bring about an improvement.

In the studies that have included the interprofessional perspective nurses play a significant role in spending time providing comprehensive information to patients (Loh et al., 2002; Burke et al., 2014; Beadle et al., 2011). However, the role of nurses to date within informed consent has not received sufficient recent acknowledgement in the UK. Meanwhile external to the UK, particularly in the USA and Australia, important frequent nursing activities centred around the achievement of informed consent denoting that the nurse's role holds value in the achievement of informed consent (Wilkes et al., 2012; Nagel et al., 2010; Catania et al.,

2012). There is room for more recent insight into the interprofessional experience in the informed consent process in the UK which may highlight role advancement as the medical standpoint is challenged or supported.

2.4 The significance of clinical trial phases for cancer patients

It is necessary for the development of a therapeutic drug to undergo some years of phased clinical trial research to realise standard treatment status. Drug research is commonly divided into 4 phases (mainly 1- 1V). The characteristics of the most commonly offered trials and the physician-patient consent issues are highlighted in Table 1.0 below.

Table C1.0 Trial phases at a glance (adapted from CRUK, 2019)

Phase	Number of patients	Cancer type /stage of disease / prognosis	Aims / objectives of trial / characteristics	Randomised? (RCT)	Patient Issues	Professional Issues
0	Small,10 to 20 people	Many cancer types / Later stages / Poor prognosis	Checking if drug is harmful	No	Same as Phase 1	Same as Phase 1
1	Small, 20 to 50 people	Many cancer types / Later stages / Poor prognosis	Find outside effects (by dose escalation) / Effect on body. Drug safety / Early pharmacological actions (Sedgwick, 2011) Offered after several standard treatments	No	Unrealistic hope expectations / 'Over estimation' (Dolly et al., 2016) / 'Therapeutic misconception' (Jansen, 2014)	Information not understood (Van der Biessen et al., 2017) ? Validity of consent
2	Medium, from 10's to over 100's	1-2 Cancer types / Earlier or Later stages	Safety is advanced & more information on the therapeutic efficacy	Sometimes	Not RCT - Same as phase 1 If RCT - same as phase 3	Not RCT - Same as phase 1 If RCT – same as phase 3
3	Large, hundreds / thousands (multi-centre)	Usually one cancer type / Earlier stage / Better - Good prognosis	Comparing the safety & efficacy of new treatment to the standard treatment / drug, pre-licensing (Sedgwick, 2011) Assigned to different arms	Yes Most scientific / rigorous / 'gold standard' (Grossman, 2005)	Mistrust unknown efficacy of trial drug (Featherstone & Donovan, 2002) Cautious Unbiased	'Clinical equipoise' - New drug outcome unknown Uncertainty - communication problems (Fallowfield et al., 2002; Albrecht et al., 2003) ? Validity of consent
4	Medium to Large	One cancer type	Finding out more about long-term benefits / Side effects / Marketing	No	Not seen often	Not seen often

Key: Green - commonly offered phases of trials

2.5 Summary

In this chapter, the origin of informed consent is outlined in relation to the ethical principles professionals need to meet. It has been indicated that the traditional medical role has had difficulties with the delivery of information to patients. The potential difficulty for upholding patient autonomy is highlighted. The more recent social dimension of seeking consent as a process appears to span the professions. In the next chapter, the philosophical concepts that underpin obtaining informed consent to CCTs are presented.

Chapter Three: The conceptual framework

3.0 Introduction

In this chapter, the foundations for this research study are presented by looking through the lens of the main concepts (ideas). The conceptual framework has underpinned the study as connections were formed between interrelated concepts, which Polit and Beck (2012) highlight as 'illuminating relationships' between the main concepts, theory, practice and the insider practitioner researcher's assumptions. This relationship can oscillate between higher level theoretical ways of understanding and some lower level theories as derived from research studies, although the literature review focuses on lower theoretical findings. The interconnections derived from the main concepts has led to the appropriate methodology chosen from which the theory is interpreted for practice. As the phenomenon explored is multi-faceted, there will be a breakdown of how the main concepts relate to informed consent in the CCT setting.

The theory sought is aimed at the experience of professional communication within informed consent in the CCT setting. The concept of professionalism for the relevant professions is set out, indicating how professional identities impact on interprofessional practice. The relevance of the concepts of power and time within the concept of professional responsibilities is presented. Following on from this; the concepts of trust and patient autonomy within CCTs is outlined. But first, informed consent is the voluntary patient authorisation of participation in a clinical trial as a result of adequate information disclosure. Three critical and essential elements are required to ensure validity; "voluntarism, information disclosure and

decision-making capacity" (Gupta, 2013, p. 1). The way professionalism interacts with informed consent is now outlined.

3.1 The concept of Professionalism

Understanding what it means to be a professional not only relies upon the regulatory components to be met to fulfil informed consent, for example the requirements of the relevant professional governing bodies, namely the General Medical Council (GMC) or the Nursing and Midwifery Council (NMC). Professionalism is also informed by the experience of practice at a given time. The professional communication mostly thought to be involved in obtaining informed consent to CCTs is derived from mainly the doctor-patient relationship and possibly the nurse-patient communication, notwithstanding the interaction between these professions in relation to the patient. The social structure and norms of the professions bears relevance to how both standard practice is experienced and challenged. There may be a gap or a disconnect between what is the norm experienced and how that is deconstructed by the contemporary experience to formulate a new reality or 'truth'.

The medical profession has held the power and responsibility over this traditional role of obtaining informed consent. Friedson (2001) emphasised that a professional is 'self - regulating' and can act on knowledge and skills to formulate judgment to make decisions, arguably competencies required to recommend a trial treatment for a patient. It is known that the physician is dominant in the informed consent discussions with patients (Butow et al., 2014; Brown et al., 2004). It has been recognised that within the forum for decision-making known as the Multidisciplinary team (MDT), there is a lack of nursing involvement and the MDT can be medically dominated (Lamb et al., 2011). On the other hand, nurses have not traditionally held the responsibility for informed consent and are believed by Davis (2000) to be adjuncts to the medical profession. Indeed, more traditionally nurses were marginalised as having lower

status by having less knowledge and autonomy (Carpenter, 1993). However, Stein (1967) believed that the nurse could influence the doctor's decision covertly by providing information rather than challenging. More recently, Banks and Gallagher (2009) described the general nursing responsibility as a 'duty of care'. However, to encompass care for a patient Davis' notion of professional identity as emotional detachment may not fit with what is inherent to nursing or what is needed / experienced in clinical trial practice.

The interprofessional experience of communication with CCT patients may provide reason to challenge the traditional norms and what has been taken for granted of the responsibilities for informed consent. To this end, it is worth considering Foucault's (1979) post-modern approach to power affecting society in a good or a bad way. He asserts that placing oneself in a discursive practice can change throughout history. He proposes a concept around sexuality as opposed to feminism which may affect nursing as mainly a female profession. In addition, the distribution of power needs to not take only a top down approach but is prevalent in all levels of society (Hoy, 1986) possibly challenging the known interprofessional power dynamics. Possible challenges within or between professional groups may have relevance for how professions exercise their power and responsibility through communication. Furthermore, external forces due to the potential for pharmaceutical and managerial target influences within the CCT setting may threaten what Evetts (2011) calls the ideology of a profession because of control from organisational objectives in contemporary practice.

In more recent years interprofessional practice has emerged as professionals complementing each other's role (Hammick et al., 2009), where roles overlap and professional boundaries have been extended, which may be relevant to CCT practice. While Hammick et al. (2009) recognised interprofessional practice as care professionals complementing each other's roles, there is potential for tension or challenges to roles due to overlap and separation

of roles. The possibility for role overlap may arise because both doctors and nurses may assume responsibility for information giving or play a part in decision-making by advocating for the patient. Possible challenges to the norm may prove morally burdensome to uphold responsibility yet work interprofessionally where boundaries are blurred in keeping with Engel and Prentice (2013). However, to understand the experience of practice it is essential to find out how the professions socially orientate themselves. It may be that the professional socialisation is in a state of continuous change because of what Abbott (1988) asserts as arising from competition over the division of labour. The way labour is defined may relate to how the availability of time impacts on roles.

3.2 The significance of time as a concept

The existing sociology emphasised the importance of professionals, namely doctors gaining consent as a 'process', 'over time' as opposed to gaining consent in a 'given moment of time' or 'one-time event' (Corrigan, 2003, p.786, 788; Jansen et al., 2014, p.30). In the context of high-risk lung cancer patients, one reason for obtaining consent over time given was that patients need time to deliberate, requiring 'slow construction' of information that is 'explained and reformulated' (Pujol et al., 2016, p.1). The professional duty to provide 'an adequate information base' supports informed consent, allowing enough time to enable an understanding of the risk-benefit in order to facilitate patient autonomy (Beauchamp and Childress ,2001, p. 321; Herring, 2006). Providing an 'adequate information base' requires professionals to spend time with patients. Strazdins et al. (2016, p.1) suggests that time is 'socially shaped'. Furthermore 'qualitative time' is the 'quality' of social time, 'derived from a group's beliefs and customs' Merton (1937, cited in Hassard, 2001) whereas, quantitative time is regulated by the 'quantity' of time, Sorokin and Merton (1937 cited in Hassard 2001). It is argued that 'quantitative time' 'understates qualitative time' which can be operated 'within irregular self-

determined temporal patterns' (Hassard 2001, p.136,137). It would be insightful to find out how 'quantitative time' and 'qualitative time' impact on obtaining informed consent.

The research in general practice has mainly explored generally how time is lived in medical practice, thereby impacting interactions with patients (MacBride-Stewart,2013; Horobin and McIntosh, 1983; Armstrong, 1985). It is noted that for doctors time is constructed in 'units' in relation to both the 'task' and 'socio-temporal structures' in keeping with Hall, (1989 cited in Deery 2008). The example used by Deery (2008) refers to doctors exercising their responsibilities within the time boundaries of outpatient appointments. Conversely, 'process time' was argued in the nurse midwifery context as 'the plural' and 'relational' 'context-linked' to the nature of time' involved in care, which is 'relationship-governed' according to Davies (1994 cited in Deery, 2008). 'Relationship-governed' time may also have a function in achieving trust within a power dynamic between the professional and the patient underlying informed consent.

3.3 Trust for diverse cancer patients

Within the sociological literature, the most prevalent components of the concept of trust is that the 'trustor (the patient) has positive expectations regarding both the competence of the professional (competence trust), the trustee, and that they (the trustee) will work in their best interest (intentional trust)' (Calnan and Rowe, 2008, p7). Indeed, there is a bioethical view that informed consent relies upon trust (Eyal, 2014). Sociological theory has suggested a power dynamic between the trustor and the trustee where the offer of the trial facilitated the expectation of hope for cancer patients by using positive language (Brown et al. 2015). However, the facilitation of patient trust and hope could be challenging for relationship building because the trial outcome is uncertain and carries the risk of unpleasant or even life-threatening side-effects. Professional-patient interactions are important for the development of

trust needed for informed consent because of the CCT clinical uncertainty. Indeed, demonstrating informed consent would require for the 'trustor' to display 'active' trust as opposed to 'passive' trust (Giddens,1990;1994), who describes 'active' trust as enabling a patient to take an active 'leap' by 'bracketing out' the uncertainty of the CCT outcome (Brown et al., 2015). As professional-patient interactions are the focus of experience, the 'micro', as opposed to 'macro' organisational trust experience requires exploration (Gilson, 2003).

Informed consent to CCTs is needed to span a prolonged process of trial treatment which involves patient care across professional teams. However, Hurd et al. (2017) found that trust can be most vulnerable to disruption during transition of care between teams. Patients may have initial trust where unconditional or what Calnan and Rowe called 'blind trust' (2008) in the doctor's expertise and knowledge is experienced, which Greener (2003) said can mitigate the degree of risk involved in patients' choices. 'Unconditional trust' can be based on dependency, hope and 'faith', which can be non-rational arising from an affective or emotional bond (Lewis and Weiger,1985). However, Calnan and Rowe (2008) found that trust was also conditional and rationally based, derived from the experience of good care, competency and effective communication skills. With regard to maintaining trust, Hurd et al. (2107) argued that the on-going 'traditional trust', is apart from the 'initial trust', a combination of emotional (affective) and knowledge-based (competency-based) trust, in an advanced stage. The possibility of the disruption of on-going trust is important and could avoid patient attrition from the trial. Furthermore, patients already on the trial have an expectation of hope (Simpson, 2004), which Barbalet (2008) proposed professionals are required to honour, possibly by upholding trust.

The definition of trust as dependent on acting in the patients' best interest according to Calnan and Rowe (2008) may have implications for professional interactions with patients. It

is possible that gaining patients' trust is likely to be influenced by what professionals believe is in a patients' best interest. Professionals aim to work in collaboration following the Multidisciplinary Team best interest decision. However, Wood et al. (2007) and Blazeby et al. (2005) asserted that medical discordance with MDT decisions in cancer care was attributed to different medical perceptions about the patients' best interest and 'unknown factors' causing practice to unfold differently outside of the MDT. Trial design, for instance was highlighted by Jenkins and Fallowfield (2000) as a communication barrier to cancer patient's trial recruitment after the MDT recommendation. Gaining and sustaining a trusting relationship based on good interprofessional communication may help to alleviate the possibility of the loss of trust and ensure improved patient understanding, arguably needed for patient autonomous decision-making.

3.4 Autonomy as central to obtaining informed consent

Previous theorists have examined the value of autonomy extensively in relation to an individual's ability to determine freedom of choice and display rationality (Dworkin, 1988, p. 103; Kant, cited in Paton, 2001; Mill, cited in Collini, 1989). Indeed, Mackenzie (2008) considers respect for autonomy as a 'cardinal moral value'. In the healthcare setting, day-to-day practice encompasses the duty of professionals to enable patients' autonomous choice and patients' decision-making. O'Neill (2002) says that facilitating what she refers to as 'individual autonomy' is a professional duty, while Beauchamp and Childress (2001, p. 64) assert that 'respect for autonomy', 'obligates the professional, to foster adequate decision-making', by ensuring information disclosure, understanding and 'voluntariness'. However, facilitating the patient's autonomy to enable consent could be problematic if the patient struggles to understand the information disclosed which could place doubt over the possibility of respecting 'full' autonomy as alluded to by O'Neill (2002). It may be necessary for the professional to

consider the validity of consent by assessing the amount of autonomy that the patient displays, depending on the patient's ability, knowledge or desire to make a decision about a trial treatment.

It has been previously recognised that the 'validity' of informed consent depends on the patient's moral power and freedom to decide or 'voluntariness' (Chwang, 2016; Bergenmar et al., 2008). Insider researcher assumptions question the validity of informed consent in the CCT setting because of the patients' emotional and cognitive perceptions about the trial. The patients' ability and freedom to consent could be impacted upon because of an asymmetry in physician/patient knowledge or a distorted understanding of information by patients. For instance, Jansen (2014, p.7) refers to 'therapeutic error', where patients are susceptible to 'therapeutic misconception' (confusing the context of the trial), 'unrealistic optimism'; and 'therapeutic mis-estimation' (due to their prior research understanding). The patients' illness stage can also impact on their emotional desire to enter the trial. Dolly et al. (2016) highlights that a feeling of patient 'desperation' impacts on informed consent for advanced cancer patients embarking on trials. Additionally, a lack of the patients' understanding of information could pose difficulties for facilitating respect for autonomy. Known associated language factors are often related to socio-economic and illiteracy barriers to informed consent in ethnic minority populations resulting in patients' lacking trial understanding (Schrank et al., 2016; Durant et al., 2014). Patients' lack of understanding of the trial could cause professionals to doubt patients' autonomous ability to choose a treatment because patients may be perceived as lacking sufficient knowledge needed to decide.

Contemporary healthcare practice is characterised by endeavouring to respect 'individual' autonomy (Corrigan, 2003). In this study, mental capacity is assumed of the adult cancer patients from whom consent is sought. However, it has been recognised that there are

'limits' to individual autonomy based on patient and physician factors (Van Kleffins, 2004), for example, professionals' preconceived view of lack of patient's trial understanding. It has been recognised that there can be physician bias or selection bias, or professionals precluding patients from trial entry or 'gatekeeping',(Melisko et al., 2005; Jansen and Wall, 2017; Sharkey et al., 2017). Some sociologists object to individual autonomy because of assumptions made by professionals about the patient's independence and self-sufficiency (Sherwin,1998). Facilitating individual autonomy could therefore be problematic in some ethnic minority groups where the influence of the family could undermine or restrict the patient's independence and capacity (Bell and Balgeaves, 2015). However, some sociologists have perceived the criticality of relational autonomy which they explain encompasses an appreciation for the family structure in decision-making as opposed to focusing on individual autonomy (Corrigan, 2003; Donchin, 1988). Differences in the way patient autonomy is viewed by professionals may impact on contemporary practice.

3.5 Summary

The theoretical linkage of the concepts has provided a lens through which the experience of practice can be viewed. The purpose of the research is to find out how these concepts may be experienced in daily practice, not only because they are integral to informed consent, but because the experiences may challenge traditional professional socialisation. The conceptual framework has formulated an approach to the methodology and how data were collected and analysed. Furthermore, these concepts guided the research studies selected on informed consent highlighting the theoretical gaps as seen in the literature review chapter.

Chapter Four: A review of the Literature

4.0 Introduction

The aim of this thesis was to explore the interprofessional experience of communication that impacts on obtaining adults' informed consent to CCTs. In this review, a synthesis of previous research and literature is provided. The structure of the review is guided by the conceptual framework in order to find out the interprofessional-patient communication gaps. The review focuses on exploring how informed consent is verbally obtained from adult cancer patients as opposed to exploring forms of written communication given to patients. The themes found in the literature are then presented according to three main sections; namely, professional roles as determined by time; gaining patient trust and facilitating patient autonomy. The conceptual framework has underpinned the categorisation of these sections. Finally, drawing the literature together the review culminates in three research questions by highlighting the gaps for exploration in this study.

4.1 The Review Process

The method used to undertake this literature review involved a critical review of peer reviewed empirically based research studies predominantly in the CCT setting, together with some grey literature on policies / standards that guide practice. Although qualitative studies were prioritised, quantitative and mixed method studies were reviewed in order to find out what is already known about the interprofessional experience of obtaining informed consent from adult CCT patients.

The four databases chosen from which to review the literature were Cinahl plus, Medline, Science Direct: Social Sciences and Psych-info. These were chosen because they are widely used for their contribution to medical, nursing and psych-social research. The word search terms comprised of three terms / word sequences per search spanning three main categories as seen in Table C4.0. When reviewing the breath of literature pertaining to more broad concepts, for instance; ‘uncertainty, communication, informed consent’ and ‘trust, and risk’, large yields were generated, thereby necessitating a 3-5-year date range search. Literature prior to this start date was needed to set the scene or develop an argument

Table C4.0 Word search sequences by categories (concepts)

Communication, Professions, Time

1	Communication	Informed consent (IC)	Cancer clinical trials (CCTs)
2	CCTs	IC	Roles & responsibilities
3	CCTs	IC	Time
4	IC	CCTs	Process
5	CCTs	IC	Doctors
6	CCTs	IC	Nurses
7	CCTs	IC	Interprofessional

Trust

8-9	CCTs	Trust	Doctors / Nurses
10	CCTs	Trust	Interprofessional
11	Trust	Cancer	Medicine
12	Building trust	CCTs	Oncology
13	Fears	IC	Cancer
14	CCTs	Best interest	Medical
15	CCTs	Trustworthy	IC
16	Uncertainty	Communication	IC
17	Trust	Risk	Uncertainty
18	Trust	Hope	Medicine
19	Motivation	Patients	CCTs
20	CCTs	Risk	Trust

Autonomy

21	Participation	Perspective	CCTs
22	Patient autonomy	CCTs	IC
23	Decision making	IC	CCTs
24	Relational autonomy	Decision making	CCTs
25	Autonomy	Cancer	CCTs
26	Paternalism	Patient	CCTs
27	Autonomy	Cancer	Physician
28	Cancer patient	IC	Autonomy
29	Autonomy	Cancer	Doctor

The inclusion criteria comprised International adult English-speaking peer reviewed studies on informed consent mainly in CCTs, and some cancer treatment consent studies between 2003-2018. Those that were excluded were too general, meta-analysis, non-cancer

specific, child-specific, cancer screening or those that were not pertaining to the overarching research aim but focused on technical and scientific aspects of individual trials. In total, 1213 studies were found. The final number of papers selected for review were 77, which included 2 literature reviews, 5 discussion papers. 32 studies were reviewed in depth, while 38 were referred to, in order to demonstrate similar findings and show the breath of research considered. See Appendix C4, The Cumulative search history for breakdown of reviewed papers. Grey literature considered were local policies for Consent Taking (Appendix C5.6) and professional regulatory body codes of practice guidance; and books pertaining to consent practices.

The synthesis of the studies was guided by the use of the Critical Appraisal Skills Programme (CASP) Table, showing an appraisal of the methods, the findings, themes and study limitations. See sample in Table 4.1. Attention is given to interprofessional qualitative studies as shown in Appendix C4.3 and C4.4. As many themes were dispersed throughout different search categories, a study is reviewed once when pertaining to the main theme taken from that study, otherwise that study is referred to. First, the perceptions of professional roles and how time contributes to seeking IC in the CCT is reviewed.

Table C4.1 Sample of Synthesis of Literature: Medline 8 (CASP adaptation, Nice, 2014)

Author and Journal	Design	Aim & Findings / Themes highlighted	Limitations	Strengths	Additional- Referred to
Loh et al. (2002) Ethical Communication in clinical trial Australian- Dept of Medicine & Psychology **Search M8**	Qualitative- 4 focus groups, comprising data managers, 14 nurses Thematic analysis	**To ascertain views of data managers (sometimes nurses) of the nature and challenges of their role and differences between physician's role.** 3 roles identified: **Information provision-**clarification of questions post consultation, RCT explained, detail not provided by doctor i.e. logistics and practicalities, but unable to provide some info **Gave quality assurance-**ensured true IC, verifying understanding, non-coercive, rights confirmed, gave balanced view, comfortable speaking to patients, felt IC still medical prerogative, patients valued on-going nursing support & QL discussions, inconsistent team messages, **Negotiated time-**to discuss difficult patient issues, needs, cultural, language, misconceptions, ethical concerns	No doctors' views on their perception of nurse's roles	Views of nurses heard Possibility of patient autonomy reduced, hence nurse role Highlighted need for more education and training for research Showed Docs limited time	**Albrecht et al. (1999)** physician talk **Fallowfield et al., (1999).**Low accrual- due to **physicians-** lack of time / communication challenges / autonomy and SDM, understanding. Other roles **Penman et al. (1984) old, Cox (2002)** Patient issues- anxiety – too much information, poor recall, not understood- passive consent. IPP role: protection, information, reports, drugs, education

4.2 Professional roles and time

The main sub-themes identified within searches 1-7 were the professional / researcher role dilemma, information-giving, and the impact of time on professional roles. First, the communication challenges encountered by mainly doctors when undertaking research is reviewed.

4.2.1 The professional / researcher role

The way doctors understand their research role may have significance for how their practice is undertaken. In a study of 22 oncology physician consultations, Barton and Eggly (2009)

identified that there is a central ethical issue in relation to the role of the oncologist as a researcher. They described how the researchers' role is governed by contemporary bioethics, where according to Beauchamp and Childress (2001) consent to research demands that the researcher ensures the autonomous patients' consent; whereas the clinician's role is governed by professional medical ethics which they describe as modelled on shared decision-making (SDM). While Barton and Eggly (2009, p297) found that these combined identities often had the effect of the clinician researcher uttering statements of persuasion in favour of the trial, they viewed such communication as 'an ethical strategy in guided decision making'. The approach to their analysis was particularly effective in identifying the physicians' main topics of information given spanning several trial phases. The discourse was analysed by assessing the statements used according to a positive or negative valence, as transcribed by trained assistants. One of the drawbacks of this study was that the cohort of doctors was small and within one interview a repeated statement accounted for one theme. Repeating positive statements may well have an influence on how consent was obtained, together with skewing the statistical analysis. Furthermore, Iltis (2005) outlines an ethical argument where clinicians sought preliminary consent from patients which may cause pressure to participate in the trial because of the patient's previous relationship with the doctor (clinician). She likens the clinician in a research role to two moral equivalents because patients do not see the physician in different roles and therefore could feel pressured.

In a mixed methods study, Easter et al. (2006) highlighted that when undertaking professional role/s, one needs to have a particular relationship with the patient. Doctors distinguished between the caring and the research role. For nurses and study coordinators their caring role sometimes conflicted with research role. For them caring entailed relationship building over time. The strength of this study was that professionals could describe their role qualitatively by the open-ended interview question format undertaken. Quantifying the themes

was useful due to the large number of participants comprising 82 multi-professionals. The focus of this study was obtaining consent to phase 1 studies which may have influenced an increased caring role for a potentially more vulnerably ill patient group. Both professional groups integrated the caring and research roles, where physicians referred to the role integration as wearing 'two hats'. Differing role identities for nurses is reviewed later.

4.3.2 Information-giving

The giving of information to patients was shown to be problematic as studies indicated depending on the trial phase offered. The 90's was a time of seminal work highlighting doctor-patient communication difficulties. Fallowfield (1995) revealed that there was a need for physicians to give more information to patients to achieve better accrual, especially to randomised controlled trials (RCTs). Albrecht et al. (2003) in a discussion paper found that there was a potential for doctors to give too much information making it difficult for patients to emotionally cope. An influential early observational small-scale study (of 5 Oncologists) by Jenkins et al. (1999) found that physicians were unsure how much or how little information to provide because of patients' lack of comprehension of the trial information. They found that risky information about RCTs was communicated to patients as unclear analogies; likening RCTs to 'a lottery' or 'tossing a coin' in almost 35% of discussions. A strength of this study was the authors did establish a grid matrix to match statements of information-giving against assisting with the analysis of the study. In a later large multi-centre patient study, Jenkins et al. (2010) found that most patients were willing to enter a trial, although only half would enter a RCT. Interestingly, the amount of participation in RCTs increased significantly if patients were given more information in the consent discussion.

Various studies form the non-medical perspective reported that physicians gave insufficient information about the trial detail (Loh et al., 2002; Burke et al., 2014). Burke et al.,

(2014) observed in an ethnographic study that the initial presentation of information posed a challenge to RCT consent. There was a lack of information clarity contributing to patient misconception of the trial. The strength of this study was the qualitative information found from the interviews, as analysed by an objective anthropological perspective. They found that patient questions were not always answered clearly at the point of trial recommendation, but were evaded, seeming to resemble achieving patient assent (a more passive agreement) as opposed to consent, although the focus was solely on entry to RCTs. Interestingly, it was following this initial recommendation stage that navigators (assumed nurses) took on the role of patient advocacy and the provision of missing information.

4.3.3 The quality of information

The language used by doctors while explaining the information was seen to have a specific effect in relation to phase I trial consent. In a qualitative study of 16 informed CCT discussions, an Anthropologist, Sankar (2004) shows how the way the trial was presented by physicians 'imposed expectations'. She relayed that doctors on the one hand explained that the trial could have no benefit, but on the other could bring about a 'wonderful response'. These constituted expressions of hope and belief in the trial, although the primary objective was to assess the dosing toxicity only. The positive language used in relation to the trial had the effect of what she called 'framing', where the trial benefits were over-emphasised. She concluded a strong likelihood for trial information misconception or therapeutic misconception as a result. Although there was a small number of participants, the study was well designed by objectively observing consent discussions and data coding were checked 3 times.

Similarly, Weinfurt et al. (2003) presented a case study of a phase 1 trial patient discussion to demonstrate the effect of doctors using 'multi-vocalarity' expressions. Multi-vocalarity referred to doctors mixing 'frequency-type statements' that referred to the

percentage benefit of a trial or by uttering 'belief-type' statements or questions to describe the trial or to seek a response from the patient. One example given was doctors saying, "What do you think your chances are?", where the use of 'chance' intimated a positive trial outcome. One of the difficulties found was that the patient's belief response statement did not reflect the factual lack of benefit of the phase 1 trial. The patient's response seemed to resemble a therapeutic mis-conception (that they would benefit from a phase 1 trial, which is factually incorrect). However, Weinfurt et al. (2003) pointed out that there were other reasons why the patient may respond with belief statements, for instance because of conflicting information given and the patient using high expectation statements communicating reassurance to relatives listening. The study drawback was that findings were based on a single case study, possibly undermining the generalisability of the study.

More recently, from US behavioural sciences Dept, Brown et al. (2011) in small US study focusing on phase 1 clinical trial consent found shortcomings in physician communication strategies. The manner by which the information was communicated was in some cases highlighted as persuasive and paternalistic physician approaches to recommending, limiting the possibility of the patient's choice or SDM. However, only 6 oncologists' communication was examined, and their discussions were not limited to phase 1 trial entry. The study identified important themes highlighting the need for additional strategies for phase 1 clinical trial discussions. The lack of clarification of phase 1 trial intent chimes with the study pertaining to RCTs by Burke (2014).

4.3.4 Physician training strategies

Borne out of the impetus to increase CCT recruitment and the subsequent need to improve physician communication, mostly physician communication training was assessed using interventional studies that analysed the efficacy of training using physician questionnaires. Fallowfield et al. (2002) assessed the efficacy of 160 Oncologists training sessions resulting in definite improvements in communication. The reason was that doctors gave more time to provide patient information, showed more empathy and encouraged patient participation, although doctors mostly did not check information was understood. However, it is difficult to rely on or generalise these findings because in effect this was a 'staged environment', not reflecting the time pressures doctors would be under in reality. However, these findings set a landmark for studies that followed.

In a series of Brown et al. (2004 a & b; 2007) studies a sequenced step-by-step communication process of information-giving was assessed. Overall, it was found that communication was poor. Only 24% of doctors included patient participation in the decision (Brown et al., 2004a), with less than a third offering another treatment option and a small minority checked if patients understood the information. In the second of the Brown et al. (2004b) studies qualitative statements observed in cancer trial consultations were quantified into 4 ethical domains (themes) as follows: giving more time to seek preferences, moving through sequencing and autonomy steps, clarifying information and avoiding coercion. This study was extremely beneficial as it categorised communication techniques that mapped with facilitating the ethical components necessary to obtain informed consent. Comparison between baseline prior to training and post was ascertained by a team of mixed disciplines including psychologists, epidemiologists and doctors. However, the study lacked nurse communication

and only focused on phase 2 and 3 clinical trial consent. The ethical domains identified were used as a basis for assessing clinical practice and devising future communication training.

Later, Brown et al. (2007) examined only 10 doctors' communication strategies based on training in the 4 ethical domains. Doctors demonstrated more patient involvement in the consent and were less coercive by not favouring the trial leaving patients more satisfied about their decision, although some patients wanted the doctor to make the decision. Both Hietanen et al., (2007) and Brown et al., (2007), found that the trained group gave more time to patients which engendered better SDM allowing time for patient preferences. However, the lack of checking patient understanding of information is supported by Brown et al., (2004) and Butow et al., (2000), who highlighted that doctors not checking patient understanding of information was unresolved. Kao et al. (2017) reviewed that post communication skills training patients had no more knowledge about the trial, although the impact of time given in the consent discussions impacted on patients' decisions and gave patients more satisfaction. The experience of the non-medical team is taken into consideration next.

4.4 The role of the non-medical team

There has been a paucity of communication studies on non-medical professionals involvement in CCT consent in the UK, although Avis et al., (2006) recognised involvement needed to span the professions.

In a qualitative US study by Davis et al. (2002) nurses provided clarity about their advocacy role in CCTs. As a patient advocate, nurses identified with protecting the patients' interests and welfare, while as a study advocate their responsibility extended to the research goals, and as a subject advocate they were conscious of the patients' rights and understanding of the trial. The strength of the methodology used was that it was designed to elicit potentially

sensitive information about nurses' roles by means of first running pilot vignettes that were structured to avoid personal references. The questions in the focus groups that followed addressed what their responses would be to particular patient dilemmas, however some questions may have been leading because of stating a dilemma which sought their response as opposed to the nurse or coordinator describing a dilemma. However, the qualitative analysis did provide insight into role conflicts experienced, although it is unclear how these conflicts changed the way they communicated with patients.

The clinical trial nurse questionnaire (CTNQ) developed and validated in the US and Canada by Ehrenberger and Lillington (2004) was used in several studies to ascertain the nurses experience of their role, which they say is undergoing significant 'transformation'. The CTNQ assessed the frequency and subjective importance of activities clinical trial nurses performed. Activities frequently performed centred around the comprehensive communication of information to patients, checking that information and managing the trial throughout on-going informed consent (Ocker and Plank, 2000; Mori and Mullen, 2007). Another important role within consent was that nurses viewed themselves as a patient advocate, facilitating patient decision-making (Mori and Mullen, 2007; Catania et al., 2012). In more recent years, the importance of their involvement in consent was rated the most important of their activities (Nagel et al., 2010; Wilkes et al., 2012; Catania et al., 2012), although Catania et al. (2012) rated their actual involvement with IC as the third most frequent activity. Wilkes et al. (2012) found that the involvement in IC was the most important and most frequent activity for Australian nurses. However, the drawbacks of this study was that physicians were required to contact nurses to take part potentially favouring nurses who were more actively involved in the IC process. Mainly, the nurse role in research was acknowledged. The CTNQ questionnaire used for most of these studies arguably provided a limited form of enquiry, potentially guiding

nurses' answers, and the results did not give a guide for how informed consent could be improved.

The UK is lacking exploration of the nurses' experience of their role in IC. However, Tomlin et al. (2014) did acknowledge nurses as information advocates in RCT consent, prioritising patient suitability and eligibility questions although nurses arguably led patients by what was termed their 'empathetic preferences' (what nurses felt was the best choice of trial arm). Only 3 out 5 were cancer trials discussions, and there was great variety in nurse training and clinical backgrounds. Tomlin et al. (2014) found a discordance between what nurses views were and how they interacted with patients. Nurses did not always align information correctly or answer patient concerns; which they felt limited patient empowerment in decision-making; while some nurses felt consent, discussions were restrictive. The methodology used varying qualitative tools, while the uptake of some was poor. Only 7 nurses undertook audio recordings, and only 9 individual interviews, while 30-34 attended group interviews. Although various common communication themes were identified, the data from the focus group may have been restrictive as often participants do not contribute equally within a group. Spilsbury et al. (2008) found through nurse focus groups that research nurses lacked confidence in the UK and did echo the conflict of role between their clinical and research responsibilities. However, these nurses were not from the cancer speciality. It may be that specialist cancer nurses are more certain of their role in IC in the UK, although this remains unclear. Interestingly, in the UK, Cox (2002) from the patient perspective found that nurses who communicated using positive trial language had an impact on gaining trial consent.

In a European survey of almost 200 cancer nurses, Beadle et al. (2011) found that nurses felt informed consent discussion fell short of ethical standards (considering physician talks). They attributed shortcomings in information-giving to a lack of patient understanding, even

coercion, because patients did not have enough time to decide. The questions and statements generated did encompass specific domains of communication, from which participants ticked and were evaluated in focus groups of 6 oncology nurses, although it is unclear if they were involved in research. The design could have led the participants to a choice of answer. Loh et al. (2002) revealed through qualitative focus groups that the nurses' role centred around information provision including answering questions in more detail than the doctors. They also ensured high quality consent by checking information was understood and verifying that the patient did not feel coerced by overestimating the trial benefits. The Burke et al. (2014) study chimes with the notion of research nurses (as navigators) exercising patient advocacy which they term 'competing ethics'. Nurses answering key questions avoided misleading patients' understanding of the trial from the start of the consent process.

4.5 Informed consent as a process

While informed consent is often understood as a contractual agreement / paper signing between the physician and the patient, much of the literature has referred to obtaining informed consent to CCTs or RCTs as an on-going process over time (Brown et al., 2004; Brown et al., 2007; Corrigan, 2003; Kao et al., 2017). These studies pointed towards both physicians and patients mostly needing more time in the clinical trial discussions.

The nursing perspective highlighted by Beadle et al. (2011) relayed the that 19% nurses felt that there was not enough time given in the physician discussions to enable patient understanding to decide on the trial decision. As previously reviewed seeking RCT consent and shared SDM particularly necessitated more time (Brown et al., 2004; Bergenmar et al., 2008; Jenkins et al., 2010); although this did not always take place (Brown et al., 2007). In a later study, Bergenmar et al. (2011) discovered although patient understanding could be improved with more consultation time for instance over 30 minutes time yielded higher patient

perceived understanding of the risks and benefits, yet there was no significant patient knowledge increase with more time. One of the strengths of this study was the use of a validated measurement tool (QuIC- the Quality of Informed consent), although the data were collected retrospectively after the patients were consented to the trial, which may well have distorted the data due to the possibility of poor patient memory recall. Importantly, these efforts to provide more time to patients yielded improved communication.

The benefit of giving more time to patients as a consent process was also found to yield an improved relationship with patients as nursing studies acknowledged (Loh et al., 2002; and Burke et al., 2014), demonstrating that such a rapport with patients alleviated their misunderstandings. However, Sankar (2004) attributes this professional-relationship improvement to the way information was delivered as opposed to the time spent, while Brown et al. (2004) acknowledged the benefit of the process of physicians 'sequencing the information' over time as a social process of interaction with patients. Easter et al. (2016) found that spending more time with CCT patients significantly improved patient care, described as 'closeness', although the focus of the study was care as opposed to obtaining informed consent. Easter et al. (2016) and Mc Grath-Lone et al. (2015) found that care was an important component in research practice, which chimes with the NMC Code of practice (2016). Easter et al. (2016) also suggest that this improved interprofessional care may influence recruiting patients in trials, although research was often referred to in negative terms while care was referred to in positive terms, suggesting a professional moral challenge for professionals undertaking research.

4.6 Interprofessional roles as influenced by time

Overall, professionals experience role dilemmas between care and research advocacy. Nurses and trial coordinators appear to have complemented the doctors' role in obtaining consent to

CCTs by spending more time giving detailed information to patients using appropriate language and checking patient understanding of the information. Many of the studies were of a quantitative design, leaving room for an exploration of how the experience of the professional-patient interaction could be impacted by time, particularly in the UK. Consequently, the following research question can be asked: How does the experience of interprofessional responsibility as determined / shaped by time influence obtaining informed consent to CCTs? The focus of the literature now shifts to trust within the professional-patient communication.

4.7 The impact of trust

Within search sequences 8-20 there were 3 main categories, namely, trust motivating patients, trust undermined, and distrust and the amount of trust needed in uncertainty. It is note-worthy that in many studies that assessed doctors' or nurses' communication strategies trust was not the main focus.

4.7.1 The patient motivation

Many theorists found that patient trust in the physician was a key motivating factor influencing the decision to enter a CCT (Jenkins et al., 1999; Cox, 2002; Loh et al., 2002; Madsen et al., 2007; Kass et al., 2009; Comis et al., 2009; Catt, 2011; Brown et al., 2011). Patients were motivated to trust in the physician because of a belief that the physicians' recommendation was in their best interest or due to the doctors' competence (Jenkins et al., 1999; Cox, 2002; Catt, 2011, Mechanic, 2000; Comis et al., 2009; Townsley et al., 2006; Daughterty et al., 2005; Brown et al., 2011). Even though patients were motivated by trust in the best treatment offer, many nurses perceived that patients felt that they had no other option (Shannon-Dorcy, 2011),

or patients were unable to refuse (Catt, 2011), raising questions as to whether patient trust was freely placed in the physician.

Certain groups of patients demonstrated trust differently. Price et al. (2012) found that older patients preferred to be guided especially when the treatment was uncertain, while Cox (2002) and Nurgat et al. (2005) found that patients were motivated to participate in trials due to self-interest and trust. In the Madsen et al. (2007) study, there was a shortcoming in the study design because only female patients who had a response to treatment were contacted for ethical reasons. The responders may have had more trust in the doctors' competence. However, interestingly, patients did experience a lack of trust when they saw too many physicians, highlighting the value of one-to-one trust relationships.

Patients often associated hope with trust. Although only in a small study of 13 patients, Brown et al. (2015) found that patients interweaved trust with hope, because of trust in the doctors' competence and hope in the trial drug, while the doctor fostered hope. A more physiological approach was undertaken by Yang et al. (2010) who found that patients had an affective response to positive statements by using the Risk Information Seeking and Processing (RISP) tool to assess patients. Such an assessment was counselling specific and would potentially require careful patient support if it were undertaken again. Similarly, Lee et al. (2016) found breast cancer patients had trust in the doctor and placed hope in the trial, even though only Asian women were assessed. Biedrzychi et al. (2011) and Godskesen et al. (2015) found from questionnaires that enabling patients hope was a predictor of trial entry for patients, although patients had more trust in the healthcare system than doctors.

4.7.2 Trust undermined and distrust

Gaining the patients' initial trust appeared crucial and involved rapport-building with the doctor. In a meaningful literature review, Hurd et al. (2017) developed an integrated model of care as applied from the business field but could be useful in CCT practice. They proposed that the consent contract required an initial 'swift' trust to enable the recruitment or consent to the trial, while the 'traditional' trust sustained the duration of the trial. Interestingly, they felt that professionals could modulate trust by ambivalent behaviour within their relationship with the patient. Such ambivalence and the previously reviewed negative potential of the doctor's positive approach, could have potential for undermining trust. Positive language used by doctors to recommend the trial was intimated as coercive and termed 'framing' (Brown et al. 2015; Sankar, 2004); which could lead to distrust. Thorne et al. (2013) advocated the value of nurses 'sitting down' with patients to allay distrust by deciphering too much information, albeit given positively by doctors. The nurses' role seemed to have the effect of allaying patient fears, or alleviating the possibility of coercion, thereby possibly maintaining trust (Cox, 2002; Loh et al., 2002).

Studies on Ethnic Minority Groups indicated that distrust was linked to patient fear, uncertainty and suspicion. Some of the common findings were that African-American patients worried about being guinea pigs and showed lower trust than white patients (Meng et al., 2016; Somayaja et al., 2015). An important study was undertaken by Durant et al. (2014) which sought the interprofessional perspective on barriers to trial entry for minority groups. The findings were most valuable as they were attained from qualitative interviews with doctors and research nurses. The main findings were that these patients were sceptical because of fear caused by distrust, negative trial connotation and the language used by professionals. The language barrier often caused stereo-typing of patients assuming they were not intelligent,

exacerbated by interpreter problems. It was reported that this group required 'tailor-made' communication and that nurses were integral to the reviewing process to identify eligible patients.

In a similar UK study, Hussain-Gamble et al. (2006) assessed the interprofessional views of research staff regarding the participation of Asian women in CCTs. The value of this study was the face-to-face private interviews. Healthcare professionals did not feel patients were excluded because physician tendencies to 'cherry-pick' patients was excused due to lack of professional time. While mistrust was found as a potential barrier to trial entry, there was emphasis on the building of a professional-patient trusting relationship, although the professions struggled to find enough time to nurture a relationship disadvantaging patients. The findings of this study could be transferrable to other ethnic minority populations. Importantly, Fisher and Kalbaugh (2012) among others pointed out that minority groups were underrepresented in CCTs.

4.7.3 More or less trust and uncertainty

Uncertainty about the trial outcome or doctors not knowing the outcome (equipoise) was cause for patient distrust. Physicians felt communicating the uncertainty of RCT outcomes could impact on patients trust in them, potentially losing trust or bringing about distrust, respectively (Jenkins et al., 1999; Fallowfield et al., 1998; Featherstone and Donovan 2002; Thorne et al., 2013). However, the ethical communication strategies and sequencing developed over various interventional studies did prove beneficial in allaying such uncertainty, thereby as a bi-product built trust (Brown et al., 2011). One of the most influential studies on how patients dealt with uncertainty was undertaken by Brown et al. (2015) who found that patients could 'bracket out' the uncertainty of the trial outcome to maintain trust and hope enabling consent to the trial.

There is an argument in the literature in relation to the notion of patients having more or less trust where Yin-Yang et al. (2010) found that more trust achieved better patient trial compliance, while passive (arguably less trust) was found to have the effect of patients handing over their trust to the clinician (Kraetschmer et al., 2004). Although a sociological discussion, Zinn (2008) argued that more trust was needed for risky decisions. In a later paper, Zinn (2016) developed the notion of 'in-between' patient strategies for example hope and faith that enabled trust formation. Interestingly, Zinn points out that all patients are not autonomous, although professionals tend to frame passive hope negatively.

4.7.4 Interprofessional trust

While trust was essential for informed consent to occur, maintaining trust could be perceived as more challenging. Hillen et al. (2011) concluded that from 45 studies the trusting physician-patient relationship facilitated decision-making, often by decreasing the patient's fear. However, the role of the doctor and the nurse differed in trust formation and maintenance, because it is not certain how they experience it or how collaborative roles impact trust. Mostly, patients trusted doctors because of a belief that doctors acted their best interest. Therefore, the questions can be asked: What is the interprofessional experience of gaining trust to CCTs, and how does acting in the patients' best interest impact on trust? Finally, attention now shifts to patient autonomy positioned as one of the bedrocks of attaining informed consent.

4.8 Autonomy as a deciding factor

The studies from searches 20-29 including over-lap from previous studies were focused on how professionals experienced patient autonomy, sometimes seeking data from patients to inform practice. There are 3 main focus areas of the literature, as follows: patient understanding

and consent validity; relinquished autonomy; the role of advocacy / 'gate-keeping' and individual autonomy.

4.8.1 Patient understanding and consent validity

One of the major drawbacks of most of the studies undertaken assessing doctors' communication excluded non-English speaking patients (Brown et al., 2004; 2007; Hietanen, 2007; Jenkins,1999; Albrecht et al., 2003). However, a number of previous studies have focused on problems with patient understanding as a reason for questioning the validity of consent or have caused barriers to obtaining informed consent (Jenkins et al., 1999; Joffe et al., 2000; Gattellari et al., 2002; Hietanen et al., 2004, and the Brown et al. 2004; 2007). The main reasons for poor understanding are outlined in relation to trial phase specific lack of understanding, therapeutic misconception, and difficulties with information disclosure and interpreter problems (Hussain-Gamble and Leese, 2006).

Clinical trial phase 1 patient misunderstanding and misconception has been examined widely (Jefford et al., 2011; Kass et al., 2009). Jensen et al. (2011) used a measurement of understanding post the decision to enter the trial developed by Joffe et al. (2001). It was found that patients had a significantly higher level of subjective as opposed to objective understanding of the trial information which correlated with a high level of satisfaction for entering in the trial. Patients particularly struggled with understanding the benefit and dose escalation of phase 1 trials. The strength of this study is attributed to the validated measurement tools used, however these perspectives were gained after consent had taken place. There is no data on patients who did not consent to the trial.

Levels of patient knowledge and understanding also differed. Bergenmar et al. (2008) reported that patients had a high level of understanding, but their knowledge resulted in only

50% understanding of the trial risks. In both studies, the patients perceived that they understood more than they actually did understand. Although these studies were multi-centred and used measurement tools, non-English-speaking patients were excluded. The disparity between the perceived understanding and actual knowledge level of patients is similar to the findings of other studies (Brown et al., 2004; Jenkins et al., 1999). The way information was delivered could be misleading for patient understanding. However, as explained, perceived patient misconception may not be cause for invalid consent (Weinfurt et al., 2003). Next, many studies found that patients resist decision-making arguably needed for valid informed consent.

4.8.2 Relinquished autonomy

A common theme in the literature was patients not wanting to decide for themselves, thereby possibly 'relinquishing' their autonomy. Cox (2002) examined the patient experience of recruitment to trials; wherein it was found that 80% of patients wanted the healthcare professional to advise them, possibly relying on the doctor to decide for them. Interestingly, a number of patients made an immediate decision, and a question about professionals facilitating autonomy arises because 40% of patients had difficulty in asking questions. A major strength of this study was that the experiences of patients related to their interactions with both nurses and doctors, highlighting that trial nurses were essential to information checking and the continuation of trial communication.

Another reason for patients making passive decisions was because they had unrealistic hope. Dolly et al. (2012) found that 80% of phase 1 patients were motivated by clinical benefit, when in fact this perceived benefit was incorrect. These findings related to patient trial mis-conception and the lack of professionals offering alternative treatment options. Of the 400 patient questionnaires given, only ¾ were returned post doctor consultation, possibly because of insufficient time given to patients to rationalise for their decision / indecision. What directly

impacted on achieving informed consent was the patient loss of locus of control, displayed as ignoring the information, found by van der Biessen (2017) in a study of 135 phase 1 patients who found that desperate patients were motivated by hope arguably not wanting to activate their autonomy.

However, doctors did not refer to 'respect' for autonomy or lack of; but referred to persuasive language or patients' willingness. Generally, in the cancer setting, it is note-worthy that patients were seen to off-set decision-making (Sinding et al., 2010), or take a passive role due to lesser knowledge (Mancini et al., 2014); or as van Kleffens et al. (2004) point out refusal was a choice. As a result of patients 'off-setting' autonomy, there was a dilemma for professionals to act paternalistically. Often while assisting patient autonomy, professionals exercised patient advocacy.

4.8.3 Advocacy or gate-keeping

Studies previously showed that professionals saw the role of communicating as a patient advocate or decision-maker. Positively framing the information however could be coercive and cherry-picking could constitute 'gate-keeping' (selecting or excluding patients), both with a leaning towards deciding for the patient (Brown et al., 2004; Barton and Eggly, 2009; Sankar, 2004; Burke et al., 2014; Hussain-Gamble and Leese, 2009). Melisko et al. (2005) and Lee et al. (2010) found physician bias existed against the trial itself. While selection bias is found against trial design, it was a predictor of participation, although as Fayter et al. (2007) pointed out that such bias is difficult to assess due to the lack of reporting of such data.

It was found that nurses recognised their patient advocacy role in pre-emptying patient questions and clarifying possible 'framed' information. However, activating this role could be problematic (Tomlin et al., 2014; Spilsbury et al., 2008) although Fisher and Kalbaugh (2012)

found that nurses used the goal of altruism to cope with this dilemma. Importantly, Tomlin et al. (2014) found that nurses became active in assessing the suitability of RCT patients as part of their advocacy role. These UK nurses voiced their concerns about restricted recruitment practices, and consent discussions were inhibited due to misleading information or patient therapeutic misconception, proposing that valid consent was difficult to achieve. Gaining patients' autonomous decision to obtain informed consent as emphasised by Beauchamp and Childress (2001) could be threatened by professionals taking on the role of advocacy. Mostly, studies sought professional and patient experiences of CCT consent that relied on the individual patients' autonomy.

4.8.4 Autonomy for the 'individual'

Achieving valid consent is pointed out as 'more difficult than guidelines and policies imply' (Corrigan, 2003, 789) and is often reduced to a tick-box exercise to evidence that the patient made an autonomous individual decision (O'Neill, 2002; Twomey, 2015). Local policies reviewed on 'Taking Consent' were focused on gaining consent from the individual patient.

In a qualitative study, Corrigan (2003) found that informed consent can be reduced to 'individual' autonomy which ignores the necessary cultural dimension. She seeks to advocate informed consent as a relational (including the family) over an individual concept. She suggests that professional training needs to better reflect the patient population an institution serves. This is a valuable study of 25 phase 1 patients, as it shows the professionals' opinion of trial rigidity and assumptions made about informed consent associated with the autocratic medical practice of consent-taking over the reality of the cultural values that shape patients' social situations.

The main studies reviewed highlighted the barriers to CCT recruitment within the ethnic minority groups (Hussain- Gamble and Leese, 2006; Durant et al., 2014), although they did not strongly focus on the need for considering autonomy in a relational way. Datta et al. (2016) and Hussain-Gamble and Leese (2006) recognised medical training as opposed to interprofessional training to incorporate relational autonomy into clinical trial consent. In general oncology, Datta et al. (2016) found doctors and nurses recognised the value of the shared and supportive role of family, while balancing patient autonomy with the relatives' desire to withhold bad news brought other challenges. In addition, Biedrzycki (2011) surveyed 197 patients, most of whom preferred SDM (83%), which included the role of asking if patient preferred the family involvement, a role that nurses valued within their collaboration. When autonomy was considered differently, Asiedu et al. (2018) found that of 33 ovarian cancer patients' decision-making was ultimately the patients' choice, but was decided upon within the context of relationships, suggesting the social construction of autonomy.

Given the challenges outlined with basing informed consent on patient autonomy within the context of a diverse cancer population given poor understanding and lack of active decision-making; the question ought to be asked: what is the interprofessional experience of facilitating autonomy in the diverse CCT setting?

4.9 Summary

The dual role of researcher and clinician has been problematic for both professions. Mainly the doctors' communication difficulties were researched, and to a lesser extent the nurses' role within informed consent discussions. Overlapping roles emerged as well as individual identities. The more or lack of time (as a process) professions spent with patients impacted on information-giving and patient understanding. Overall, the nurses and trial coordinators roles

appear to have complemented the doctors' role. It would be interesting to find out if the traditional medical role of taking consent has advanced and is challenged.

While trust appears essential for IC to occur, maintaining trust could be perceived as more challenging. There is a need to explore the way trust was gained or differed between the professions and how collaborative roles impact trust. One resounding message is that patients trusted doctors because of a belief that doctors acted in their best interest.

It is uncertain if autonomy can always be truly achieved due to the patient issues professionals face, thereby questioning obtaining informed consent at all. It would be insightful to find out if IC relies on the policy requirement of patient autonomy, or if IC more relies on an interprofessional social endeavour. To bring about an answer to the research questions raised in the literature review, the methodology undertaken is next discussed in Chapter 5.

Chapter Five: The Methodology

5.0 Introduction

In this chapter, the methodological approach undertaken to answer the research question is presented. The overarching research question is: *What is the interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials?* To begin with, the research setting is outlined. Following on from this, the rationale for choosing the philosophical approach, case study and the reflective approach is explained. The approval for the research application including ethical considerations are described. In the next section, the research methods are presented and discussed, followed by an explanation of the data analysis. Finally, the validity of the study is presented.

The conceptual framework and the literature review have provided more clarity and highlighted gaps within seeking informed consent, culminating in supporting questions as follows: *What is the professional experience of responsibility as shaped / determined by time? What is the interprofessional experience of trust? And what is the interprofessional experience of facilitating autonomy?* An explanation of the chosen research methods supports the purpose of finding out why, so few potentially eligible cancer patients are recruited to CCTs, as guided by the supporting research questions.

5.1 The research setting

This research was undertaken within the CCT department setting comprising two day-care units and 4 wards in an NHS tertiary Trust specialist centre in London, delivering cancer treatment to 1.5 million people, many from the local diverse community or referred patients.

For each speciality, there were 1-3 research nurses (RN), supported by non-nurse practitioners and assistants, 1-3 clinical nurse specialists (CNS), 8 clinical managers covering different sub-departments and 1-7 consultants; each quantity depended on the speciality. The Trust has turnover of in excess of £1.1 billion and has approximately 16,000 employees. Medical and nursing specialist education is supported by the affiliated University or by the neighbouring Universities respectively. The Cancer Research Delivery Team sit within the Cancer Academic Group (CAG), comprising specialist nurses and doctors, some sharing University academic posts or with the UK Experimental Cancer Medical Centre.

5.2 The Philosophical approach

The purpose of this case study was to explore and analyse the interprofessional experience of communication that impacts on obtaining informed consent to CCTs. A phenomenological approach was undertaken originating from hermeneutic philosophy (Heidegger, 1962; Gadamer 1976) as will be explained.

5.2.1 Consideration of previous research methodologies

The previous research reviewed was used to consider how well quantitative interventional methods ascertained the efficacy of communication improvement strategies (Fallowfield et al, 1995; Jenkins et al, 1999; Kao et al, 2017; Brown et al, 2004; 2007; Hietanen et al., 2007). Professional perceptions of their roles via nursing surveys or questionnaires (Beadle et al., 2011; Catania et al.; 2012; Wilkes et al., 2012) confirmed role identities. While these studies demonstrated reliability through validated methods, they lacked an in-depth exploration of how their experience of communication struggles could change the course of interprofessional CCT practice.

Dated qualitative studies ascertained the experience of IC, providing more rich data. Davis et al. (2002) used interviews which gave insight into how CCT nurses struggle with their role. An ethnographic approach was illuminating by finding out only doctor's communication shortcomings via their consent talks (Sankar, 2004), while Burke et al., (2014) observed professional-patient interactions during consent, contributing to defining different role identities. Focus-groups for nurses provided insight on how non-medical research professionals viewed their role (Loh et al., 2002). Interprofessional and patient interviews found communication themes within the diverse cancer population (Durant et al., 2014). There were limitations to the UK's Tomlin et al. (2012) and Spilsbury et al. (2007) studies; which of both relied heavily on data from focus groups, comprising 3 out of 5 cancer trials and non-cancer research for the latter. Considering these contributions, it would seem timely and important to undertake a qualitative approach to seek the experience individually from all involved professionals.

5.2.2. Phenomenology: a rationale

This study falls into the qualitative research family. Blaxter et al. (2010) further describe qualitative research within the context of a naturalistic phenomenological mode where the subjective experiences of individuals are sought in a real-life setting. The conceptual/philosophical approach chosen was based on the work of Heidegger (1962) and Gadamer (1976). The phenomenological approach was most appropriate in order to explore and understand (give meaning) to the 'lived experiences' of the participants (Polit and Beck, 2012, p. 494; van Manen, 1990). Qualitative is preferred over quantitative methodology because it seeks to explore the personal meanings of experiences often through interviews. A qualitative observational (ethnographic) approach was not taken because I perceived that

observing an already contentious ethical context could cause disruption to patients or alter professional behaviour.

Seeking the 'lived-experience' in the natural practice setting as a case study where the researcher was also a practitioner is intended to add value to the meaning and make sense of a phenomenon (Smith and Osman, 2015). The type of phenomenology engaged insider practitioner interpretation as opposed to eliciting solely descriptive data. The use of descriptive phenomenology developed by Husserl (1859-1938) may limit the meaning of the data because it brackets the practitioner's interpretation and reflection. Interestingly, Dewey (2010) explains that the facts become meaningful when linked to knowledge, performance or role, even judgement, which is part of the epistemological focus of enquiry through the research practitioners' interpretation. In keeping with Heidegger (1889-1976) the aim was to account for suppositions and assumptions by exercising reflexivity in a research (reflective) diary. The research diary included the researchers' world and life experiences in keeping with Creswell (2007). Within the data analysis, the interaction as a practitioner sought to bring about as complete a meaning as was possible. The researcher was aware of certain assumptions about the culture of professional responsibility that needed to be understood, 'viewed as truth without conscious or explicit testing' (Rebar et al., 2008, pp.221).

Reflexivity is addressed in two places in the thesis. First, within the Methodology Chapter as an approach to guiding the research, and later within Chapter Nine within the limitations of the study. To assist with reflexivity, from the outset, I set out my different identities/positionalities and assumptions in hierarchical order informally in my diary, as Thurairajah (2019) recommends. The meanings of these identities and how each one interacted with the data unfolded during and within the writeup phase of the research. See Table 5.0 which illustrates my different identities which also became my reflexivity tool.

Table C5.0 Reflexivity Tool for Insider research practitioner

Adapted from Thurairajah (2019)

(Hierarchy from top down)

	Positionality / Identity	**Motivations**	**Oppositions**
1	Research Nursing (Cancer Nursing) Female Mother	• Patient advocacy as means of protection • Partial, caring role • Improve practice • Therapeutic, empathy • Collegial support • Examples: • Assumed nurses' lack of value / doctors' hierarchy • Assumed inability to validate consent	• Unable to directly protect • Maintaining objectivity • Re-experiencing own difficulties in practice / life due to constraints • Unable to judge • Nursing bias that they play a key role
2	Manager	• Improve practice • Non-threatening • Maintain patient safety • Improve patient access to trials • Service benefit • Examples: Assumed Limitations in raising issues	• Protect participants • Refrain from taking sides • Maintain confidentiality • Refrain from interviewing line managed (prevent data skew) • Policy and targets that impact practice / service
3	PHD researcher	• Genuine passion for topic / practice advancement • Improve IC to CCTs • Maintain good researcher-participant relationship • Academic credibility- good data / dissertation • Easy access to participants • Example: Uncertainty about value of interprofessional practice	• Time – prioritise 'actual job' • Facilitating within others' jobs • Potential to affect collegial relationship • Ability to step back when shared emotional experiences • Lack of objectivity / keep separate - Mason (2002) • Perceived as practice challenger • Need for staff support • Threats from gate-keepers • Impartiality • Assumptions about doctor's lack of appreciation of nurse role • Lack of appreciation of doctor's difficulties

Given these assumptions and competing role identities, Munhall (1989) explains a fusion resulting from the interpreter's transaction with the world where one reality constitutes and constructs another. There may be more than one truth where epistemology was derived from interpretation of the participants' experience, hence there is potential for argument about what the truth is. Where some participants' views stood outside the common themes, these were considered deviant cases that challenged and enhanced the 'true' picture of the situation.

5.2.3 Research design

The Research design incorporated an instrumental local institution case where the subject is the interprofessional experience and the object is informed consent to CCTs. The case study was appropriate as it investigates according to Yin (2008) the real-life context within boundaries by using different sources of evidence.

The boundary was set out from the outset as the single centre tertiary cancer centre in keeping with Silverman (2010). The triangulation of methods by using the research diary and different levels of professional interviews enabled 'getting close to reality'; as described by Flyvbjerg (2001) thereby enhancing the research validity. The study neither seeks to change nor is it experimental as with a nomothetic generalisable approach used in the natural sciences. There was a cautious attempt to make generalisations, although the findings could well be perceived as typical to other research practice settings. Therefore, the findings may be in keeping with Flyvbjerg (2006) who vehemently defends the misunderstanding that case studies cannot generalise and that knowledge cannot arise from practicality or the practice area itself.

5.3 Approval for the study

Approval was sought via the IRAS study application and subsequent Clinical Effectiveness Unit (CEU). Academic approval was gained from Royal Holloway University of London (RHUL).

5.3.1 The approval process

The applications requesting permission to undertake the study were sought. See below for the list of approvals received. No ethical concerns were raised and ethical considerations were included within the application. See Appendices C5.1- C5.4 for approvals.

Approval
IRAS Approval (Integrated Research Approval System)
Clinical Effectiveness Unit
RHUL Approval
Self-certification of Ethical Content
RHUL Ethics Approval Form

5.3.2 Ethical considerations

Ascertaining the participants' experience of communication challenges involved in hard cancer patient consent decisions was considered in accordance with the ethical principles of Beauchamp and Childress (2001) and the ethical guidelines of the Belmont Report (1979).

Beneficence

Polit and Beck (2012) highlight that the guiding research principle ensures increased benefit over risk for participants. The study aimed to benefit the staff by allowing them to have a voice regarding the consent communication difficulties they experienced with CCT patients, potentially contributing to patient care and professional practice. In ascertaining potentially

sensitive information I was aware that the success of data collection partly relied on the collegial trust and rapport with staff. The researcher however was in a fortuitous position as an inside field expert, having 'finer discernment' and sensitivity (Mason, 2002). The researcher was aware of the possibility of a 'pseudo therapeutic' relationship developing which must not be exploited.

Protection from harm (non-maleficence)

The main consideration was that some data regarding professional communication could be emotive. The participants had access to an NHS counsellor and clinical supervision, which was made known to the staff in the Letter of invite (see Appendix C5.5) In keeping with Polit and Beck (2012) measures used to maintain confidentiality and protect misuse of information were undertaken. Each participant was given an ID preserving anonymity. The interviews were held at an agreed time in a private booked clinic room. The data storage and disposal was treated in accordance with the Data Protection Act (2018) and the RHUL Data Management Policy. A Consent Form was created to capture participants' consent as well as demonstrating that there was agreement to the researcher communicating patient safety issues to the authorities (see Appendix C5.2). Participants did not fall under the vulnerable person group/s, thereby no additional strategies were required.

Autonomy

All participants were invited to participate voluntarily. After responding, participants were given the Participant Information Sheet (see Appendix C5.7). They were allowed up to two weeks to decide on participating and then signed the Consent Form voluntarily, which was locked in the data collection cabinet. The participants were required to *consent* to providing

demographic information and an interview and an optional short second interview (see Appendix C 5.6). Participants had the right to withdraw at any time.

Justice

Blaxter et al. (2010) recommend that the researcher observes responsibility for the data collection, analysis and dissemination. In the event that practice concerns were raised (knowingly or unknowingly), the participant would be informed as to the seriousness and a formal concern raised if needed. A decision would be made as to whether the study is more beneficial than harmful to the participant.

5.4 The Sampling Strategy

The overall intention was to select the experiences of representative professionals who could be accessed within the CCT trial practice area. Participants were purposefully sampled aiming to seek a good cross sectional interprofessional group of an intended 25 professionals. 26 participants were selected (see Table C5.1)

5.4.1 Sampling (purposeful sampling)

The central goal of purposeful sampling (non-probability) sought out the professionals most involved with IC to CCTs. Blaxter et al. (2010, pp. 170) recommends selecting participant suitability by 'handpicking supposedly typical' as opposed to randomly picking cases. This ensures similarity, supporting the purpose of knowledge sought, as intended to represent the phenomenon identifying non-probability sampling as purposeful sampling. However, variation within the similarity was derived from snowball cases. The inclusion / exclusion criteria can be seen in Table C5.2. The sampling strategy limitations are explored under the validity section.

Table C5.1 Table of Participants (P) - Demographics

RN= Research Nurse N= Registered Nurse (in Haemato-Oncology)

P	PN1	PN2	PN3	PN4	PN5	PN6	PN7	PN8	PN9 MN	PN10	PN11	PN12
Age	20-29	20-29	30-39	30-39	30-39	40-49	30-39	20-29	30-39	50-59	30-39	20-29
Gender	F	F	F	F	F	F	F	F	F	M	M	F
Job	RN	RN	RN	RN	N	N	RN	RN	N	RN	RN/N	N

Con= Medical Consultant (CD = Consultant Doctor) Prof= Professor of Medicine (Haem-Oncology)
SpR= Specialist Registrar F2 = Senior House Officer Doctor

P	PD1	PD2	PD3	PD4	PD5	PD6	PD7	PD8	PD9	PD10
Age	30-39	30-39	30-39	20-29	30-39	60+	40-49	30-39	30-39	30-39
Gender	F	M	F	F	M	M	F	F	M	M
Job	Con	SpR	SpR	F2	SpR	Prof	Con	SpR	Con	SpR

OPM = Outpatient manager CM = Clinical manager
BTM =Blood Transfusion Manager Dip = Diploma

P	PM1	PM2	PM3	PM4
Age	40-49	20-29	30-39	20-29
Gender	M	F	M	F
Job	CM	CM	BTM	OPM

Table C5.2 Inclusion / Exclusion Criteria

Inclusion criteria: (within the Clinical Academic Group (CAG) for Cancer Services)

- Consultants
- Specialist Registrars
- Research Nurses
- Specialist Nurses
- Managers- clinical or non-clinical (from professional backgrounds).
- English speaking nurses

Exclusion criteria:

- Non-English-speaking nurses
- Pre-Registration students
- Temporary/agency nursing staff/non-professionally qualified staff
- Locum doctors

The variation was derived from nurses and doctors depending on their role and seniority, and the experiences of clinical managers. Purposeful sampling was chosen over theoretical sampling as there is theory available on informed consent. Additional participants through snow-balling self-selected potentially assisted with data validation because suitable participants volunteered.

Letters of invite were sent to potential participants, preceded by a short conversation to explain the study. This approach was thought to improve access. If an initial strong interest was apparent, the letter invite was sent with the Participant information sheet (Appendix C5.5) on the same day / next day via email or in a printed version. All potential participants were sent a reminder after 5-7 working days (flexible according to leave), and up to two weeks to sign the consent form. All potential participants were given the option to recommend a colleague.

Every effort was made to facilitate the interview. Participants were not pursued after a reminder, nor were they pursued if they declined.

The researcher recruited, interviewed, transcribed and verified the content of each interview verbatim while incorporating the initial analytical process. The sample size was estimated, but was determined by the depth and quality of information achieved as indicated by Polit and Beck (2012). There was an attempt to validate the themes and form a temporal view over time. However, professionals' time limitations permitted one interview, except for one candidate.

5.4.2 Access

Access was achieved by presenting the initial proposal and application to the medical and nursing leads in keeping with Blaxter et al. (2010) who recommends discussion with gatekeepers to outline the research purpose to them. Interim reports on the study progress were presented to the Clinical Effectiveness Unit ensuring transparency while maintaining access and support.

5.5 Data collection methods

The data collection methods used were mainly the semi-structured interviews and the reflective research diary. Policies and standard operating procedures were used as benchmarks that guided contemporary practice. A short demographic form (questionnaire) was completed to provide more role context. For instance, the dual clinical and managerial roles were highlighted and verification of consent training. Interestingly, the Good Clinical Practice (GCP) course, mandatory for all research staff was not always considered by participants and therefore was not ticked.

5.5.1 Semi-structured interviews

Semi-structured interviews were the main tool chosen because they could provide an in-depth qualitative exploration of the participants' experiences (Fielding and Thomas, 2008). Quantitative data collection tools would limit capturing experiences (Bryman, 2008). Exploration of the lived experience was possible as a result of skilled interviewing through probing responses and feelings unlike questionnaires (Bell, 2005). The interview style also enabled expression and tone of language (Bell, 2005) transcribed in bold to highlight its importance within the analysis.

The semi-structure style allowed the participant to expand and reflect through guided questions enabling flexibility (Creswell, 2004; Mason, 2002). Seidman (2006) points out that the interview can flow and that periods of silence are beneficial. This time allows the participant to relay narratives, opinions and feelings, observed by van Manen (1990). The interview Schedule (see Appendix C5.9) comprised of a semi-structured / loosely guided style hinging on 6 main questions, supported by prompting phrases. The interview schedule was not piloted mainly because of clinicians' time limitations. The researcher was aware of the possibility of leading questions due to own assumptions. However the questions were peer reviewed by the CEU and supervisor to allay the risk of this limitation happening. The use of open-ended questions, paraphrasing and summarising enabled the exploration, Sullivan (1998), allowing participants' 'thinking time' and clarification which closed questions would not allow (Byrne, 2004). I refrained from strictly keeping to the interview order of questions to enable participants' flow of expression.

One-to-one interviews were decided over a focus group, for the potential to yield better data than previous research. Protection of participant confidentiality was observed via one-to-one interviews (Holland et al., 2010). Within a focus group there was potential for some

participants to dominate others as advised by Holland et al. (2010). The researcher assumed that the medical profession or senior nurses could dominate the group. Coordinating a focus group with time constraints would prove very difficult.

The scheduled time and privacy of interview location was facilitated. The interview was audio-taped over 45-60 minutes. The researcher felt that longer time would detract from concentration levels and increase participants' inconvenience. A copy of the transcript was sent to each participant for verification (Appendix C5.12). Creswell (2007) highlights that this allows time for the participant to confirm or add to the data, enhancing the validity. Van Manen (1990) proposes that this process of data checking is essential to the depth of the information.

5.5.2 Diary keeping and Reflexivity

The researcher's reflective diary was intended to assist with interpreting the meaning of the data, enabling reflexivity to occur. The reflective process described by Rolfe et al. (2001) was deployed to rigorously analyse my own practice and CCT practice. In keeping with interpretation of the meaning, the diary acted as an aide memoire where prompters were collected in keeping with Thomas (2011). Although the meaning was interpreted, the intention was not to change the content. The exercise of reflecting on the diary content was guided by Schon's (1983) approach to practitioner research, however reflecting-in-action was difficult for the researcher due to the insider researcher limitations. The practitioner also held management responsibilities, therefore keeping the diary required discretion. The value of the reflective diary could only be fully realised later when the data were analysed as the reflection-on-action. In keeping with experiential learning from reflection, judgement occurred to interpret the meaning which formulated the themes, (Dewey, 2010). The limitations of the insider researcher is explored in the conclusion chapter.

5.5.3 Documents used

Silverman (2010) recommends analysis of documentary evidence relating to policies, green and white papers in exploring a phenomenon. The primary documents were derived from the local standard operating procedures (SOPs) for consent taking (see Appendix C5.10). Job descriptions were considered which indicated the practitioners' responsibility within consent. The guidance provided by the Nursing and Midwifery Council (2015) and the General Medical Council (2008) on consent taking were mainly used to determine the (sometimes vague) professional practice and duty. While policies ought to be considered 'neutral', Blaxter et al. (2010) point out that they can be a means of expressing power depending on context. Meeting minutes and letters were too sensitive to use, for which there was not ethical clearance. The National Institute for Health Research (NIHR), cancer care guidelines, governance and team management were considered for their impact on contemporary practice. The National Institute for Health Research (NIHR) targets and the National Patient Cancer Survey on Patient Experience (2018) have assisted in gaining study access and peer review due to a desire to improve CCT uptake. The guide to the researcher's selection of documents policies was their ability to impact or challenge practice.

5.6 Data Analysis

The data analysis involved mainly inductive reasoning from the interview data (Boyatzis, 1998), while the research diary accommodated the use of the conceptual framework and suppositions and the interpretative analysis of the participant experiences. Schutz (1973) describes this as using the clarity of the conceptual framework, followed by the participants' subjective meaning; and then finding consistency between the concepts and the experiences. An example of this was forming linkage between codes that related to how trust was gained or lost to the overarching concept of trust. Furthermore, when considering 'professionalism', I

was guided by what people thought their roles were. Their interpretation of roles signified how different professions have emerged and advanced over time. The steps taken to analyse the data resembled the Colaizzi (1978) 7 steps (see Appendix C5.11), although used to assist the thematic analysis rather than just describing participants experiences.

5.6.1 Data analysis steps

The data were read through the conceptual lens by analysing the interviews as they were transcribed. Typing up the transcript (see Appendix C5.12) enabled familiarity with the content (Fielding and Thomas, 2008). This approach was not intended to test a hypothesis.

Step 1 and 2 were undertaken simultaneously by reading the content at least twice, numbering the lines and pages. Within this process significant statements were highlighted (colour coded on paper) that pertained to the phenomenon. As recommended by Bryman (2008) a large margin was allowed within the transcript where reflective notes or annotations were inserted. These notes were cross-referenced with the reflective diary to ascertain parts of the consent process, the timing of consent conversations and who undertook them. Consistent with Thomas (2011), the researcher has kept the typed raw material and made notes on margins, a working copy and backed up copy ensuring validity of analysis.

Step 3 and 4 involved grouping / categorising these statements into clusters of themes. A bank of codes was derived from statements and were categorised containing as Bryman (2008) describes familiarity or unfamiliarity in what was spoken about by participants, sometimes accounting for frequency of word used, suggesting a ‘discourse’. Further categorisation occurred by including statements into codes that pertained to each professional role. This bank of codes was entered into the NVIVO 10 IT management system to enable sorting categories, resembling a Code Manual. See Appendix C5.13 for how statements were

coded and categorised by formulating the meanings as interpreted through the conceptual lens. Often one statement could evidence more than one main theme and therefore these statements were entered into the code manual twice taking the most impactful participant statement within the results.

Steps 5 and 6 occurred continuously to link the meanings form the interviews as related to the phenomenon. The clusters of themes were reduced under the main themes and presented. The writing of the results was presented by firstly linking with the themes and explained as set against a background of the concepts. The analytical discussion incorporated previous research. The way the interpreted findings could impact practice and knowledge was alluded to, but brought together in the Chapter 9.

Considering step 7 of Colaizzi's process of analysis, participants were unable to validate the interpretation of their subjective experiences, although they were asked to verify the transcripts. The validation of the interpretation was undertaken by relaying to my supervisor how the participants' experiences were interpreted, examples given above. The conceptual lens was a significant bedrock for the validation of interpreted experiences.

5.7 The research validity

When ascertaining the validity of this qualitative study the types of validity as devised by Lincoln and Guba (1985), and Rebar et al. (2008) in nursing are considered. Validity is ascertained by assessing credibility, dependability, confirmability and transferability of the study methods and findings. These considerations centred around the interviewing and researcher rapport with the participant as described by Cohen et al. (2007). Reliability refers more to quantitative research methods and is not discussed.

Adequate data were collected using semi-structured interviews, and the research practitioners' meaning was shown to be convincing due to the balanced meanings presented (for instance that doctors valued nursing practice). Robson's (2002) strategies for off-setting threats to validity comprised the use of triangulation and highlighting negative cases (when two doctors sought consent from the family). First, data were collected via the interviews using person level triangulation where data from one level of person (research nurse) validated data from the next level (doctors) or highlighted incongruences or deviants. The research diary was used to understand the meaning of the experiences, accounting for the practitioner identities. Linkage of codes and themes to theories and concepts provided accuracy in answering the research questions.

The prolonged researcher involvement was an advantage, demonstrating the dependability and trustworthiness based on the collegial rapport. However, there are limitations to the study replicability because of researcher subjectivity when interpreting the data. To counter-balance this, the data quality was ensured by rechecking the coding as peer reviewed by the CEU and supervisor as themes were identified. The data were kept as coded in auditable fashion.

The research validity was confirmed and attained by an appropriate interview schedule, using valid questions to ascertain communication experiences of obtaining informed consent in CCT practice. Possible threats as an insider researcher for instance bias or researcher assumptions were documented. Member checking was achieved by sending the participants the transcripts to verify the content and an additional interview was offered. Assumptions / bias prior were accounted for. Volunteer participants from the snowballing effect assisted in accommodating for selection bias by purposeful sampling. However, snowballing may have brought about a 'Hawthorne effect', which Thomas (2011, pp.150) describes as productivity

increasing, evidenced by increased staff interest. To counter-balance the effects of the 'experimenter effects' or respondent bias (participants saying what the researcher wanted to hear), a deliberate attempt was made to avoid sampling line managed staff. I was also aware of prioritising conclusions poignant for nursing practice due to my own background.

Possibilities to allow for generalisation were considered under study transferability. The case study boundaries were well defined, thereby permitting transferability to a similar/broader practice setting. The data collected was in-depth and consistent with practice and previous literature. Practice implications and research possibilities are accounted for in the concluding chapter.

5.8 Summary

In this chapter the methodological approach, the ethical considerations and the data collection method and analysis have been presented and discussed. It has been argued to fully answer the research aim and the experiences sought, a qualitative methodological approach was undertaken. Data were collected from semi-structured interviews with 26 participants comprising doctors, cancer nurses and clinical managers. The research diary supported reflexivity and policies informing practice were considered. Data were examined by means of thematic analysis. The research validity was defended. Limitations of the insider researcher are discussed in Chapter 9. The data will be presented as results followed by an analytical discussion in the empirical chapters. The empirical chapters begin with an exploration of how responsibility was shaped / determined by time.

Chapter Six: Professional responsibility as determined / shaped by time

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6.0 Introduction

In this chapter, the supporting research question addressed is: *How does the experience of interprofessional responsibility as determined / shaped by time influence obtaining informed consent to CCTs?* This question supports the overarching question: What is the interprofessional experience of communication that impacts on obtaining informed consent to CCTs? The results of the study in relation to the associated themes and sub-themes are presented. Following on from these themes, there will be an analytical discussion, which will link the findings with the literature to support the discussion. The role of obtaining informed consent has traditionally been a medical responsibility. However, knowledge regarding the role of time and the timing of interprofessional involvement in the consent process is lacking. Therefore, a further aim of this chapter is to find out whether the traditional roles are challenged.

The way professional responsibility was experienced within the time spent communicating with cancer trial patients when seeking consent was a major theme expressed by participants. The structure of the chapter comprises of two parts. First, there is a focus on the timing of professional responsibility for diagnosing and recommending the trial, which includes the patient assessment and the Multi-disciplinary (MDT) interprofessional involvement. Second, there is an exploration of how time is used differently by professionals to give information to patients. The exploration begins with the timing of exercising professional responsibility of diagnosing and making a trial recommendation.

6.1 How timing impacts on diagnosing and recommending the trial

The participants spoke frequently about the timing of exercising their responsibilities prior to the patient's informed consent to the trial. Both professions felt that doctors held the responsibility for diagnosing and making an initial trial recommendation, although there was some disagreement about how the trial was presented. Additionally, many research nurses and managers felt that the timing of the patient's assessment and nurses' involvement in the MDT decision could challenge the initial trial recommendation, which could potentially impact informed consent.

6.1.1 The importance of the initial trial offer

The timing of the doctor's involvement with the patient was important, signifying for them making a diagnosis and offering the 'best option' of treatment to the patient which was sometimes a trial over standard treatment. The importance of the timing doctors' involvement was described below.

> RD8: "So first off, the diagnosis has to be confirmed and that's before you even think about a clinical trial and then you liaise with part of the medical team and this includes the Clinical Nurse specialist (CNS) and the research nurses."

Another Registrar felt that the timing of his involvement had a definite impact on recruitment of patients to the trial.

> RD2: "Yes, I do because I am one of the people who see patients on the front-line. All our patients need to be recruited by a consultant …but I see them first-hand and surely, I can have an impact on the number of recruits and to start the process off."

For doctors, the trial didn't necessarily need to be offered by a consultant. However, research nurses said that consultants were responsible for confirming the diagnosis and offering a treatment option.

> RN11: "Ideally, I think the consultant should be the primary information-giver as to whether the trial offers them (patients) a best chance or …at least the same prognostic outcome as the standard treatment."

The general view of doctors making a diagnosis and trial offer is supported by Davis (1995) who asserted that the complexity of skills needed has been perceived as a medical and a hierarchical responsibility. Diagnosing and recommending in this CCT setting was acknowledged as mainly the consultant's responsibility particularly because trial medicines are unlicensed. This is supported by Breier-Mackie (2001, p.5) who argued that doctors have 'the knowledge, expertise and authority to recognise physiologically viable or futile treatment'. The timing of recognising treatment viability was particularly relevant for a cancer diagnosis which informed these doctors' treatment judgements.

The way some participants described how doctors initially offered the trial was felt to have an important impact on how patients perceived the trial, constituting the first impression for the patient. Doctors referred to 'identifying' a potential trial patient, or 'suggesting' a 'good' treatment option when 'approaching' a patient. Doctors frequently described presenting the trial using positive language to the patient as illustrated.

> CD1: "The first step is informing the patient of the potential options relating to the clinical trial and then having an informal discussion about what the trial is and why they would be suitable, why we think it is a good treatment option… as opposed to the standard treatment if there is one."

This extract is one of many similar extracts which illustrates as Barton and Eggly (2009, p.301) have argued how doctors presented the trial in a positive way to the patients. However, these theorists argued that doctors use of positive statements, for example, 'better outcome' / 'good option' could be persuasive by presenting trials with a 'positive valence' (on a continuum from positive to negative). Mostly nurses and managers intimated that the initial medical approach could be persuasive, indicated in the language nurses used to describe how doctors offered the trial.

> CN5: "They (patients) might have been propositioned by the doctor about it. If doctors are able to, they will give them (patients) time to think about it and come back to decide and agree to it."

The use of 'propositioning', where 'giving time' seemed uncertain may suggest a persuasive urgency. In keeping with the possibility of persuasion, research nurses and managers explained the medical recommendation as 'pushing' for the trial or not giving enough time to the patient to decide as illustrated below.

> M3: "Definitely there is an element of really pushing. Doctors will try anything and let's be honest x speciality is a very good example. Doctors say 'I will keep on pushing and pushing until the last minute even giving as many drugs', sometimes nurses say 'Is this really fair on the patient? Have you discussed this with the patient and is that going to be causing more co-morbidities (additional conditions and complications) to the patient?' So, I can see where they (doctors) are coming from because they want the best for the patient but sometimes it doesn't come across as this."

The nurse and manager's perception of the doctors' initial communication is interpreted as a divided view. On the one hand, they spoke about doctors 'pushing for the trial' or pressurising the patients regardless of more co-morbidities or complications. Yet, the manager did not seem to object to the doctors' persuasive approach as he said that doctors 'want the best for patients'. Similarly, theorists have noted that persuasion may exert pressure on patients which Brown et al. (2011) says may challenge the bioethical principle of respecting patient autonomy to achieve informed consent. Furthermore, Chwang (2016) argued that the way risk is 'framed' could exploit benefits for patients. However, physicians presenting risk judgments in a positive light was asserted by Brown and de Graaf (2013, p.1) as enabling patients to construct 'positive future time'. Indeed, in the cancer setting the physicians' role was suggested as a 'paternalistic recommender' (often not giving an alternative option), thereby giving 'unrealistic hopefulness', and oncologists expressed optimism twice as much as pessimism in patient consultations (Brown et al., 2004, 2011; Robinson et al., 2008). However, Barton and Eggly (2009, pp.297) emphasised that 'persuasion is licensed in treatment recommendations which sometimes included clinical trials'. Positive language may have had significance in obtaining informed consent, because in keeping with Jonson et al. (2015) positive prognostic information given by doctors can appeal to the generation of hope for cancer patients.

It is unclear if the nurses voiced their concerns about this persuasive approach to the doctors or to the nursing managers. However, questioning the trial recommendation was perceived as central to the MDT decision-making. Interestingly, only one consultant who led the MDT expressed what appeared to be his dissatisfaction about 'pushing' for the trial in this extract.

> CD6: "And they (patients) might say: 'do you really think this will make a difference?' In your heart of hearts there may be a bias that you come to pushing

towards that or pushing towards what you feel might be better more conventional and some trials are just plain boring… I think sometimes they (doctors) are pushing. It means that nobody questions some of the MDT decisions saying, 'is there an alternative?'"

It may be significant that CD6 felt he could say that doctors were 'pushing' for the trial. Within his role as an MDT lead, he held the responsibility to encourage team involvement and he possibly had additional autonomy to voice concerns, unlike more junior colleagues who may not have the autonomy to 'question'. The 'pushing' approach described was in keeping with Eigenmann (2015, p.1) who interpreted the MDT recommendation as sometimes aggressive, suggesting the MDT recommendation may not always have a positive effect and can be 'miserable' for the patient.

The responsibility for diagnosing and the way the trial was initially offered by doctors greatly impacted on the patient's perception of the trial and subsequent consent, although there was interprofessional disagreement about their approach. Furthermore, the timing of the matching of the trial with the diagnosis was significant to enable the recommendation.

6.1.2 The timing of the eligibility and suitability matching

Some doctors and research nurses highlighted that the eligibility and suitability assessments have an impact on the timing of trial recommendation and subsequent consent. Many participants seemed to use these terms interchangeably providing lack of clarity about responsibilities as the Registrar describes below.

RD5: "Often it is the clinicians who identify patients who are suitable for the clinical trial. Often these are clinicians who are not directly involved in the trial and they may refer to the Investigators who are running the trials and

see whether that person feels that the patient may be eligible for the trial…"

This extract shows that patient's diagnosis can alert doctors that the patient may be suitable for the trial and therefore refer the patient. However, it would be the specialist team who decides on the patient eligibility later. Another doctor referred to disease confirmation as 'compatible' with the trial recommendation. However, the timing of when they matched the patient diagnosis with the trial, or the trial with the patient's suitability differed because other participants formed a distinction between eligibility and suitability as below.

> RD8: "A person can be eligible if they can tick the boxes, so the age requirement and the blood tests. But they might not be suitable if there are other personal situations ..or social or language even, they might not be entirely suitable."

Although the timing of eligibility is considered before suitability by RD8, the assessment distinction did concur with Sharkey et al. (2010, p.363) who highlighted eligibility as a 'factor' where patients fit the trial criteria based on mainly 'disease factors' and 'medical history and age', whereas 'suitability' referred to the patient's 'personal situation', opposing RD5's original view where 'suitability' was identified as the compatibility test referring to disease matching the trial suitability only. Importantly, CD5 confirmed that eligibility may not always be confirmed until after the recommendation. This is important because patients found unsuitable after the satisfactory eligibility (test results), could mean that such a recommendation may be devastating or misleading for patients who anticipate the trial offered. The uncertainty about the timing of the eligibility or suitability assessments is in line with Kidger et al. (2009) who found that most professionals preferred to seek patient suitability after the MDT treatment recommendation in the clinic consultation where time is spent with the patient. However, a minority of Kidger et al.'s respondents sought the patient's suitability prior to making a recommendation in the clinic. The reason given in favour of assessing suitability

before clinic was to ascertain the patient's social needs and preferences which the recommending consultant may not have knowledge about. The patient's suitability was clarified by the senior consultant.

> CD6: "And also, the patients age if they can tolerate the treatment. The other thing is the social circumstances of the patient and if the family agree with the trial. If the family doesn't want how can you reconcile the patient and family?"

Nurses, including nursing managers seemed more aware of the need for patients' suitability assessment prior to the trial offer as they felt it impacted on informed consent. For instance, N5 felt that patient motivation and understanding was part of the trial suitability assessment.

> "So, their (patients') motivation…what is actually the most important thing is making sure that they are suitable and that they understand it. Initially they need to be sure that they can understand it so that they are suitable."

In a similar way, this research nurse felt that lack of patient compliance, possibly due to lack of understanding of the trial would make a patient unsuitable.

> RN10: "It is more important that it is right for the patient. They (the patient) were failing to turn up and it was a while before the medical team decided that they were not suitable even though it was kind of obvious that even if we did get them on to the trial, they were not going to be compliant."

In many cases it was the doctors in this study who made the decision about patient suitability without actually making this assessment, having already offered the trial to the patient. This appears in keeping with Wenger and Vespa (2010) who argued that doctors made decisions about the appropriateness of 'patient factors' that were compatible with the trial, not limited to

diagnostic matching. The timing of MDT challenges to recommendations on the basis of patient's eligibility and suitability can impact on gaining or maintaining informed consent.

6.1.2 Multidisciplinary team (MDT) professional involvement

An overwhelming majority of participants spoke about the MDT as an opportunity for decision-making and agreeing treatment recommendations. Both professions spoke of medical dominance in the MDT meeting, where many research nurses felt their role lacked impact. However, many doctors spoke about how the nurses' role was important in challenging the MDT recommendation. Managers spoke about the hierarchical constraints of the MDT, but rarely attended except for auditing of practice purposes.

A minority of doctors affirmed that the MDT was medically dominated. However, while these doctors highlighted that nursing involvement was lacking, they did not always explain why nurse involvement was important.

> CD9: "I am not convinced that I know the role of the research nurse and there is the question of where the research nurse / staff fit in. The model that we run is that the patient doesn't have any contact with the research nurse until they are quite far down the line, after they have already been given the information sheet. Then meeting the patient is essential to the screening [after consent] and getting them started. I'm not sure that we integrate the role enough here, to get research nurses involved early enough in the patient journey."

There was uncertainty about what benefits involving the research nurse earlier would bring leading up to informed consent. Most of the doctor's references to MDT working were from CD6, the most senior consultant who had a managerial responsibility to encourage team attendance as mandated in policy (Improving Outcomes, 2016). CD6 recognised that nursing

involvement was beneficial in questioning doctors 'pushing' the trial, illustrated previously, and, that nurses were not as "active as they should be in the MDT", which he said resulted from nurses and others not being "aware of it and therefore they don't question it."

Despite doctors encouraging nurse involvement, nurses' lack of trial awareness was in line with Ulrich et al. (2012) who linked nurses' lack of involvement to their knowledge deficit. Interestingly CD6 did not mention if doctors questioned medical decisions. However, it was possible that the non-consultant doctors' responsibilities may be unclear in the MDT. Sidhom et al. (2008) found that only 48% of UK doctors believed they were responsible and 'liable' for MDT decisions, if they attended. Failure to attend the MDT might account for why junior doctors may not question MDT meeting decisions afterwards, together with not knowing the patient's suitability which could be reason for challenge. Both nurses and doctors in the current study highlighted that the nurses' role (particularly the clinical nurse specialist role or CNS) was that of a 'challenger' who 'should' be involved in the patient suitability assessment within the MDT discussion.

> CD6: "Absolutely, we use them (CNSs) that way, as an advocate. They are very much part of the team and the decision-making, listen to them, ignore them at your peril because they are a very good radar that tells you … because they act as a conscience that if you are not thinking about things quite properly they are a reasonable conscience that reminds you, 'do you really think they (patients) are actually going to cope with it?' ".

This extract illustrates that CD6 viewed the CNS as a 'conscience' checker possibly necessitating rethinking the medical recommendation on the grounds of patient suitability, which he likened to an 'advocacy' role. Interestingly, RD8 initially was firm about the lack of nursing input, although intimated that the hierarchy of the MDT may affect CNSs' involvement

depending on their seniority and individual 'capability'. On further discussion and probing, RD8 described how the CNS or Research nurse is needed for decision-making with new patients because the CNS knows the patients' background, as illustrated below.

> RD8: "No and it is the doctor will present and they will talk amongst themselves and come up with a treatment. I have to say depending on who it is and depending on the condition, because the CNSs are often the ones who have seen the patient and spent more time with the patient or know the background so actually although my initial gut thing was no, I have to say it depends on what the question is. If it is about a new patient and treatment trials, I think there is a question to the CNS or Research Nurse regarding what they think and if they (patients) should have it".

These extracts illustrated that the primary decision-makers regarding the trial were the doctors in the MDT meeting in line with Eigenmann (2015). However, the role of the nurse was acknowledged by some doctors in this study as a voicing the patient's preference and contributing to supportive care discussions in the MDT, although this involvement did not always happen. The lack of nurse involvement is similar to Taylor et al. (2012, p.8) who observed that a lack of CNS or any nurse involvement explained 'the lack of patient-based information' in their study, although they emphasised that nurse involvement is expected since the National Institute for Clinical Excellence (NICE) guidelines (2004). In line with Lamb et al. (2011), the doctors' view was that interprofessional and professional hierarchy exists in the MDT and contributes unequal contributions resulting in 'poor consideration' of suitability, social issues and preferences. The MDT literature has not referred to the nurse as a 'challenger'.

Research nurses were less emphatic than doctors about their advocacy role. They described their role only as a 'challenger' by questioning the eligibility and suitability assessment, after the MDT recommendation was decided. The timing was important.

> RN3: "The doctors will just know the exclusion and inclusion criteria. I have to make sure that before the consultant says 'Oh we have a potential patient'. There are certain things that doctors might not know about the protocol, so I have to say to the consultant, 'Oh I think this patient cannot go into the study because of …either one, two or three things'."

This research nurse implied that she has a role in the eligibility and suitability assessment by assuming this responsibility. The research nurses felt they would know 'certain things' about the patient that provided reason for them to challenge the trial recommendation, which according to this extract the doctors needed. It is intimated that nurses providing patient suitability details may not be perceived as a hierarchical challenge.

A minority of research nurses expressed discontent regarding insufficient time given to patients to deliberate, even outside emergency situations because of the potential for patient lack of understanding of the trial. RN11 explained how research nurse involvement earlier in the consent process would benefit the patient.

> RN11: "The first time I see the patient after signing the consent it is to review the consent form and try to review their understanding of the trial to ensure that it has not been a rush job and if I thought that I needed to revise or refer back to the consultant to say that I thought that the patient needed a bit more time to properly understand. Sometimes in particular instances of emergency there is not that luxury of time to give them the PIS (Patient Information Sheet). After

> they have had the information for a time then they usually come back to me. Typically, I have not met patients before consent."

Interestingly, this extract shows that the consent was undertaken before the research nurse met with the patient, thereby preventing an opportunity to review the patients' understanding of the trial. In the reflective diary, it was noted that nurses were unable to contribute to the discussion leading up to the decision and expressed discontent about their lack of involvement. Another research nurse, RN10 expressed unhappiness about the trial consent being rushed, although there were sometimes medical reasons for this.

> RN10: "But the patient won't know anything about it until they are seen in clinic. I think for patients sometimes it can be a bit rushed. I mean there may be clinical reasons for that and if it is important to start treatment quickly. They might be given a form to go away and read it for an hour and come back. I'm not very happy with that but it does happen from time to time."

The element of the recommendation being 'rushed' was poignant for nurses, but it appeared necessary sometimes depending on the clinical need or urgency, thereby allowing patients less time to deliberate. This finding is in keeping with Alby et al. (2017, pp.1) who found that high-risk patients have less time to decide, although could be pressured to choose in the consultation where the treatment recommendation was presented as 'mandatory' because of the clinical urgency.

The element of being 'rushed' was a concern for research nurses as they linked it to the patients' lack of understanding of the trial information. RN10 said there was no opportunity because patients were considered for the trial before any nurse involvement. Furthermore, RN11 spoke of concerns voiced about 'unsafe care' if staff were 'overstretched disadvantaging

patients', resulting in 'challenging' by 'feeding back concerns', but said that staffing did not prevent the trial offer, if the patient has no other option. RN11 explained that there was a reluctance to voice a concern after the MDT decision because it may 'not be heard or acted upon' and challenging depended on the doctor-nurse relationship. The importance nurses placed on the timing of challenging the decision echoed the Kidger et al. (2009) study where it was found that nursing personnel were unable to take an active part in the case discussion due to the MDT hierarchy. Furthermore, Klimaszewski et al. (2008) identified the US advancing research nurses' role in patient safety monitoring, due to their knowledge and skill. Some research nurses in the current study felt they could challenge the patient's ineligibility or lack of suitability on the grounds of patient safety. However, there was general uncertainty among nurses whether they could challenge MDT decisions. This may resemble a lack of nursing confidence and autonomy needed to voice concerns (Spilsbury et al., 2008; Hyland, 2002).

Many research nurses explained that nurse involvement in consent was team-specific and depended on their relationship with the medical team. For instance, RN4 explained that the nurse has to 'gauge' what the doctor wants of her role, but involved checking the documents were signed 'in the right place'. Another research nurse, RN2 explained that in one sub-specialty the MDT involved only the doctors, described as a doctor's 'huddle' before the clinic commenced. She added that her role involved filling in the "missed out steps" in the process after the patient had consented.

The notion of the research nurse role 'fitting' in with the doctor, or supporting the doctor did not constitute for them responsibility for informed consent. For the most part research nurses did not want to claim responsibility for the consent, except for mainly their supportive role to the doctor. In line with Lee et al. (2010) nurses checking consent documentation as described by RN4 was similar to a witness or adjudicator of the doctors' role.

Furthermore, for many nurses, their ad-hoc involvement was in keeping with the traditional role of fulfilling the doctor's wishes and instructions, likened to the nursing stereotypical 'handmaiden' image (Fagin and Garelick, 2004; Roberts and Vasquez, 2004).

The formal hierarchical structure of the MDT appeared to fall short of interprofessional involvement at the time of decision-making, except for the possibility of CNSs or research nurses' 'challenging', encouraged by the doctors in some specialities, often after the consent was taken. The information-giving role was integral to supporting the trial recommendation.

6.2 The Impact of time on information-giving

Doctors and nurses described their overlapping role in providing information during their social encounters with patients. Both professional groups liberally referred to this role which may indicate that information-giving was perceived as an essential responsibility for both. Three main elements of information-giving as shaped by time are explored. First, there is an exploration of the problems associated with the time of signing the consent form. Second, the way professionals spent their time in the delivery of information to patients. Finally, how time-constraints may impact on professionals' responsibility when obtaining informed consent.

6.2.1 Problems with the time of signing of consent form

Most nurses and doctors placed huge importance on when consent was 'taken from the patient' and referred to it as the time of 'signing of the consent form' following a trial recommendation. This time signified when the patient's understanding of the risks/benefits were assessed and confirmed. However, some participants spoke about problems associated with the time the consent form was signed, and questioned the quality of the consent. Nurses and junior doctors were emphatic that consent taking 'should' be undertaken by the Principal investigator or consultant, emphasising clear separation of role responsibilities.

> RN2: "The only people in my team that consent are the consultants and no one apart from our two consultants can consent to our clinical trials."

Although the consenting was separated as the senior doctor's responsibility, participants explained that this doctor may not know the patient. RN2 explained that the doctor who sees the patient in the clinic may neither have been present at the MDT, nor have met the patient before, but is required to follow the MDT recommendation, which some participants previously intimated as an aggressive recommendation. In line with Eigenmann (2015, p.1) not seeing the patient before an MDT decision was problematic because he says that 'collective' decision making in the MDT may be 'biased towards recommending aggressive treatments'. Furthermore, CD6 felt that the MDT recommendation can involve 'pushing', but the physician who sees the patient directly may have a different bias in favour or against the trial if he knows the patient. RD10 alluded to the nursing role as an obvious contributor to enabling informed consent in situations where the doctor may not know the patient.

> RD10: "I think that the initial recruitment and consent should come from the clinician who sees them, and then the research nurse would take over because it is very difficult to consent a patient you don't know."

General cancer nurses reported that the responsibility for information-giving needed to achieve informed consent lay only with the physician giving information at the time of the consent 'agreement' with the patient. Some doctors, for instance RD8 said the timing of the information-giving supports the doctor 'ultimately' achieving consent at the time of signing of the consent form, although she alluded to consent as 'everyone's' responsibility.

> RD8: "I think the doctor taking the consent and signing the form it is their ultimate responsibility. They are the ones who are going through the last check

> but before that I think everyone is responsible for making sure that whatever they are telling the patient they understand it and retain it and the benefits and cons but obviously, the final signing of the consent form needs to make sure 100% that there is understanding and there is consent."

While RD8 highlighted that it was the doctor's responsibility as he took the consent, she also said that 'everyone' was responsible, but did not elaborate on those responsibilities. Interestingly, RD3 described that the signed form counts for 'full' patient awareness at the time when the doctor gives the information to enable a decision.

> RD3: "I think the patient is fully aware of his medical condition. He is fully aware of his treatment options and that the clinical trial is the best option for him. So, it's just letting him know that he has the information to make his final decision."

From this extract, 'full' patient understanding was achievable at the time the patient signed the consent form. These registrars seemed to defend the validity of informed consent achieved by doctors, by claiming that patients had 'full' understanding at the time of consent, although it is uncertain if this understanding was checked. In fact, Bergenmar et al. (2011) asserted that rarely did investigators/physicians assess if the patient understood the information in consent discussions. Furthermore, by way of contrast to these registrar and nurses' views, regardless of signed consent paperwork, its 'usefulness' has been previously recognised as 'incomplete' (Jordens et al., 2013, p.76; Shannon-Dorcy & Drevdahl, 2011). Similarly, O'Neill (2002, p.157) speculated that procedural practices enabling informed consent are merely informed 'consent requirements' and argued that 'strictly speaking' consent can never be 'fully informed'.

It may be significant that for some registrars there may be more active checking of patient understanding as registrars were responsible for what they called 'frontline' immediate patient safety. The perspective that some doctors and cancer nurses assumed the consent was 'fully' achievable at the time of signing the form is questioned by most participants who felt that valid consent was not possible at the time of signing the form, but that consent was an on-going 'process' over time.

6.2.2 Information giving as a process

Most participants explained was that consent was an on-going 'process' of information-giving intended to allow patient understanding and 'deliberation time', which they connected with following the Good Clinical Practice (GCP) guidelines. For instance, CD6 emphasised that day-to-day encounters with patients provided opportunity for them to revisit information-giving and confirm consent. Doctors admitted that giving detailed information in one encounter was 'a lot to take in' for the patient.

> CD9: "There is a culture of this in the institution, this would be first broached in a clinic consultation in broad terms. Usually with our patients there is sufficient time that we are able to drip feed the information.. and what their options are."

Doctors suggested that this slow delivery of information was 'drip fed' in more than one encounter which is similar to Pujol et al.'s (2016) speculation that slow construction of information provides the patient with more deliberation time. RD8 explained that consent was best taken place in more than 'one sitting', which allowed the patient to take away the written information, giving time to consider questions prior to the next 'sitting'. There was agreement with Bergenmar et al. (2011) that giving the patient more time is likely to impact positively on

consent, although Bergenmar et al. (2011) linked giving more time to 'easier' patient decision-making but did not specify that more time improves patent understanding. The significance of comparing to Bergenmar et al. (2011) is that for participants in the current study giving information over time was an important factor which did contribute to patient understanding. 'Frontline' participants and managers spoke about professional responsibility for information-giving as a process. Their concern related to potential patient safety problems because of a lack of handing over trial information from the research team to frontline staff which they said could negatively impact patient safety.

> JD4: "I am not saying that we should give detailed information but the general things like checking bloods tests. I was doing an on-call day and the research nurse asked me to chase the bloods. We didn't know what to do. Then something may happen to that patient and I don't know what to do."

M2 pointed out that if 'frontline' staff lack this trial knowledge "the patient can be put off the trial", potentially causing withdrawal of consent. One research nurse highlighted that lack of trial "familiarity" among 'frontline' staff can cause lack of "ownership", or lack of responsibility. Many research and cancer nurses who administered the trial spoke about the research nurse's role as upholding patient safety throughout as illustrated.

> RN11: "I don't think informed consent ever ends particularly if it is a complex trial. They (patients) probably haven't been able to fully understand the trial. You need to revisit things. While a patient has said yes and signed the consent perhaps you might liaise about well are there any potential safety issues. And any time you are treating them you should re-confirm that they wish to continue on the trial. I see informed consent while they are on the treatment up until the publication of the trial."

The responsibility for information-giving over time by re-iterating information between professionals at the frontline was deemed a factor in maintaining patient understanding and safety. Giving information over time was described as undertaken in an ad-hoc way as the process of consent unfolded because 'qualitative time' is likened to "irregular self-determined temporal patterns" (Hassard, 2001, p.136). The 'frontline' medical and nursing role of trial safety monitoring is supported by Klimaszewski et al. (2008) who acknowledged that the research nurse's responsibility for trial consent has developed in this way. Furthermore, the time allowed in the delivery of information is developed in the next section.

6.2.3 The way professionals spent time with patients

Many doctors and nurses spoke about how they spent time providing trial information to patients. Doctors and nurse managers recognised how the nurses' relationship with patients contributed to 'valid' informed consent. Doctors explained the potential constraints with 'clinic time', which some described as likely to have a strong impact on difficulties they experienced obtaining 'valid' informed consent. Many participants referred to nurses spending more time with patients. The majority medical view was that nurses are best placed and knowledgeable about the 'logistical information' of the trial and can explain the information in detail which was not possible for the doctors to relay in the clinic because of lack of time.

> RD10: "It would be really difficult for doctors, because they (research nurses) are experts in the trial. They (research nurses) are experts and they have a lot more time to sit down with the patient. They are prompting everyone to make sure that they are sticking to the trial."

Both doctors and research nurses referred to nurses' beneficial informal approach with patients. RD5 referred to nurses improving patient understanding by "taking time and space" to explain

terminology, particularly in relation to the complexity of randomisation. Furthermore, research nurses were described by doctors as checking the information after the clinic appointment or answering questions.

> CD7: "That is (the research nurse's role) to reiterate and to go through the information again because it is a lot of information to take in and sometimes the patient will ask the nurse questions that they won't ask the doctor. They (patients) may just have small questions that they may not feel are appropriate to ask the doctor and it gives them another opportunity to raise any questions."

Nurses were described as re-iterating the information doctors had given and answering 'small questions', yet these small questions could require more detail and more time. The reference to answering 'small questions' may have devalued the role of nurses. It is interesting that CD7 separated the type of questions by saying certain questions were 'inappropriate' to ask the doctor. This suggests that the nurse had a different skill set or merely more time to answer such 'small questions'. The consultant's perception could be that patients do not want to waste the senior doctor's time. Research nurses said that patients felt reassured because they spent more time with patients re-iterating the information to support the medical recommendation. However, many research nurses said that they are often not involved although they wanted to be present before the consent to enable patient understanding.

The research nursing view of the clinic appointment was described by RN3 as an opportunity to provide an overview of the trial 'in simple terms', which could be interpreted as not complicated. Giving information 'in simple terms' is interesting because one might expect the physician's explanation to be scientifically more complicated. The overview may well be scientifically complicated although portrayed simply, but was described as leaving gaps in the

technical detail, although it appeared to refer to the day-to-day practical details as described below.

> RN3: "The physician obviously, I wouldn't say is going into the detail of the consent, they kind of explain in simple terms and then the research nurse will go into all the technical bits, whether they need to come every day, but they (doctors) are just there to tell the patient about the study and then take the consent."

The doctor's simple overview seemed to set the tone for the initial informed consent. Giving information in understandable terms however was qualified by both professions and nursing managers as giving more detail to include the 'the technical bits' and the 'minutia' and the 'intricacies' of the trial which they said falls outside the clinic appointment and sometimes referred as taking the form of a 'chat'. Many research nurses referred to 'going through' the information with patients in a detailed way outside of the doctor's clinic appointment as described.

> RN4: "So, he (Consultant) would normally say here is the PIS (Patient Information sheet) and the research nurse will go next door and go through the trial in more detail with you. Obviously, we (research nurses) will go through the drugs and he gives them the option of both treatments and I go through the intricacies of the trial. He wouldn't go through the in-depth details of the bloods and so on."

Doctors communicating simply may mean the brevity of the overview given the clinic appointment which may undermine the quality of communication. Brown et al. (2004) advised medical communication courses that focuses on 'quality' of information exchange. Research

nurses appeared to give more time to patients, providing more detail, seen as enabling the patients' understanding of the trial information that the doctor presented. It is possible that professionals may have encountered more communication problems with the diverse cancer trial patient group, where prognostic information is often referred to in doctors' consent discussions about trials, although participants did not refer to percentage information delivery problems. It is known that that cancer patients needed sense to be made of numerical prognostic information which they struggled to understand in the medical appointment, although they didn't say that nurses were responsible for making sense of this information according to Thorne et al. (2007 cited in Johnson et al. 2015).

A minority of doctors spoke about gaps in what they could feasibly deliver due to their time-constraints. They emphasised how nurses spend their time by responding to patient's needs which they said was an 'essential' requirement for informed consent. Where physicians acknowledged time-constraints they highlighted how research nurses spent their time with patients differently.

> RD2: "We tend to be so absorbed into the care of our own patients that we do miss a lot of the information aspect of the trial. I think the research nurses are the only ones who can deliver that, informed consent and following that is not just the piece of paper. To be honest if it wasn't for them I don't see that the service could run. Clinicians don't have time. We don't have the time. Really informed consent needs much more details than 10-15 minutes in the clinic so I believe that the nurses do have flexibility in terms of time to meet the patient either before or after or during the clinic to make sure that that word informed consent is truly happening. To deliver informed consent as per clinical trials research nurses are an integral part of the team."

This extract shows how the lack of time available in the clinic appointment meant that doctors missed information, and the way that RD2 felt the 'service could run' was for nurses to see patients outside of the clinic appointment to enable 'truly informed consent'. The clinic time constraints in the CCT setting is in keeping with MacBride-Stewart (2013, p.564) who described that in general practice doctors' work is, as she terms it, 'colonised' by time where she explained 'medical time' is structured by management scheduling, portrayed as 'clock time' in minutes. The way nurses experienced their time with patients fell outside of clinic time which for them became an on-going process of patient encounters. In line with Davis (1994) this 'process time' was cyclical / rhythmical and importantly he described this social construction of time as 'relationship governed time' as opposed to time that was governed by a 'clinic slot'. It seemed that the missing information that the doctor was unable to give due to time constraints has been fulfilled as an essential part of the research nurses' time spent with patients. RD2 placed importance on consent as not just a "piece of paper" by emphasising the word 'informed'. In keeping with MacBride-Stewart (2013, p.1), these doctors lacked sufficient time, ensuring 'informed' consent (traditionally a medical responsibility) became 're-distributed' to the CCT nurse.

Another consultant described how nurses enabled "good consent" by developing a meaningful relationship with the patient. In this extract 'good' consent is likened to "informed consent" by contrasting it with "uninformed consent".

> CD6: "They (nurses) are an essential part of it. I can give overview of an exciting new treatment, but I may not be as aware of how much time and effort and everything else the patient might have to go through. If they are explained at the beginning then their informed consent is really good informed consent, as opposed to uninformed informed consent, which is so much the minutia and it's

> the minutia that often gets the patients and upsets them not the big picture. So, I think it is an essential part. So, it is as an information-giver, coordinator, and also a friend of the patients by which I mean the patients like to know whom do I deal with and they want to know who the team is and want to know that you are part of my team or I am part of your team. They need to know that if they talk to me I will talk to you and keep everybody informed so making them feel comfortable."

In this extract although coordination was needed it was the 'extra time' effort to develop the 'reliable' relationship of 'friendship' that nurses experienced with patients that brought about this 'good consent'. CD6 implied that the nursing relationship makes it easier and more comfortable for patients, enabling them to talk to nurses and feel sufficiently reassured. Interestingly research nurses did not refer to their relationship with patients as a 'friendship', unlike Dowling (2008, p. 5) who observed that friendship was a key theme which nurses felt permitted intimacy with cancer patients. She attributed the creation of a friendship to 'self-disclosure of information' and the creation of a 'homely atmosphere'. The 'homely atmosphere' is not too dissimilar to the team togetherness portrayed by CD6. Importantly this friendship, as Campbell (1989, p.50) explained resembled 'skilled companionship', and develops with a 'time-phased' approach to intimacy, as found by Dowling (2008). Strazdins et al. (2016, p. 21) identified that time is required for 'building strong and supportive relationships'. Although most research nurses acknowledged their time with patients as an informal approach, they did not directly attribute 'good' or 'truly' informed consent to this approach. However, nurses related the building of their relationship with patients to the creation of trust.

Only nursing managers spoke about how nurses made a significant impact on gaining informed consent because of how nurses spent time with patients. The crucial element M1 spoke about was that nurses are "more people-based", by taking the time to give detailed information that the "patient can understand" enabling 'valid informed consent' by making the patient feel comfortable enough to ask questions. The nurse managers were responsible for ensuring a good patient experience, therefore they had interest in nurses developing a good relationship with patients.

Doctors recognised that unstructured 'process' time is needed for research nurses and 'frontline' professionals to give detailed information to enable patient understanding and maintain patient safety. However, most nurses, except nurse managers did not connect the process of time as a defining element of 'valid' informed consent. A minority of doctors and managers emphasised that clinic time constraints have brought about the need for valuable time constructed as a process by nurses which they felt enabled 'valid' informed consent.

6.4 Summary

This chapter has answered the research question that asked how does the experience of professional responsibility as shaped / determined by time influence obtaining informed consent to CCTs? The experience of professional responsibilities in contemporary interprofessional CCT practice has been explored to ascertain if the traditional standpoint was challenged. The majority of participants confirmed that the consultants made judgements and undertook the responsibility to diagnose and make trial recommendations. However, there was disagreement and discontent about their sole responsibility in coming to a recommendation. The positive, even persuasive language used by doctors to present the trial was a source of discontent for all participant groups.

The MDT meeting was identified as a forum when professionals exercised their responsibility regarding trial treatment decisions, although was described as dominated by the medical profession, deterring nurse involvement. A minority of doctors recognised the need for nursing involvement to give a view on patient suitability assessment for the trial, although it was often unclear what suitability or eligibility meant to professionals. The timing of making a patient suitability and eligibility assessment was of concern for the research nurses because they felt they wanted to challenge the trial recommendation prior to the patient consenting. A minority of doctors acknowledged the possible advocacy role of the CNS relayed as "challenging". Research nurses acknowledged their role as a 'challenger', although nurses lacked autonomy in decision-making and mostly did not challenge the traditional standpoint. However, some doctors and research nurses could be seen as challenging the traditional standpoint when they did question decisions and seemed to welcome the nurse as a 'challenger' of decisions. It was not clear if research nurses felt the role of a 'challenger' resembled that of an advocate.

Both professions placed huge importance on the time needed to fulfil their responsibility for information-giving where arguably roles did overlap. Some registrars seemed to defend the 'completeness' of the consent form. Nurses and doctors described how they spent their time with patients differently; whether as 'clinic time' or as a 'process'. The reason why 'frontline' professionals felt consent was incomplete at the time of signing the form was that information-giving as a process maintained patient safety. Doctors explained that giving information slowly was necessary for cancer trial patients, although they gave a brief overview of the information in 'clinic time' and relied on nurses to re-iterate information informally over time. Some senior doctors and managers described the way nurses spent time with patients as essential to obtaining 'valid' and 'good' informed consent because of the nurses' relationship with patients over time. These doctors delegated or expected that the once traditional medical

role of achieving consent in the CCT setting is now best supported by nurses. However, nurses emphasised that consent was the doctor's responsibility.

This chapter has shown how interprofessional responsibility as shaped by time can enable 'valid' and 'good' informed consent to CCTs. Professional roles have been made somewhat more explicit thus challenging the traditional standpoint of informed consent as solely a medical responsibility. The way professionals experienced their role has another function as it is linked to how they created trust. The creation of trust is the focus of the next chapter.

Chapter Seven: Trust

7.0 Introduction

The focus of this chapter is the interprofessional experience of trust. The supporting question addressed is: *How does gaining trust enable informed consent and how is interprofessional trust associated with the patients' best interest in the CCT setting?* This question supports the overarching question: *What is the interprofessional experience of communication that impacts on obtaining informed consent to CCTs?* Trust was a common theme that mainly nurses and doctors spoke about, including how they associated acting in the patients' best interest with the creation and erosion of trust. The positive language used to recommend the trial in Chapter Six may have initiated a trusting relationship and created a patient expectation of hope regarding the trial outcome. However, it is likely that patient trust is needed to span the informed consent process.

The structure of this chapter is divided into 3 parts. First, it will be established how participants gained relational trust enabling informed consent to CCTs. Second, there is an exploration of how team transition impacts on trust maintenance, and finally, an exploration of how interprofessional perceptions of the patient's best interest could affect trust. It is hoped that presenting these thematic findings will provide an enhanced understanding of how trust impacts on enabling informed consent to CCTs. The exploration begins with how professionals gained relational trust.

7.1 The creation of relational trust

This thematic finding refers to how both professions experienced the ways emotional and competence-based trust was built up or gained through their interactions with patients. Professionals explained the impact of maintaining the initial trust gained on consent and the patient experience. Professional communication and competence was experienced in relation to building up trust, off-setting distrust and preventing the erosion of trust.

7.1.1 How emotional trust was gained

Registrars explained that showing support of the trial offer as part of their initial interaction with the patient gave them an opportunity to establish the patients' 'willingness' to accept the referral to the trial team at the tertiary centre. The initial interaction with the patient was explained as starting the informed consent 'process' as Registrar Doctor 2 (RD2) explained:

> "I see patients on the 'frontline' and am one of the first people who encounter the patients… I can have an impact on the number of recruits and to start the process off…If the trial drug is an advantage over the standard treatment or if the patient has failed multiple lines of treatments, we (doctors) look for experimental therapy."

Another Registrar Doctor (RD5) used this initial interaction with the patient to develop a rapport with the patient that enabled the referral for the trial by first establishing the patient's 'willingness' to participate in the trial.

> RD5: "Often referring clinicians who are not directly involved in the trial may refer to the Investigators who are running the trials and have the preliminary discussion to see if the patient is willing to participate in the trial."

The role of the Clinical Nurse Specialist (CNS) who worked outside the trial team was acknowledged by many doctors as gaining trust because of their close emotional relationship with patients that preceded referral for the trial as Consultant Doctor 9 (CD9) explains:

> "There is a situation there where the patient transfers from someone (known CNS) they trust."

The importance of the 'initial trust' interaction is supported by Hurd et al. (2017, p. 175) who asserted that the referral to the trial team confirmed this initial, which they called, 'ex-ante' trust between teams. Therefore, the referral between teams for the trial appeared to have two functions. It gave clinicians whom the patient already trusted an opportunity to point out the advantage of the trial and gained the patients' willingness to accept the trial offer allowing them to refer the patient to the trial team.

For referred patients and for those who were already attending the tertiary trial centre, the trial was 'broached' initially by the consultant in the clinic. Many doctors spoke about the time available for them to gain informed consent, but a minority attributed the time they spent with patients as contributing directly to trust creation. There were two ways that repeated interactions over time with patients were important for these doctors in gaining patient trust. First, Consultant Doctor 9 (CD9) said that in an emergency situation it was difficult to 'build up trust', whereas in non-emergency situations there is an opportunity to 'drip feed' information and to include the relatives, which enabled building up trust. In addition, CD9 intimated the possibility of less trust in emergency situations because consent was difficult by saying:

> "In my area...of lymphoma and myeloma…we can build up the trust with patients so that we can drip feed them information and meet with their relations,

> in contrast with the doctors who treat acute leukaemia, where the patient may be coming in the middle of the night, acutely unwell and need immediate treatment. So, in terms of recruiting people the process of informed consent is difficult in those (emergency) situations."

The second instance for doctors where repeated interactions and time were highlighted as trust gaining factors was also in the Haemato-oncology sub-speciality as Consultant Doctor 6 (CD6) described below.

> "They have (other cancer sub-specialists) more numbers whereas we tend to have fewer patients but a greater intensity of work because they (other cancers) are quite complicated and quite often they are quite ill and certainly have things that are life changing, so I think we have more trust because we have more time because of more interaction with the patients."

CD6 suggested the possibility of gaining 'more trust' in Haemato-Oncology when contrasted with 'other areas' within oncology where there is less time due to illness complications. Gaining trust from positive interactions lends support from Calnan and Rowe (2008) who found that patients' trust was conditional and was earned by positive experiences with professionals, although they said that 'familiarity' over time with the clinician did not make a difference to diabetic patients' trust. However, Jackson et al., (2004) found that trust developed over time through doctors' positive experiences with cardiac patients on the basis of doctors drawing from evidence-based recommendations. In this study, the repeated encounters positively contributed to building the relationship, where 'more interaction' gained 'more trust' with Haemato-oncology trial patients, although it was not clear if these doctors based creating trust from an emotional interaction.

The comment about gaining 'more trust' suggested that trust could be increased over repeated interactions with patients. The possibility of gaining more or less trust has similarities to research by Zinn (2008, p. 439) who argued that trust was a 'measureable experience' in the risk management field. Of relevance, Zinn asserted that 'increased trust' is needed when there is 'less knowledge' and 'less time', akin to 'contemporary decision-making'. Contemporary decision-making could relate to cancer emergency decision-making situations where clinicians in the current study said there was less time to build relational trust because there was less time to 'drip feed information' to patients about the trial, which implied that gaining trust depended on time and a rational information-giving component. Clinicians' descriptions of decreased availability of trust in emergencies was different to the need for more trust was in emergencies according to Zinn (2008). The possibility of sufficient trust, although it is implied as less by this clinician in an emergency may be explained by Simmel (1950 cited in Mollering, 2001, p. 407) who points out that 'unaccountable faith' is needed to support uncertainty (the uncertainty of the emergency decision). The reason given by Brown et al. (2015) for patients accepting the uncertainty of cancer treatment decisions was that patients 'bracket out' the uncertainty. However, doctors did imply that more trust was needed in cancer trial decisions which presented uncertainty because their repeated interactions increased 'more trust', implying that CCT patients may require more interactions with them to create trust, which didn't completely rely on information-giving. It appeared that the rational component of information-giving relied on the repeated professional encounters with patients to gain trust, which lends support from Keynes (1936 cited in Zinn, 2008) who pointed out that trust doesn't solely rely on rationality.

Within the trial team nurses and doctors gave examples about how positive interactions over time were important for the creation of emotional trust with patients. For instance, Research Nurse 4 (RN4) explained how she built up trust with patients.

> "It is about getting someone's trust. You are starting to build that relationship with somebody it is the stepping stones and building blocks and explaining it all to them. It is motivating to be able to explain in a way that they understand."

RN4 felt that the relationship built via 'stepping stones' enabled getting someone's trust'. She referred to the trial as a 'good' option, possibly reinforcing the patient's positive trial expectation which demonstrated positive evaluation by affirming the trial benefit. The creation of patient expectation because of providing a positive evaluation is in line with Nekolaickhuk et al., (1999) who asserted that both practitioners and patients felt that professionals who provided a positive evaluation also created the expectation of hope. Nurses in particular connected responding to patient expectation through their emotional interactions.

Emotional closeness was mostly discussed in terms of how verbal communication gained cancer trial patient's trust. Nurse communication was described as gaining trust by building supportive emotional relationships (even 'friendship') with CCT patients. Nurse Practitioner 9 (NP9) explained how gaining emotional trust impacted on achieving informed consent by describing trust gaining qualities below.

> "A lot of reassurance about the treatment and there are medications to counteract the side-effects. It's more like reassurance that these patients need…Yes, the trust comes with this as well. And I think for patients knowing that you are on the other end of the line… also to offer counselling to the patient and to give information."

NP9 explained that responding to the patients' emotional need for reassurance and reliability was part of creating patient trust. These findings lend support from theorists, Sabo (2001) and Simpson (2004) who argued that reliability and repeated emotional reassurance gained non-

rational trust because the trust was based on patient's dependence and hope. It is possible that reassuring patients helped to sustain patients' hope at the same time as gaining emotional trust. Similarly, Weidan et al., (2016) found that emotional support was a predictor of 'more' hope, which they said further increased trust. Of significance, NP9 took consent for procedures and therefore had first-hand experience of the value of reliability and reassurance in gaining patients' emotional trust.

Emotional relationship building was also derived from the body language of the professional. CD6 emphasised the importance of the professional's body language below in interpersonal encounters with patients form different religious groups.

> "They haven't got all of the skills, they judge body language and other forms of non-verbal communication. You need to deal with these people (from different religions) differently because they have different customs and habits and therefore you respect the fact that you might not shake hands of some people. Women (from different religions) don't want to do that."

Respect seemed to constitute regard or thoughtfulness for religious practices, which may have appealed to emotional-based trust. Many participants also spoke of 'sitting down' with patients, which they felt was of relational benefit in gaining emotional trust during a patient consultation because they said it made patients feel 'comfortable'. Additionally, gaining trust through respectful body language is supported by Wynne (1996a,b cited in Zinn, 2008) who explained that lay people judged body language as a means of evaluating a decision-maker's trustworthiness.

The interactions described were poignant examples of how gaining relational trust impacted informed consent by positive affirmation of the trial, repeated encounters with

patients and by respectful body language particularly during professional interactions with patients from other religions. More interaction seemed to enable ‘more trust’ with cancer patients, although gaining more trust was difficult in emergency cancer decisions, although implied as needed. Professional competency was experienced as a trust gaining quality which is explored next in relation to enabling informed consent.

7.1.2 Competency-based trust

Professional competence was rarely referred to directly by participants. However, participants referred to ways in which rationally based trust was gained and not eroded depending on their particular profession. Doctors based competence on the knowledge the professional showed the patient which they said prevented patients’ ‘mistrust’. On the other hand, nurses based competence on nurses showing confidence and skills to patients, which they said gained trust.

A majority of participants referred to the patient or public perception of patients used as ‘guinea pigs’ in clinical trials. In response to this perception, showing knowledge competence was described by doctors as a means of them not losing patients’ trust. Many doctors linked ‘patient suspicion’, ‘resistance’ and ‘mistrust’ with minority ethnic groups as Registrar Doctor 5 illustrated.

> RD5: “You have a big demographic (ethnic minority patient group) who are intrinsically suspicious of the medical profession, and it is not uncommon here for you to feel that the patients think you are trying to trick them.”

The way doctors created competency based trust was by communicating their trial knowledge to patients as a means of protecting them, thereby dispelling mistrust. Registrar Doctor 10 (RD10) illustrated how honest and clear communication with patients dispelled mistrust and the possibility of cancer patients’ ‘guinea pig’ perception as follows:

> "I think to be very clear and honest. People need to trust you. I think it is important to inform the patient and take away any worries that they might have about entering into a clinical trial. In my experience cancer patients who are introduced to a clinical trial they may think that they are guinea pigs, so they need to feel protected. We need to show them that we have evidence that it might be better at least not worse and explain that their safety is first for them."

The use of 'evidence' suggested a defence of the clinical trial which relied on honesty and knowledge clarity by emphasising the benefits over potential harm of the trial. The use of the word 'protected' was revealing because it implied CCT patients' vulnerability to which RD10 responded by saying that patients need to 'feel protected' while on the trial. The sentiment of protecting patients was connected to 'frontline' doctors and nurses who spoke repeatedly about their concern for patient safety on the trial and was not limited to protecting patients from ethnic minority groups. Communicating honestly to gain trust is similar to previous research on Oncologists' communication where communicating honestly maintained patient hope and expectation (Mendrick et al., 2011).

A consultant doctor emphasised that dispelling the patient's 'guinea pig' perception also required communicating 'non-biased' information, and that competence trust was created by providing the patient with the correct knowledge.

> CD6: "There is a perception that trial means I am a guinea pig and the patients need to trust their physician, needs to be able to have medical trust and to trust what you are saying about the trial is correct and we need to impart an informed non-biased approach that tells them what the trials are about in words that they can understand."

The correctness of information was described as a trust gaining factor because patients could understand the information. CD6 implied that presenting the trial in a 'non-biased' way enhanced trust by emphasising patients 'needing to trust' the physicians' information. CD6's explanation of 'non-biased' information and correctness could allay the fear of the patients' 'guinea pig' perception. Allaying fear is supported by Quinn (2002, p. 5) who highlighted that 'fear' is often associated with the 'guinea pig' perception because patients feared being 'experimented on'. Additionally, giving corrective information may have had the function of allaying patient fears in accordance with Kenny et al. (1999).

Nurses were less concerned with gaining competence trust by dispelling the 'guinea pig' perception, but instead nurses felt confidence and skill showed their professional competence. The administration of trial treatment 'at the frontline' was described as requiring the 'clinical confidence' of both the research staff and cancer ward nurses. Research Nurse (RN1) explained that lack of 'skill' and 'confidence' may mean the patient 'won't get it', meaning won't understand the trial. However, the lack of patient understanding may not mean lack of sufficient 'active' trust needed for consent to occur, as 'passive trust' can still bring about informed consent. NP9 linked the importance of confidence with trust gaining behaviour to gaining cooperation from the start with the patient as the following extract demonstrates.

> "Yes, from the start, if they (patients) trust you they will cooperate with you. If you are the one giving the information you should present yourself as you know what you are saying… if you are not sure what you are talking about obviously patients won't trust you."

The finding of displaying professional confidence as a trust gaining factor is supported by Gambetta (1988 cited in Mollering, 2001) who associated the notion of cooperation with 'trustful' behaviour, demonstrating a functional outcome of trust. Furthermore, the patient's

cooperation chimes with the 'active' trust action as explained by Giddens (1984) that demonstrated informed consent.

Doctors were concerned more about maintaining trust already gained and dispelling mistrust by using their knowledge clarity and honesty to protect patients. Many nurses at the frontline felt that competence based trust was derived from clinical competence and confidence. Overall, it appeared that rational or competence based trust did rely on an emotional element to support it because showing correct 'non-biased' trial knowledge and clinical confidence had the potential to allay the patients' fear of the guinea pig perception. Perspectives as to whether trust is achievable and possible to maintain with minority ethnic groups and lower socio-economic groups is explored in the next theme.

7.2 The difficulties with trust in specific patient groups

There were mixed views about whether language barriers associated with what participants called 'ethnic minority groups' impacted on gaining or eroding patients' trust. Mostly research nurses found language and family pressures were a barrier to gaining informed consent in minority ethnic groups. The reason given was that research nurses explained difficulties in building a relationship solely with the patient, which caused them to question if the consent was obtained from the individual patient. RN2 said that language barriers caused lack of patient understanding. Even though the patient had already consented by the time she met them, these barriers caused practical logistical trial problems for research nurses. RN3 questioned the validity of the consent in minority ethnic groups and potentially related the problems directly to lack of family trust in the following extract.

> RN4: "Yeah, they (patients from ethnic minority groups) come with a lot of people and sometimes there is a lot of heavy family pressure which does impact.

> Maybe they (the family) don't trust in what we are doing or I'm not quite sure what those reasons are, but sometimes we have patients who have not consented or otherwise maybe have consented when you feel they were not very keen but the children were very keen and you are thinking well, 'are they (patients) 100% aware of what is involved?', but so sometimes you don't know what goes on there, so sometimes you sense that."

It appeared that the family influence or scepticism impacted on gaining trust as well as ethnic families lacking trust in the trial which could change the patient's willingness to consent. The 'heavy family pressure' RN4 described seemed to primarily put pressure on the patient to make a decision in accordance with the families' wishes. Certainly, professionals found it difficult to know what the individual patients' wishes were, potentially causing barriers to gaining trial consent. This finding supports previous research which found that scepticism was a source of 'distrust' in racial and ethnic minority groups and was attributed to previous historical 'fear of mistreatment in clinical research' (Durant et al., 2014 p.1100).

In contrast to the experiences of research nurses, a minority of doctors felt language and cultural family influences were not necessarily seen as a barrier to trust creation, irrespective of the families' religious background. This minority of doctors implied that trust could be maintained because these individuals trusted doctors unconditionally. Another example of how trust was maintained was by appropriately respecting and supporting patients through consistent accurately translated information. However, JD4 explained the possibility of a barrier or decline in the already available trust as can be seen in the extract below.

> "They (minority ethnic groups) trust the doctors. They don't think that the doctors don't know what to do here. They think whatever we are doing we know what kind of trial they are on and they don't know that this miscommunication

is happening."

JD4 implied that ethnic minority groups already have available unconditional trust in what the doctor is doing. However, below she implied a potential for trust erosion due to 'miscommunication' as a result of the poor interpreter services.

> "The way they translate it is different from what you say because they don't have medical knowledge... The wife told me that the interpreter is translating something else she was asking about the type of chemotherapy before and after the transplant and is really confusing. Dangerous, yes. And so, you are having someone giving you confusing information and you don't know what is happening to you (the patient) and then they (the patients) are not going to go for that trial."

The discrepancy in translation described could dissuade patients from consenting by undermining the initial unconditional trust. Also, it was necessary for the frontline doctor to recognise the disparity of information translated, otherwise the patient could consent to the wrong treatment, which was described as 'dangerous'. Similarly, M4 reported "lots of problems" with interpreters or absence of booking them which affects trial patients as the following extract illustrates:

> "We have lots of problems with interpreters. I am sure that this affects the patients coming in for trials... They will be booked interpreters and they won't come. If patients are new patients being referred from the GP, they have to book the interpreter and that doesn't happen. Some patients don't even get seen and they have to go home because there is nobody to interpret for them."

Interestingly the manager pointed out that it was the referring GP's responsibility to book the interpreter for their patient to support language differences which further emphasises the importance of maintaining the initial trust gained for the referral to take place successfully. Additionally, while 'written communication in the patient's own language' was described as essential to gaining consent, the patient's ability to read was only a possibility as illustrated below.

> RN10: "You can try and get information sheets produced in Bengali for instance. Just because the patient speaks Bengali doesn't mean that they can actually read Bengali. I think consent is an issue yes…"

In the absence of an interpreter there was a failure to gain initial trust or maintain it because reliable communication was limited. The significance of the interpreter and correct translation in this case study was supported by Gul et al. (2010) and Rubin et al. (2014) who highlighted the importance of the initial contact with minority ethnic groups. The translation problems interfered with gaining trust which lends support from Durant et al. (2014, p. 1101) who highlighted that translators could pose a barrier to obtaining informed consent.

CD6's view contrasted mainly with the research nurses above because he explained that different cultural practices did not negatively impact on consent to clinical trials. The reason he explained was that the professional needs to build the relationship of respect with the patients, not excluding the family within the consent as below.

> CD6: "The culture of these people is that they are really ill and they want something to happen to get them better; I don't find that a cultural problem at all. I may be biased. You need to deal with these people (EMG) differently because they have different customs and habits and therefore you respect."

Interestingly, the consultant said because of his experience working with minority groups his view could be a 'biased', because he explained that he had experience of previously living abroad in a Muslim community and therefore was familiar with ways to build a trusting relationship in this community. Regardless of what he calls his 'biased' view, this perspective was likely to be significant because there was a large minority ethnic patient population served in this case study. Dealing with ethnic minority group 'patients differently' supports previous literature which found the need for 'culturally sensitive' approaches (Rubin, 2014). Building a relationship with minority ethnic group families is further explored in Chapter 8.

CD6 explained that cancer patients start off with trust in the doctor's expertise and knowledge and are supportive to the doctor because of this trust. CD6 explained how a patient's unconditional trust can be eroded by failing to communicate with them in a language they understand and by making assumptions about their lack of education. He refers to patients from deprived socio-economic groups.

> "Actually, they (from deprived socio-economic areas) are an easy bunch of patients to treat because actually if they trust you they would almost have their head cut off for you if they thought that was going to make them feel better cause you are the doctor and you are good and you know what you are about and they are very supportive to you but you need to earn that support... People who treat them as fools because they may not have necessarily have the same P's and Q's are idiots because they are not stupid. So, they always bring up the question of education. Actually, they are very intelligent. It is actually being able to communicate in the right language, the right way."

It appeared that unconditional trust could be eroded where an effort is not made to re-enforce the already available trust. 'Earning' it was described as relying on this tailored

communication. Showing professionalism by individual patient respect regardless of the patient's education was important for maintaining trust. This is supported by Calnan and Rowe (2008) who asserted that relational trust is built by interpersonal interaction where they say professional's personality and professionalism is integral.

Many participants were concerned with either alleviating mistrust or maintaining trust because of the language barriers and family influences associated with minority ethnic groups. Research nurses felt that these families posed challenges to gaining and maintaining trust because they questioned the validity of the individual patient's consent. There was a possibility of cancer patients' unconditional trust. However, this could be eroded by inappropriate professional behaviours that demonstrated lack of support for cultural issues or socio-economic status according to a minority of doctors. The notion of trust as an on-going process where initial trust (whether already available or earned) needing to be re-visited and maintained is explored in the next sub-theme.

7.3 The difficulties with maintaining trust across teams

Many doctors referred to the possibility of a change or a loss of patients' initial trust they had gained which they felt could put the patient at risk of harm because of not starting treatment while transitioning teams. Nurses explained the potential for trust decline due to care fragmentation. Managers were concerned about the lack of trial knowledge among non-research staff which they felt could contribute to a poor patient experience while on the trial. Such an experience could create patients' unhappiness and frustration potentially leading to patient ambivalence about the trial. The potential for trust erosion due to increased risk to the patient is first explored.

7.3.1 Increased risk affecting initial trust gained

The potential for increased risk to the patient's safety as a result of referral delays to the trial team was emphasised by doctors. For instance, one Registrar felt it necessary to offer a 'safeguarding' appointment, to off-set the possibility of this risk.

> RD5: "I think the most important thing as a regular doctor.. is to keep an eye on that patient so I usually give them a safeguarding appointment within a few weeks of the appointment if they haven't been seen by the clinical trials team or slipped up. Then they have an opportunity to come back and re-discuss conventional treatment and see me. I have started patients on conventional treatment at their request because that patient has become upset or unhappy with the duration of time that they are waiting for tests or to begin some kind of treatment."

The use of the term 'safeguarding', although a policy term, captured the vulnerability of the patient because of the risk that RD5 felt the patient was exposed to while transferring between teams. The Registrar perceived the patient as still reliant on him (as the referrer), to which he responded by providing a 'safeguarding' appointment. RD5 said that the patient could become 'unhappy', which suggested a change to the initial emotional trust necessary for referral for the clinical trial. The finding that the patient's sufficient trust for referral could be altered was in line with previous research which speculated that the already established trust needed to be 'honoured' by maintaining the patients' expectation of the trial offered (Barbalet, 2009), and by professional behaviour that responded to the patients' expectation of hope (Simpson, 2004).

Team transition was felt mostly by doctors to contribute to the erosion of patient trust because doctors had established the initial trust necessary for the referral to the trial team.

Delayed treatment is explored for its impact on trust under the best interests' theme. 'Frontline' professionals seemed more aware of the reasons for care fragmentation, and how fragmentation altered the patient rapport because of their patient safety concerns.

7.3.2 How fragmentation of care potentially erodes trust

Many participants spoke about how fragmentation of care across teams could alter the rapport with the patient. The damage to the relationship was attributed to professionals working in separation akin to 'silo working', and where discrepancies regarding 'ownership' of the care of the patient was described in Chapter Six. CD6 referred to care being 'slightly divorced' once the patient has been referred to the trial team. The use of 'divorce' implied a severing of the emotional, interpreted as possibly loss of the trusting relationship because of the change of team directly looking after the patient. CD9 explained how this fragmentation affected the patients' trust as below:

> "The patient transfers from someone they trust to someone they don't know and then when they are finished their treatment they go back to the care of the original person…so it's a bit fragmented."

Doctors explained how there can be confusion because care could be separated between the research and the non-research teams. In addition, when the patient had finished the trial drug and was returned to the non-research team (although still on trial follow up), RN4 indicated there may be a 'reluctance to accept the patient back' into the standard team. One reason for care fragmentation could be that (as identified in Chapter Six), there were often disagreements about who was responsible for the trial patient. Additionally, Junior doctors (for instance, RD3) linked 'frontline' staff with avoiding trial patients, but highlighted the importance of 'frontline' staff for detecting problems.

> RD3: “The main (‘frontline’) staff feel that they shouldn’t touch the research patient but they are always around if something happens so mostly they are mostly like this and if they need to call someone else they will.”

Research nurses explained that the main reason given for the detachment of frontline staff from care was that nurses were scared because of lack of clinical trial knowledge of an unlicensed drug, as described by RN2 below.

> “I think whenever you say trial or unlicensed drug while we (research nurses) have better training, we have the protocol and more information than they (ward nurses) are given and yes it is scary and whilst you are doing your chemo training ..you don’t come across trial drugs and how things are different to standard treatments.”

Research nurses concurred with doctors who said that CNS nurses detached from the care of the research patients. RN10 explained how this ‘hands off approach’ negatively impacted on the patient.

> RN10: “Things that normally a CNS would do I end up doing because they basically say, ‘well that’s your patient’ which may not be great for the patient.”

The detachment occurred from the patient previously known to them with whom trust had been established, before patients were referred for the trial. N5 said that if nurses are not ‘comfortable’ with the trial, ‘it could put people (patients) off’, which was interpreted as a potential for patient ambivalence regarding continuing the trial. As previously highlighted, body language can also impact on trust where the ‘hands off’ approach may have fuelled the lack of trust. The resulting patient discontent described below by RN3 as patient ‘frustration’ had the potential to ‘put barriers’ to patients continuing the trial.

> "If the nurses in the day-care are not treating as per protocol that might delay patients you know. On a visit to the day unit patients might get frustrated. And think "why am I on this study? Because the other patients came and they were seen before me."

Managers were concerned about how fragmentation of care affected the patient experience. Mainly managers attributed this to lack trial knowledge among non-research staff. M1 said that there was a lack of 'actual explanation' about the trial to the 'frontline' staff which caused further fragmentation of care. Another manager, M4 pointed said that 'a good patient experience' was created by patients' day-to-day experience of professional competencies, which they said required staff knowledge of the trials. As these nursing managers were responsible for continuous workflow (ward nurses administering trail treatments) in the clinical area, fragmentation of care was of relevance to them.

The fragmentation and poor patient experience was intimated by research nurses and managers as negatively impacting on the patient's willingness to stay on the trial, although it is not explicitly stated that poor experience caused trust erosion. Some doctors felt that the (although subject to change) original relational trust created good interpersonal encounters. In accordance with Robbins (2016, p. 16) 'social trust influences relational trust', although they described in the business economics sector. The comparison to this previous research is useful because Robbins explains that 'social trust' was derived from 'general cooperativeness and helpfulness' in the everyday experience with individuals that 'fosters high levels' of relational trust where 'trustworthiness' and brings about the 'function of trust'. It is possible that an interruption to the patients' positive day-to-day experience because of the fragmentation and team transition had the potential to erode or fail to maintain trust. Furthermore, lending support from Hurd et al. (2017), there was potential for patient ambivalence or mixed feelings as

described by doctors and nurses who referred to patients' unhappiness and frustration due to transition delays and fragmentation. There was also a potential for the loss of trust because of differences in how professionals perceived the patients' best interest as the next theme explores.

7.4 How best interest differences affected trust

Many research nurses and consultant doctors explained how professionals had different views about the patients' best interest which in some cases opposed the trial offer as the 'best option'. Both professions referred to doctors making treatment recommendations that were in the patients' best interest. Although the nursing impact on the patients' best interest was in line with Beauchamp and Childress' (2001) by advocating for the patients' quality-of-life perspective, research nurses were concerned that differing best interest perspectives could affect their ability to build 'trustworthiness' with the patients. Managers appeared significantly less concerned with best interests and infrequently referred to it, as they had little patient contact and therefore were unaware of the patients' treatment preferences. The areas that will be explored are, medical advocacy and the presumption of patients' trust; the impact of differences in professional beliefs about the uncertainty of trial design on building trust, and how targets could influence the trust relationship. First, there is an exploration of how medical advocacy and decision-making could have interfered with the patient's trust.

7.4.1 The relationship between advocacy and the assumption of trust

Doctors frequently intimated that patients trusted them, often unconditionally to decide on treatments according to the patients' best interest. Consultant doctor, CD1 explained that the doctor's advocacy role was fulfilled by offering 'the best option for the patients even if that was a trial', as previously quoted. Doctors may have assumed that patients trust in the doctor

to decide on the best treatment for them. Medical advocacy may impact on the patients' consent to the trial, where patients expect the doctor to advocate by deciding in their best interest. The meaning of advocacy for CD1 seemed merely 'giving balanced information' and on that basis making a trial recommendation. This meaning contrasted with Beauchamp and Childress' (2001) definition of advocacy as a surrogate decision-maker on behalf of someone else, or as legally defending a person's rights, according to Spence (2011). However, the use of advocacy to bring about the patients' decision could be interpreted as a 'paternalistic-style' of doctoring where doctors lead by deciding the best recommendation which could influence patients' consent, although doctors fulfilled their assumption of patients' trust.

CD6 was probed as to whether the patient had a choice if the MDT best interest decision was already made. There was some uncertainty about whether the consultant's choice and the patient's choice amounted to the same thing as shown in this extract.

> I: "Yet, informed consent is too about patient choice, isn't it? As opposed to best interests is slightly different than patient choice. How would you understand that?"
>
> CD6: "I disagree with that. The answer is the best interest of the patient in as much as not the medical team looking after them. Why want things that are more demanding and more difficult to deliver? If they are not offered then it is not informed consent. I think you have to / should be looking at alternatives. I think you should try. I agree, it is a difficult thin line that you are treading between what's patient's choice and what's consultant / physician choice."

This 'thin line' between best interest decision-making and patient choice could be difficult if the patient decided against the doctor's trial decision. Where the doctor made the best interest

decision for the patient, the patients' choice could be subdued, thereby resembling 'ascent' to the clinical trial, as opposed to patients showing 'active trust' by consenting to the trial. However, where the patient assented to the trial because of the doctor's decision to offer trial treatment, the assent shows the patient's trust, albeit in line with 'passive' trust (Giddens, 1984).

Doctors described themselves as best interest decision-makers or advocates possibly based on the presumption of the patient trusting in them to decide the 'best option'. Nurses were not perceived as making best interest decisions, except for knowing the patients' quality-of-life preferences as was previously highlighted in Chapter Six as their expected role in the MDT. It appeared that because doctors held the power needed for patients to trust them to make a best interest decision, the impact of the nurses' role on the patients' best interest was important in gaining trust, but not explicitly explained. However, both doctors and nurses spoke about how conflicting best interest views and beliefs might affect patients' trust.

7.4.2 How 'beliefs' and views about trial uncertainty impacted trust

Mostly doctors spoke about their difficulties in gaining patient trust due to their differing views about the clinical uncertainty that the cancer clinical trial presented, aligning with increased uncertainty and risk potential because of efforts to advance medicine (Fox, 1980; Bauman, 1991; Adamson, 1997). Managers explained that patients' trust could be also difficult to maintain after the patient had consented to the trial due to nurses' beliefs regarding the trial. Research nurses to a lesser extent expressed difficulties with maintaining trust after patients had consented. This was because they felt their relationship with the patient declined if they didn't view the trial favourably and if patients' lacked understanding of the trial, as explored in Chapter Eight.

The clinical uncertainty presented by the trial caused some doctors to hold conflicting views and beliefs or even 'bias' regarding the trial best interest decision. In particular differing perspectives about trial design and randomised controlled trials were problematic for building patients' trust. Although RCTs were considered 'the gold standard' by doctors, in some cases, the RCT decision conflicted with the doctor's perception of the patients' best interest. Some doctors (for instance CD6) felt randomisation or trial design further increased the uncertainty of the trial outcome which impacted on their belief in the trial, especially if the trial did not meet patient's suitability for the trial offered. CD6 felt gaining trust partly relied on the physician giving a non-biased approach.

> CD6: "Patients need to trust their physician and to trust what you are saying about the trial is correct and we need to impart an informed non-biased approach too… In your heart of hearts there may be a bias pushing towards that or pushing towards what you feel might be better, …sometimes trials are not offered because people (nurses and doctors in the MDT) say, 'oh a trial is tough and I don't believe in the design'. There is a bias for or there can be a bias against it, the overall package, the decision at the bottom of the report would be what is in the best interest of the patient not what the doctor said or thinks so other people within that set up can question that…"

It seemed that there was an internal conflict experienced by the physician because he felt that an un-biased view of the trial was necessary to gain patients' trust, yet he explained that the physician may be biased for or against the trial which can sometimes run contrary to the MDT best interest decision. His view questions if a physician's unbiased view was possible. CD6's best interest preference or view was based on what the physician believed was 'best' for that individual because of the physician's knowledge of and relationship with that patient. This

finding is partly in line with Calnan and Rowe (2008) who asserted that professionals are obligated to act in the patient's best interest to fulfil the patient expectation. As the patients were described as needing to trust in the doctor's view, if the doctor didn't believe in the trial design, then it is possible that the patient won't believe in the trial. This extract illustrates that as Featherstone and Donovan (2002) have argued, patients trust in the clinician was a key factor that extended to patients' trust in the trial. Trust in the clinician is likely to extend to trust in the clinician's beliefs indicated from what the clinician is saying about the trial to the patient. The way the trial was presented by doctors was described previously as influencing the patients' decision by some participants. Therefore, as Jenkins and Fallowfield (2000) asserted the physician's 'enthusiasm' could influence the cancer patient participating in the trial. The professional's belief or hope in the trial possibly then directly affected the patients' hope and trust in the trial.

Many professions expressed the difficulties they encountered with gaining or sustaining trust due to patients viewing randomised controlled trials (RCTs) 'with suspicion' and 'mistrust' in line with Featherstone and Donovan (2002). Doctors spoke previously about their communication struggles with patients because of patients' mistrust about the trial (ethnic minority groups), but also because of the uncertainty randomisation posed as relayed by RD5:

> "You have a big demographic who are intrinsically suspicious of the medical profession."

Doctors explained that the uncertainty of randomisation (RCTs) and trial design affected their communication with the patient. The following extract illustrated the difficulties doctors experienced when communicating with patients about taking part in RCTs in the general cancer patient population.

> CD9: “I think a big part is the uncertainty. Quite often people (patients) want us to put them on the trial arm that is best, but the whole point is we don’t know what is best. It is important that that patient understands that there is uncertainty and the arm that they are randomised to may not help them and that is quite a difficult concept for them to understand. It is a risk that those who get the standard treatment arm (after randomisation) may drop off and lose their motivation because they are aware that they are not getting the exciting drug.”

CD9 explained the importance of the patient understanding the uncertainty of randomisation, but alluded to the doctor-patient relationship difficulties because of patients’ failing to understand the ‘concept’. In line with previous research by Featherstone and Donovan (2002), the difficulties doctors faced posed by randomisation had the potential to dissuade patients from participating in trials due to distrust, lack of motivation and patients’ unacceptance of randomisation to the standard treatment arm. The communication difficulties experienced by clinicians and patients because of clinical uncertainty was in line with previous theorists (Davis,1960; Adamson, 1997) who argued the difficulties doctors faced when communicating uncertain prognoses.

Furthermore, RD5 said that patients’ ‘unhappiness comes from the uncertainty’, which he said caused doctors to commence standard treatment.

> RD5: “It can very easily drag on, recruiting small cohorts and then closing again and all the uncertainty for the clinician about will I be able to recruit that patient or will they come to any harm in the meantime... I have started patients on conventional treatment at their request because that patient has become upset or unhappy with waiting to commence treatment (trial). And “oh, we are expecting this trial to be open”, which is unethical to talk to them about that trial. But, in

the absence of any other option or decent option I think many doctors do that. I do find that uncomfortable."

RD5 had ethical concerns about talking to a patient about a trial that may not come to fruition. Such concerns could impede the physician's ability to build patient trust as the expectation of the trial offer was uncertain, causing the doctor to commence standard treatment instead of the trial, which has similarities with physicians' biased view against the trial as explained by CD6. Where standard treatment was commenced instead of the trial due to the physician's belief or bias against the trial, there was a deviation from the MDT best interest decision. Although deviations from MDT best interest decisions have been found (Wood et al., 2007; Blazeby et al., 2005), physician bias was not mentioned previously as a reason for the deviation.

To a lesser extent, research nurses also experienced difficulties building trusting relationships with patients' due to RCT uncertainty where RN3 found that patients 'would rather be safe' by having the standard treatment. Similarly, RN10 spoke about professional struggles to assess patient understanding of 'the process of randomisation' and if patients 'were happy with it (the trial)', having consented; interpreted as a difficulty with maintaining emotional trust where the outcome was uncertain.

Nursing managers expressed how nurses' beliefs could affect everyday practice because of their attitudes to the trial, which in turn could affect the patient's trust in the trial. M1 described how professionals were motivated by their 'belief in the trial'. This manager held the view that professionals must themselves believe in the trial to gain willingness from the patient. Another manager, M3 explained how nurse's personal beliefs may influence' nurses' 'judgement' about the trial because the nurse may have lacked knowledge and may 'not know the boundaries' of emotional involvement and could be influenced by the patients' views. Managers worried that nurses' views could affect maintaining the on-going trusting

relationship where those administering the treatment don't believe in the trial as a best option, yet managers explained that 'they are unable to challenge it'. It was interpreted that where differences of professional beliefs occurred, patient experience could be affected by professional attitudes. This is in keeping with Hurd et al. (2017) who pointed that the maintenance of trust is affected by the presence or absence of team shared goals and values.

The increased clinical uncertainty was seen as posing relationship difficulties for doctors gaining patients' trust. Although lack of doctors' bias was described as needed to gain patient trust by fulfilling the patients' best interest expectation, trial design and randomisation uncertainty was shown to bias or change doctors' beliefs in the trial, thereby commencing non-trail treatment. Research nurses struggled with assessing patient understanding and happiness with the randomisation decision after patients consented and worried about relationship decline. Managers worried that differing nurses' beliefs could affect the patients' experience on the trial. Additionally, participants reported that external pressures affected their practice and impacted on patient trust as explored in the next theme.

7.4.2 External pressure impacting on patient trust

Research nurses were acutely aware of recruitment targets (the quantity of patient participants) set by the study centre and the National Institute for Health Research (NIHR). They spoke about how pressure to recruit challenged their patients' best interest perspective and could negatively affect their care priorities and relationship building with patients.

RN11 described that 'trustworthiness' could be undermined if research nurses pressured patients (badgered them) to recruit to the trial, especially given the fact that many patients mistrusted science in some religions. It is interesting that RN11 felt that such mistrust could be alleviated by the nurse's leadership in showing trustworthiness as illustrated.

> "Obviously, there are no hard and fast rules and there are people who mistrust science in all religions. But there are concentrations of mistrust in the communities that we serve… I honestly think that the best thing that you can do is to lead by example if you will that you are trustworthy then you are trustworthy. I don't think that you can 'badger them'. You just have to take the time to prove to them that you have their best interest at heart and to build a trusting relationship with them."

RN11 says that building a trusting relationship needed to be 'balanced with patients' best interest'. It seemed that spending the time to build the trusting relationship was a way of demonstrating acting in the patients' best interest, while spending less time with patients to build a trusting relationship was implied as pressuring patients to enter the trial. Similarly, RN7 intimated below that working to a target could subordinate what the research nurse felt was best for the patient:

> "The recruitment target- they (the study centre or NIHR) want to finish (finish recruiting) ten people, 20 people. I know for sure that every healthcare professional wants to help treat patients and that's why we are all doing this. That is another factor other than the target. Influenced by the study centre, you have to meet the targets. My first and foremost objective is to help the patient… probably targets come secondary cause I always feel sorry when they progress and get off the trial."

While RN7 implied that it is healthcare professionals' priority to treat patients, her description of 'having to meet targets' implied pressure on the research nurse to recruit patients to the trial, as an imposed priority. The pressure on professionals to recruit patients is in keeping with Evetts (2011) who speculated that professionalism is 'imposed from above' and is defined by

effectiveness and target achievement which has become integral to practice. While pressure to recruit was a concern, for RN7 the target was secondary to helping patients, which may have had the potential to conflict with the MDT decision. Another research nurse, RN10 highlighted that the pressure to recruit should not ethically contravene patient care, for instance if the patient lacked understanding of the trial.

> RN10: "Ethically, we have to be convinced that the patients do understand the information and are able to make an informed decision and are able to understand randomisation…and that the whole process of the trial is not detrimental to them anyway."

A minority of participants spoke about how financial pressure and pressure to benefit the medical portfolio could affect patient recruitment to the trial, although these pressures were not associated directly with eroding patient trust. One Registrar doctor, RD10 linked the more patients recruited to career gain, as illustrated in this quote.

> "I would like to get as many patients in the trial as possible because I know then that you get answers quicker. But also, I am very competitive so I always want to be number one in the inclusion (of patients into a trial), because I know I want to be in charge and be on top and if wherever possible."

Financial and medical career pressures were a concern for RN11 which caused discontent because of lack of the research nurse's control which was explained as 'frustrating' to work with. The medical career gain due to doctors' active trial involvement was described as causing pressure to recruit patients which RN11 explained nurses had no control over.

> "Other benefits to the consultant would be it is effectively cost neutral for the hospital. It is good for them in their professional career to have active

> involvement in CCTs and to have their name attached to a published piece of research… funding is based on recruitment so there is a great deal of pressure to recruit patients. That pressure is generally put on the research team. It is a frustrating system where the people who identify the patients are the consultants because we wind up getting a lot of pressure over something we don't have much control over."

The language was emphatic repeating 'pressure' to recruit patients with particular career and financial benefits for the doctor and the hospital, while there was no account of career benefit for the nurse. Unlike Ellis (2015) who raised concerns about research integrity because of the pressure placed on medical staff to publish papers, the 'pressure' in this extract seemed associated with nurses' professional dissatisfaction and 'frustration'. There was concern that this pressure could impact negatively on the nurses' relationship with patients and nursing morale because nurses had no 'control over it'. In line with Spence (2012, p.57) the financial and recruitment targets were described as commonly prioritised or imposed, but 'at the expense of the relational quality between care-givers and receivers'.

Research nurses emphasised the pressure on them to recruit which was not always in agreement with their perception of the patients' best interest. Research nurses encountered professional difficulties in building a trustworthy relationship with patients. The reason they explained was that their care priorities were sometimes challenged due to imposed targets, sometimes potentially compromising their relationship with patients. Doctors didn't speak about pressure on them to recruit, while increased recruitment was pointed out by a Registrar doctor as potential for career gain. It was interpreted that trust was at stake where the team were not in agreement about what was in the best of the patient. The negative impact on building trust due to differing views of care priorities is in line with Robbins (2016) and Hurd

et al. (2017), who asserted that 'pushing' towards the trial resulting from differing beliefs impacted on trust.

7.5 Summary

In this chapter, the research questions relating to how gaining trust can enable informed consent to cancer clinical trials has been answered. It has been argued that the maintenance of trust is as important as the initial trust gained or already available. The findings have given insight into how differing professional perceptions about patients' best interest could interfere with professional practice, thereby impacting on trust creation or erosion.

Doctors and research nurses illustrated how relational trust was created by building up emotional and competency-based trust with patients. Doctors found it particularly important to create sufficient initial trust because gaining initial trust enabled doctors to refer patients for the trial, which signified for them the commencement of the informed consent process. Many participants felt that positive and supportive affirmation of the initial trial offer not only created a trust expectation, but also an emotional expectation of hope for cancer patients.

Doctors emphasised that 'more interaction' gained 'more trust' with patients, however they did not associate more patient encounters with the creation of emotional trust. Within emergency situations for instance in Haemato-oncology there was less opportunity for gaining 'more trust'. Research and senior cancer nurses described how they built emotional trust with patients through the creation of positive caring experiences, reliability and by reassuring patients; the latter may have sustained patients' hope. Both doctors and research nurses explained how appropriate body language was found to support building emotional trust and maintained unconditional patient trust through respectful professional behaviour. They felt that

by showing respect for the customs of the ethnic minority patient population and treating them 'differently', they maintained the essential trust needed for consent.

Research and senior cancer nurses explained that clinical and professional confidence and skill were trust-gaining behavioural qualities of frontline professionals. For them, professional competence enabled patient cooperation and trial participation which they felt showed that patients trusted them. Nurses felt that informed consent was achieved by patients 'actively' showing they trusted them. Many doctors on the other hand felt that showing knowledge competency was an important factor that dispelled the patient's initial mistrust and suspicion about the trial. They explained that showing knowledge competency meant giving non-biased, honest information, which they felt showed they protected the patient. It appeared that cognitive or competence based trust was supported by an emotional element which allayed patients' 'guinea pig' fears by ensuring patients felt protected.

There were mixed views as to the impact of language and culture on trust creation where the majority participant view was that sufficient trust was difficult to achieve in the ethnic minority groups. Many research nurses struggled to build a consensual trusting relationship with the patient because they described that in some religious cultures the family scepticism influenced the patients' trial decision. Research nurses found the planning of trial logistics difficult because of their indirect communication with the patient, which caused nurses to question the individual patient's consent. Only a minority of doctors felt that ethnic diversity did not pose any problem for patients' consent, because they felt that many patients regardless of their ethnic background trusted doctors unconditionally. However, these doctors felt it was necessary to support patients' unconditional trust by appropriate language translation and by not making assumptions about education depending on a patient's socio-economic status.

Doctors and managers explained how interpreter service difficulties could erode a patient's initial or gained trust by incorrect or lack of translation.

Many doctors were concerned that referral and fragmentation between teams could potentially damage patient trust which they had gained or which was already available. A minority of doctors spoke about patient safety concerns due to care fragmentation which could subsequently cause the commencement of standard treatment in preference to trial treatment. The transition delays were found to affect the rapport with patients, potentially causing patients' unhappiness and unwillingness to participate in the trial as patients' initial expectations were not being met, thereby potentially eroding trust. Managers were particularly concerned that lack of 'frontline' professional knowledge and helpfulness could directly impact on the patient experience or could cause barriers to patients having the trial because of a decline in the relationship with professionals.

It has been shown that doctors were particularly concerned with acting in the patients' best interest, which they felt patients expected or trusted them to do. There was uncertainty that doctors' best interest decisions interfered with patient choice because the doctor's choice could differ from the patient's choice in some cases. A minority of participants felt that the professional's belief and 'bias' could differ from the MDT trial best interest decision. Doctors felt that communicating in an unbiased way was needed to gain patients' trust. However, it was found that consultants could also be 'biased' against the MDT trial decision if they didn't have belief in the trial or felt it was not right for the patient, resulting in a deviation from the MDT trial decision. However, the MDT decision to offer the trial was intended as a best interest decision, therefore 'bias' against it could interfere with patient trust in the trial as a best interest decision. Nursing managers worried that nurses' beliefs could impact on the patients' experience of the trial.

External ‘target’ pressures from the NIHR and the ‘push’ to benefit the medical research portfolio resulted in research nurses feeling pressured by managers to recruit patients to the trial, which they explained could interfere with maintaining ‘trustworthiness’. The reason was that some research nurses felt their care priorities were different to the trial best interest decision. As a result, some research nurses were found to struggle with building a relationship of trust with patients while balancing best interest, which they felt ‘frustrated’ about, and had no ‘control’ over. Furthermore, there was the potential for a negative impact of targets on building trust because nurses’ care values were different to the trial best interest decision.

Overall, it was found that trust, gained by professionals’ relational interactions with patients was needed to enable and maintain informed consent to CCTs. The ways in which patient trust was maintained and not eroded were outlined. Additionally, it has therefore been argued that differing professional beliefs about patients’ best interest can affect the doctor and research nurse’s trusting relationship with the patient. Even where trust was gained, some professionals were unsure about the validity of patients’ informed consent. The next chapter focuses on facilitating patients’ autonomy within ‘valid’ informed consent.

Chapter Eight: Facilitating Patient Autonomy

8.0 Introduction

The focus of this chapter is how professionals experience facilitating patients' autonomy when obtaining informed consent to cancer clinical trials (CCTs). The supporting research question addressed is: *How does the professional experience of facilitating patients' autonomy provide insight into the 'validity' of informed consent to CCTs?* The prevalent theme participants spoke about was their efforts and difficulties with facilitating the patient's individual autonomy to provide valid consent to a cancer trial treatment offer. The challenges professionals experienced while facilitating patient autonomy will be explored in relation to two interlinked sub-themes. First, the difficulties they experienced when facilitating patients' autonomy in the ethnic minority patient group is explored, and, secondly, how cancer as an illness impacted on patients' ability to provide 'valid' informed consent to the clinical trial.

This chapter begins with an exploration of professional perceptions about how patients' lack of trial knowledge affected the 'validity' of informed consent. Secondly, assumptions made by doctors and nurses about the patient's individual ability to provide valid informed consent; and in some cases, their concerns about the family involvement in obtaining informed consent.

8.1 Perceptions about patient knowledge

Doctors and research nurses spoke at length about patients' lack of trial knowledge and subsequently questioned the 'validity' of patients' consent. They perceived that a certain amount of trial knowledge is necessary for the patient to make an autonomous informed

consent decision. Professionals spoke about struggles to facilitate autonomy within the ethnic minority patient group mainly. While cancer as an illness was perceived as affecting the patient's retention of information, professionals did not always perceive this lack of knowledge as necessarily a limiting factor to facilitating informed consent, although some doubted the validity of consent they obtained.

8.1.1 Knowledge defects among ethnic minority groups

The majority of doctors and research nurses spoke about the possibility of language difficulties impeding patients' autonomous decision-making in the ethnic minority patient group pertaining to non-English speaking patients. Interestingly, managers were concerned about the validity of the consent because of the difficulties with the translation service provided in the hospital for which they held responsibility. The main barrier language difficulties presented was the difficulty for professionals to communicate the trial knowledge needed, and the subsequent perceived lack of patient understanding of trial information. RD2 not only spoke of language itself as a problem but also spoke of the difficulties in facilitating the language barrier when obtaining informed consent.

> RD2: "Course it does and there are different ethnicities and the language barrier can be an issue and ..when there is a significant language barrier it does reduce the chances of this patient being recruited to a CCT. Because having to cross that barrier and facilitate the communication every time won't be a viable option so that's from a research point of view."

It was intimated by RD2 that the language barrier may not be feasible to cross every time to obtain informed consent. A consultant doctor (CD9) linked language difficulties and socio-

economic problems to increased patient vulnerability, highlighting the organisational difficulties in surmounting the problem.

> CD9: "Yes massively, there is a real danger that there is a group of patients that get a raw deal.. so the most vulnerable in our population are the lower socio economic group where a number of patients do not have English as their first language and up to 60 per cent in English and are not even literate in their own language so there are huge barriers in accessing health care, then late diagnosis and advanced disease and then when they present they may not have the support network to help them through treatment and they are less likely to be enrolled into a CCT because of the barriers in terms of providing consent that we think is adequate. In order to change that would require huge investment of man power – there are massive problems it is a heterogeneous problem for example by having just Bengali advocates because there are huge numbers of people who speak Bengali, Polish, Korean and Russian and all sorts of other languages. It's not solvable."

These extracts illustrate as Shrank et al. (2016) found that among cultural factors, above all language barriers were deemed to have the most effect on the quality of communication. It was intimated by CD9 that the consent that was achieved could lack validity because consent may not be 'adequate', as a result of these communication difficulties. Doctor participants showed their willingness to 'cross the barrier' and considered 'investment in manpower' to facilitate what they called 'vulnerable' patients with language difficulties. The majority of doctors seemed to associate the lack of being able to facilitate non-English speaking patients' informed consent with institutional deficiencies and staff shortage problems they felt needed to be addressed to solve the language barrier issues. Previous theorists associated

professionals' restricting trial entry as 'gate keeping' due to cultural, language and socio-economic barriers in the United States (Ford et al., 2007). Hussain-Gamble and Leese (2006) in a UK study found that staff 'stereotypical assumptions' about non-English-speaking patients caused professionals (nurses and doctors) to judge the patient's ability to consent or participate in the trial. Although doctors in the current study said that the translation facilities and staff shortages were considered a major problem for the facilitation language consent barriers, they seemed to endeavour to surmount these obstacles to facilitate patients' autonomy to consent. While doctors were keen to facilitate informed consent, they expressed discomfort about the validity of the consent they could achieve when patient understanding was lacking as indicated in the following extract.

> CD9: "I can speak for myself. It is a difficult situation and makes me feel uncomfortable. On the one hand, you don't want to expose somebody to a CCT that you feel they don't understand or be able to provide valid informed consent but at the same time you don't want to deny them access to potentially the best treatment for them and this creates a bit of a conundrum and I'm still not exactly sure how to resolve that."

In this extract, CD9 expressed a dilemma regarding precluding trial entry on the grounds of invalid consent. In keeping with Howerton et al. (2007), doctors in the current study felt uncomfortable about consent although they accepted the patient's consent even if there were communication difficulties. Another doctor, RD8 said that "99% of patients' are on a particular trial 'even if English isn't their first language', interpreted as part of the course. It appeared for RD8 language was less of a barrier to informed consent. It is possible that some doctors were more comfortable with lesser patient understanding than others to fulfil valid informed consent or merely obtain consent.

Research nurses seemed more concerned about the validity of the consent because they encountered practical problems associated with the patient's lack of knowledge understanding, which led to them to question patients' consent. In the following extract RN3 expressed doubt over the patient's consent because of the associated difficulties in trial planning with non-English speaking patients.

> RN3: "Yes, Barriers could be language. The majority of the patients don't speak particularly good English or that English isn't their first language so there are barriers for example if they are going into the study their bloods need to be 3 days old. If they were being treated on a standard treatment their bloods don't matter. To be honest it is a sham because the patient doesn't speak English and you think maybe if they had they would probably make their own decision."

This extract illustrated the difficulties of patient compliance needed to meet with the trial regulations ('the 3 day old bloods'), where RN3 found facilitating a standard treatment would be less difficult for non-English-speaking patients. The use of the slang word 'sham' gives the impression that the consent was perceived as 'false' or the validity of consent was questionable because the patient lacked the knowledge needed. Another research nurse, RN1 felt that consent for some patients "can happen without patients knowing everything". It was intimated by these nurses that individual patient understanding was linked with the validity of consent because patient understanding enabled the patient's autonomy to choose to enter the trial. In keeping with Van der Biessen et al. (2017), research nurses implied that the more information the patient understands and retains, the more valid the consent will be on the basis of improved patient autonomy ('making their own decision'). By way of contrast, Chwang (2016) disagrees that the validity does not rely on patient knowledge alone, but is based on the patient's 'moral power' which is perceived as the freedom to consent, thereby making it

valid, regardless of the knowledge understood. Further exploration of facilitating autonomy within the ethnic minority group may demonstrate 'moral power' or freedom to make a decision within a social context.

Research nurses and junior doctors found that the translation service was either inadequate or that the translation was not always correct, previously highlighted as affecting patients' trust. However, managers were particularly concerned that inadequate translation impeded professionals' ability to achieve 'valid' consent. Managers explained that the translator issues were further complicated by family members translating the information, which they appeared to discourage as this extract illustrated.

> M3: "I am going to be honest with what we have found is that there will be interpreters in the family and if the interpreter is not around and how is this interpreted? We don't know how much is truly translated. Their interpretation might be completely different and that has a big impact on informed consent."

Although attempts were made to facilitate non-English speaking patients by requesting information in their own language, the problem faced was that the said patients were also illiterate. Patient illiteracy was not only described by research nurses as a reason to preclude informed consent but also precluded the running of the trials where it was not possible to complete quality-of-life questionnaires.

> RN10: "I think the assumption was made that she could read the language and I don't think anyone went through the information sheet with her and translated it. Also, quality-of-life questionnaires was an issue."

The majority view was that language difficulties within the ethnic minority group was the main barrier to the achievement of valid autonomous informed consent because it

precluded professional communication of knowledge and patient understanding. While some doctors and many research nurses felt that informed consent was achievable irrespective of the quality of the consent, many felt that such consent could be invalid. The majority attributed possible invalidity of consent to lack of patient knowledge and lack institutional services needed to support language or communication problems. Patient insufficiency of knowledge was not limited to language. Cancer as an illness posed different knowledge barriers also causing professionals to question the validity of consent.

8.1.2 The impact of illness on the validity of consent

Many doctors and research nurses spoke about how cancer patients struggled to understand trial information, in particular trial design. Doctors not only spoke about their difficulties in gaining trust to RCTs because of patients' suspicion and lack of understanding and the trial uncertainty; they also questioned the cancer patients' autonomous ability to decide because of patients' lack of trial knowledge. Research nurses spoke about the impact of cancer and poor prognosis on the validity of patients' consent, particularly in relation to phase 1 clinical trial consent. Many research nurses perceived that a 'desperate' patient situation and cancer patients' reluctance to decide caused them to question patient autonomous decision making.

8.1.2 The 'desperate' patient

Although, many doctors seemed more concerned about the cancer patient's initial trust, some questioned the patient's lack of sufficient knowledge to enable valid informed consent. For instance, CD9 consultant doubted if valid consent was achievable because of cancer patients' insufficient scientific knowledge as this extract illustrated.

> CD9: "And also about what is true informed consent, whether it is actually possible for patients to really (emphasised) make an informed decision when

> they haven't got a professional medical background, especially when the science which we are dealing with is becoming much more complicated."

CD9 placed doubt over any possibility of gaining what he calls 'true' consent which could be interpreted as 'valid' consent, due to the differences between patient and physician knowledge. On this basis, in keeping with Jansen (2014), it seemed unlikely to achieve valid consent, because CD9 associated knowledge and understanding as a key element of informed consent.

A majority of research nurses spoke about the difficulties with facilitating consent with cancer patients embarking on phase 1 clinical trials. For instance, RN7 explained below that patients could make hasty consent decisions possibly questioning the validity of consent because of what she referred to as the 'desperate' patient situation or because there were no other options.

> RN7: "Usually what I have noticed, not saying in general and just applies with our trial, patients are desperate and want to be on the trial as soon as possible. They are lung (patients)."

RN3 found particular differences between early and late disease stage patients, where in the later stages (more advanced disease) patients were prepared to try anything which could mean that patients were desperate.

> RN3: " I kind of feel when patients are in their late stages they just want anything to get better and of course they want quality-of-life as well, but they just want that. Unlike the patients who first get diagnosed in early stages they feel like they have more choices in terms of treatment."

When research nurses were probed about differences in patient consent decisions they felt that there was a consent issue with early phase trials. They explained that patients' 'desperation' caused 'an issue' for valid consent because the trial was not 'going to be of any benefit' and was the only 'option'. RN8 below gave an account of how the patient misinterpreted the phase 1 trial purpose and questioned the consent decision on the basis of patients' incorrect understanding.

> RN8: "Their (patients) train of thought is: "what is the worst that can happen?" Because they are there and the illness is going to kill them at the end of the day so, "what is the difference in having the trial?" And (they say) "how long am I going to be on this trial or how long is it going on for?" Maybe they probably would make the same decision and at the time they understood it, but that changes because even though you have been told your disease has gotten smaller and that's good but that doesn't mean forever. People suddenly think: "it is going to get smaller and smaller and go away but it has gotten smaller but it is not going away."

This extract shows that in keeping with Dolly et al. (2016), research nurses found that patients' understanding over-estimated the response possibly caused by patients' 'desperation' or clinging to unrealistic hope. RN8 found this problematic for valid consent because it seemed that the initial understanding was questionable because later the research nurse needed to repeat the trial purpose. Furthermore, in keeping with van der Biessen et al. (2017); nurses described the 'desperate' patient as possibly 'ignoring' the information given at the time of consent, further questioning consent validity. While research nurses spoke of consent difficulties due to no other treatment option, interestingly most of them didn't link lack patient 'desperation' to lack of patient 'voluntariness' or freedom to decide directly. However, in

keeping with van Kleffins et al. (2004), where there was often not another option, it did influence the patient's ability to provide valid consent.

Research nurses were generally more concerned than doctors with trying to facilitate consent because of their perceived lack of consent validity which they associated with cancer patients' distorted understanding or patients' unrealistic trial outcome estimation. This was particularly problematic in phase 1 studies for advanced stage cancer patients whom they felt were 'desperate', causing them to question the patients' ability to consent. Although most participants did not link lack of understanding or lack of choice with voluntariness, a minority of research nurses spoke about how patients opted to give up their freedom of choice or 'voluntariness'.

8.1.3 'Relinquished' autonomy

Most participants spoke at length about the doctor deciding on the trial recommendation if doctors felt it was the 'best' option for the patient, even if there was no other option offered. Although the doctor decided, the majority view was that patients would then consent to what the doctor felt was best for patients. However, in many cases it seemed that the patient assented to the trial, which for some professionals meant that patients gave up their autonomy. There were few instances described where patients did not agree to the trial and sought a second opinion. It was not perceived that the doctor deciding on what was best for the patient interfered with patient voluntariness, except for the instances of perceived 'pushing' for the trial previously explored which in keeping with Gilson (2003) could have interfered with 'voluntariness'. Although only a deviant case, one research nurse described the patient's wish for the professional to make the consent decision for them or on their behalf.

RN3: "I think from my experience I have noticed that you know those patients

> who are academically aware, or those patients who ask you; “Nurse what would you do if it was you?”, and if a patient comes and they don’t speak English or have poor English sometimes you find you make decisions on their behalf.”

The research nurse pointed out that patients who lacked the knowledge or language skills seemed to give up their ability to consent by either asking or preferring the professional to decide; interestingly, in this case the nurse to do so. Although the research nurse was aware of the lack of perceived patient autonomy to consent, it seemed acceptable for the purpose of gaining a version of consent. In keeping with previous studies, because patients were overwhelmed with information, they wanted professionals to decide or particularly doctors to ‘direct’ them, thereby assenting to the trial, termed as ‘relinquishing’ autonomy (Mc Kinstry, 2000; Sinding et al., 2010). Furthermore, while Madsen et al. (2007) pointed out that where the patient had only one option they felt patients’ freedom was limited and many patients experienced the ‘loneliness’ of autonomy; and therefore, wanted professionals to decide with them. Conversely, Mendrick et al. (2010) argues that patients felt autonomous even if they saw no choice, and felt ‘ownership’ of the decision if they asked doctors to decide because they interpreted the doctor’s ‘paternalistic’ approach as a recommendation.

It appeared common practice that professionals accepted assent (agreeing with the doctors’ decision or advice) as patients’ consent. However, for some nurses this assent appeared to support the patient’s lack of knowledge or ability to decide. It was interesting that patients in some cases also wanted nurses to decide for them. In keeping with O’Neill (2002) in some instances, ‘fully informed’ consent is not achievable, which may place doubt over facilitating autonomy and ‘voluntariness’ as advised by Beauchamp and Childress (2001) bioethical principle of respecting autonomy. It could be that assent to CCTs in the cancer and ethnic population is accepted as a form of informed consent. However, there were some

instances where professionals could impede informed consent by making assumptions about the patient's autonomy based on the factors particularly associated with the ethnic minority patient population.

8.2 Professional assumptions made about patient autonomy

Despite many participants referring to potential barriers to informed consent in the ethnic minority population and patients from the local lower socio-economic group, only a small minority of doctors and one research nurse spoke about how professionals could make assumptions about the patient's ability to consent. These limited accounts may represent a much higher assumption than the ratio of professionals who spoke about them. Possible professional assumptions made were because of the patient's culture, perceived intelligence and level of education. The assumptions made caused some doctors and nurses to underestimate the patient's ability to consent or the patient's autonomy. Some participants described assumptions as having a direct effect on facilitating autonomy, where there could be a 'steering' away from the trial or at a minimum these patients were described as being 'treated differently'.

8.2.1 How professional assumptions affected facilitating autonomy

Some doctors referred to assumptions that were made about the patient's ability to decide depending on their patients' socio-economic and educational status as illustrated in this extract.

> CD6: "People (doctors and nurses) who treat them as fools because they may not have necessarily have the same P's and Q's are idiots because they run rings around them because they are not stupid. They always bring up the question of education being part of things actually there are quite and very intelligent."

CD6 expressed his disapproval of those who question intelligence on the grounds of education by referring to such professionals as 'idiots'. It is possible that such an assumption may be frequent because he refers to professionals 'always' bringing up the question of education. While he doesn't elaborate on the possibility of professionals excluding such patients from the trial offer, it is interpreted that this could be a possibility. A Registrar elaborated on what the impact of the assumption might be, where judgements are made about the patient's autonomous ability. There is a possibility of trial exclusion on the grounds of presumed lack of patient engagement and compliance as illustrated in the following extract.

> RD8: "People (doctors) assume that if you have a certain level of education and language you might be more keen to go onto trials. Compliance and engagement, they (doctors and nurses) might think is a problem because no-one has looked into it but you should treat everyone the same obviously but I don't know if that is always the case just sub-consciously and people (doctors) make judgements about people depending on language and what they wear. I think everybody is going to be different, every doctor is different, any person out there will always have/ no matter how people deny it/ will have always preconceived views and it will depend on how that affects what they do, but in terms of going back to trials and ethnic groups I can't see necessarily that they (patients) would be more resistant to taking part in CCTs. I think the problem lies on the doctor's side where we don't put people off and to make sure there is an extra level and to make we go through things with the patient and they are fully on board."

In this extract, a 'judgement' was described on the basis of patients' ethnicity, education or even clothing as to whether the patient will engage with the trial. Interestingly, RD8 said that doctors can make this judgment 'sub-consciously', or even if they are conscious of it, they

could ‘deny’ it. Where there is a pre-judgment made about the patient’s ability to decide about a trial offered to them, there could be professional lack of respect for autonomy. In keeping with Howerton et al. (2007) and Bell and Balneaves (2015), bias or assumptions position health care professionals as ‘gatekeepers’, potentially precluding trial entry of such patients. Similar to the sub-conscious bias described by RD8, Hussain-Gamble and Leese (2006) found that patients can be ‘cherry picked’ for the trial, or certain groups can be treated with ‘passive exclusion’, which they say can be institutional.

Within this contemporary London setting, the demographic details of the participants interviewed was not sought. However, the researcher is aware that both these doctors are familiar with ethnically diverse patients whether from their own family background or in a previous workplace. It seemed that these doctors had an appreciation for facilitating ethnic and diverse patient autonomy in the contemporary setting because they highlighted professional presumptions about autonomy and the need for more diversity among the staff as this extract illustrates.

> RD8: “I would have been more alert to it when other people might not be. It helps if you have gone through it and leads to an understanding. It might lead to people being more aware of different cultures I suppose and cultural sensitivities and increased awareness.”

These doctors appeared to have an understanding of the value of different approaches to patient autonomy which is in keeping with Barvosa (2007) who described how doctors seemed to display appreciation for diversity in the contemporary setting due to what Barvosa calls a ‘hybrid experience’, which factors in different cultural approaches. Furthermore, RD8 explained how a more culturally mixed and sensitive workforce would be ‘aware’ of cultural

needs in line with Hussain-Gamble and Leese (2006), thus, providing improved facilitation of such patients' autonomy.

Assumptions made about the patient's ability to consent was not generally described as a concern for nurses, although research nurses found that language and ethnicity were cause for questioning of the patient's consent. However, one research nurse (RN10) spoke about professional assumptions about a patient with a possible learning disability (although the patient was assumed as having capacity initially) causing a 'steering away' from a clinical trial as illustrated.

> RN10: "I had a case recently where a patient was given trial information and it was obvious that they didn't necessarily have learning difficulties (LD) but they didn't understand the process very well. I was kind of encouraged to steer them away from consenting and when I spoke to them initially they said they did want to consent to the trial but then after talking to them a bit more they didn't kind of understand the whole randomisation issue and weren't very happy with that and another issue was it would have delayed them starting treatment if they had gone on the trial and they did decide not to go on. But yes, I was encouraged to steer them away."

This situation was difficult for the research nurse due to denying the possible LD patient access to the trial based an assumption about the patients' autonomy to decide. Secondly, taking away the initial LD patients' consent, possibly damaged the patient's expectation of the trial. However, RN10 described how such patients struggled with the concept of randomisation, and therefore it was intimated that deterring them from a trial that could be justified. In keeping with Tobias (1998), deterring patients from the trial could be justified because he recognises that rigid positions about obtaining informed consent ignore the

realities and difficulties of gaining consent and calls for a 'more directive', even paternalistic approach, which arguably could be perceived too much a shift away from facilitating autonomy. Furthermore, Jansen and Wall (2016) condone what they call 'soft paternalism' in similar cases to RN10's case where a patient's therapeutic misconception and lack of understanding is cause for a doctor to decide against the trial. The reason they give is to 'safeguard' the patient and limit the risk of harm.

It is interesting that only a minority of participants spoke about assumptions professionals made about patients' autonomous ability to consent given that this case study is set in a culturally diverse, socio-economically challenged location. Of those who did speak about these assumptions, they explained that the impact on practice was that patients are potentially treated differently and could be precluded from trial entry. Precluding trial entry on the basis of presumed lack of the patient's individual autonomy was also significant for another reason. Many professionals described their difficulties in facilitating informed consent because of how the families of ethnic minority group patients influenced 'individual' patient autonomy.

8.3 Individual versus relational patient autonomy

There were mixed experiences described by participants about how they perceived the ethnic family involvement in the patient's consent. Many research nurses and managers felt that the family involvement was a barrier to achieving informed consent from the individual patient. A minority of doctors spoke positively about the family involvement in the patient's consent decision. In this sub-theme, the way professionals perceived the influence of the family on the patient's autonomy and the subsequent impact on how professionals facilitated informed consent is explored.

8.3.1 The family influence on 'individual' autonomy

Participants spoke about the influence of the ethnic minority family on achieving patient consent. A minority of doctors spoke positively about the family influence. Many research nurses and nursing managers spoke about challenges in relation to achieving what they called the patient's 'own' consent, as opposed to the family decision or consent to the trial, as illustrated in this extract.

> RN4: "I know that sometimes we have sensed that there is a lot of family influence to not come onto it (the trial) and vice versa and sometimes it is hard to gauge how much family pressures are going on. Or you might think they think, 'oh yes brilliant', and then they go away and next day the son rings up or family rings up and says, "no we are not doing it", and you think how much family pressure has gone on.."

RN4 questioned the family influence which she perceived as 'pressure' on the patient to make a consent decision because she struggled to know what 'goes on' within the family. In this instance, the 'son rings up' and decided to decline the trial that the patient had previously appeared positive about. As a result of what RN4 considered the family pressurising by the son deciding it appeared that the patient's 'individual' autonomy was questioned. In line with Ho (2008), it could be that the patient's lack of autonomy was presumed, who highlighted professionals presuming patient involuntariness due to family involvement in decision making. Similarly, RN10 said that achieving autonomous consent was a concern because 'the family make the decision'. Previously, RN3 explained that there was no communication directly with the patient, and that the consent was a 'sham' or false as a result. M3's concern was because of 'children translating' for patients and voicing the decision. In keeping with Bell and Balneaves (2015) and Hussain-Gamble and Leese, (2006) research nurses

particularly felt that family influences questioned 'individual' autonomy and were perceived as a barrier to patient consent in this CCT setting.

Although the research nurses pointed out their concerns about not achieving consent from the individual patient there does not seem to be any resolve offered for this discontent, except in the case of RN3, who says:

> "Whenever we speak about these trials they always have a choice so I just have to respect their relatives wishes and hopefully that was their (the patient's) wish and just wish them the best really."

There was an exception made here for the family involvement in the hope that the family wishes reflected the wishes of the patient. It is possible that RN3 appealed to accepting a relational version of autonomy where the patient is positioned within the family social context. In line with Kihlbom (2008) accepting consent according to Beauchamp and Childress (2001) appeals to the positive belief that the patient's preferences are intentionally expressed (by the family), and that there is patient understanding and control of outside influences, which determines 'individual' autonomy needed for consent. Many research nurses knowingly undertook the pressures and influences of family as the day-to-day accepted version of facilitating consent, even though they felt uncomfortable with the ethnic family influence. Additionally, some nurses alluded to adhering to the policy for gaining consent from the individual patient, where 'the subject's' consent is sought or else that of an 'impartial witness' or 'legal representative' if language is a problem as opposed to the family being used for the purpose of gaining consent. For the most part, research nurses questioned 'individual' autonomy and generally did not appear to consider relational autonomy within the context of the family as a contributing factor to patient autonomy.

Of the minority of doctors who spoke about the ethnic family influence on consent, it was felt that the family played an important positive influence on the patient's autonomy. RD8 previously spoke with disapproval about ethnic minorities being 'treated differently' generally, but feels strongly that the family are an important part of the consent as he explained below.

> RD8: "I don't think that has ever posed a problem for them (patients) in clinical trials because they have been part of clinical trials because the family members explained it to them. Just that the demographics are that a lot of children should have been born and brought up here and are able to explain things in a way that the parents can understand."

Interestingly, RD8 incorporates the family, even the children into trial discussions and finds it helpful for gaining consent. The notion of engaging the family was implied as beneficial and was not seen to contravene policy or patient autonomy, but places the patient as part of a family relational structure needed to achieve consent to the trial. Similarly, CD6 endorsed particularly the ethnic family in the decision about the trial consent as illustrated below:

> "Having relatives and people around with them can be quite helpful on occasions because I think trials should be a family decision sometimes rather than just an individual and the individual goes back to the family and talks to them and they say don't let them do that when they really don't. They are as uninformed as most other people in the general public whereas if they are all there and they understand then you have support of and from the home when the patient is feeling tough and not too good they stick with it because the relatives are all there and they are all part of the treatment team so I think involving the family when you can is important and that is especially with the

more ethnically diverse patients more important and we don't do enough of it."

This extract illustrates in keeping with Knobf (2007) the importance of 'relationship building' by involving the family presence who provided social support they for the patient's trial entry and continuing on the trial when things are 'tough'. There was no doubt placed over the patient's autonomy here even where the family made the decision together. Similarly, Corrigan (2003) found that informed consent can be reduced to 'individual' autonomy which ignores the cultural dimension she feels is necessary, and a patient who acts within the family commitment according to Mc Kenzie (2008) *is* autonomous. CD6 expressed disapproval of not involving the family as accepted common practice as he referred to professionals not doing enough of it, implying a change in the way professionals facilitate autonomy within the family context.

For the most part, research nurses and managers found that the family involvement in patients' consent was a barrier to the patient's individual consent and caused them to question the patient's autonomy. A minority of doctors valued the family presence and involvement and believed it necessary to achieve patient consent within the relational context of the family.

8.4 Summary

This chapter has answered the research question that asked how professionals experienced facilitating patient autonomy when consenting in a diverse CCT setting. It has been argued that questioning the validity of consent is an important problem within the context of two patient groups: namely the cancer trial patients and the ethnic minority patient group. It was found that the majority of participants experienced certain patient knowledge and understanding defects which posed a challenging problem for them when facilitating autonomy needed to fulfil informed consent requirements, questioning the validity of consent they achieved.

Some doctors felt that language barriers were an insurmountable problem, but they were reluctant to use this as a reason to preclude trial entry. Doctors attributed the 'massive' language problem to the organisation's translation service and staff shortages. They found the possibility of invalid consent a dilemma for patient inclusion in clinical trials, while other doctors varied in what patient understanding they were prepared to accept as consent, acknowledging the asymmetry of information with the physician and the patient.

Research nurses encountered language difficulties affecting the logistical planning and subsequent patient compliance. In some cases nurses felt that the consent was invalid or false. Nurses intimated that the more knowledge that was understood by patients, the more valid was their consent. Managers were mostly concerned about the validity of consent because of deficiencies in the translation service or the involvement of the family.

The other reason why knowledge deficiency caused difficulty with facilitating ill patients' autonomy was because research nurses found that they demonstrated lack of understanding of trial design and in phase 1 studies misunderstood the trial purpose, thereby overestimating the response. While they managed a 'desperate' situation by going over the consent and trial purpose, nurses did not indicate that the patient's 'voluntariness to decide was threatened as a result. Research nurses found that patients who lacked understanding often wanted doctors to decide. It was described as common practice for the doctor to present the best option, to which the patient consented or sometimes it seemed patients assented to the trial, or even gave up their autonomy to decide. Interestingly, despite the diverse cultural and socio-economic patient population served, only a minority of doctor participants gave accounts of assumptions that professionals made regarding such patients' ability to consent. There were instances when assumptions made were justified to protect the patient, presenting a dilemma for the facilitation of the patient's autonomy.

The question about facilitating 'individual' patient autonomy was of concern for many research nurses and managers who found family involvement a barrier or even falsified the patient's consent, questioning voluntariness, as there was no direct communication with the patient. Research nurses were aware of following the policy requirements for consent and ideally sought direct patient preferences. While research nurses felt uncomfortable about their views on family involvement, they incorporated the family in their daily practice and endeavoured not to let it preclude a version of consent. A minority of doctors spoke about the inclusion of family as an essential aspect when seeking consent in cultural situations; off-setting the risk of patient attrition later. They did not feel that family inclusion posed a threat to the patient's autonomy, but reconciled facilitating autonomy by suggesting the need for more culturally mixed staff and a culturally family sensitive approach. None of the participants suggested more training to equip them to facilitate the difficulties they encountered due to family cultural practices, although it was intimated.

This chapter has shown that although professionals experienced difficulties with facilitating patient autonomy in a diverse CCT patient setting a variation of consent or assent was often accepted. The following Conclusion Chapter will draw together and summarise the key themes. The study limitations will be highlighted and how the findings have advanced the literature and formulated theories for practice or proposed future research.

Chapter Nine: Conclusion and Recommendations

9.0 The study summary

In this study, the interprofessional experiences of communication involved in obtaining informed consent to cancer clinical trials (CCTs) was explored. In the role of nurse practitioner researcher and manager, my regard for valid diverse cancer patient consent has been a guiding principle. Identifying the need for a triangulated interprofessional voice has personally inspired this study, which is aimed at advancing CCT interprofessional practice and making a contribution to the literature. The problematic communication resulting in poor accrual to CCTs has provided an impetus for undertaking this study in a single tertiary London CCT centre.

The research design entailed a phenomenological approach within a case study setting, comprising of 26 semi-structured interviews with mixed professionals and the upkeep of a reflective diary to enable reflexivity. The conceptual framework was built upon the main concepts and assumptions within the overarching research question which guided the literature review and data collection. Supporting research questions were focused on ascertaining the interprofessional experiences of responsibility, as shaped by time, trust and facilitating patient autonomy. The experiences have been presented and discussed with the use of the literature. In this chapter the main findings are summarised and the contribution to the literature is highlighted. The strengths and limitations of the study are outlined. It will be demonstrated how the researchers' (my) interaction with the findings has been able to answer the overarching research question. As a result of the findings, recommendations will be provided which can either contribute to implications for practice or form a basis for future research.

9.1 Responsibility as shaped by time

The timing of the doctors' role is affirmed as important because of confirming the diagnosis and making the initial offer of the trial to the patient in keeping with Friedson (2001) and Davis (1995). There was interprofessional discontent or internal professional conflict regarding the positive (even persuasive) language used by doctors to offer the trial, which many referred to as 'pushing for the trial'. Initially some managers and nurses and a senior doctor seemed in support of nurses challenging this 'pushing' for the trial'. Yet they acknowledged that the trial was often 'the best option' and 'doctors wanted the best for patients'. The research practitioner empathised with the moral difficulty these opposing views had for nurses mainly. Regardless of this difficulty, it is intimated that the language used by doctors could have a positive effect on patients' consenting to the trial. This could mean that obtaining informed consent to CCTs relied on presenting the trial in a positive, even persuasive way potentially created hope. The use of positive language in support of the trial chimes with previous theorists (Barton and Eggly, 2009; Brown et al., 2015), although conversely could be perceived as 'framing' the trial according to Chwang et al. (2016).

Although participants presented a divided view regarding the timing of eligibility (medical / diagnostic factors) and suitability (social factors), most were in agreement that assessments spanned a process across professional boundaries. Research nurses and managers were more concerned about whether patients were suitable and gave reasons for patients' poor suitability pertaining to day-to-day difficulties patients experienced on trials. The MDT decision-making forum was dominated by the doctors as found previously (Lamb et al., 2011; Eigenmann et al., 2015). However, some doctors encouraged the nurses' role as a 'challenge' or patient advocate or even as a 'conscience' checker. It is deduced that direct challenges to medical recommendations were welcomed in contemporary CCT decision-making. Doctors

and managers linked nurses challenging decisions to nurse acting as patient advocates. Most research nurses were cautious about challenging decisions, but did contribute to the suitability assessment of the patient. However, they were often not involved in patient assessment prior to the trial recommendation or the actual consent which contrasts with Kidger et al. (2008) who deem suitability assessment essential prior to the trial recommendation. Although Davis et al. (2002) considered the importance of the nurse advocates, they did not specify as that of a 'challenger' of the recommendation. Nurses' autonomy could mean the ability to challenge, although, some research nurses described their role as dependent on the support of the medical profession, akin to the doctors' 'handmaiden'; or similar to the adjudicator roles respectively (Roberts and Vasquez, 2004; Lee et al., 2009).

Some nurses and registrar doctors described the signing of the form as a time for doctors to confirm that informed consent has been 'fully' achieved. This contrasts to Bergenmar et al. (2008) who recounted studies where doctors rarely did check if information was understood. Nurse participants questioned the quality or 'usefulness' of the consent paperwork validity in-line with the literature (Jordens et al., 2013, p.76; Shannon-Dorcy & Drevdahl, 2011; Corrigan, 2003; O'Neill, 2002). However, nurses did not want responsibility for the consent and often referred to the doctors' responsibility in accordance with policy guidelines. Junior doctors and nurses at the 'frontline' felt that the 'process' of information-giving was on-going derived from ad-hoc social encounters with patients, which they said maintained patient safety and enabled informed consent by gaining better patient understanding. There was agreement with Bergenmar et al. (2011) that giving the patient more time is likely to impact positively on consent, although the reason was not necessarily because patients in their study had better understanding or trial knowledge.

Information-giving over time was likened to a social encounter, like 'chatting with the patient' particularly for nurses, which could be likened to Hassard (2001) who refers to such time as 'qualitative'. Both professions felt such quality time enabled patient understanding of that information. Doctors reported time-constraints in the clinic setting, as identified by Jenkins (2010) and others. The constraints described in clinic time ('10-15 minutes') in the cancer trial setting is in keeping with MacBride-Stewart (2013, p.564) although described in general practice. Lack of doctors' clinic time caused nurses to 'fill in the gaps' that the doctors could not attend to. Some doctors referred to these nursing tasks (information-giving and checking) as essential to 'good' informed consent. Importantly, the nursing time seemed to equate to as what Davis (1994) referred to as 'relationship time' as opposed to the 'clinic slot' controlled doctors' time. When doctors lacked sufficient time, ensuring 'informed' consent (traditionally a medical responsibility) became 're-distributed' to the research nurse, potentially changing practice. The unstructured social process by which nurses gave information was referred to as a 'friendship' with the patient as developed over time. This supportive relationship resembles the time-phased' approach to intimacy, as found by Dowling (2008) and Strazdins et al. (2016). The unfortunate finding was that many nurses did not equate the nurses' role or relationship as a defining component in obtaining 'valid' informed consent.

9.2 Trust

It has been argued that the maintenance of trust within informed consent is as important as the initial trust gained or already available. Doctors were more concerned with maintaining the 'initial trust' that they had gained. While Calnan and Rowe (2008) found that patient trust was conditional and was earned by positive experiences with professionals; by way of contrast to the CCT setting they found that 'familiarity' over time with the clinician did not make a difference to diabetic patients' trust. For professionals in this study, the repeated encounters

over time with cancer patients engendering familiarity was trust-forming, in keeping with Jackson et al., (2004). Repeated patient encounters with patients gained 'more trust', except for the difficulty described in gaining 'more trust' in emergency situations. While Zinn (2008) asserts that when there is 'less knowledge' and 'less time', akin to 'contemporary decision-making', 'increased trust' is needed. The descriptions of decreased availability of trust in emergencies was different to the need for more trust in emergencies according to Zinn (2008). However, these clinicians did not mention that a 'leap of faith' (Giddens, 1984) was needed by patients. It could be that physicians lacked comprehension of how emergency trust came about for patients, although they felt they achieved it.

Nurses explained the possibility of reinforcing the patient's positive trial expectation when the trial was presented as a 'good' option, in-line with Nekolaickhuk et al., (1999) who associated a positive evaluation with creating an expectation of hope. Nurses also seemed to associate gaining trust with reassuring patients, potentially sustaining the patients' hope, appealing to the patients' emotional trust in a non-rational way in keeping with Sabo (2001) and Simpson (2004). Similarly, Calnan and Rowe (2008) found that patients' trust was earned by the quality of care they experienced from nurses, although they found that reassurance was attributed to the information patients received. The body language of the professional, for instance nurses' 'sitting down' with the patient and observing religious customs was described as 'making patients feel comfortable', demonstrating respect. It is uncertain if these practices were trust-forming, although they did strengthen the professional-patient relationship.

Some doctors felt that ethnic patients had unconditional trust, while others felt that these patients were suspicious. Many doctors dispelled the possibility of 'mistrust' or loss of trust and the 'guinea pig' myth. They showed their competence by communicating trial knowledge to patients honestly, in an un-biased way as a means of protecting patients and allaying fear.

Nurses felt their clinical confidence and competence 'at the frontline' showed competence when caring for patients. Nurses also associated gaining trust with gaining the cooperation of patients, in keeping with Gambetta (1988 cited in Mollering, 2001) who associated cooperation with 'trustful' behaviour as an 'active' component of trust Giddens (1984). Managers gave accounts of how professional interactions with patients affected the patient experience. It appeared that rational or competence based trust did rely on an emotional element.

There were mixed views about whether ethnic minority group factors associated with language issues impacted on gaining or eroding patients' trust. Mostly research nurses found language and family pressures were a barrier to gaining informed consent for minority groups. The reason given was that research nurses explained difficulties in building a relationship solely with the patient, questioning the validity of the consent and potentially related the problems directly to lack of family trust aligning with Durant (2014) who found that distrust was associated with ethnic groups. For a minority of doctors, it was implied that patients from minority groups trusted them unconditionally, but that trust could be eroded by poor translation of the information in keeping with previous researchers (Gul et al., 2010; Rubin et al., 2014; Durant et al., 2014). One consultant and a registrar welcomed the ethnic family involvement in decision-making. These doctors described trust as 'earned' for diverse patients, by tailormade communication and treating them 'differently', showing respect, without which the gained trust could be eroded. Dealing with these patients 'differently' aligned with the need for 'culturally sensitive' approaches (Rubin, 2014).

As noted in the research diary and interviews, the positive rapport needed to gain the initial trust or maintain it could change due to care fragmentation between teams. Maintaining the initial trust resembled honouring the patients' expectation of the trial offered (Barbalet, 2009), and by professional behaviour that responded to the patients' expectation of hope, in

keeping with Simpson (2004). 'Frontline' professionals in this study highlighted that lack of ownership of the patient and even 'avoidance' of trial patients caused fragmentation of patient care, although this was often because the general team or the CNSs lacked trial knowledge and were fearful of an unlicensed drug. The 'hands off' approach to patient care was interpreted as ambivalence which was found to erode trust, in-line with previous research by Hurd et al. (2017). It was interpreted that what mattered to patients was the day-to-day rapport with staff that was built up through positive social encounters had the potential to change, in-line Robbins (2016), although in the business sector. Managers were concerned that patient experience would wane due to care fragmentation.

There were differing views about what constituted the patients' best interests. Doctors felt that they fulfilled the patients' trust in them by offering the trial in the patients' best interest. It was uncertain whether the doctors' decision-making and the patients' choice amounted to the same thing. It was interpreted that when a patient 'choose' the trial that the doctor had already decided on, it more resembled assent, in-line with the 'passive trust' referred to by Giddens (1984). Nurses were concerned that the trial recommendation could affect their ability to build a trustworthy relationship in instances where they questioned the quality-of-life of the patient, although nurses came across as having lesser importance in gaining trust on the basis of best interest decision-making.

The uncertainty of the trial outcome impacted doctors' trust creation. One consultant explained that having an unbiased approach to the trial may not be possible, as doctors were relied upon to act in the patients' best interest, echoing Calnan and Rowe (2008), thereby questioning the collective MDT decision-making if it differed to the individual doctors' view. The doctors' view had the potential to influence the patients' consent, in-line with Jenkins and Fallowfield (2000). As was expressed many times previously (Fallowfield, 2000; Davis, 1960;

and Adamson, 1997), RCTs posed communication difficulties for physicians. Another doctor believed that the patient relationship would be negatively affected when patients became unhappy waiting for the trial to commence or a cohort to open. This delay caused doctors to commence a non-trial treatment constituting a deviation from the MDT best interest decision. Although deviations from MDT best interest decisions have been found, (Wood et al., 2007; Blazeby et al., 2005), physician bias was not mentioned previously as a reason for the deviation, which contributes to the literature enabling an improved understanding of MDT deviations. The nurse-patient trust relationship was affected due to trial uncertainty and randomisation. Although managers were not clinical, they were concerned if the nurses' views about the trial differed because it may influence the nurses' 'judgement' about the trial. Managers felt the maintenance of the on-going trusting relationship could be eroded where those administering the treatment don't believe in the trial as a best option, yet interestingly managers asserted that 'they (nurses) are unable to challenge it'.

External targets from above were repeatedly reported as causing pressure for the participants because of the drive to recruit patients to trials, impacting on practice. Nurses felt this pressure could undermine their trustworthiness and that recruitment needed to be balanced with the patients' best interest. Nurses were explicit in their views; and felt that this pressure could ethically contravene patient care if patients lacked understanding, subordinating their view of the patients' best interests, while their primary objective was to help patients. Financial pressure and career gain was another pressure that nurses felt impacted on doctors' clinical trial practice and was difficult to work with as it was implied as affecting patient relationships, possibly interpreted as an expense of the relational quality between care-givers and receivers' (Spence, 2012). The influence of targets chimes with professionalism that is 'imposed from above' which has become integral to practice (Evetts, 2011).

9.3 Facilitating patient autonomy

Doctors and research nurses spoke at length about patients' lack of trial knowledge and subsequently questioned the 'validity' of patients' consent. Professionals spoke about struggles to facilitate autonomy within minority groups mainly. While cancer as an illness was perceived as affecting the patient's retention of information, illness did not preclude consent necessarily although some participants questioned the validity of consent due to the patient's knowledge deficit.

Language was relayed by many professionals as problematic, although it was the translator difficulties (institutional services) that caused the problem, because the consent taken might not be 'adequate'. Some doctors questioned cancer patients' autonomous ability to decide because of patients' lack of trial knowledge and questioned if this was 'true' consent. However, doctors were emphatic that they did not use this issue as a means of not considering foreign language speaking patients; unlike the 'cherry picking' described in the Hussain-Gamble and Leese (2006) study. Some doctors in this study surmounted the problem even if it meant that the consent validity was lacking but did say that this caused a dilemma to preclude trial entry on this basis. Not all doctors felt this was a dilemma, interpreted as them accepting lesser patient understanding as consent. Nurses experienced the lack of validity as a result of patients' lack of compliance and lack of information retention, in keeping with van der Biessen et al. (2017). Another complicating factor in gaining consent from minority groups was family translation which the manager disapproved of (in accordance with local consent policy).

Research nurses spoke about the validity of patients' consent, particularly in relation to phase 1 clinical trial consent, referring to patient desperation and patients not wanting to decide for themselves, thereby giving up their autonomy. Nurses also experienced how patients over-estimated the trial benefit and not retaining the information akin to van der Biessen et al.

(2017), together with patients often feeling it was their only option; thereby influencing their consent as found with van Kleffins et al.(2004). Rarely did a patient seek a second opinion. It was not perceived that the doctor deciding on what was best for the patient interfered with patient voluntariness, except for the instances of perceived 'pushing'. It was a nurse who relayed a patient seeking them to decide on the trial. Previous theorists reported that patients wanted professionals to decide, but did not necessarily say nurses (Sinding et al., 2010; Madsen et al., 2007), all of which placed doubt on the facilitating true patient autonomy in the cancer setting even with the best facilitation.

Possible professional assumptions made were because of the patient's culture, perceived intelligence and level of education. The assumptions made caused some doctors and nurses to underestimate the patient's ability to consent or the patient's autonomy. The senior consultant vehemently disapproved of this type of patient judgment on the basis of patient ethnicity and socio-economic status. While it was intimated that judgement did take place, it was not explicitly spoken about. Although a research nurse spoke about judgement as a possibility with a patient who had learning disabilities where the patients consent was revoked by doctors. The patient's clear inability to understand could be interpreted as 'soft paternalism' indicated as justified in certain trial situations (Jansen and Wall, 2016).

There was a possibility of precluding patient autonomy on the grounds of family influences, although doctors often welcomed families in the decision-making process together with their means of social support, in-line with Knobf (2007) and Corrigan (2003) who applauded relational autonomy as a means of facilitating informed consent. It was the nurses and managers who felt uncomfortable about what they felt was family pressure on patients which research nurses believed failed to meet individual autonomy requirements and were perceived as a barrier to patient consent specific to the CCT setting, in keeping with theorists,

(Bell and Balneaves 2015; Hussain-Gamble and Leese, 2006). Interestingly, none of the participants explicitly suggested more training to assist them with these family and cultural issues.

9.4 Strengths and Limitations of the research

The methodological strengths and limitations were considered in relation to the phenomenological approach within the case-study setting where the insider researcher interpreted the experiences of the participants.

The case study

For the most part the phenomenological approach within a case study setting provided good access to the interprofessional group involved in obtaining patient consent situated within the boundaries of the Cancer Academic Group (CCT real-life practice setting). In-line with Polit and Beck (2012), the case enabled insight into how participants behaved and clarified concepts and was enlightening of other relationships, for instance how doctors welcomed the research nurses challenging their decisions.

However, in this case study two main limitations were identified that pertained to the research methods used and the generalisability of the study. Yin (2008) advocates using different sources of evidence, but this study mainly derived evidence from the interviews with participants and the reflective diary to interpret these experiences from different level professionals. On reflection, the use of observation as a data collection tool could have provided more rigor enabling more insight into the professional-patient interactions as it would have provided first-hand information, as opposed to professionals relaying how they experienced it. Yet, early on in the planning, I decided against observation, which could be seen as a limitation as observational data may have enhanced the generalisability. The reason

I decided against observation of a potentially contentious patient interaction was that it could prove difficult and may interfere with patient care and translators services were already struggled. Although there was an attempt to seek a pattern as case studies can do over time (Polit and Beck, 2012), I was only able to obtain one second interview due to the time constraints of the clinical staff.

Case study and phenomenological generalisability

Initially, the Integrated Research Application System (IRAS) did not gleam that the study would provide generalisable findings. To overcome this challenge to generalisability, it was recommended that the study ought to go through clinical effectiveness, which in turn approved the study commencement along with the RHUL approval with no ethical concerns. My supervisor recognised the knowledge sought could contribute to clinical practice and the sociology of informed consent, and I have illustrated how the case study could formulate a theory for practice.

However, the generalisability of the case study could be difficult to defend because the findings reflected a particular situation or culture / way of working within this centre. For instance, one consultant explained that they did not involve the research team until much later and after the patient had consented. This way of working even differed from one cancer sub-speciality to another, never mention the potential for different ways of working in another CCT centre, plus as one research nurse explained the nurse seemed to align her practice with the residing physician. These examples show the difficulty in making generalisations on the basis of human interactions and unpredictability. Moreover, the thrust of the research was to voice clinical practice and advance it which held meaning for me as a practitioner and researcher. I wanted to understand how each professional group viewed their own role and how they interacted with each other within the social context of the case study. One way to look at it is

that as Thomas (2011) explains, abduction is possible which he explained as deriving conclusions from day-to-day generalisations as opposed to induction described as conclusions from specific generalisations. The case study none-the-less sought the practice experience informing the practical knowledge. 'It is in practice that phronesis (as Aristotle found) is developed and in practice that it comes into play' (Thomas, 2011, p. 214). The themes held specific meaning within the diverse CCT setting but could be generalisable in a similar cancer diverse setting, or within the general trial setting.

The limitations of phenomenology

From the outset, I felt that seeking the 'lived-experience' in the natural practice case study setting where the researcher was also a practitioner would make sense of the consent practices. However, I was mostly reliant on what the participants said when essentially it could be perceived as their interpretation of events and not the reality as ethnography would more likely reveal.

There was a deliberate decision to undertake interpretive phenomenology. This choice accounted for suppositions, assumptions, knowledge and experiences within the research (reflective) diary by exercising reflexivity in keeping with Heidegger (1889-1976) who emphasises that we cannot stand outside our understanding. Although descriptive phenomenology developed by Husserl (1859-1938) may limit the meaning of the data because it brackets the practitioner's interpretation and reflection, its use could have provided more objectivity of the data and would have been less of an emotional conflict for the insider research practitioner as discussed below. However, having considered the researcher's role as a practitioner (research nurse) and a manager it was very difficult to bracket out the knowledge and personal beliefs as is required in a solely reductive approach (Streubert and Carpenter, 2011), which is the essential difference with interpreting experiences.

The limitations of differing role identities

The familiarity I had with the group whom I interviewed made objectivity difficult as my differing role identities were at loggerheads as outlined in the research methods chapter. The roles were the research nurse's role (clinical duty), the manager's role and the researcher's role, although my clinical duty to the patients took priority.

To enable reflexivity, I had initially intended to use the diary to assist me with a complete cycle of reflection thereby interpreting each theme identified, as advised by van Manen (1997). I quickly realised that complete sense could not be made of these experiences in real time because reflexivity carried on for the entire study including the write up, and reflection-on-action (Schon, 1987) was more appropriate and fruitful. Secondly, there were differences between what Argyris and Schon (1995) termed the espoused theory (world view of behaviour as guided by values and beliefs) and theory-in-practice (behaviours driven by values and beliefs in reality) for both myself and my participants. Suffice to say that there were boundaries because of my practitioner researcher role that limited my actions although my beliefs of what ought to be as a nurse or manager sometimes differed.

The nurse / clinical role

As an experienced cancer nurse my underlying assumption that doctors may not recognise the value of nurses in obtaining informed consent was uppermost and therefore I did not expect professions to challenge the traditional standpoint. I had seen how hard it is for nurses to challenge medical decision-making to ensure that the patient was given a voice and sufficient time to consent to high risk cancer treatments. I had lived the moral dilemma of caring for vulnerable patients, wanting to protect them, when faced with treatment decisions that I felt they may not be suitable for, posing a challenge to the patients' best interest. I questioned how

managers could improve practice or if it mattered to them. These experiences possibly over-elevated my empathy towards nurses because of the struggles they faced.

Furthermore, my suppositions as derived from experiences with patients were a strength because they caused me to have a valid viewpoint based on contemporary practice. I believed that obtaining informed consent in reality cannot rely on patient autonomy to fulfil the ethical principles of consent in the instance of many diverse cancer patients. I felt that the policy did not appropriately reflect practice for this patient group and could be misinterpreted. I had lived the journey with patients in gaining their trust, which I felt was more meaningful in gaining consent validity than autonomous consent.

The manager's role

The research practitioner's role as a manager proved initially desirable in making the research application locally because of the possibly of bringing patient benefit and revenue capture for the Department due to increased uptake of patient consent. However, the study was intended to highlight consent issues through the experiences of professions as opposed to any promise of improved recruitment or financial gain. Another strength in my managers' role was that I perceived that staff would communicate issues to me. For instance, many nurses spoke of patients being 'pushed' into the trial, or not getting enough time, or their challenges not being heard, but I was bound by confidentiality not to disclose unless a concern was raised.

The researcher role

One of my main strengths was the degree of collegial trust that the participants had in me as a clinician to begin with and as a fellow colleague whom they confided in. As an insider researcher, I was most flexible in the planning of interviews and moving them at short notice while factoring into the researcher's own job at the same time. The usefulness of the diary and

reflection only really came into its own when the thematic analysis of the interviews was taking place because of the annotations inserted in the margins indicating direct interpretations of the contextual reality experienced by the researcher as a practitioner. For example, when nurses expressed unhappiness about the persuasive language used and how they could not challenge decisions on the grounds of patient unsuitability, I was able to confirm my own assumptions by these recurrences, thereby also validating the themes.

One of the limitations of the study was that the research was time dependent on the clinical professionals' availability which had a particular impact on the recruitment of medical participants, although a sufficient number were very willing to participate. It took me by surprise that doctors were interested in taking part regardless of their lesser time availability as they were essential to the findings.

Insider researcher sampling bias by purposefully selecting participants who would provide experiences that answered my questions in a way that met with my assumptions is defended. The snowballing effect counterbalanced this from occurring, together with the practice of research ethics, for example, member checking of the data and frequent reviews by my supervisor. Furthermore, I firmly held back my views, and only encouraged in the form of probing. My experience of counselling training was most beneficial in this regard. I was aware of the possibility that interviewees might communicate practice that misaligned with policies. Furthermore, the interview could be and was used as a means of venting their concerns which the purpose of the research was not intended to resolve. Within the ethical considerations I have shown ways to best manage this constraint by deliberately not interviewing line managed staff and by offering an impartial staff support facility.

Another limitation of the study was that no clinical nurse specialists were interviewed although their input to MDT decision-making was spoken about at length by doctors. It is

uncertain why CNSs did not participate, although they may have not perceived themselves as part of the research team but their practice outside of the research team could cause fragmentation of care.

9.5 Implications for practice and future research

This study has added value to the CCT practice of obtaining informed consent by challenging traditional practice. The study emphasises that informed consent is an interprofessional practice. Within this section, recommendations will be provided for incorporating this interprofessional view into CCT practice, as well as for future research. These recommendations will be aligned to the main findings of the study, thereby addressing the original research purpose and questions.

9.5.1 Multi-disciplinary decision-making

It appears particularly from the accounts of senior doctors and nurse managers that there was a definite responsibility for Research or CNS nurses to be involved or 'challenge' MDT patient decisions, thereby challenging what often is purely medical decision-making. This is a change in culture for the interprofessional team, in terms of how they involve themselves or are accepted by other professionals. Senior doctors had experienced the relational value of nurses with patients due to their (doctors') lack of clinic time. The reason why nurses were valued was due to their relationships with patients which positioned them well to express the patient preferences and provide a more accurate patient suitability assessment which avoided 'pushing' an unsuitable patient to consent to the trial recommendation. Upcoming doctors focused mainly on the interprofessional contribution to patient safety as opposed to nurses' value within decision-making. However, in practice nurses struggled to voice challenges to the MDT decisions due to their fear of not being heard or due to their lack of CCT knowledge. It

is questionable how much support managers could or did give to the nurses who felt this way. It could be possible for managers' to improve the support of nursing involvement in the earlier suitability assessment and within the MDT, which I found myself more responsible for encouraging in my managerial role, thereby potentially enhancing or challenging medical decisions. While the Improving Outcomes (2011) mandated multi-disciplinary involvement in MDT decision-making, still the interprofessional presence is lacking. As physician bias (based on individual patient suitability assessment) could be a reason for MDT decision changes, so too can the interprofessional suitability assessment be reason for MDT challenge as well as eliciting suitable trial patients.

9.5.1.1 Recommendation for MDT practice

- The standard operating procedure (Sop) for MDT practice should be made available to the MDT members, showing the alignment with Improving Outcomes (2011). Within the Sop; it is suggested that a directive is issued/revised by clinical managers to allocate nursing time for the mandatory involvement of CNSs and Research nurses in the MDT decision-making.
- The mandatory interprofessional involvement should be supported by clinical managers (alternating their attendance with other clinical leads) wherein their visibly demonstrates support by their contribution to MDT decision-making, essentially 'walking the walk'.
- Research and CNS nurses or other professionals ought to be encouraged to present patient cases (and patient preferences if known) wherein they will have an opportunity to highlight patient suitability for the suggested trial.

- For patients who are presented as possible candidates for a trial, nursing suitability assessment should be undertaken first before the patient consent discussion, especially before the time of signing of the consent form.
- Interprofessional MDT attendance should be monitored by role checking to meet the percentage requirement and for auditing target attendance purposes.

9.5.2 The consent discussion with patients

It was identified that often research nurses were not involved in patient care until after patients had signed a consent to the CCT, which both they and many consultants felt was not soon enough in the process of informed consent. The main reason why nurses seeing the patient earlier in the process was important was that nurses were depicted as essential to the process of information-giving whether at the time of or after consent by clarifying and checking if the information given was understood. This role (responsibility) of information-giving was not only considered part of the nurses' role, but was considered by senior doctors and managers as essential to 'good' informed consent. Yet, nurses themselves did not feel they were responsible for obtaining consent, but were upset if they were excluded from their information-giving/checking role.

9.5.2.1 Recommendation for obtaining consent

- Managers ensure that patients are seen by nursing staff prior to or within their consent to CCT discussion as part of the Sop for undertaking consent. Their role should be defined as an information-giver and an information-checker who are encouraged to highlight lack of patient understanding or misinterpretation of the trial.

- Ensuring this interprofessional inclusion should encourage and emphasise the nurses' role as a patient advocate highlighting their responsibility for 'Prioritising People' in accordance with the NMC Code of practice (2008).

9.5.2.2 Research recommendation for interprofessional practice

- A qualitative study ascertaining the quality of patient consent that accounts for earlier nurse involvement. This would be both a patient and staff facing study. The aims of the study could be fourfold; to find out whether patients understood the purpose of the trial, whether nurses felt patient preferences were included in the trial decision, whether the uptake of CCTs has increased, and whether the attrition from the CCTs has decreased.

Both these practice recommendations should address how the undertaking of interprofessional responsibility as shaped by time can be enhanced. Nurses challenging or contributing to decision-making together with providing and conveying essential suitability checking information could be perceived as a challenge to the traditional medical standpoint of responsibility for informed consent in CCTs. Most nurses felt that they did not hold the responsibility for consent. It is likely that the success of these recommendations may rely on or bring about a cultural change as a result of how nurses exercise their professional confidence, identity and acknowledged role.

9.5.3 Trust underlies obtaining informed consent

To enable informed consent to CCTs, the theory for gaining consent was clearly shown as an interprofessional combination of doctors gaining of the 'initial' patients' trust, and the nurses / frontline staffs' maintenance of that trust. Both appeared to hold equal value. Competency based trust relied on relational trust. These findings are impactful for CCT practice and

necessary to communicate to the professions. At each junction the availability or possibility of trust could be unattainable or eroded because of communicative practices for example disrespect, targets, mismanagement of trial uncertainty or team transition. The NCPES seeks to find out if patients have confidence and trust in doctors and ward nurses by asking only two questions, but does not seek to find out how trust is gained or eroded.

9.5.3.1 Recommendation for trust

- Managers (nurse leaders) should ensure that during the handover of patient care staff are required to name an appropriate professional to whom the care is referred. The reason for the handover of care is explained while reassuring the patient that they will not break contact but the research nominated professional is more knowledgeable about the trial or the nurse specialist for their on-going care.
- The National Care Patient Survey (generated by NHS England and NHS Improvement) could ask more questions about how trust can be gained, maintained or eroded. This would allow for these answers to be responded to as part of the already in existence local patient experience action plan.
- Further trust related recommendations are found under the education sub-heading.

9.5.3.2 Research recommendation for trust

An ethnographic study may be a suitable research approach to ascertain the availability and decline of patient trust. The aim of this study would be to ascertain the behavioural traits of CCT patients by the observation of trustful behaviour and to ascertain how these traits can be mapped to patients' willingness to provide informed consent to CCTs. Running alongside the patient observation could be observation of the associated interprofessional behaviour/s that correspond such patient trustful behaviour.

9.5.4 Consent Policy

The policy for consent taking is focused on actualising individual patient autonomy. In many instances it was difficult to achieve complete patient autonomy due to lack of patient willingness to make decisions or their mis-understanding of the trial purpose for example in 'desperate' phase 1 trial scenarios. Also, individual autonomy may not be always achievable for patients from diverse groups who are non-English speaking or who are illiterate. Nurses and managers expressed discontent or discouraged respectively a practice that involves the family members in making consent decisions. A minority of physicians appeared to challenge the 'rigidity' of consent policy by emphasising the need to directly involve the family of ethnic minority groups in informed consent, thereby formulating a need for policy allowances in these instances.

9.5.4.1 Recommendation for consent policy

- The roll out of the policy should be clearer by adding a concluding sentence that does allow for the inclusion of the family in the consent decision to accompany the impartial witness (translator).
- The pitfalls in the way the policy is interpreted should be included within the GCP training or local training on consent taking, for example to make clear that the family involvement can support and be involved in the family consent decision.
- The provision of institutional improvements to support language barriers by ensuring that translators are more readily available at the time of information delivery and consent taking when the family member is present.

9.5.5 Consent training and education

Although generic consent taking courses are taken online as part of Good Clinical Practice, there is a need to enhance professional communication skills or prepare staff for the needs of the diverse CCT patient group. An education session could be delivered locally to address the following items.

- The correct interpretation of the newly revised Sop for consent taking by demonstrating examples of poor interpretation. This could be delivered using role-play scenarios.
- Highlighting of the 4 ethical domains to be met within the consent discussions with patients in accordance with Brown et al. (2004).
- Training that incorporates a revision of the difficulties with patient understanding of different clinical trial phases by giving examples.
- The use of an anonymised patient case study to demonstrate the suitability and eligibility criteria.
- Training (to include ward staff) that includes information about how to respect patients generally and cultural practices specific to particular ethnic groups engendering trust for example appropriate body language.
- More readily available trial information for ward staff allaying misinterpretations and fear of clinical trials.
- Communication training via role-play scenarios led by an education facilitator requiring informal peer review of role-played professional-patient interaction/s.
- Further interprofessional research is encouraged within the Department and that IRAS welcomes qualitative research studies.

Adopting these managerial recommendations may be challenging due to additional work for clinical managers and the reluctance to make cultural changes. However, the first step is to set these recommendations out to the clinical effectiveness team and research gatekeepers who have been and can provide practical support to clinical managers and professionals aiming to improve CCT practice by assisting with putting interventions, audit or study proposals in place. It is intended that the findings of this study will be communicated via a series of papers in relevant journals for example, Clinical Trials or The Sociology of Health & Medicine. This will facilitate the adoption of the findings in this study for consent practice improvements, advanced practice or Masters courses in the future. Such publications would also support qualitative research attaining greater recognition within the Integrated Research Application System.

9.6 Conclusion

The way contemporary informed consent in the CCT setting is obtained has challenged the medical standpoint, and elevated the need for interprofessional responsibility. The boundaries between the medical and nursing profession in relation to obtaining and maintaining informed consent to CCTs are defined for their contribution, although roles do overlap. This research has shown the importance of promoting professional values, respecting interprofessional communication as opposed to unchallenged prevalence of the hierarchical dominance (Warelow, 1996). The social process of consent has a function in achieving the necessary relationship between professionals and diverse cancer patients to break down the known communication challenges enabling and improving informed consent to CCTs. It is hoped that this thesis not only contributes to the sociology of the professions but can also impact improvements in interprofessional communication and practice needed to enhance informed consent to CCTs.

The possibility of valid consent if relied solely on patient autonomy is seen to be subordinated by the relational component of informed consent wherein patient trust in professionals above all else obtained informed consent to CCTs. I leave you with the words of Stephen R Covey (1932-2012):

> "Trust is the glue of life. It's the most essential ingredient in effective communication. It's the foundational principle that holds all relationships."

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Appendices

Appendix C4.1 Cumulative Literature Search History

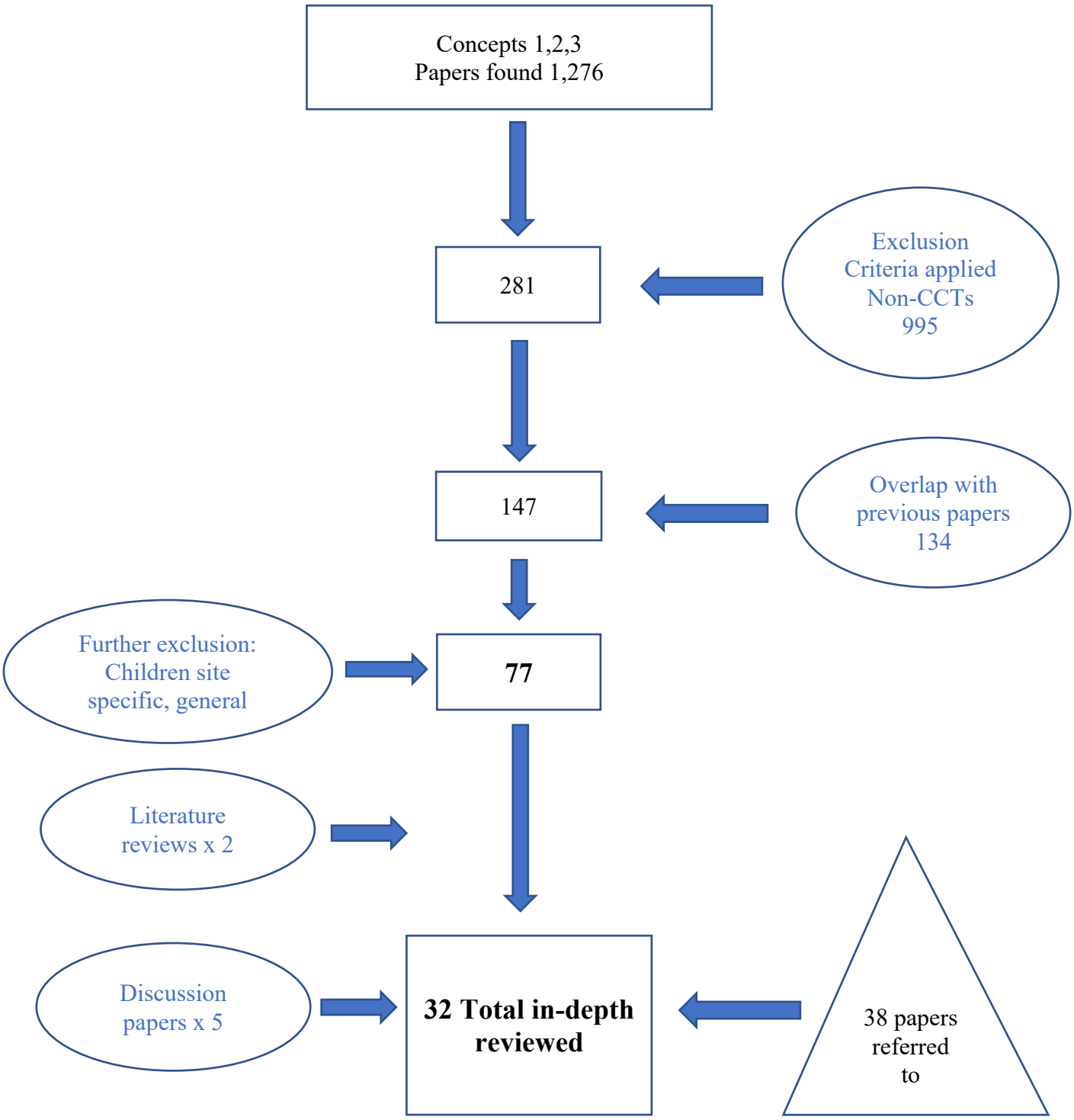
Limits applied (2003- 2018; refined to last 3-5 years if yield too large, peer reviewed, adults, English speaking, exclude meta-analysis, include literature reviews & discussion papers if relevant)

Search sequences x 4 data bases	Possible papers found (plus non-CCT if broader concepts)	Excluded (not specific enough)	Overlaps from previous searches	**Final papers selected for initial review (new)**
S1	24	9	0	**15**
S2	16	12	0	**4**
S3	29	17	5	**12**
S4	29	0	20	**9**
S5,6,7	23	13	7	**3**
S8	22	8	7	**7**
S9	14	11	3	**0**
S10	0	0	0	**0**
S11	100	67	1	**32**
S12	17	15	0	**2**
S13	34	30	1	**3**
S14	52	49	0	**4**
S15	47	44	1	**2**
S16	88	73	3	**12**
S17	279	274	1	**4**
S18	57	53	3	**1**
S19	46	28	11	**7**
S20	42	33	6	**3**
S21	81	74	7	**5**
S22	2	0	2	**0**
S23	81	47	31	**2**
S24	27	20	3	**4**
S25	51	35	10	**6**
S26	1	0	1	**0**
S27	48	35	6	**7**
S28	3	0	2	**1**
S29	12	8	2	**2**

Final selected for review	Further exclusion	**Papers selected**	Studies referred to	Literature reviews included	Discussions included	In-depth studies reviewed
147	70	**77**	38	2	5	32

Appendix C4.2 Condensed Synthesis of Literature

Process of Literature synthesis



Appendix C4.3 Synthesis of Literature- (Using adapted CASP tool)

(Focus on interprofessional qualitative)

Nursing research / Interprofessional/ Nursing practice (From search history & referenced) **x 24**

Author & Journal	**Design**	**Aim & Findings (highlighted relevant themes)**	**Limitations**	**Strengths**
Kao et al. (2017) *European Journal of cancer care (EJCC)* Nursing review **Search C1**	Varied- Qualitative & quantitative	***Literature review-*** Communication strategies for informed consent (IC) to CCTs (Good assessment of patient knowledge & understanding; showed post communication skills- no more knowledge, but more time for decisions given, & more patient satisfaction CCTs). Time was an important component in reassessing patient understanding of information.	Few studies that looked at qualitative data to evidence success of verbal communication strategies-content or modes of communication Nursing – invalid tools for measuring	Good filtering system Filtering driven by patient understanding outcomes
Beadle et al. (2011) *EJCC* Researchers - Academic medical, nursing and math's. **Search C1- Ref study & C3**	Surveys to 446 members of Oncology society- 43% participation. SPSS- exploratory factor or related themes.	**To ascertain the perceptions of oncology nurse's perceptions of CCT conduct-** (physicians' conduct). Predominance of patient hope and unrealistic expectations & lack of understanding of trial Willingness of patients to participate even if limited efficacy Consent mostly misunderstood, freely consented Care of trial patients-better as supported- not assessed	Perspectives of nurses only examined Did not seek their own experiences of their practice	Good-Nurses who were mainly involved with trial patients Themes identified that question consent communication Limitation – poor participation

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Shannon-Dorcy et al. (2011) *Cancer Nursing* Researchers- nurses, US **Search C1-ref study**	Qualitative- Semi-structured interviews-25 patients/ 20 carers- intervals before, 80 days post, 365 days post	**To examine how patients and carers decide to participate in stem cell transplant research studies** / treatment options. Majority decided to participate before consent consultation. Pts felt no other option, followed Doc's recommendation, not wanted to hear all information, Altruism x 4 as reason for choice.	Nurses only discernment Only those who decided to participate were discussed	Nurses identified key themes- concerns in patient consent- questionable autonomy, cognitive uncertainty, underestimated emotional content, usefulness of paperwork.
Burke et al. (2014) *BMC Medical Ethics* Anthropologist **Search M1**	Qualitative- Observation in clinics, and semi-structured interviews with patients (37) & providers (15).	**To provide ethnographic insight into the ways in which research is discussed and related to standard treatment.** Communication struggles with initial presentation of RCT, patient not remembering, Initial purpose to ascertain if patient interested, no % outcomes given- likened to assenting. Pt showing therapeutic misconceptions. Immediate patient concerns and questions re doses pushed aside. Doctors –lack of information clarity. Role of navigator to give more information and act as **advocate**- competing ethics between roles.	Participants were paid Do not know for sure if navigators were nurses. Done in specific clinic-? if generalizable.	Qualitative themes identified Different roles identified (unclear how many nurses) Objective view from outside the professions. Strength in the quality of observation. Pts from all demographics – included poor English speaking.

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Catania (2012) *Journal of Oncology Nursing* Nursing research, Italy **Search C2**	Quantitative- Questionnaires- assessing activities: frequency and importance of role components. Analysed by SPSS, Likert, Chi-square.	**To assess the role of the clinical trial nurse- 30 participants.** Role highly valued by physicians and team. IC- thought to be most important, but 3rd most frequent activity Roles included 3 **advocacy** components -balance of rights, study quality, Nurses gave appropriate language, verifying information, oversaw form signing.	Given options to choose from Not a free narrative to explain their experiences	Gave CTN role clarity by frequency of tasks Gave importance as per nurses' view Approved data collection tool (CTNQ) Referred to Ocker & Plank (2000) -similar findings- role advancing to include organisational, clinical & ethical
Davis et al. (2002) *Journal of Law, Medicine and Ethics* Medical Faculty Grant- mixed researchers, US **Search C2- ref study**	Qualitative- 3 vignette focus group interviews: 45 subjects- 68% nursing, none medical Thematic analysis	**To assess the challenges of protecting subjects** (From the perspective of the CTN) Study coordinator encompasses several roles , centrality in relationships, complexity of relationships, role expectations and conflict of role Key **advocacy** role components identified: Patient advocate- for needs, interests & welfare Subject advocate- to enrol, understanding, risk & safety, lawyer-like- protecting rights Study advocate- research goals, clean data, career less, police **Conflicts**- re caring & detachment, hope v realism, resonate with duality of physician, less trained	Would they have been less outspoken if medical professionals included	Sought the nursing perspective of consent to CCTs Clarity on nursing role Advocacy prioritised Conflicts within role Objectivity of research analysis

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Mori & Mullen (2007) *Research Practitioner* Nursing research, US **Search C2- ref study**	Quantitative- Using CTNQ to quantify. Themes derived from quantitative date and analysis 109 survey participants	**To define the role of the CRN (research nurse)** Most likely to be involved in the SIV and **not in** the developmental stage and in IC and recruitment CTN- assessed IC- mostly verification, patient satisfaction, goal and purpose, continued consent, Act as **advocate**-ensuring IC Recruitment- not a view, except communicate information, barrier factors, IC- did use appropriate language, explained, helped decision making (DM).	Given options as opposed to relaying narrative No assessment of trust Poor for assessing social dimension of the relationship Potentially not generalizable	Recognised tool used to assess Nursing role clarity- for themselves. Self- affirming
Wilkes et al. (2012) *Nurse Research (Australia)* Nursing research **Search C2- ref study**	Quantitative- 67 CTNs surveyed (cross sectional). Analysis via SPSS CTNQ Themes derived from quantitative date and analysis used	**To ascertain the role of the CTN** Showed complex role – due to the combination of contractual and accountability arrangements Encounter practical and ethical issues Frequency and importance of role assessed Involved in **IC- higher** frequency, 2nd- implementation, 3rd –data, 4th- recruitment Importance- 1st IC, 2nd- Data, 3rd- Investigational procedure, 4th- Protocol planning Professional issues- undervalued, lacked education and confidence	Given options as opposed to relaying narrative No assessment of trust Poor for assessing social dimension of the relationship	Tool used was effective Correlation between frequency and importance of role in IC

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Ehrenberger & Lillington (2004) *Oncology Nursing Forum* Nursing research, US **Search C2- ref study**	Qualitative- Testing of CTNQ (Clinical Trials Nursing Questionnaire) n=40 Focus group assessment	**Reliability of tool verified** Assessed by focus groups and expert judges Met the desired outcome Has responsibility to ethics Recruitment in approaching patients and information giving	Small group	Significant for nursing role in research Significant for showing nursing attributes, responsibilities
Biedrzychi (2011) *Oncology Nursing Forum* Patient research done by nurses, US **Search C2- ref study**	Quantitative- Cross sectional descriptive model for 197 pts Themes identified	**To describe factors and outcomes related to the decision-making process regarding participation in CCTS.** SDM (shared decision making was most frequently preferred) v patient autonomy-83% v 17%. Examining disease and socio-economic factors Multiple other factors assessed that influence. Hope & Trust were predictors; more trust in healthcare system than doctors Decisional conflict reported after the decision Suggested- Shared family DM is preferred	Validity of the tool may be questionable Assessed after the decision to enter trial- may have skewed data	New model not used before so innovative Good key factors in DM identified Consideration for socio-economic factors in DM Leaning towards the social dimension of consent
Spilsbury et al. (2008) *Nurse Research* UK **Search C2- ref study**	Qualitative – NVIVO Focus group, N=9	**Explores the potential contribution of CRNs to clinical trials.** Showed role in transition- lack of confidence, role conflict between clinical and research role, challenges for nursing staff with patient compliance- gaining consent but not cooperation, wide range of skills and knowledge identified, RCT issues and self-motivation.	**Not focused on CCTs-** general Clinical trial focus Small study of 9 Focus groups could have impeded flow of conversation	Still relevance for CCTs Lack of confidence in like in Wilkes study in Australia Similar to Davis; Mori & Mullen; Catania for conflict and advocacy respectively

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Easter et al. (2008) *Sociology of Health & Illness* USA Analysed by lawyers, philosophers, physicians, sociologists **Search -Psych-info 2**	Mixed to find themes Quantified the thematic findings- helpful for thematic priorities Interviews closed and open- ended Coded and electronically divided into codes- themes Telephone interviews	**To find out a normative model of care in research- what physicians perceive of their research role, plus study coordinators (nurses), and patients.**1/2 pts saw Docs and SC as taking care of them, ½ Docs said they were conducting research, 1/3 SC said they were conducting research. Pts considered research care differently, although as care, Research activities considered as care- i.e., monitoring side effects, Docs said care of research pts involved 'two hats', Docs made **the distinction,** SC appeared uncomfortable with just the research role. Many pts thought research happened elsewhere. Care described in positive terms; research in negative terms, SC said different to Doc as pts more comfortable- **closer relationship**, Research care was improvement on standard care.	Not analysed by nurses Half the studies were cancer (9) Small size (37) Possible leading questions re care and title of study Telephone interviews curtailing quality	Reasonably objective analysis, although doctors assessing own practice Takes account of study coordinators Two hats identified-Docs Nurses as caring role even if researchers

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Loh et al. (2002) *Ethical Communication in clinical trials* Australian-Dept of Medicine & Psychology **Search M8**	Qualitative- 4 focus groups, comprising data managers, 14 nurses Thematic analysis	**To ascertain views of data managers (sometimes nurses) of the nature and challenges of their role and differences between physician's role.** 3 roles identified: **Information provision-**clarification of questions post consultation, RCT explained as level of detail not provided by doctor i.e.: logistics and practicalities, but unable to provide some info, **Gave quality assurance-**ensured true IC, verifying understanding, non-coercive, rights confirmed, gave balanced view, comfortable speaking to pts, felt IC still medical prerogative, pts valued on-going nursing support & QL discussions, inconsistent messages from team, **Negotiated time-**to discuss difficult patient issues, needs, cultural, language, misconceptions, ethical concerns if trial was disadvantage to pt.	No doctors' views on their perception of nurses' roles	Views of nurses heard Possibility of patient autonomy reduced, hence nurse role Highlighted need for more education and training for research Showed Docs limited time

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Kass et al. (2009) *J of Empirical Research on Human Research Ethics* Institute of Bioethics & Behavioural Sciences, US **Search C3**	Mixed- 12 audiotapes of patient oncologists with 84 pts agreed to be taped. 30 pts were offered ph 1 and 35 ph 2. Patient surveys 45- 60mins structured surveys on purpose & benefits of CTs. Pts were re-contacted after 1-2	**To find out what patients understand from oncologists' clinical trial discussions.** Options discussion- almost all oncologists stated **safety** and dosing re phase 1. Then quickly moved to discussion about the **therapeutic** intent using 'therapy' and 'medicine', one of the efficacy for the research purpose, or another treatment option Ph 2- more on the efficacy discussed Survey-54% said purpose was to see if trial worked / benefits- more with ph 2, 11% to cure. Ph 2 more likely to mention dosing. Only 12% said purpose was safely & dosing from both. In-depth interviews- 18/27 described **purpose**. Most joined because good chance of survival. Docs **re-enforced** the therapeutic intent- ph 1 'might work for you' Decision 68% planned to join 58% said trial had promise	Audiotaped discussions may have inhibited doctors' speaking Not qualitatively explored with doctors Only done at 2 centres – query about generalisability Weakness? In-depth interviews-one week after the survey	Key themes identified from discussions- much hope given in early phase trials, mixed messages about trial benefit May lead to pts therapeutic Misconception Good data management- Coding by 2 staff members Random selection of tapes Interviews coded & entered into electronic system
Ulrick et al. (2012) *Contemporary clinical trials* Bioethics, health economics, health sciences & nursing, US **Search C3**	Quantitative- Questionnaires 455 primary care NPs, 53% response, 173 unusable, Attitudes measured on Likert scale assessing if comfortable discussing CCTs, Ethical 8 points on a scale, high risk, RCTs, Beliefs,	**Nurse practitioners' attitudes and beliefs towards CCTs, and if they would recommend to a patient.** 2/3 in favour of recommending, 1/3 time was an issue, ½ wd prefer themselves on trial, Issues with RCTs, 50% comfortable discussing, 2/3 wanted to maintain a relationship- agreed would leave to doctor, ½ felt would get better care on trial, 50% ethical concerns over RCTs- high risk and guinea pig worry.	Large lack of response NP do refer to tertiary centres Query if applicable to different geographical locations Is the discomfort more related to cancer trials?	Highlighted important themes - 50% not comfortable discussing ¼ were positive re trials Unlikely to recommend Ethical concerns Leave to doctors

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Holmes et al. (2012) *The American Journal of Surgery* Nursing research, **US** **Search C4**	Quantitative- Did not explore the experience of IC Amalgamation of 2 roles- no data on same from UK perspective	**To evaluate the oncology nurse navigator role in terms of CCTs recruitment & cost effectiveness** 39% increase in black breast ca recruited patients of the 86% that were eligible	Only cost / role analysis	Showed nurses role in eligibility, screening of pts, and nurses' definite involvement in IC Good focus on the cultural deficits in recruitment- benefits of community navigation
Hussain-Gamble et al. (2004) Health Policy Health policy and public health, UK **Search Psychinfo 4**	Qualitative- In depth interviews with 60 South Asian women; topics were- terminology, DM, WTP, recruitment and trial involvement 25 HCPs (mix of docs and nurses, Coordinators, academics); topics- barriers to trials, the way forward. Thematic analysis	**Exploration of Asian population view of research to include the professionals view of the population** Pts showed no antipathy towards trials Motivation was altruism/helping community Tension between personal responsibility and to community / worried about who would look after family Deterrent- testing drugs and long -term side effects, Not being approached as a concern, not being referred, felt ethnicity of doc mattered HCPs- more than ½ said language was a problem- causing extra burden on staff, interpreters- not readily available and can distort information, lack of time, poor organisational support, Age-worse language problem, young people not always available, felt at risk signing, often declined. HCPs shocked if these pts were excluded, thought 'passive' lack of inclusion- due to institutional racism/problems, pts were 'cherry-picked'. Lack of familiarity & cultural insensitivity- stereotyping i.e., poor time keeping, women lack of interest, mistrust, that doc looked down on patients, women were not intelligent, Muslim women would not seek care.	These people had not taken part in a trial Hypothetical evidence	Non-English speaking patients included –context specific Both nurses and docs interviewed HCPs –gate keeping highlighted and stereotyping these women Language as huge problem Highlighted value of ethnic minority doctors Mistrust highlighted in this population

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Corrigan (2003) *Sociology of Health and Illness* Part of PhD student thesis, UK **Search Psychinfo 4**	Qualitative- Participants as in aims and semi-structured interviews. Thematic analysis.	**To analyse the social process involved when ph 1 patients and healthy volunteers consent to clinical trials.** She examines the process of consent, from perspectives of patients, volunteers (26), nurses and doctors (7). Not a 'one-time event' Main focus- **events leading up** to consent, reasons to participate, factors influencing, benefits, risks, understanding of trial. Informed subjects- unclear re RCTs and misunderstood, struggled with complexity of information. Pts understanding based on previous experiences. Generalisation of side-effects were unclear- 'smaller number' Terminology used was important- this one uses 'study'- loaded with **positive connotations.** Few were concerned re side-effects / mainly subjects did not express a great deal of concern re side-effects. Subjects tended to believe that drugs tested were safe- possible **therapeautic misconceptions implied**. Subjects **showed trust in** doctors, nurses and the authorities- felt reassured drugs were tested on animals. Pt used term guinea pig- illustrates he was object of research. Choice- pts felt they were not coerced, but unclear about an alternative. Consented because **wanted better treatment, and willingness** to please the doctor. Doctors- felt mutual participation, equipoise is satisfied by genuine uncertainty. Pt when offered is looking for advice & reassurance. Volunteers had no prior expectations. **Pts asked for more time.**	Limits -Pts may have been influenced to join because in the doctor's clinic. Small sample. Mixed participants.	Key parts of the lead up to consent examined Not one- time event Major communication shortcomings identified- positive statements leading to lack of understanding and therapeutic misconception Trust of patients Doctors felt mutual participation- researcher illustrates differently Emphasises verbal communication strategies and shortcomings

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Sankar (2004) *Medical anthropology quarterly* Researcher-anthropologist Undertaken by bioethics dept, **Search Science Direct 1** **US**	Qualitative- 16 informed consent discussions observed. Transcribed and coded using descriptive coding.	**To argue that the one factor overlooked in the theoretical paradigm that guides the practice analysis of IC- where the paradigm poses an ideal model of communication falls to include the social dimension.** Overview of IC-mostly 100%, 81% no disclosure of alternatives, 6% no statement about withdrawal or confidentiality. **Time was not a problem.** **Framing identified-** over elevating the benefits, confused purpose of the trial, **positive statements,** confused therapy & experimental part, dosing schedule not clear, risks & benefits, FDA detracted from toxicity arm.	Small amount of participants Only phase 1 observed Unclear arm of study Gave % for the statements observed (gives prioritisation of the themes identified)	Coded, recorded and checked 3 times Qualitative statement explained to discern the social meaning of the content Good data for phase 1 trial communication issues Refers in discussion to transmission mode of communication (Shannon & Weaver, 1949)- sender/receiver which fails to include the social dimension
Cox (2002) *Clinical Effectiveness in Nursing* Search C1- referred to study, UK **Nursing Research**	Qualitative- 55 patients assessed Via constant comparison of semi-structured interviews	**To identify the psychosocial impact of participating in early anti-cancer drug trials** Patients are 'desperate'- (phase 1 and 2) the offer of a trial was seen as the 'turning point' Reasons for participating was that the offer was in their best interests Nearly 80% of pts wanted the HCP to decide/ DM was passive; 20% were active and collaborative inc families Deciding- 'found it lonely', active role- do not welcome responsibility Could weigh up Influenced by initial trial presentation in positive terms ('study' not 'trial') Autonomy 'over-ridden' by positive approach	Seeks the patient experience as opposed to the professionals Gave % of themes identified- giving priority to consent problems	Early phase consent issues highlighted Recommendations that neutral person presents the trial Pts interviewed more than once (pre- and post-recruitment) Insightful of pts perspectives Language used highlighted for its influence Could assess the communication of Docs and Nurses via pts perspective

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Tomlin et al. (2012) **USA** *Health Expectations* Social and community medicine- nurse/sociology researchers, UK **Search Psycho info 14**	Qualitative- Semi-structured interviews / in-depth, audio recording of appointments, thematic analysis, Topics were rationale for trial, views on the arms, patient eligibility, patient preferences, recruitment difficulties, to measure the information provided and whether the patient participated actively.	**To explore the views and experiences of nurses recruiting patients into CTs in terms of their patient- centredness and patient empowerment.** Nurses had keen sense of being **clinicians & advocates**, many practices made it difficult for pts to play active role in IC- undermining quality, Nurses had empathetic preferences, view of as intervention burdensome. Ethical unease re recruitment- due to patient misconceptions. **Nurses scrutinised decisions made by MDT.** Recruitment interactions- struggles to have their voice heard & the 'silenced patient'. Active engagement confirming understanding, **partially informed** patient.	Small number of participants	The nursing experience; not only cancer trial nurses Dual roles identified MDT issues highlighted Unable to voice That nurses' data was independent of the management team Two- pronged data collection – interviews & audio recorded appointments
Charalambous et al. (2008) *European J of Oncology Nursing* Nursing research on pts, carers and nurses, **Cyprus** **Search Science Direct 15**	Qualitative- A hermeneutic phenomenological study Participants -25 patients, 20 nurses, patient advocates- 6 focus groups Interpretative Researchers were active participants in the interpretative process To point of saturation Had ethical approval	**To find out the meanings of 'quality nursing' care through the experiences of pts with cancer, their carer, and their nurses.** How was quality assessed 1-Easily accessible care 2-effective communication- two-way, off set complaints, helped cultural 3-empowered pts by giving information when often pts did not have enough, was vague or misleading, better than doc communication 4- clinical competence engendering trust relationship, professional meant std of care and dedicated, 5- Attention to spiritual, beliefs 6- enabled SDM- promoted clinical effectiveness, key to SDM was relationship with patient, 7- Family presence- physical and emotional supportive role	NOT specific to CCTs Only the nursing perspective as per professionals- bias possible Small size- may not be generaliseable	Useful for the importance of certain experiences denoting quality of care Could be generalizable because off concepts raised as relationship social dimension of care Empowered patient to SDM (Shared decision making)

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Durant et al. (2014) *Cancer* Medical & Surgical Oncology divisions Didn't say researchers were nurses, US **Search C21**	Qualitative- 91-interviews- 5 US centres 4 stakeholder groups Cancer centre leaders, PIs (doctors), research staff, referring clinicians Coders used grounded theory	**To find out the perspectives of CCT personnel on the barriers & facilitators for clinical research pertaining to minority recruitment.** 1-Minority groups are influenced by scepticism. Facilitators at institutional level & participant level encourage participation-opportunities varied 2- Potential barriers of offering – insurance, language discordance, non-English speaking forms, unmet needs, time issues, competing responsibilities 3-Faciliators- developing rapport with groups, tailor made approach, assistance at institutional level, -built by individuals 4- Internal & external means- nurses reviewed clinics for eligible pts, explicit by informing centres about trials, giving feedback as important	Says not generalizable Participants mainly white-70%	Combination of professional views- multi-centre Interviewers were trained over 2 days, independent review of codes Power in individual rapport Nurses roles in discerning eligibility Main themes evidenced Distrust, Scepticism Language and education Level of skill and data collection excellent to include pilot and reviews Could apply to ethnic minority clinical setting
Kao et al. (2018) *Nursing and Cancer council Australia and Taiwan* **Search C23**	Quantitative- Groups of items identified from statements Positive snowballing approach, consisting of 3 rounds of online surveys Participants- 5 groups, 222 in total, 28 patients, 15 family members, 32 physicians, 58 HCPs (including CCT nurses) Round 1- list the essential information 2& Refinement	**Identifying essential information to support patient DM regarding participation in CCTs: A Delphi approach** In order to improve IC Generated into 8 headings: purpose of trial, understanding of trial, participation in trial, risks and discomforts, benefits to future patients, ethics and governance, communicating the result. 3 as essential (80%) Risks in relation to risk/benefit, ethics & governance, future pts, differences in care, contact persons, remaining purpose of trial, right to withdraw	Not qualitative Didn't explain the meaning of	Qualitative statements grouped Included nurses and doctors

Author & Journal	Design	Aim & Findings (highlighted relevant themes)	Limitations	Strengths
Krishna et al. (2015) *Nursing* **Search M 24** **Singapore**	Qualitative- Case study For purpose of illustration of the points Data is the description of the case	**Limits to relational autonomy** Palliative care case study of pain killer denied Nursing views on family (relational) influence on patients' autonomy Family denied on grounds that takes away pts autonomy because causes drowsiness	Not CCT focused Significance of the case –showing how family influence can oppose individual autonomy	individual This case circumnavigates patient autonomy Referred to Yang et al. (2010)- 80% docs prefer patient autonomy although as per Foo et al. (2013) – 60% of docs would override pts autonomy

Appendix C4.4 Synthesis of Literature Medline 8 Search

Search Table 8 (Layout adapted from NICE, 2014). sequence = Search Trust, CCTs, Doctors

13 hits of which 4 were discarded, leaving 9. Of these 4 were overlaps from previous searches; Madsen et al, 2007;Yang et al, (2017); Daughterty et al, (2005); Brown et al, (2011). The 5 new studies are presented below:

Author /Journal	**Study design**	**Aim & Findings** (Themes highlighted)	**Limitations & Strengths**	**Papers in Ref lists**
1- Fracasso et al. (2013) Coaching intervention As a Strategy for Minority Recruitment to cancer clinical trials Journal of Oncology Practice	Qualitative- Screened 268 patients- a coaching intervention was evaluated v usual care (UC). (the coach gave extra education and support to pts allocated). End point to include those enrolled to trials.	**Assessing the efficacy of a coach in the impact on ethnic group recruitment.** **Findings:** Higher quality of life (FACT- G QOL) and positive attitudes towards CCTs improved enrollment. Analysis of trial enrollment during or after intervention made no difference than UC for enrolment. Poor adherence related to depression	Not usual care provision – so poor value add. Role of physician not assessed. .	Barriers to CCTS for minority groups. Comis et al. (2009) Ford et al. (2008)- barriers to recruitment in under - represented populations.

Author /Journal	**Study design**	**Aim & Findings** (Themes highlighted)	**Limitations & Strengths**	**Papers in Ref lists**
2- Lee et al. (2016) Barriers and facilitators for CT participation among diverse Asian patients with breast cancer: a qualitative study. BMC Woman's health Biomedical central Singapore	Qualitative- 16 participants, 5 focus groups, open ended questions, 2 moderators, coders Thematic analysis with NVIVO	**To examine the barriers and facilitators to CT recruitment in patients- with a particular focus on Asian breast cancer women.** Findings: 1. Prevalent knowledge/attitudes- **1/3- lack of understanding**, sought more info, range of attitudes (anxiety-optimism). 2. Factors - Individual: family influences, 'last resort', more benefit, altruism. Barriers- previous **bad experience with doctors and drugs**, health care system, conservative/cautious- 'less adventurous'. 3. Factors related to CCTs- majority motivator **was hope** in trial, then lower cost, Trust in care, trial conduct- ethical, monitoring. **Majority barrier was fear and uncertainty /** and chance factor / stress of therapy. **Main motivating factor= Trust in doctor/ local governance.** In polite manner /pictures etc.	Limitations: Small numbers No men interviewed But could be transferrable to other Asian and ethnic minority settings Strengths- Affirming the barriers for ethnic groups for IC to CCTs	Referred to literature: Mills et al. (2002)- difficulties with recruitment in ethnic-minority groups. Grandfield et al. (2002)- barriers classified as physician-related and system factors. Russell et al. (2008)- health care professionals' attitudes Murthy et al. (2004)- mistrust and inconvenience as major barriers.
3- Nurgat et al. (2005) Patient motivations surrounding participation in phase 1 and phase 2 clinical trials of cancer chemotherapy British Journal of Cancer Cancer research UK	Quantitative- Questionnaires- open and closed ended questions. 38 phase 1/11 patients participated. SPSS analysis was done	**To examine the motives of patients to enter early clinical trials of novel cancer therapies.** Findings: Asking their motivation- 17% said altruistic, 58% gave hope of therapeutic response. 82% - helping future pts, 89%- possible benefit, 66%- trust in doctors, 76% trust in nurses, treated by latest treatment- 66%, 61%- better follow up, 58%- closer monitoring. Men more positive, 47%- said alternatives explained, info sources- mainly oncologist-82%.		Referred to literature: Appelbaum et al. (1987)- patients lack of understanding of the therapeutic benefit. Self- interest as motivating factor- Daugherty et al. (1995), Penman et al. (1984)

Author /Journal	Study design	Aim & Findings (Themes highlighted)	Limitations & Strengths	Papers in Ref lists
4- Meng et al. (2016) A comparison between Caucasians and African Americans in Willingness to Participate in CCTs: The Roles of Knowledge, Distrust, Information Sources and Religiosity. *Journal of Health communication.* Communication, Journalism and organizational sciences.	Quantitative: 898 respondents. 2/3 Caucasians Monthly on-line or phone survey for a year randomly selected based on the knowledge networks panel. Knowledge was assessed on a scale of 1-4. Distrust -Corbie- Smith on a 5 point Likert scale. Religious beliefs on a 1-5 Likert scale. WTP- measured by 3 parameters; 1- might improve length of life, 2- improve QL, 3- might help others. All 3 on a 1-10 scale of likeliness. Barriers to CTP scale 1-10.	**To explore the effects on individuals' WTP in seeking trial information from doctors, interpersonal relationships and the internet- comparing as per title.** **And religiosity in influencing CT participation according to ethnicity.** **Knowledge and distrust – considered baseline predictors** Findings: Distrust hugely reduced WTP. Caucasians- much higher levels of WTP AA- higher levels of religious belief, distrust in medical professions religious activity and distrust in medical professionals. For both distrust was negatively related to WTP. Concerns around RCTs. Factual knowledge was needed for WTP. For Caucasians seeking info from doctors was positively associated with WTP Religious was not a significant factor in WTP. Religious activity for Caucasians was associated with lower levels of WTP v AA from sources through the church.	Not got the experiential instances that give these results	Byrne et al. (2014)- why pts not participating- distrust in medical profession. Frank (2004)- knowledge of CT- important for WTP. O'Hanlon (2013)- African-American distrust due to past. More info re risks and benefits- Tanner at al (2014). Advanci et al. (2003)- AAs' more likely to hold religious belief God would determine fate and decreased WTP or provides CT resources.

Author /Journal	Study design	Aim & Findings (Themes highlighted)	Limitations & Strengths	Papers in Ref lists
5- Townsley et al. (2006) 'Understanding the attitudes of the elderly towards enrolment into CCTs' **BMC Cancer** Canada Biomedical	Mixed methods Survey – analysis by stats and semi-structured interviews analysed as per grounded theory approach	**Pt research – 94 elderly pts.** **To assess the attitudes of elderly pts to CCTs** 70% would participate if nothing else available Reasons to participate-Role 1- Cancer physicians' recommendation or for ALL participants or doc should decide, 2- to feel better, 3- benefit others.	Strengths- QC as per 2 members of research team independently coded- increasing reliability, 4 investigators reduced question list to final version, Weaknesses- Participants were paid ? increase possibility to enter the trial	**Cox (2003) – as above**
6- Loh et al. (2002) Reviewed in previous Appendix				

Author /Journal	Study design	Aim & Findings (Themes highlighted)	Limitations & Strengths	Papers in Ref lists
Possible Related study x 3- **Krieger et al. (2015)** 'Comprehension of randomisation and uncertainty in CCT decision making among rural Appalachian populations' **USA** **J Cancer Education Medicine, Communications & Behavioural Science**	Qualitative semi-structured interviews- re randomisation comprehension	To assess pts comprehension of RTCs 49 pts: Appalachian pts Uncertainty:-2 types of uncertainty; cognitive and affective (neutral and negative) RTC- increases uncertainty- as doc cannot choose treatment Regardless of level of comprehension, uncertainty still existed, Increased comprehension didn't improve participation narratives Affective uncertainty- affected perception i.e. guinea pig)- links with Trust	Strengths- triangulation of textual composition of labelling of codes as per 1-4 investigators, memo keeping of key decisions and developments Limitations- Appalachian only group, Paid participants	Brown et al. (2004) Sinha (2007) Joffe et al. (2001) Featherstone & Donovan (1998) Brashers (2001)
Avis (2010) – re advocates were previous trial or cancer patients				
Dellson (2011)- Not focus of current study as written				

Appendix C5.1 IRAS Approval

Full Set of Project Data IRAS Version 5.0.0

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters) The interprofessional experience of informed consent to cancer trials. A single centre case study.

1. Is your project research?

Yes No

2. Select one category from the list below:

Clinical trial of an investigational medicinal product

Clinical investigation or other study of a medical device

Combined trial of an investigational medicinal product and an investigational medical device

Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

Basic science study involving procedures with human participants

Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

Study involving qualitative methods only **-Yes**

Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

Study limited to working with data (specific project only) Research tissue bank
Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? No

b) Will you be taking new human tissue samples (or other human biological samples)? No

c) Will you be using existing human tissue samples (or other human biological samples)?

No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

England / Scotland
Wales
Northern Ireland

UK

3a. In which country of the UK will the lead NHS R&D office be located:

England 1
Scotland
Wales

Scotland Wales

Full Set of Project Data IRAS Version 5.0.0

Northern Ireland

= UK

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

2

No

3a. In which country of the UK will the lead NHS R&D office be located:

England
Scotland
Wales
Northern Ireland
This study does not involve the NHS

4. Which review bodies are you applying to?

HRA Approval
NHS/HSC Research and Development offices
Social Care Research Ethics Committee
Research Ethics Committee YES
Confidentiality Advisory Group (CAG)
National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create SiteSpecific Information Forms for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

It looks like your project is research requiring NHS R&D approval but does not require review by a REC within the UK Health Departments Research Ethics Service – is that right?

Yes

4b. Please confirm the reason(s) why the project does not require review by a REC within the UK Health Departments Research Ethics Service:

Projects limited to the use of samples/data samples provided by a Research Tissue Bank (RTB) with generic ethical approval from a REC, in accordance with the conditions of approval.

Projects limited to the use of data provided by a Research Database with generic ethical approval from a REC, in accordance with the conditions of approval.

Research limited to use of previously collected, nonidentifiable information

Research limited to use of previously collected, nonidentifiable tissue samples within terms of donor consent

Research limited to use of acellular material

Research limited to use of the premises or facilities of care organisations (no involvement of patients/service users as participants)

Research limited to involvement of staff as participants (no involvement of patients/service users as participants)

5. Will any research sites in this study be NHS organisations?

Yes ○ ○

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

No

If yes and you have selected HRA Approval in question 4 above, your study will be processed through HRA Approval.

If yes, and you have not selected HRA Approval in question 4 above, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

If yes, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after

If yes, and you have not selected HRA Approval in question 4 above, NHS permission for your study will be processed

IRAS Version 5.0.0 *through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).*

Full Set of Project Data

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

No ○

If yes, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before submitting other applications. If you have selected HRA Approval in

question 4 above your study will be processed through HRA Approval. If not, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

6. Do you plan to include any participants who are children?

No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

No ○

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

No ○○

9. Is the study or any part of it being undertaken as an educational project?

Yes

Please describe briefly the involvement of the student(s):
This is part of a Professional doctorate in Health and Social Care based at Royal Holloway University of London. The student (myself) will interview nursing and medical staff involved in cancer care and deploy thematic qualitative data analysis to extrapolate themes useful for interprofessional working. The student will examine the documentary evidence surrounding cancer clinical trials and will keep an observation diary of interprofessional working. ○

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

Yes

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

No ○

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

No ○○

Appendix C5.2 CEU Approval

Clinical Effectiveness Unit

9 Prescot Street London E1 8PR

Switchboard: 020 3416 5000 **General fax:** 01234 567 890 **www.bartshealth.nhs.uk**

Prof Jon Gabe

12th October 2015

Dear Prof Gabe,

Laura O'Regan's Evidence of Quality Improvement Project Registration

The following Quality Improvement Project:

What is the interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials? : A single centre qualitative case study.

...was registered by **Laura O'Regan** on the 1st October 2015 and subsequently endorsed by the appropriate Clinical Effectiveness Lead on the 9th October 2015.

Ms O'Regan is now free to begin her project. Yours sincerely,

Clinical Effectiveness Unit
Direct line: 020 7480 4830 clinical.effectiveness@bartshealth.nhs.uk

Appendix C5.3 RHUL Approval

Department of Social Work

Dr Frank Keating, Director of Research

Royal Holloway, University of London
Egham, Surrey TW20 0EX

Department of Social Work

Department • +44 (0)1784 414964
frank.keating@rhul.ac.uk

www.rhul.ac.uk

9th June 2015

Laura O'Regan

(via email)

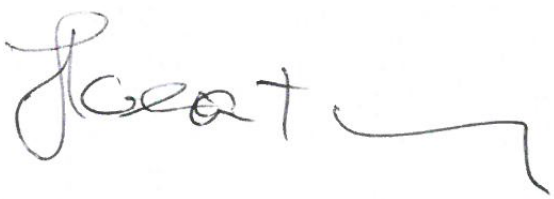
Dear Laura

RE: Upgrade Outcome

Thank you for attending the upgrade meeting and I can confirm that your proposal has been approved and you can now proceed with the next stage of your project, i.e., seeking the necessary ethical approvals and arranging a meeting with your supervisor to plan future steps. I attach the ethics form which has to be signed by your supervisor before submission to the departmental research committee (via me).

Congratulations and well done for reaching this milestone in your academic journey.

Yours sincerely,



Frank Keating

Appendix C5.4 (a) Self- Certification

(Both sent to Supervisor prior to data collection)

Ethics Review Details

You have chosen to self- certify your project.	
Name:	O'Regan, Laura (2013)
Email:	RXJD002@live.rhul.ac.uk
Title of research project or grant:	What is the interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials? : A single centre qualitative case study.
Project type:	Royal Holloway postgraduate research project/grant
Department:	Social Work
Academic supervisor:	Professor Jon Gabe
Email address of Academic Supervisor:	J.Gabe@rhul.ac.uk
Funding Body Category:	No external funder
Funding Body:	
Start date:	30/12/2015
End date:	30/12/2018

Research question summary:
The purpose of this study was to explore and analyse the interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials.
What am I trying to find out?
1. The professional perspective on why so few potentially eligible cancer patients are recruited to CCTs? The recruitment rates, documentary review and known patient barriers that impact on obtaining consent provide background rationale.
2. To identify how the interprofessional discourse impacts on obtaining informed

consent to CCTs, identifying elements of and gaps pertaining to interprofessional working.
3. To identify how different professionals perceive their role and the role of others in the phenomenon. Professional values and motivations are sought. Documentary evidence on competencies and policies informing practice are explored.
4. To identify the professional developmental needs that can improve obtaining informed consent to CCTs. The aim is to identify the potential for process and interprofessional communication improvements ultimately improving patient outcomes.
5. To address the knowledge gap on the interprofessional experience of this phenomenon.

Research method summary:
This study falls into the qualitative research family. Blaxter et al. (2010) further describe qualitative as a naturalistic phenomenological mode where the subjective experiences of individuals are sought in the real life setting. Giving meaning to the structure is referred to by van Manen (1990) as the lived experience. Qualitative is preferred over quantitative research as it is the most appropriate methodology because it examines personal meanings (Poger and Thomas, 2000). It seeks depth as opposed to a breadth of information. It is preferable in the natural and practice setting as a case study where the researcher was also a practitioner. The study neither seeks to change not is it experimental.
The Research design uses an instrumental local institution case where the subject is the interprofessional experience and the object is the impact on informed consent to CCTs.
The data collection methods are semi-structured interviews, diaries (reflective diary) and documentary evidence.

Risks to participants

Does your research involve any of the below? Children (under the age of 16),
No

Participants with cognitive or physical impairment that may render them unable to give informed consent, No

Participants who may be vulnerable for personal, emotional, psychological or other reasons,

No

Participants who may become vulnerable as a result of the conduct of the study (e.g. because it raises sensitive issues) or as a result of what is revealed in the study (e.g. criminal behaviour, or behaviour which is culturally or socially questionable),
No

Participants in unequal power relations (e.g. groups that you teach or work with, in which participants may feel coerced or unable to withdraw),
No

Participants who are likely to suffer negative consequences if identified (e.g. professional censure, exposure to stigma or abuse, damage to professional or social standing),
No

Details,
If in the instance that participants feel uncomfortable by any of the questions asked because of their role, it is made clear to them that all information is non-identifiable, and only issues that could be at risk to patient care would need reporting. There is on site counselling available for professional supervision if needed.
This poses none to minimal risk to any participants.

Design and Data

Does your study include any of the following?

Will it be necessary for participants to take part in the study without their knowledge and/or informed consent at the time?, No

Is there a risk that participants may be or become identifiable?, No

Is pain or discomfort likely to result from the study?, No

Could the study induce psychological stress or anxiety, or cause harm or negative consequences beyond the risks encountered in normal life?,
No

Does this research require approval from the NHS?, Yes

If so what is the NHS Approval number, 6397

Are drugs, placebos or other substances to be administered to the study participants, or will the study involve invasive, intrusive or potentially harmful procedures of any kind?,
No

Will human tissue including blood, saliva, urine, faeces, sperm or eggs be collected or used in the project?, No

Will the research involve the use of administrative or secure data that requires permission from the appropriate authorities before use?, No

Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?, No

Is there a risk that any of the material, data, or outcomes to be used in this study has been derived from ethically-unsound procedures?, No

Details,

Risks to the Environment / Society

Will the conduct of the research pose risks to the environment, site, society, or artifacts?, No

Will the research be undertaken on private or government property without permission?, No

Will geological or sedimentological samples be removed without permission?, No

Will cultural or archaeological artifacts be removed without permission?, No

Details,

Risks to Researchers/Institution

Does your research present any of the following risks to researchers or to the institution?

Is there a possibility that the researcher could be placed in a vulnerable situation either emotionally or physically (e.g. by being alone with vulnerable, or potentially aggressive participants, by entering an unsafe environment, or by working in countries in which there is unrest)?, No

Is the topic of the research sensitive or controversial such that the researcher could be ethically or legally compromised (e.g. as a result of disclosures made during the research)?,
No

Will the research involve the investigation or observation of illegal practices, or the participation in illegal practices?, No

Could any aspects of the research mean that the University has failed in its duty to care for researchers, participants, or the environment / society?,
No

Is there any reputational risk concerning the source of your funding?, No

Is there any other ethical issue that may arise during the conduct of this study that could bring the institution into disrepute?, No

Details,

Declaration
By submitting this form, I declare that the questions above have been answered truthfully and to the best of my knowledge and belief, and that I take full responsibility for these responses. I undertake to observe ethical principles throughout the research project and to report any changes that affect the ethics of the project to the University Research Ethics Committee for review.

Certificate produced for user ID, RXJD002

Date:	03/11/2016 21:11

Signed by:	O'Regan, Laura (2013)
Digital Signature:	Laura J O'Regan
Certificate dated:	11/3/2016 9:19:08 PM
Files uploaded:	Full-Review-314-2016-11-03-21-11-RXJD002.pdf Laura O'Regan CEU Barts Approval Oct 2015.pdf

Appendix C5.4 (b) RHUL Ethics Approval Form

Royal Holloway Ethics Approval Form

Please complete all parts of the form and the checklist. Please append consent form(s) and information sheets and any other materials in support of your application.
If relevant, please also append the appropriate department-specific annex.

All applicants should refer to the Royal Holloway, University of London Research Ethics Guidelines document.

Check one box:

☐STAFF Project X POSTGRADUATE Project ☐ UNDERGRADUATE Project

Start date _11/2015_____ Duration_2 years_____ Funding Agency_____Self_____

Title of project: What is the interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials? : A single centre qualitative case study.

Name of Researcher(s): Laura J O'Regan_

Name of Supervisor (Student Project): _Professor Jon Gabe__ Date: _2.11.2015_

Contact e-mail address: _l.oregan@sgul.kingston.ac.uk__

Does your project involved NHS patients, staff and facilities? Yes X No ☐

*If your project **only** involves NHS patients, staff and facilities, you do not need to complete the rest of this form. Please send the above information, along with a copy of your initial NHS ethics application to your departmental ethics coordinator and the college ethics committee secretary. Please provide any interim communication about amendments required. Final approval by the college can only be provided once evidence of NHS approval has been provided. The researcher should provide an electronic version of the final approved NHS application, with all its attachments and a photocopy/scanned copy of the final letter of approval from the NHS ethics committee.*

1

Appendix C5.5 Letter of Invite

Dr/Nurse. XXX

Cancer Clinical Trials team

/Cancer services (Daycare /Ward)

London Cancer Clinical Trials Office

Xxxxx Hospital

London

Re: Research Study: **What is the interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials? : A single centre qualitative case study.**

Dear Sir/Madam,

I am currently undertaking a research study as part of my Professional Doctorate in Health and Social Care at Royal Holloway University. I am working as a Senior Research Nurse in the Haemato-Oncology section of the Cancer Clinical Trials Office and have been as a specialist nurse in the Haemato-Oncology specialty for some years.

Recruitment of patients to cancer clinical trials is one of the primary objectives of the clinical trial team. I am interested in how professional communication and collaboration can impact on informed consent and how different professions view the roles and responsibilities.

This study aims to answer the question: **What is the interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials? : A single centre qualitative case study.**

The purpose of this case study is to use a phenomenological approach to gain an understanding of how different professionals (both clinical and non-clinical) experience interprofessional communication that leads to obtaining informed consent. The researcher is particularly interested in how different professions conceptualise their role and the role of others and how all professionals experience interprofessional discourse and how that impacts on informed consent. My hope is that this study will identify the main themes in relation to the challenges for professions and interprofessional challenges that preclude recruitment or that recruit non-compliant patients. This may have a positive educational and practice impact on the cancer clinical trial local delivery team and other centres in the future.

This is a generic invite which aims to recruit a minimum of 25 participants collectively from the medical and the nursing profession. I am inviting consultants and registrars, research nurses and specialist nurses some of whom may not be clinical. I am not writing to each staff

member individually. Therefore this letter can be passed on to a colleague who might be interested.

Anyone who chooses to take part will be requested to sign a Consent Form. The participant commitment will be partaking in a 45 minute audio taped interview (interview can be terminated earlier at request) and is held in a private clinic room. A second short interview of ten minutes approximately 2 weeks after transcription gives participants to add any further comments. All participants complete a demographic details form used to categorise the professions and grades.

Data collected from you at the time of interview and via the demographic form is treated with the strictest confidence and is anonymous. You have the right to take part or at any stage withdraw your consent without penalty.

Thank you for taking the time to read this letter. Should you wish to find out more about the study before you take part and/ or part take in the study, please feel free to contact me on my work phone or email below.

Email:l.oregan@sgul.kingston.ac.uk

If you are happy to proceed and part take in the study please sign the consent form attached, and return it to me in the pre-stamped envelope. I have enclosed the information sheet for you to retain for your reference. Should I not hear from you I will assume that you do not want to take part and I will not contact you again.

Yours sincerely,

Name: Laura O'Regan

Appendix C5.6 Consent Form

I _____ have read and understand the letter of invitation to take part in the research study: **What is the interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials? : A single centre qualitative case study.**

I have received sufficient information about the study and I understand that I will need to answer a demographic form and will be interviewed to obtain my experiences.

I am aware that I can withdraw at any time without penalty. I understand that I will be asked to meet for a second short interview for the verification purposes at which time a transcription of my interview can be kept.

I agree to the researcher communicating to the authorities any governance concern that has or may have a negative impact on patient care while making all attempts to maintain confidentiality.

Should I have any concerns about the study or conduct of the researcher the research supervisor, Professor Jon Gabe can be contacted at j.gabe@rhul.ac.uk

I hereby consent to participate in this research study.

Please indicate:

I have read the information sheet about this study (Yes/No)

I have had an opportunity to ask questions (Yes/No)

I have received satisfactory answers to my questions (Yes/No)

I understand that I am free to withdraw from the study at any time, without giving a reason (Yes/No)

I agree to participate in this study (Yes/No)

Participants Signature: _____

Name: _____

Date: _____

Researcher's Name: Laura O'Regan

Date: _____

Appendix C5.7 Participant information sheet

Royal Holloway University of London

Department of Health and Social Care

Re: Research Study:

What is the interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials? : A single centre qualitative case study.

I am currently undertaking a research study as part of my Professional Doctorate in Health and Social Care at Royal Holloway University. I am working as a Senior Research Nurse in the Haemato-Oncology section of the Cancer Clinical Trials Office and have been as a specialist nurse in the Haemato-Oncology specialty for some years.

Recruitment of patients to cancer clinical trials is one of the primary objectives of the clinical trial team. I am interested in how professional communication and collaboration can impact on informed consent and how different professions view the roles and responsibilities.

This study aims to answer the question: **What is the interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials? : A single centre qualitative case study.**

The purpose of this case study is to use a phenomenological approach to gain an understanding of how different professionals (both clinical and non-clinical) experience interprofessional communication that leads to obtaining informed consent. The researcher is particularly interested in how different professions conceptualise their role and the role of others and how all professionals experience interprofessional discourse and how that impacts on informed consent. My hope is that this study will identify the main themes in relation to the challenges for professions and interprofessional challenges that preclude recruitment or that recruit non-compliant patients. This may have a positive educational and practice impact on the cancer clinical trial local delivery team and other centres in the future.

This is a generic invite which aims to recruit a minimum of 25 participants collectively from the medical and the nursing profession. I am inviting consultants and registrars, research nurses and specialist nurses some of whom may not be clinical to attend the interview in a private clinic room as convenient for you within the hospital. I am not writing to each staff member individually. Therefore this letter can be passed on to a colleague who might be interested.

Anyone who chooses to take part will be requested to sign a Consent Form. The participant commitment will be partaking in a 45 minute audio taped interview (interview can be terminated earlier at request) and is held in a private clinic room. A second short interview of ten minutes approximately 2 weeks after transcription gives participants to add any further comments. All participants complete a demographic details form used to categorise the professions and grades.

Data collected from you at the time of interview and via the demographic form is treated with the strictest confidence and is anonymous and the consent form is separated and stored

separately from your answers. You have the right to take part or at any stage withdraw your consent without penalty or impact on your position, and you can choose to not answer a question if you so wish. You may retain this information sheet for reference.

Should you have any concerns or queries about the study or conduct of the researcher the research supervisor, Professor Jon Gabe can be contacted at j.gabe@rhul.ac.uk

Thank you for taking the time to read this letter. Should you wish to find out more about the study before you take part and/ or part take in the study, please feel free to contact me on my work phone or email below.

Email: l.oregan@sgul.kingston.ac.uk

If you are happy to proceed and part take in the study please sign the consent form attached, and return it to me in the pre-stamped envelope. Should I not hear from you I will assume that you do not want to take part and I will not contact you again.

Yours sincerely,

Name: Laura O'Regan

Senior Research Nurse

Cancer Research Delivery Group

Anonymous Hospital

Appendix C5.8 Full Demographics

Demographic details collected from the Nurse Participants at Interview

RN= Research Nurse N= Registered Nurse (in Haemato-Oncology)

P	PN1	PN2	PN3	PN4	PN5	PN6	PN7	PN8	PN9 MN	PN10	PN11	PN12
Age	20-29	20-29	30-39	30-39	30-39	40-49	30-39	20-29	30-39	50-59	30-39	20-29
Gender	F	F	F	F	F	F	F	F	F	M	M	F
Job	RN	RN	RN	RN	N	N	RN	RN	N	RN	RN/N	N
Take consent	No	No	No	Involved	No	No	Partly	No	Yes	No	Involved	No
Formal Training (not specified)	No	No	No	No	No	No	No	No	Yes	No	Yes	No
Education	BSc	BSc	BSc	MSc	BSc	BSc	BSc	BSc	Diploma	BSc	BSc	PGDip /BSc

Demographic details of Doctor Participants

Con= Medical Consultant
Prof= Professor of Medicine (Haem-Oncology)
SpR= Specialist Registrar
F2- Senior House Officer Doctor Day-care

MD= Medical Degree
PHD=Doctorate
MSc=Master of Science

P	PD1	PD2	PD3	PD4	PD5	PD6	PD7	PD8	PD9	PD10
Age	30-39	30-39	30-39	20-29	30-39	60+	40-49	30-39	30-39	30-39
Gender	F	M	F	F	M	M	F	F	M	M
Job	Con	SpR	SpR	F2	SpR	Prof	Con	SpR	Con	SpR
Take consent	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No
Formal Training	No	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes

Demographic details of Manager Participants

OPM= Outpatient manager
BTM=Blood Transfusion Manager

CM= Clinical manager
Dip= Diploma

P	PM1	PM2	PM3	PM4
Age	40-49	20-29	30-39	20-29
Gender	M	F	M	F
Job	CM	CM	BTM	OPM
Take consent	No	No	Yes	No
Formal Training	No	No	No	No
Education	Dip	BSc	BSc	BSc

Appendix C5.9 Interview Schedule

(a) Interviewee Data Collection Schedule

Study Title: What is the interprofessional experience of communication that impacts on obtaining informed consent to cancer clinical trials? : A single centre qualitative case study.

Demographic Section

1. **Please tick your age**

   20-29

   30-39

   40-49

   50-59

   60+

2. **Please tick are you**

   Female

   Male

3. **Please tick one of the following**

   Are you a Consultant?

   Are you a Specialist Registrar?

   Are you a research nurse?

   Are you a specialist nurse?

   Are you a manager who is professional but non clinical?

4. **Do you undertake consenting patients to cancer clinical trials?**

   Yes

   No

5. **Do you have formal training in consent taking**

   Yes

   No

6. **Please tick what level of academia you have taken**

   Diploma

   Degree

   Masters

   PhD

(b) Interview Guide

Q1 - How is a patient consented to a Cancer Clinical Trial?

Probes

When does the process of obtaining consent start?

Who are the professionals involved?

Do you think that has significance?

Would that be the general view?

Tell me your experience of this?

Q2- What is the role of the physician in obtaining consent?

Probes

Is this the general view?

Explain what your experience has been?

What are the most important motivating aspects for you?

Please feel free to give examples for above points.

Q3 - What is the role of the research nurse in obtaining consent?

Probes

Is this the general view?

Explain what your experience has been?

What are the most important motivating aspects for you?

Please feel free to give examples for above points.

Q4 - What is the role of the wider team regarding obtaining consent to cancer trials?

Probes

Does the wider team have an impact on clinical trial consent?

Explain what your experience has been?

Please feel free to give examples for above points.

Q5 – What are the barriers to obtaining cancer clinical trial consent?

Probes

How do different professionals respond to these barriers?

Should professionals respond differently?

Explain why?

What is your experience?

How can staff influence/ impact clinical trial consent?

Q6- How do patients experience cancer clinical trial consent?

Probes

What does this mean?

Has this significance in terms of decision making?

Explain examples from your own experiences.

Is this the general view?

Appendix C5.10 SOP for Consent taking

Local Standard Operating Procedure: Informed Consent for Clinical Research

(main points / unable to duplicate due to copyrights).

Referenced from:

Declaration of Helsinki (2008): that physician or another qualifying individual must seek the potential subjects freely given informed consent, preference in writing and witnessed.

General Medical Council (2008): Consent Guidance.

Nursing and Midwifery Council (2015): Consent Guidance.

Good Clinical Practice (2008): Consent Guidance.

3 Steps Process which includes:

1- The giving of information

2- The discussion and clarification of the information

3- Taking the subjects verbal and written consent

Effective communication is the key to participants enabling informed decisions about participation in a clinical trial. When providing information, researchers should do their best to find out about participants condition and treatment beliefs, culture, occupation or other factors that may have a bearing on the information they require. Confirms that the practice of IC is an on-going process performed by all members of the clinical trial team.

Legally acceptable representative (according to GCP 1.37):

"An individual or juridical or body authorised under the applicable law or consent, on behalf of a prospective subject, to the subjects participation in the Clinical Trial".

Impartial Witness:

"A person who is independent of the trial, who cannot be unfairly influenced by people involved in the trial, who attends the IC process if the acceptable legal representative cannot read the Informed Consent Form and any other written information supplied to the subject."

Other staff responsibilities:

- If agreed to suitably qualified number of the research team and is considered on a trial-by-trial basis, taking into account the local circumstances, sponsor requirements and GCP.

- Staff are prepared to take on the additional responsibility and feel confident to take informed consent in line with the relevant code of professional conduct.
- Has a comprehensive understanding of the study and all training is documented.
- An effective line of communication is maintained back to the Principle Investigator.

Time:

All participants are given ample and sufficient time to make an informed decision with regard to the trial entry. IC is gained before the start of the trial.

Reading and Writing:

If the subject is unable to read or write; an Impartial Witness should be present (to read and explain) or the Legally Acceptable Representative.

Non-English speaking:

Every effort is made to not exclude non-English speaking speakers. Access to CCT is enabled by incorporating an impartial interpreter or Impartial Witness- ***they cannot be a family member.***

Appendix C5.11 Colaizzi's 7 steps of analysis (as adopted by Sanders, 2003)

1. Each transcript should be read and re-read in order to obtain a general sense about the whole content.

2. For each transcript, significant statements that pertain to the phenomenon under study should be extracted. These statements must be recorded on a separate sheet noting their pages and lines numbers.

3. Meanings should be formulated from these significant statements.

4. The formulated meanings should be sorted into categories, clusters of themes, and themes.

5. The findings of the study should be integrated into an exhaustive description of the phenomenon under study.

6. The fundamental structure of the phenomenon should be described.

7. Finally, validation of the findings should be sought from the research participants to compare the researcher's descriptive results with their experiences.

Appendix C5.12: Transcript

I: Welcome xxx and we have gone through the background. So, can you describe how a patient is consented to a cancer clinical trial?

CD1: So, I suppose the first step is informing the patient of the potential options relating to the clinical trial and then we start by having an informal discussion about what the trial is and why they would be suitable to go into that trial, why we think it is a good treatment option at that stage. So, informal discussion around and why we think a clinical trial is a good option as opposed to the standard treatment if there is one. And then give them an opportunity to ask any questions at that very early stage and then probably the next step is to give them more details if it is something they are interested in pursuing, then we give them written information in the form of a PIS and we would allow them to take that away and read that and give them at least 24 hours to go through it and let the information assimilate and come back to us with any questions they might have relating to the information that they have read.

I: So, at that point in time it is the patient who is involved with you. Are there any other professionals involved up until that point?

DC1: Yeah, I suppose on a basic level we would generally discuss in the context of the MDT so already discuss at that level and the clinical trial has been suggested as a recommendation coming out from the MDT and probably before I see the patients I (myself) would make myself familiar with the trial that is on offer. I might liaise with whoever is leading the research from a nursing point of view just to make sure that the trial is open and that I am allowed to give out information to the patient.

I: So, the role of the physician, how would you see the role of the physician yourself?

DC1: I suppose I see my role as being a / I am the patient's advocate so I would be informing the patient about the trial to the best of my ability, giving them a balanced overview and what the trial involves but also if they decide to not go for the trial what treatment is on offer. So, giving them a fairly/ recommending the best course of action regarding the trial but also laying out the other options so that they can come to an informed decision on their own really.

I: So, what /so you would rely on the patient to make the decision?

DC1: Well I would see it as / ultimately it would be their decision but it would be my recommendation, and a clinical recommendation would be a trial at this stage but I wouldn't decide, I can't dictate that that's going to happen. So, they would have to willingly consent.

I: So, you mention about the role of being an advocate, so what would be the most motivating aspect from you as a physician? And how would you conceptualise that and what is the thing that motivates you?

DC1: To enter the clinical trial?

I: Yes, with regard to the consenting of patients to clinical trials? You can be honest.

DC1: Ask me again?

I: What motivates you to consent patients to cancer clinical trials?

DC1: So, because if I think it is a trial that has shown great promise like a phase 2 or 3 trial and there is good data coming out of it from other institutions or from other trials that have gone before and if there is standard or care or there is no standard of care at that stage. I suppose if I think obviously there are issues around recruiting patients to trials and we are active in this institution and we are always trying to consent people to trials as much as possible but it has to be in the best interests of patients and we wouldn't put patients into trials because we need to make up numbers. Primarily it is that it has to be in the best interest of patients when there is no standard and the alternative is more attractive I suppose.

I: And so, the general view would be similar to your view.

DC1: Yes, and in amongst that is the general drive to find newer or better approaches to patient care but you still can /make sure that you were selecting patients that it was in their best interests over and above everything else.

I: Even if it was a phase one trial?

DC1: Well I think that would come down to a discussion with the patient as to what was their best interests again they might decide that having no treatment is preferable than having it. And you would have to have that discussion with them but obviously I think a lot of patients would view even phase one trials as a good opportunity maybe not necessarily knowing what is going to come out of it for them because they know that it is going to help to gain more information for other patients in the future. But you would have that discussion openly with them that they would know going into it that there would be no guarantees about what the outcomes would be.

I: So, I mean irrespective of what phase the trial is what would you say the role of the wider team is, nursing as a profession in that process? Do you think they have a role?

DC1: Yes, so I think that /well from a nursing perspective/the role is primarily to support the patient once they are in the trial/whether that is helping to give them more information they have read about and reiterating like with chemotherapy. So, whenever I consent for chemotherapy then one of the CNSs would go through it again and make sure they have the information and ask any questions and so certainly to support my role in consolidating any information we discussed in the case of informed consent, but also in trials facilitating the screening process.

I: Ok really helpful yes. And does the wider team outside of the clinical trial team/ cancer research delivery team have a role here and if they do what is their role like the CAG the rest of the people do they have a role in terms of accrual of patients, consent? Do you see them as having any impact?

DC1: I suppose some of the more senior consultants might have more of an opinion about that but I think in general you want to work within a supportive dept so as dept who is very active in recruiting patients to clinical trials and if you don't have that support from the broader infrastructure then I think that the work and effort that goes into setting up and running a trial / it becomes very difficult unless you have that/ those people in the broader team.

I: So, it is the ideal is to have the support from both sides from within and outside the clinical trial team?

DC1: Yeah

I: Let's suppose there are sometimes barriers to recruiting or consenting patients to clinical trials what do you think that those might be in your experience?

DC1: So on occasions it takes a long time to get trials open so there might be trials that we have accepted or that we want to open and that have been through the process of set up but that set up can take a long time so it can be frustrating when you know that you have a patient whom you know can be very suitable and you can't quite/ and don't know what the time line is going to be and obviously you are going to have at some point but you don't know when and so then it becomes very difficult to make decisions about does the patient have time to wait or should we be looking at other treatment options so that can be a big challenge I think.

I: so how do the physicians and people at your level respond to that challenge? Can you respond to that?

DC1: Am, I mean I think if you are the PI in charge of the trial you probably have a little more weight in terms of what the issues are in terms of the set up and trying to identify ways to resolve those issues but then that involves the support of the infrastructure and the support of the wider Dept and that is not always forthcoming.

I: Do you think that's just your experience here or everywhere or is it just here?

DC1: I think that is really difficult for me to answer because this is the only place that I have been a consultant and I am not in a position where I have had so much exposure to recruiting patients to a clinical trial and also consenting for clinical trials so I think I don't know was I am aware of the issues in the other places that I have worked.

I: And so apart from delays in getting a trial open what other obstacles have you encountered in getting patients recruited or consented to clinical trials?

DC1: Getting patients consented to trials?

I: Because on trials are a much smaller percentage than patients who are not on trials so there is a much smaller percentage of patients but then there are a lot of trials that maybe patients could have access to so where are the other challenges or obstacles in getting those people that are the larger percentage the opportunity to join a trial?

DC1: mm.

I: From your experience do you know of any other issues that you have encountered here?

DC1: I suppose before you actually get to the stage of consenting patients it is identifying patients who are suitable to go into the trials can be a challenge so I think we have gotten better at it in the year that I have been here. I think unless the trial is in the forefront of people's minds and that everybody knows it is open or you have got one person who is advocating for that trial and they are very proactive in looking for patients who might be

suitable to enter. I think it is very difficult sometimes you might forget or miss patients who could be eligible. I think it has gotten better here since we have had a research presence at the mdt and we discuss / and can go through new diagnosis and we can go through any trials that might be suitable or just having the forum/ the trials meeting once a week keeping people up to date about what is active and what is out there so that you can and everybody is aware of what is available so you are always thinking about it whenever you see patients so I think before it wasn't quite as forthcoming.

I: So those meeting are interprofessional meetings; there is representation from doctors and nurses at those 2 meetings.

DC1: Which I think is really important.

I: Would that be a more joint approach to what pathway of care that patient actually takes?

I: So, the fact that they are definitely multi professionals at those meeting; would you say that everybody communicates what their perspective is at those meetings and that it is useful in making a decision?

DC1: Yeah definitely. I think haematology is a good example of how every professional works together as every patient with a diagnosis or relapsed diagnosis is discussed within the context of the MDT so we are used to doing that that is the Gold Standard and that is how patients should be managed and with that same structure should be in place with regard to clinical trial options so I think there has to be in the same forum because that is how our patients are discussed and that is how we make treatment decisions for patients. We don't ever really do that unilaterally so ..

I: So, this is quite new this involvement of different professionals along with the medical profession her is quite a new thing?

DC1: Yeah, I guess it is and it has been a more recent thing with regard to clinical trial recruitment potentially. So, we have been doing it for a long time with standard treatments.

I: That's really helpful and that takes me through what your perspective of what other people's role is and what your role is and then the wider team and if they have an impact as well so that is generally what we have talked about so did you want to add anything else at all?

DC1: I suppose my overriding impression of the clinical trial activity here is that as a kind of team as clinicians we all have the same ethos to clinical trials and all are very encouraging of active recruitment to trials but in order for that to flourish it has to be in the right environment / with the wider institution and that does not always necessarily feel.

I: Why is that the case?

DC1: I am not sure. I think trial activity within haematology is not prioritised whereas it might be prioritised in other departments. I think that there is not a brilliant infrastructure in terms of staffing levels for running clinical trials here so I think we suffer because we don't have/ we need a bigger team essentially, I think to promote clinical trial recruitment and activity. I think the willingness is there but it is not necessarily backed up by the ability to

deliver on a basic numbers level. I think research staff are really stretched and they are thinly spread.

I: Why is that/ is that just the state of play in the NHS anyway or is it here?

DC1: I think it is here. I think other places that I have worked have had more / better recruitment and more nursing staff /more visible research nursing teams that can help you facilitate getting patients into trials whereas here I think it is really difficult because it falls to a very small number of individuals and there are a lot of trials that we want to have open.

I: Yes, there is a huge portfolio here.

DC1: Yes, and the numbers don't match up.

I: Compared to other centres; trials that are open or opening up.

DC1: It needs to be matched by the resources to deliver that to help recruit and to help support patients into the trials and into the process but I don't think that it necessarily matches up at the moment.

I: And am but do you think that the physicians have a say in this obstacle that you have raised?

DC1: I don't know. I don't know that I have been here long enough to determine that but I think probably I think they are kind of *Here* cancer institute doesn't have as much representation within haemato-oncology as it could do. JG is a big advocate obviously for the clinical trials and what we do here but it is a kind of high level within the BCI but I don't think there is enough haem-Onc clinicians that can help kind of shape what we need from a resources point of view so it falls to one person which is JG. He is only one person and there is a limit to the time as to what he can achieve.

I: It is really helpful to see as it is a single centre case study and what are the problems here and maybe they are similar to problems elsewhere and we know that there are obstacles and so it is just about hearing what everybody has to say and what they have to say and what their experience is here. So, I think there is lots of useful information here in what you have said. Thank you very much *name.*

Appendix C5.13 Code Manual (Steps 3 and 4 of analysis)

Significant statements	Step 1 and 2 (linkage to phenomenon)	Formulated meanings	Code bank (Manual in NVIVO 10)
CN5: They (patients) might have been propositioned by the doctor about it. If doctors are able to, they will give them (patients) time to think about it and come back to decide and agree to it.	Doctors obtaining consent	Doctors offers trial and gives information	Information giving
	Doctors' communication	More than offers- makes a proposal (language used)	Timing of offer
		The possibility of giving time to patient to deliberate	Time to patient
		Giving time is uncertain	Language used to offer
RD10: It would be really difficult for doctors, because they (research nurses) are experts in the trial. They (research nurses) are experts, and they have a lot more time to sit down with the patient and go through. They are prompting everyone to make sure that they are sticking to the trial.	Doctors' constraints within informed consent	How the nurse augments the doctor's role due to doctor's difficulties (? time constraints)	Nurses' as information-giver
	Nurses' communication in obtaining informed consent	Doctor's (not consultant) highlighting nursing role as trial expert and go through (information)	Nurse as social communication
		The relaxed manner in which nurse communicate with patient to include body language	
		The nursing role to ensure quality control	

Formulated meanings	Theme clusters / sub-themes	Interpreted theme (related to obtaining informed consent)
Doctors offers trial and gives information	Decision-making role	The way responsibility is experienced by doctors (this quote is nurse's view)
More than offers- makes a proposal (language used)	Timing of initial offer	The impact of time on how the doctors' role is undertaken
The possibility of giving time to patient to deliberate	Timing of consent	
Giving time is uncertain	Doctors' information-giving role	

Formulated meanings	Theme clusters / sub-themes	Interpreted theme (related to obtaining informed consent)
Doctor's (not consultant) highlighting nursing role due to constraints- as trial expert and goes through (information)	Information-giving	Doctors' is responsible, constraints- knock on effect on nurse role
The relaxed manner in which nurse communicate with patient	Time as a factor	Nurses' role -responsibility has developed form difficulties the doctor experiences i.e. lack of time
The nursing role to ensure quality control	Social dimension of communication	Out of this nurses' role has emerged as a different way of communicating
		Nurses can still be experts