Conducting randomised controlled trials in an acute stroke unit: an ethnographic study

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ABSTRACT

Background

Stroke is a major cause of death and disability in the UK. Few treatments exist and those that do, such as thrombolysis ('clot-busting' treatment) must be given urgently and are not risk-free. Large scale randomised controlled trials are crucial for the development of safe, effective, acute interventions, but progress has been limited, ostensibly due to ethical and regulatory difficulties. Theoretical work in this area has focussed primarily upon the requirement for prospective informed consent, but has also considered potential conflicts of interests inherent in the dual role of clinician-researchers, and the notion that research and clinical practice are, can be, and should be conducted separately. Empirical evidence on this topic is lacking. By providing such evidence, this study examines claims made in the literature regarding the difficulties encountered or perceived in conducting emergency research. It also explores whether, how, and to what effect, the distinction between research and clinical activity advocated in the bioethical literature is maintained.

Methods

Ethnographic methods were employed, including participant observation, semi-structured interviews, and audio-recording of research consent interactions in an acute stroke unit. Data were analysed drawing upon constant comparative and framework methods.

Results and conclusion

Whilst providing empirical evidence supporting some of the theoretical and conceptual literature, the data also furnish a detailed account of pragmatic issues encountered and managed daily by healthcare professionals in the acute stroke environment. Whilst attempts were made at the study site to separate, at least in part, clinical and research activity, it was observed that absolute separation of clinical activities is neither attainable, sustainable, nor desirable. Placement of research nurses within the clinical environment may promote transparency and greater understanding of their role, whilst simultaneously demystifying research concepts. Ultimately this may promote closer working relationships, contributing to enhanced recruitment, retention and management of research participants.

Dedication

This thesis is dedicated to the memory of my
mother, Jenny Stobbart, and to the eternal
optimism of the late Trish Wakenshaw, who I
knew only briefly but who I will never forget.

Acknowledgements

Chapter 1. Introduction

This thesis describes the findings from an ethnographic study exploring the way in which randomised controlled trials of acute and hyperacute stroke interventions are conducted in an acute stroke unit. It seeks to determine whether the barriers identified in the literature are indeed those experienced in day to day practice, as well as reviewing whether, how, and to what effect, the distinction between research and clinical activity advocated in the bioethical literature is maintained. Chapter 1 introduces the topic and research design, and provides an outline of the thesis structure.

1.1 The Case For Emergency Research In Stroke Management

Stroke is the third largest cause of death in the UK and is the biggest cause of disability (National Audit Office, 2010). Ischaemic stroke is caused by a sudden blockage of blood flow to or within the brain and may result in varying degrees of paralysis of the limbs, speech and/or visual disturbances, cognitive deficits and fluctuating or diminished level of consciousness. Many survivors remain disabled and require the support of carers. In our increasingly ageing population, it is predicted that the incidence of vascular events, including stroke, will increase by 33% by 2020 (Hankey, 2005). Few treatments are available, and those that are, such as thrombolysis, ('clot-busting' treatment) must be given urgently and are not without their own major risks (Hacke *et al.*, 2004). Until relatively recently, possibly until the advent of thrombolysis, there has been a somewhat nihilistic view of stroke. The National Audit Office (2005) noted that 'an emergency response to stroke with efficient and effective acute care is generally lacking' ((National Audit Office, 2005; p.7). Nevertheless, reducing disability from stroke is recognised as a key priority in the Draft Regional Health Strategy for the North East (Singleton, 2007).

Large scale randomised controlled trials are crucial for the development of safe and effective acute interventions for stroke but data from the 2008 National Stroke Audit indicated that only 6% of patients included in the audit were enrolled in research protocols (not all of which were acute interventions) (Intercollegiate Stroke Working Party, 2009). Further research is urgently required but little progress has been made in

recent years. Of 75 therapeutic strategies tested in acute stroke trials during the twentieth century, only 2 (3%) are considered to be of proven benefit (Kidwell *et al.*, 2001). This lack of progress is attributed not least to the perceived difficulties in conducting research in the emergency situation in general, and in acute stroke care more specifically.

1.2   Structure Of The Thesis

1.2.1 Literature review and background

The medical and bioethical literature, reviewed in Chapter 2, suggests that the difficulties facing acute and hyperacute stroke research (and other emergency situations) are, for the most part, related to ethical and regulatory issues, often focussing primarily on the requirement to obtain prospective informed consent. Questions are also raised about the dual role of clinician-researchers, the attendant conflicts of interests, and the notion that research and clinical care are, can be and should be conducted quite separately. These issues shaped my research and the context in which this work was conducted.

This study aims to provide empirical evidence to situate claims made in the literature regarding the difficulties encountered or perceived in conducting emergency research. It explores whether, how, and to what effect the distinction between research and clinical practice was maintained in daily practice in an acute stroke care environment.

In order to contextualise my fieldwork, in Chapter 3, I provide data regarding the study site, personnel, admission processes and the current position of pharmaceutical research within the field.

1.2.2 Study design

In Chapter 4, I outline the ethnographic approach I used. Having secured a favourable ethical opinion (See Appendix A, Letter of Confirmation, application not included as this would compromise anonymity of the site and certain individuals), data collection was undertaken over an 18 month period from June 2006 to November 2007. Participant observation, and audio-recording in the case of consent interactions, provided a detailed account of how acute and hyperacute research was conducted in the acute stroke unit. Informal discussions and semi-structured interviews with clinical researchers and other non-research healthcare professionals facilitated the development of a more subjective record of their experiences, behaviours, involvement in, and more

general views about, conducting research in the clinical environment. When combined, these different sources of evidence, alongside the literature, furnish a more detailed understanding of day-to-day conduct of randomised controlled trials in the acute stroke environment.

1.2.3 Results

In Chapters 5, 6, 7 and 8, I present my empirical findings. In Chapter 5, I demonstrate how organisational issues shaped the temporospatial context of the research team, exerting both positive and negative influences upon access and interaction with patients and colleagues. In Chapter 6, I consider the way in which the clinical team perceived and positioned research and the research team as something 'separate and mysterious'. In Chapter 7, I explore the ways in which the research nurses performed their research identity, extending the traditional role and negotiating new boundaries. Finally, I draw these elements together in Chapter 8, to illustrate the work of the clinician-researcher and the performance of research within this acute stroke environment.

1.2.4 Discussion

Whilst the data provide empirical evidence in support of some of the theoretical and conceptual literature, they also provide a more detailed account of pragmatic issues encountered and managed every day by health care professionals in the acute stroke environment. In Chapter 9, I discuss these findings with reference to the literature, before considering implications for practice and recommendations for change.

Chapter 2. Literature Review And Background

2.1 Introduction

In Chapter 1, I outlined the need for clinical research in emergency medicine, and in stroke management in particular. In the first section of this chapter, I review some of the theoretical and conceptual issues that are perceived to be problematic in this area. Next, I review relevant empirical work which aims to explore lay opinion regarding emergency research, with or without prospective informed consent; perceptions of alternative forms of consent, including the option of waiver; and the accuracy and acceptability of proxy consent (or substituted judgement). Finally, I review literature examining the advantages and disadvantages of integrating research within clinical practice and the role of the nurse in this setting.

2.2 The Need For Clinical Trials In Emergency Care

As noted in Chapter 1, high quality clinical trials are crucial in order to improve the treatment and outcome of life threatening emergency illness or disease, but controversy persists regarding the ways in which persons incapacitated by such events can be successfully enrolled in research whilst being adequately protected from associated risks (Booth, 2007). Because of these difficulties, many current critical care interventions implemented and embedded before the introduction of our current rigorous regulatory procedures, are at best untested and at worst inappropriate, but are perpetuated due to custom and practice and remain unchallenged by empirical evidence (McRae and Weijer, 2002; Gefenas, 2007). This has been described as an 'illusion of efficacy' whereby therapies and procedures in everyday practice are perceived to be beneficial , but do not stand up to closer scientific scrutiny in terms of effectiveness or safety (Lewis, 1999; p.771).

Such optimism is not restricted to the lay public. In a study of Emergency Medical Service (EMS) providers in the US, it was reported that despite the large proportion of cardiac deaths resulting from out of hospital cardiac arrest, 57% of respondents thought that treatments for cardiac arrest were effective, and 40% believed that trauma treatments were effective (Schmidt *et al.*, 2009). Lewis suggests that accident and emergency practitioners should openly and honestly inform patients about the uncertainties and limitations of some of the therapies currently employed in the

emergency situation. It is postulated that greater public understanding of the limitations of current interventions may result in greater awareness and understanding of the need for research in this field. Limited understanding is not the only barrier however, as I demonstrate in the following section, in which I review some of the theoretical and conceptual issues purported to restrict the conduct of emergency research.

2.3   Theoretical And Conceptual Issues

It is generally accepted that the enrolment of neurologically compromised patients to clinical trials presents a number of difficulties, often including complex ethical dilemmas, for healthcare professionals (Miller, 1993; Tobias, 1997; Watts, 1997; Fost, 1998; McHale, 1998; Flanagan *et al.*, 2011). Whilst much is written on this subject from a theoretical or conceptual perspective there is considerably less empirical evidence about the practical impact of these difficulties upon the day to day conduct of research in acute and/or hyperacute situations. In this chapter I explore the difficulties discussed in the medical and bioethical literature. Some are common across a number of research environments, whilst others are specific to, or exacerbated in, emergency research situations, such as acute and hyperacute stroke.

The literature abounds with theoretical and conceptual pieces on the difficulties of conducting research in the emergency setting, issues which are also pertinent to the acute and hyperacute stroke situation. A substantial proportion of this work suggests that most of the problems in these areas of research are related to ethical and regulatory issues. These in turn are usually distilled to matters pertaining to decision making capacity and informed consent, and it is this latter topic that I explore first.

2.3.1 Informed Consent

Ethical issues raised in emergency research often focus upon the requirement to protect the patient's autonomy by means of informed consent. In 1914, Justice Benjamin Cardozo recognised the individual's right to refuse medical treatment, when he declared that 'every human being of adult years and sound mind has a right to determine what shall be done with his own body' (Schloendorff v. Society of New York Hospitals, 1914; p.1). Subsequently, the principle of informed consent was extended to encompass all treatment, whether standard or experimental, and is one of the fundamental underlying ethical foundations of biomedical research (Watts, 1997). In most Western societies informed consent is recognised in law, and by acknowledging the right to autonomy in the medical context (Miller, 1993), aims to uphold the right of

the autonomous individual to self determination and freedom of choice. Ethical issues in clinical research had long been recognised, and codes established, before the end of the nineteenth century, for example, Percival's Medical Ethics (Leake, 1927), and the Prussian 'Directive on Human Experimentation' (Vollman and Winau, 1996). However, it was The Nuremburg Code, formulated after the 'research' atrocities of World War II, that emphasised that the 'voluntary consent of the human subject is absolutely essential' (The Nuremberg Code, 1946-49 p.181) . The Code provided the basis for further regulation and legislation regarding the involvement of human subjects in clinical research, although the World Medical Association's (WMA) Declaration of Helsinki, Clause II.5 (1964) and the International Conference on Harmonisation (ICH) Harmonised Tripartite Guideline for Good Clinical Practice (GCP) (4.8.15), adopt a slightly more liberal approach, and acknowledge rare exceptions to this rule.

Informed consent serves two purposes, the first of which is to respect the individual's right to self determination, thus fulfilling the ethical principle of respect for autonomy. Whilst respect for autonomy is undoubtedly one of the cornerstones of medical ethics, the apparent supremacy it is afforded in the West is not universal (Tzamaloukas *et al.*, 2008). In fact it has been argued that the current western preoccupation with the primacy of individual autonomy may jeopardise the quantity and quality of clinical research undertaken in incapacitated patients and in emergency research in particular. It has been stated that an over emphasis on autonomy, growing individualism, and an increasing litigiousness is likely to adversely influence carers in their decisions about incapacitated relatives participating in research, and thus deterring research amongst these populations (Warner *et al.*, 2008). Although referring specifically to dementia studies, Warner's concerns could be similarly applied to those experiencing other incapacitating illnesses or events such as stroke.

A broad definition of autonomy is that it is the ability to determine one's own course of action according to one's own wishes (Beauchamp and Childress, 2001). However, some reflect that full autonomy is an ideal notion (Henry and Pashley, 1990) that can only be approximated, as in reality, circumstances are such that a person's autonomy may be restricted for various reasons. It is often argued that in the emergency situation, autonomy is almost always compromised to some extent by either physiological, neurological or emotional factors. Thus protection of the potential research participant must encompass and balance broader fundamental principles, not just autonomy, but also non-maleficence and beneficence. (Gefenas, 2007).

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The ethical conduct of research involving critically ill patients requires consideration of complex issues relating to the seriousness and severity of the illness or injury, as well as the patients' vulnerability, resulting from a combination of functional, neurological and/or cognitive impairments, any or all of which may render the patient unable to provide their valid and informed consent. Even without cognitive impairment, the complexities of assessing decision making capacity are familiar to all involved in the care of acutely ill patients. Further, the very context of the emergency situation may impact upon one's decision making capacity, giving rise to barriers that are 'conscious and unconscious, intellectual and emotional' (Roth *et al.*, 1977; p.282), but these issues are further amplified in acute stroke. In some cases communication may be impaired giving a false impression of impaired capacity, whilst conversely, language may be preserved despite impaired executive function, implying that a patient has capacity when in fact this is not the case (Savage, 2006). In such circumstances, to insist on prospective, informed consent may mean that only those who suffer a mild stroke would be able to provide consent and thus be eligible to participate. This situation is problematic both in terms of recruitment – which may lead to delays in completion of the study, and of outcome measurement – which may lead to flawed interpretation of results (Warlow, 2005).

A number of alternatives to prospective informed consent have been proposed and are discussed below.

2.3.2 Proxy Consent

Those who experience diminished capacity and are unable to consent themselves require extra protection from research risks, and with this in mind, the World Medical Association recommends that an investigator should obtain proxy consent from a legal representative in accordance with applicable law (Declaration of Helsinki, 2000). Until 2007, and the enactment of the Mental Capacity Act 2005 , English law did not include a concept of legal representative, nor did it recognise the notion of 'proxy-consent' for incapacitated adults. In any event, it is questionable whether this requirement truly does afford protection to the vulnerable patient (Alves and Macciocchi, 1996).

Proponents of proxy-consent (also referred to as substitute decision-making) claim that it represents an attempt to maintain autonomy by elucidating, from someone close to the incapacitated person, what their wishes would have been had they not become incapacitated (Lazar *et al.*, 1996). Although incapacitated persons have the

same right to self determination as those who have the capacity to consent, Lazar observes that in practice they are unable to exercise this right. However, it is acknowledged that even those close to the incapacitated person do not always accurately convey that person's wishes (Mason *et al.*, 2006) and tend to make their enrolment decision based on what they believe will maximise the patient's wellbeing (Karlawish *et al.*, 2008). Nevertheless, Lazar claims that although flawed, substitute decision making is a means of making decisions on behalf of incompetent patients, and that it attempts to extend the patient's control over his/her own health care. For this to be possible it is important that the proxy should be the person(s) with the best knowledge of the patient's specific wishes, values and beliefs, related to the present situation. Lazar suggests that in most cases this would be a close relative, who could reasonably be expected to base their judgement upon their knowledge and experience of the patient's own values and beliefs, and would approximate what the patient would want if they were able to decide for themselves, rather than what they themselves would do in a similar situation (Dickens, 1994). Others however, suggest that in practice this is not always the case (Seckler *et al.*, 1991; Emanuel and Emanuel, 1992; Biros *et al.*, 1995; The Law Commission, 1995; Alves and Macciocchi, 1996; Sulmasy *et al.*, 1998; Coppolino and Ackerson, 2001; Demarquay *et al.*, 2005) and postulate that these people are not always best placed to make such decisions (Fost and Robertson, 1980; McHale, 1993; Dickens, 1994; Biros *et al.*, 1995; Capron, 1999).

Lazar (1996) suggests that where a patient is estranged from family members, a friend or primary care physician may be a more appropriate proxy. He also raises the question of what should be done when relatives disagree, but is unable to suggest a solution. He quotes studies by Emanuel and Emanuel (1992) and by Seckler and Meier (1991), demonstrating that next-of-kin cannot accurately predict patients' preferences for life sustaining treatment. Other commentators identify similar issues in emergency and intensive care settings (Weijer, 2005; Del Giudice *et al.*, 2009; Kasner *et al.*, 2009) and in patients with terminal diagnoses (Sulmasy *et al.*, 1998) thus raising concerns about substitute decision making per se. The overall goal of substitute decision making is to 'replicate the decision the patient would make if [they] were still capable' (Lazar *et al.*, 1996; p.1436). However, Brazier notes that whilst this approach may appear attractive, because next of kin may often be aware of the patient's beliefs, values and desires, it may also potentially be dangerous, because they may also be the persons most likely to encounter conflict between their own interests and those of the patient (Brazier,

2003). Similarly, McHale refers to a Consultation Paper from the Lord Chancellor's Department (1997) questioning the objectivity of a proxy, when their own welfare, or that of a close friend or relative may be at stake (McHale, 1998). Emanuel and Emanuel (1992) also refer to the potential conflict of interests which may also be influenced by psychosocial issues (Bramstedt, 2003). Thus, although proxy consent is the most commonly employed alternative to traditional informed consent, it is not without its own problems.

Despite acknowledgements that next-of-kin may not always be the best persons to act as proxy (McHale, 1993; The Law Commission, 1995) the Mental Capacity Act 2005, for the first time in the UK bestowed legal status on such an arrangement. However, unlike The Human Tissue Act (2004) no family hierarchy is defined and therefore domestic disputes between family members may give rise to further dilemmas. Such disputes may hinder the decision making process both with regard to the decision itself and the time taken to reach consensus. Even amongst close knit families, proxies may be asked questions about the patient's values, preferences and beliefs that they are unable to answer (Bigatello *et al.*, 2003). Some patients may have no living or known relatives and it seems unjust to deny them the opportunity to participate in potentially beneficial research on this basis alone. Further, some may be estranged from their families and it would therefore be unrealistic to expect them to be aware of what the incompetent patient would want (McHale, 1993).

In acute stroke care, as in other emergency situations, delay in locating next of kin may place the patient outside the therapeutic time window for routine (e.g. thrombolysis) or experimental intervention. Even where next of kin are available it should be borne in mind that they have just received devastating news that their loved one had sustained a potentially life threatening medical event and are consequently usually somewhat distressed (Abramson and Safar, 1990; Miller, 1993; Biros *et al.*, 1995; Watts, 1997; Pochard *et al.*, 2001; Jones *et al.*, 2004; Pochard *et al.*, 2005). Whilst some of the work cited here refers to patients and relatives requiring clinical care in the critical care setting, Abramson and Safar (1990) reported that the wife of a patient involved in a cardiac arrest study, suffered a myocardial infarction herself on being told of her husband's condition – even without the added stress of considering his enrolment in a research study.

More recently, stroke researchers undertaking the FAST-MAG study have successfully applied an innovative 'in-field' consent process where patients were invited

to participate in a stroke study pre-hospitalisation if either they, or an appropriate adult person at the scene were able to speak to an investigator via a dedicated mobile phone in order to obtain prospective proxy-consent (Saver *et al.*, 2006). The process was reported to be acceptable to patients and proxies (38% refused, including 17% competent to consent), with no subsequent withdrawals. Researchers also reported a reduction in the time from ictus to administration of study intervention, without prolonging the time period for delivery to the emergency department.

As with in-hospital arrangements for proxy consent however, there remains a potential concern with this method as it does not fulfil the requirement stated in the ICH Harmonised Tripartite Guideline for GCP (1996), that where proxy consent is sought, the proxy must be allowed time to consider all treatment options, the implications of study involvement, to ask questions and to seek further advice if necessary. In practice, in the emergency situation time is a luxury that can rarely be afforded, as efficacy of treatment is often time dependent. Lazar (1996) recommends that the healthcare professional should act as facilitator to the process of proxy-consent, guiding the substitute to consider the patient's previously expressed wishes, values and beliefs, or (where unknown) best interests.

Even if the proxy is able to safeguard the patient's best interests however, many authors reject the suggestion that proxy consent respects patient autonomy, and consider it a violation of this fundamental principle (Miller, 1993; Biros *et al.*, 1995; Corrigan and Williams-Jones, 2003). These authors and others (Tobias, 1997; Fost, 1998), acknowledge the potential conflict posed by clinical research, between the obligation to provide personal care to the patient and the obligation to develop better treatments for future patients. Miller (1993) makes clear however, that future patients do not have a right held against current patients that they participate in research. He argues that proxy consent does not respect patient autonomy and claims that there are few cases where the proxy can be certain that their decision is synonymous with that which the patient would have made. The proxy can therefore only consent or refuse on the basis of 'best interest' – an argument which cannot truly be upheld in the research situation. Seeking to address some of the difficulties noted here, and referring to clause II.5 of the Declaration of Helsinki, attempts have been made to establish criteria identifying situations where further alternatives to prospective informed consent may be more appropriate (Miller, 1993; Biros *et al.*, 1995; Doyal, 1997). These include deferred, advanced, presumed and waived consent and are outlined below.

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2.3.3 Deferred consent

Until recent changes, deferred consent was permitted in some emergency research studies where a study intervention is administered to a, usually unconscious or otherwise compromised, patient in the absence of prospective informed consent, on the grounds that potential efficacy is so time critical that to seek out next of kin or a legal representative would be prohibitive. 'Deferred consent' is sought either from the patient, when his/her condition is stabilised, or from next of kin if the patient remains incapacitated. Referring to the work of Abramson and Safar (1990), Miller condemns deferred consent as nonsense. Although it has the advantage of being undertaken after initial enrolment, when there is time to fully explain the protocol and the patient or proxy has had time to regain composure, it is not possible, as Miller (1993) states, to consent to something that has already taken place, and describes the concept more accurately as 'ratification' or 'consent to continue'. It is not the same as waiver of consent, which requires specific preconditions and processes which must be reviewed by Institutional Review Boards, Research Ethics Committees or equivalent.

2.3.4 Advanced consent

A further alternative aiming to avoid some of the difficulties evident in the emergency situation is 'advanced consent'. Although sometimes confusingly referred to as prospective consent , this refers to a process whereby individuals who may potentially become eligible for study enrolment consider and give their consent in advance of eligibility (for example, elective surgery patients who may unexpectedly require subsequent intensive care management) (McHale, 1993; Olson, 1994; Watts, 1997; Bigatello *et al.*, 2003). At the time of writing I have been able to identify little evidence of application of this policy, except for some work in a South African Intensive Care Unit which used this method, with limited success to secure enrolment to one of three antibiotic pharmacokinetic studies and a study investigating the use of a haemoglobin substitute in acute anaemia (Pinder *et al.*, 1998).

2.3.5 Presumed consent

The concept of presumed consent is based upon what a 'rational patient' would do. Miller (1993) claims that any rational patient with a life threatening condition would consent to immediate treatment, if they were able to do so. Consent, he suggests, should therefore be presumed to any treatment demonstrating a favourable risk/benefit ratio, on the assumption that the patient's values, goals, plans, lifestyle and preferences are

within the 'normal range' – although unfortunately this is not defined. Nonetheless, Miller states that this temporary infringement of the patient's autonomy is only justified whilst a situation of medical emergency exists; once the emergency is over, consent (to further involvement) must be sought.

Throughout his criticisms of these approaches, Miller reaffirms the individual's right to autonomy, but, like Doyal, contends that this may be over-ridden for a narrow range of reasons (Miller, 1993; Doyal, 1997), where research may proceed under waiver of consent.

2.3.6 Waiver of consent

In the run up to and following, the implementation of the European Directive (EU Directive, 2001) by means of the Medicines for Human Use (Clinical Trials) Regulations 2004, and (in the UK, except Scotland) the Enactment of Mental Capacity Act 2005, concerns were raised about the potentially limiting, and damaging effects of what many considered to be over-regulation of clinical research (Singer and Mulner, 2002; Stocchetti *et al.*, 2003; Druml and Singer, 2004; Pincock, 2004; Stobbart *et al.*, 2006). Although acknowledging the usefulness of the recognition of proxy consent for Clinical Trials of Investigational Medicinal Products (CTIMPS) (EU Directive, 2001) and the requirement to confirm 'lack of objection' for enrolment in non-CTIMPS (Mental Capacity Act, 2005), concern persisted about the vagaries of some of the terminology and the lack of provision for situations in which the time dependent nature of the intervention under study precludes the procurement of prospective consent, whether from patient or proxy (Coats and Shakur, 2005; Coats, 2006). Citing the Medical Research Council (MRC) funded CRASH Study (Corticosteroid Randomisation After Significant Head Injury) as an example, there was widespread concern that answers to important health questions would be delayed (Roberts, 2004; Wright *et al.*, 2008) or flawed (Warlow, 2005).

Data from the CRASH study illustrated the delay incurred when proxy consent is mandatory (Roberts, 2004). Time from injury to randomisation was just over one hour in hospitals allowing waived consent, compared to almost two hours in those where proxy consent was sought, with lower recruitment rates in the latter group. The requirement for prospective or proxy consent could jeopardise both the quantity and quality of hyperacute research. For example, UK centres were unable to participate in the TROICA study (Böttiger *et al.*, 2008) because at the time of recruitment (January

2004 – July 2006) waiver of consent was not permitted and the concept of 'legal representative' was not recognised in the UK. Similarly, it was estimated that the National Institute of Neurological Disorders and Stroke (NINDS) rtPA (recombinant tissue plasminogen activator) Stroke Trial, which completed recruitment in three years and nine months, would have taken over 12 years to complete had proxy consent not been permitted. Apart from the delay, this would very likely have introduced a selection bias which may have invalidated study findings (Flaherty *et al.*, 2008). The requirement for prospective informed consent may have meant that only those who had suffered a mild event would have been eligible to participate. For these patients the hazards of treatment might outweigh the potential benefits because they may recover without treatment. Outcome for these patients would be quite different from those with more severe symptoms, where the treatment hazard may be worth accepting for the greater potential benefit. This may result in a situation where stroke studies are undertaken in only moderately ill individuals and could thus lead to the abandonment of potentially useful treatments for severely ill patients. The autonomy of more severely impaired individuals would have been respected but possibly to their detriment as well as the detriment of millions of future stroke patients (Warlow, 2005).

For some, the need to not only allow but facilitate such research, rests on the premise that, contrary to the first principle of the Nuremburg Code, the voluntary consent of the human subject is 'neither necessary nor sufficient for ethically and legally responsible research' (Fost, 1998; p.163; Emanuel *et al.*, 2000; p.2701). In a consensus statement on Informed Consent in Emergency Research, recommendations are offered to help resolve some of the problematic issues related to informed consent and waiver of consent in emergency situations (Biros *et al.*, 1995). Biros et al claim that patients should not be denied the opportunity to participate in acute resuscitation research simply because they or a legally authorised representative are unable to give consent. Subsequently, in the U.S., provision now exists to allow an exception to the requirement for informed consent in well defined circumstances (Title 21, Code of Federal Regulations [21 CFR] Section 50.24). Some argue that this is the only way that emergency research is possible (Lemaire, 2007), but the associated complexity of research design means that this waiver is rarely employed (Nichol *et al.*, 2004; Hiller *et al.*, 2005; Mitka, 2007).

In Europe however, the Ger-Inf 05 Study, a sepsis study conducted in France between 1995-1999 (i.e. prior to EU Directive 2001/20/EC), introduced waiver of

consent 10 months after the start of the study, with the effect of accelerating the recruitment rate from four to ten patients per month (Annane *et al.*, 2004). And in the UK, in an attempt to address some of the issues raised, a subsequent amendment (Rodrigue *et al.*, 2004) endeavours to outline situations in which prospective informed consent may be waived, in very specific circumstances and according to very strict protocols, along similar lines to those suggested in the U.S. Exception From Informed Consent in Emergency Research (EFIC). In addition to the points already raised, such provision is necessary because it is postulated that the default position of exclusion, is inappropriate (Baren and Fish, 2005), and is arguably no less likely to undermine the autonomy of a potential participant than inclusion with waived consent (Harris, 2005). It is also argued that according to the ethical principles of beneficence or social justice, citizens have a moral obligation, or at least a civic duty, to participate in medical research, provided that safeguards against malpractice are in place (Evans, 2004; Harris, 2005; Schaefer *et al.*, 2009).

Despite recognising the need for research in the emergency situation, it has been emphasised that the determinant for application of the emergency exception rule should be related to the efficacy of the treatment (i.e. time dependent) rather than the availability of proxies. Robertson, on the basis of her review of family availability for proxy consent, suggests that if time to treatment is not expected to influence the outcome, the recruitment time window should be widened, in order to maximise the likelihood of being able to contact relatives or other authorised persons (Robertson *et al.*, 2007)

It is a well rehearsed argument that patients would not want to be entered into a research study without consent. However, it has also been noted that it would be helpful to know what patients and their representatives feel about waiver of consent (Fost, 1998). It has been suggested that the way to promote public acceptance of the need for emergency research without prospective consent is to develop 'the level of public knowledge, trust and credibility in the healthcare system' (Gonzalez and Helling, 2008; p.1670). More recently attempts have been made to empirically address the question of patient and public opinion, some of which are outlined below.

2.4 Empirical Research About Conducting Emergency Research

Much of the debate about the difficulties encountered in emergency research and/or research involving incapacitated persons, is theoretical in nature, primarily

because conducting research about conducting emergency research is both practically and ethically challenging. However, in recent years a number of empirical studies have been undertaken in this area with a view to informing policy and practice pertaining to emergency research. These fall broadly into the following areas: lay individuals' perceptions about consent in research, including proxy or waived consent; views and experiences of patients and/or potential participants; research participants' understanding of research information as perceived by themselves and/or their clinician-investigators; and the accuracy of proxy decision making.

2.4.1 Lay individuals' perceptions of consent procedures in research: next of kin and emergency department attendees

In 1998, Fost cited the work of Abramson and Safar (1990) as the most extensive study of public opinion on the subject of emergency research without prospective informed consent although it addressed only one aspect – i.e. the views of next of kin (Fost, 1998). Abramson and Safar (1990) conducted a randomised controlled trial of brain resuscitation after cardiac arrest, where in order to be efficacious, the treatment had to be commenced within 30 minutes of restoration of circulation. The participants (n=558) were, by definition, unconscious and therefore unable to give consent. Because treatment had to be administered immediately, proxy consent was not practicable and therefore deferred consent was employed. Family members were contacted after the initial dose of study medication (or placebo) had been administered, and were asked to consent to continuation in the study. This process, referred to as 'deferred consent', was employed in 531 (95%) cases and reactions to the process were available in 78% (226/343) of American and 47% (102/215) European cases. In 12 cases, families refused consent to continue. In all cases however, the refusal was based upon quality of life issues rather than the nature of the experimental intervention. Six negative reactions to the use of deferred consent were documented, half of which related to concerns regarding survival, not about the experimentation itself. The results indicated that the 'vast majority' of families were in favour of the deferred consent mechanism and provided no evidence that waiver of consent was perceived as morally problematic (in this instance). Where prospective consent was obtained however, it was reported that families often felt 'pressured into making a decision before they were ready' (p.782). Some relatives had no objection to study involvement but declined the responsibility of

signing the consent form explaining 'it's for doctors to decide', 'I don't want to be responsible' (p.783) (Abramson and Safar, 1990).

A more recent French study of 56 patients entering acute stroke trials found that only 23 patients were able to provide consent. The responsibility for consent usually fell upon relatives, of whom over half felt uncomfortable because of psychological stress induced by the need for urgent decision-making (Demarquay *et al.*, 2005). Other studies have reported similar findings in relation to family members' desire for involvement in clinical decision-making in the critical care environment (Azoulay *et al.*, 2004). More recently, work has been undertaken to determine the ability of patients enrolled in studies without prospective informed consent, to subsequently ratify their inclusion and continued participation (Harvey *et al.*, 2006). Less than 3% (13/498) of patients provided consent before randomisation. Relative assent was secured for 81% of the remaining patients. Of the 482 patients for whom consent was not secured prior to randomisation, 188 (39%) survived. Retrospective consent was obtained from 93% of these patients and was withheld in 3%. The remainder did not regain mental capacity.

As noted, with the exception of Harvey's work, the studies noted above address only the views of the next of kin rather than those enrolled in, or eligible for enrolment in, emergency research. Attempts have been made to address this issue by investigating the opinions of emergency medicine patients concerning waiver of informed consent for emergency research (Smithline and Gerstle, 1998; McClure *et al.*, 2003). In a survey of a convenience sample of 212 patients attending a tertiary care, academic, urban emergency department, 73% stated that they would be willing to be entered into an emergency research study if unable to consent but where absolute risks were minimal. Where absolute risks were more than minimal, 50% would still be willing to participate if incremental risks were appropriate, and 74% of those surveyed indicated that a family member could decide on their behalf. Responses were influenced by educational status and acuteness of their illness, but not by age, gender or social group. Others have addressed similar issues (Agard *et al.*, 2001; Wilets *et al.*, 2003; Gammelgaard *et al.*, 2004b; Kenyon *et al.*, 2006; Saver *et al.*, 2006)

2.4.2 Views of potential research participants

A further study collected data on the actual preferences and values of a group most likely to be directly affected by the Exception from Informed Consent (EFIC) – those at risk of stroke. Interviews were undertaken with 12 patients hospitalised as a

result of stroke in the preceding 12 months. All felt that the development of new treatments for stroke was important, but they were unclear about the distinction between 'research for stroke' and 'emergency research for stroke'. Following clarification of these terms, 10 patients stated that they would be willing to participate in the latter, and in the absence of a surrogate, 11 were willing to be enrolled by a physician (Blixen and Agich, 2005). These patients may have already been eligible to participate in research or may become so in the future and therefore this work is not entirely hypothetical. It is likely however that their apparently positive experiences and outcomes may have predisposed a more positive and accommodating attitude towards EFIC. Most of the respondents expressed confidence in family members' ability to act on their behalf and in accordance to with their wishes. However, this is a population that may have discussed such issues following their previous stroke. It cannot be assumed that such discussions would have occurred spontaneously. Further interviews and focus groups were planned to inform development and testing of a validated questionnaire about values and preferences for emergency (stroke) research involvement.

Work has recently been undertaken to ascertain the views of emergency department attendees who have been approached to participate in clinical research (consenters and non-consenters.) Having obtained consent whilst the patient was in the department, telephone questionnaires were conducted seven days post-discharge in order to explore patients' perceptions of participating in research in the emergency department. Whilst exploring actual rather than hypothetical experiences, the study included only patients who were not critically ill, and who were considered to have capacity to make their own decision about research participation. A further limitation of this study is its small sample size (n=46), which is probably due to the timing and process of data collection (Paradis *et al.*, 2010).

Similar work in the UK included a qualitative study conducted with women recruited to a randomised controlled trial (RCT) of antibiotics in preterm labour. Results suggested that women in this critical situation may not have been able to absorb the information given about the RCT, despite that fact that the quality of written and verbal information was generally considered to be good. Their accounts also suggested that decisions were made based not only on the information given, but were influenced by socioemotional aspects of their interactions with healthcare professionals (Kenyon *et al.*, 2006)

With the exception of Kenyon's study, much of the work attempting to ascertain the views of patients and the public on the subject of emergency research, is U.S. based and is hypothetical in nature. For the most part it relies on accounts of intended, rather than reported or observed behaviour, in response to questions that are mostly generated from theory, rather than identified by the patients/participants themselves. Nevertheless despite the limitations of these studies, they make a start to address what patients want, rather than solely what 'experts', whether ethicists or clinicians, think is 'right' for them and provide a starting point from which to explore these issues in greater depth and perhaps to provide the basis for further work.

2.4.3 Willingness to participate in clinical research

Abboud et al note that in their survey of 420 patients (207 emergency department attendees and 213 geriatric out-patients) a greater number of patients were more likely to be willing to receive an experimental treatment outside a study protocol than as part of a research study. (Abboud *et al.*, 2006). Perhaps this is because they have an overall mistrust of the non-individualised process of research, but feel that they are being treated more personally if a clinician offers them a 'special' treatment because they believe that it offers them a better chance. Paradoxically however, their safety is more likely to be upheld and properly scrutinised within the confines of a 'non-individualised' research protocol.

2.4.4 Participants' understanding of research information in the critical situation: clinicians' and patients' perceptions

More recently, those concerned about regulatory threats to emergency research have endeavoured to conduct empirical work in this area, focussing upon the ability of emergency department attendees to understand research information documentation and therefore, their ability to provide autonomous informed consent. Foex (2004), reviewing the work of others in the field, noted that in Agard's study of 544 Swedish cardiologists, 86% felt that patients were unable to understand all of the information given to them and therefore, by definition, were unable to give informed consent (Agard *et al.*, 2004; Foex, 2004). In the same study, patients themselves felt that their level of consciousness was too low to understand the information given and some were in too much pain to engage with the process (Agard *et al.*, 2001). A review of ISIS-4, (Fourth International Study of Infarct Survival) revealed that of 150 participants who returned a

questionnaire, only 31% perceived that they fully understood the nature and purposes of the trial, whilst 19% felt that they had no understanding (Yuval *et al.*, 2000).

Likewise, in the HERO-2 (Hirulog and Early Reperfusion or Occlusion) Consent Sub-study, few patients were considered to have given consent that was 'truly autonomous and informed' (Williams *et al.*, 2003; p.920). Similar findings have also been reported with respect to understanding of other research protocols in unstable angina and acute myocardial infarction (Kucia and Horowitz, 2000), as well as capacity for, and recall of, consent in subarachnoid haemorrhage (Schats *et al.*, 2003). These findings are not universal however; in a study exploring how patients in the acute phase of myocardial infarction experience the research consent procedure, only 28% of participants and 7% non-participants read the information sheet before making a decision. Nevertheless, 76% and 63% felt able to make a decision and 50% and 34% found it acceptable to ask in these circumstances. These authors therefore suggest that clinicians should ask potential participants whether they feel able to make a decision (Gammelgaard *et al.*, 2004a).

Research in the critical care arena is commonly thought to pose serious risks to participants. Weijer suggests that a more useful approach to the information and consent process in this area would be to focus on the incremental risk incurred by study involvement, rather than the unavoidable risks associated with the illness/event itself. Potential participants would then need to consider the question 'what difference will it make to me to participate in this study as opposed to being treated in accordance with routine clinical care?' (Weijer, 2004; p.86)

2.4.5 Other lay perceptions of medical research

Outside the emergency arena, work has been undertaken to ascertain the views of patients in waiting rooms of medical oncology, radiation oncology and radiology outpatient departments about their attitudes towards medical research. Whilst some respondents reported that they had experience as participants in medical research (30% of the 1882 respondents), for the majority of those interviewed their responses were hypothetical. Most respondents (90%) expressed a favourable, or very favourable, attitude toward medical research and 70% believed that it usually or always advances medical science. However, 42 % were concerned about exposure of participants to unreasonable risks, and 6% felt that participants are often unduly pressured (Sugarman *et al.*, 1998).

In Sugarman's study there was a wide range of reasons for participating in medical research, from exclusive self-regard to altruism. In addition, a rationale that I have not noted to be reported elsewhere, was that there was 'no reason not to' (64%) (1998; p.4). Even those who advance altruistic reasons for participation however, usually hold concomitant hope for some personal benefit and have faith in their clinician's recommendations, implicating factors other than assimilation of facts and the application of rational thought in the decision-making process. Sugarman (1998) notes that of those who did, or said they would, decline participation, 59% did so because they wanted to make decisions regarding their treatment and care, either themselves or in partnership with their doctors; they did not want these decisions to be made by medical researchers. Whilst this might suggest that potential participants may be more comfortable about participating in research if the clinical team is involved, such familiarity may be a double-edged sword, enhancing trust but potentially engendering coercion and undue influence.

2.4.6 Accuracy of proxy decision-making.

Whilst the above studies concentrate on lay views about deferred and waived consent, another focus of research in this area is the accuracy of proxy-consent and substitute decision-making. Although not conducted in the context of research involvement, these studies raise important questions about these concepts. Studies investigating the accuracy of substituted judgement in patients with terminal diagnoses have concluded that the likelihood of proxies making the same judgement as that of the patient is dependant upon a number of factors relating to both patient and proxy (Sulmasy *et al.*, 1998). The authors claim that by examining these factors the clinician may determine whether the patient is at risk from an inaccurate proxy decision. However, if one of the arguments against proxy consent for emergency research is the time factor, carrying out such an assessment is unlikely to be practicable.

A similar study involving geriatric rather than terminally ill patients, demonstrated that the concept of proxy decision making may be 'seriously flawed', and provided data to illustrate that resuscitation preferences of the patients studied were not adequately understood by their proxies (whether these were physicians or family members) (Seckler *et al.*, 1991; p.95). These authors cited several other broadly comparable studies demonstrating similar findings (Uhlmann *et al.*, 1988; Ouslander *et al.*, 1989; Zweibel and Cassel, 1989; Lo *et al.*, 1990; Emanuel and Emanuel, 1992).

Emanuel and Emanuel (1992) review some of the aforementioned studies and acknowledge the serious implications of their findings, suggesting as an alternative, the promotion of advance directives and living wills.

Other concerns about informed consent for clinical research hinge on investigators' focus on the information giving aspect of informed consent rather than a more robust concept encompassing competence and voluntariness (Silverman, 1996). As well as affording the patient (or their family members), the opportunity to make an autonomous choice about research participation, a secondary purpose of the consent interaction is to alert them to the fact that, in the research situation, their doctor's actions are dictated by scientific protocols, and are hypothesis driven, rather than patient directed and needs driven (Hallowell *et al.*, 2009). It is argued that the moral dilemma inherent in the clinician-investigator role rests within the conflicting values of science, which searches for truth, medicine, which seeks to act beneficently towards the patient, and the personal and/or professional aspirations of the investigator (Pellegrino, 1992). Questions about emergency research however, are not entirely limited to issues of consent; nor are they limited to when, or who to ask. There are also issues about who should do the asking, who should subsequently conduct and manage research activities, and where this should all take place. Focussing on arguments for and against the integration of clinical and research activity, I explore these issues in the following section.

2.5 Theoretical And Pragmatic Issues For And Against The Integration Of Research And Clinical Activities

Research aims to generate medical knowledge to benefit future patients, with or without potential benefit for the patient participating, whilst clinical practice focusses on achieving therapeutic benefit for individual patients. They are thus often viewed as dichotomously split, if not opposing, concepts. Despite the theoretical distinction, at a pragmatic, practical level, associated activities overlap and become blurred such that the two are often conflated by researchers and participants alike (Hallowell *et al.*, 2009). A confounding factor is the apparent interchangeable use of the terms, clinical 'practice' and 'care' which, if research and practice are to be separated, seems to imply an absence of care, or caring behaviours, in the research role. Hallowell (2009) questions whether research and clinical activities really are so different; whether researchers and participants can always tell them apart; and whether this is important.

In North America and Europe it has been common practice to undertake clinical research within the clinical care setting (Lemaire, 2004a). For many clinicians, research is seen as an essential component of clinical care with up to 70% of paediatric cancer patient in the U.S. enrolled in clinical trials (Joffe and Weeks, 2002) because their oncologists feel that this is the best way to provide the best care. Some argue that this combined practice should become the reigning standard; the clinician's daily work should include a combination of patient care, research and quality assurance and that such integration should be a matter of routine, rather than an unusual exception (Rhodes, 2005). Others note, but reject this approach and in the sections that follow I discuss the rationale behind separation of these activities.

Although many commentators discuss the difficulties encountered in the broader area of emergency research Slyter (1998) contends that logistic and ethical considerations make the design of acute stroke trials even more difficult. In some areas of investigation it is possible to conduct research in a separate physical environment, but in emergency research, pragmatic concerns and limited resources generally preclude such an approach. Research suggests that outcome following stroke is improved if patients are cared for in specialist stroke facilities and recommendations are made accordingly (Stroke Unit Trialists' Collaboration, 2004). However, capacity issues, such as inadequate provision of 24 hour imaging facilities and a national shortage of allied health professionals required to staff multidisciplinary teams for stroke care, mean that high quality stroke care, let alone research, continues to be compromised. In 2005, the National Audit Office reported that fewer than 20% of stroke units had access to computerised tomography (CT) imaging within three hours of admission (National Audit Office, 2005) and even by 2009, only 25% of sites were able to provide thrombolysis at nights and weekends (National Audit Office, 2010). Further, few stroke staff actively participate in research because there is no career framework for them in research (Jenkinson and Ford, 2006). Thus, in many institutions, resources dictate that stroke specialists or teams provide both clinical care and conduct research, delivering practical efficiencies on the one hand but bestowing conflicting roles of care giver and researcher on the other (Slyter, 1998). Routine and experimental interventions are delivered in the same setting, thus blurring the boundaries between these activities for patients, families, and their clinicians, particularly if some are occupying dual roles (Morin *et al.*, 2002; Williams and Haywood, 2003). In such situations, and for the reasons noted, pragmatic necessity may sometimes be afforded greater weight than

certain ethical considerations, but does not eliminate them, as discussed in the following section.

2.5.1 Therapeutic misconception

Ethical arguments for the separation of clinical and research activity are predicated mainly upon concerns that the integration of the two can lead to coercion of vulnerable persons and can perpetuate the 'therapeutic misconception' (Appelbaum *et al.*, 1982) whereby study participants are convinced that they will receive at least some therapeutic benefit, even if they have been told –and claim to understand – that this is quite categorically not the case (Fisher, 2006b).

Those who advocate the separation of research and clinical activity, argue that by merging them and by conducting them in the same space, or under the auspices of the same clinician(s) one denies the differences previously noted (Brody and Miller, 2003; Fisher, 2006b). Fisher suggests that the conflation of research and clinical roles gives rise to a 'procedural misconception' (p. 253) which occurs when a situation is constituted by aspects which are both familiar, such as the hospital setting and clinicians, and foreign – such as clinical research. She considers that this in turn contributes to the therapeutic misconception (Appelbaum *et al.*, 1982).

A further factor potentially contributing to the therapeutic misconception is the notion that study participants derive benefit from participation, regardless of randomisation (Chalmers, 2000). Those who advance this claim suggest that such a benefit might be due to the additional monitoring and superior care associated with academic centres of excellence, but such findings are not consistent (Edwards *et al.*, 1998), and an 'inclusion benefit' has not been verified (Lemaire, 2004b; Peppercorn *et al.*, 2004). It is evident then, that the therapeutic misconception is not exclusive to patients and the lay public, and cannot therefore be attributed solely to differences between lay and professional knowledge or understanding. For example, in a study involving Emergency Medical Service (EMS) providers, 61% of respondents stated that investigators in medical research would act in patients' best interests even though, by definition, this cannot be the case (Schmidt *et al.*, 2009).

Despite these concerns, the fact that a patient/participant holds a therapeutic misconception does not in and of itself render a study unethical and failure to dispel such a belief does not necessarily invalidate an individual's consent (Sreenivasan, 2003). Further, Snowdon et al (2007) suggests that a potential participant's or proxy's

ability to separate research from clinical practice does not necessarily equate to an enhanced decision making process. On the contrary, she suggests that for some, the process of clarifying the distinction between the two may propagate 'an overstated sense of risk and threat' (p.199), resulting in what she terms an 'injurious misconception' which, like the therapeutic misconception, may give rise to a 'decision borne of misunderstanding' (p.199), rather than an autonomous and voluntary choice (Snowdon *et al.*, 2007). In addition to these potential misunderstandings however, the patient's (or proxy's) vulnerability may also influence their decision making, particularly where clinicians occupy dual roles, as discussed below.

2.5.2 Coercion of vulnerable patients: dual roles and conflicting responsibilities

When participants are patients, research can be difficult because of their vulnerability and lack of power in the clinical situation (Holloway and Wheeler, 1995). If patients and their families cannot, or do not, always distinguish between routine care and research, they will usually do what the doctor recommends, based on the expectation that the duty of the treating physician is to promote and safeguard their welfare. This is a particularly sensitive issue in the case of critically ill patients whose decision making capacity is often compromised to the extent that it may impact upon the voluntariness of a decision made to enter a clinical trial when their treating physician occupies the dual role of clinician-investigator (Silverman and Lemaire, 2006).

Whether the clinician-investigator is a doctor, nurse or other healthcare professional, there exists a duality and dichotomy of roles, attempting to balance research integrity with the welfare of the individual (Beale and Wilkes, 2001; Karigan, 2001). A quandary exists between professional responsibility to perform the role of caring and maintaining patient welfare, versus contributing to the scientific and medical knowledge base with the aim of benefitting not (only) current patients but the future patient population. Renée Fox describes this dilemma very clearly in her seminal work 'Experiment Perilous' and refers to a 'rather complicated moral titration process' undertaken by clinician-investigators (Fox, 1998 p.241).

Silverman contends that there may be an element of coercion if patients or their family members perceive that a decision to decline participation will adversely affect the delivery of care (Silverman and Lemaire, 2006). He suggests therefore, that someone other than the treating physician should obtain informed consent, whilst others

advise that the roles of treating physician (or team) and researcher should be separated entirely (Beecher, 1959; Spiro, 1975; Brody and Miller, 2003). In order to avoid deception or exploitation of study participants, it is important that they are made aware of the difference between research participation and care (Brody and Miller, 2003). One way of explicating this difference is to employ dedicated research staff, often nurses, to undertake the day to day administration of clinical trials, although this too presents dilemmas, which I explore in the following section.

2.5.3 The role of the clinical research nurse

It is 40 years since the Briggs Report identified a need for formal recognition of 'research mindedness' among nurses (Briggs Report, 1972). Since then, numerous publications and initiatives have advocated a broadening scope of professional practice, including the development of research roles (United Kingdom Central Council for Nursing Midwifery and Health Visiting, 1992; UKCRC Subcommittee for Nurses in Clinical Research (Workforce), 2007; Nursing and Midwifery Council, 2008). These publications were accompanied by a proliferation of specialist nursing roles, as nurses extended their roles to undertake traditionally 'medical' roles such as venepuncture, cannulation and prescribing. Although poorly defined, and functioning under a range of titles, one such role was that of (Clinical) Research Nurse (Deave, 2005). Clinical research nurses are registered nurses employed to facilitate and conduct clinical research; they may be based in research sites (not defined), or within a clinical environment (Jeong *et al.*, 2007; UKCRC Subcommittee for Nurses in Clinical Research (Workforce), 2007; Spilsbury *et al.*, 2008). It is noted that their role differs from that of the nurse researcher (Deave, 2005; Gordon, 2008), who not only conducts research, but is also considered central to the integration of research findings within inpatient settings (Dennis and Strickland, 1987).

In a literature review seeking to determine the nature of the clinical research nurse, Raja-Jones was unable to identify many articles examining this role (Raja-Jones, 2002). Those that exist were mainly anecdotal but most noted the issue of title confusion, and identified typical components of the role as administrator, educator, clinician/practitioner, consultant and researcher. Others have noted considerable variations in background, expertise and remit of those undertaking these roles (Deave, 2005). Deave also notes that those who enter research nurse roles, as opposed to nurse researcher roles, often do so without specific research training or expertise, and function

primarily as data collectors or research assistants, usually under the auspices of medical principal investigators. This has knock-on effects in the perception of the role, and may contribute to what some consider to be the incompatibility of nursing and research roles (Hicks, 1996).

Hicks suggests that the term 'nurse researcher' is an oxymoron. She states that the core values embodied within research are entirely different from those of nursing and that the ways in which nurses construct themselves as professionals are at odds with those characteristics required by a good researcher. More recently, similar perceptions have been noted elsewhere (Woodward *et al.*, 2007). Although Hicks' and Woodward's work refer to nurses' reluctance to undertake and/or implement the recommendations of nursing research, such incompatibility may also extend to some degree to nurses' reluctance to engage with medical research. This may also illuminate the findings of others who describe difficulties faced by those who take on research nurse roles, in distancing themselves from the clinical routine (Easter *et al.*, 2006; Fisher, 2006a). The argument that research and clinical work should not be conducted in the same environment or by the same personnel is broadened to encompass the idea that those who 'care' i.e. nurses, do not possess the requisite skills for analytic thought and vice versa.

For some, caring represents nursing's moral ideology (Smerke, 1990). Referring to Larson and Ferketich (1993), Greenhalgh defines caring as 'intentional actions that convey physical care and emotional concern and promote a sense of security in another' (Larson *et al.*, 1993; Greenhalgh *et al.*, 1998; p.927). James, presents a formula for care and suggests that it is the sum of 'organisation +physical labour +emotional labour'; she claims that the provision of care is fundamental to the nurse's caregiving role (James, 1992; p.488). It seems, however, that physical labour itself is quite specific, and is generally considered to refer to performing or assisting the patient to perform their daily activities, particularly those that are considered more intimate. In my own clinical and research experience, and noted by others, for some nurses, physical care **is** nursing (McFarlane, 1976; Leininger, 1986; Staden, 1998). A role without this aspect is therefore not considered to be 'real' nursing (Bassett, 2002) and there is often suspicion regarding nurses who wish to pursue a career outside this traditional perception of the role. This criticism has often (though usually light heartedly) been directed towards psychiatric nurses in particular, but as we will see in subsequent chapters (Chapter 5) this perception is also becoming associated with the role of the research nurse.

In opposition to the views noted above however, it is also suggested that the research co-ordinator/nurse requires dynamic creativity and strong clinical skills, sound ethical principles and exemplary interpersonal and organisational skills. He/she should be able to develop good rapport with participants, maintain accurate study records, demonstrate administrative and leadership skills and understand research terminology (Raybuck, 1997). In addition to these transferrable skills, new skills such as management of clinical, ethical and financial concerns are required. Contrary to claims of role incompatibility however, some commentators suggest that nurses are ideally placed to contribute to successful trial coordination because of their dedication to 'care work' and their nursing related knowledge and interactional skills, identifying these as facilitatory factors, rather than sources of conflict (Mueller, 2001; Mueller and Mamo, 2002; Colbourne and Sque, 2004). The liaison element of their role, between patient, principal investigator, study sponsor and administrative staff is considered vital and has, it is claimed, contributed to greater research activity in terms of number of ongoing studies and patient recruitment, retention and completion rates (Isaacman and Reynolds, 1996; McKinney and Vermeulen, 2000). Given the commonality apparent in the first set of skills noted above, Raybuck (1997), unlike some other authors, contends that '[T]he goals of nursing practice and clinical trials **are** mutually compatible' (p.18, my emphasis).

Amongst the aims of the UKCRN are noted, improving patient recruitment and retention rates, improving research coordination, improving care of patients enrolled in clinical trials, maintaining and enhancing quality and improving links between research and treatment (Department of Health, 2004c). However, there is a considerable body of work in the nursing literature pertaining to the reluctance of nurses to conduct or act upon the findings of research. Much nursing practice is still fundamentally rooted in custom and practice and is historically entrenched rather than empirically validated. Although referring to the acceptance and integration of nurse researchers (and nursing research), rather than research nurses, Mulhall suggests that in order to achieve implementation of research based practice, the process and culture of research must be embedded within the world of practitioners who are expected to utilise its outputs (Mulhall, 1997).

Earlier sections of this chapter have focussed upon theoretical, conceptual, or perceived barriers to emergency research. In the following, and final section, I review some of the motivating factors that may facilitate the achievement of the aims of the

UKCRN, and the embeddedness espoused by Mulhall, but also consider ways in which these factors may present conflicts of interest.

2.6   Reasons For Participating In Clinical Research: Motivation Versus Conflict

Motivation for undertaking research as a healthcare professional can be as diverse as the reasons for participating as a patient, and can vary at in individual or professional group level. Paradoxically, these motivating factors can also represent conflicts of interest.

2.6.1 Professional motivators

Conflicts of interest in relation to the integration of clinical care and research are not limited to those discussed previously, pertaining directly to the patient and the conflict between individual and societal benefit. Perceived to be a hallmark for good practice, quality, efficiency and innovation, research activity is often considered an indicator of professional credibility (Porter, 1993). It has thus been suggested that in the UK, research has been taken up by nursing in an effort to professionalise its activities and to proffer a means for the advancement of this social group (Mulhall, 2002). It is evident therefore, that research is far more than a means of providing evidence upon which good practice should be based. Mulhall (2002; p.49), states that research is 'not simply a value free exercise conducted to benefit patients and clients' but rather, has been 'constructed as an ideology' which some consider incompatible with the care-giving definition of nursing (Hicks, 1996).

Mulhall (2002) also suggests that since the shift of nurse training to higher education, and its metamorphosis to an academic, rather than a solely clinical discipline, the coming together of these different cultures has further highlighted a gap between research and practice. Traditionalists may not feel that nurses 'fit' into research roles, and research itself is often perceived with an element of fear (Gordon, 2008).

Whilst a motivating factor for many clinicians is the development of more effective interventions and thus the improvement of patient healthcare outcomes, participation in research necessitates acknowledgement of uncertainty, and conveying that uncertainty to the potential research participant. Thus, there are concerns pertaining to the potential impact of disclosure of study rationale and processes upon the doctor-patient relationship (Ellenberg, 1997). Traditionally afforded a position of authority and respect, it is not unusual for clinicians to experience difficulty in admitting that they do not know which treatment is best, and some may feel that to do so will damage rapport

with their patients (Ross *et al.*, 1999). Ross also notes that clinicians may perceive a loss of clinical autonomy due to the requirement to follow a study protocol.

2.6.2 Financial and reputational motivators, and external accountability

When considering conflicts within the clinician-investigator role, we are most commonly alerted to those arising between their duty to the patient and the goals of the investigation (Slyter, 1998), but there may also be other conflicts pertaining to financial, academic and reputational status of both the individual clinician(s) and the institution (Hewlett, 1996; Morin *et al.*, 2002).

Financial conflicts may relate to the provision of equipment or stock, remuneration or salary support, whilst academic or reputational stakes may include publications or the potential for promotion. The industrialisation of medical research also introduces a further potential conflict – that pertaining to the requirements of the sponsor. Academic and healthcare institutions are economically pressured to meet the goals of their pharmaceutical sponsors and may thus lose sight of the human purpose of medical research (Tzamaloukas *et al.*, 2008).

2.7   Summary

The bioethical literature suggests that a major factor restricting the conduct of clinical research in the emergency situation is the problem of securing informed consent from, or on behalf of, eligible individuals who are incapacitated. We have seen that there are some theoretical alternatives, such as deferred, proxy or waived consent, but these too are problematic, and their uptake appears limited. Whilst gaining prospective informed consent is clearly the preferred option, an obvious knock-on effect of the lack of clinical research in the emergency situation, is that research *about* emergency research is also limited, and thus alternative approaches have not been empirically explored or evaluated. Despite the wealth of theoretical and conceptual literature therefore, there remains a gap regarding the actual day to day conduct of clinical research in a hyperacute or acute clinical situation.

Although there is a developing body of empirical research about the conduct of emergency research, it is often based on hypothetical scenarios and is usually confined to exploration of reported, or intended behaviour. My research therefore aims to address this gap by means of an ethnographic study focussing upon the conduct of research activities (randomised controlled trials) in an acute stroke unit. I aim to determine whether the issues noted in the literature, namely obtaining informed consent, and the

organisation of research and clinical activity, were indeed the main obstacles encountered in practice, and whether, how and to what effect, the distinction between research and clinical practice was maintained.

I describe my methodological approach more fully in Chapter 4, but first, in the following chapter, I provide data in order to contextualise the area in which I conducted this research.

Chapter 3. Situating the Study

3.1 Introduction

In Chapter 2, I discussed the theoretical and conceptual literature pertaining to difficulties encountered or anticipated in conducting clinical research in the emergency situation. I also reviewed the growing, but sparse, body of empirical work examining these difficulties, and alternative ways in which these issues may be addressed. Having identified that there remains a gap in the literature as regards actual conduct of emergency research within the acute clinical environment; my study aims to address some of these issues. In Chapter 4, I will outline my theoretical position and the methodological framework adopted, but first, it is necessary to situate the study in the context of the local stroke service provision, as well as current issues influencing pharmaceutical company activity in acute and hyperacute stroke research.

The issues postulated in the literature focus mainly upon difficulties in obtaining informed consent, as well as ethical issues associated with the conflation of research and clinical activity. Here, I describe the context in which I sought to observe the impact (if any) of these factors. I briefly describe practicalities and policies relating to the admission and management of patients in the acute stroke unit, the working arrangements of clinical and research staff therein, and recent changes in availability of, and arrangements for, the conduct of clinical research. I begin by outlining the way in which suspected stroke patients were received at the study site.

3.2 Recognition, Referral, And Admission Of Suspected Stroke Patients

Clearly the number of patients participating in research is determined by the number eligible to do so, which is dependent upon early recognition of stroke symptoms, appropriate referral and prompt diagnosis and intervention. Although few treatments have so far been demonstrated to be effective in the treatment of acute stroke, those that are, i.e. thrombolysis, and those under investigation (e.g. neuroprotectors) have been shown to be, or are mostly likely to be, effective if administered immediately post ictus (stroke event). The optimum time period is considered to be within 3 hours, when there may be a possibility of restoring blood flow to the ischaemic brain, thus preventing (further) infarction (Marler *et al.*, 2000). Therefore, the single most important factor in optimising outcome for an acute stroke patient is prompt transfer to an appropriately equipped stroke unit (Stroke Unit Trialists'

Collaboration, 2004). Despite increasing emphasis on the notion that stroke is a medical emergency of similar magnitude to a heart attack and that 'time is brain' (Hill and Hachinski, 1998), delays in time to admission, or time to investigation, have sometimes meant that otherwise eligible patients have been unable to receive thrombolysis (in the clinical context), and time delays may similarly influence study eligibility. Locally, in the study site examined, steps had been taken to address this issue, and are outlined below.

The Acute Stroke Unit (ASU) where I carried out my fieldwork was housed in Nearstreet Hospital, one of three hospitals comprising the Northend NHS Foundation Trust. Despite housing the ASU, Nearstreet had no accident and emergency (A&E) facility. Until the establishment of the Rapid Ambulance Protocol in 1997 (Harbison *et al.*, 1999) patients admitted by ambulance were often taken to the A&E facility at Union Hospital, prior to transfer across the city to the ASU, a practice which delayed assessment, diagnosis and treatment.

The rapid ambulance protocol aimed to bypass unnecessary transfer to the A&E facility at Union Hospital, thus expediting admission to ASU of those patients who contacted the ambulance service directly by dialling 999. Following introduction of the protocol, when attending a call to a suspected stroke patient, paramedics undertake assessment using a stroke identification instrument known as the Face, Arm, Speech Test (FAST) (Harbison *et al.*, 2003). If this test is positive, the crew contact ambulance control, who notifies the Emergency Assessment Suite (EAS) at Nearstreet Hospital that a suspected stroke patient is en route.

Patients who contact their own general practitioner can be referred by telephone to the EAS via a centralised admissions office. If stroke is not diagnosed by the ambulance crew, or if stroke is diagnosed but head injury is also suspected, or the patient's Glasgow Coma Score (GCS) is less than eight, patients are taken to A&E in the first instance (not least because neurosurgery is located at the same site as A&E). Self referring patients who continue to present via A&E are assessed and resuscitated as required, prior to transfer to the EAS or ASU.

When the EAS is notified of the impending arrival of a suspected stroke patient, they contact the Stroke Research Team and/or the stroke nurse practitioner, who then attend to undertake initial patient assessment and liaise with the medical team. The patient trajectory is outlined in Fig 1 overleaf.

STROKE ONSET

PATIENT / OTHER CONTACTS
GP OR AMBULANCE SERVICE

PATIENT SELF REFERS
TO A&E

PATIENT SEEN BY
GP/PARAMEDICS

PATIENT SEEN BY A&E
PERSONNEL

GP/AMBULANCE CONTROL
NOTIFIES EAS OF PENDING
ADMISSION

A&E INFORM ASU VIA
CENTRAL ADMISSIONS AND
ARRANGE TRANSFER

EAS STAFF ADVISE STROKE TEAM

PATIENT SEEN BY STROKE TEAM

ARRANGE
CT SCAN

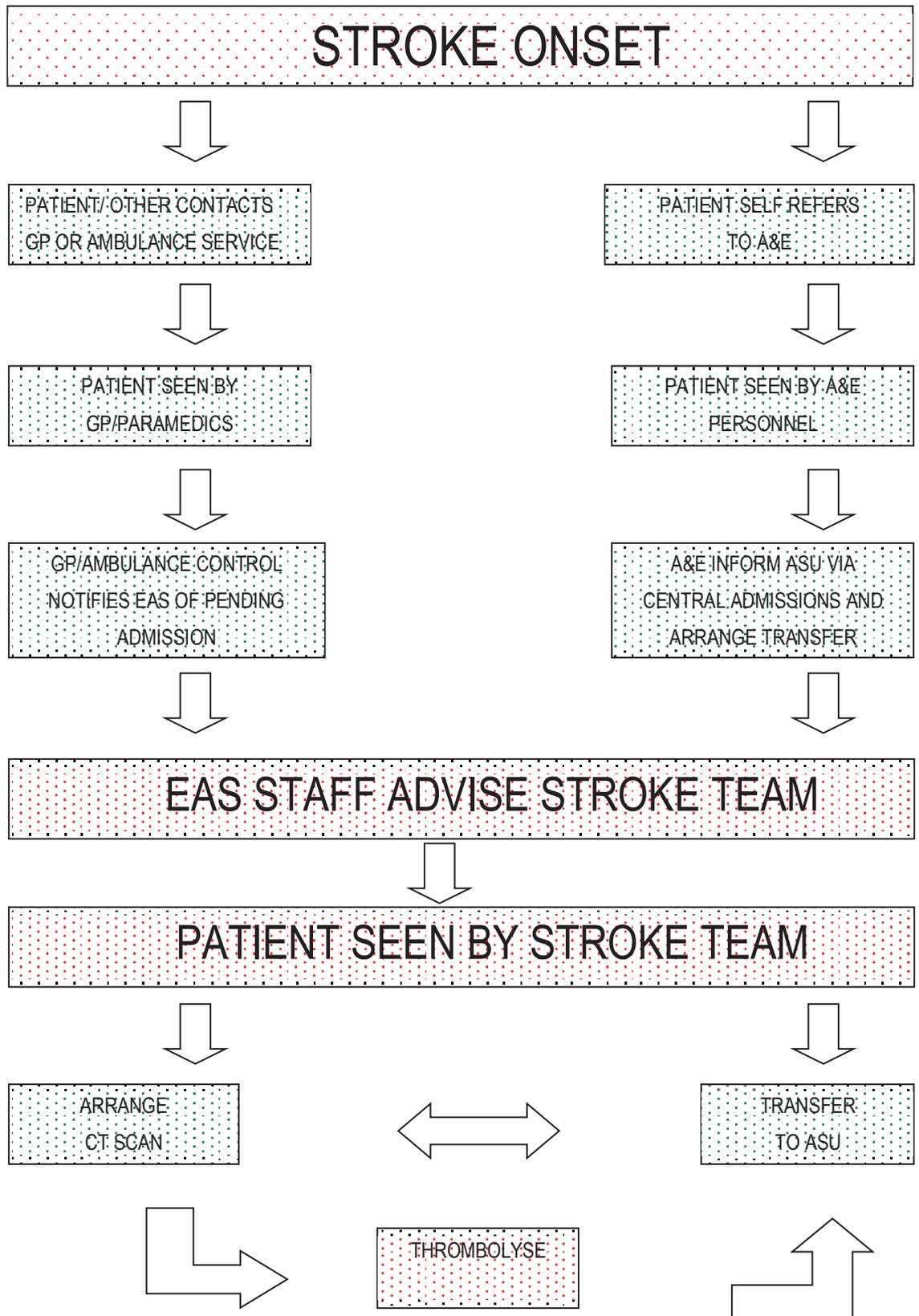TRANSFER
TO ASU

THROMBOLYSE

Figure 1: The patient trajectory

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Involvement of the Stroke Research Team in the initial assessment of suspected stroke patients came about at least in part, because of the way in which the clinical provision of a thrombolysis service has developed. Thrombolysis was initially offered only either off licence, on an individual patient basis, or as part of a RCT (e.g. ECASS II). Research nurses, and for a time, the stroke nurse practitioner (in order to minimise costs and duplication of effort), were responsible for assessing stroke admissions for study eligibility, and as such underwent specific training in stroke assessment. Although early thrombolysis is now established as a proven therapeutic intervention (Hacke *et al.*, 2004) and has become part of the clinical service provision, the skills and training of the research and specialist nurses are still utilised in the initial assessment of new stroke admissions.

3.3 Potential External Influences Affecting Research Activity

3.3.1 Effects of changes in pharmaceutical companies' activity

Aside from the number of people referred and admitted with stroke, another factor influencing recruitment to RCTs of acute and hyperacute stroke therapies is the perceived decline in the number of studies in recent years. In the six years prior to commencement of my fieldwork, approximately 15 acute and hyperacute studies were conducted at the study site, compared with three currently ongoing (see Chapter 5).

Several reasons were offered for the dearth of research activity. A 'chicken and egg' situation appeared to exist, whereby it is difficult to determine whether there are fewer studies because of previous problems with recruitment (due to ethical and regulatory restrictions in the UK), or whether the recruitment rate has diminished because inclusion criteria have become more restrictive over recent years.

Negative outcomes, particularly in some of the neuroprotective studies, were likely to have been due to the long time windows for treatment, which meant that patients were treated beyond the point at which treatment was likely to be effective. Further, many previous studies were too small to demonstrate an effect. Resultant changes in recruitment criteria, particularly with regard to the tightening of the time window, have in turn reduced the potential number of participants (Kidwell *et al.*, 2001).

Whilst these changes have arisen on the basis of scientific evidence, there are also financial considerations. The stroke population is very heterogeneous with numerous comorbidities and physiological instabilities; therefore a large gap exists between

practice and controlled animal experiments. From an industry point of view, homogeneity of sample is preferred in order to maximise chances of demonstrating an effect, but restrictive criteria may mean that it takes longer to recruit an adequate sample size, thus driving up research costs. Conversely, some funders prefer a more pragmatic approach whereby recruitment criteria allow for the inclusion of all patient groups likely to receive a treatment should it become licensed. Such a design reflects variations between patients that occur in real clinical practice, but as such, demands a larger sample size.

Other financial considerations may also impact upon the pharmaceutical industry's investment in research activity at specific sites. A general lack of awareness of stroke signs and symptoms, and deficiencies in stroke care in the UK (Intercollegiate Stroke Working Party, 2002; National Audit Office, 2005; Intercollegiate Stroke Working Party, 2009; National Audit Office, 2010), has meant that only a limited number of sites are adequately resourced to participate in acute and hyperacute stroke research. Although these centres usually achieve satisfactory recruitment rates, the cost of establishing an infrastructure to manage such a small number of sites is prohibitive, and therefore some pharmaceutical companies prefer to concentrate their efforts elsewhere.

Historically, commercial studies were well remunerated and usually generated sufficient income to employ a full time research nurse. This is no longer commonplace, and the decline in stroke research activity among the bigger pharmaceutical companies means that funding is no longer available to support staff on 'soft' money. Nevertheless, none of the research nurses expressed concern about their job security, although some of the clinical staff quizzed me about the financial precariousness of contract research work.

3.3.2 Regulatory influences

Another financial consideration beyond the direct control of the host organisation is that relating to the implementation of the European Working Time Directive (1993) and its subsequent amendment (2003). The restrictions on working time and stipulations regarding rest time are yet another reason why it is not currently cost-effective to offer an on-call service for research purposes because, in effect, more staff are required to provide adequate cover. Even without provision of an on-call service the research team

struggled to provide cover for holiday, sickness or other unexpected absences, therefore offering extended availability was not feasible.

3.4   Impact Of Local Stroke Management Policy

In the case of studies such as ECASS III (Third European Cooperative Acute Stroke Study - administration of rtPA up to 4.5 hours post ictus), the clinical policy of thrombolysing all eligible patients within three hours of ictus reduced the pool of study eligible patients. No patients were enrolled to this study at this site, despite having been open to recruitment for over two years. This was primarily because patients who may have been eligible, were usually assessed within the three hour time frame that allowed them to receive thrombolysis as per clinical practice. It would therefore be unethical to delay their treatment and/or introduce the possibility of them receiving placebo. Recruitment was further restricted by what some considered to be an unwritten policy not to include a patient in more than one study, although this need not be problematic where one of the studies is non-interventional.

3.5   Personnel And Resource Issues

3.5.1 Clinical staff

Inpatient stroke care is usually physically demanding and labour intensive with many patients requiring maximum nursing care. Almost all of the participants in my study commented that staffing levels on ASU were suboptimal for the purposes of daily management, let alone taking on additional workload related to the conduct of clinical trials. The ASU is a 30 bedded ward, but for most of the duration of my fieldwork, six beds were closed due to inadequate staffing levels. The clinical team operated a shift system comprising:

- Early shift: 07.15 – 14.15hrs
- Long day: 07.15 – 20.15hrs
- Late shift: 12.45 – 20.15hrs
- Night shift: 20:00 – 07:45hrs

It was usual to have three qualified and four non-qualified staff on an early shift, and two qualified and three non-qualified on a late shift (including those on a long day, who spanned both shifts). There were usually three nurses on duty overnight. During my field work there were usually two student nurses allocated to the ward. They were not always present on the ward however, and in any event were supernumerary, so the

figures noted refer only to qualified staff and healthcare assistants. Allowing for breaks, ward rounds and accompanying patients visiting other departments, this meant that the workload was considerable.

3.5.2 Research staff

The research nurses were funded either from payments made to the Trust by the sponsor companies, or more recently, by the Stroke Research Network. Funding from sponsor companies is made on either a 'per patient' basis, depending on recruitment rates, or pro rata, according to the amount of time a nurse is expected to allocate to a particular study. This usually means that it is necessary to host more than one study in order to generate enough funds for a whole time equivalent research nurse or research fellow.

In 1999, when Nurse Higgs (one of the key informants) took up his research post, research activity in the ASU generated sufficient income from pharmaceutical company funding to fund three full time and two part time research nurses, and a research fellow. This funding also supported provision of a limited on-call service , if not 24 hours per day, at least from 17:00hrs – 23:00hrs (it was unusual, though not impossible, for stroke patients to be admitted during the night as those who have a stroke during the night are generally unaware of this until waking in the morning). Although the on-call service was primarily to support research recruitment it also facilitated the provision of clinical thrombolysis. The volume of research made it possible to employ more staff, which in turn enhanced recruitment rates. This generated a positive spiral of activity, raising the profile of the research team and awareness about ongoing studies. Now that thrombolysis is purely a clinical service and there are fewer research nurses, it is not feasible, due to cost and resources, to offer an on-call service, and thus it has not been possible to sustain the previous level of research activity.

At the time of my fieldwork there were initially two full time research nurses and a research fellow. On completion of her one year contract the junior research nurse was replaced, after a brief hiatus, by two research nurses, seconded on a job share basis from research posts in another specialty. There were insufficient studies running simultaneously to warrant the cost of an on-call service and thus the research nurses usually kept regular working hours of 09:00 -17:00hrs, Monday to Friday. They occasionally worked extra hours but were expected to take time in lieu rather than receive overtime payments, which then also impacted upon further recruitment, as it

reduced their availability. This situation arose partly from limited availability of funds to support such a service and partly as a result of the European Working Time Directive, as noted previously.

3.5.3 Availability of resources/facilities

In 2004 government targets recommended that suspected stroke patients should undergo diagnostic CT scanning within 24 hours of hospital admission (Intercollegiate Stroke Working Party, 2004). This was reduced to three hours, in view of the fact that diagnostic imaging is required prior to initiation of thrombolysis, which should be commenced within three hours of ictus. The National Stroke Strategy, following the lead of the NICE guidelines on head injury management, recommends that suspected stroke patients should undergo urgent CT scanning within 60 minutes of admission, with skilled radiological and clinical interpretation available 24 hours a day (Department of Health, 2007; Intercollegiate Stroke Working Party, 2009) but is as yet some way from meeting this target. Despite these targets, some units still did not have 24 hour immediate access to CT scanning facilities and even those that had the facilities did not always have adequate personnel. At the time of my study, even at Nearstreet, with its Acute Stroke Unit, they relied on a non-resident, on-call radiology service outside office hours, and shared this facility with the rest of the hospital.

3.6   Conclusion

In this chapter I have outlined a number of organisational or external factors that may influence working practices and the integration (or otherwise) and conduct of research activity within the Acute Stroke Unit at Nearstreet Hospital. I provide these data as background to the more detailed analysis which follows in Chapters 5-8, but before moving on to this, I describe my theoretical position, the methodological framework underpinning my study and the methods by which it was undertaken.

Chapter 4. Methodological Framework and Methods

4.1 Introduction And Description Of The Research

The aim of this thesis is to explore how recruitment to randomised controlled trials of acute and hyperacute treatments for stroke is achieved in an acute stroke unit. Research in this area is considered by many to be hugely problematic, particularly in the case of patients who are unable to fulfil the requirement for prospective informed consent. In Chapter 2, I illustrated the perceived difficulties in conducting such research. The focus falls largely upon the requirement for informed consent and its resultant ethical and legal implications. Centrally, this is largely drawn from theoretical and conceptual literature or from expert opinion; there is little empirical work to confirm or refute these claims. As noted in Chapter 2, research about emergency research recruitment tends to focus upon the quality of informed consent, and does so by measuring information given, recall and understanding. Medicolegal concepts of consent tend towards a positivist stance, whereby the appropriate information for obtaining consent is treated as an almost tangible 'thing' which is 'given' to patients or family members during a specific 'event'. Research recruitment however, including obtaining consent, is more than an isolated event (Goodenough *et al.*, 2004; Sin, 2005); it is a process beginning before, and continuing after, the face to face, researcher-participant discussions about interventions, schedules and potential risks and benefits. This pragmatic study therefore aims to examine not an event but a process, constructed through the formative actions of participants, including patients and their families and healthcare professionals involved in clinical and research practices within a research active, acute stroke unit.

I begin from the perspective of social constructionism (Berger and Luckmann, 1966), a theoretical orientation drawing upon philosophy, sociology and linguistics and underpinning critical psychology, discourse analysis, deconstruction and post-structuralism (Burr, 1995). Social constructionism is interested in the social practices engaged in by people and their interactions with each other. More specifically, but not exclusively, I draw on the assumptions of symbolic interactionism as espoused by Mead (1934) and Blumer (1969b). I outline the reasons for adopting this approach below.

4.1.1 Methodological issues and framework

The approach of this thesis is located within a relativist ontology and a subjectivist, constructionist epistemology (researcher and researched co-create

understandings). I adopt naturalistic methodological procedures and aim to address issues of credibility, transferability, dependability and confirmability rather than internal/external validity, reliability and objectivity (Denzin and Lincoln, 2005a). Drawing upon the assumptions of symbolic interactionism I employ ethnographic methodology as a mode of inquiry congruent with this paradigm.

4.1.2 Social Constructionism

Social constructionism can be considered both realist and relativist or anti-realist. It rejects the notion that the person possesses any 'pre-given content' but purports that one 'becomes' a person by means of one's interactions with and toward objects within one's 'life-world'. Its proponents are interested in the performative role of language and in the social processes engaged in by people and their interactions with each other. According to constructionism we do not 'create' meaning from thin air, but construct it from 'materials' that are available to us i.e. things that are 'always, already there' (Heidegger, 1962; Merleau-Ponty, 1962) - the world and objects in the world. Potter (1996) contends that language does not 'reflect' reality, rather it is a representation of reality, of which there may be many. He rejects the 'mirror' or 'correspondence' model of language and instead draws upon the metaphor of the construction yard, whereby a house is built, but depending upon the persons building it may consist of different materials, employ different techniques and result in a different end product (Potter, 1996). Similarly we construct reality by the ways in which we talk or write about it. This means that accounts do not simply represent reality by mirroring 'what is there' but rather the sense we make of them (Crotty, 1998; p.64). An extreme constructionist view would be that there can be no 'objective fact', but as noted somewhat more subtly by Rose: 'The realities that are fabricated, out of words, texts, devices, techniques, practices, subjects, objects and entities are no less real because they are constructed'; what is perhaps more important than what things 'are' is how they are 'made to work' (Rose, 1998; p.168).

Crotty (1998) (and others) also notes that there is some dispute as to whether social constructionism denotes 'the construction of social reality' or the 'social construction of reality' (p.54). The argument for the former notion would be that physical objects exist whether or not any individual is aware of their existence and thus such objects are not 'socially constructed'. The latter assumption however, contends that constructionism refers to **meaningful** reality and thus makes epistemic rather than

ontological claims, i.e. although a chair may exist as a physical object independent of anyone's consciousness of it, it only exists **as a chair** when conscious beings construe it as such. Thus a chair, like social class, is indeed socially constructed, this does not however render it any the less 'real'. In relation to the area of study in this thesis, a positivist argument may be that the pathophysiological diagnosis of 'stroke' is not constructed but is defined by physical evidence arrived at by means of medical and scientific techniques. Nevertheless, what patients, families, and healthcare professionals perceive to be a stroke, and the meanings therein, are constructed from their experiences, knowledge and perceptions, which are in turn contingent upon historical and cultural factors. For example, lack of awareness of stroke treatments and fatalistic perceptions of outcome may contribute to the delay observed in seeking medical advice. These issues of interpretation and meaning are taken further within the tradition of symbolic interactionism which I outline further in Chapter 4.1.3.

Social constructionism can be considered to be relativist because it is open to the possibility of multiple realities and the absence of 'ultimate truth'. It suggests rather, coexisting, multiple and varied 'situation-dependent ways of life' (Burr, 1995; p.9). Different people, even within the same environment inhabit different worlds, which constitute different ways of knowing and different sets of meanings. Thus, separate realities are experienced and presented, depending upon the standpoint taken (Plummer, 1996).

According to Gergen (1985), and summarised by Burr, social constructionism is founded on one or more of four basic assumptions, namely:

- Social constructionist inquiry takes a critical stance towards taken for granted knowledge, challenging the view that conventional knowledge is based on objective, unbiased observations,
- The ways in which we understand the world are historically and culturally specific,
- Knowledge is sustained by social processes; people construct their knowledge of the world between them,
- Knowledge and social action are interlinked.

(Burr, 1995; p.3-5)

It should be noted however that as any individual proponent may adopt any or all of these assumptions, any commonality between those identifying themselves as such is

merely a 'family resemblance' rather than a definitive identifying feature (Burr, 1995; p.2). I describe below how these assumptions relate to my research.

I have shown in Chapter 2 that despite the paucity of empirical evidence it is generally accepted that emergency research, including acute and hyperacute stroke research, presents ethical and regulatory dilemmas for those involved in their conduct and that inadequate resolution of these dilemmas is assumed to contribute to the difficulties in enrolling patients to such studies, and consequently their failure to demonstrate an effect. In the main, these dilemmas are seen as related to the maintenance of respect for the autonomy of patients who, due to functional or cognitive impairment relating to the stroke, are unable to provide prospective informed consent for study involvement and are therefore considered ineligible for participation. In relation to the first of the assumptions noted above, my research will challenge the notion that informed consent is the main obstacle to undertaking emergency research, that autonomy is the foundational ethic and that exclusion (from clinical research) is the appropriate default position.

This is related to the second assumption regarding historical and cultural specificity. I suggest that these commonly perceived difficulties are not necessarily the only, or even the main barriers to successful patient recruitment, but that they are perceived as such in a society that gives prominence to individualism, the self, and autonomy above other values. Historical and cultural changes have altered our perception of medical and nursing professions, patients and their rights, and have promoted the notion of the 'agentic' individual (Bandura, 2001). Agency is important to those living in a culture influenced by Judaeo-Christian traditions that emphasise personal choice, and therefore the language of such a culture is that of choice, free will, autonomy, personal strength or weakness (Burr, 1995). This may not be the case in other cultures however, such as those based on Buddhist philosophy, which emphasise the nonexistence of the bounded self (Hughes, 2007) or in those where a 'duty-based' rather than 'rights-based' worldview predominates, such as in South Asian bioethics (Coward, 2007). As noted by Geertz, our construction of the individual is not universal. He states:

> 'The Western conception of the person as a bounded, unique, more or less integrated motivational and cognitive universe, a dynamic centre of awareness, emotion, judgement and action, organised into a distinctive whole and set contrastively against other wholes and against a social and natural background

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is, however incorrigible it may seem to us, a rather peculiar idea within the context of the world's cultures' (Geertz, 1974; p.31).

Even within our own culture, not all 'people' have always been considered 'persons' in a legal or political sense, and have therefore not always been able to exercise agency. Whilst Geertz is concerned with alternative concepts of personhood, historical and cultural factors also contribute to the fluidity of other notions and also share a reciprocal relationship with the development of knowledge. This brings us then to the third assumption of social constructionism, that knowledge is sustained by social processes and that people construct their knowledge of the world between them, Cromby notes that:

> '[i]t is the social reproduction and transformation of structures of meaning, conventions, morals and discursive practices that principally constitutes both our relationships and ourselves' (Cromby, 1999; p.4).

Thus, in the context of this study, what people understand about the experience of stroke or the process, practices, and nature of research may be said to be derived from their interactive experiences. The way that stroke patients are managed and cared for has changed significantly in recent years, with the development of medical knowledge and scientific diagnostic and therapeutic techniques, and this will influence subsequent perceptions of the nature of stroke and those affected by it. For example, the wife of a patient suffering a stroke today may have a very negative outlook regarding his prognosis if she has previously experienced say, a grandparent suffering a stroke when interventions, whether curative or rehabilitative were less advanced. She may however have an entirely different outlook if she is familiar with someone who has undergone thrombolysis and subsequently made a full recovery.

Finally, to exemplify the assumption that knowledge and social action go together, I refer to the proliferation of guidelines and regulations surrounding clinical research noted in Chapter 2 (for example The Nuremburg Code, 1947 and the Declaration of Helsinki, 1964 and subsequent), and the way in which they demonstrate and arise from 'punctuated equilibrium' and 'moral panics' (Fitzgerald, 2005). A recent example can be seen following the TeGenero 1412 incident at the Northwick Park Hospital in 2006. The incident in which six young men suffered serious adverse events whilst taking part in a Phase 1 pharmaceutical study prompted an investigation and subsequent report from the MHRA Expert Scientific Group on Phase One Clinical Trials. Their report, published in December 2006 made 22 recommendations for

changes to the way in which 'first-in-man' Phase 1 studies are reviewed and conducted in order to increase the safety of future clinical trials involving first human exposure to agents with potential high risk (MHRA., 2006; Stobbart *et al.*, 2007). This example simultaneously illustrates the effects of the 'controversy machine', whereby crisis cases and 'moral panic' precipitate regulatory change whilst also demonstrating how knowledge and social action are indeed interlinked.

4.1.3 Symbolic Interactionism

Sharing similar epistemological claims to those of constructionism, symbolic interactionism arises from pragmatism and the social philosophy and social psychology of G.H. Mead (1863-1931). For the pragmatist, practical, problem solving application is paramount. Pragmatism, constructionism and symbolic interactionism, all take account of the historical and cultural contexts of meaning, acknowledging that there is not necessarily one, or even multiple truths that will be so for all time and in all locations (geographical or cultural). Embedded in the reality of life, pragmatism is concerned first with the individual's direct experience of the world which s/he inhabits. Echoing Kant (1929), the pragmatist view suggests that the existence of an ultimate reality cannot be known, and thus we have to make do with a sufficiency, rather than a totality, of understanding. Pragmatism therefore purports that nothing is inherently true or false, but that ideas or theories can be treated 'as if' they are true, **if** to treat them thus makes the world 'work better'. Contrary to accusations of extreme relativism, this means that a *laissez faire* attitude is avoided because ideas such as 'the earth is flat' would be rejected, because believing so would not 'make the world work better' than believing it to be round.

Symbolic interactionism has been described as 'pragmatism in sociological attire' (Crotty, 1998; p.62). Although attributed largely to Mead, his work was subsequently and posthumously published and taken forward by Herbert Blumer, who coined the term and presented three basic interactionist assumptions:

- That human beings act toward things on the basis of the meaning that the things have for them;
- That the meaning of such things is derived from, or arises out of, the social interaction that one has with one's fellows;

- That these meanings are handled in, and modified through, an interpretive process used by the person in dealing with the things he encounters.

(Blumer, 1969a; p.2)

Arising from pragmatism, symbolic interactionism is based on the precept that we are constructed as persons by means of our interactions(s) within our society and via the use of 'significant gestures' - primarily language and other symbolic tools. Mead (1934) suggested that the use of language allows the human actor to engage in an internal dialogue in which he is both an acting subject and object of self and other. Mead identifies the 'I' as the origin of action, whilst the 'Me' is the object of self awareness. This dichotomy, as well as allowing the actor to interpret and define his own actions, also enables him to take the role of the other and to imagine another's responses to those actions. Thus he is able to monitor and modify his own behaviour according to the other's anticipated or perceived perceptions. His actions are therefore not merely a process of stimulus-response but involve definition and interpretation. Furthermore, the 'me' is the 'self made visible' but may be displayed differently in a number of social contexts. For example, one presents a different 'self' in the company of friends, employers, children etc. However this is neither automatic nor deterministic but represents a response to one's interpretation of the current 'reality'. Each time we interact with another the 'other' summons up a different 'self' (Rock, 2001) - but even so, this is not to say that the same 'other' will always summon up the same 'self', as a performance will always be edited or modified according to the situation. For example, as I will discuss in Chapter 8, whilst some clinician-researchers are able to freely switch between their clinical and research roles within the same patient/participant encounter, others remain firmly fixed in either one role or the other, sometimes in order to fulfil the expectations of the patient/participant, but at other times completely at odds with them.

In conjunction with this social production of the self, symbolic interactionism proposes that the 'world' of an individual or group is composed of 'objects' and that these too are socially constructed by means of our interaction both with the object, and with others who also act toward the object. An object is therefore defined in terms of the meaning that it has for any given individual, and may thus be different for different individuals. To employ an example from my data, a patient, for the radiographer is someone upon whom a diagnostic procedure must be performed; for the research nurse

both patient and potential study participant, and for the patients' family, husband, bread-winner and now vulnerable, sick person.

The enrolment of patients in clinical research involves communication of often complex and unfamiliar information and concepts to and between patients, families and distinct but related professional groups. Focussing upon issues such as language, communication, inter-relationships and community, symbolic interactionism is therefore an appropriate approach within the context of my research. Its central precept is its focus on the views and meanings of those studied rather than those imposed by a detached observer. Unlike a more general social constructionist approach symbolic interactionism considers interpretation and responsiveness. It goes beyond the expectation that a nurse (for example) will behave in a certain way **because** she is a nurse and because this is how nurses behave in accordance with the social construction of their role. It takes a step further, to say that the nurse behaves in this way because she has a certain goal she wishes to achieve **and** because the patient behaves toward her in such a way as to indicate that she should respond in a particular way. Similarly it cannot be said that all patients are the same and will behave in a similar fashion according to the way in which they are socially constructed. As I will demonstrate in Chapters 5, 6, 7 and 8, patients, their families and healthcare professionals behave differently in different contexts, depending upon what they wish to achieve and what is, and what is perceived to be expected of them; identity and meaning are developed within their interactions, not imposed upon, or by them.

Whilst Rock acknowledges that one determines one's own behaviour by rehearsing the action and anticipating the other's action, he also notes that we do not always have the capacity or the desire to 'check' every action in this way and so 'much interaction must be taken on trust and much must be conventionalised' (Rock, 2001; p. 29). Also, he suggests that we employ 'formalism' - a system of general forms via which we organise, interpret and identify experience. Although we may never encounter the same experience twice, Rock suggests that we refer to a general 'grammar, lexicon or logic of forms' (2001; p.28) based upon previous experiences in order to help us assess and respond to new but perhaps similar situations. Thus, for example, when approached by a doctor to participate in clinical research, unless one has already had a similar experience it is likely that one will refer to other interactions with medical professionals and will engage in the interaction accordingly. Only when one realises

that the doctor is **not** interacting as anticipated might one then modify one's own behaviour in accordance with the 'new' situation.

For symbolic interactionists, social constructionism in its broader sense may seem too deterministic, failing to allow for the ongoing interpretation and definition that is inherent in social life. Rock (2001) notes the constant action (c.f. Strauss, 1993), formulation and reformulation of ideas and questions that are fundamental to symbolic interactionism. It seems that within a specific version of the social constructionist perspective any given 'construct' changes at a macro level, in a similar way to which 'paradigm shifts' occur as postulated by Kuhn (1970). Within symbolic interactionism however, there is room for constant and continuous change and manipulation. Symbolic interactionism is perhaps therefore less deterministic and more flexible than a more general social constructionist approach.

Interactionist work appears to be popular in healthcare such as Becker's work with medical students, Atkinson's exploration of suicide, and Jeffrey's observation of categorisation of patients in casualty departments (Becker *et al.*, 1961; Atkinson, 1978; Jeffery, 1979). Fox outlines what she considers a basic property of social interaction itself, and also of participant observation:

> '... The roles that a person assumes - the ways they are defined, structured and played out - are never completely self determined. Rather, they emerge as the joint product of the dynamic relationships between an individual and other persons with whom he or she is interacting' (Fox, 1998; p.215).

Much of Erving Goffman's work (1959; 1961; 1963) is often cited as espousing the interactionist tradition although Goffman himself denied this association. Some consider the symbolic interactionist approach to be primarily suited to the investigation of micro-level social analysis, claiming that the emphasis on identities, specific situations/encounters and interpersonal management preclude analysis of social structures, institutions or organisations. Others however challenge this criticism, arguing that the approach can be equally well applied to joint or collective action involving a number of individuals, such as an army for example, as such interaction is still 'constructed' following a process of interpretation whether individual or collective (Blumer, 1969a). Similarly, responding to the charge that symbolic interactionism represents an overly individualistic approach to social life it is countered that this is not so because 'personhood and identity are inescapably social, collective and cultural

processes' (Atkinson and Housley, 2003; p.63); interactionists do not accept this micro/macro dichotomy (Plummer, 1996).

Despite Goffman's rebuttal of the interactionist label I refer to him here because some elements of his dramaturgical approach appear pertinent to my research. He refers to 'back' and 'front stage' and the way in which actors employ roles, scripts and 'stage props' (Goffman, 1959; p.32 and 124), concepts which are empirically demonstrated in Chapter 5. His concept of impression management also seems particularly relevant to my study of the interactions between researchers and other staff groups or patients and families and is further discussed in Chapters 6, 7 and 8. Goffman suggests that interaction is a performance, undertaken by the actor, and shaped by the environment and target audience. The performance is framed in such a way as to convey an impression consistent with the actor's desired goals and is thus highly dependent upon the situation. For example, undertaking a research consent interaction in the controlled environment of an outpatient clinic, compared to the unpredictability of the emergency assessment suite. In addition to these goals, individuals differ in the way in which they respond to the interactional environment; some may be unresponsive to the audience's reactions whilst others actively respond in order to elicit positive results, as I demonstrate in Chapter 8.

Other elements of symbolic interactionist thought which may have some bearing on the findings of this study include 'negotiated order theory' whereby societal arrangements and procedures are in constant flux, subject to readjustment and reassignment, and shifting responsibilities (Strauss *et al.*, 1963). Strauss et al developed this theory from their work in American psychiatric institutions, but it has since been applied to healthcare settings more generally and latterly to other organisations where there is a diversity of professional inter-relation. In keeping with their general symbolic interactionist approach, Strauss et al conceptualised social order as relatively fluid and constituted through the social act, challenging conventional organisational sociology which emphasises formality, bureaucracy and rule following. Within its application in the hospital setting, the concept of negotiated order is often applied to professional-patient or doctor-nurse interactions. Allen's work in this area however suggests that although blurring of the boundary between some nursing and medical roles may be widely accepted there is little explicit face-to-face negotiation (Allen, 1997). Like Allen, I will demonstrate in Chapter 5 that overt verbal negotiation is not always evident in practice, and that as Strauss later suggested, the term 'processual ordering' might be

more appropriate, indicating the action but not necessarily overt and explicit negotiation (Strauss, 1993). Within my research, although such negotiation is probably most evident in the role of the researchers, it can also be seen in the way in which other staff groups and patients interact with the researchers in different environments and is explored in Chapter 5 in particular, which illustrates an apparent temporary role reversal between medical and nursing staff in the initial assessment of a newly admitted stroke patient.

Having established my theoretical position, I now outline my chosen methodological approach, before presenting an account of how the research was actually undertaken.

4.1.4 Ethnography

As noted in section 4.1.1, ethnography is a mode of enquiry considered congruent with the constructionist paradigm and the symbolic interactionist approach. Developed from anthropology, a minimal definition of ethnography is that of iterative-inductive research, that evolves in design throughout the study, drawing on:

> '[a] family of methods, involving direct and sustained contact with human agents within the context of their daily lives (and cultures). The ethnographer watches what happens, listens to what is said, asks questions, and produces a richly written account that respects the irreducibility of human experience, that acknowledges the role of theory, an open-endedness in the direction of study, as well as the researcher's own role and that views humans as part object/part subject.' (O'Reilly, 2005; p.3)

More specifically, the focus is usually on a single setting or group, with data being gathered from a range of sources, including but not limited to: participant observation, informal interviews, documentary analysis, diaries, life histories, and discussion or focus groups. The predominant methods however are participant observation and informal interviews and it is this combination that I have employed within this study.

Ethnographers study behaviour in everyday contexts and in an unstructured fashion. The method is considered by some to be too subjective and individualistic, taking little account of wider historical or cultural implications. The work of the Lynds (1956) however, contradicts this claim. In consecutive studies of American culture conducted in Middletown they interpret their findings differently in accordance with the economic and historical context and their own shifting political allegiances. New issues surfaced as being more important in their second study as the Lynds' own world views had changed, thus shifting their focus from religious to political values (Lynd, 1956).

Rock (2001) places ethnographic methods, and participant observation in particular, at the heart of interactionist enquiry. As he noted, in conducting such enquiry the ethnographer is in effect doing what the participants (the 'observed') do on a daily basis - they go into the world and interpret it.

Ethnography, like symbolic interactionism, focuses upon taking the place of the other. It is:

> '…a form of research in which the social settings to be studied, however familiar to the researcher, must be treated as anthropologically strange; and the task is to document the culture - the perspectives and practices - of the people in these settings. The aim is to 'get inside' the way each group of people sees the world.' (Hammersley, 1985; p.152)

This can be facilitated by observing the group(s) in its day to day practice and also by discussing these practices in informal interviews, methods which I outline below.

4.1.5 Participant observation

Participant observation allows for close contact with actors interacting and constructing reality in their own particular meaning worlds. Only by observing, interpreting and making sense of the shared symbolic meanings and microsociological interactions which occur between 'socially situated' actors can the researcher gain an accurate understanding of their social world (Silverman, 1985). To be a participant observer is to adopt a role within the research field which enables access to the chosen setting and allows the researcher to gain a close and intimate familiarity of the population to be studied and their everyday practices, activities, beliefs and organisational structure. This requires intense involvement with people in their 'natural' and social environment. It also involves the researcher drawing upon a range of data collection methods: direct observation, conversations, structured to unstructured interviews, collective discussions, analyses of personal documents produced within the group, self-analysis and life histories, all whilst monitoring and adapting their own behaviour and its effects. Data collection is facilitated when the researcher is to all intents and purposes metaphorically 'invisible' to those observed but attaining such invisibility is perhaps best achieved by participating at least peripherally rather than making oneself conspicuous by avoiding doing so. By this I mean that the researcher should aim to become 'part of the furniture', seen and acknowledged by those she observes, but exerting minimal influence upon their activities.

Patterns, customs, conflicts, ambiguities, surface and hidden details (like taboo behaviour) are more easily observed and understood over a prolonged period of time. Participant observation is therefore usually undertaken over an extended period of time ranging from several months to many years. Prolonged immersion means that the researcher will be able to obtain more detailed and accurate information about the people he/she is studying, whilst also lessening the effect his/her presence may have on the group observed as the 'novelty' of being observed wears off.

Participant observation involves the generation and collection of an immense volume of words, events and texts including the researcher's personal thoughts, feelings and experience. The richness of observational data is fundamental to the understanding of **how** and **what** the actors do in the environment and situation(s) under examination. In order to develop a better understanding of **why** they act in a certain way however, an additional approach such as informal interviewing may offer greater explanatory depth.

4.1.6 Ethnographic interviewing

Ethnographic interviews aim to describe the cultural knowledge of the informant (Sorrell and Redmond, 1995). Whilst participant observation allows the researcher to collect data pertaining to the social group's observable behaviour, customs and daily life, ethnographic interviewing requires the collection of linguistic data from individual group members to help the researcher understand why group members do what they do. Such investigation of ideas, beliefs and knowledge shared (or not) by the group facilitates understanding of their behaviour and allows the researcher to compare what they do with what they say they do, and to explore the reasons why discrepancies might exist. The interviewer is interested in what people say they think, and how one person's perspective compares with another. This comparison helps the interviewer to identify both shared values and differences among members of a cultural group. Ethnographic interviews differ from those conducted in isolation because they are informed by and conducted within the context of the concurrent fieldwork observations and relationships. They allow for follow up and clarification of aspects of observational work. Furthermore, the ethnographer may develop a more nuanced understanding than one approaching interviewees 'cold'. The sense that the researcher has shared in the 'world' of those observed allows a greater sense of reciprocity and facilitates a relationship of trust between researcher and researched.

In this chapter so far I have outlined my theoretical position and my rationale in selecting these particular research methods. Below I present an account of how the research was conducted.

4.2   Research Design, Selection Of Methods And Conduct Of Research:

In this section I describe the conduct of the study including setting and participants, negotiation of access to the field, method of obtaining informed consent as well as detailing the actual conduct of participant observation, recording of consent interactions and the conduct of interviews with healthcare professionals. I conclude this section by considering matters of methodological rigour, ethical issues and initial reflexive considerations which influenced my decisions about how I would undertake this research. A reflexive account of issues arising during the study is presented in Chapter 4.4.

4.2.1 Setting and participants

Sampling of the setting and individual participants was purposive. I selected a research active site where I would be able to elicit the views of professionals who had experienced the phenomenon under investigation and where I would be able to observe the type of activity that I wished to study. Thus the primary study site was the Acute Stroke Unit at Nearstreet Hospital, in the north of England. The unit comprised one thirty bedded ward and admitted patients via the Emergency Assessment Unit on the same site (although this policy changed during the course of the study). During the period of fieldwork three acute/hyperacute randomised controlled trials of stroke treatments were ongoing. These studies were:

- ECASS III, a thrombolysis study aiming to assess the safety and efficacy of extending the treatment time window and recruiting patients between 3 to 4.5 hours post ictus,
- Two blood pressure management studies (using already licensed medications), one with a 24 and one with a 48 hour time window.

An acute observational study and a number of secondary preventions studies were also actively enrolling patients at this time. The unit admits around 500 patients per year, of which I was advised that approximately two patients per month are enrolled in acute/hyperacute stroke treatment RCTs. Nurse staffing levels at the time of the fieldwork consisted of a Senior Sister (Grade G), a Junior Sister (Grade F) 14 Staff Nurses at Grade E/D (one on maternity leave and one on sick leave), and 10 unqualified

healthcare assistants. There were four junior doctors at Foundation Level 1 or 2, as well as a Specialist Registrar. Five consultant stroke physicians covered the unit. In addition to the ward based staff, there was a stroke nurse practitioner and a stroke research fellow as well two whole-time equivalent research nurses (constituted differently throughout the study and explained more fully in Chapter 5). Table 1, below, provides a list of staff observed during fieldwork, identified by role and pseudonym.

Table 1: Dramatis Personae

Pseudonym	Role	Gender
Dr Green	Consultant Stroke Physician	F
Dr White	Consultant Stroke Physician	M
Dr Suni	Consultant Stroke Physician	M
Dr Brown	Consultant Stroke Physician	M
Dr Silva	Consultant Stroke Physician (formerly Stroke Research Fellow)	M
Dr Sterling	Consultant Stroke Physician (Seaford Hospital)	M
Dr Black	Consultant Stroke Physician, Principal Investigator	M
Maxine Potts	Dietician	F
HCA Dixon	Health Care Assistant	F
HCA Atkinson	Health Care Assistant	F
HCA Wilson	Health Care Assistant	F
HCA Wallace	Health Care Assistant	F
HCA Winn	Health Care Assistant	F
HCA Taylor	Health Care Assistant	F
HCA Clark	Health Care Assistant	F
HCA Mitford	Health Care Assistant	F
HCA Jackson	Health Care Assistant	F
HCA Barker	Health Care Assistant	M
HCA O'Neil	Health Care Assistant	M
HCA Simpson	Health Care Assistant	F
Dr Foster	Junior Doctor, Foundation Level 1	F
Dr Persaud	Junior Doctor, Foundation Level 1	F
Dr Jones	Junior Doctor, Foundation Level 1	F
Dr Carr	Junior Doctor, Foundation Level 1	F
Dr Bates	Junior Doctor, Foundation Level 1	M
Dr Raey	Junior Doctor, Foundation Level 1	M
Dr Scott	Junior Doctor, Foundation Level 2	F
Dr Craig	Junior Doctor, Foundation Level 2	F
Dr Modha	Junior Doctor, Foundation Level 2	F
Dr Wright	Junior Doctor, Foundation Level 2	M
Sister Mitchell	Junior Sister ASU	F
Claire Effard	Occupational Therapist	F
Steph Barnes	Physiotherapist	F

Pseudonym	Role	Gender
Mr Young	Physiotherapist	M
Research Nurse Fowler	Research Nurse	F
Research Nurse Webb	Research Nurse	F
Research Nurse Slater	Research Nurse	F
Senior Research Nurse Higgs	Research Nurse	M
Sister Hatfield	Senior Sister, ASU	F
Sr Mackay	Senior Sister, EAS	F
Marion Miller	Social Worker	F
Dr Narendran	Specialist Registrar	M
Dr Hutchinson	Specialist Registrar	M
Joanne Armstrong	Speech & Language Therapist	F
Melanie Cox	Speech & Language Therapist	F
Linda Hill	Speech & Language Therapist	F
Nurse Lynch	Staff Nurse	F
Nurse Smith	Staff Nurse	F
Nurse Kane	Staff Nurse	F
Nurse Lawson	Staff Nurse	F
Nurse Ramsay	Staff Nurse	F
Nurse Oliver	Staff Nurse	F
Nurse Norton	Staff Nurse	F
Nurse Ross	Staff Nurse	F
Nurse Cooper	Staff Nurse	M
Nurse Evans	Staff Nurse	M
Nurse Johnson	Staff Nurse	M
Sister Stone	Stroke Nurse Practitioner	F
Dr Chatterjee	Stroke Research Fellow	M
Student Nurse Mallen	Student Nurse	F
Student Nurse Parker	Student Nurse	F
Student Nurse Robson	Student Nurse, EAS	F
Mrs Bridges	Ward Clerk	F
Mrs Hirst	Ward Housekeeper	F

At the time this work was undertaken there were only a handful of units conducting similar acute and hyperacute stroke research in the UK. In his capacity as Principal Investigator (PI) for most of the ongoing studies in the unit, and as Director of the UK Stroke Research Network, Dr Black (pseudonym) advised me that the activity ongoing at Nearstreet was fairly typical of these units.

4.2.2 Gaining access to the field

Access was negotiated via the Clinical Director responsible for the Acute Stroke Unit and the lead researcher within the Stroke Unit. They acted as gatekeepers and were fully apprised of the plan of work and were also members of my supervisory team. With their approval, and prior to submitting an application for ethical opinion, I contacted senior nursing staff, research nurses, consultant medical staff and the research fellow, in order to introduce myself and the study protocol. I arranged preliminary, individual, face to face meetings so that I could address any queries that staff might have. I also discussed the proposed study with the Directorate Manager. These meetings facilitated a useful exchange of ideas and informed my plans for fieldwork and timetabling arrangements, and allowed me to secure agreement in principle and verbal consent to undertake this study at this site.

During the course of the study it became apparent that fewer patients than anticipated were being admitted and/or being approached for consent to participate in the ongoing acute and hyperacute studies. This in turn limited my opportunities to observe and record consent interactions. Therefore, following discussion in supervision meetings it was agreed that I should extend this aspect of the study to include another stroke unit in a different NHS Trust but within the same Strategic Health Authority. The site chosen was the Stroke Unit at Seaford Hospital because it was known that the same studies plus an additional hyperacute study were underway at that site. I spoke to the Consultant Stroke Physician, Dr Sterling, and provided him with my study protocol and supporting documents, following which he agreed, in principle to audiorecord any acute/hyperacute research consent interactions that he undertook. Given the timescale and logistics of the project it was not feasible for me to conduct observational work at this site. I applied for, and successfully obtained, approval from the Research and Development Department at Seaford Hospital prior to advising the Research Ethics Committee of my intention to extend the study.

4.2.3 Participant observation

Participant observation was undertaken in the Acute Stroke Unit at Nearstreet Hospital over a 13 month period from June 2006 to June 2007, in four phases, totalling 279.5 hours of observation as detailed in Table 2, overleaf.

	DATE	OBSERVED	NO. DAYS	HOURS
Phase 1	June - Aug 2006	Stroke team	12	76
		Ward		6
Phase 2	Oct-Nov 2006	Stroke team	17	39
		Ward		72.75
Phase 3	Mar-April 2007	Stroke team	9	30.25
		Ward		21.00
Phase 4	June 2007	Stroke team	6	14
		Ward		20.5

Table 2: Observation periods in the Acute Stroke Unit

The observation periods were phased in order to allow adequate time for write-up, reflection and refinement of the research plan, to allow the participating clinical area some respite from constant observation, and to avoid oversaturation of the researcher. Observational work, particularly when undertaken in such an acute environment, requires intense concentration and focus from the researcher. It can be difficult to 'switch off' from this mind set when outside the setting under observation and this can contribute to researcher fatigue. These planned breaks helped me to disengage from the observer role and thus avoid these potential problems. I also used this time out of the field to undertake further methodological and theoretical training and development.

Participants included all those engaging in daily activity on the ASU, including patients and family members. Although the more specific focus of the study was that of the research consent interactions, observation included all aspects of daily activity in order to provide contextual data. Observation took two forms; either general observation, by basing myself at the nurses' station or ward bay and observing activity within that space, or a more focussed approached during which I shadowed an individual member of staff. I undertook shadowing with three of the four research nurses and with the stroke nurse practitioner because they were more likely to be specifically involved in assessment of stroke patients, and any subsequent approach for research participation. Furthermore, clinical staff were more likely to be involved in more intimate and personal patient care, and I considered that my intrusion in this aspect of their activity was not warranted. Patients, family members, or staff were excluded from observation only if they declined to participate. Any interaction where consent was sought for participation in a randomised controlled trial of stroke treatment within 48 hours of onset of stroke symptoms was considered eligible for recording/observation (i.e. acute/hyperacute studies). Patients and family members were excluded from observation of consent interaction if verbal consent was not given for the

first stage or if written consent for data analysis was subsequently refused. Arrangements for consent for this study are detailed more fully below.

4.2.4 Consent

The ward sister agreed to display an information sheet regarding the observational aspect of the study at the nurses' station, and also on a notice board displaying information for patients and their visitors near the entrance to the ward. I also arranged with the ward clerk that she would provide copies of this document to all members of staff, and to patients and their families on admission to the ward. On a daily basis I chose to base myself either at the nurses' station, or within one of the six bedded bays. I always reaffirmed verbal consent from the nurse in charge and advised other staff that they should let me know if they did not want me to observe their activity. On occasions when I based myself in the bay areas, I confirmed with the nurse responsible for that area that he/she was happy for me to do so. I advised the patients that I would be observing the staff in the bay and depending upon their level of awareness and understanding, explained a little about the nature of the observation.

Staff members' verbal consent to allow general observation also included observation of research consent interactions occurring within the unit but with the proviso that this consent could be withdrawn at any time, and for any individual case, where this course of action was not considered appropriate. During the fieldwork periods I was based within the clinical area for three days per week and at these times I was immediately available to attend during a consent interaction. In such a case the initial approach was made by the attendant clinician who introduced me to the patient and sought verbal consent for me to observe and record the consent interaction. As the RCT consent process was the primary focus of my study it was unavoidable that the patient/family member was required to make a decision virtually immediately as to whether to allow me to observe and record the consent interaction (ethical implications are discussed later in this chapter, section 4.6). However, as soon as possible after this interaction, I visited the patient and/or family member and gave a full explanation of the study, along with an information and consent document. Written consent to transcribe and analyse these data was sought after the acute period, when the patient or family member was able to take time to fully consider the implications of participation. They were encouraged to take as much time as they required in deciding whether or not to allow transcription and analysis of the data collected.

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On occasions when I was not on site, the research nurses agreed to contact me by mobile phone to invite me to observe the interaction. This process was implemented once (unsuccessfully, see Chapter 4.3.2) during my periods of fieldwork.

As I was not present at Seaford Hospital, the arrangement for obtaining consent for audiorecording and transcription of research consent interactions was slightly modified. Dr Sterling (Consultant Stroke Physician) obtained verbal consent to record the RCT consent interaction and provided the patient with written information about my study. He advised the patient that I would visit as soon as possible thereafter, in order to explain the study more fully, and to obtain written consent to use the audiorecording. He made clear to the patient that this would not be made available to me until written consent had been secured. When the RCT consent interaction was completed Dr Sterling advised me that a recording had been made and provided me with the patient's name so that I could visit the patient on the stroke unit and seek consent for transfer, transcription and analysis of the recording. Having confirmed that consent had been obtained, Dr Sterling transferred the recording to me via encrypted electronic transfer for subsequent transcription.

4.3   Data Collection

4.3.1 Participant observation

Observations at Nearstreet Hospital were conducted on different days and at different times in order to develop a broad picture of the ward activity and the daily routine of the research staff. Individual periods of observation were usually approximately eight hours, with or without a meal break, and covered the period from 7:30am to 8:45pm. I did not observe at weekends or overnight as changes in admission policy meant that patients were not admitted during these times. Also, staffing levels were particularly poor on night duty and I considered that the potential disruption my presence may cause could not be justified in relation to any further insight I might gain. Most of the clinical staff rotated to night shift and some referred to this experience in their interviews or in informal discussion during my periods of observation.

My initial sessions on the ward allowed me to familiarise myself with the routine and environment, to introduce myself to the staff, and also allowed them to get used to my presence. Subsequently, I either attached myself to a member of staff for a span of duty or confined myself to one area of the ward and focussed on activity within that space. During the period of fieldwork the ward also accepted non-stroke patients if other

wards within the medical directorate were full. For this reason, when choosing an area of the ward for observation, I endeavoured to choose the bay which housed the most stroke patients. Although the main focus was on research related activities I observed and made field notes regarding general behaviours and interactions which would enable me to describe and examine areas including but not limited to the research culture, introduction of new projects, methods of information/knowledge sharing, teaching/training, awareness of existing studies, understanding of research concepts, integration with clinical work and resource issues.

Initially I felt somewhat uncomfortable making notes whilst in the clinical area, but this became less problematic as I became more familiar with the setting and daily routines, and as the staff got used to my presence. Nevertheless, I found it easier to make notes whilst at the nurses' station, as this was the point where most of the administrative work was conducted and therefore my activity 'fitted in'. Contemporaneous note taking was slightly more difficult whilst accompanying the research nurses in their daily tasks, not least because of their almost constant transit. At such times I relied on recording key words and phrases for further expansion later. I usually managed to develop my notes whilst the research nurses were occupied with their own administrative work when they were back in the research office.

4.3.2 Observation and recording of consent interactions

I was able to attend one acute research consent interaction, for which verbal consent for my observation and audiorecording was secured from the patient. In addition to the audiorecording I made detailed field notes about my observations. Transcription and analysis were not undertaken until written consent was obtained from the patient's next of kin, who did not feel their mother was well enough to give her own consent.

I observed, but was unable to record, two further acute consent interactions. In the first case, the research fellow had already begun to present the RCT to the patient before I arrived and therefore I made fieldnotes only. On the second occasion, the patient lacked capacity to participate in the decision making process regarding consent and on approaching the patient's family regarding study participation the discussion was curtailed by a family member before a request for audiorecording could be made. Again, fieldnotes only were made.

Two consent interactions were recorded at Seaford Hospital. In the first case, the process of obtaining consent for the use of the audiorecording proceeded according to plan. Dr Sterling advised me that he had made the recording and I visited the patient on the ward the next day to explain the study more fully and to obtain written consent. Dr Sterling accompanied me onto the ward in order to introduce me to the staff and to the patient before leaving me to explain the study and secure consent. In the second case, although the same procedure was followed and I made arrangements to visit the patient on the ward, the patient was discharged before schedule and was therefore not present on the ward when I arrived. Dr Sterling was confident that the patient wished to participate in the study and therefore obtained the patient's permission for me to telephone him at home to answer any questions about the study and to make arrangements to obtain written consent. I telephoned the patient and he confirmed that he wished to participate in the study and that Dr Sterling could pass on the audiorecording. He also agreed that I should post the consent documentation to him along with a stamped addressed envelope, and that he would forward the signed consent form by return. On receipt of the signed consent form Dr Sterling released the audiorecording to me.

4.3.3 Interviews with healthcare professionals

On commencement of my fieldwork I was able to identify all nursing and medical staff within the ASU from the nursing duty rotas and medical on-call rotas. During the period of study all nursing staff (qualified and unqualified) and consultant medical staff in the ASU, including research staff were invited to participate. Rotating medical staff and new staff were invited to participate when possible. Other healthcare professionals (e.g. physiotherapists, occupational therapists, speech and language therapists) were not approached for interview as they were not involved in ongoing research within the unit and patient involvement in the ongoing RCTs was unlikely to impact upon their workload. Furthermore, a larger sample size was unlikely to be manageable within the wider context of the study. Nursing and medical staff were invited to participate regardless of whether they had been involved in the enrolment of patients to acute/hyperacute stroke treatment RCTs as I wanted to explore their views and perceptions about research, not just their experience of it. All staff received a personalised letter of invitation and an information sheet with a return slip for expression of interest. The majority of respondents simply informed me verbally that

they were willing to participate. Participants had at least 24 hours, and in most cases several weeks to decide whether or not to take part in the interview study.

Twenty one staff members verbally expressed an interest in taking part in a face-to-face interview, none explicitly declined but 20 did not respond either in writing or verbally. Of those who expressed an interest 16 were interviewed between November 2006 and October 2007, at which point thematic saturation was considered to have been reached. The main reason for not interviewing the remaining five staff members who had expressed an interest was time restriction, both in terms of actual time available and in co-ordinating my time with the individuals themselves, one of whom had an extended period of sick leave and another of whom had a period of maternity leave.

Interviewees were given pseudonyms and are listed in Table 3 below.

Name (pseudonym)	Discipline and/or Grade	Gender
Dr Black	Consultant Stroke Physician	M
Dr White	Consultant Stroke Physician	M
Dr Brown	Consultant Stroke Physician	M
Dr Silva	Consultant Stroke Physician	M
Research Nurse Higgs	Senior Research Nurse (F)	M
Research Nurse Fowler	Research Nurse (E)	F
Research Nurse Slater	Senior Research Nurse (F)	F
Research Nurse Webb	Senior Research Nurse (G)	F
Sister Stone	Stroke Nurse Practitioner (H)	F
Sister Hatfield	Senior Sister (G)	F
Sister Mitchell	Junior Sister (F)	F
Nurse Kane	Staff Nurse (E)	F
Nurse Lawson	Staff Nurse (E)	F
Nurse Cooper	Staff Nurse (D)	M
Dr Chatterjee	Stroke Research Fellow	M
Dr Bates	Junior Doctor (Foundation Level 1)	M

Table 3: Interviewees (pseudonyms)

Face-to-face, semi-structured audiorecorded interviews were conducted at a time and location convenient to the interviewees, usually within the ASU in as quiet a location as possible or in the respondent's office. Every effort was made to avoid interruptions although on occasion the interviewee was required to be available in case of emergency. Where possible I endeavoured to conduct the interviews during my allocated spells of fieldwork but some were conducted outwith these sessions for the convenience of participants and to minimise attrition. Inevitably some interviews had to be rescheduled due to clinical considerations. With the written consent of each participant the interviews were audiorecorded. Recording did not commence until I had reviewed the information and consent document with the participant, including purpose, aims and methodological approach of the research. I also clarified at this time that the interviews formed part of my empirical work for my doctoral research.

All interviews were conducted by me, as researcher. Interviews were guided by a schedule (Appendix B) which was informed by the literature, as well as drawing upon the findings of an unpublished, qualitative study undertaken during my MSc in Health Science (Research Methods) (see Chapter 4.4.1), and my own experience as a research nurse in a neurosciences environment. As the observational aspect of the study was conducted concurrently with the interview study, ongoing observation also contributed to the iterative process of schedule development. I advised the interviewees that the schedule was a guide only and that they may discuss any aspect that they found relevant. As all interviews were audiorecorded I did not make notes during the interviews but made notes as soon as possible thereafter regarding my general impression of the process. The interviews lasted on average 60 minutes (range 29 minutes to 93 minutes).

4.3.4 Transcription of consent interactions, field notes and interviews

With the consent of participants I transcribed the audio-recordings of the consent interactions verbatim into a word processing package. The decision to transcribe the consent interactions myself was made in consideration of the fact that the environment and circumstances in which an acute or hyperacute consent interaction takes place is unpredictable and beyond the researcher's control. These factors may influence sound quality and clarity, and there may also be important contextual factors which would not be known to the professional transcriber. Furthermore, it was considered an important part of the analytic process for me to become immersed in the interaction as a complete

scenario rather than purely as a textual representation. For the interaction at which I was present I was able to transcribe the recording with reference to my field notes, which prompted recall and identification of passages which may have otherwise been difficult to decipher. Completed transcripts were then re-checked alongside the original recordings.

As noted above (Chapter 4.3.1) the extent to which I was able to make detailed notes whilst in the field varied depending upon the location and the activities ongoing at the time. Transcription and expansion of my fieldnotes was undertaken as soon as possible on leaving the field. This was usually the same day, but on some occasions when I had observed a 'late shift' (i.e. finishing at 20:45hrs) the notes were transcribed the following morning. When notes could not be transcribed immediately, I endeavoured to avoid activities that would disrupt my subsequent recall of events (Emerson *et al.*, 1995). I transcribed my notes using colour coding to identify those that were made 'in the field' and those that were substantially expanded in the process of transcription. Any details or preliminary analytical additions that were made on subsequent readings were also allocated a different colour code. Thus my writing was both a method of data collection and a method of data analysis (St. Pierre, 2005).

Interviews were transcribed verbatim, either by an external transcription service or in-house, by a secretary experienced in research and transcription. As well as adhering to the standards proscribed within the Data Protection Act, 1998, employees of the transcription service were bound by the University's data protection regulations. Transcriptions were checked alongside the original recordings by myself. They include my questions as well as the participant's responses. Short comments such as those indicating encouragement or requests for clarification were included as were nonverbal 'um's and 'er's. Pauses and interruptions were also included but intonations and speed of delivery were not recorded as this was not considered necessary for the type of analysis to be undertaken. Identifying data such as names of people, places or specific studies were changed to preserve anonymity. The transcribed documents were imported into NVivo7®, a computerised qualitative data analysis and storage package, in order to facilitate data management.

4.3.5 Data analysis and interpretation

Although I separate data collection and analysis here for explanatory purposes, they were, in practice inextricably linked as illustrated above in the evolutionary nature

of my fieldnotes. In ethnographic work some element of data analysis is inherent even at the data collection stage as the researcher is always already deciding what is or is not to be recorded. As noted above, during transcription and re-reading of my fieldnotes I used colour coding to identify notes that were made 'in the field' and those that were 'recalled later' or expanded in the process of transcription (Lofland and Lofland, 1995). Any details, theoretical notes or preliminary analytical additions that were made on subsequent readings or during coding were also allocated a different colour code as were reflexive notes (Schatzman and Strauss, 1973; Emerson *et al.*, 1995; Hammersley and Atkinson, 1995).

This process of reflective writing allowed me to develop my analysis by moving through the steps outlined below:

- Descriptive writing, which formed my initial fieldnotes;
- Descriptive reflection, which added depth to the above;
- Dialogic reflection, where I was able to consider rationale for, and possible alternatives to, my own judgements in my writing up of my observations,
- Critical and multidimensional reflection, in which I considered and presented my observations in the light of differing perspectives, professional and organisational contexts, and other relevant literature.
  (Hatton and Smith, 1995; Moon, 2002).

In analysing the data I have drawn on some of the principles of first generation grounded theory, originally referred to as the constant comparative method (Glaser, 1965), in combination with aspects of framework analysis. A later version of grounded theory (Glaser and Strauss, 1968) has tended to be associated with a more positivist, objectivist stance, whereas a more recent incarnation, proposed by Strauss and Corbin, reflects Strauss's interactionist roots and allows for greater flexibility (Strauss and Corbin, 1998). In both grounded theory and framework analysis, emergent themes or categories are identified from the data. In addition however, Strauss and Corbin (1998) also allow for interaction between researcher and the data, where the researcher openly and reflexively draws on his/her own experiences in the process of analysis (O'Reilly, 2005).

In framework analysis, data are sifted, charted and sorted according to key issues identified *a priori* from the aims and objectives of the study and from conceptual and theoretical literature (Ritchie and Spencer, 1994; Pope *et al.*, 2000). As with other methods of qualitative data analysis, framework analysis begins with a process of

familiarisation. Data are then coded (or indexed) according to the *a priori* themes, before being charted so that data can be read across the whole data set.

As noted by Charmaz, who takes a constructivist approach to grounded theory, 'conceptual categories arise through our interpretations **of** data rather than emanating **from** them' (Charmaz, 2005; p.509) and thus must take into account issues beyond the data. Thus, the decision to combine these approaches in order to undertake my analysis was a pragmatic one. As noted above, the framework approach allowed the exploration of themes identified *a priori* and considered to be important (even in their absence), whereas my analysis was also inductive, with themes emergent and emerged in and through the constant comparative element of grounded theory.

Verbatim transcription and coding of the interviews was an iterative process concurrent with further data collection. After multiple readings of the transcribed interview data I summarised each interview in order to identify general categories. Codes were applied to early stage issues derived directly from the data, in the terms used by the study participants, in accordance with the constant comparative method. Having imported the interview transcripts and fieldnotes to NVivo®, codes were applied to sections of text within each data source (interviews and fieldnotes). Subsequent data sources were interrogated for similar themes and coded accordingly. New themes were identified and added as they emerged and new sources interrogated for these also.

Following the constant comparative method, categories were generated in, and through codes, or by merging collections of codes. Simultaneously, and following the framework approach, categories were also derived from the literature and from more theoretical ideas which may not have been raised directly by the participants.

For example, in Chapter 5, I discuss the category of Temporospatial Dislocation, which emerged from the data and, as the title suggests places an emphasis on time. Passages and quotes referring to time were coded under the main heading 'time' but were also allocated subcodes (48 in total) of which 18 (Time\availability; Time\care trajectory; Time\constraints; Time\filling time; Time\initial contact; Time\management; Time\on call facility;Time\preparation; Time\recruitment; Time\related incidents; Time\time of admission; Time\'right' time; Time\time in transit; Time\time to admission; Time\time to assessment; Time\timing of investigations; Time\timing of treatment; Time\use of time) were then condensed within the category 'Temporospatial Dislocation. The multidimensional development of this category thus retains detail and

sensitivity, allowing exploration of its constituent parts, rather than as a more general code.

Reflecting the framework component of the analysis, Chapter 7 draws upon *a priori* issues such as those noted in the literature with regard to the lack of clear definition of the research nurse role and the perceived incompatibility of such roles with those of the 'traditional' nurse (Hicks, 1996; Raja-Jones, 2002; Woodward *et al.*, 2007). The individual characteristics and components described therein are then drawn together to illuminate the research nurses' performance of identity.

Having combined these analytic approaches, and demonstrating compatibility with each, categories were then summarised across all data, data were compared with data, data with categories and category with category (Charmaz, 2005). This facilitated charting of each category across all individual sources (interviews and fieldnotes) and all categories across each source (Ritchie and Spencer, 1994)

Codes and categories were applied to the expanded fieldnotes and any additional or sub-categories identified. A similar process was undertaken with the transcribed consent interactions. Moving between the data and the literature this process continued until no further categories were identified and thematic saturation was considered to have been reached.

Having described how my research was undertaken, I provide below, a reflexive account of some of the issues I was required to consider, acknowledge and address prior to, and during, my completion of this work.

4.4   Situated Reflexivity

In this section, I reflect on my values, preconceptions, behaviour or presence, as well as those of the respondents, with regard to the ways in which they may have affected the outcomes of this research (Parahoo, 1997). The researcher is an integral part of the social world studied and will always have an effect upon the research setting and its methodological rigour. Adopting a reflexive approach to one's research involves a commitment to understanding the effects of oneself upon the research scenario, an acknowledgement that the researcher is a participant in the research process rather than just a detached outsider, and an acceptance that the theories developed to explain the behaviour of those researched also apply to the activities of the researcher. As acknowledged by Blaikie (1995) there is no such thing as a value free position; there is no view from nowhere (Haraway, 1988; Blaikie, 1995), all interpretation must be seen

as subjective. In this section, I will explore how aspects of myself, namely my situatedness, foreshadowed and influenced my approach to this inquiry and reflected my particular views about patient safety, the advancement of medical and scientific knowledge, personal responsibility and moral obligation.

4.4.1 My professional background

On completion of my nurse training in 1987, I took up a position as staff nurse in a Regional Neurosciences Centre where much of my experience involved caring for neurologically compromised patients who had suffered neurotrauma or other neurological emergencies. After a period of clinical experience I took up a research post which mainly involved investigational products for the treatment of acute head injury, subarachnoid haemorrhage, ischaemic stroke or cerebral tumour; surgical intervention for intracerebral haemorrhage; and intracranial pressure monitoring studies.

During my time as research nurse and then as clinical trials manager, I developed an interest in research ethics, specifically pertaining to the difficulties of enrolling neurologically compromised patients in randomised controlled trials for which, by definition, they are unable to provide their own prospective informed consent. I witnessed a number of situations where enrolment could not be secured either because next of kin were unavailable to give their consent on the patient's behalf, or where questions were raised about the suitability of the patient's next of kin to provide proxy consent due to lack of understanding or strained family relations and socioemotional issues. For example, I once overheard the brother of a head injured patient, who was eligible for study participation, ask the patient's wife if she would marry him if her husband died. I was forced to question what impact this may have on their response to a request for study participation. Similar circumstances may occur when a family member believes that study participation may result in their family member surviving in a severely disabled state and requiring constant, and possibly costly, nursing care, rather than imminent death and the prospect of inheritance. In either case, McHale (1993) contends that assent from such a party would seem inappropriate and unrealistic.

In the light of these and other issues, I was concerned that patients may become 'therapeutic orphans' (Shirkey, 1968) and may miss opportunities for potential benefit if no next of kin was available to give proxy consent. Equally, they may be inappropriately enrolled if family members did not understand the proposed research or did not respond of the basis of what they perceived to be the patient's values and

beliefs. My concerns were all the more pointed because in the area of head injury and stroke in particular the effects are often devastating and treatments very limited; high quality research is therefore urgently required, as noted in Chapter 1.

As well as difficulties pertaining to potential trial participants, I also noted some degree of antipathy amongst clinical staff towards myself and other members of the research team, whose role involved the enrolment of unconscious patients in emergency research, and to the research protocols themselves. In an attempt to explore the nature of some of these difficulties, as part of an MSc in Health Sciences (Research Methods), I undertook a qualitative study investigating the experiences of healthcare professionals involved in caring for neurologically compromised patients (and their families) enrolled in randomised controlled trials (Treadwell, 2001). As a result of this work, it became apparent that the issues that were important to me as a researcher, seeking to ensure the safe and ethical enrolment of patients into clinical trials, were less important to the clinical team striving to save the patient's life. However, this was a very small study and investigated only reported opinions and behaviours. Thus, in the current study, I sought to investigate observed practice in a different, but similar, acute care environment, by means of an ethnographic approach.

4.4.2 Why did I choose to explore stroke?

I chose to investigate the area of stroke research for a number of reasons. First, as noted above, it is an area in which therapeutic interventions are lacking. Second, it was a diagnostic area with which I was familiar both clinically and in a research context, and in which I had encountered the problems noted above. Third, a senior stroke physician with a strong research interest was part of my research group within my (then) school, and was keen to support my research, as was an academic colleague with an interest in my chosen methodology as well as research ethics. The stroke physician also facilitated access to lead clinicians and researchers in the local stroke unit. Although I had been involved in ECASS II (European Cooperative Acute Stroke Study, II) the majority of my clinical research work had been with head injured patients. However, given its epidemiology, to undertake the kind of ethnographic work that I intended in the head injured population would have been too demanding for a single researcher, as it would have necessitated an overnight on-call arrangement in order to ensure adequate, appropriate and timely observation. Stroke admissions tended to occur within slightly

more sociable hours and therefore, in theory, observation would be more convenient to manage.

When seeking feedback in the initial stages of study design a potential drawback highlighted by colleagues was related to my close professional experience with the topic under investigation, specifically regarding observation of consent interactions and subsequent interviews of staff members. It was suggested that this familiarity may lead to difficulties in maintaining a critical analytic perspective and may cause 'blinding' to some aspects that an outsider may be able to decontextualise and to view in a different light (Lipson, 1991; Streubert and Carpenter, 1999). However, although my clinical and clinical research experience involved a similar patient group and was within the same NHS Trust, it was in a different hospital and therefore involved different staff. There were also however potential advantages. There were similarities between the two sites in the way that clinical research was managed and therefore it was anticipated that there would be at least some commonality in terms of the issues raised.

4.4.3 Why study stroke now, and in this place?

The main factor in terms of timing of this work was a pragmatic one, related to my securing a longer term contract in my host organisation. Beyond this local issue however, stroke was becoming a national concern and developing a higher profile, and at the time of my application for funding to the Department of Health National Coordinating Centre for Research Capacity Development (since superseded by National Institute for Health Research) the improvement of stroke care, and thus recruitment to stroke studies, were high priorities. It therefore seemed politic to tap into a national initiative.

As noted above, the stroke physician who was part of my research group was able to facilitate links with the local stroke unit and I was keen to conduct the research at a local site for obvious reasons including convenience and ease of access. Further, although the unit was known to have a strong research portfolio, the Principal Investigator was keen to explore ways to improve recruitment and retention to stroke studies. Access was greatly facilitated by the fact that my supervisory team included the Director and Associate Director (Patient Involvement) of the Stroke Research Network, and the Clinical Director responsible for the Acute Stroke Unit. However, this also meant that I was observing and reporting on their behaviour within these environments. There was the potential for conflict of interest here in that a) in discussing progress at

supervisory and project meetings I did not wish to divulge information that may influence subsequent behaviours and thus potentially skew study findings, and b) difficulties may have arisen in the unlikely event that I became aware of misconduct or malpractice. Whilst clearly this latter issue may arise in any research situation, the fact that my observations were likely to include members of my supervisory team meant that it was possible that I would find myself faced with similar issues to patients who are in a dependent relationship with their clinician-investigator. These issues were discussed in supervision and it was established that during the data collection period, ongoing data collection and analysis would only be discussed with the nonclinical members of the team. I also established and documented an agreed course of action to be followed if malpractice or misconduct became evident.

Despite the advantages noted above, as all members of my supervisory team were named in the participant information documentation it was possible that the study may be perceived to be an audit or service evaluation on behalf of management and that this may have influenced the quality and content of information disclosed. I endeavoured to minimise the opportunities for this misunderstanding arising by personally contacting healthcare professionals at the study site rather than relying on the Clinical Director or Research Lead to introduce my work. I continued to clarify the nature and purpose of the research throughout my periods of fieldwork and at the time of the interviews. Such considerations also impacted upon the way in which I presented myself at the study site, which I discuss below.

4.4.4 How did I present myself during the period of data collection and why? Insider/ outsider issues

Throughout my study, as will be demonstrated in subsequent chapters, an important issue was the way in which researchers presented themselves to patients and other healthcare professionals. This was equally important in the way that I presented myself in the study environment and managed my insider/outsider position. There was no question that my observations would be anything other than overt, but boundaries were required regarding the extent to which I would 'participate' in either clinical or clinical research activities, and whether or not I would wear a nurse's uniform (research or clinical) whilst doing so. Although still holding active first level registration on the Nursing and Midwifery Council (NMC) Register, I chose not to present myself as such or to display this status by means of a uniform. Whilst there were some advantages

conferred as a result of my nursing background, I do not believe that it was essential to the successful conduct of the study for me to appear as a nurse. Further, in the same way that I do not see the necessity to point out that someone is a 'male' nurse, I do not feel obliged to explicitly identify myself as a 'nurse' researcher. I consider myself to be a researcher who happens to come from a nursing background. I therefore referred to myself as a researcher, and if asked, acknowledged my nursing background.

Whilst a uniform may convey an advantage of recognition and perhaps acceptance in the clinical area, amongst healthcare professionals and patients, it may simultaneously promote misrecognition and raise expectations of action that I was not able to fulfil. From my experience as a clinical research nurse I was aware that patients and the public (and some staff) did not appreciate the subtle difference indicated by nursing uniforms. I did not want to place myself in a position where I was misidentified as a nurse but unable to provide patients and their families with information or assistance should they request it. Further, I did not want patients or their families to feel pressurised to take part in my study because they thought that I was in some way involved in, or could influence, their clinical management. I considered that it would be misleading at best and coercive at worst, to staff, patients, and families alike, if they were to perceive my role as a clinical one.

Another factor influencing my decision not to wear a uniform was that I was thus able to circumvent the hierarchical structure that exists in the healthcare environment and in hospitals in particular. My intention was to communicate with the study participants at their own level and thus to develop trust and rapport. I therefore considered it important that I was not perceived to be part of the NHS hierarchy or to have greater status than the healthcare professionals participating in the study. If they thought that I was reporting directly to senior NHS staff this may have led to them altering their behaviours, withholding information, or giving responses driven by a wish to provide answers that they felt would meet with my approval. Whilst I avoided taking up an 'NHS identity' this did not negate the difference between my researcher role and the role of clinical or research nurse. However, the co-construction of the research relationship and the data garnered therein can be facilitated and enhanced by means of a reciprocal approach. Oakley (1981), for example, as well as advocating a non-hierarchical relationship between research participants, also suggests that the interview is most successful when the interviewer is prepared to 'invest his or her own personal identity in the relationship' (Oakley, 1981 p.41). I aimed to achieve this by engaging in

general conversation during fieldwork and prior to interviews, briefly disclosing personal details regarding my career and experiences in order to encourage mutual sharing of information. I was open and honest regarding the aims of the research, including my personal goal of achieving a PhD. I was also able to reciprocate by helping the research team with ethical issues, on the basis of my experience on the local NHS Research Ethics Committee. Humour was also found to be valuable; the sharing of an 'in' joke was very useful in breaking the ice and was used as appropriate with good effect.

Traditionally, the social science researcher is an 'outsider', entering the research setting as a visitor for the sole purpose of undertaking the research. Much healthcare research however is undertaken by practitioners, former or current, who subsequently find themselves situated upon a continuum from 'outsider' to 'insider', with a hybrid position falling somewhere between these two extremes (Reed and Procter, 1995). Although an 'insider' at least by virtue of my professional background and current NMC registration, my lack of clinical remit positioned me towards the 'outsider' end of the spectrum. Nevertheless, to some degree I shared language, meanings and assumptions, mutual acquaintances and experiences with the clinical and research staff, which was advantageous in developing a trusting relationship (Gearing and Dant, 1990) and facilitated disclosure of information. My previous experience also meant that I was familiar with some aspects of custom and practice, and understood something of the culture and values of the interviewees, a factor which contributed to the co-construction of the data for analysis. The positivist tradition has implied that to view research data from the practitioner perspective is to threaten the 'purity' of the research; I share the view of Reed and Proctor (1995) however, that to disregard the practitioner view is to lose important knowledge.

These issues were discussed at the design stages of my study and further at annual progress reviews. However, debriefing sessions with my supervisors who were not familiar with this clinical area, enabled me to expand upon and further explore issues which I may otherwise have taken for granted as a result of my familiarity with this field of work.

4.4.5 Level of engagement with patients and the public
Throughout my fieldwork, the ad hoc interactions, observations and discussions were for the most part conducted with the healthcare teams rather than patients and their

families. I have considered this at great length and have wondered whether I should have endeavoured to seek greater interaction with the patients, asking them how they felt, or might have felt, about participating in clinical research. There were several reasons why I chose not to do so however. First, I was involved in another study, running parallel to my observational study, which sought to interview patients and/or their family members if they had been eligible to participate in any of the ongoing acute or hyperacute studies. They were interviewed about their experiences of being approached for study participation (whether or not they were enrolled) or if they were eligible but not invited to participate, they were asked about their views on emergency stroke research, particularly in situations where patients are unable to consider participation. I did not want to influence these interviews by having similar ad hoc conversations with patients in the ward environment. Second, I did not wish to have such conversations entirely randomly as I did not want to give patients or their families either false hope, or the impression that they had missed out on something that could have been tried and may have influenced their outcome. Futhermore, in most cases this would have resulted in hypothetical discussion and conjecture, where my main concern within my study was to document what actually happened in the clinical area on a day to day basis. A third consideration was undoubtedly my neophyte status as an ethnographer. This was a new research role to me, being accustomed as I was to doing, rather than watching, and I can state with confidence (and now on the basis of further experience) that my approach to participation has developed during the course of, and as a result of, this work.

Having chosen not to present myself as a nurse, it was necessary to consider what role I would adopt in the study environment. On the basis of my previous experience and skills, it could be argued that I could have adopted a more active participant role, with regard to either clinical or clinical research activity. However, as well as issues of potential misrecognition as noted above, greater participation in day to day activities also raised the possibility that I might miss the research activity that I was seeking to observe in one area, if I became embroiled in clinical or research activity, which I could not easily leave, in another.

Nevertheless, although it was never my intention to participate directly or indirectly in clinical or research activity, the term 'participant observer' is perhaps misleading as this does not necessarily indicate that the researcher participates **in the same way** as those 'native' to the research setting (Delamont, 2004). For example,

although I have maintained my nursing registration, I did not, in the course of this study, participate **as a nurse** in the research environment. I did, however, participate in general conversation, social activities - such as joining group members at lunch or coffee breaks - and occasionally helping out with more mundane matters, for example collecting a piece of equipment from another ward.

There were also occasions when some level of involvement could not realistically be avoided, or occurred almost involuntarily. For example, whilst observing activity in a six bedded bay, I became aware that an aphasic patient had been given a bowl of water with which to wash herself, but that she could not reach either it, or her toiletries. Nor could she reach the call bell to summon a nurse. My options were to continue to observe and to take no action at all, to seek a nurse, or to move the bowl closer to the patient. I chose the latter option, but clearly this had no impact upon the type of activity that I was hoping to observe.

On other occasions however, when shadowing the research nurses, I occasionally became more involved than I had anticipated, and sometimes in such a way that I felt I did influence research activity. This sometimes occurred because the research nurses directly asked my opinion or advice in an area which they knew me to have considerable experience, or because my act of seeking information about a study or course of action prompted a behaviour or intervention on the part of the research staff. For example, by inquiring about the inclusion criteria of a particular study, I drew one of the research nurse's attention to a potential patient (Mrs Clarke – The Consent Interaction That Never Was, Chapters 7 and 8). This was not a deliberate intervention on my part, but this was the effect nevertheless, demonstrating that one can rarely be entirely non-participative.

Related to the subject of participation and inclusion, the eclectic nature of ethnographic research raises the question of what may be included as 'legitimate data'. Are there any topics which are 'off limits'? Are some spaces 'private' and thus not amenable to data collection? I endeavoured to make it explicit that my observational work included all aspects of activity unless someone specifically requested otherwise. Thus I included comments made in general conversation, or even those overheard, as legitimate data. In the event that a participant stated that they were telling me something 'off the record', or requested that I did not document a particular activity, I complied with their request. Nevertheless, such information, even if not formally recorded cannot be un-heard or un-known, and therefore may have exerted some influence on my

interpretation of the data, a fact that I acknowledge in order to uphold methodological rigour, which I discuss further in the following section

4.5   Methodological Rigour

Having described the design and conduct of my study, I now consider its evaluation. The lack of defined guidelines for the conduct and presentation of ethnographic work, whilst allowing for creativity, raises questions regarding rigour. Qualitative and quantitative researchers neither employ the same research methods nor seek to address the same issues and therefore their work cannot be evaluated by the same positivistic canons (Cutcliffe and McKenna, 1999). Rather than striving for evidence of reliability and validity, terms which some researchers consider semantically incompatible with qualitative research (Slevin and Sines, 1999), the qualitative researcher aims to demonstrate rigour by other means. Numerous proposals have been made suggesting criteria more appropriate to qualitative work but the terms suggested are often defined differently, used interchangeably or simply employed as a 'qualitative translation' of the original quantitative criteria. Criteria such as congruence, truth-value, applicability, and neutrality have been proposed (Guba and Lincoln, 1981; Sandelowski, 1986; Marshall and Rossman, 1989; Rose *et al.*, 1995), but disagreement persists as to which of these are 'criteria' in themselves, and which are means of evaluating whether criteria have been met. Furthermore, whichever criteria are ultimately accepted, this is based on a misguided assumption of homogeneity of qualitative research and seems likely to ignore the researcher's epistemological claims. Drawing together the work of several qualitative researchers, Hammersley (1992) identifies seven criteria for the evaluation of ethnographic studies including consistency, credibility, transferability, reflexivity, novelty, and production and development of theory. He notes however that these criteria are neither always necessary nor sufficient. These criteria can be distilled still further, to suggest that we review the topic's importance or relevance; its plausibility, based on existing knowledge; and the degree to which the evidence presented in the study supports the credibility of its claims (Seale, 2004).

Lack of consensus notwithstanding, for the purpose of demonstrating rigour within this thesis I consider the issues of congruence, consistency, credibility, transferability and relevance. In the following section, I briefly describe what I understand by these terms in the context of my research before evaluating the degree to which my research meets these criteria.

4.5.1 Congruence

Congruence refers to the degree to which the methods and conduct of the study are compatible with the research question and the researcher's epistemological position. The approach of this thesis is located within a relativist ontology and a subjectivist, constructionist epistemology. Drawing upon the assumptions of symbolic interactionism I employ ethnographic methodology as a mode of inquiry congruent with this paradigm as outlined earlier in this chapter.

4.5.2 Consistency

Guba and Lincoln (1981) uphold 'auditability' as the measure of consistency in qualitative studies and propose that the reader should be able to follow a 'decision' or 'audit' trail in order to replicate either the study, or the analysis. It has been suggested that the maintenance of a reflexive journal or research diary, other than that in which fieldnotes are recorded, enhances the collection of rich data, so that the work will be credible and recognisable to others (Koch and Harrington, 1998). Although I did not maintain a separate reflexive journal, I employed a research diary and kept reflexive notes within but distinguishable from, my field notes. I referred to both these data sources during analysis, and in my writing, in order to demonstrate consistency by explicating my rational for decision making at all stages of the research process. Nevertheless I acknowledge that the subsequent analysis is my own interpretation and therefore, whist this decision trail may enable the reader to apprehend my position, it is unlikely to guarantee that they would come to the same conclusions should they attempt to follow that trail to replicate either the study or the analysis. For the reasons noted in Chapter 4.4 above, whilst they would undoubtedly observe similar activities and events, they may select a different focus or alternative interpretations.

Like Hagemaster (1992) and others I contend that the researcher must identify personal preconceptions, responses, theories and training at the beginning of a study, and I have done so above. However, my aim in doing so was not, as Hagemaster suggests, to segregate them from later interpretation of the data, but rather to acknowledge that they are instrumental in that interpretation (Hagemaster, 1992; Koch and Harrington, 1998; Draucker, 1999).

4.5.3 Credibility

Often replaced by the term 'truth value', credibility can be considered in relation to three elements of the research: the researcher; the researched and the data provided; and the research findings.

Credibility of the researcher

In ethnographic practice the researcher is the main instrument of data collection and inevitably has some effect upon the researched, the research data, interpretation and output. The personal biography of the researcher means that she speaks from a particular class, gender, racial, cultural and professional perspective. This gendered, multiculturally situated researcher approaches the world with a set of ideas, a framework that specifies a set of questions that can be examined in different ways. From the outset I was aware that in my own case, my identity as a former nurse and more specifically, my experiences as a research nurse and clinical trials manager in neurosciences, were likely to have considerable impact on the conduct of the study and my interpretation of study findings. I had considerable experience of nursing neurologically compromised (i.e. incapacitated) patients, and of facilitating their enrolment in RCTs of pharmaceutical agents, and surgical and monitoring techniques. I had managed and co-ordinated such studies and was also an active member of an NHS research ethics committee. Furthermore, during the course of my research I became a clinical trial participant, although this was later in the research process, and may therefore have influenced analysis and interpretation, rather than data collection and interaction.

My participation in clinical research illustrates my own prioritisation of research, and reflects my views that as beneficiaries of previous patients' or volunteers' contributions, we are morally obliged, or at least have a civic duty to contribute to research in some way. Whilst I acknowledge that this need not necessarily involve direct participation as a patient, I consider it a professional obligation to maintain an up to date knowledge of one's area of practice and to contribute to its evidence base by facilitating high quality research. My study was therefore directed not only by an interest in what was happening, but by a desire to improve and develop research capacity and activity. These factors also contributed to the way in which I chose to analyse, interpret and subsequently present the data, which I describe more fully below. It may be argued that these experiences, views and aims constitute potential sources of bias that may detract from my credibility as a researcher. However, I suggest that they

added depth of knowledge and understanding, not previously accessible to me, about the ways in which clinical research is managed in different clinical areas. In particular, my participation in research conducted on an outpatient basis contrasted with, and thus further highlighted, issues specific to medical emergencies and the conduct of clinical trials in an acute environment. By owning these experiences and acknowledging their impact, I believe that they contribute to, rather than detract from, my credibility.

Credibility of the data and subjects

Ethnographic inquiry allows for the collection of both (relatively) objective (for example, staffing levels, geographical layout), and subjective data (such as behaviours, interactions and processes) by means of observation, in order to establish the practices and inter-relations of the group studied, and interviewing to establish why group members engage in such behaviours. Other methods such as documentary or policy analysis may also be included, although I have not done so here. Whilst these methods do not constitute a hierarchy of data credibility, each may enhance the other and provide an 'in-built triangulation' of methods, data and sources. It should be noted however that whilst each aspect confers advantages and disadvantages it cannot be assumed that triangulation will ensure that the deficiencies of one method will be addressed by the precision of another.

Interviewing is flexible and adaptable to many diverse situations. Particularly where audiorecording is used, the researcher has the opportunity to observe surroundings and non-verbal behaviour, to correct any misunderstanding and to record spontaneous comments and responses not made explicit in the interview guide. It has been postulated that in addressing research questions involving highly complex, subjective and emotional issues, relying on reflection upon experiential and humanistic perceptions rather than what is perceived to be more clearly defined, factual knowledge and theories, the semi- or unstructured interview can dig deeper, allowing a richer understanding of peoples' experiences, opinions, attitudes and feelings (May, 1997) and providing rich and detailed descriptions of previously unexplored phenomena (Morse, 1991). Unstructured interviews allow the interviewee to respond within their own frame of reference. Although this may lead to what some consider as 'rambling', others argue that this is in fact advantageous as it reveals something about the interviewees concerns (Bryman, 2001).

It may be argued that a significant disadvantage of the interview component is its inherent potential to introduce various sources of bias, at a number of levels.

Commensurate with my epistemological position however, bias is not a central issue here. Although the data may indeed be influenced by the respondents' poor memory of events, embarrassment, misunderstanding or outright lying, these factors are no less important than what is actually reported. For example, why do some of the clinical staff report that the research nurses endeavour to provide teaching sessions when it is apparent from the observational data and from other interviews that this is not currently the case?

The interviewer may unintentionally misrepresent or omit questions; she may misunderstand the response, or if not audiorecording the interview may record inaccurate data. Equally, she may intentionally subvert the interview by altering or omitting responses or by influencing answers by appearance, tone, attitude and reaction to previous responses. Gender, race, political beliefs and linguistic characteristics of either party may influence the interview (Briggs, 1986) and it must be acknowledged that each come to the interview with their own agenda. It has been suggested that the information given by the interviewee must be considered to be accurate (Burns and Grove, 1987). However, the concepts of accuracy and truthfulness are somewhat nebulous and thus, following Appleton (1995), and in keeping with my interactionist approach I acknowledge that the expression of subjective perceptions and values does not render an account any less pertinent; the reasons **why** a respondent chooses to present a particular account can be as illuminating as the account itself.

The chosen method of recording the interview is also important. Note-taking is time consuming and may disturb the natural flow of the interview, and if the interviewer chooses to paraphrase, this will automatically introduce bias by her choice of what to record and equally importantly, what to leave out. Audiorecording tends to be the preferred option providing that the interviewee is in agreement with this. Nevertheless, I made brief notes after each of the interviews recording data such as participant's affect and body language and my own feelings and impressions (Bogdan and Taylor, 1975).

Credibility of study findings

With regard to the study findings it is important that steps to ensure credibility are built into the process of data analysis. Convention upholds verbatim transcription of recorded data as a means of enhancing credibility if the interpretation is plausible. Ashworth suggests that this rests in the data being judged by the participants as revealing accurately their portrayal of the life-world of the phenomenon and many recommend the process of 'member checking' or 'respondent validation' as one of the

most robust means of assuring truth and consistency in qualitative research (Ashworth 1993; Burnard 1991; Holloway & Wheeler 1996; Lincoln & Guba 1985; Baker 1992).

There are some difficulties in seeking the views of respondents on the honesty and consistency of findings. Where research is undertaken in an environment of continuing change, as was the case in this study, verification of accounts may be difficult if in the interim participants have moved on or have had other new experiences which may have altered perceptions and attitudes. Additionally, this method implicitly privileges one person's viewpoint over another, which is incompatible with my acknowledgement of 'multiple realities'. The respondent can only provide verification from their own view point and not from an 'overall view' available to the researcher. Finally, member checking gives rise to the generation of further data which then necessitates further analysis, particularly where feedback is contradictory to the researcher's perspective and thus raises the question, where does one stop? (Bloor, 1997) . In this regard member checking may undermine rather than support the trustworthiness of a project (Sandelowski, 1993). For these reasons I did not follow this procedure.

Involvement of an independent researcher to generate categories from the transcripts without prior knowledge of those already identified has also been advocated to promote credibility of the identified themes if congruence is demonstrated (Burnard, 1991). This in itself is not foolproof however. Agreement may demonstrate that the original category analysis was reasonably complete and accurate, but may equally indicate that it was too broad and general in nature and thus easily corroborated, or that the colleague anticipated the researcher's categorisation and offered the researcher 'what she wanted to hear'.

Whilst I did not seek wholly independent review of my data, presentation of the data and resultant analysis to my supervisors ensured rigorous examination of the categories identified. I also presented aspects of my work at academic conferences throughout the process thus opening the analysis to scrutiny by my peers.

Triangulation has been proposed as an alternative to, rather than a method of validation. Whether relating to data sources, data collection, theory or analysis, triangulation, it is suggested, affords a strategy that adds rigour, breadth, complexity, richness and depth. Ethnographic inquiry, drawing upon a suite of research methods, may be considered to demonstrate 'built in' triangulation. It has been suggested however that the term 'crystallisation', rather than triangulation, is perhaps more appropriate (Richardson, 2005a). Richardson states, 'Crystals are prisms that reflect

externalities and refract within themselves, creating different colours, patterns and arrays casting off in different directions' (p.963). In crystallisation the writer tells the same tale from different points of view. There is no 'correct' telling - each 'story' simply reflects a different point of view, which is what I endeavour to achieve in the empirical chapters that follow.

4.5.4 Transferability

Whilst quantitative work usually seeks a degree of generalisability of its findings (Hammersley, 1992; Slevin and Sines, 1999), transferability, applicability or fittingness are more often the terms of choice in relation to qualitative approaches (Guba and Lincoln, 1981; Rose *et al.*, 1995). Although generalisation was not the aim of this research it is not unreasonable to expect that findings should be at least transferable to similar situations outwith that researched and familiar to similar professional groups or individuals.

Purposive sampling allowed identification of sites where relevant activity was ongoing and personnel who had the relevant experience and information, potentially enhancing the transferability of the study findings to other similarly structured stroke units. It could be argued that a multisite investigation may have further enhanced transferability but this was not logistically possible within this single researcher study and given the unpredictable nature of the phenomenon under investigation. Nevertheless, whilst not addressed formally within the remit of this study, in informal discussions with clinical and research colleagues in similarly structured units, many of the issues raised here were recognisable.

4.5.5 Relevance

Social research is often concerned with particular situations and groups and cannot therefore always be considered relevant to society as a whole. It should, however, be of importance to researchers, should contribute to what is taken by researchers to be established knowledge, and should be useful to practitioners in terms of their daily experiences (Hammersley, 1992). This study was conducted in a research orientated environment in a teaching hospital where there is a firm emphasis on evidence based medicine. It is therefore anticipated that the study will be relevant to personnel employed in similar facilities.

More broadly, it is relevant to the conduct of emergency research and to the organisation of stroke care and stroke research. The government White Paper

'Choosing Health' promotes people's right to make their own decisions about health related choices (Department of Health, 2004a). It has been proposed that this choice should extend to decisions regarding research involvement. However, as described in Chapter 2, stroke patients (amongst others) are not always able to exercise their right to choose and may therefore face restrictions regarding participation in hyperacute RCTs which may jeopardise the quantity and quality of research conducted in this area.

Following the report of the Research for Patient Benefit Working Party (Dept Health and DTI, 2004), the UK Clinical Research Collaboration (UKCRC) sought to develop research capacity and excellence by promoting specialist research into the treatment of four major diseases, one of these being stroke. This topic of research is therefore relevant in relation to this initiative, aiming to enhance research capacity within the NHS in general, stroke in particular and also a focus on developing careers for nurses in research. Despite practical and ethical difficulties, RCTs are crucial to understanding and developing effective treatments for acute stroke. This study sought to address some of the complex issues encountered in hyperacute stroke research in order to promote research capacity in this area. Whilst the findings of the research are perhaps not widely transferrable, it is anticipated that the study will be relevant to personnel employed in similar facilities.

4.6   Ethical Issues

As this study involved NHS staff, patients, and their families, and was conducted on NHS premises, scrutiny by an NHS Research Ethics Committee was required. Within the application for ethics committee review the following issues were identified and addressed.

As noted in Chapter 2, one of the concerns about conducting research in the acute and hyperacute situation is the potential additional distress to patients and their family members. In seeking consent for the observation and audiorecording of the RCT consent interaction there was the potential to cause further stress and place further pressure on the patient and/or family member. The very nature of the research question itself meant that it was unavoidable that the patient or family member would be required to make an almost immediate decision whether or not to allow me to observe and record the RCT consent interaction. Clearly this meant that I would potentially cause or add to one of the problems that I was endeavouring to avoid and/or investigate. For this reason, having sought the advice of an academic ethicist, consent for this aspect of the study

was a staged process, whereby only verbal consent was sought in the first instance. My rationale for this approach was that if I had attempted to obtain written consent at the outset it would have had to be secured prior to seeking consent for RCT participation. I considered that this would cause an unnecessary and unacceptable delay in the patient being enrolled to the RCT which often have very short recruitment windows. I did not wish to jeopardise either the individual patient's enrolment or overall recruitment to a treatment study by introducing further obstacles at this point.

As outlined in Chapter 4.2.4 above, having secured verbal consent I provided the patient and/or family with written information and returned to discuss this and to obtain written consent as soon as possible thereafter dependent upon the patient's condition. Although the situation arose only twice (the second was not recorded) even this method proved problematic because the section of the interaction pertaining to consent was not always easily identifiable and it was unclear at which point to request permission to record or indeed to begin recording. Nevertheless, this compromise allowed me to obtain prospective, observational data rather than relying solely on retrospective subjective accounts or presenting hypothetical scenarios to a non-patient population.

A second area of concern was that of placing an undue burden upon the patient. Multiple research participation is generally avoided, especially in interventional studies but by definition, this research included people who were being approached to take part, or to allow their family member to take part in a randomised controlled trial. Furthermore some patients and family members who agreed to participate in the observational aspect of the study were also later invited to take part in the parallel, linked interview study. This meant that some patients would be participating in two, or perhaps three, research studies. Some may consider that these additional invitations to participate in further studies, albeit observational and/or low risk, constitute an unjustified burden and may exacerbate some of the perceived problems that I was seeking to avoid and/or investigate. There was however no other way to investigate this phenomenon. Although this may be seen as problematic, I considered that if handled sensitively multiple participation would strengthen study findings by providing the opportunity for triangulation of observational, recorded and interview data (Patton, 1980; Denzin and Lincoln, 2005b).

4.7   Conclusion

Having outlined in this chapter my theoretical position, methodological framework and the methods by which the study was undertaken I now move on to present the empirical findings of the study.

As noted in Chapter 2, much of the bioethical and medical literature suggests that the main obstacles to the conduct of clinical research in the emergency situation are related to obtaining informed consent, and include concerns regarding the existence of a therapeutic misconception which may result, at least in part from the integration of research and clinical activities and personnel. In Chapter 5, and in light of these considerations, I describe the degree to which research and clinical practice are integrated (or not) at the study site, and how this is determined by pragmatic and operational, rather than ethical, factors. In Chapters 6 and 7, I illustrate the way in which the resultant distinction between research and clinical practice, and between those delivering each, is perceived and enacted by the clinical and research nurses respectively. Finally, I draw these strands together in Chapter 8, to demonstrate the effects of this distinction upon the day to day transaction of clinical research, and its recruitment processes, in an acute stroke unit.

Chapter 5. Separating Research and Care: The Temporospatial Dislocation of Research and Care

5.1 Introduction

As noted in Chapter 2, it has been hypothesised that clinical research and routine practice should be segregated in order to avoid the ethically troubling notion of the therapeutic misconception, and also to minimise the potential for intrapersonal conflict for the clinician-researcher, with regard to the potentially conflicting aims of research and clinical practice. Indeed when I went to undertake my observations in the Acute Stroke Unit, I found that research and clinical activity are separated in a number of ways, the most immediately obvious being that different staff are employed for the specific purpose of undertaking research. This chapter will focus on the temporospatial split between research and clinical teams, and their associated activities, within the acute stroke unit; looking at the spaces in which the activities of these separate groups are conducted and the temporal organisation of their work. I demonstrate how the geographical mobility of the research team, juxtaposed with temporal restrictions upon its activities resulted in its occupation of liminal spaces, both physically and metaphorically, and how this in turn gave rise to a stratification of legitimacy (c.f. Goodwin *et al.*, 2005), which determined to whom and what the research nurses had access to and what they were permitted to do in these spaces. I also illustrate how and where clinical and research teams came together and the functional significance of such collaborations.

5.2 Identifying The Focus Of My Research: Ongoing Acute And Hyperacute Research In The Acute Stroke Unit

The way in which stroke patients were managed within the study site, including potential study participation, was in part determined by practical issues, including departmental custom and practice, and Trust policies. These in turn impacted upon operational and resource issues, including the overall organisational structure (physical and operational) and resource allocation. These factors influenced the way in which research was conducted and how non-research staff embraced and embodied the research culture (or not). Current practice at the study site was that research responsibilities were discharged by research specific staff; it was therefore necessary that these staff were appropriately trained and were afforded suitable accommodation.

At the study site, research was undertaken alongside but separate from clinical practice; alongside in that there was overlap and sharing of some of the physical spaces in which each was conducted, but separate in that different staff fulfilled clinical and research roles. As noted in the literature review (Chapter 2.5) strong ethical arguments exist for and against the physical and/or symbolic integration of research and clinical activity. Whilst no such arguments were explicitly noted during the conduct of my study, related issues such as the potential for research requirements to divert attention and resources away from clinical needs and activity, were often proffered as reasons why clinical staff did not, could not, or should not, take a more active and consistent role in research activity. Some facilities were shared (for example, patient accommodation, hotel services, and radiology and laboratory services) and there was some overlap of roles and responsibilities varying from research only, to clinical only, with a considerable area of blurring and 'hybridity' in between (Bhabha, 1994). For example, some of the stroke research nurses I observed were involved solely in research activity, whereas others participated in a very specific aspect of clinical care - assessment for and administration of thrombolysis - but did not participate in more general clinical activities. Also, in conjunction with the administrative aspect of his research role, Senior Research Nurse Higgs furnished senior clinicians and managers with information pertinent to clinical service provision. I did not observe the stroke research fellow undertaking clinical duties on the ward, although he did on occasion assist with the Joint Stroke Clinics. Apart from the stroke nurse practitioner (SNP), a very specific case which will be discussed further later (Chapter 5.5), there was very little involvement of the clinical staff in any research related activity – a finding supported by both observational and interview data. Other departments and staff were involved in research activity by necessity (e.g. radiology and laboratory staff), performing investigations and/or assays for clinical, research or combined purposes and with varying levels of cooperation.

It has been suggested that in order to attain and uphold research based practice 'research must become embedded within the culture of […] practitioners' (Mulhall, 1997; p.973). On entering the clinical area to begin my fieldwork, my first most striking observation was the distinct lack of embeddedness, highlighted by the fact that the stroke research nurses were temporospatially dislocated from their clinical counterparts and their potential participant population. Although there were some points of connection, research and clinical teams were for the most part 'misaligned' both in

terms of their temporal and spatial availability and by varying degrees of mobility and flexibility. Whilst the geographical disjuncture was the most immediately obvious manifestation of the distinction between research and care it soon became apparent that the organisation of work, particularly in relation to working hours, also served to segregate clinical and research staff and consequently their activity. Table 4, below, summarises the clinical research ongoing at the study site at the time of my fieldwork.

STUDY ACRONYM	FULL TITLE	RECRUITMENT WINDOW	INTERVENTION	NO. RECRUITED (during fieldwork)
ECASS III	European Cooperative Acute Stroke Study.	3-4.5 hours post ictus	Hyperacute stroke management: Placebo controlled trial of alteplase (rtPA) in acute ischemic hemispheric stroke	0
CHHIPS	Controlling Hypertension and Hypotension Immediately Post Stroke	36 hours post ictus	Acute management : blood pressure control	5
COSSACs	Continue Or Stop post-Stroke Antihypertensives Collaborative Study	8 hours post ictus	Acute management: blood pressure control	4
PROFESS	Prevention Regimen For Effectively avoiding Second Strokes	120 days post ictus	Secondary prevention – anti thrombotic therapy	0
CRESCENDO	Comprehensive Rimonabant Evaluation Study of Cardiovascular ENDpoints and Outcomes	Up to 3 years post ictus	Secondary prevention: appetite suppressant	0
PERFORM	Prevention of cerebrovascular and cardiovascular Events of ischaemic origin with teRutroban in patients with a history oF ischaemic strOke or tRansient ischaeMic attack	>48 hours, < 3 months post ictus	Secondary prevention – anti-thrombotic therapy	21

Table 4: Ongoing clinical research at Nearstreet Hospital: June 2006 – July 2007

In sequential order rather than order of importance, the primary task of the research nurses was to assess new patients' eligibility for a) clinical thrombolysis, b) hyperacute/acute clinical research and c) other clinical research, such as secondary prevention studies. This was the most obvious example of clinical and research roles overlapping (the research nurses and the SNP assessed the patients for eligibility for clinical thrombolysis and/or research participation) but nevertheless, assessment for thrombolysis took priority because it was the only treatment currently known to be effective and the time window was very short. At the time of my fieldwork the licensing

criteria for administration of rtPA was such that it should be administered within three hours of the ictus, and subject to confirmation by CT scan that the stroke was **not** haemorrhagic in origin. It has been reported however, that even within that time window there is evidence that earlier administration yields better results (Marler *et al.*, 2000). Patients who presented outside this time window but within 4.5 hours of onset of symptoms could be considered for inclusion in the ECASS III study (Hacke *et al.*, 2008)[1]. Two further studies focussing upon blood pressure management were ongoing, as were three secondary prevention studies which had much wider recruitment time windows. For the purpose of thrombolysis and/or hyperacute study eligibility assessment the research nurses needed prompt access to their potential participant group. However, it was immediately apparent on entering the field that they were not based where new patients were first received, - the Emergency Assessment Suite (EAS) - or where they were subsequently managed, - the Acute Stroke Unit (ASU). In order to understand the research nurses' working environment it is necessary to outline here the areas encompassed within the patients' care trajectory.

5.3   Landscape Of The Research Team

As noted in Chapter 3, despite housing the ASU, Nearstreet hospital had no A&E facility. There was however an Emergency Assessment Suite (EAS), where suspected stroke patients were received prior to transfer to the ASU. The EAS was located on Level Two and was accessed directly from the main service road to the hospital. The radiology department, to which patients were transferred for CT scanning, was only a short distance along the corridor from EAS and a patient could be transported between the two in approximately three minutes. The ASU was a 30 bedded ward (Ward 2) located four floors above EAS. It comprised four six bedded bays and six single occupancy cubicles. Typically, two bays accommodated male patients whilst the remaining two were occupied by female patients although this arrangement was flexible according to need. Each of the six bedded bays had its own toilet and shower facilities. There was also a separate bathroom and further sluice facilities. Hotel facilities included a patient day room (rarely occupied by patients but sometimes utilised for multidisciplinary team meetings), a physiotherapy room, and a small kitchen housing cupboards, a water boiler, fridge and microwave. Administrative space on the ward included the nurses' station – a centrally located open area with workspace and

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[1] Time window increased to 4.5 hours in accordance with the findings of the ECASS III Study.

computer terminal - where most of the clinical staff congregated when not engaged in hands-on, physical, patient related activity. There were also several offices occupied by the Sister/Ward Manager, junior doctors, Clinical Director and three other Consultant Stroke Physicians (separate offices). There was a small preparation room for preparing intravenous drugs and decanting blood and other samples for investigations. Several storage areas were available for clinical supplies and equipment and laundry, with one of these areas doubling as a staff cloak-room.

The research nurse role comprised a considerable administrative component and therefore required an administrative base; the Stroke Research Office (SRO). Due to physical limitations of space, this office was not in the clinical area to which stroke patients were received and/or cared for but was located directly across the landing from ASU on Ward 1. Ward 1 had no clinical connection with the Acute Stroke Unit; it was simply **the closest place** in which office space was available to house the research nurses. The patient group residing on Ward 1 was considered 'at risk' and access to the ward was therefore strictly controlled by the Trust ID swipecard system. The research nurses had no connection with the clinical staff on Ward 1 either clinically or managerially (but were granted swipecard access).

Not only were the research nurses located in a different area but they moved throughout different areas. Several authors have described how organisation of work creates boundaries for the groups or individuals undertaking that work and that the physical workplace is instrumental in the formation of identity (Gergen, 1991; Miller and Rose, 1995) . Others note that nurses are generally confined to a single ward or clinical area whereas medical teams may be involved in patient care across several wards, clinics and operating theatres (Allen, 1997; Reeves and Lewin, 2004; Goodwin *et al.*, 2005). The effect of the research nurses' mobility therefore, was to set them apart from the clinical nursing team who were based in a specific area and to whom the patient was 'delivered'. Simultaneously, however, they were aligned to some extent with members of a different discipline – doctors - who as noted above are similarly mobile. Such mobility is not typical of the nurses' role, although it is perhaps becoming more prevalent with the advent of Clinical Nurse Specialists and Nurse Practitioners, who are ascribed a particular diagnostic group rather than bounded within a physical clinical area. Thus, the research nurses traversed not only territorial boundaries, but also those of professional (and social) groups and identities, and as such, they can be seen as occupying a liminal space. Liminality has been defined as a state of being 'betwixt and

between the positions assigned and arrayed by law, custom, convention, and ceremonial' (Turner, 1969; p.95). Moving and working within and across different boundaries the research nurses were neither in between nor all-encompassing, but occupied a liminal identity and liminal spaces at the penumbra of the clinical sphere.

In order to identify new, and follow up existing patients, the stroke research team made numerous trips between the SRO, ASU and EAS each day – a time and energy consuming activity. The ward staff as well as the research nurses were aware of this almost constant transit and commented that it would be more convenient for the research nurses if they were based within the ASU. The effect of their mobility reached far beyond temporal inconvenience however – it also rendered their role 'other' than the traditional role of the nurse, as noted above. Those who suggested that the research team would be more conveniently located within the stroke unit did so not only because it would save time and energy for the research nurses but also because it would make the team visible and raise its profile on the ward, thus enabling the clinical staff to see and learn something about the research nurse role. I explore this theme more fully in the following chapter.

The process of patient assessment was not static but ongoing, and took place across and within a number of clinical areas. The primary role of the stroke research nurses was to identify, assess and facilitate enrolment of patients to RCTs of stroke treatments or preventive therapies and to manage their study related procedures thereafter. It was striking that despite the need to identify patients as a matter of urgency in order to facilitate prompt treatment and/or study enrolment the stroke research nurses were not based in either the Acute Stroke Unit or the Emergency Assessment Suite. Instead they worked within and across several discrete areas which I categorise as first and second order spaces. Within these spaces a 'stratification of legitimacy' (cf. Goodwin *et al.*, 2005; p.863) existed which determined to whom and what the research nurses had access and what they were permitted to do in therein. I describe these permissions and their impact below.

5.3.1 First order spaces

I have defined 'first order spaces' as those spaces where stroke patients were legitimately admitted and managed, for example the ASU, EAS and the radiology department. In these spaces, legitimacy of access for the patient was determined by suspected or actual diagnosis of stroke, whilst for the research nurse it was determined

by the presence of, and interaction with, the stroke patient. The patient's presence within these spaces legitimated the presence of the research nurse, who visited or accompanied them as a 'guest'.

Reinforcing the concept of guest status, the research nurses seldom visited EAS or the ASU without first arming themselves with various documents which represented a symbolic 'key' allowing access to patients and their records. The ward clerk or a member of nursing staff was usually at or near the nurses' station and was aware of the research nurse's arrival but if this was not the case the research nurses did not explicitly announce their presence. In this respect they were perceived as 'insiders' by clinical staff, patients and their families, with a legitimate role and purpose necessitating access. Conversely, although they were not obstructed in this data trawling, information was rarely volunteered to them; they were positioned outwith the clinical management of the patient, both geographically and metaphorically and thus crossed the boundary into an 'outsider' role. In this context they were procedurally invisible because this particular aspect of their activity **fitted** within the area in which it was undertaken and in a sense this invisibility can be taken to indicate acceptance. Within these various spaces the research nurses were facilitated or restricted in the discharge of their duties in a number of different ways. The privileges conveyed by their 'guest' status were not exhaustive however, even within first order spaces, because they were first order spaces **for the patient;** the research team had no specific place that was wholly and singularly their own, as I illustrate below.

The research nurses often visited the ASU for reasons other than patient contact, and in these instances were afforded less freedom of access. For example, one of the study drugs was stored in a cupboard in the ASU and the pharmaceutical company required daily temperature recordings to be taken from the cupboard to ensure that the drug was stored at the correct temperature. The cupboard was locked and the research nurse had to locate the member of staff holding the keys in order to obtain access. The cupboard did not contain controlled drugs and there was no reason, in terms of safety or security, that the research nurses may not have their own key to this cupboard. Both the act of seeking permission and the means of access to the cupboard symbolised legitimacy of purpose, a territorial hierarchy and the 'guest' status of the research nurse in the ASU. Although I have categorised the ward as a first order space because of the legitimate presence of stroke patients, even within this spatial hierarchy there were degrees of legitimacy and corresponding rights and privileges. In the example given

here, although within a first order space, the research nurses' legitimacy was diminished because they were not engaged in direct patient activity. The situation was something of a paradox. On the one hand the drug was stored in a cupboard on the ward and was therefore under the control of the ward staff. On the other, the ward staff took no responsibility for the drug, or its appropriate storage. Recording the room temperature required no specialist skill; there was no reason why the clinical staff could not maintain a daily temperature chart which the research nurse could then retrieve on a daily or weekly basis. This would facilitate research involvement of the clinical staff and would reduce the time taken by the research team to conduct this very basic activity. Although time would be saved by the research team, as they would not have to make another visit to the ward, maintaining the log would not unduly impact upon the workload of the ward team because the cupboard was located within their area of practice. Furthermore, as the activity was quite straightforward there was no reason why delegation of this basic task should impact upon study integrity. However, the clinical staff did not perceive any research related activity to be a part of their role. In fact, a kind of stalemate existed, whereby the research team did not ask for assistance and the clinical team did not volunteer it.

The 'otherness' of research was demonstrated much more clearly in an incident involving the storage and administration of study medication. A patient had been enrolled in one of the acute blood pressure management studies the previous evening and was due to receive her second dose of study medication the following morning. I observed the following interaction:

> Nurse Lynch comes to check I.V. antibiotic with Nurse Smith. Nurse Smith asks did she give "that stuff" [study medication] – Nurse Lynch replies that she has not because she couldn't find it and that Research Nurse Higgs is looking for it now. Nurse Lynch wanders off and Nurse Higgs comes to the nurses' station, looking on and under the benches etc. I ask what he's lost and he replies "A greet [sic] big box of study drug!" […] Nurse Smith is on the phone and no one is really taking much notice of Nurse Higgs rummaging about. He wanders off; I think he's still looking. A few minutes later Nurse Smith hands over her patients on the board round. When she gets to [study participant] she mentions that the patient is on [the study] and that "Nurse Higgs is sorting her drug out". No further information is given or requested regarding the study. [FIELDNOTE: November 2006].

It is notable that the nurse refers to the study medication as "that stuff", engendering a sense of 'otherness', denying ownership and associated responsibility. In this particular study the medication was not actually a novel compound but was a

licensed drug familiar to the clinical staff; it was **the regimen** rather than the drug itself that was experimental. The sense of mystery regarding "that stuff" illustrates a commonly claimed misconception that research must involve new or novel compounds or treatments and is therefore associated with a commensurate level of risk. Notwithstanding this lack of understanding, the fact that the study medication was temporarily missing was not an issue of mismanagement, rather a perception that responsibility for the safekeeping or administration of study medication lay solely with the research staff. The delay in administration of the study medication was of no apparent significance to Nurse Smith and was therefore, not communicated to the rest of the team. However, this lack of engagement was not unilateral; Nurse Higgs did not take the opportunity to join the round and advise the team of the patient's study involvement or educate them regarding the importance of adhering to the study protocol. Clinical and research activity on the ASU were performed in parallel rather than in communion.

5.3.2 Second order spaces

I have defined 'second order spaces' as those unconnected with the day-to-day clinical management of stroke, such as the Stroke Research Office and a treatment room, both located on Ward 1. In these spaces, unlike first order spaces, neither the patient nor the research nurses had a clinical reason for being there and thus both patient and practitioner were 'guests'. This 'guest' status impacted upon the research nurses' identity and perception of their role and is examined more fully in Chapter 7.

Although the research nurse role involved almost continuous transit, it also comprised a considerable administrative component and thus required an administrative base. Housing two or three research nurses and sometimes shared by the research fellow and the stroke nurse practitioner, the Stroke Research Office was located, as previously noted, on Ward 1, directly across the landing from the ASU. It was not a 'purpose built' office and had previously been utilised as a treatment or preparation room. As such it was small, approximately 9 x 11ft^2, and poorly equipped. There were no desks. Workspace consisted of benches with shelves above that were not easily accessible. There was one cabinet of desk drawers, several filing cabinets, a fridge, a freezer and some monitoring equipment. This equipment was squashed into a corner and could not be used without reshuffling most of the other items in the room. There was a fax machine and two telephones, one of which was connected to an answerphone. Initially

there was one computer in the room, which was primarily the senior research nurse's domain. Later, the stroke nurse practitioner had her computer moved to this room but for the duration of my fieldwork it was never connected to the network and therefore served as a notice board displaying numerous post-it notes. This conveyed a lack of recognition of the importance of her role and an impression of transience which she shared with the research nurses.

The size and contents of the stroke research office rendered it unsuitable for patient consultations; hence an alternative space was required. For this purpose, the Senior Sister on Ward 1 allowed the research team access to another 'second order space' – a treatment room, which was not currently being used for that purpose. The day to day function of this room was to provide storage space but it was utilised on an ad hoc basis should the research nurses need to see a patient post-discharge, for example, for study screening or consent. The research nurses were permitted to use the room because the ward staff rarely did so, but they had little or no control over this environment. There was a desk and chair where the patient and doctor or nurse could sit for the 'consultation' but the rest of the room was untidily packed with equipment including bath hoists, drip stands, weighing scales (on which I sat to observe a consent interaction, there being nowhere else easily accessible) and electronic blood pressure machines – the trappings of clinical work. During my observation of a consent and screening visit in this room there were several interruptions by ward staff. Although they always knocked they did not wait for a response before entering, thereby negating the opportunity to delay the intrusion or 'put the setting in order' (Goffman, 1959; p.223). The knock simply signified an intention, rather than a request for permission, to enter and at one point prompted a comment from the patient (after the person had left the room) "It's a good job we weren't in the nuddy [naked]" (FIELDNOTE: August 2006). Had this room been required for some other **clinical** function, for example, a patient returning to the ward for a standard clinical procedure such as changing of a dressing or suture removal, it seems highly unlikely that it would have continued to be utilised, simultaneously, as a store room.

The fact that the room was not cleared out to allow an uncluttered, clean and tidy space in which the research team could see patients privately and without interruption seems indicative of the value placed upon research and researchers. Nursing is often perceived by others to be synonymous with physical care (Bassett, 2002) and those who are not seen to fulfil this aspect of the role are often viewed with suspicion or are not

considered to be 'real' nurses. The example above illustrates that whilst the research nurses are perceived not to be 'real' nurses, patients participating in research are in some ways, and at some moments, perceived not to be 'real' patients and as such do not always warrant the same level of care and respect from clinical staff. In this space both the research team and the patient were 'guests' or perhaps 'squatters', left to their own devices and receiving no hospitality from the ward staff. In contrast to the procedural invisibility experienced within first order spaces in these second order spaces, particularly the treatment room on Ward 1, the research team was physically accommodated but not embraced.

Some time after the completion of my fieldwork the senior research nurse, told me that the research team was no longer able to use the treatment room on Ward 1. Without any consultation with, or prior warning to the research nurses, the desk and chairs had been removed in order to provide more storage space, demonstrating the apparently low prioritisation of research and those undertaking and participating in it. The research nurses found alternative accommodation in a clinic which had no direct link to the patients or their diagnostic group so once again both patients and practitioners were 'squatters'. Although the research nurses worked within and between a number of areas they were in effect 'homeless', occupying a liminal space both literally and metaphorically. They moved between clinic, ward and emergency areas but 'belonged' to none of them and had few rights, a situation which impacted upon their identity and the enactment and perception of their research role. Their mobility therefore, although essential, was instrumental in reinforcing their liminal status as were the tasks which they performed.

The research nurses were dislocated from their clinical counterparts temporally as well as spatially. In the following sections I describe the effects of their temporal separation and also how the combination of these two factors impacted upon their working practices and ultimately upon the recruitment of patients, an issue which is more fully explored in Chapter 8.

5.4   Temporal Dislocation

At a very practical level, the ward staff's day was fairly formally structured around patients' meal times and clinical ward rounds. It was usually the case therefore, that ward staff tended to have their meal and/or coffee breaks at around the same time each day, whereas the research nurses tended to have a coffee whilst working in the

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Stroke Research Office (if at all) and took their lunch break as and when a suitable break in their workload arose. This temporal disjuncture, along with their geographical separation meant that the clinical and research teams rarely spent 'social' time together and therefore, missed a potential opportunity to develop some insight into each other's respective roles.

I have already noted that the research nurses were in almost constant transit throughout a number of different spaces at Nearstreet Hospital, but their peripatetic existence began to have an even bigger impact upon their time when, towards the latter period of my fieldwork, there was a change in stroke admission policy. Under the new policy, all new stroke patients were received at King's Hospital in the first instance, prior to subsequent transfer to the ASU at Nearstreet. This change meant that in order to promptly identify patients for acute stroke studies the research team had to visit the Medical Admissions Unit at King's Hospital on a daily basis. Although less than three miles from Nearstreet, its city centre location meant that travel to and from King's Hospital could be quite time consuming depending upon volume of traffic. On average the journey between sites took approximately 30 minutes (each way) and was somewhat disruptive to the research nurses' daily schedule, as they were clearly unavailable during transit. Paradoxically, the research team needed to be mobile in order to identify and assess potential study participants promptly, but their almost constant transit reduced the time available in which to do so. Their mobility, however, was not the only factor that impacted upon their temporal availability as I discuss below.

Financial restrictions meant that unlike their shift-working, clinical colleagues the research nurses did not provide 24 hour cover. The research nurses provided an assessment service for clinical thrombolysis, and it would therefore have been useful for them to provide an 'out of hours' service which could also have covered research activity. However, as there was no funding for such a system, they usually worked from 09:00 -17:00 hours, flexibly depending upon workload. This effectively limited the enrolment of research participants to 'office hours' even though this did not necessarily correspond with the time of presentation of potential participants. Nor was this arrangement necessarily convenient for consultation and communication with patients' family members/carers as visiting hours were 11:00-13:00hrs and 16:00-19:30hrs.

An example of the impact of this temporal disjuncture occurred during my third phase of fieldwork, an incident that I have called 'The Consent Interaction That Never Was'. The following three extracts pertain to this incident, which occurred when

Research Nurse Webb identified a patient, Mrs Clarke, on the ASU who was potentially eligible to participate in an acute blood pressure management study (COSSACS). This study had a recruitment time window of 48 hours from onset of symptoms – much wider than that of the hyperacute studies. Nevertheless, it was still important to initiate the assessment and enrolment process as soon as possible, as time was often lost prior to arrival at hospital. Further delays sometimes ensued when patients were admitted outside the working hours of the research team, and because the team was not based in the clinical area, they did not usually find out about new patients until they actually visited the ward and trawled admission records and patient notes. Mrs Clarke, however, was well within the 48 hour recruitment window (more than 24 hours remaining) and appeared, on first review of her notes, to fulfil most of the eligibility criteria. Nurse-led consent was not permitted for this study and therefore Research Nurse Webb contacted the research fellow, Dr Chatterjee, to advise him of this potential participant. It is important to note that although more than 24 hours of the recruitment period remained, this did not mean that the research team had 24 hours in which to assess and recruit the patient. The research team did not work a shift system; they did not provide 24 hour cover and thus would not be available to undertake recruitment throughout the whole of the time remaining. It was therefore important that they made prompt progress but on visiting the patient they were reluctant to act, as can be seen in this exchange:

> Mrs Clarke is in bed and appears to be asleep. [...] Standing at the bottom of the patient's bed Nurse Webb and Dr Chatterjee look at the patient, look backwards and forwards at me and at each other. They debate whether or not to wake her. Should they wake her now or come back later, or wait until tomorrow? Research Nurse Webb suggests that they could wake her and give a brief explanation then leave the information with her to discuss with her family if they return this evening then they could come back to take consent from either the patient, if appropriate, or her family when they come to visit tomorrow morning. Visiting time is 11:00-13:00 hrs and they have until 14:30 tomorrow to randomise her. Dr Chatterjee ponders this for a minute or two then agrees that it is a good idea but makes no move to wake the patient. [...] After a few minutes Mrs Clarke begins to cough and wakes up. [...] She closes her eyes again and looks like she's going to drift back off to sleep but she has another couple of coughing spells. Dr Chatterjee is still wondering what to do [...] Eventually he decides to approach her but it is established in conversation that the patient lacks capacity to give her own consent to participate in the study. [FIELDNOTE: April 2007, Extract 1]

Although at this point questions about the patient's capacity curtailed the interaction, if the clinical team had taken a proactive approach and had informed the

research team of the patient's admission, while family members were present, it may have been possible to secure proxy-consent to enrol the patient in the study. This interaction demonstrates the way in which the timing of research activity was constrained by the perceived dichotomy between research and care, and also by the somewhat hierarchical dimension of this split. The research nurse and the research fellow negotiated between themselves regarding the time available and the priorities **for the patient** at the present time. In their negotiations they orientated to Mrs Clarke as a **patient** who was eligible for a study, not simply a potential participant. As well as the exchange noted here, they discussed various possible scenarios, with the aim of maximising the chances of recruitment. Ultimately however (and properly), they recognised the patient's basic need for rest, and prioritised this over immediate study enrolment. In doing so they positioned themselves within the more traditional aspects of their role as carers rather than investigators/scientists.

Based on numerous observations throughout my fieldwork, this reluctance to approach/wake the patient was unlikely to have occurred had the intrusion been a clinical one, such as to take the patient for a scan or other investigation. If a junior doctor had arrived to clerk the patient he/she would most likely have woken her because, a) an assessment of the patient is required in order to establish a treatment plan, and b) there is a need to fit a number of tasks into their busy schedule, but **this** intrusion was different because it was seen as something extra and not **clinically** necessary – a distinction made by the research fellow himself in his subsequent telephone conversation with the patient's son (see Fieldnote, Extract 3, below). Their reluctance, whilst demonstrating concern for the patient's physical needs, suggested that despite the relatively short time window, even the researchers themselves did not consider the research to be a priority.

Whilst time was of the essence for the research team, the ward staff's lack of familiarity with the various research protocols meant that they were unaware of the urgency and therefore failed to appreciate how they could facilitate communication and subsequent recruitment. When Mrs Clarke was admitted three family members/friends were in attendance. Had the ward staff been familiar with the research protocols and taken a proactive role in recruitment, they could have informed the research team of the patient's admission and potential eligibility thus enabling the research team to visit the patient when her relatives were present. Mrs Clarke's family members would have received the information sooner, had more time to consider their mother's participation

and to discuss this between themselves. They would also have had an opportunity to discuss the study with the researchers, who would have still been available on site for consultation. Such cooperation and collaboration may have facilitated patient recruitment. In the absence of such cooperation and in light of the patient's diminished level of capacity it became necessary to contact her next of kin in order to discuss potential research involvement, but even this decision involved much discussion and negotiation:

> Dr Chatterjee asks Mrs Clarke if she will be having any more visitors today and she says yes. After a bit of a struggle he manages to establish that she thinks her son, Graham, will come in tonight. She is unable to say what time this might be. Dr Chatterjee apologises for troubling her and says he will speak to her family later. Nurse Webb and Dr Chatterjee then leave the bay. In the corridor they ponder what to do next. Dr Chatterjee suggests that they [...] keep popping back to see if any visitors turn up but visiting time is restricted and the next session will not begin until 16:00 hrs. Nurse Webb suggests that they ask the ward staff to ring them if anyone else turns up but Dr Chatterjee remarks that they might not come back until after 17:00hrs [by which time neither he nor Nurse Webb will be available]. Nurse Webb suggests that Dr Chatterjee could ring the relatives to see if and when they might come in and could arrange to attend when they are present, but as this may be after 17:00hrs he seems reluctant to make such an arrangement. [...] Nurse Webb then suggests that they ring the patient's next-of-kin and if they aren't coming in till later this evening ask if it would be ok to leave some information for them to read and then catch up with them when they come to visit tomorrow to discuss fully. Dr Chatterjee agrees to do this. They look in the patient's records and find telephone numbers for two family members. [...] The nurses' station is quite crowded and noisy so Dr Chatterjee and Nurse Webb return to the Stroke Research Office to make the call. [FIELDNOTE: April 2007, Extract 2]

In the example above , the research staff endeavoured to manage their time in order to comply with organisational restrictions and the effects of those restrictions such as the fact that the patient's family were prohibited from returning to the ward before 16:00 hours and in fact were unlikely to return during the researchers' span of duty. They also endeavoured to do this in such a way that impacted as little as possible upon the workload of the clinical staff. Unfortunately, in their consideration of other people's priorities their own were relegated.

As well as trying to avoid increasing the workload of the clinical team, the research team was also reliant upon the cooperation of the patient's family. Communication with the patient's family however was dependent upon the time available to the research team and the degree to which this coincided with the availability of others, whilst also minimising any impact on third parties (i.e. the clinical

team). This negotiation between different actors and their temporospatial availability is demonstrated in the following extract:

> After several failed attempts Dr Chatterjee eventually manages to contact Mrs Clarke's son. [...] He explains that he is a doctor from Ward 2, Nearstreet and that 'we' were wondering when someone would be coming in because we would like to speak to someone about including Mrs Clarke in a research study [...]. - **something extra from her usual care**. [He mentions that the patient seems a little confused so we cannot ask her personally for her consent and therefore need to ask her next of kin]. He explains the voluntary nature of involvement but does not give any details about the study itself. [...] The patient's son [...] says he will try to get in before 19:00hrs but cannot be certain about this. Dr Chatterjee asks whether he may leave an information sheet at the patient's bedside for him to have a look at and take away to discuss with other family members if he wishes, to see what they think and then he will catch up with whoever comes to visit tomorrow. He agrees to this and Dr Chatterjee thanks him. [...] Dr Chatterjee plans to leave the information sheet on Mrs Clarke's bed table or cabinet. I suggest that he could give it to Sr Mitchell and ask her to make sure that Mrs Clarke's relatives get it. He is concerned that if the ward gets busy Sr Mitchell won't have time to do this so instead he sticks post it on the front of the document which says "Study information for Mr Clarke". Research Nurse Webb takes it to the ward and leaves it on patient's bed table but also asks Sr Mitchell to point it out to relatives if she sees them. Sr Mitchell agrees to do this. [FIELDNOTE: APRIL 2007, Extract 3, my emphasis]

It can be seen that the recruitment process was threatened because of the research team's disjuncture with the clinical team and because their working hours restricted their ability to be present when the patient's family were likely to be in attendance. Whilst a formal shift system like their clinical counterparts may not be absolutely necessary, an arrangement for on-call and/or overtime payments may have helped to address this issue. Although there was some degree of flexibility in the research team's working hours, this generally meant that they were expected to take time off in lieu for any additional hours worked. This had a knock on effect however in that if they took time off to make up for extra time worked in order to meet with a patient's family (for example) they then risked missing another potential patient during the time taken in lieu. A vicious circle therefore developed where research staff were reluctant to work extra hours, even in order to secure recruitment, because in doing so they may jeopardise future recruitment opportunities, particularly in the hyperacute situation, unless they forgo their time to be taken in lieu. 'Care' was required and provided 24 hours per day, seven days per week; research was not, and this presented difficulties when trying to make contact with family members when patients lacked capacity to provide their own consent.

The catalogue of events outlined above indicates how time and timing of events and interactions can impact enormously upon the conduct of the research team and the outcome of research activities. Whilst the research team was mobile and thus, flexible in a geographical sense, this flexibility did not extend to team members' working hours, thus limiting their availability and potentially placing a constraint upon the number of patients that they were able to recruit to research protocols, particularly in the acute and/or hyperacute situation. The interaction outlined above, provided further examples of the circular relationship between time, space and execution of research duties the following day when a plan of action was required in order to facilitate recruitment of Mrs Clarke. This scenario is discussed further in Chapter 8. Nevertheless, whilst these temporospatial splits may have impeded the progress of research, to some extent, this did not mean that clinical and research teams led a totally separate existence. As the next section shows, researchers and clinical staff came together in some circumstances to work as a 'virtual team'.

5.5   Clinical And Research Connections: Forming A 'Virtual' Team

Logistical and operational issues notwithstanding, there were some situations where researchers and clinical colleagues worked together as a 'virtual team'. This was usually advantageous for the clinical staff in that it frequently involved the research staff temporarily relieving the clinical team (nursing and medical) of an element of their clinical workload, for example, the research nurses' assessing patients for, or administering, thrombolysis. As previously noted (Chapter 3) thrombolysis was originally offered at the study site only either off-licence or as part of a RCT, and as such, was delivered by the research team. Although thrombolysis had now become part of clinical service provision, the research team was still instrumental in providing this service because they were already trained and experienced in the specialist skills required to undertake assessment and administration. Furthermore, ongoing reconfiguration of emergency medical services at the study site (in terms of facilities and personnel) meant that for a period of time, the stroke nurse practitioner, and some members of the research team, were required to share the out of hours rota with the medical staff, in order to provide cover for the thrombolysis service. The effect of this research-clinical amalgam was that research and specialist nurses were at least temporarily repositioned on what may be becoming a nurse-doctor continuum (Baumann *et al.*, 1998).

Following the patient trajectory, as outlined in Chapter 3, the research team's first point of contact with new patients potentially eligible for acute/hyperacute research was in the Emergency Admission Suite, where new patients were initially accepted. The actual time of contact as well as frequency and duration were also important. At the time of interaction with EAS staff the patient's situation is critical and the focus is on undertaking assessment and initiating appropriate investigations and treatment as soon as possible. In conjunction with the stroke nurse practitioner, on arrival in EAS, the research team took over the admission assessment procedure although EAS staff assisted with observations, prepared equipment and attended to the general comfort of the patient and relatives. The resident medical officer (RMO) was advised of the patients' admission but, in the interactions I observed, usually had minimal involvement at this stage. In the following extract I describe a fairly typical stroke admission episode in which a patient, Mr Adams, had been admitted with self reported onset of symptoms approximately one hour previously. Having been advised of the patient's imminent arrival Research Nurse Higgs and Sister Stone (SNP), were waiting for him when he arrived and took a brief handover from the paramedics.

> Nurse Higgs introduces himself to the patient as a research nurse and explains that the research team assess patients who have had or may have had a stroke to see whether they are eligible for emergency stroke research and that he'll be "asking a lot of questions and running around a lot". […] Nurse Higgs completes neurological examination. RMO pops head into cubicle during this procedure but does not interrupt and leaves immediately. Nurse Higgs exits cubicle after completing examination but I hear him just the other side of the door describing patient's presentation and indicating that urgent CT is required. Sister Mackay asks if Nurse Higgs needs the RMO now and Nurse Higgs indicates that this would be helpful. However the RMO asks what he can be doing if Nurse Higgs and Sister Stone aren't finished. He says he's "not sure what his role is in all of this". (I discuss this with Nurse Higgs later and he tells me that he used to feel very uncomfortable about asking the RMOs etc. to let him do his trial assessments when he first started but feels more confident now and he is probably more experienced in conducting neurological examinations than a lot of the RMOs, especially immediately after the medical staff changeovers such as now [August]). […] Nurse Higgs says that it would be useful if the RMO could insert a couple of cannulae, take some bloods, do an ECG and sign a CT request form. RMO asks whether the patient needs to be clerked and should he do it. Nurse Higgs responds that patient will need to be clerked but stroke team will probably do this as it seems very likely that the patient will be thrombolysed. Nurse Higgs is very forthright in asking the RMO to undertake these tasks for purely pragmatic reasons so that he and Sister Stone can get on with preparing for thrombolysis. […] Whilst Nurse Higgs and Sister Stone are out of the cubicle RMO introduces himself to patient and as he's siting

the venflon explains that he gets to do all of "the mean jobs". [FIELDNOTE: August 2006]

This extract illustrates the flexibility of the research nurse's role and others' understanding and acceptance of that role. Here, Nurse Higgs quite openly took control of the situation. By telling the patient at the outset that he would be "running around a lot" he implied a sense of controlled urgency. In contrast to behaviour I often observed in less acute situations, he did not defer to the medical staff. For example, if a member of the clinical team needed case notes that a research nurse was reviewing to determine a patient's eligibility for secondary prevention studies, the research nurse invariably handed them over immediately, often without any direct request being made, thus privileging clinical need over research requirements and differentiating between the two. This negotiated ordering of roles, responsibilities and priorities was not verbalised but was based upon the actors' anticipation and/or previous experience of the actions of their colleagues. However, where the research nurses did defer to their clinical colleagues this further perpetuated the notion that research activity was separate from, and somehow less important than, clinical 'care'.

Because the first course of action was thrombolysis wherever possible, patient assessments were undertaken with this in mind, prior to consideration for study involvement. The RMO or specialist registrar from the stroke team could perform this assessment but this would necessitate repetition and loss of valuable time if the patient was then to be screened for study involvement. Time, therefore, primarily determined task allocation and, thus, the research nurses or the stroke nurse practitioner undertook the assessment for clinical **and** research purposes, ensuring that neither was delayed. This was not intended to exclude or undermine the clinical team however, rather it was a purely pragmatic response to the urgency of the situation and a recognition of each individual's skills and attributes. Many nursing staff now extend their role to include venepuncture and cannulation, often in order to alleviate some of the demands on junior medical staff; this was not the purpose here. It was simply that economy of time was maximised if the research nurse and the stroke nurse practitioner concentrated on preparing for thrombolysis, a procedure which the RMO was unlikely to be familiar with. In other words, all parties involved here responded to each other's actions rather than acting upon predefined role attributes and functions (Blumer, 1969b; Rock, 2001).

The above interaction illustrates a role reversal between medical and nursing staff, with nurses leading the process and the doctor undertaking tasks as required by the

nurses. In addition, it demonstrates how, for a **moment** within this clinical episode, individuals from otherwise disparate research and clinical teams came together to function as a 'virtual team' in order to ensure prompt completion of the task in hand, i.e. patient assessment and appropriate treatment. It also demonstrates how both the research nurse and the stroke nurse practitioner functioned beyond the traditional boundaries of their nursing role.

In the scenario described above, although not strategically engineered, the RMO's lack of specific knowledge about thrombolysis and/or study protocols worked to the research nurses' advantage because by directing **his** activity the research nurses were able to concentrate on their own tasks unimpeded by other medical or administrative requirements. This malleability of the relationships between the doctor and the clinical and research nursing staff was predicated upon the urgency of the task in hand and the experiential knowledge of the practitioners; each assumed the role and completed the tasks that they were most familiar with. However it was specific to this particular set of circumstances and was fluid and negotiable. I did not observe reciprocal engagement of clinical nursing staff in research activity or interactions. Furthermore, the dynamic shifted in other areas and at different time points within the patient's trajectory, impacting both positively and negatively upon the research nurses' performance of their role and described more fully in Chapter 7 (Performing Research Identity).

Whilst connections between the research and clinical teams were generally transient and variable, a more permanent although equally fluid link was that between the research nurses and the stroke nurse practitioner. Like the research team, the SNP also discharged her role in a number of clinical areas and travelled to and with the patient rather than residing in a fixed environment. She was allocated office space even further away from patients than the research team, on site, but separate from the main hospital building. During my fieldwork she seldom used this office space, but frequently took up guest status, not within the stroke ward, but in the stroke research office, as I recorded on more than one occasion in my fieldnotes:

> Sr Stone must be in today as her coat is on the back of the chair [in the SRO] [FIELDNOTE: April 2007].

Like a vagrant, she transported her personal and work related belongings into the SRO on a daily basis, rather than leaving them in her other allocated office space or taking them into the ward area, even though there was not really sufficient space to store

them. She evidently felt more 'at home' in this environment and with other 'migrant workers' than in either of the other two spaces, and it was the physical presence of her belongings, rather than her name on a duty rota, which facilitated colleagues' awareness of her whereabouts.

Because the SNP moved between spaces, and was often the first point of contact for new suspected stroke patients, it was she, rather than the ward staff, who was more likely to advise the research team of new admissions. Her close liaison with the consultant medical staff also meant that when the more research active staff were on-call she was likely to be advised of potential research eligibility, which she was asked to convey to the research team. Whilst such interactions illustrated some cooperation and collaboration between the clinical and research teams they occurred only between specific personnel and in specific circumstances, facilitated by the very factors – mobility and hybridity –that prohibited or at least restricted such interactions between research and ward based staff. On one occasion, when based in the Stroke Research Office I observed the following interaction:

> Sr Stone turns up just then and tells Nurse Higgs about a patient that Dr Silva thinks might be eligible for PERFORM. […] A discussion follows regarding which study, if any, the patient may be eligible for. […] In discussion about the patient/study Sr Stone says "which study he goes into has nothing to do with me, Dr Silva just said let Nurse Higgs know he might be eligible for PERFORM". Dr Chatterjee says 'so what are you now then, Ward 2 nurse?" "No" replies Sr Stone, "I just float about - I keep an eye over there and get involved over here". [FIELDNOTE: April 2007]

Even the SNP's closest colleagues were uncertain where she 'belonged'. It is significant that the question was not 'where are you based now?' but 'what **are** you now?' (my emphasis) - suggesting that one's base is a defining factor of one's identity. In some respects the level of independence and autonomy experienced by the research nurses and the SNP may be considered to be liberating and empowering, but there was also a sense that their individuality could be alienating and isolating (as will be further explored elsewhere – Chapter 7). Born out of their shared mobility, fluid role definition and their physical and temporal **dis**-connection from the ward based staff, the stroke nurse practitioner and the research nurses were united in their **difference**, even though that difference was not **the same**. This scenario is reminiscent of Carmel's description of the obscured boundaries which exist between medical and nursing staff in Intensive Care Units (Carmel, 2006). Here the boundaries of nursing and research were obscured,

as specialist nurses and research nurses were brought together, whilst simultaneously differentiated from 'the ward nurse'.

5.6 Discussion: The Temporospatial Dimensions Of The Relationship Between Research And Clinical Activity

As noted earlier (Chapter 2.5), it is argued that it is advisable to separate research and clinical activity, mainly in order to avoid procedural and therapeutic misconceptions and promotion of unrealistic hope of benefit in research participants (Miller and Brody, 2003; Fisher, 2006b; Miller and Joffe, 2006; Charuvastra and Marder, 2008). There is also a presumption that by separating the two activities, clinician-investigators are less likely to feel the burden of competing interests embodied in their responsibilities to the individual patient, to society and to their pharmaceutical sponsors (Brody and Miller, 2003). In practice however, particularly in the emergency context, to split the two may be no less ethically fraught, not least because of the logistics of setting up a research specific service and the effect that this may have on the provision of clinical facilities and care. Provision for stroke care in the UK, although improving, is not optimal (National Audit Office, 2010). To insist upon separate facilities for stroke research would either be wholly unworkable or would necessitate shifting specialist personnel (already in short supply) from the clinical area to the research forum, which would seriously disadvantage those patients ineligible for, or unwilling to participate in, research protocols. For these reasons collaboration, if not total integration, was the aim within the study site.

Integration however was beset by a number of difficulties, some of which have been illustrated throughout this chapter. Although geographically mobile, the research team was temporally restricted, both in terms of actual working hours and also in relation to when, within those hours, they can perform research tasks. With the exception of initial assessment which tended to be a combined effort, research activities typically happened **after** clinical activities had been completed, and were perceived to be secondary. Depending upon the nature of the research activity, (for example recording of vital signs or retrieval of blood samples), it may take place within the patient's clinical area, but was frequently undertaken in a different location altogether (for example, completion of case report forms and screening logs). Thus both space and time impacted upon task orientation.

The separation of clinical and research activities that I witnessed in the ASU seemed incongruous, given that the focus of the activity – the patient – cannot be similarly **physically** compartmentalised. The 'wholeness' of the patient seems self evident. Whilst a patient cannot be physically divided into 'the part that is participating in research' and the 'part that is receiving clinical care' in practice such differentiations are made every day, usually for good reason and to good effect. In different departments and across different disciplines, different configurations of the patient exist, for example in the radiology department, laboratories, finance. The differences are relatively obvious and can be considered to lie in the physical closeness of the staff group to the physical body of the patient. Radiology staff, for example, have physical contact with the patient whilst they perform diagnostic tests, but thereafter their representation of the patient resides in the radiological films which they have taken. For laboratory staff the connection with, and their configuration of, the patient is even more fragmented, and is represented by one or more samples of bodily fluid or tissue. None share the same physical closeness as the ward based nursing staff. They all deal with patients, but construct them differently in different spaces and in relation to different activities and outcomes.

The dichotomised view of the 'stroke patient' versus 'patient plus' (i.e. patient and research participant) is perhaps more difficult to uphold than the perspective of the radiologist or the lab worker. For example, when a blood specimen is sent to the laboratory it has no **contemporaneous** effect on the patient on the ward until it is analysed and the results acted upon. When a patient is enrolled in a study and receives study intervention it is likely to affect the whole patient, not just the part that the study intervention aims to treat. It seemed that this dichotomisation of research and care was more prevalent amongst the clinical team than the research team. Perhaps this was because they had no experience of the research arena, whereas the research team members had previously been employed in the clinical field. The research team and the SNP saw and interacted with patients in some of the same spaces as clinical staff, and might therefore be expected to orientate towards them in the same way, but they did not. They constructed the patient differently, as did clinical staff when the patient was somewhere other than their legitimate clinical area. This can be seen in Chapter 5.3.2 above, in which I discuss activity in second order spaces and describe interruptions to the consultation between the research team and a potential study participant. The interactions that went on in the research room (the ward store) were not seen - by the

ward staff - as care, and the participant in this instance was therefore, not afforded the same level of dignity and respect as a 'real' patient. This was surprising, because an argument raised several times throughout the interviews with the clinical staff was that they 'know' and were responsible for their patients in a far more holistic sense (c.f. May, 1992b); it seemed incongruous then that they were unable or unwilling to incorporate their patients' research involvement within their delivery of care.

Similarly, in relation to the incident regarding the missing study drug for example, if the patient had been diabetic and her insulin could not be found, one would not wait until a diabetes nurse specialist arrived on the ward to look for it; nor would he/she be responsible if the insulin could not be found. Whilst patient participation in research is 'non-compulsory', once a decision has been made to do so, study related procedures **become** compulsory and are then part of his/her care. Equally, timely adherence to the study protocol and schedule is important not only for the individual patient, but for the integrity of the study and, by extension, the safety of future participants and the wider stroke population. However, it is important, at this point, to acknowledge that the clinical staff were responsible for the care of up to 30 patients, whilst the research nurses were responsible only for patients enrolled in research protocols, and even then, only for very specific aspects of their management. Although the drug in question was being administered within the context of a study, it should be delivered with at least the same precision and accuracy as any of the patient's other medications or interventions. Due in part to poor ward staffing levels, a large proportion of highly dependent patients, and less than optimal communication between clinical and research teams, some elements which could (and arguably should) be shared, remained the sole territory of the researcher.

Organisational factors relating to the provision of care meant that the research nurses necessarily moved between clinical areas regardless of their base. They followed the patient and, as a result, some aspects of their work always took place beyond the observation of the clinical team. However, even when undertaking activities within the clinical area, the research nurses did so largely without input from the clinical team, even in the case of joint research/clinical tasks such as history taking and initial assessment. The research nurse or research fellow was invariably unaccompanied when discussing study involvement with patients, thus the clinical staff were not privy to decision making processes enacted by the researchers in these situations. Completing the 'virtual exclusion zone', the research team's subsequent administrative work was

conducted in the SRO, away from the clinical area where stroke patients were managed. This meant that the clinical staff were unable to observe other aspects of the research nurse role and therefore did not comprehend its scope. The impact of their sequestration is discussed further in the following chapter.

Following Goffman's dramaturgical theory we may consider the Stroke Research Office to be a 'backstage' region where the research nurses relaxed from and prepared for the role that they enacted in the clinical area (Goffman, 1959), but such removal perpetuated lack of awareness and thus, limited their colleagues' understanding of the research nurse role.

Like the temporary employees described by Garsten, the research nurses were perceived as 'insiders' (Garsten, 1999). However, the relative ease with which the research nurses accessed the patients and became their 'intimate guests' contrasted with the way in which they were required to request access to the store cupboard (ASU) or the treatment room (Ward 1). The research nurses were able to access patients because they were conducting research into the treatment/prevention of stroke and these patients were thus diagnosed; they accessed the ward bays and cubicles in the ASU without express time-limited permission because that was where these patients were. Conversely, they sought explicit, time bounded permission to access the treatment room on Ward 1 because stroke patients would not normally be seen on this ward and therefore neither they, nor the research nurses, had legitimate, unrestricted access to that area. The patient did not act as a 'key' to these settings; the 'guest -host' relationship took on a more formal note and the researchers became 'outsiders'. They traversed the boundaries not only of social groups and identities, but also their associated territories, thus occupying a liminal space both physically and metaphorically.

5.7 Conclusion

In this chapter I have illustrated ways in which the research nurses in the ASU were temporospatially differentiated from their clinical counterparts. This temporospatial dislocation impacted upon the enactment of their role, in that certain things must be done in certain places, and within a relatively fixed time frame. They occupied liminal spaces, both physically and metaphorically, and were constructed and constructed themselves in different ways, according to their location and the activities they were legitimately allowed or expected to undertake there. In the next two chapters I explore other ways in which doing research impacts upon identity, first discussing the

clinical staff's perceptions of research and the research nurse role before considering the research nurses' performance of their role identity.

Chapter 6. Separating Research and Care: Positioning of Research by the Clinical Staff

6.1 Introduction

As I have described in the previous chapter, one of the main ways in which research and clinical activities were separated at the study site was that they were undertaken in different places, by different personnel, who were available at different times. The distinction between clinical and research staff however, was as marked in what their activities entailed, as in where and when those activities were undertaken and invoked a range of responses from their clinical colleagues. It is crucial to note that nursing involvement in the conduct of clinical trials has evolved considerably in recent years. The role of research nurses has shifted from duties of a technical or support nature to those of implementation, administration and co-ordination. The role has thus become a dynamic hybrid of nursing, medical, technical and administrative tasks encompassing surveillance, communication, diagnostic tests, teaching, support and care. Research nurses traverse several boundaries, such as those between medical science and medical practice; research and care; doctors and nurses, but may also encounter boundaries within the discipline of nursing. In this chapter, I examine how the roles of the clinical nurse and the research nurse serve to further separate these two areas of practice. In Chapter 2, I explored how the literature positions the research nurse within the discipline of nursing; here, I explore how and/or why research activities are considered by some to be alien to the role of the clinical nurse. Further, I look at how clinical staff observe, understand and integrate (or not) the research nurse role and research activities within the clinical area.

6.2 The Positioning Of Research By The Clinical Staff

At the study site, the stroke research nurses needed to follow the patient in their pathway through the healthcare system. Thus, their activities took place in a number of different areas (see Chapter 5). This led to difficulties in maintaining identification with a specific clinical team or service. In effect the research nurses were dislocated, not only in time and space, but also with regard to their professional identity. This disconnection raised a number of issues which were echoed throughout the data and were clearly summarised by one of the clinical nurses in the extract below:

[T]he research nurses, they used to **come and get the information off us** how well were the patients? how poorly? Diagnosis and things like that, and then it was sort of **taken out of hands** and then that was **like a separate department** coming in, [...][R]esearch nurses come in and look at the files as in blood pressure and things like that, but **we don't know** what you're looking for. If, if we, if we can assist it would, it would be- it would be beneficial, but at the end of the day **we don't know** what you wa- what you're doing. You're getting all this information, but what information are you getting, what are you doing with it, where is going to? **We don't know**. [INTERVIEW: Staff Nurse Cooper, August 2007, my emphasis]

Nurse Cooper conveyed an impression of a unilateral relationship existing between clinical and research nurses, one in which the research team 'take' data from the clinical staff, but give little in return. The clinical staff, their records and systems, were accessed as if they were a resource to be interrogated, but were not treated as if they required, or warranted, information about the studies or about interactions with potential participants. This lack of reciprocity led to a sense of exclusion on the part of the clinical staff, as if the research team was an entirely separate department, despite their commonality of training and interaction with the same patient group. They were viewed as being 'the same but different'; a position which rendered both research and the researchers separate and mysterious. The clinical nursing staff concluded that they did not know what the research nurses did, needed or wanted and that they were therefore, unable to assist them. It was demonstrated here and throughout the data that research was generally perceived to be important and valued, but for a number of reasons, which often were ill-defined, the clinical staff felt excluded and unable to participate in the research process.

So, the main issues this interviewee explicitly raised were that:

- The research team was "**like** a separate department", that 'took' data from the clinical staff with little reciprocity,
- The clinical staff did not know what the research nurses needed, did or wanted, because they did not understand study protocols
- The clinical staff were willing, but unable, to help either the research team in their tasks, or the patients/families in their decision making about potential research involvement, although they recognised that there may be potential benefits in doing so.

A fourth issue, related to, but not made explicit in the quote above, was that the clinical staff were limited in the extent to which they could participate in research

activity, not only because of their lack of knowledge, but also because of competing priorities. In the sections that follow, I will expand upon these issues in order to explore the way in which the clinical staff experienced and understood the activities of the research team, and how this impacted upon the integration and conduct of research within this acute stroke environment.

6.3 The Nature Of The Clinical-Research Team Relationship: Separate And Mysterious

In the interview fragment above, Staff Nurse Cooper suggests that the research team was **like** a separate department, but acknowledges that it was not entirely separate; clinical and research teams were the same in that each included nurses (and doctors) and dealt with stroke patients, but there was something about what the research team did (or did not do), that rendered them 'other'. At the heart of this perception of difference was what the research team was seen to do.

The temporospatial dislocation of the research team (see Chapter 5) meant that the clinical staff were presented with only a 'snap-shot' of the research team's work, mainly data collection and paperwork. The research team was seen as **taking something from** the ward staff and/or the patient, shifting activity out of the ward staff's hands and by implication, removing these data and activities from their control. Whilst ward staff were aware that the research team visited and assessed patients, and obtained informed consent for study enrolment where necessary, they did not understand the whole recruitment procedure or subsequent management, because they were neither invited, nor did they volunteer, to participate in research activities.

They typically saw the research nurse arrive on the ward, review the 'bed board' (a wall mounted white board beside the nurses' station displaying in tabular form patients' names and location on the ward), admission book (recording patient demographics and admission details), 'ward returns' sheet (a document detailing admissions, discharges, transfers and deaths which is 'returned' on a daily basis to patient services) and relevant patient notes. These data were required for completion of study screening logs, determination of patients' potential study eligibility, and completion of the European Stroke Database (ESDB) proforma. The research team was then sometimes seen to approach potential study participants to discuss involvement, but these approaches were rarely accompanied by clinical staff. The clinical staff were, therefore, unaware of the interpersonal skills required, or demonstrated by, research

staff. As noted in Chapter 5, the 'virtual exclusion zone', of the SRO, in which the research team's subsequent administrative activity was conducted meant that the clinical staff did not see or comprehend the scope of the research nurse role. They were thus unaware of negotiations regarding potential new studies and participants; ethical debates about individual patients or studies; the time consuming and repetitive nature of data collection, recording and electronic data entry; and the labour intensive nature of addressing data queries. They were not party to discussions in which the research nurses drew on their relational and interpersonal skills to decide if, when and how to approach a patient or family. Nor did they observe the research team's deliberations about study involvement, based on criteria other than those stipulated in the study protocol. The clinical staff were not privy to these, often internal debates that the research staff engaged in, regarding appropriateness at a human level, of a study for a patient, rather than eligibility, at a procedural level of a patient for a study.

It is unsurprising then that the clinical nurses made numerous comments about the research nurses' apparent focus on data collection and interrogation - comments that were echoed by other members of the clinical team, including junior medical staff, who observed that the research nurses come onto the ward and "ask a lot of questions" (INTERVIEW: Dr Bates, November 2006). Such comments were typical and reiterated the idea of a 'one way' flow of data. The junior medical staff, like the clinical nurses, had very little interaction with the research team, usually only answering basic questions pertaining to patients' study eligibility. They did not, and were not expected to, engage in discussion with patients about study participation, because they were not considered experienced enough to do so. I was advised that some of the middle grade medical staff occasionally assisted in such negotiations, but only in situations when the Principal Investigator or research fellow was unavailable, and when arrangements had been made in advance to provide research cover if necessary. However, I did not witness this during my fieldwork.

Whilst interactions between clinical and research nurses were more frequent than those between the doctors and research nurses, they were equally superficial. As Sister Stone noted, this perpetuated the sense that there was a marked difference between 'the research team' and 'the nurses on the ward', prompting a sense of 'them' and 'us'. She also noted, by referring to the period of her previous employment as Senior Sister in ASU, that there had been little input from the ward staff in research activity but equally, the research nurses appeared to have expectations of the clinical

team which they did not help or support them to fulfil. Referring to a previous study which relied considerably upon input from the clinical team, she commented that this had directly impacted upon the clinical team's workload but that this had not been taken into consideration by the research team. Situations had arisen that may not otherwise have done so outside the context of the research protocol:

> …[these events were] something else that you had to sort out, the research nurses weren't around, to help with this, they purely felt it should be nurse led, […] I think I probably didn't give it the support that I could have done had I felt as though we were being a bit more supported […] I felt it was a case of "Oh, the nurses can do that, and the nurses can do this" without really being that supported by the research team. [INTERVIEW: Stroke Nurse Practitioner (and former Stroke Unit Senior Sister), May 2007]

This perceived disregard precipitated a lack of support for research by the clinical team. Importantly however, the SNP also suggested that there was something about research itself, not just those conducting it, that contributed to the clinical staff's sense of exclusion:

> I think people [she includes herself here] are a little bit **frightened by research** and they think it's going to be something that's […] maybes **above them** or, […] 'Oh, we're **not going to understand**' [INTERVIEW: Stroke Nurse Practitioner, May 2007; my emphasis]

For her, the perceived academic element of research, that this was something potentially complex, added to the sense of distance and mystery, and 'a little bit' of fear. Nevertheless, some nurses do choose to embrace research, although with differing reported, and perceived reasons for doing so, as I now explore.

6.3.1 Moving to a research nurse role: a way up, or a way out?

Whilst the research nurses were separated from their clinical colleagues by virtue of **what** they did, this distinction was reinforced and perpetuated by the clinical staff's suggestions regarding **why** nurses chose to take on research roles. Having previously been employed as a research nurse herself, in the same stroke unit, the senior ward sister stated that she had taken on a research role for the purposes of developing her own career. She stated that she had enjoyed the experience and had learned from it, but did not want to continue in a research role because she felt that there was something fundamentally different about research and clinical nurses. She went on to say that she felt that she embodied the characteristics of, and fulfilled the requirements of, the latter rather than the former:

I did the research erm, because I felt that I needed it for my career, [...] but towards the end I thought no, this isn't for me, I'm not a research nurse. [...]I think that you are either a research nurse or you're not. [...] Erm, I think [research nurses are] harder, I think I'm too soft. [INTERVIEW: Sr Hatfield (Senior Ward Sister and former research nurse), July 2007]

When new nursing roles began to be discussed towards the beginning of the 1990's it appeared to be the case that career progression would be contingent upon (at least in part) one's experience and skills in conducting clinical research; indeed Mulhall notes that in the UK the drive for nursing involvement in research has primarily been grounded in its desire for professionalisation (Mulhall, 2002). Whilst this appeared (at a personal level) to have been a positive factor in Sister Hatfield's decision to take on a research role, the desire for advancement, whether at a group or individual level is often viewed with suspicion. This was noted by Dr Black (Consultant Stroke Physician), during his interview. A highly active researcher himself, Dr Black suggested that some took the cynical view that researchers were motivated by the prospect of 'fame and fortune'.

Other interviewees offered alternative rationale for what they perceived to be a marked distinction between research and clinical staff:

We do and they don't, we do a lot - we do a lot of the nasty things, well, you know, things like beds and whatnot, […] - we work out things socially, we work out the problems, family-wise, they don't deal with anything like that, and again if they, we couldn't do what they do because we haven't got the time to do what - I know that they're on the computer a lot [...] - they go to a lot of conferences and things, but we haven't got time to go off the ward and do things like that [...] as I say, that's why they got out of nursing, because they were sick of er bed baths and things like that. [INTERVIEW: Nurse Cooper, August 2007]

The clinical team prioritised care – the main aspect of which was considered to be physical labour and emotional work. The perception of the research nurses' disengagement from clinical activity, especially that involving direct physical contact, contributed to notions such as those outlined by Hicks (1996) regarding the mutual exclusivity of the roles of nurse and researcher. From their own accounts, and illustrated clearly above, clinical staff saw their role as including those tasks complying with the traditional expectations of the 'nursing' role, such as physical work, social work and 'dirty' work (c.f. James, 1992), and therefore they did not have time to undertake research tasks. Research staff, on the other hand, were considered to be largely office bound, mostly undertaking administrative and technical work and travelling the country

to attend meetings and conferences – a luxury which was not open to ward staff who complained that they could not even get away from the ward to attend in-service training sessions. It was noted however by Dr Black, and by some of the research team, that it may be the case that these issues were heightened in a stroke unit, as the nursing work was physically demanding and staffing levels and skill mix were never adequate for the level of patient dependency compared to other wards. This was supported by Research Nurses Webb and Slater, who held joint posts and noted a much more integrated approach in cardiology, for example, but noted that staffing levels were better and patients generally less dependent. They reported that the cardiology team, both medical and nursing, appeared more interested in ongoing research but also noted that there was usually only one, or perhaps two, studies ongoing at any one time, whereas historically there have been several studies running concurrently in the stroke unit. Although, as noted in Chapters 3, 4 and 5, there were fewer studies in the recruitment phase at the time of my fieldwork, there were still three acute or hyperacute studies ongoing, as well as a number of secondary prevention studies; unless one is involved on a daily basis it is difficult to keep up with all of the various inclusion/exclusion criteria, study procedures and requirements.

Whilst it was taken for granted that the research nurses were not expected to engage in delivering routine care such as feeding and personal hygiene tasks, some clinical staff found the research nurses' ability to disregard call bells (for example) counter intuitive to the ethos of nursing. However their own practice was not entirely dissimilar. In the ASU a variation of team nursing was employed, with the aim of promoting continuity and quality of care for the patient, and a greater sense of autonomy and job satisfaction for the nurses (O'Connor, 1993). It also ensured a clearly designated accountability attribution. Conflicting definitions of team nursing exist and many equate it with task allocation (Bloom and Alexander, 1982). In the ASU however, it would be more accurate to say that it was a system where a small group of nurses carried out all of the care for a smaller group of patients, rather than all of the nurses carrying out different elements of care for all of the patients on the ward (Watkins, 1993). As applied in ASU, a number of nurses were grouped together and allocated to a group of patients for a substantive period of time.

The ward staff claimed that this enabled them to care for and 'know' their patients in a much more holistic sense, and to develop a relationship that they did not consider possible for the peripatetic research team. In practice however, during my periods of

observation I witnessed little of the type of interaction that would furnish such a holistic picture (c.f. May, 1992a). This was in part due to reduced staffing levels and limited resources, which meant that clinical staff were not necessarily on the same 'team' every day, or that patients might be moved to different geographical areas of the ward, thereby switching teams. Nevertheless, despite their perceptions regarding the research nurses' disengagement from clinical activity, the ward nurses demonstrated similar behaviour, as a consequence of their team nursing approach, whereby Nurses from Team A invariably passed on requests of patients from Team B to that team, rather than addressing them themselves.

The clinical staff's contact with patients was often primarily functional and conversation, if it involved the patient at all, tended to be superficial. In fact, patient interactions with therapy staff were observed to be more prolonged and more substantive, if less frequent than those with clinical nursing staff. Paradoxically, despite being based outside the ASU, the research nurses' mobility and smaller patient group, meant that they had more, rather than less, of an opportunity to develop relationships with their patient participants.

Centrally, research was perceived to be something extra, over and above clinical activity, that the clinical staff did not have the capacity to take on. This reflects Sr Hatfield's observations - and relates to the rationale of labelling psychiatric nurses as not real nurses (Bassett, 2002) - because research staff were not seen to undertake physical care they were therefore considered to hold fundamentally different values to their clinical colleagues. More tellingly however was the reasoning as to why this was the case. Echoing the idiom that 'He who can, does. He who cannot, teaches', (Shaw, 1903; p.253) it was suggested that clinical staff did not get involved in research because of resource (particularly time) limitations; research nurses however chose not to participate in clinical care because they either could not, or did not wish to do so. The suggestion was that this was a personal choice, unimpeded by other restrictions and based on the divergence of values and characteristics that some consider to be evident between clinical and research nurses (Hicks, 1996). In fact, Nurse Cooper suggested that this distance from 'hands on' clinical work or doing "nasty things" was why some nurses left traditional clinical roles, although this implied, erroneously, that there was no equivalent to this unpleasantness in research work. In addition to the concerns raised above, there were other, more subtle demonstrations of this role distinction and

divergence of priorities, as illustrated in the following exchange which I observed whilst shadowing Research Nurse Fowler:

> One of the Stroke Unit Staff Nurses told Research Nurse Fowler that she was leaving as she had been offered a job at another hospital in Care of the Elderly]. She explained that although she thought that the type of care required would be similar she felt that there would be more time in this new job to deliver that care. Describing activity in the ASU she remarked to Nurse Fowler "no disrespect but it's all about **this** [leaning with both hands on Nurse Fowler's paper work] and not about **that** [indicating patients in ward bay area]". [FIELDNOTE: June 2006]

Although not referring specifically to research, it was noteworthy that the staff nurse cited Research Nurse Fowlers' work as an example of what she considered to be gratuitous and disproportionately time-consuming paperwork. This was particularly significant as this interaction took place at the nurses' station, surrounded by a plethora of paperwork and administrative props. However, as paperwork was probably the most frequently observed aspect of the research nurses' work, it was hardly surprising that it seemed to symbolise and be synonymous with research. By suggesting that the proliferation of paperwork in her own role was preventing her from doing what she wanted to do and what she thought nurses should want to do, i.e. deliver care, she also implied that the research nurse role and its perceived abundance of paperwork was devoid of any element of care. The logical conclusion of this statement was that real nurses did not do paperwork/research, the corollary being that research nurses were not real nurses, a distinction which exerted its impact beyond the teams' professional remit, as I describe below.

6.3.2 The socio-professional impact of doing research

The effect of the separateness of clinical and research staff impacted not only on the 'doing' of research but on the opportunity for informal social interaction between the two teams. Professional issues notwithstanding, it has been suggested that nursing teams exhibit a 'social' component, exchanging small talk about professional and personal issues, providing each other with social support and sharing a degree of physical intimacy (Reeves and Lewin, 2004). In contrast, my data demonstrated a lack of integration of the research nurses with the clinical teams. Geographically and professionally, relationships between research nurses and clinical staff and therapists (speech, physiotherapy, occupational) differed from those between the latter two groups. When discussing management of patient trajectories, reference is made to 'co-

operative work' and 'interdependence in work' (Schmidt, 1992; p.13) and indeed observations of general interactions in the ASU suggested mutual dependence and reciprocal exchange of information and support between ward staff and therapists. However, this reciprocity was less evident between clinical and research staff and reflected the suspicion with which we tend to view those who engender 'otherness' (Bauman, 1991). Ward staff and therapists appeared to answer research nurses enquiries about current or potential study participants to the best of their ability but did not volunteer information and rarely elaborated, with more general information about the patient's ongoing management or progress. However, nor did the research nurses volunteer opinions on clinical or nursing management, even regarding patients enrolled in the studies within their portfolio.

Additionally, this lack of integration was reflected beyond the realm of geographical and professional disjuncture and exhibited social manifestations as indicated in the following extract:

> Research Nurse Higgs arrived [at nurses' station] to review some patient data. Whilst there, he noticed two large boxes of sweets and asked Sister Hatfield (Senior Ward Sister) if he could open them. She refused to let him do so. The following day I joked with Nurse Higgs about this and he told me that Sister Hatfield does this every year "for the ward staff" but explained that this doesn't include him or even Sister Stone (SNP). [Research Nurse Fowler was not employed here last Christmas]. As it gets nearer to Christmas, Sister Hatfield puts away any gifts donated by patients and relatives and has a free 'tombola' for the staff so that they all get a gift. [Despite their frequent presence on the ward and their participation in clinical thrombolysis] the research nurses are excluded from this activity. [FIELDNOTE: November, 2006]

Despite frequent ward visits, and engagement with patients for either research purposes or following administration of thrombolysis in the Emergency Assessment Suite, the pervading perception of difference led to the research team being entirely excluded from this sharing of rewards. The fact that the stroke nurse practitioner was also excluded however, demonstrated how these two groups were conflated and considered similar in their difference. Thus, like the liminal entities described by Turner, who 'tend to develop an intense comradeship and egalitarianism' (Turner, 1969; p.95) they provided support to each other, whilst isolated from the wider clinical team.

6.3.3 The desire to support research, and the commitment to deliver care

The dichotomies between research and clinical practice, however manifest, contributed to an ongoing tension between ideals and practice that impacted upon the

accommodation of research activity within clinical practice. In general, most of the clinical nursing and medical staff spoke enthusiastically about research and appeared to appreciate its importance, although operational difficulties were observed which impacted upon its achievement in this setting. It was evident throughout the fieldwork that clinical and research staff, without exception, considered cooperation and communication between the teams to be fundamental in conveying the value and importance of research, not only amongst clinical and research staff, but also to patients and their families and, equally importantly, managerial and administrative staff. However, contrary to the argument that research should be incorporated within clinical care (Rhodes, 2005), some of the clinical staff deemed research separate from clinical management and nursing care and therefore, considered the involvement of clinical staff optional – a goodwill gesture – resources permitting. Nevertheless, senior staff, including one of the consultant stroke physicians, were keen to promote integration and collaboration in order to demonstrate that the clinical team was supportive of research and to avoid sending out what Dr Black described in his interview as "mixed messages" that may precipitate an impression of dissent, disinterest and/or confusion.

Successful research therefore required more than a dedicated research team; it was also heavily reliant upon the support of all those involved in the care and management of potential participants, and thus the disjuncture previously highlighted was a major potential barrier both to recruitment and ongoing management of study participants.

6.4   Suggestions For Change

Several suggestions were made regarding ways in which integration and subsequent research capacity could be enhanced, and I illustrate some of these below before moving on to present and discuss some possible reasons why this did not happen during the period of my fieldwork.

6.4.1 Promoting visibility and continuity

Throughout the data collection period, both clinical and research staff acknowledged that Dr Black was the most research active of the senior medical staff. This was hardly surprising; for as well as being a consultant stroke physician, Dr Black was Principal Investigator for most of the ongoing studies and was Director of the associated Research Facility. He acknowledged in his interview, "research is, is very much part of what I do", and was very keen to promote integration wherever possible.

He had endeavoured to facilitate this by appointing a former nurse from the research team (Sister Hatfield) to the post of Senior Ward Sister but this had not resulted in integrated practice. Nevertheless, despite his enthusiasm Dr Black acknowledged that complete integration was difficult, due to the lack of 24 hour teams to provide research cover, and that a critical mass of ongoing research and research personnel was required, so that both the process and the people were visible on a continuous basis. However, he cautioned that even with improved integration and better staffing levels on the ward, it would still be necessary to have a core research team because the privileging of clinical work meant that it would always expand to occupy the staff available and that *"the service side just tends to suck people in completely" [INTERVIEW: Dr Black, March 2007]*.

Some of the ward nurses also had ideas and suggestions about potential facilitators. One of the issues that concerned some members of the clinical team was that they perceived a lack of continuity of research related care because the research nurses worked 'office hours' but patients' questions were not similarly confined. Ward staff stated that their own inability to address these questions and to provide appropriate information may have meant the difference between someone staying in a study or dropping out, which had implications for research practice and findings. As well as being a potential source of discord between clinical and research staff the clinical staff's lack of familiarly with the research protocols had implications for both the patient/professional relationship, and the patients' trust in these teams. In addition to potentially jeopardising study recruitment and retention, the clinical staff were also concerned that their inability to address research related queries may undermine their own expertise and patients' trust therein.

For example, Sister Mitchell described the research team as "insular". For the reasons already noted, the researchers spent only brief moments in any one clinical area during the course of their working day and even within that time, not least because of workload commitments for all parties, there was little opportunity to establish meaningful connections between teams whether at a professional or personal level. Sister Mitchell shared a view with several of her clinical colleagues that a more visible research presence on the ward, with or without the provision of out of hours cover, would facilitate the development of a rapport between research and clinical staff and would thus provide an opportunity for each to become more familiar with the roles, responsibilities and commitments of the other. By extension, there was also a

suggestion that this would be beneficial in terms of recruitment to, and retention in, clinical trials, because by learning more about the ongoing studies the clinical staff would be better equipped to address the queries and concerns of patients and relatives already enrolled or considering participation in clinical trials, for example:

> "we are limited, you know, if a patient asks me, I can give them [...] the basics but anything more than that I'll phone the research office […] sometimes they're not there, they work Monday to Friday, sometimes they're busy and sometimes the patients don't necessarily want to talk to them before they make their decision or "I've got a headache, could it be that..that tablet you think that he's given me?" [INTERVIEW: Nurse Kane, November 2006].

It should be noted that these suggestions applied not only to the research nurses. The research fellow was rarely seen to participate in clinical activity and tended to visit the ward, clinic or EAS only to check for new patients or to visit those referred to him by the research nurses. He had little interaction with either nurses or doctors from the clinical team. He sometimes shared office space with the research nurses, but also had some space in another building. Very few of the ward staff mentioned the input or role of the research fellow although some did refer to the previous incumbent, and described his involvement and visibility as being considerably greater. Related to this observation, Dr Brown described a very different model which he had found to be effective in his previous employment as research fellow in another hospital:

> ... there was much more of a quid pro quo thing going on between the research cover and the clinical cover. Having said that there were more [...] of us, I know at one time [...] I had three other colleagues who were- […] in inverted commas 'research people'. […] at any given time there was one research person rotating through the ward that we would do like a month on the ward, doing the sort of registrar bit on the ward, which meant that the, unlike here where it's a Care of the Elderly Registrar- […] It was actually a registrar who was interested in stroke medicine, [...] patients just were never missed for studies, because there was always somebody around who knew what was going on, on the research side. Whereas here, the research person, that's really all they do and they don't dip in and out of the ward really doing clinical work. [INTERVIEW: Dr Brown, October 2007]

Visibility and a more continuous presence, as suggested by Sister Mitchell, appear to have been instrumental in achieving prompt communication and patient recruitment in Dr Brown's previous employment. He acknowledged however that the complement of research staff (nursing and medical) was considerably greater than at the study site. Operational issues and recent structural changes (such as on-call

arrangements) at this study site presented challenges to the establishment of a joint research-clinical middle grade doctor team. Thus, being reliant on only one research fellow, integration was highly dependent upon the individual.

6.4.2 Secondment of clinical nurses to research teams

A further suggestion raised by some of the ward nurses was that a period of rotational secondment of clinical nurses to the research team would improve communication, integration and understanding. There was also an expectation that secondment would have an ongoing educational impact, as on return to the ward the secondee would be able to share their knowledge and experience with the rest of the clinical staff. It was anticipated that a 'snowball' effect would be achieved in raising awareness, knowledge and participation (of both staff and patients). It was often stated by members of both teams, that clinical nurses could not participate in research activity because they did not know enough about it; however, it was also postulated that one of the reasons that they did not know enough about it, was that they did not get involved. Clinical staff suggested that a secondment rota might help to address this situation in the two ways. First, involvement of the clinical nurses would address a gap which had arisen because of the temporospatial dislocation of the research team and second, it would facilitate unbiased and unpressured discussion with patient and family members about potential study involvement. Thus, secondment would enable the clinical nurses to help the research team, whilst also helping them fulfil their advocacy role in facilitating patient decision making. Ultimately, it was felt that this would enhance recruitment and retention. Senior nursing staff however, felt that this was not possible because of the already diminished staffing levels and poor skill mix in the Acute Stroke Unit – a recurring theme throughout the fieldwork that was recognised by all.

6.4.3 Feeding back research results

In more general terms, there were concerns that the clinical team received little or no feedback on research studies that had been completed and therefore, were not encouraged to engage in other studies. Nurse Cooper stated that he had never been made aware of the results of any of the studies that had been completed, and noted that awareness of study results would enable the clinical staff to support patients making a decision about current participation:

these results as well would be handy for us to know, because we can give the information to the patient, say well the last trial this happened, that happened, the other [INTERVIEW: Nurse Cooper, August 2007]

Lack of feedback may have been due to the significant number of previous studies that had failed to demonstrate an effect, but reporting of negative outcomes is important as this may provide rationale for future studies. There was also a perception that 'drug studies' were not 'nurse orientated', and that clinical nurses may be more willing to incorporate research in their daily practice if it was seen to be more directly related to patient care.

The SNP in particular stated:

> … if you did some research pertinent to their particular area, which I think would probably […] work more, maybes nurse-nursey orientated as opposed to drug orientated. […] I'd like to think that that area of research could be taken forward by the ward staff […] so I think maybe something which was geared towards patient care and improving patient care […] you might get the nurses taking it on board […] if it wasn't going to increase their work load too much […] and if they can understand the benefits of it [INTERVIEW: Stroke Nurse Practitioner, May 2007]

It can be seen from the extracts above, that the clinical staff were ostensibly willing to assist the research team, and recognised the importance and value of research, but its conduct remained problematic nevertheless. In the sections that follow, I explore some of the reasons for these difficulties, and the tensions evident in accommodating research activity within daily clinical practice.

6.5 Limited Knowledge And Understanding Of The Research Protocols

As previously noted, organisational and operational issues precluded the total integration of research and care. However, another reason proffered for the clinical staff's lack of engagement was that they did not know what the research nurses did, needed or wanted, and how their activities and requirements related to the ongoing study protocols. I have already illustrated that lack of knowledge about the role of the research nurse was attributable at least in part to the fact that the clinical team witnessed little if any of this activity, but there were also issues of communication pertaining to the study protocols themselves.

> and all we got to know is if they were signed up to [a study] we had to give a certain drug at a certain time of day, and that was it, that was as much as knew about it. […] Because **half the time we don't know**, it's, it's sometimes, it's

box A and box B sometimes, box A in the morning, box B at night-time, **we don't know** what, what they are - well I know **yous don't know** what they are, but **we don't know** what potential that they could be. [INTERVIEW: Nurse Cooper, August 2007; my emphasis]

Having already expressed concern about what happened to the data that the research team collected, the extract above exemplifies the clinical staff's frustration that they knew little about the potential effects and side effects of study medication. They were given brief instructions about administration of study treatment, rather than information and explanations about the intervention. Thus although they knew what to do, they were sometimes uncertain why they were doing it, and perhaps more importantly, what the outcome of their actions might be. In order to avert potential criticism regarding issues of accountability the clinical staff were careful not to declare total ignorance, but nevertheless recognised, and seemed concerned, that this lack of information, particularly regarding expected effects or possible side effects, had implications for individual patient safety. Whilst this was indeed so, the implications of potentially omitting to recognise and report an adverse event extended far beyond any individual patient. If an event was not appropriately managed subsequent patients may be unnecessarily exposed to similar risks which may ultimately influence the integrity of study findings.

Still further, this exclusion and lack of information impacted upon the clinical staff's conduct of their own duties, not just their engagement with the research team. Despite the aim of collaboration and the oft repeated concern regarding the lack of involvement of clinical staff, they did not proactively take the opportunity when research staff were present in the clinical area, to engage in information giving and consent interactions. Echoing the research team's reluctance to intrude in the clinical situation some of the clinical team noted similar reservations about intruding in research interactions, despite their claims to patient advocacy and the provision of holistic care. Research was viewed as something other, separate and extra, and the clinical team did not spontaneously engage in this arena. This demonstrated a marked difference from the way in which they interacted and engaged with other professional groups and disciplines. For example, when therapy staff were working with a patient it was not unusual for the ward nurses to ask questions or to offer ad hoc contributions to the assessment or exchange between therapist and patient. It was far less likely however

that they would contribute, or even listen to, a consent interaction or discussion about possible research participation.

The explanation offered for the reluctance to participate was that the clinical staff did not know enough about research, at either a general or study specific level to offer a knowledgeable and meaningful contribution to such an exchange:

> …if [Research Nurse is] talking to a patient and I'm around, you do have a tendency to sort of listen in, but that's as much as - information. [...] I think wh-that's between the patient and er, the research nurse and I think it's, it's not nice for me to interrupt and say "Oh, can I listen?", because […] sometimes these patients might have a, a question they want to ask without the nurse being there, sometimes we're an advocate for the patient as well because often they come back to us and say "Oh, the doctor said this, what's that?" So - but it works in both ways, so we often listen but we don't - I don't interrupt anyway, so, and again I can't interrupt because I don't know enough anyway [INTERVIEW: Staff Nurse Cooper, August 2007]

Nurse Cooper stated that he had never been given any direct information about the ongoing studies, other than how, and when, to administer the study medication. He had never been directly involved in discussions between research staff and patient; he had occasionally 'overheard', but considered it rude to interrupt or to invite himself into the discussion. In his subsequent remarks however, it was unclear whether his hesitancy was a matter of politeness or whether his lack of confidence limited his willingness to participate. Whatever the reason, this was not an unusual situation.

Other ward staff also reported that they did not usually participate in, or even observe, the information and consent procedure and I did not witness any such involvement. As a consequence, they knew little about ongoing studies, to the extent that the SNP expressed concern that if questioned, the clinical nursing staff would not be able to articulate study aims, objectives or the balance of risks and benefits. This was also a cause for concern in her own practice, as illustrated here:

> ... [a patient] asked me my opinion about [secondary prevention study] and basically I said to her errm I don't feel as though I can give you adequate information about the trial in order to…to help you make a decision one way or the other [...] I didn't think I'd handled it very well because I need to know more about the trial myself because they keep ask..you know if […] a patient asks me what's the best thing to do then I felt a bit uncomfortable […] because I didn't feel [...] as though I'd given her a good answer […] I think I was honest in saying I don't know enough about it, which makes me think I have to find out more about it because people are going to ask me questions, [INTERVIEW: Stroke Nurse Practitioner, May 2007]

She was uncertain about, and lacked confidence in, her own level of knowledge, and was aware that this limited her ability to adequately help and support the patient in her decision making. Here, as in some of the other examples noted, it was evident that the clinical nurses considered themselves to be disadvantaged by their lack of knowledge. As well as being cited as a reason why they were unable to help the research team, this was also seen to compromise their ability to fulfil an important part of their nursing role, that of patient advocate.

Clinical staff felt uncomfortable when they were not able to respond to patients who asked "what do you think?", or those who had questions about possible side effects of treatment. Such issues were reported by a number of the clinical team, who suggested that their inability to respond to patients' or family members' queries engendered a sense of incompetence and lack of confidence.

> you can't always answer them but […] you'll say that we'll get in touch with yourselves or whatever but I think that's hard […] they think 'oh well if **they** don't know what it's about then…' [INTERVIEW: Junior Sister Mitchell, October 2007, interviewee's emphasis]

The clinical team felt that patients valued honesty and integrity, and demonstrated both in acknowledging their own limitations, but they were also cognisant of the fact that this might impact adversely on recruitment and retention if patients felt that the whole team was not fully appraised of or engaged with, ongoing research work.

A paradox was evident here, in that clinical staff expressed a desire for information from the research team but did not appear to pay much attention to the information that was provided, and spoke about this in very vague terms, for example:

> There is a [research] file …. I surmise we've still got it [INTERVIEW: Staff Nurse Kane, November 2006]

Because the research team was not housed within the ASU, documents such as Investigator Brochures and Study Protocols, which contained information pertaining to anticipated side effects and potential adverse events, were not conveniently accessible to the clinical team. Once a patient was enrolled to a study, the most obvious place to find study information was via the Study Information and Consent Documents. These were filed in the patient's case notes and easily accessible by the nursing staff, although this did not address the issue of learning about, and thus being prepared for, new studies prior to recruitment.

Clinical staff stated that they did not have time to look at the research information on the noticeboards during working hours and had no desire to stay after the end of a shift to do so. However they also hinted that the overabundance of information on display around the ward (not just pertaining to research) was sometimes counterproductive:

> you don't look at these noticeboards, because they look the same all day every day, [someone] takes one down and puts another one up, you think "oh it's the same thing", you don't read it. [INTERVIEW: Staff Nurse Cooper, August 2007]

Nurse Cooper suggested that a newsletter, placed in each member of staff's individual post ducket, might be a more efficient and effective way of conveying study information. This method would not promote the research team's presence in the clinical area, but may be more successful than the information displayed on notice boards in enhancing the clinical team's knowledge about the study treatments and progress to date.

6.6   Prioritisation Of Learning And Activities

A further reason for the lack of engagement between clinical and research nurses, was the fact that the ward was invariably very busy and demanded a lot of physical nursing work, such as bathing, catheter care, and feeding, which was privileged above other activity. This physical work was seen to be part of the holistic care delivered by the clinical nurse to the patient and his/her family members, and was considered essential. Clinical work was undertaken with the intention of improving the health outcome of the individual patient with whom one was engaged at any one time, and also to maintain a safe environment for all patients in their care. The aim of research however, was concerned with the wider population, current and future, that may stand to benefit from the products of research, and as such was considered to be non-essential, for either patients or those healthcare professionals not directly involved. What the clinical staff seemed not to appreciate, was that although a patient's initial decision to participate in research was indeed voluntary, having made that decision there were certain aspects of his/her management that then became, for the duration of the study period, essential.

Whilst differences in time, space and function contributed to the sense that the research team was a separate department, there were occasions when it appeared that it

was considered not only separate but less important. This applied to both training and workload distribution issues as illustrated below:

> ... there's other things happening within the ward, so we, from a nursing point of view we're prioritising on those, rather than the research where there's - you've got research nurses to do things like that, we are prioritising the res-, that, to, any in-house training on what we need to know, things like SNOBS and observations, incontinence, everything like that, even, even classification of stroke, it's what we as nurses need to, need to do and look for, [INTERVIEW: Staff Nurse Cooper, August 2007]

Despite having identified a need for research training, ongoing in-house training was prioritised to address issues that were perceived to be important from a nursing point of view. It is clear from the extract, that research was not included, implying that it was not a priority and/or that it was not considered to be a nursing task. By extension this also implied that nurses who chose to engage in the research arena were therefore not real nurses, a theme repeated both implicitly and explicitly throughout interviews and fieldwork. Yet, it was noteworthy that one of the issues that was considered pertinent to the nursing staff was stroke classification, which was actually a diagnostic issue, usually addressed by medical staff, the stroke nurse practitioner or research nurses. Nevertheless, by expressing willingness, but claiming to be unable to take up opportunities for learning and engagement, the clinical staff were able to eschew responsibility for this deficiency; it was considered beyond their control.

Several tensions and contradictions were evident here. On the one hand there was concern amongst clinical staff that they were inadequately trained and informed regarding research activity both at a generic level during their basic training and more specifically regarding individual research protocols ongoing within the clinical area. Simultaneously however, when attempts were made to facilitate research training (see Chapter 7.5), this was not perceived to be a priority. In fact several training sessions had been cancelled due to failure to register viable numbers of attendees. Similarly, whilst the clinical team claimed to feel excluded by their lack of involvement, they made little effort to become involved, and expressed the opinion that research tasks were the research nurses' responsibility. There was a strongly held and very clearly articulated view that these were two separate areas of work:

> what also the research nurses have to remember is that the qualified nurses have got **their own work** to do [INTERVIEW: Senior Sister Hatfield, July 2007 – my emphasis]

Previous research experience notwithstanding, Sister Hatfield considered that individual patient and research requirements could not share equal priority. As argued by many (for example, Beale and Wilkes, 2001), she stated that the clinical nursing staff were responsible for the safety and wellbeing of all of the individual patients in their care, and could not compromise their individual safety by becoming diverted to research activity Paradoxically however, if the clinical team did not engage with the ongoing research protocols, they would not be able to protect those patients participating in research by anticipating risks and identifying research-related adverse events if and when these occurred. The claim that they could not become involved in research activity because they were too busy 'protecting' the patients, may unintentionally result in lack of protection. Conversely, whilst the individual patient could not be the research nurses' sole priority, that was not to say that their safety and wellbeing were not important both at an individual personal level, and in terms of study integrity and benefit to future patient populations.

There was also a sense that the research nurses had only their research duties to attend to and that these were primarily administrative and technical (see Chapter 7). The ward nurses on the other hand, expected and were expected to, fulfil a number of diverse roles, but did not consider research to be one of them. One of the more senior staff nurses, appeared to be very much in favour of research being undertaken in the stroke unit but could not reconcile this as being part of her role because, she stated, she had "such a lot of other roles that are, you know, that I need to…to fulfil" [INTERVIEW: Staff Nurse Lawson, June 2007]. These 'other roles' were more clearly identified in the following extract, which placed further emphasis on what was considered to be important as a nurse, physical care again being privileged; study participation was not considered a priority:

> We've got more other things worrying than whether they're going to go on a trial, I know again that sounds nasty, but we've got a lot of – you know **as a nurse** there's, there's too many things going on and you're looking after their physical sides than – and you look at things holistically but to me that's [research], that's another part of the jigsaw [INTERVIEW: Staff Nurse Cooper, August 2007 – my emphasis].

Here too a paradox exists, whereby although research was considered "another part of the jigsaw" it was evident that for Nurse Cooper, it was actually a piece of a **different** jigsaw – one that he did not engage with. This seemed to be at odds with

claims that the clinical staff delivered a holistic approach to care, and further demonstrated the lack of understanding of the research nurse role.

The tensions that existed between research and care in daily practice were clearly illustrated in the following account, in which a patient who had consented whilst in EAS to participate in a study investigating blood pressure control was then transferred to ASU for further management.

> The ward staff gets [the patient] into bed and Research Nurse Higgs starts to prepare for his first dose of study medication. ¼ or ½ hourly observations have to be made for the first few hours and if the research nurses are around they would normally do this […] but if they fall outside their normal hours the research registrar would do it. […] Dr Chatterjee […] (half) jokingly asks, I don't have to stay till [8pm] though do I? […] Research Nurse Higgs says he'll stay if Dr Chatterjee doesn't want to but after bringing a BP machine into the patient's cubicle he begins to explain the protocol requirements to Nurse Oliver and one of the students who will be looking after the patient tonight. He explains that they will need ¼ hourly blood pressure recordings for 4 hours then ½ hourly. Nurse Oliver says she'll set up the BP machine to do them automatically and asks do they just want them recorded (in the machine) or do they want them actually written down on the observation chart. Research Nurse Higgs says it would be helpful if they could be written on the observation chart but not to worry if it's not possible as long as there's a record actually on the machine. […]Dr Chatterjee asks the student if she will do this and she is agreeing but Nurse Oliver just says that **they'll do the best they can because 'we have got other patients to see to you know'** [ABRIDGED FIELDNOTE: November, 2006; my emphasis].

Again, this episode conveys the sense that engagement of the clinical nurses in research activity is optional, resources permitting. The need to involve them in such activity arose because the research nurses, due to resource limitations were unable to provide 24 hour cover. Although this meant that recruitment was usually limited to 'office hours', subsequent care and study management was not similarly restricted. Once enrolled a patient's participation was continuous and observation could not be confined between the hours of 09:00 – 17:00. This being so, the research team had either to delegate some of the ongoing research tasks to other staff, namely members of the clinical team, or, to rely upon automated monitoring equipment. A conflict between research and clinical practice was clearly illustrated here; whilst the student nurse was willing to help, Nurse Oliver made it clear that patient care – for **all** of the patients was their priority – implying that in her opinion research activity **is not** care. It is worth noting here however, that if a patient required this level of observation for clinical reasons they would typically be deemed to be medically very unstable and would

probably be on an intensive care unit, or at least high dependency unit, where there is a greater nurse:patient ratio. Taking this into account, the research demands may be perceived as unreasonable, especially on a late shift, when there were frequently only four nurses (two qualified) on duty. As reported repeatedly, the pressures on clinical staff were enormous - dealing with families, doing drug rounds, as well as attending to the usual demands of highly dependent patients.

Similar conflict of priorities was highlighted by another nurse, who described an earlier period when a particular study was being undertaken, and it became necessary to ask the research team to restrict the number of patients that they enrolled to the study, because the workload implications for the clinical team were such that this was impinging upon their ability to undertake their clinical duties. Therefore, clinical resource limitations impacted upon the successful conduct of research. It was this nurse's perception that in the interests of patient safety (all patients) and study integrity, in some cases, it would be better to limit recruitment than to fail to adhere to study protocol. During this period, the research team had appeared unaware that the clinical staff was becoming overwhelmed by the requirements of the research protocol, a situation possibly indicative of the fact that the research team spent only brief moments on the ward. Although they had all previously had some clinical experience, and therefore had an idea of the workload, they may not, unless they had witnessed it, understand how their activity impacted upon it in the context of these particular studies at this particular time.

It should be noted however that the prioritisation of clinical practice over research was not restricted to the nursing staff. One of the consultant clinicians, who had previously been employed as a research fellow in the same unit, explained that in his former role he was completely focussed on research and was disappointed if patients did not participate. Currently however, as a clinician with a research interest, he stated that he found himself "juggling between two responsibilities" [INTERVIEW: Dr Silva, June 2007] but that delivery of care was now his first priority and he did not experience such an emotional or personal response if unable to recruit.

6.7 A 'Deviant' Case – Where Research Helps Care

Despite the prevailing sense of separation and exclusion, there were moments when the research nurses became 'visible' and their input and involvement was actively sought. There were a number of examples of the senior research nurse in particular

delivering 'fringe benefits' to the organisation as a by-product of research activity. For example he regularly extracted data from the European Stroke Database (ESDB) for clinical applications such as, identification of service use, or for clinical audit purposes. Such activities however demonstrated a blurring of the research nurses' role with managerial or administrative functions which still went largely unnoticed by the clinical nursing staff. They did however take advantage of the assumption (whether based on gender or perceived research role attributes) that the senior research nurse would possess a certain level of technical competence:

> Senior Research Nurse Higgs stops [at the nurses' station] to ask me a question […]. Whilst we are talking we're politely interrupted by Nurse Lawson (senior staff nurse). Excusing herself she tells Nurse Higgs that she can't get ECG machine to work, and asks him to have a look at it. Nurse Higgs jokes that he's not an ECG technician but goes to have a look anyway. [FIELDNOTE: November, 2006]

It was not clear whether Nurse Lawson's assumption that Nurse Higgs would be able to resolve the problem was contingent upon his gender or his researcher status, but whichever was the case, Nurse Higgs attempted to do so. Because research was not integral to the clinical nurses' daily routine, a considerable degree of goodwill was involved in securing their cooperation, not to say assistance, in the enrolment and management of study patients. Research Nurse Higgs' willingness to help with matters outside his scope of expertise served to develop and reinforce a more reciprocal relationship and foster good relations between the clinical and research team. This was in sharp contrast however to his instruction to Research Nurse Fowler not to become involved in clinical tasks (see Chapter 7).

6.8   Discussion

There is a considerable body of work in the nursing literature pertaining to the reluctance of nurses to conduct or act upon the findings of research (Hicks, 1999). Much nursing practice is still fundamentally rooted in custom and practice and is historically entrenched rather than empirically validated or evidence based. The examples discussed throughout this chapter suggest that this reluctance may be related to perceptions regarding prioritisation, concepts of professional role definition, and expectations and previous experience.

6.8.1 Perceptions regarding the prioritisation of clinical versus research demands

Although sometimes frustrated at what was perceived to be a lack of cooperation or enthusiasm from the clinical staff, the research team acknowledged that practical pressures restricted the clinical staff's opportunities to become involved in research activity. A recurring theme throughout my study, and evident in both observation and interviews, was the poor staffing levels in the ASU. Clinical staff reported they felt that this limited their capacity to contribute to research, and moreover, potentially adversely influenced study recruitment and retention, which suggested that they were aware that they potentially had a role to play. Research staff adapted their own behaviour and expectations accordingly and endeavoured to cause as little impact as possible upon the clinical team's workload. However, there was a fine line between unobtrusiveness and exclusion, which was on occasion, perceived to be crossed.

6.8.2 Concepts of professional values and role definition

Cognisant of the staffing issues, the research team was mindful not to criticise the clinical staff too harshly and found ways to rationalise their lack of involvement in research. The clinical staff however, was not quite so accommodating of what they perceived to be less desirable traits on the part of the research team, and interpreted these characteristics as a conscious decision to move away from hands on care and 'dirty work'. The clinical nurses perceived their own rebuttal of research related tasks as a reflection of other extraneous factors beyond their control, but considered the research nurses' withdrawal from 'hands on' care, to be a personal, values-based choice. Being unfamiliar with the duties and responsibilities undertaken and held by the research staff, they perceived them to have abandoned the very relational and interpersonal skills that these unseen aspects of the research role required.

As will be expanded upon in the following chapter, the research nurses adopted different positions depending upon the clinical environment and the requirements of their role at any given time point. In the Acute Stroke Unit they endeavoured to cause as little disruption as possible to the clinical staff's workload and for the most part fulfilled their own responsibilities in parallel to whatever clinical interventions were ongoing. However, this perceived detachment represented another way in which their role blurred with that of their medical colleagues and thus contributed to their alienation from their clinical nursing counterparts.

6.8.3 Expectations and previous experience

A very specific version of the role of the nurse was presented and expected by the clinical staff and it was for the most part, the socially constructed stereotypical image of the caring professional 'tending the fevered brow'. Those who operated outside the boundaries of this circumscribed role – in this instance the research nurses - were viewed with suspicion and were more or less socially excluded.

The research nurses were able to empathise with the clinical team and the difficulties that they faced because they had all also worked in a clinical environment. This was not the case for the clinical team however, who, with the exception of Sr Hatfield had not experienced a research nurse role. They therefore expected the research nurses to behave like nurses, i.e. like them – and found this difficult to assimilate when they did not.

A further, unfulfilled expectation was that of reciprocity. The clinical team expressed a sense that the research team 'took' from them but did not reciprocate. This is perhaps an unfair interpretation of the research nurses' activity, as they did indeed contribute to clinical care, for example in the assessment and management of patients eligible for and receiving thrombolysis. However, although this helped the clinical team, it was a different clinical team, outwith ASU, and again, the activity was unobserved. Nevertheless, direct reciprocation may have been helpful in building relationships with the ward staff and raising the research profile. This could possibly have been achieved by providing feedback about the research findings; including members of the clinical team in meetings, and feedback in order to promote a sense of academic involvement, and also an offer of help with understanding the patient's needs, diagnosis or aspects of their treatment (as was reported to be the case with researchers in other specialties).

In this chapter then, I have demonstrated the way in which the clinical staff perceived the research nurses, how they engaged with them, and the basis for some of the functional difficulties, as perceived by the clinical team. In the following chapter, I explore the research nurses' perception of their own role and identity, before finally considering how these two standpoints come together to sustain (or not) the research endeavour.

Chapter 7. Separation of Research and Care: Performing Research Identity

7.1 Introduction

With the proliferation of new nursing roles, spawned at least in part by the publication of the UKCC Framework on the Scope of Professional Practice (United Kingdom Central Council for Nursing Midwifery and Health Visiting, 1992), there came confusion and conflict regarding role responsibilities and definition. Commentators who have attempted to define the role of the research nurse frequently struggle to identify supporting literature, and that which exists is often predominantly anecdotal (Raybuck, 1997; Raja-Jones, 2002). There is however, a recurrent theme of title confusion and conflation, including research nurse, study site co-ordinator, data manager and clinical nurse specialist in research. The title chosen, or imposed, is instrumental in determining the identity of the title holder and the way in which their responsibilities are recognised and enacted; the title 'data manager' for example, conveys quite different expectations from those of 'research nurse' but both have been used to signify similar, if not identical, roles. Nevertheless, at the study site, even those sharing the same titles i.e. Research Nurse or Senior Research Nurse, described broadly similar aspects of their role, but prioritised these components differently and engaged in them to a variable extent.

Among their roles and responsibilities the research nurses listed: patient assessment and delivery of care (for clinical as well as research purposes), facilitation of thrombolysis where appropriate, and longer term follow up, including resolution or investigation of other health problems, whether or not they appeared to be related to study involvement. They also facilitated study enrolment and informed consent, provided information to staff, patients and family members, acted as patient advocates and undertook administrative and technical tasks. In order to achieve the overarching aims and objectives of their role they performed all of these component parts. In the sections that follow I describe and illustrate these discrete elements, but also outline how the research nurses were more than the sum of these parts, and how the amalgamation of these elements shaped their overall identity and function.

7.2   When Is A Nurse Not A Nurse? When S/he Is A Research Nurse?

Although limited in their level of clinical commitment, members of the research team at the study site still bore the title 'nurse' and some chose to retain the visual identity afforded by this affiliation. The argument that we manage our appearance and conduct in order to present ourselves in a certain way to certain other individuals or groups is well rehearsed. Goffman (1959) has described how management of appearance affords access to different settings and determines how one is perceived and accepted (or not) therein, whilst Gergen suggests that by adopting a particular style of clothing one 'becomes' what that clothing represents (Gergen, 1991). Others suggest that the workplace is instrumental in the formation of identity, but the research nurses inhabit a liminal space, both temporospatially and operationally, and therefore perhaps this visual identity was one of the few concrete or enduring identities available to them (Miller and Rose, 1995). The wearing of a uniform conveys many messages, both positive and negative, to the wearer and to the observer (Livingston, 1995; Mangum *et al.*, 1997). In some circumstances however the decision to wear a uniform is not a matter of personal choice but is governed by external influences such as institutional or professional policies (Hochschild, 2003). Healthcare organisations are by no means exceptional in utilising uniforms in order to communicate membership, status and role both within the group and to those external to it. When my fieldwork began there was no mandatory uniform policy in place for research staff and it was left to the individual to decide how they wished to present themselves. Whilst it would be naïve to suggest that appearance alone determined the socialisation and acceptance of the research nurses in the clinical setting, it would be equally disingenuous to suggest that it did not influence the way in which they were perceived by their clinical colleagues, patients and the visiting public. The options available, decisions made, and implications of these decisions are discussed below.

7.2.1 Being a research nurse: dressing the part

The designated research nurse uniform was distinct from that of the clinical staff and consisted of maroon tunic/navy trousers or a maroon dress for females, or navy blue trousers/white tunic with maroon epaulettes for males. The research nurses had three options: do not wear a uniform; wear a uniform at all times; or wear a uniform only when in the clinical area/conducting clinical tasks. Each of the research nurses demonstrated clear, though different, rationales regarding their choice of dress. Nurse

Fowler's preferred option was to wear a uniform at all times. Her rationale was pragmatic; the uniform was free of charge and she did not have to waste time and energy thinking about what to wear. Her choice allowed her to continue to identify with her professional colleagues whilst at the same time demarcating the difference in her role. In practice however, although her uniform was distinct from that of the clinical staff, the functionality of this distinction was questionable, as illustrated below.

> One of the cleaners asked me the other day what was my job and she's seen me for the last year […] I think it was just the uniform, you know, they see all these different uniforms and they were just curious… [INTERVIEW: Research Nurse Fowler, January 2007]

Nevertheless, despite, or perhaps because of, this lack of distinction, the wearing of a uniform conveyed some advantages, as noted by Research Nurse Slater, who switched from everyday clothes to a uniform after a few weeks in post. She stated that she '[felt] more comfortable' wearing a uniform on the ward and seemed to be 'more accepted' by other staff (summarised from fieldnotes). Holliday likens uniforms to masks, with positive or negative connotations (Holliday, 1999). The esteem (or other attributes) attached to the group is bestowed upon the individual thus identified, along with associated rights, such as access. Echoing this observation, Nurse Slater reported that she was questioned less often about who she was and what she was doing if she was in uniform. Her decision was therefore based upon her interpretation of other people's reaction towards her. It was also context dependent, as she explained that if she was conducting a blood pressure clinic for example, she would not wear a uniform because of the so-called 'white coat effect' (Mancia *et al.*, 1983).

It was evident that whilst no mandatory uniform policy was in existence for the research nurses they faced a cost-benefit analysis regarding their decision to adopt a particular visual identity. In its favour, the nurses' uniform facilitated access to different areas and may also have facilitated execution of the research nurse role, by influencing others' perception of that role. It conferred rights – such as access – but also obligations related to the commonly perceived characteristics of the nurse i.e. the delivery of physical care – which the research nurses were not always able to fulfil. Thus despite the potential advantages, this misidentification may have resulted in subsequent discomfort for the research nurses if they were asked to perform clinical tasks that they could not or would prefer not to undertake (Zuzelo, 2007), and disgruntlement for the patient if a 'nurse' failed to address his/her needs.

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Some of the research nurses chose not to wear a uniform, and offered several reasons for their decision. Some did not see themselves as fulfilling a clinical role and did not wish to be called upon to do so. They therefore chose not to wear a uniform in order to avoid the misrecognition previously noted. Further, some equated the wearing of a uniform with diminished autonomy and told me:

> 'I wouldn't like to have to work in uniform again. I could wear uniform here [ASU] but I choose not to; I like the fact that I have more autonomy here.' [Direct quote from fieldnotes, Senior Research Nurse Higgs, October 2006].

Research Nurse Higgs indicated that when the mandatory uniform policy was introduced he would endeavour to schedule his workload so that he wore the uniform on days when he needed to access the clinical area, but not when working solely in the office. The ASU Sisters already employed this policy one day per week, when they undertook solely administrative tasks. In response to suggestions that doctors should also wear some form of uniform he responded that this would not happen 'Doctors will never [wear uniform], they've got too much power' [FIELDNOTE: April 2007].

Although some writers suggest that uniform signifies professionalism, status and power amongst nurses (DeKeyser *et al.*, 2003; Allen, 2004) Research Nurse Higgs considered it a demonstration of power that doctors did not wear uniform and therefore believed that amongst doctors (and perhaps managers), the nurses' uniform was perceived as a symbol of subordination.

For some a uniform may instil confidence and engender respect, whilst for others it presents a barrier and undermines the clinician/patient relationship (Brennan *et al.*, 1995; Mangum *et al.*, 1997). These opposing arguments were partly illustrated in Nurse Slater's rationale. On the one hand, she stated that her uniform facilitated recognition and access, but simultaneously noted that there were some situations where she thought she quite definitely should not wear it. For example, such as when conducting the clinic for a blood pressure study (cardiology), because she knew from experience that patients' blood pressure recordings are often significantly higher when she approaches them wearing a uniform rather than everyday clothes.

Despite the pros and cons associated with the symbolic function of a uniform as noted above, a decision not to wear a uniform was no less problematic. Although avoiding misidentification as a clinical nurse, and the accompanying expectation of the provision of physical, clinical care, the non-uniformed research nurses, carrying some of the paraphernalia usually associated with doctors and undertaking some traditionally

medical tasks (e.g. venepuncture, electrocardiograms), may be misaligned with medical staff or managers/administrators. Doctors on the ASU seldom wore white coats, so even though the (non-uniformed) research nurses introduced themselves to patients as such, it was possible that they may have been mistaken for doctors. Such misrecognition may alienate them further from the clinical nursing team. Indeed one of the ward nurses noted that he initially mistook some of the research nurses for doctors and believed that some patients had been similarly confused. Considering the traditionally gendered nature of nursing there is also the possibility that this may have contributed to role confusion regarding Research Nurse Higgs, but this was not evidenced in my data (c.f. Fletcher, 2007) As noted above, the ASU Sisters had allocated 'management days'. On these days they remained in their everyday clothes, which was perceived as signifying that they would not participate in any clinical activity. On these occasions other staff oriented to them differently, primarily as administrator, not clinician or researcher. Perhaps this also addresses the assumption that the (non-uniformed) research nurses were primarily occupied with administrative issues – synonymous with paperwork, which brings us to another of their identified roles, that of data collector.

7.3   Research Nurse Or Data Collector

When a ward domestic asked Research Nurse Fowler what her job was, her first response was that she 'collected data'.

> I told her I was a research nurse, that I collected data and that's what my job was and trying to get people to take part in trials…[INTERVIEW: Research Nurse Fowler, January 2007]

A criticism levelled at many research nurses is that they are little more than data managers who 'collect numbers for doctors' [personal experience], and for a number of those interviewed this was initially the way in which they were introduced to research.

> I got into research through Dr Black […] I did some work […] for him […] mainly just blood sampling and 24 hour observations [INTERVIEW: Senior Research Nurse Higgs, November 2006]

It has been noted that this is often a source of derision (Hill and MacArthur, 2006) from other nurses but it was suggested by the research nurses that this may be due to the fact that the ward staff in general did not understand the importance of the data collected, or the precision and degree of rigour required in collecting it, as noted here.

[Research Nurse Higgs says that the ward staff] do not appreciate the **precision** required for completion of study procedures and documentation. He offers the example that all of the observations (e.g. blood pressure recordings) on the ward are documented as being assessed at 6 o'clock, when clearly it is not possible to check every single patient at exactly the same time. [FIELDNOTE: June 2006, my emphasis]

Accuracy is important in recording study data because unlike assessment for clinical purposes, which relates solely to the individual, observations and measurements for study purposes need to be correlated with other variables and with the administration of study intervention. The ward staff was not familiar with study protocols or procedures and therefore did not appreciate this.

Whilst the research nurses in this study agreed that data collection was a major part of their role, it was apparent that they did not view it in the same way as their clinical counterparts. The research nurses recognised the relevance and importance of data collection in ensuring the effective and safe management of research protocols and, thereby, the safety and wellbeing of participants recruited to them.

the clinical side […] has a lot of paperwork that's unnecessary, […] care plans [...] that you just slotted the patient's name in, […] this is just ridiculous and it's pointless […] research paperwork is sometimes very tedious and very monotonous and very repetitive but, it's just making sure you're collecting all the right data and, you know, you can see the point to it, you know, you're writing down all the medications, you're writing down all the medical history and they have to, you know, reference each other, so if they're on a tablet they have to be on a tablet for a reason and that reason has to be on their medical history, you know, it makes sense to me so I don't have a problem with it [INTERVIEW: Research Nurse Webb, June 2007]

Centrally, the research nurses' data collection was about safety. Thus, whilst the majority of the clinical team equated research with copious amounts of paperwork, the research nurses viewed this as purposeful, when compared to the clinical and organisational bureaucracy associated with some of the clinical team's paperwork. One of the research nurses even reported that she had left the clinical arena, and indeed the NHS altogether shortly after qualifying (she emigrated to Australia), at least in part because of the proliferation of 'ridiculous and pointless' paperwork that occupied so much of the clinical staff's time that it took them away from direct patient contact and hands-on caring.

Nevertheless, whilst research data collection was seen to be important, it took second place to clinical activity. For example, although the research team was seen to

take control in the emergency assessment of new patients (see Chapter 5.5), the situation was quite different when reviewing patient case notes for potential study eligibility on the Stroke Unit. The research nurses invariably handed the notes over almost immediately to the clinical team, often without any direct request being made, thus privileging clinical need over research requirements, and differentiating between the two. This negotiated ordering of roles and responsibilities was not verbalised but was based upon the actors' anticipation and/or previous experience of the action of colleagues. Such indiscriminate deferral to the clinical team further perpetuated the notion that research was separate from and somehow less important than clinical care. Consequently, whilst research itself appeared to be perceived to be less important, there was concern amongst the research nurses that their chosen speciality was not afforded the status of a recognised professional role in its own right, but rather as support role to another professional group (usually doctors), as illustrated in the following section.

7.4 Research Nurse Or Research Assistant: Hand-Picked Team Or Handmaiden?

At the study site, rather than an overall acceptance of, or commitment to, a research ethos, individuals were seen as research champions. For example, Dr Brown referred to 'Jack's' (Dr Black's) research fellow', as if Doctor Black commanded a hand picked team of 'helpers'. Perhaps such perceptions could be addressed by reviewing the historical assumption, noted by Mulhall, that research is the responsibility of individuals rather than professions or organisations (Mulhall, 2002), but in the meantime, some of the research nurses remained concerned that their role was perceived by others as one of 'doctor's assistant'. They worried that they continued to be perceived as hand maidens, and the struggle for seniority and status therefore persisted, although ways in which they could demonstrate their expertise and exercise their authority were often undermined.

Research is widely perceived to be a symbol of professionalism; a hallmark for good practice, quality, efficiency and innovation and therefore goes beyond the role of providing evidence upon which good practice should be based. It is suggested that research has been 'constructed as an ideology' (Mulhall, 1997) – according to Hicks (1996), one incompatible with the care giving definition of nursing. Most senior doctors who undertake research still undertake clinical activities identical to non-research active senior medical staff (albeit less). This integration of research within medical practice in a structural way has avoided senior research medical staff being

considered a completely separate group (comments about glory seeking and lack of experience notwithstanding). Unfortunately, whilst there are some exceptions, this model of practice is not widely available to senior nursing researchers (or for that matter senior nurse administrators) within the study site, and inevitably means that they are seen at best as doctors' research assistants or at worst, as a different, clinically incompetent group.

Several of the research nurses, like others known to me personally and including myself, initially became involved in research at the request of senior medical colleagues, and on a relatively small, and sometimes informal scale. Regardless of the means of their initiation to research however, they have since gained considerable experience, undergone training and assimilated substantial specialist knowledge. They argued that they dealt with their ongoing research protocols every day, and were therefore more familiar with all aspects of their management, whilst the doctors, even the research fellow, were less familiar, an observation exemplified in the following interaction:

> … at the nurses' station [...] there are boxes [of study drug] all over the desk. [...] They have just seen a patient in EAS and randomised her to CHHIPS [...] Research Nurse Higgs is explaining to Dr Chatterjee how to titrate, prescribe and administer the initial doses including how to use the tablet crusher [...]. He reminds Dr Chatterjee that labetolol also needs to be prescribed. […] Research Nurse Higgs is explaining to him that he will have to administer all of the titration doses and complete the observations but once the patient is onto the maintenance dose the ward nursing staff will be able to administer this. [...] Research Nurse Higgs is whizzing very quickly through the instructions with Dr Chatterjee, although he reassures him that he can ring at any time tonight if he has any queries or problems. [FIELDNOTE: 13th November, 2006]

> [Referring to the above] Research Nurse Higgs notes 'at least you did see me babying Dr Chatterjee through the procedures' [FIELDNOTE: 14th November 2006]

Research Nurse Higgs felt that he had had to coach the research fellow through the procedures and processes required, in order that he could regurgitate this information for the patient. When interviewed however, the research fellow provided a very different description of his role and responsibilities, stating that this particular study was 'doctor oriented' and was managed solely by him, although some of the other studies, mainly those in secondary prevention, included greater nursing involvement. It was interesting that the research fellow perceived the management of these studies in this way because what I actually observed, as noted in the extract above was the

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research nurse(s) guiding him through most aspects of study processes and procedures, regardless of their acuity. Moreover, this element of guidance and instruction was not restricted to the medical staff's interaction with study participants. I also observed several occasions where the research nurses had to guide medical staff through the electronic randomisation process, completion of case report forms, and adverse event documentation.

The concept of 'assistant' thus seems somewhat misplaced, and gave rise to frustration amongst the research nurses, not least because despite being more familiar with most of the studies than the medical staff, they were not generally permitted to obtain informed consent from patient or family members and were not allowed to prescribe study medication.

> I feel…regret the fact that as nurses we can give all the information and guide the patient through and guide the doctor through to an extent about what the study is and then at the end of the day it's the doctor's signature that goes on the bit of paper […] if you accept the risk of extending your role and, and you understand the implications of that, you're still working closely with the doctors anyway […] does it really make any difference whose signature it is on that bit of paper as long as it's somebody that's representing the study and representing the research, who knows the research and knows the implications to that patient? […] that's part of the responsibility of you being a professional nurse; […] you have to take responsibility for your own practice. [INTERVIEW: Senior Research Nurse Higgs, November 2006]

Research is a highly regulated practice which inevitably requires a high level of administration and coordination. The research nurses' therefore identified their main role as the identification and subsequent facilitation of recruitment of potential study participants. They undertook this role with variable input from their medical colleagues. The research nurses searched for, and identified patients who were eligible to be approached for consent to participate in the ongoing studies. They provided information which the patient was able to consider in order to decide whether or not to give consent to participate. Having provided this information, they assessed, albeit mainly tacitly, the degree to which potential participants understood the information and therefore had the capacity to consent. They answered questions that may influence a patient's decision to consent, and yet, in this particular environment, were not permitted to actually obtain consent from the patient, or agreement from their family members. The research nurses felt that referral to the research fellow or other medical staff was tokenistic, and undermined their authority and expertise amongst their clinical counterparts, –

reinforcing the notion of 'doctor's little helper' - and patients alike. This lead to dissatisfaction on the part of the research nurses in situations where they felt that they were willing and able to extend their role, e.g. prescribing and obtaining informed consent, but where this was not accepted at a medical or policy level. Some of the research nurses argued that they should be able to write up a prescription arising from an approved randomisation procedure. As they were always working under the auspices of the Principal Investigator (PI) and as part of the research team, they argued that as long as the PI was consulted, and was in agreement that the patient fitted the inclusion criteria, patient safety would not be compromised.

It can be seen above that the element of 'assistant' comprised a considerable element of communication and information giving, to research colleagues and to patients/families, but there was a broader remit to this aspect of the role which I now move on to discuss below.

7.5   Research Nurse Or Educator: Communicating And Informing

The research nurses, medical staff, and ward nursing staff, all acknowledged the limited attention paid to research concepts and methodologies within the basic training of doctors, and particularly, nurses. They also noted a perception that the general public knew little about research, other than seeing market researchers in the street, or of high profile scientific advances (or blunders) reported in the media. Most people, it was argued, neither realised nor expected that research was undertaken in the hospital environment, nor that they may be approached to participate in it. Given this lack of awareness, it fell to the research nurses to educate the clinical staff about the specific ongoing research studies and also to inform potential patients of their rights and responsibilities should they agree to consider participating in a study.

Senior Research Nurse Higgs reported that he considered it his responsibility to ensure that the clinical staff knew enough about each of the ongoing studies to ensure the safety and wellbeing of those patients participating in them. However, opportunities for him to deliver, and for them to receive, adequate and timely training were limited. All clinical staff noted that he tried to keep them up to date with new studies, but also followed these statements with various rationales as to why this was difficult, either due to their own or the research nurses' workload or, to the relative paucity of patient recruitment. The infrequency and irregularity of recruitment meant that it was difficult for the clinical staff to accumulate knowledge about, and confidence in, undertaking

study procedures. It was also difficult for the research team to provide teaching/training about individual studies in the abstract. The teams therefore relied upon individual one-to-one information giving, as and when patients were enrolled to studies. Unfortunately, one of the effects of this approach was that clinical staff were only ever informed, rather than educated. That is to say, they were provided with enough information to fulfil specific tasks, rather than being furnished with background information regarding study rationale. The focus was on short term requirements for task completion rather than longer term education and development. This contributed to the chicken-and-egg situation previously described [Chapter 6], whereby the clinical staff did not get involved in research activities because they did not know enough about the studies, and they did not know enough about the studies because they did not get involved.

Several staff members, clinical and research, noted that the stroke nurse practitioner tried to organise regular (approximately quarterly) in-house training events, which usually included a session from the research team covering ongoing trials (although not basic research concepts or methodologies). However, due to the poor staffing levels on the ward during my period of fieldwork, planned sessions were cancelled and it was not possible to reschedule them. A schism existed whereby attendance at training sessions was simultaneously perceived as work and not work. If training was not perceived to be work, then time away from the busy clinical area could not be sanctioned, but if it **was** perceived as work there was a feeling that staff members should not have to participate in their own time. Whatever the underlying reason, lack of training perpetuated the mystique surrounding research and also contributed to the disjuncture of the research team. This disjuncture however was also evident in what some consider to be the very essence of the nurse's role – caregiving.

7.6   Research Nurse Or Caregiver

It has been noted that some research nurses, like Nurse Higgs, are able to prioritise different aspects of their role (Easter *et al.*, 2006) but some are unable to shed the care-giving definition of their profession. Thus, nurses in research roles may find it difficult to accept that 'research is not care' (Fisher, 2006b). But should they accept this statement? Treatment is still treatment whether licensed or experimental and although the desired outcome may not be for the sole benefit of the patient, it will undoubtedly have some (hopefully beneficial) impact upon him/her. Failure to recognise this and subsequent attempts to separate clinical and research activity contribute to what has

been termed 'moral distress' (Krishnasamy, 1999; Zuzelo, 2007) – an observation exemplified in Nurse Fowler. 'Good nurses' are generally seen as being 'hands on' while the researcher must be logical, analytical, rational, and organised (Hicks, 1996; Woodward *et al.*, 2007). Several respondents stated a view that research nurses and clinical nurses were fundamentally different in some way, although this view was more commonly voiced by those who had never worked in a research role, or those who had done so but had returned, or intended to return to the clinical arena.

> I think you've got to be a certain person to be a research nurse. […] in my other job although it […] was office based […] I was still involved with the ward rounds, I was still involved in the community and I was still involved in clinics, […] I just miss the hands on approach and I'm more your people's person and interact better […] I never come into nursing to do paperwork. [INTERVIEW: Research Nurse Fowler, January 2007]

For a number of reasons, not least the desire to protect research and ensure that it 'gets done', research activity was separated to a greater or lesser extent from what was considered more traditional aspects of nursing care, because of the tendency for staff to be overwhelmed by clinical demands. Nevertheless, this did not eradicate the research nurses' ability, capacity or desire to 'care'. Tensions existed with regard to research nurses' relationships with patients in terms of conflicts or incongruities between what one would do as a nurse, and what one was expected to do as a researcher. The established and socially constructed identity of the nurse appears, at least superficially, to be at odds with the developing but as yet liminal role of the research nurse and has intraprofessional implications.

For the layperson, the role of the nurse is most frequently perceived to be that of physical carer, undertaking or assisting in a patient's daily and often intimate activities (Bassett, 2002). For Research Nurse Higgs however, although he did not consider himself to fulfil a clinical role, and could separate clinical and research activity, he still saw his role as one in which he was responsible for delivering care to the patient (c.f. Easter *et al.*, 2006)

> I am concerned that one, I do a good job and I do a thorough job and two, that I'm […] giving the appropriate information, the appropriate advice and that…three, - I'm rea.. and probably should be one…that I'm **looking after the patient above all** [INTERVIEW: Senior Research Nurse Higgs, November 2006, my emphasis]

It is of note, that even between the research nurses, there was a difference of opinion as to the caregiving element of their role. Despite the lack of sustained, or intimate physical contact, Research Nurse Higgs saw his job as "looking after the patient above all". Care, for Research Nurse Higgs, involved offering patients, either directly or via their family members, the opportunity to participate in research, which may or may not benefit them, but ultimately would benefit the stroke population. For patients who decided to take up this opportunity, it was then the research nurses' responsibility to ensure that they were appropriately looked after - cared for - throughout their study involvement.

Conversely however, Nurse Fowler found her role lacking in this respect and decided not to renew her contract at the end of her first year in post because she wanted to return to 'hands on' care. She suggested that this may have had something to do with the fact that she initially trained as an enrolled (Level 2) nurse, traditionally more involved in the practical aspects of nursing rather than administrative or managerial elements. Furthermore, her clinical background was primarily in the area of spinal injuries, which typically requires considerable physical input.

In some cases it was considered that the care offered by the research team was actually more holistic because the research nurses were not bogged down in the day to day bureaucratic paperwork that accompanied clinical activity. This would appear to support claims that research participants receive better care, and hence experience better outcomes, than their non-participating counterparts (Majumdar *et al.*, 2008). Such claims are comprehensively countermanded however, by a number of authors, including a Cochrane review (Braunholtz *et al.*, 2001; Peppercorn *et al.*, 2004; Vist *et al.*, 2008). Nevertheless, the research nurses did have more time to spend with individual patients enrolled in their studies than the ward staff. The research nurses' involvement with patients frequently continued beyond the boundaries of the patient's current clinical presentation, often necessitating intervention in areas other than that for which the patient was originally admitted. For example, although clinical staff often stated that they looked after the 'whole patient', it would rarely be the case that a patient would telephone the ward, post discharge, to report a problem that they thought might be related to their medication. It was not unusual however, for study participants to contact the research team with a symptom or problem, and even if it was highly unlikely that this was related to their study participation, the research team made the necessary arrangements for a clinical appointment and/or investigations to determine the nature of

the problem and an appropriate course of action. Research Nurse Webb adopted the view that:

> It's a trial related issue as soon as they phone you, isn't it? […] we're even making sure they get referred for care for something that's completely unrelated so … […] you have to take the whole deal basically […] you want [participants] to report everything to you anyway so you've got to be seen to be helping them [INTERVIEW: Research Nurse Webb, June 2007]

The extract illustrates that whilst the research nurses did not always directly provide **physical** care, they were not oblivious to this requirement and provided a **route** to appropriate care. In doing so they demonstrated care not only for study participants but for the integrity of the trial and of science in general. To maintain this, they ensured that trial participants received appropriate and timely physical/clinical care. The research nurses' engagement with the provision of care beyond their own immediate remit also had the effect of promoting research and research participation as a 'good thing', with some patients noting the benefits of the 'M.O.T.' [thorough examination] associated with study participation [from fieldnotes, June 2006].

The research nurses' role also transgressed the boundaries of clinical care when they undertook assessment of newly admitted patients. Even amongst the research nurses however, there were differences in the ways that they perceived, and undertook this aspect of their role. Having identified or being advised of a new patient, the research nurse reviewed their records in order to determine their eligibility for thrombolysis and/or acute study enrolment. The research nurses were trained to conduct stroke assessments but Research Nurse Higgs advised them only to do so when study eligibility had been confirmed from the patient's records. They had no clinical obligation to undertake this assessment. In keeping with the holistic philosophy of nursing, Research Nurse Fowler stated that as a nurse, she would have preferred to conduct a full assessment of all new stroke patients but that guidance from Research Nurse Higgs was that as a **research** nurse she should not become clinically involved. Confirming this, Research Nurse Higgs mentioned on several occasions that Nurse Fowler spent longer than necessary on ASU or EAS and that "it's not her responsibility to be giving bed pans" [Quote from fieldnotes, Senior Research Nurse Higgs, August 2006]. However, there may have been multiple reasons for Nurse Fowler's desire to participate in 'dirty work'. First, it reinforces her own identity as a nurse and her commitment to the care giving aspect of the role, but secondly this willingness to

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engage in the clinical routine, as similarly noted by Spilsbury et al, may also represent a strategy to facilitate the ward staff's reciprocal participation and cooperation in ongoing research (Spilsbury *et al.*, 2008) or to diminish the potentially perceived power differential (c.f. Allen, 2004). For Research Nurse Higgs this was primarily a resource issue; the difficulty here was that having become involved in a clinical situation it was not always possible to extricate oneself should a patient be admitted who required urgent assessment for study eligibility. It was therefore possible, that in undertaking clinical activity the team may miss a subsequent research eligible patient. By ensuring their availability for the assessment of potential study eligible patients the research nurses demonstrated 'care' for, and about, the trial. The associated rationale was no different from that of the clinical team who claimed that they could not undertake research tasks because they could not, and did not have time to, divert their attention away from the rest of their patients, a fact repeatedly acknowledged by the research nurses.

In the previous chapter it was evident that the clinical nursing staff did not generally perceive the research nurses to be involved in the delivery of care. Contrary to this view however, Dr Black was of the opinion that it was the very fact that they **were** involved in care that encouraged patients and families to participate in research. Because the research nurses were involved in the clinical assessment of new patients, with a view to research participation and/or thrombolysis, they were seen to be part of the team delivering care and this was considered to engender a sense of trust among patients and their families. Dr Black claimed that this may explain why patients were more willing to participate in acute and hyperacute studies, because they were being approached by people directly involved in their care, rather than secondary prevention studies when their involvement with the research team was likely to have less of a clinical care giving component and may therefore be viewed as something extra and unnecessary. In either situation however, whether delivering physical care or not, the research nurses often delivered psychological and emotional support and described themselves as an advocate for patients and family members.

7.7   Patient Advocate: Protecting Participants

Beauchamp and Childress state that, 'controlled trials are scientific instruments intended to protect current and future patients against medical enthusiasm and hunches' (Beauchamp and Childress, 2001; p.321). Acting as patient advocate, the research

nurses also aimed to afford such protection by mediating between healthcare professionals in positions of power and authority, and vulnerable patients and their families. Whilst the safety of patients enrolled in clinical research can be safeguarded by the proper application of, and adherence to, rules and regulations including research governance edicts, strict inclusion and exclusion criteria, and standard operating procedures, the research nurses also employed tacit and experiential knowledge and skills pertaining to the patient, rather than the study.

The role of advocate encompassed recognition of a patients' expectations and concerns as well as consideration of their values and beliefs, and incorporation of these factors in the decision making process, and in the patient's subsequent care and management. It was the research nurses' responsibility to assess patients' capacity to exercise autonomous choice (albeit informally). This included ensuring that the patient was able to make an informed decision, without coercion, from either healthcare professionals or family members. Research and clinical staff noted on several occasions the element of shock that often accompanied the event and diagnosis of stroke and how this was perceived to cause fear and anxiety for the patient and their family members. Whilst such a response was undoubtedly related to the condition itself and uncertainty regarding prognosis, it was also thought that this anxiety was potentially exacerbated when patients were approached to participate in clinical research. In this respect the research nurses were sometimes viewed as 'independent' practitioners who were in a position to judge the level of patient and family engagement and therefore the quality of the decision made. In order to do so, it was important that the research nurses were able to engender a non-threatening environment in which patients and family members were able to express their fears and concerns and to ask questions.

According to Dr Brown, in his previous role as research fellow in another hospital, the senior clinical nurse on duty would usually accompany him when talking to a patient about research participation to "just be kind of reassuring" [Interview: Dr Brown, October 2007]. At the study site however, clinical nurses were rarely involved in these interactions. Thus, in such circumstances, the research nurses drew upon the skills and attributes perhaps more closely associated with their clinical counterparts, i.e. those of caring concern, intuition, reactivity and subjectivity, kindness, compassion, good communication and reflectivity (Abraham and Shanley, 1992; Telford, 1992; Niven and Robinson, 1994; Hicks, 1996). They reported that by taking such an intermediary role in consent and decision making processes they provided patients and

family members with a 'real' opportunity to refuse. This notion is perhaps evidenced by reports that some patients/family members who initially expressed a desire to participate when approached by senior medical staff, then declined after discussion with the research nurse.

Beyond the process of information giving and facilitating informed consent, the advocate's role was not limited to those patients who decided to participate in a study. The research nurses also provided reassurance to those who chose not to participate, that their subsequent care and management would not be compromised in any way because of their decision.

Nurses are traditionally seen to recognise and fulfil patients' emotional needs and can do so within their advocacy role. Whilst advocacy and emotional work are not synonymous, the examples that follow illustrate how the research nurses' emotional and humanistic responses to the status and individual circumstances of potential study participants influenced the way in which they exercised their role of advocacy. The position the research nurses took as advocate was determined by their own emotional and relational response to the patient, rather than solely by consideration of clinical data and study protocols, as exemplified below.

7.7.1 Seeing the whole person: eligibility versus suitability

Several of the research nurses described the influence of intuition, gut feelings, and tacit and experiential knowledge upon their perception of the patient's level of capacity, cognition, and general willingness and ability to engage in either deliberations about potential study involvement or subsequent protocol requirements:

> … sometimes you get a feeling that there is something just not quite, quite right […] just sometimes there is little things that they say, erm just reading in between what they are saying and looking deeper […] I'm thinking something's, it's just not quite ringing right […] you do have to look a little bit deeper [INTERVIEW: Research Nurse Slater, October 2007]

For Research Nurse Slater, 'looking a little bit deeper' meant following up the idea that although the patient appeared to understand the information given and to be in agreement with the terms of study participation, she felt that there was something about his manner which suggested that there may be information retention issues or potential compliance problems. On reviewing the patient's case notes Nurse Slater found that there was a history of possible alcohol dependency which may impact upon compliance with aspects of the study protocol. Therefore recruitment did not proceed, thereby

protecting the patient from unnecessary risk and inconvenience whilst maintaining study integrity.

A similar account was provided by Senior Sister Hatfield, referring to her previous role as research nurse and her tacit assessment of patient capacity. For Sister Hatfield however, what she perceived to be her own intuition, emotionality and desire to act as patient advocate, conflicted with the requirements of her research role. She described such a conflict quite clearly in the following extract:

> There were occasions when I thought I don't agree with this, but this is my job and I've got to do it. […] there were some patients who I thought you know this isn't fair on this person, whether it was because […] I thought they were too old but their age still fitted [the inclusion criteria], or whether I thought their stroke is so bad and yet it still fitted, you know, there were occasions when inside I thought I don't agree with this, but- [INTERVIEW: Senior Sister Hatfield, July 2007].

Sister Hatfield stated that during her time as a research nurse she was confident in her own ability to apply inclusion and exclusion criteria, and did not worry about misidentifying a patient because criteria were so precise. However, as noted above, at a more personal level she reported that sometimes she felt that even though patients fitted the inclusion criteria they should not have been approached on the basis of other more 'humane' reasons such as 'too old' or 'too frail'. Dickson-Swift et al explore the emotion work/emotional labour required of qualitative researchers, but my data suggest that clinical research staff undertaking randomised controlled trials, or other quantitatively based work also found themselves experiencing conflicts between emotionality and rationality, and that they too employed similar skills in order to negotiate these difficulties (Dickson-Swift *et al.*, 2007). In the example above Sister Hatfield described an emotional, personal judgment which conflicted with the requirements of the research nurse role and criteria of the study. She went on to say that she thought she was "too soft" to be a research nurse, i.e. she could not divorce herself from her emotional response to patients' situations. Hunter (2004) suggests that such intrapersonal conflicts exist when there is divergence between differing professional ideologies. It is widely espoused in the literature that the ideology of nursing dictates that nurses care for their patients at a humanistic level, whilst the ideology of research dictates that the research nurse should endeavour to enrol every patient who fits the physiological criteria by the application of logic and reason. It is ostensibly then, at the recruitment moment that this ideological conflict is most pronounced. Whilst I do not

suggest that such tensions were not evident within my study, indeed examples are included throughout the thesis, the idea of the research versus care dichotomy and their incompatibility is that presented in much of the literature, rather than a reflection of my personal position.

The extract above clearly illustrates the oft noted dichotomy and duality of roles whereby the practitioner finds him/herself in a quandary, faced with balancing research integrity with concern for patient welfare (Beale and Wilkes, 2001). As patient advocate the nurse has a responsibility to protect patient interests but in a research role he/she also has other obligations. There may be tensions between the interests of the investigator, the sponsor company and the individual patient and the research nurses' loyalty may be split between patients' rights, the investigator (who is often their line manager) and the organisation that may –directly or indirectly- provide the nurses' salary (Hill and MacArthur, 2006). Nevertheless, all nurses, whether of clinical or research orientation, are bound by their professional code to support the accrual of knowledge contributing to the advancement of medical science, and thus the health of society as a whole.

Most of the respondents noted the importance of an empathetic approach and the need to provide emotional support in their role as patient advocate, and the previously described tacit objection to the inclusion of certain patients may arise from such empathy. However, by trying to imagine oneself in the patient/family member's position it is possible that one's own beliefs and values are projected, for example:

> I went to a lady yesterday who errrr is on Warfarin, but she's just started and there's a new trial errr coming up…a drug versus Warfarin […] I said to her 'Oh, I understand one of the doctors has approached you' and you could tell by her face that she knew nothing, […] so when I started to explain it, although she was happy…she was wanting to take part, she was a bit unsure because she thought she was allergic….she had allergic reactions to medication…so I just went "no that's it then…we'll stop right here and she says "but you know I'm quite happy but you know every time I go to the doctor they go oh here she comes again" … and I thought, […] it's not fair…I mean she's… "and I'm 83" [...] no, I just stopped it there and then, I just thought, no it's not….that's my opinion [INTERVIEW: Research Nurse Fowler, January 2007]

Similar to Sister Hatfield's 'softer' inclusion and exclusion criteria Research Nurse Fowler considered it 'unfair' to expect some older people to participate in research. On occasions where she felt that the situation was too stressful, or that study requirements would be too intrusive or demanding of the patient, she took it upon

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herself either to decide not to approach the patient at all or to curtail discussion before the patient/carer had reached a decision about study involvement, or even in contradiction of a provisional decision. This approach contradicted the dichotomisation of emotion and rationality, and the associated perception of the researcher being purely logical and analytical (Hicks, 1996; Woodward *et al.*, 2007).

For these nurses in their research role, their personal feelings about the 'state' and wellbeing of the patient and/or family conflicted with the requirements of that role and their own desire to promote medical research and knowledge. 'Silent decisions' such as that illustrated above contradicted the dichotomy that reifies reason and suggested that patient autonomy did not always come first (Whitney and McCullough, 2007; pp.33). Further, such actions raised the question whether attempts to be 'fair' to the patient actually resulted in the opposite, if undertaken in a paternalistic, or at least protectionist way which infringed upon autonomy.

Whilst it is clear from the examples noted above that the research nurses experienced conflict between their own ideals and values, the requirements of the research nurse role, and the study criteria, Hunter suggests that such concerns are rarely articulated and are instead interpreted as personal dilemmas or even failings (Hunter, 2004). The feeling of failure is noted below:

> Research Nurse Fowler […] doesn't want to renew her contract when it expires […]. She explains that she misses the "hands-on" patient contact and finds it hard to "step back" and limit herself purely to the research aspects of her involvement. […]She tells me that at first she felt that she had failed and couldn't do the job but now she's realised that it's just not for her. […]. She also says that she thinks that her training has something to do with the way she feels about patient contact and hands-on work. She initially trained as an enrolled nurse where the emphasis was always on the more practical side of nursing and she tells me that she still feels that that's what she wants to do. (Abridged fieldnote, August 2006)

For Research Nurse Fowler however, these concerns are recognised, articulated and successfully managed by her decision to return to a clinical role. Much has been written about 'emotional work' undertaken by nurses (and other service related work) with particular emphasis upon the relationship between patient and professional. In my study however, the data demonstrated a greater affinity with Hunter's findings in her study of midwives. In Hunter's study, hospital and community based midwives found themselves undertaking emotion work in order to deal with the personal frustration arising from the dissonance that resulted from the coexistence of conflicting ideologies

of practice in these different working environments (Hunter, 2004). Some of the interpersonal conflicts experienced by the stroke research nurses in Nearstreet Hospital may be related to conflicting ideologies which are perceived to exist within **one** environment.

7.8   Research Nurse Or Specialist Support And Facilitator

As described in Chapter 5.5, a further role of the research nurse is one of support and facilitator, not only in research situations but also in conducting clinical assessments, specifically pertaining to eligibility for thrombolysis. I also noted however, that the way in which these duties are discharged is often contingent upon the environment in which they are undertaken and the other personnel or teams involved.

In the following extract, we see the research nurse endeavouring to expedite a diagnostic procedure in order to secure the prompt treatment of Mr Briggs, a newly admitted stroke patient. However, unlike the clinical assessment of Mr Adams, described in Chapter 5.5, the research nurse is not in a position to assume authority and take the lead, and must therefore adopt a more passive role. Mr Briggs was received in EAS within three hours of the onset of his symptoms and, as with the assessment of Mr Adams, his clinical assessment proceeded quickly and efficiently, led by the senior research nurse and the SNP. Having established a likely diagnosis of ischaemic stroke, an urgent request for CT scan was submitted and Mr Briggs was promptly transferred to the radiology department. However, although the urgency remained for the patient and for the stroke team, it was the possession of technical expertise and ability and authority to handle the equipment, which determined the locus of control in the interaction that follows.

> Student radiographer is performing the scan and deliberating over scout films. Senior radiographer is explaining and taking some time. Nurse Higgs gesticulates, (though not actually making any comment at first) for senior radiographer to encourage student to speed up or to take over. Senior radiographer is aware of his movements and looks across reproachfully. Nurse Higgs begins to mouth "hurry up" and continues to gesticulate. She (fairly light heartedly) admonishes him for his impatience. Nurse Higgs explains the tight time window but she says that there's still half an hour. Nurse Higgs explains that although thrombolysis can be undertaken up to 3 hours post-ictus, even within this period there is evidence to suggest that earlier administration gives an even better prognosis. Senior radiographer tells him not to harass her staff, 'everyone has to learn'. The exchange is generally good natured but Nurse Higgs is genuinely concerned about administering the drug as soon as possible. Dr White arrives in the middle of this exchange when the senior radiographer is

saying, '5 minutes won't make any difference'. Research Nurse Higgs says that it may do - 'do you know how many neurones will be lost in those few minutes?' When she doesn't appear to be taking this too seriously Dr White also stresses the tight time window and uses the analogy that if you're stopped driving at 31 miles per hour in a 30 mph zone you may still be fined - i.e. even the smallest deviation can make a difference [FIELDNOTE: August 2006]

Unlike the EAS scenario described in Chapter 5.5, where a new 'virtual team' was formed and worked together, this interaction illustrated interdisciplinary conflict. In the EAS scenario the research nurse was in possession of at least as much, if not more, knowledge and expertise than the RMO, and was therefore able to orchestrate events. The scan room however was the domain of the radiographer and she determined the nature and pace of activity. The research nurse, once again was an interloper, and moreover, an interloper operating in a clinical, rather than a research context. For the stroke team, the priority was to get the patient scanned promptly so that thrombolysis (or study intervention) could be commenced as soon as possible, if indicated, and it was the research nurse's role to facilitate this. The radiographer however had dual priorities here; she had a responsibility to the patient to provide clear and accurate diagnostic views of his compromised brain but she also had a responsibility to provide training for the student radiographer, and to do so in an environment free from harassment and undue or avoidable pressure.

This is not unusual; all healthcare professionals have an educational element to their role. The issue here however was the way that this aspect of the radiographer's role was enacted in these circumstances, and its encroachment upon the very short time window within which treatment could effectively be administered. Nurse Higgs explained to me later that he understood the need to ensure appropriate training, but for him, whether in a clinical situation such as this, or in the context of research, the patient comes first. In the long term, the appropriate training of staff is clearly important, but for the patient in the emergency situation this was unlikely to be an immediate priority.

When Nurse Higgs became frustrated with the length of time the student was taking, he endeavoured to speed up the process by the use of body language. In order to avoid distressing the student this was directed towards the senior radiographer. When this strategy failed, he verbalised his concern by referring, albeit in vague terms, to research based evidence regarding the time-critical nature of thrombolysis, quantifying the effect of a delay by raising a rhetorical question about neuronal damage. The question had the effect of inferring the potential extent of damage, whilst implying that

the radiographer did/should know this. The vagueness of the reference to research allowed Nurse Higgs to make a point without being overtly challenging and thus drawing the radiographer's knowledge or expertise into question. Furthermore, citations of research evidence (in this environment) are more commonly associated with medical, rather than nursing personnel; doctors are entitled to refer to the work of other doctors or scientists (Potter, 1996). A more specific reference may thus have had the effect of making Nurse Higgs appear to be a 'know-all', or of being particularly didactic. It is of interest that he chose to make his point in this way rather than offering a more practical and possibly more tangible, incentive to expedite proceedings. For example, a brief explanation of how much time would be required to actually initiate treatment would have given the radiology team a more realistic indication of how much time could be spent on undertaking the CT scan. Healthcare professionals are encouraged to consider research based evidence but sometimes pragmatic issues are equally important, and perhaps more effective, in justifying a course of action. Such an approach however would mean that Nurse Higgs was directly requesting a change in the radiographer's behaviour in order to meet his own, albeit professional requirements. His more subtle approach allowed him to avoid being identified as bossy, demanding or interfering with clinical practice, because the change required, i.e. to speed up the procedure, was recommended by an 'unidentified other'.

The tension throughout this interaction was palpable, and reflected other similar situations observed by myself and reported by a number of participants throughout the fieldwork, which at best conveyed a sense of lack of interest on the part of the radiology staff and at worst obstructiveness. It was noted by several respondents that the radiologists sometimes tried to 'slot in' a patient (particularly inpatients) for CT scan, even though they knew that a stroke patient was en route from EAS, mere minutes away. For the radiology team this meant that they were able to undertake imaging on as many patients as possible, and thus expedite their progress through their hospital experience. For the stroke team however, it meant that a stroke patient may have an unnecessarily prolonged waiting period prior to being scanned, with potentially serious consequences if the delay placed the patient outside the therapeutic time window for thrombolysis or for a research intervention. For the research team time was a sliding scale where time taken to treat and outcome were inversely proportional; the quicker treatment can be initiated the greater the likelihood of a favourable outcome. In the extract described above, the radiographer appeared to focus on the 'absolute' limits of

the time window for the conduct of the CT scan, whereas the research team were more aware of the prognostic impact of even the slightest changes in 'time to treat'. The differing approaches of the two teams arose not from a **lack** of knowledge or interest on the part of the radiology staff, but rather a different **application** of knowledge and interpretation of the clinical situation. In light of this tension, and the sometimes strained interdepartmental relations, Nurse Higgs' subtle (although ultimately unsuccessful) approach to expedite the scanning process appeared even more politic, as did the very 'sociable' presentation of Dr White's analogy of a motoring offence. The latter had the effect of dissipating the tension whilst emphasising the research nurse's point, but it too failed to influence the conduct of the procedure in progress.

In the EAS scenario described in Chapter 5.5, the RMO's unfamiliarity with thrombolysis and/or study protocols legitimised the research nurses' authority. This was advantageous because having delegated specific tasks to the RMO they were then able to concentrate on their own tasks, unimpeded by other medical or administrative requirements. In the radiology setting however, the radiographer's lack of awareness of the pragmatic issues of treatment/research initiation was an obstacle that may lead to further delays in the patient's treatment and possibly influence the eventual outcome. The senior radiographer's interpretation of the three hour time window was absolute rather than relative. Like the RMO, she was unfamiliar with the practicalities of the thrombolysis (or research) protocol beyond her own aspect of it. Thus, when she quite accurately stated that 'there's still half an hour' she was referring only to the time required to perform the CT scan, not how long it was likely to take to get the patient back to EAS, reassess his clinical status, explain to him the proposed treatment plan and secure his agreement, before preparing for and initiating thrombolysis, because this was information that she had not been made aware of. One operates in the context of what one knows; in this respect, providing other professional groups with information only on what might be considered a 'need to know' basis can be counterproductive.

In contrast to the EAS episode the research nurse took a much less dominant role here, despite his frustration, because the things that needed to be done could only be done by the radiology staff. In EAS his experiential knowledge allowed him to assume authority by 'doing', but here there was nothing that he could do, likewise Dr White. The research team's position in EAS could be said to be determined by their expertise and the urgency of the situation, but in the radiology department their lack of technical equipment and capabilities meant that they had to adopt a more passive role.

In this situation Research Nurse Higgs was not attempting to recruit the patient to a research protocol, but used his research background to try to influence practice. Despite his limited success, he endeavoured to provide specialist support by means of practical application of the knowledge and expertise gained within the research role – knowledge and experience that was not routinely accessed or encountered by clinical staff.

7.9   Discussion

In the sections above I have outlined how the research nurses perceive and undertake their role, although it is of interest that even amongst the research nurses themselves there are inconsistencies regarding their perceptions of this role and its priorities, particularly with regard to their interpretation of and provision of 'care'. I have described and illustrated the various components of the research nurse role, but as noted at the outset, the whole is greater than the sum of the parts. Further, there are areas of overlap with their clinical counterparts that may not be immediately evident in considering these individual aspects.

To illustrate, a survey of registered nurses in Hong Kong identified that their perception of care encompassed three main categories: endeavouring to meet clients' needs; effective communication; and providing a safe environment (Yam and Rossiter, 2000). It can be seen from the examples given that whilst these values were also upheld by the research nurses at Nearstreet, they were enacted via different means and further, that their other commitments and obligations influenced the prioritisation of these aims.

7.9.1 Endeavouring to meet clients' needs

Like their clinical colleagues, the research nurses endeavoured to meet their clients' needs, but an important distinction was the definition of those clients and how their needs were to be met. Research nurses endeavoured to meet the patients' needs by offering them, where appropriate, the opportunity to participate in research which might influence their own health outcome, but would also contribute to a body of medical and scientific knowledge which may improve stroke management and therefore associated outcomes for future stroke patients. Whether clinically or research oriented, nurses have a responsibility to protect patient interests. However, they also have an obligation to support the accrual of knowledge, which will directly impact upon the health of society as a whole (Johnson, 1986).

The research nurses achieved this by caring for the individual within a research protocol that ultimately sought to address the healthcare needs of a wider society. This

therefore addressed the immediate needs of the current patient(s) in front of them whilst also planning and developing care for the future. They may, however, have been compromised in meeting patients' more basic and intimate needs because in trying to meet the needs of their other 'clients', i.e. the study sponsor, they endeavoured not to become embroiled in, and therefore diverted by or to, clinical demands. For example, having taken a blood sample for central analysis the research nurse could not let this wait until she had assisted with the patient's feeding or bathing before preparing it for shipping. Whilst it may be argued that ultimately the nurses' duties to an individual patient are always paramount, in the situation described these everyday duties were delegated to the clinical team. This was necessary because it was not physically possible for the research nurses to adhere to the timely completion of study requirements whilst also participating in clinical activities.

7.9.2 Demonstrating effective communication

The research nurses attempted to communicate effectively with patients, their families, and their research and clinical colleagues by explaining their role function and purpose both verbally and by means of written information. Effectiveness however, was sometimes hindered by a number of factors pertaining either to the patients themselves, resource implications or issues of general awareness and knowledge. Heavy clinical workload also impacted upon opportunities for communication between clinical and research teams, as well as influencing availability and willingness of clinical staff to engage in research activity and to become familiar with research concepts and procedures.

Effective communication between patients and researchers was sometimes precluded by the patient's clinical status and the physical or cognitive effects of their condition. The sudden onset and severity of symptoms also had an impact, as many patients and their families were perceived to be in a highly emotional state, and perhaps not receptive to information about or requests for study participation. This perception influenced the way in which the research staff oriented to, and interacted with, potential study participants, and may have given rise to a self-fulfilling prophecy if those who were approached less than positively then declined to participate. Communication with patients was also perceived to be constrained by their limited understanding of research in general, and their lack of awareness of ongoing research in the healthcare environment.

Communication was also contingent upon fulfilment of expectations. In this respect the wearing of a nurse's uniform could potentially facilitate or hinder communication with colleagues and patients/families alike. The perception of a positive effect of being recognised as a nurse was not restricted to the nursing staff. Throughout his interview, Dr Black commented on the importance of trust in the recruitment and retention of patients to clinical trials and emphasised that patients and their families were more likely to trust, and therefore respond positively to, someone whom they perceived to be a knowledgeable professional, committed to restoring them to health. The adoption of a nurse's uniform reinforced the perception that the research nurses were part of the care giving team, and thus bestowed rights associated with their professional affiliation, such as access to patients and their medical records. However, this almost instantaneous recognition tended to by-pass, or at least over-shadow, subsequent introductions and explanations of role, and therefore may have contributed to patients' conflation of research and clinical activity.

A further aspect of communication within the research nurses' role, and one which appeared to be poorly understood by the clinical nurses, was the precision required in order to communicate accurate and timely information to the study sponsor, which is also pertinent to the final category noted by Yam and Rossiter (2000) – providing a safe environment.

7.9.3 Providing a safe environment

The research nurses endeavoured to maintain the safety of participating patients by ensuring that only those who were eligible for study entry, and for whom the study was deemed suitable, were approached to consider participation. They achieved this by:

- offering eligible patients the opportunity to participate in clinical research which may (but not necessarily) offer the prospect of an improved outcome, or, may enable the potential participant to fulfil what they may perceive to be a moral obligation to contribute to the advancement of medical and scientific knowledge,
- spending time with those patients considering or consenting to study involvement to ensure that they fully understood their rights and responsibilities in relation to study participation, and that subsequent participation was voluntary and uncoerced,

- ensuring that the care of non-consenters was not jeopardised by their decision, and that those who did agree to participate in the ongoing studies were managed according to the study protocols.

Thereafter, they continued to ensure the patients' safety by the timely and proper conduct of study interventions and follow up activities. Simultaneously, by endeavouring to avoid placing undue workload pressures on the clinical staff, they also avoided jeopardising the safety and wellbeing of other patients on the ward.

7.10 Conclusion

It is clear from this, and the preceding empirical chapters, that members of the research and clinical teams considered themselves to belong to quite different groups. In this chapter I have explored how the research nurses perceive and discharge their role, notwithstanding the constraints placed upon them by policy and intraprofessional relations. I have demonstrated that they remain true to the values and principles of the nursing profession, but prioritise, experience and apply these skills, values and competencies, in a different way and to a different end, than their clinical counterparts. This is not to say that either position is right or wrong, but that each is tailored by the individual professional according to the requirements of their role and the desired outcome. In the following chapter I discuss how the amalgamation of these factors impacts upon the performance of the research endeavour and how the differences previously noted are manifest in their interactions with each other and with patients and family members.

Chapter 8. Separation of Research and Care: The Work of the Clinician-Researcher

8.1 Introduction

In the preceding chapters I have described the environment where stroke patients were received and subsequently managed, including the areas in which they were identified and approached for participation in clinical research. I have introduced actors or groups of actors, involved in the enrolment and management of patients participating in clinical research. With reference to the observed activities and reports of the research and clinical teams I have described the ways in which research and clinical activities were delineated, as well as some examples of cooperation and collaboration. In the sections that follow I draw these strands together to illustrate the effects of this delineation upon research activity, focussing on interactions between healthcare professionals and patients. In particular, I examine specific elements of research activity within the acute stroke unit, namely, the identification and assessment of new patients, and the process of negotiating informed consent.

It is clear from the preceding chapters that members of the research and clinical teams considered themselves to belong to quite different groups. Here, in order to exemplify these differences, I will present three scenarios. First, I describe a fairly typical example of obtaining consent for emergency medical treatment of ischaemic stroke. Second, in contrast to this clinical situation, I explore the way in which patient and clinician orientate towards each other in the research consent encounter before finally, demonstrating the way in which the research team work together when attempting to enrol a potential study participant.

8.2 Consent For Thrombolysis v. Consent For Research

As noted in Chapters 3, 4 and 5, during the course of my fieldwork the number of patients admitted to the ASU who fulfilled the eligibility criteria for the ongoing acute and hyperacute studies was considerably fewer than anticipated. This meant that I had fewer opportunities to observe and record consent interactions in this context, but I did witness several clinical consent interactions. Here, I return to the example of Mr Adams, first noted in Chapter 5.5. The interaction between Mr Adams, his wife, and Dr White, was typical of the clinical consent interactions that I witnessed and provides a point of reference and contrast for the research scenarios that follow.

As noted in Chapter 5, Mr Adams was received in EAS with a provisional diagnosis of stroke, well within the three hour time window for thrombolysis. I described in Chapter 5, how Research Nurse Higgs assumed the lead in Mr Adams' admission and assessment process, and immediately began a neurological examination. Meanwhile, Sr Stone (Stroke Nurse Practitioner) completed a CT request form, obtained a signature, delivered the request form in person to the radiology department, and contacted Dr White, who was the consultant stroke physician on-call for thrombolysis. All of this activity relieved the clinical team of most of their immediate duties pertaining to the care of this patient.

Dr White arrived to asses Mr Adams at 9:45am. The following extract describes events:

> Dr White arrives at 9:45 hours. He introduces himself to patient and wife but then seeks history from patient's wife as patient's speech is still quite slow and slurred and he seems a little drowsy. Dr White explains that is seems likely that the patient has had a stroke and that it is probably the sort caused by a clot. He explains that "clot busting" treatment is an option. Nurse Higgs and Sr Stone are completing documentation and taking blood samples whilst this conversation is going on. Patient is able to confirm that his mother died of a stroke and his wife says that she died quite young. Dr White explains to wife and patient that a scan is required to determine whether it is safe to give the clot busting treatment and explains that the treatment itself can be dangerous but that it is a "balance of risks". He explains that it can cause bleeding in the brain which would make matters worse, but in this case it is something that he would recommend. He asks the patient and his wife what they would like to do, are they happy to "go for it?" The patient is slow to respond and his wife interjects encouragingly "do you want the doctor to help you?" (rather than 'do you want the treatment?'), "do you want to put your hands in his hands?" and "let him make the decision". She tells Dr White that she doesn't think her husband "is in any state" to make such a decision at the moment so if he'll let her speak on his behalf she thinks they should take Dr White's advice and have the treatment. The patient appears to consent (eye contact and facial expression). Dr White thanks the patient's wife for her confidence; he explains that he is usually quite conservative about using this treatment but does so in cases where he feels the risk of using it is minimal compared with not doing so and feels that this is such a case. "You're a good man" says the patient, to which Dr White replies "Thank you, I hope it turns out that way". [FIELDNOTE: August 2006, Extract 1]

It was not usual practice at the study site to obtain written consent for thrombolysis and therefore this interaction (i.e. Mr Adams' and his wife's actions) was taken to constitute consent. The interaction between Dr White and the Adams' lasted approximately 10 minutes, during which time Research Nurse Higgs and Sr Stone continued to record observations, take blood samples and prepare the room for the

eventuality of administering rtPA. By providing practical support they enabled Dr White to concentrate solely upon extracting a concise history and to determine the appropriateness and acceptability of thrombolytic therapy. Following this interaction, Mr Adams was taken immediately to the radiology department for urgent CT.

The scan confirmed that there was no haemorrhage and by 10:10hrs Mr Adams was back in EAS and the bolus dose of rtPA was administered. (rtPA is given intravenously over a period of 60 minutes. The first 10% of the dose is given as a bolus over 1-2 minutes, followed by the remainder by infusion.) A few minutes later, Dr White returned to speak to Mrs Adams:

> Dr White explains that there was no bleed on CT scan therefore this is a "clotting type of stroke rather than a bleeding type of stroke" and the clot busting treatment can be given to dissolve the clot so with her permission [in the 'pre-scan' interaction] they've just "got on and done it". [FIELDNOTE: August 2006, Extract 2]

During the brief exchange between Dr White and Mr Adams, although drowsy and a little slow to respond at times, Mr Adams was able to give a brief, but relatively clear, verbal history of the onset of his symptoms, general health status (he was a known epileptic) and a little about his family history, which was supplemented by his wife. In accordance with the Mental Capacity Act (2005) Dr White attempted to respect Mr Adams' autonomy as far as possible, by including him in the discussion and allowing time for his responses. Nevertheless, ultimately he accepted Mrs Adams' assent to proceed with investigation and treatment.

It is noteworthy that unlike research consent interactions where the researchers generally attempt to maintain neutrality, in this instance Dr White proffered an opinion regarding the suitability of this treatment, explaining that although it was a 'balance of risks', 'in this case it is something that he would recommend'. He reinforced his recommendation by stating that he 'is usually quite conservative about using this treatment, but he does so in cases where he feels the risk of using it is minimal compared with not doing so and feels that this is such a case' [from Fieldnote, August 2006; for full extract see Extract 1 above].

By framing this nonetheless risky option as a recommendation, Dr White offered an element of moral relief in the form of professional guidance which was not usually considered possible or desirable in a research consent interaction. To illustrate, in interview, Dr White stated that:

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accepting the invitation to be paternalistic in one's management of the case […] under certain circumstances is entirely appropriate in the clinical scenario. […] I think certainly a paternalistic approach if the patient, […] actually asks for it, is appropriate in a clinical scenario but I don't think in the research scenario, to me it reflects sort of the vulnerability that I think that one, one has a duty to protect so I think there is a difference [INTERVIEW: Dr White, April 2007].

This was further exemplified in a similar situation just a few days later, when Dr White assessed Mr Briggs, another patient who was admitted within three hours of the onset of his stroke symptoms, and therefore also potentially eligible for thrombolysis.

> Dr White arrives and is obviously aware of the very tight time frame [1 hour remaining]. He introduces himself to Mr Briggs and tells him that it is likely that he's had a stroke. He mentions 'clot-busting' treatment to Mr Briggs and explains that he and the nursing staff need to assess his eligibility for this type of treatment. He mentions the very short time frame and points out that for the best chance of effectiveness the drug must be given within 3 hours of the onset of stroke symptoms. […]

> [POST CT SCAN] Dr White explains to Mr Briggs that he has had a stroke that is **not** caused by a bleed and that it is developing as they speak. He explains that the aim of the clot busting drug is to reduce the severity of the stroke, although the treatment itself has risks, for example it can cause bleeding […] Dr White advises that the treatment should be given, and supports this recommendation by mentioning that thrombolysis is recommended by NICE, if it is possible to give it within three hours. He asks Mr Briggs if he has heard of NICE, and also asks whether he patient would like to go ahead with the treatment. Mr Briggs states that he wants Dr White to make the decision. Dr White asks if he wants him to use his clinical judgement, and says that if it was his father or uncle requiring the treatment he would go ahead and give it. [FIELDNOTE: August 30th 2006]

In this encounter, at Mr Briggs' request, Dr White made a decision based upon his professional knowledge and personal opinion. However, in Mr Adams' case, Dr White was not accepting a direct invitation from the patient to be paternalistic, but from the patient's wife. Mrs Adams suggested that she did not think that her husband was 'in any fit state' to make a decision regarding treatment and thus asked his permission to defer to the doctor's recommendation on his behalf. Later however, once the treatment had been initiated, she confided to me that this was not the only reason that she made a decision on her husband's behalf. While she stated that she thought her husband 'probably wasn't thinking straight', she also reported that he did not like taking drugs and therefore may have refused the treatment. Although not framed in these terms by Mrs Adams herself, it may appear that she had allowed beneficence and consideration

of what she considered to be her husband's best interests to over-rule maintenance of his autonomy.

As others have noted, whilst proxy decision making by family members may aim to safeguard the patient's best interests, it does not necessarily uphold autonomy (Miller, 1993; Alves and Macciocchi, 1996; Corrigan and Williams-Jones, 2003). However, this was not necessarily the case, and in any event her intervention may not have been required. Mrs Adams' assumption that her husband would have refused treatment failed to take into account what Cox White and Zimbelman refer to as 'values evolution' (1998; p.448). Recognising the role of context and the problem of the hypothetical, they note that patients do not necessarily change their minds, but rather reassess the values driving their decisions when confronted with a hitherto unknown situation (Cox White and Zimbelman, 1998). Mrs Adams could not be certain that her husband did not, or would not, similarly reassess his previously held values and beliefs. Furthermore, although she wanted to take the decision out of her husband's hands, she also stated that she did not want to 'get the blame for agreeing to treatment if things go wrong', hence her desire to defer to the clinician. This potential burden of guilt was noted by a number of members of the clinical and research teams as being a potential reason for relatives' refusal to allow their loved ones to be enrolled in clinical research, particularly when equipoise and neutrality inhibited the likelihood of clinician recommendations. Rather than promoting patient autonomy and informed, uncoerced choice, the clinician's maintenance of a neutral position may result in the patient feeling a sense of abandonment.

It can be seen in this example, that despite concerns arising following scandals such as Shipman, Alder Hey, and more recently, the disastrous Phase I drug trial at Northwick Park, about the perceived erosion of trust in those in positions of power and authority, at an individual level, healthcare professionals are still generally held in high regard (Department of Health, 2001; O'Neill, 2002; Department of Health, 2004b; Department of Health, 2006). Thus, even within this brief interaction, Mr and Mrs Adams rapidly made an assessment of Dr White's character, and were willing to place their trust in him.

> [Mrs Adams] interjects encouragingly "do you want the doctor to help you?" (rather than 'do you want the treatment?'), "do you want to put your hands in his hands?" and "let him make the decision". […]The patient appears to consent (eye contact and facial expression). Dr White thanks the patient's wife for her

confidence; […] "You're a good man" says the patient, to which Dr White replies "Thank you, I hope it turns out that way". FIELDNOTE: August 2006]

However, Dr White's explanation of 'clot-busting' treatment was brief, and noted only the most serious potential side effect (excluding death). He did not explain any other options, which at least initially in this case would have been to do nothing except monitor Mr Adams' condition.

Like Dr White, other staff, in clinical and research roles expressed the view that they either were, or would expect to be, more confident in giving an opinion regarding a known therapeutic intervention, compared to the uncertainty associated with experimental interventions. For the clinical staff this reflected their lack of familiarity with individual research protocols, but was also related to their lack of knowledge of and engagement with research more generally. The interactions above supported these observations and provided a point of contrast with the research interaction which follows.

8.3 Seeking Consent For An Acute Stroke Study (Medical Admissions Unit, King's Hospital)

The clinical interaction between Mr Adams and Dr White took place under considerable time pressure, and in a potentially life threatening situation. Whilst not involving a hyperacute research protocol, the interaction between Dr Chatterjee and Mrs Banks, described below, was also time limited, and further constrained by other logistical factors. I begin with a summary of events that occurred leading up to the face to face encounter with the patient.

> 8:30am on a Monday morning - the Stroke Unit is full. Revised admission policy now in place whereby suspected stroke patients are admitted to the Medical Admissions Unit at King's Hospital outside 'normal office hours' and transferred to Nearstreet as soon as possible thereafter. Dr Black has telephoned ASU to advise that there is a patient to be transferred as soon as a bed becomes available. In the Stroke Research Office (9:05am) the Research Fellow advises the senior research nurse that he reviewed two potential study patients at weekend including Mrs Banks, a lady admitted to King's on Sunday. He considered her for CHHIPS [blood pressure management study] but she was normotensive (blood pressure within normal limits as defined by study protocol) and therefore ineligible. Research Nurse Higgs, Dr Chatterjee and I return to ASU to join the 'board round', where it transpires that this is the same patient awaiting transfer. Dr Black reviewed her earlier this morning and found her systolic BP to be 190 mmHg. She is therefore now potentially eligible for CHHIPS although time of ictus currently unknown. At the end of the round (10:20am) lengthy discussions follow between Dr Black, Research Nurse and

Research Fellow regarding her eligibility, particularly in relation to the uncertain time of ictus. Recruitment window for CHHIPS is 36 hours. The Research Fellow telephones MAU, King's to ascertain time of ictus, or time last known to be symptom free. Mrs Banks' case notes suggest 7:30pm Saturday evening. Based on this information she is outside the CHHIPS time window.

Research Fellow and Research Nurse consider COSSACs – 48 hours time window but time of onset still to be determined. I accompany Research Fellow to King's to see the patient. A free minibus service operates between the three hospital sites and we leave Nearstreet for King's at 11:15am but miss the 11:15 minibus. We catch the next one at 11:30am and arrive at MAU approx. 12 midday. Having introduced us both to the ward sister and explained the reason for our visit we see the patient, Mrs Banks, at her bedside in 6 bedded bay. Dr Chatterjee establishes in discussion that Mrs Banks first noticed symptoms at approximately 10:30pm, Saturday evening and could therefore be recruited up until 10:30pm Monday evening. He discusses potential study participation and she has no specific objection but wants to discuss with family. Dr Chatterjee leaves documentation for their perusal and says that he will review when she is transferred to Nearstreet.

We return to Nearstreet, at approximately 1:00pm and await patient transfer. She arrives later in the afternoon but her relatives have not arrived by the time the research team finish their shift. The following day, having missed the recruitment deadline, there is no further discussion with Mrs Banks and she is not offered an explanation that option to participate had expired. [ABRIDGED FIELDNOTE: November 2006]

These fieldnotes show that much work was undertaken prior to the actual 'point of consent'. As previously outlined (Chapter 5), the stroke research nurses were usually the first to see the patient. Typically, they garnered as much information as possible prior to approaching the patient to introduce the possibility of research participation. This accrual of information usually comprised review of the patient's case notes and at least some discussion with the nursing or medical staff involved in the patient's care. The research nurses would then contact the research fellow for further review and initiation of the information and consent process. In Mrs Banks' case however, the gathering of information was further complicated by the fact that she was located at a different site.

The research fellow had minimal interaction with the clinical team at Nearstreet and was even less familiar with the team at King's. On arrival at the ward, Dr Chatterjee introduced himself and me to the Ward Sister and made enquiries about the most basic inclusion criteria, Mrs Banks' ability to swallow. The aim of his question was to check fulfilment of the criteria, rather than being a clinical or personal question about Mrs Banks' wellbeing. His approach was study oriented, and the question was necessary

because the study may involve the patient taking oral medication; if Mrs Banks was unable to swallow there would be no point in proceeding further. From the outset then, Dr Chatterjee cast Mrs Banks as 'potential study participant'. While the ward sister attempted to determine Mrs Banks' swallow status, Dr Chatterjee reviewed her notes to check in particular whether any further information had come to light regarding the time of ictus. It was reported in the clerking notes that Mrs Banks was symptom free when she made herself a cup of tea at approximately 9:30pm on Saturday evening. It appeared therefore that she was still well within the study recruitment time window and having determined that Mrs Banks was able to swallow, Dr Chatterjee and I approached her.

Dr Chatterjee introduced himself and me to Mrs Banks as researchers, but he did not ask permission to record the interaction at first so I did not begin recording immediately. Initially he was still trying to clarify exactly when Mrs Banks' symptoms began and to determine her level of capacity. Thus, for the purpose of determining eligibility, Dr Chatterjee questioned Mrs Banks about the onset of symptoms and her admission to hospital. After some initial confusion regarding the day of admission, she was able to answer reasonably clearly, and he was able to make a crude assessment of her general level of capacity and to establish that she first noticed her symptoms at 10:30pm on Saturday. This meant that she could be enrolled into COSSACs until 10:30pm on Monday.

Although in general, Mrs Banks was able to answer questions and give a fairly clear history, some of her responses were somewhat vague and not particularly helpful, although it could not be said that she was confused. Furthermore, her responses were neither unreasonable nor inappropriate given the way in which some of the questions were asked. For example, when trying to establish her level of understanding, Dr Chatterjee asked closed questions such as: "So have you, have you so far understood what I have told you?" which elicited the response "Ah ha, I can understand it". Mrs Banks' responses may have been influenced by the doctor's accent or phrasing of some of the questions rather than any confusion on her part. Furthermore, although Dr Chatterjee and I were aware that he was asking questions from a research perspective, there was nothing inherent within the questions or in Dr Chatterjee's appearance or conduct that would differentiate him from any other doctor, or this interaction from a clinical one. Located as she was then, in a clinical setting, surrounded by clinical staff and 'props', it is perhaps unsurprising that Mrs Banks remained in 'clinical mode', and appeared to identify herself purely within the patient role.

Having established that Mrs Banks was still within the recruitment time window, Dr Chatterjee went on to introduce the study. For Dr Chatterjee, this was where the 'consent interaction' actually began, and at this point he requested verbal permission for me to record the conversation. Mrs Banks had no objection to this, and I assured her that I would give her further information about my study later. Although this request heralded the start of the 'formal' consent approach, for Mrs Banks, nothing had actually changed. She was in the same environment, speaking to the same people, about elements of her care that were already in place for clinical reasons.

The consent interaction unfolded thus:

> **Dr Chatterjee**: Now, we are doing some studies, study meaning it's er, er, trial, right? As you know, after the stroke sometimes your blood pressure can be raised, yeah? **[Mrs Banks**: Ah ha**]** Now whether to treat it or not, is, there is no clear cut evidence, or in the sense people don't know the answer to that, whether they should be treating it or not. Now one theory says you should not treat it because it, it can reduce circulation in the brain, and one theory says you should treat it because if your blood pressure is high it can have more swelling of the brain but exact answer is not known now, okay? Now this particular study looks at the effect of blood pressure on, on the stroke. What it means, those people who are willing to participate in the study either we'll ask them to continue their blood pressure **[Mrs Banks**: Mm**]** or ask them to stop their blood pressure **[Mrs Banks:** Mm**]** and we closely monitor their blood pressure on a regular basis. At the same time we also see like how they are doing from a stroke point of view and we compare both the results, whether those who were continued on the treatment for the stroke did better or those who discontinued, you know blood pressure tablet did better **[Mrs Banks:** Aha**]**. So if you say yes, either you'll be tak, continue taking your blood pressure tablet or you wouldn't take any blood pressure tablet for two weeks. It would be just for two weeks. **[Mrs Banks:** Aha**]** After that, if medical team feels you need some blood pressure tablet then you go on your regular treatment **[Mrs Banks:** Right**]** Right. There are no major risks involved in the study except sometimes your blood pressure can go, if, if you are randomised, if you are, if you are selected to participate in the group where we stop your blood pressure your blood pressure can go high, but if it is a medical emergency or if it is a risk to you, we can always restart your tablets, that's not a problem. So if for some medical reason you need to discontinue we can always discontinue this particular trial, but that's not a problem. So always patients' health and patients' medical care come first. If there is no problem from that point of view we continue with the trial. **[Mrs Banks:** Right**]** [AUDIORECORDED CONSENT INTERACTION: November 2006].

Following this explanation, in order to determine Mrs Banks' level of capacity in relation to this particular decision, Dr Chatterjee attempted to establish what she understood about the study:

> **Dr Chatterjee**: So have you, have you so far understood what I have told you?

Mrs Banks: Ah ha, I can understand it. […]

Dr Chatterjee: Now, tell me what I have told you, like what's your understanding about what we are going to do.

Mrs Banks: Will I be alright if I don't like, if I don't take any tablets? [AUDIORECORDED CONSENT INTERACTION: November 2006]

By asking the patient about her understanding of "what we are going to do", Dr Chatterjee anticipated consent and this was reiterated later during the interaction. Mrs Banks' main concern appeared to focus upon the risks of not taking her established antihypertensive treatment, and was grounded in her identity as a patient, rather than potential study participant. The research element of the interaction did not appear to register with Mrs Banks, and did not lead her to consider the risk of continuing her current treatment. Her fears about stopping a longstanding intervention were reflected in the staff interviews, where several participants raised concerns regarding the reluctance of patients to consent to a study that may alter treatment regimens that have usually been initiated in the context of a longstanding relationship, either with their primary care team or with another hospital consultant. They commented that some patients are reluctant to change, especially when benefit is uncertain and not necessarily personal to them. Moreover, it was noted that patients have usually been advised, repeatedly and persistently, that they must not stop taking their medication(s) abruptly. Consequently, to suggest that this would be a possibility if taking part in the study, can be a cause for concern.

In this particular example, a decision to stop or continue antihypertensive treatment in the immediate post-stroke period is currently based on the clinician's personal preference, experience and clinical judgement, but not, at the present time, on scientific evidence. Thus, even if a patient refuses to participate in the study, on the grounds that they are happy with their current regimen, this is no guarantee that the regimen will not be changed, simply that it may be changed for uncertain clinical reasons rather than on the basis of randomisation in a clinical trial. In essence, patients taking part in the COSSACs study were consenting to have their treatment randomly allocated; if they did not participate the same decision may still have been made without randomisation and without the follow up that the study offered.

Apart from the initial discussion when Dr Chatterjee tried to establish the time of onset, the rest of the consent interaction focussed upon the transfer of information from doctor to patient. Nevertheless, although such a focus may convey the impression that

the interaction was controlled by the doctor and was 'study oriented', Mrs Banks frequently oriented to Dr Chatterjee's questions in such a way that she was able to raise her own concerns about possible changes to her treatment regimen, rather than answer Dr Chatterjee's questions directly. In response to Mrs Banks' question "Will I be alright?" Dr Chatterjee reassured Mrs Banks that study involvement would only potentially alter her treatment regimen for a two week period. He also mentioned that she would be allocated to stop or continue her antihypertensives by a process of randomisation which he likened to flipping a coin, although he did not explain why this was necessary. Still he continued to furnish her with information that he was bound by legal requirements and professional guidelines to provide ('The Medicines for Human Use (Clinical Trials) Regulations,' ; Franke *et al.*, 2000; General Medical Council, 2008), such as reminding her about the voluntary nature of study participation, confidentiality and indemnity, rather than that which would answer her question, "Will it be alright?" Thus when he repeated his question regarding her understanding of the study, Mrs Banks once again reoriented the question in order to prioritise issues important to her, regarding the understanding of her own health status and existing treatment regimen, as noted below:

> **Dr Chatterjee**: so, tell me, […] what's your understanding about it? What, what we're going to do?
>
> **Mrs Banks**: I understand I'm not right, you see when I was at home I used to take one every morning
>
> **Dr Chatterjee**: Sorry?
>
> **Mrs Banks**: I used to take a one every morning.
>
> **Dr Chatterjee**: Yeah, yeah.
>
> **Mrs Banks**: And if I missed a one I, I used to get worried in case anything happened, with me blood pressure tablets [AUDIORECORDED CONSENT INTERACTION: November 2006].

Although the question was posed to illicit a response about what the patient understood about the study, Mrs Banks told the doctor instead what she understood about her general wellbeing; that she was "not right". She took the opportunity to describe her own routine management of her chronic health condition, and began to explain her treatment regimen. Her oblique response seemed to cause some bewilderment for the doctor ["Sorry?"], and allowed her to continue to emphasise her

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usual behaviour and how she worried about changes to her routine. Occupying a purely 'patient' position, Mrs Banks described how she managed her health and her worries about non-compliance with prescribed drug regimens which may result if she participated in the study.

After another brief attempt to explain the research, Dr Chatterjee asked Mrs Banks again to recount her understanding of it, but she remained unable or unwilling to do so. When asked how she felt about the study, Mrs Banks persisted in interpreting this question as a more general inquiry and stated that she felt "alright" – making no reference to the study.

> **Dr Chatterjee**: So tell me wha, what, what's the understanding about the study? Wha, what do you feel?
>
> **Mrs Banks**: Oh, I feel alright.
>
> **Dr Chatterjee**: Yeah, so what's your understanding, what we will be doing if you say yes?
>
> **Mrs Banks**: I don't know. [AUDIORECORDED CONSENT INTERACTION: November 2006]

Repeatedly Dr Chatterjee attempted to reorientate Mrs Banks to the role of potential participant by returning to issues specific to the research protocol. Mrs Banks however, did not engage with the study specific element of Dr Chatterjee's question. She continued to locate herself firmly in the patient role, and Dr Chatterjee was unable to change this. He asked again:

> **Dr Chatterjee**: So tell me if you say yes to this study what you will be doing. What, what exactly will happen to you?
>
> **Mrs Banks**: Nothing will happen, will it?

Although Dr Chatterjee was asking about the process of the study, Mrs Banks focussed upon its outcome, and sought reassurance that there would be no adverse effects. The doctor appeared not to understand her response and explained again that study involvement might mean that she stopped taking her antihypertensive medication for two weeks.

> **Dr Chatterjee**: So are you happy either continue to blood pressure tablet or discontinue blood pre.., either way you are happy?
>
> **Mrs Banks**: As long as I'm going to be alright I'll not mind.

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Dr Chatterjee: Sorry, as long as you are going to be alright?

Mrs Banks: Am I going to be alright?

Dr Chatterjee: I don't know.

Mrs Banks: I'm not going to die, I'm not gonna die though am I?

Dr Chatterjee: No, you're not going to die. Don't worry we wouldn't let that happen. [AUDIORECORDED CONSENT INTERACTION: November 2006]

Mrs Banks continually sought reassurance, and although at first Dr Chatterjee answered honestly that he did not know if she would be alright, when she indicated the extent of her concern by asking if she would die, he gave her the answer that she almost certainly wanted to hear, but that he could not actually know. The entire interaction proceeded as if two parallel conversations, with each participant engaging in the encounter from an entirely different perspective. Their individual contributions to the conversation could be linked, but not necessarily in the way, or to the effect, which either required or anticipated. Mrs Banks never deviated from her self-assumed, patient role, whilst for the most part, Dr Chatterjee adhered to that of researcher. Only briefly, in the exchange noted above did his frame of reference momentarily switch from the position of uncertainty he occupied as a researcher, where he appeared comfortable to state "I don't know", to that of experienced clinician who "wouldn't let" the patient die. Dr Chatterjee was able to make this switch because although his main focus was Mrs Banks, potential study participant, his clinical experience enabled him to recognise her concerns **as a patient** and respond to them as a doctor, as she required. This was only a fleeting departure from the research role however, following which he resumed his efforts to secure study enrolment. Mrs Banks however had likely had no previous experience of research, and therefore responded to Dr Chatterjee in the only way that her experience allowed, as a patient responding to a doctor.

After this brief attempt to respond to Mrs Banks' need for reassurance, Dr Chatterjee reinstated himself in the researcher role and presented Mrs Banks with the study information sheet. Asking her if she would like to read it, he warned her that it was quite lengthy (six pages of 12 point font) but suggested that he leave it with her and come back in "15, 20 minutes or half an hour" to obtain her signature. Mrs Banks stated that she would not be able to read it as she had been unable to read her newspaper that morning. Once again she attempted to bring what she perceived to be the **doctor's** attention to a problem that she was having – namely, reading – by noting something that

had already happened, and by offering this as a reason why she could not do as he wished. As Mrs Banks remained firmly within the patient role, similarly Dr Chatterjee adhered to his research remit, and did not investigate Mrs Banks' clinical symptoms, which at this point were irrelevant to him, other than in relation to the extent to which they may impede her ability to read and sign the study documentation. In order to circumvent Mrs Banks' visual difficulties, Dr Chatterjee read some sections to her – the sections that **he** considered important for her to know, such as an excerpt regarding arrangements for compensation.

> **Dr Chatterjee**: […] what if something goes wrong, […] I will read that bit, yeah [**Mrs Banks**: Aye]
>
> **Dr Chatterjee:** It says 'medical research is covered by mishaps in the same way as patients undergoing treatment in the National Health Service er, that is compensation is only available if negligence occurs. Regardless of this if you wish to complain you have, and if you are concerned in any aspect er, er, aspects of the way you have been approached and treated in the course of the study, the normal Health Service complaints mechanisms should be available to you.'

For comparison, the extract below represents the actual text in the Patient Information Sheet:

> "**What if something goes wrong?** Medical research is covered for mishaps in the same way as for patients undergoing treatment in the National Health Service, i.e. compensation is only available if negligence occurs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you" [From COSSACS Study Patient Information Sheet].

It can be seen that when reading the information sheet to Mrs Banks, Dr Chatterjee made few deviations from the text, and did not attempt to simplify the language. Nor did he endeavour, either here or elsewhere during the interaction, to explain any concepts which might have been frightening or upsetting, such as the risks of further stroke or swelling of the brain, either of which may be fatal and were noted in the information sheet. At this point, Mrs Banks suggested that she would read the document, and that Dr Chatterjee should telephone her daughter. In effect, the patient herself subtly indicated that she did not have the capacity, or perhaps simply did not wish to take responsibility, to make this decision alone, and that she would like the input of her family. Alternatively, perhaps this was simply Mrs Banks' strategy to say no – by deferral – without actually having to do so.

Having established that Mrs Banks did not wish to consent to study participation without first discussing the matter with her family, Dr Chatterjee left the information with her for their perusal. He did not take the opportunity to telephone a family member, even when the ward sister offered to do this for him. The eventual outcome was that this patient was not included in the study because her understanding of the study appeared inadequate and her family was not seen within the time window to enable proxy consent. Throughout the interaction, Mrs Banks engagement **as a potential research participant** was minimal, and was always constrained by her active adoption of the more familiar 'patient' identity. She maintained this role, despite Dr Chatterjee's attempts to reposition her as a research participant.

I move now to a similar situation, where the roles of the participants were determined not only by their own actions but by the influence and expectations of the other parties in the interaction.

8.4 Seeking Consent For An Acute Stroke Study (Acute Stroke Unit): The Consent Interaction That Never Was.

I first referred to the interaction between Dr Chatterjee, Research Nurse Webb and Mrs Clarke, in Chapter 5.4, in order to demonstrate the temporospatial dislocation of the research team, and its effect upon the identification and initial assessment of potential study participants. Here, I explore subsequent events involving the same patient, and demonstrating the impact of the research team's liminal status, which ultimately resulted in the exclusion of Mrs Clarke, from the research protocol in question.

Mrs Clarke was admitted to the ASU within 48 hours of the onset of stroke symptoms and was therefore eligible for enrolment in the COSSACs blood pressure management study. The research team was unable to secure consent directly from the patient at their initial approach because of concerns about her capacity at that time, and the absence of any family members to act as consultee (Mental Capacity Act, 2005). The research team therefore contacted Mrs Clarke's son by telephone, and agreed to leave information for perusal by family members as none of the research team would be available to discuss the study with them when they visited that first evening. As I illustrate below, this situation provided further examples of the relationship between time, space and the execution of research duties, when a plan of action was required in order to facilitate recruitment of Mrs Clarke the following day. The scenario also

demonstrates how the roles adopted by, or assigned to, the actors were influenced not only by the current context but by relationships, experiences and expectations.

The morning after the initial approach, Research Nurse Webb visited the ward to establish whether or not Mrs Clarke's family had visited the previous evening, and if so, whether they had commented on her potential study involvement. As anticipated by Dr Chatterjee (see Chapter 5.4), the ward had indeed 'got busy' and Sr Mitchell informed Nurse Webb that she was not sure whether Mrs Clarke's family had visited. There was a sense of deference in Nurse Webb's enquiry which was not evident when requests were made of the ward nursing staff regarding clinical matters. Emphasising the perception of the extra-curricula nature of research, although it was noted that the ward had been very busy, this 'busy-ness' did not include research activity, however peripheral. This reported failure to notice whether Mrs Clarke's family had visited relieved the ward staff of the task of ascertaining whether or not they had reviewed the information left by the research team. It also meant that they would not have to address any questions that the family might have raised, and which they did not feel confident or adequately equipped to deal with. This reluctance to communicate with family members was not evident in other, clinical, situations. On occasions when an aspect of **care** required communication with, and approval from, patients' next of kin, proactive steps were taken to ensure that contact was established and timely decisions made. For example, when it was deemed necessary, on one occasion to employ physical restraints to ensure a patient's safety, a meeting was promptly set up with the patient's consultant, senior nursing staff and the patient's family, in order to determine the best course of action in the best interests of the patient. Research requirements, in contrast, were not similarly prioritised, and relied on a more *ad hoc* approach. Engagement in any type of research activity was perceived, by the clinical staff, to be an optional extra for them as well as for patients and their families. At the micro level it was apparent that clinical activity almost always took precedence over research activity, whether at an individual patient or ward level.

Returning to the example of Mrs Clarke, in the absence of any information from the patient's family, no attempt was made to telephone them again. Instead, Research Nurse Webb asked Sr Mitchell to telephone her in the SRO if and when the family visited. However, by doing so Nurse Webb was more or less forced to confine herself to the office to wait for a call as at this point the research team did not have dect (mobile) phones. This meant that she was unable to visit other wards, sites or clinics to trawl for

patients. Nurse Higgs, who was out of the office assisting Dr Chatterjee with some technical issues, was unenthusiastic about this plan. He stated that the ward staff would not remember to ring, and so Nurse Webb should visit the ward regularly to check whether any relatives arrived. Nurse Higgs' lack of confidence in the ward staff's cooperation placed an additional burden on Nurse Webb, and resulted in an inefficient use of time which was unlikely to have been evident had the research team been based in the clinical area.

Ultimately, the ward staff did not ring the research team when the patient's family arrived and **I** noticed that they were present when I visited the ward for an unrelated reason. At approximately 11:55am I advised Nurse Webb, who went to speak to them. At this point, Mrs Clarke had six visitors, including a daughter, who told Nurse Webb that her brother (who Dr Chatterjee had telephoned) had visited the previous evening and had read the information sheet and signed the consent form. Nurse Webb did not check the documentation at this point but offered the visitors further time to read the information themselves and advised them that she would ask Dr Chatterjee to come and speak to them about the study. At this time, Dr Chatterjee and Nurse Higgs were working in another office, on site, but away from the main hospital concourse and had to be radiopaged to return to ASU. At 12:55hrs, with only five minutes of visiting time and 95 minutes of the recruitment time window remaining, Dr Chatterjee and Nurse Webb went to speak to the patient and her family. By this time only one visitor, a young girl (Clare), remained. Mrs Clarke was in bed with the sheets pushed back, and was fiddling with her compression stockings. Even before Dr Chatterjee began to introduce himself, as a non-uniformed male on a hospital ward, Clare identified him as a doctor and began to make a request pertaining to her grandmother's care:

> 'Can I just tell you, my grandma is finding these stockings very uncomfortable and is keep trying to take them off. Does she have to have them on?' Dr Chatterjee explains the importance of the stockings and says that although they might feel a little strange at first her gran will get used to them. He says it's better to put up with the discomfort for a while than risk the consequences. [FIELDNOTE: April 2007]

Having been asked this question as a doctor, Dr Chatterjee responded as a doctor, referring albeit vaguely, to the potential clinical consequences of not wearing the stockings. Nevertheless, in order to ensure closure of this line of discussion and to avoid further clinical topics, Dr Chatterjee immediately reverted to researcher role, and introduced us both as researchers. He then asked Clare about her relationship to Mrs

Clarke, even though she had already indicated that the patient was her grandmother. When he then asked whether she was Mrs Clarke's next of kin and whether she could make decisions on her grandmothers behalf, Clare took this as a prompt and, without hesitation and without being asked, stated that her grandmother would not be participating in the study:

> … the study information sheet is still on the bed table and on the post-it on which Dr Chatterjee had written "Study information for Mr C" someone has written "NOT PARTICIPATING IN STUDY". Clare nods towards the papers and says if he's referring to 'that study' (nods head and eyes towards study info on bed table) no, she won't be participating in it and [Clare's] written that on there. She spoke to her uncle last night and they decided no, they think she's too poorly […] they don't want anything else to be done to her. Dr Chatterjee explains that that's fine and that the study is entirely voluntary and he had explained this on the phone to her uncle. Clare says no, if she wasn't so poorly it would be ok but she doesn't think she's well enough. Dr Chatterjee asks if she'd like to discuss it further or have anything else explained but she does not. She says she's read the information and while she doesn't see any problem with the study itself she just doesn't think her gran is well enough. [FIELDNOTE: April 2007]

Nevertheless, despite her immediate and emphatic response, Clare seemed uncomfortable in making an unqualified refusal to allow her grandmother to participate in the proposed study. She therefore justified her decision on the grounds that she and her family thought that her grandmother was too poorly to have something else, by implication something unnecessary, done to her. Justification of refusals is commonplace in everyday life, and usually hinges on a claim for or against ability (Heritage, 1984). For example, we might state that we cannot accept an invitation because we have a prior engagement, rather than merely stating that we will not accept. In this case, ironically, the very factor that rendered the patient eligible to participate in the study, i.e. her medical status, simultaneously – in the eyes of her family – rendered her 'unable' to do so; they considered her to be too ill to participate. Framing the refusal in this way rendered it 'blame free' in two respects. Firstly, it avoided implying that there was anything untoward about the request to participate, or about the study itself, and secondly it would not reflect unfavourably upon Clare or her family because it was presented as a joint decision, influenced by factors beyond their control.

It has been described how research participants position themselves upon a continuum from patient only, to participant only, with a range of hybrid positions in between (Heaven *et al.*, 2006). In this brief exchange, Mrs Clarke exhibited a passive

lack of engagement, and took no active part in the research oriented interaction, thus accepting the patient, or sick role, by default. She was however, actively cast in this role by her granddaughter who clearly considered that her grandmother was too sick to be anything other than a patient. Equally important, was her status as grandmother, an identity encompassing all of the emotionality that resides within such a relationship, and thus eliciting, in this context, a protective response. It is noteworthy that whilst paternalistic behaviour from physicians was not sanctioned in the research arena, family members' paternalism generally went unchallenged.

For Clare, research and care were clearly quite separate, a dichotomy emphasised by the absence of the research team at the time at which Mrs Clarke's family were perusing the information documents and may have had questions to ask. When the research team did make contact with Mrs Clarke's family, although it was not clear whether or not they had read and/or understood the information, they had already reached a decision about Mrs Clarke's potential participation. They had determined that Mrs Clarke was "too poorly" and that research participation would incur unnecessary risk and burden to her, and therefore should not go ahead. Much concern has been noted about what has been termed the therapeutic misconception (Lidz and Appelbaum, 2002; Appelbaum and Lidz, 2006; Miller and Joffe, 2006), which arises when study participants are unable to distinguish between clinical research and ordinary treatment, thus bestowing unrealistic expectations upon the research element of their management. More recently, a counter argument has been posed, and introduces the concept of 'injurious misconception' (Snowdon *et al.*, 2007). Snowdon suggests that a potential participant's successful separation of research and care does not necessarily facilitate informed or enhanced decision making. Rather, she suggests that for some, in making this distinction, the element of novelty often perceived to be associated with research, may be over-inflated, and as such may over-exaggerate the associated element of 'risk and threat'– or in Clare's case, unjustifiable burden. Thus, like the therapeutic misconception, injurious misconception may give rise to 'a decision borne of misunderstanding rather than a legitimate choice' (Snowdon *et al.*, 2007 p.199).

Such is the emphasis on autonomy and voluntariness, that Dr Chatterjee did not feel comfortable to continue to provide a verbal explanation of the study following Clare's potentially 'uninformed' refusal. To do so may have been interpreted as coercion or undue pressure to participate. He was thus, unable to explain that participation in the study would not jeopardise the standard of care that Mrs Clarke

received. Participation simply meant that the decision whether to continue or suspend antihypertensive medication, a decision which would have to be made regardless of study participation, would be made via a formalised randomisation process, rather than according to non-evidence based personal preference of her clinician. Clare's decision exemplified Snowdon's theory regarding the perception of novelty and risk, and also supported the comment made by Dr Black in interview, that he believes that the public perception of research is that it must always involve something new (see also Snowdon *et al.*, 2006; Snowdon *et al.*, 2007) and must therefore always be more risky. In his view, patients and the public do not understand that research may also be undertaken in order to determine the most effective **existing** treatments or treatment regimens.

8.5   Discussion

The scenarios that I have explored within this chapter have demonstrated a number of areas of contrast between research and clinical interactions. Primarily, these differences related to the way in which informed consent was sought and decisions made.

The requirement to obtain informed consent for diagnostic or therapeutic interventions, whether medical or surgical, routine or experimental, is a cornerstone of medical ethics (Declaration of Helsinki, 2000; Beauchamp and Childress, 2001). Failure to observe this requirement may result in litigation. Nevertheless, despite consent being a requirement prior to the initiation of both clinical and research activities, the way in which consent is obtained may be quite different as illustrated in the encounters described. In clinical scenarios, consent may be implied - for example a patient who holds out his/her arm for the application of a blood pressure cuff. However, implied consent is not informed consent and while the former may suffice for treatment, the same cannot be said of research encounters in which consent should be both voluntary **and** informed.

In order to give (or withhold) consent, the patient must have capacity to do so. In cases such as Mr Adams' (Chapter 8.2), for clinical decisions, where capacity may be compromised to some degree and/or where there is a degree of urgency pertaining to the potential efficacy of treatment, the clinician may make a recommendation based on all the available evidence about the treatment and in what he/she considers to be in the patient's best interests. In Mr Adams' case, the time critical nature of the proposed treatment meant that at least a provisional decision regarding its acceptability was

required so that the necessary investigations could be undertaken. Thus, whilst providing information to Mr Adams and endeavouring to include him in discussions, Dr White accepted Mrs Adams' instruction to make a decision on her husband's behalf. Dr White's initial interaction with the Adams' lasted only approximately 10 minutes, but this was long enough for Mr and Mrs Adams to develop a sense of trust in Dr White and to follow his recommendation. Similarly, Mr Briggs (Chapter 8.2) devolved responsibility for medical decision making to Dr White, because he trusted in his medical expertise and professional judgement. Patients and their families have certain expectations about members of the caring professions and based on these expectations, in the absence of any evidence to the contrary, they are generally willing to accept their advice, particularly in an emergency or life threatening situation. The corollary of their placement of trust was that Dr White was able to move to a position of paternalism and to do so relatively swiftly, unlike the research encounters I observed, where paternalism is neither sanctioned (Declaration of Helsinki, 2000) nor overtly demonstrated.

In a clinical scenario, the physician may treat patients who lack capacity without consent using the defence of necessity. In contrast, potential research participants are expected to make informed decisions about research interventions when incapacitated, or have non-medically trained proxies consent on their behalf (EU Directive, 2001). Not only are they expected to consider consent when capacity may be diminished or fluctuating, as in the cases described above, but also, the (potential) participant is being asked to participate in the evaluation of an intervention of unknown efficacy. Participation in research, on this basis, cannot be said to be in the patient's best interests, indeed, it may even harm them (sometimes fatally). Therefore, the final decision regarding study participation lies with the patient, who may also consult others, such as family members. When no decision can be reached, either because of time restrictions, lack of understanding, or non-availability of next of kin, the default position, is exclusion from the study.

In the final scenario described, Mrs Clarke's clinical status precluded her personal involvement in an information giving and consent discussion. The restrictions upon the working hours of the research team meant that they were not available to discuss the study protocol when a number of family members were present, and this limitation ultimately resulted in the non-inclusion of Mrs Clarke. Mrs Clarke's granddaughter's refusal of study participation on her grandmother's behalf demonstrated a further difference between the clinical and research scenario. Clare's refusal was made without

having received a verbal explanation of the study, and based on indeterminate reference to the patient information document. Her presentation of her family's decision was taken as absolute and final, and was accepted without question, even though there appeared to be a lack of understanding about what refusal might mean (or might **not** mean – it did not necessarily mean that Mrs Clarke's treatment regimen would not be altered).

In the clinical scenario, is not uncommon for patients to refuse the treatment that they are offered, or to select an option that their clinician may consider less than optimal. Our interpretation of autonomy requires that in the clinical situation (with the notable exception of abortion) all relevant information should be given, whether this is desired by the patient or not (Foster, 2009). The GMC outlines a course of action if patients expressly refuse information (General Medical Council, 2008). Thus appraised of the alternatives available to them, they may refuse the treatment offered, despite prevailing expert opinion and often considerable evidence of expected clinical benefit. A common example of such 'informed refusal' is seen amongst patients who decline the administration of blood products on religious grounds (Bodnaruk *et al.*, 2004).

In the research scenario however, although it is incumbent upon the researcher to fully and adequately inform the potential participant about the nature of the study and implications of participation in order that they may give their voluntary and informed consent, it is not incumbent upon the patient to read or listen to all of the study information if they do not wish to do so. Nor is it mandatory that the researcher explain the study protocol to the potential participant in order that they may fully understand what they are refusing. Thus, the patient or their proxy, may express an 'unqualified' refusal rather than what has been termed 'meaningful non-consent' (Williams *et al.*, 2007; p.59). In fact, efforts to engage the patient further, when they have already indicated, albeit without a full explanation, that they are not interested in study participation, may be perceived as coercion. This discrepancy exists because in the research situation, by definition, it is not known which option is 'best' and it cannot be argued that the patient is placing him/herself at a disadvantage by refusing to participate. Nevertheless, this highlights another difference between research and care.

As indicated in previous chapters, the role of the clinician-researcher is not easily defined and the effects of the permeable boundaries of such roles are demonstrated in the examples given above. For the most part, the clinician-researchers approached potential study participants as researchers, seeking to determine eligibility and

willingness to participate in research. For example, Dr Chatterjee's questions about Mrs Banks' clinical status were related to her eligibility to participate in a study, not a precursor to a clinical intervention. He approached her as a researcher and remained in this role throughout the interaction, with only one brief and rapidly reversed transgression – to assure her that she would not die. This was his only deviation from the 'research script' and the only time that he responded directly to Mrs Banks' needs as a patient, rather than seeking to fulfil an important requirement of his role, i.e. that of patient recruitment. Similarly, in his interaction with Mrs Clarke's granddaughter, after dealing with Clare's first question he did not engage in any clinical discussion regarding her grandmother.

8.6 Conclusion

The examples discussed in this chapter illustrate that those participating in research participant assessment, information giving, and consent interactions have different expectations of themselves and of each other. The research team adhered to their research roles and scripts in order to ensure that potential study participants understood the distinction between research and care, were not seduced by the therapeutic misconception, and could not be said to have been coerced to participate. However, the researchers' apparent lack of engagement at an individual patient level may have been confusing and isolating for the patient, particularly those unfamiliar with the clinician-researcher role and inexperienced in participating in decision making about their own healthcare. In contrast, a practitioner-patient relationship appeared to develop much more quickly, in the clinical consent interactions observed.

Chapter 9. Discussion

9.1 Introduction

In Chapter 1, I outlined the clinical manifestations of stroke and noted the dearth of interventions to treat this condition in the acute and hyperacute phase. I then reviewed some of the practical and ethical difficulties encountered, or perceived, in the conduct of randomised controlled trials of therapeutic interventions in the early post ictal period. I did not consider non-therapeutic research as this presents different challenges. Much of this work in this area focusses upon theoretical issues pertaining to the fulfilment of ethical and legal requirements for obtaining informed consent when patients are neurologically, functionally or cognitively compromised as a result of their stroke (or other emergency condition). In particular, concerns are raised about the voluntariness of consent (Katz, 2002) which may be compromised by what has been termed the 'therapeutic misconception' (Appelbaum *et al.*, 1982), and leading some to advocate the separation of clinical and research activity. However, there is little empirical work in this area and what there is, often relies upon reported or anticipated behaviour, based upon consideration of hypothetical situations.

While theoretical and hypothetical work provides some suggestions as to the difficulties encountered in undertaking research in the emergency situation, as Brody noted over 20 years ago, 'only empirical investigations can reveal to us the major problems actually faced by healthcare providers and the ways in which they deal (or think they deal) with them' (Brody, 1990; p.162). My aim in this ethnographic study was to explore whether the difficulties noted in the literature are, in fact, the main barriers to the conduct of emergency research in the acute stroke environment, and the extent to which these arise from efforts to maintain or demolish the research/practice dichotomy that is advocated within the bioethical literature.

In this thesis I have presented my observations and interpretations of the conduct of clinical research in an acute clinical environment, in which the aim of participating teams and team members may be considered to be collaboration and cooperation, rather than the total integration of research and clinical activities.

In this final chapter, I will discuss the findings of this study and will demonstrate that research is not the value free entity that some expect, believe or desire it to be. Beyond enrolment criteria and ethical and regulatory requirements, recruitment was also influenced by organisational issues such as the temporospatial dislocation of the

research team. This also influenced the way in which the clinical team perceived and positioned research and the research team, and the ways in which the research nurses performed their research identity. All of these elements impacted upon the work of the clinician-researcher and the day to day conduct of clinical research within this acute stroke environment. I now discuss these findings in relation to the literature, beginning with the need to separate research and care.

9.2 What Are The Advantages And Disadvantages Of Separating Research And Clinical Practice?

As discussed in Chapter 2, a major rationale for the separation of clinical and research activity is that of avoiding the therapeutic or procedural misconception (Appelbaum *et al.*, 1982; Fisher, 2006b). As illustrated in the interactions described in Chapter 8.3, my data confirm that there are indeed occasions where potential study participants, for example Mrs Banks, are unable to distinguish between research and routine clinical activity. However, I did not, during the course of my study, witness interactions where misrecognition of research personnel, or misunderstanding of their activities, led to a therapeutic misconception resulting in unrealistic expectation of benefit. On the contrary, some of the interactions illustrated an overestimated perception of potential risk – Mrs Banks asking if she would die (Chapter 8.3) - or burden, – Mrs Clarke's family's perception that study participation would be too much for her (Chapter 8.4). In contrast to the therapeutic misconception, such negative perceptions have been termed 'injurious misconceptions' (Snowdon *et al.*, 2007), which occur when potential participants or their proxies take an overly cautious stance in relation to research risk and burden. Although evidence of this phenomenon was limited by the small number of research consent interactions I observed, it was also reported by several clinicians in my study.

The purpose of trying to separate of clinical and research activity at the study site, by means of the employment of dedicated research staff, was pragmatically determined – the aim was to ensure the timely and proper completion of study specific activities. This rationale reflects the idea that distinguishing research from non-research activities can protect scientific or professional autonomy, by shielding researchers from political or outside interference (Gieryn, 1983). Research staff pursued the goals of the ongoing studies, e.g. recruitment and physiological assessments such as timed blood sampling, without being side tracked by clinical demands, because the latter tasks were the

responsibility of others – the clinical team. This was evidenced by the fact that the research nurses did not participate in routine care or 'dirty work', such as bed bathing or giving bed pans. The research nurses' supported this division of labour by referring to the time critical nature of many of their activities (as noted in Chapter 7.5). Some of the clinical staff however, suggested that the research nurses' non-participation in clinical activity was not task related but a deliberate choice reflecting their preferences, as noted by Nurse Cooper, (Chapter 6.2). Some staff in this study, from both clinical and research teams (Chapters 6.2, 6.3.1 and 7.7.1), suggested that research nurses and clinical nurses possess different characteristics and attributes, implying that one precluded the other, and formed the basis of the choices noted above (c.f. Hicks, 1996) . It can be seen therefore that whilst this separation of clinical and research roles and responsibilities prevented the research team being overwhelmed by clinical demands, it did little to promote research awareness and had implications for the development of working relationships between clinical and research teams.

In addition to the issues associated with the employment of dedicated personnel, balancing ethical and logistical considerations means that conducting research in emergency situations such as stroke , is particularly difficult (Slyter, 1998). These difficulties may be exacerbated by the ways in which workload is distributed, and by the environment in which research and clinical activities are conducted (Fisher, 2006b). For example, facilities are often shared and activities overlap because it is more cost effective. As noted in Chapter 2, management of acute stroke, although improving, remains less than optimal in the UK (National Audit Office, 2005; National Audit Office, 2010) due to availability and accessibility of facilities, including imaging equipment, and appropriately trained personnel. Total separation of clinical and research activities would require the provision of separate premises, equipment and personnel. This may divert these scarce resources from the clinical arena and may ultimately result in a situation where only those eligible or willing to participate in research would have access to these facilities. A more integrated approach, such as that adopted at the study site, means that services are utilised by researchers and clinicians without the need for duplication of resources. However, there may be occasions where conflict arises between the clinical and research demands for finite resources. This was particularly notable in relation to CT imaging, and the 'slotting in' of non-urgent inpatient cases prior to suspected stroke patients (Chapter 7.8).

It has been suggested that one way to pre-empt and manage such conflicts, may be to employ research staff with clinical experience within the department(s) in which research is being undertaken, so that they will be familiar with, and can work within, the current systems (Kendrick *et al.*, 2007). Although this policy was not purposively adopted at the study site, at least one of the research nurses had held a clinical role in the ASU. However, such familiarity presented its own difficulties as it fostered an expectation of participation on the part of some members of the clinical team, which some of the research nurses were not able to fulfil.

Nevertheless, these issues notwithstanding, conducting research alongside routine practice has advantages. For example, the study site in this research became an early adopter of thrombolysis as a routine treatment for acute stroke, having trained staff and developed expertise in this area as a result of participating in a safety and efficacy study of this intervention (Hacke *et al.*, 2004).

Further, it has also been suggested that research could be facilitated within the NHS by raising the research profile so that patients using the service are aware of its research mission in the same way that those attending a teaching hospital are made aware of the likelihood that they will be involved in some way in professional education (Souhami, 2006). Integration or at least parallel conduct of research and clinical practice may contribute to raising research awareness amongst non-research personnel, patients and the lay public, who may be visiting or accompanying patients. Although Souhami (2006) was referring to research involving access to patient data, such measures could also promote research awareness more broadly.

However, while the physical organisation and availability of resources may affect the relationship between research and care, there are other things that serve to maintain these distinctions, namely the staff perceptions and relationships with/to the different activities.

9.3 Clinical Staff's Engagement With Research Activity

Throughout my study, clinical staff repeatedly claimed that they 'know' their patients and delivered holistic care (cf. May, 1992b; May, 1992a). However, just as research staff are able to disengage from hands-on care, clinical staff are similarly able to justify their own dissociation from research, a phenomenon that can be explained with reference to what have been termed 'discourses of ignorance' (Michael, 1996; Turner and Michael, 1996).

Turner and Michael's work refers to the lay public's ignorance of, and justification of their ignorance of, science and scientific expertise. They refer to three discourses which people draw upon to justify or excuse their ignorance: mental constitution; division of labour; and deliberate choice. All can be applied to my data to illustrate the way in which those not directly involved in clinical research activity were able to justify their disengagement from it.

First, the discourse of 'mental constitution' holds that those who cannot, do not, or will not, engage with science (i.e. clinical research), justify this on the grounds that they lack the mental capacity to do so, either due to lack of appropriate education or an inherent incapacity to engage in and with scientific matters. This perception was clearly illustrated by Sister Stone's claim that some nurses think that research is 'above them' (Chapter 6.2), and was supported by further reports from clinical staff where participants deemed themselves lacking the capacity to grasp scientific or research concepts, downplaying not only their ability to understand research concepts but also the extent and adequacy of their training in this respect (Chapter 6.4).

Second, 'division of labour' discourses, may be used to defend ignorance by claiming that one does not **need** to know about, or engage with, a concept because it is not a fundamental component of their role i.e. 'it's not my job'. This is exemplified in the current study by Sister Hatfield and Nurse Cooper, in Chapter 6.6.

Finally, the discourse of 'deliberate choice', allows the uninterested or disengaged to claim that their lack of knowledge about research concepts and practice is the result of a conscious decision. Moreover, this discourse can be used strategically to diminish the importance of the research endeavour and the position of the researcher, by portraying both as potentially detracting from more important issues, in this case clinical activity. This position, in contrast to the 'mental constitution' discourse, in effect turns the tables on the researcher and suggests, like Nurse Cooper (Chapter 6.6), that research is not only different to, but is also less important than physical and clinical care, and that it is the researcher who is ignorant of these issues.

However, whilst these discourses of ignorance have been drawn upon by my study population, other claims made constantly and consistently throughout the study, regarding poor staffing levels and skill mix, and heavy clinical workload cannot be ignored. Time restrictions and prohibitive workload responsibilities of clinical staff should not be allowed to undermine potential participants' opportunity to contribute to clinical research (Bond Sutton *et al.*, 2003). Similar operational and capacity issues are

also noted in work conducted outside, but equally pertinent to, the UK, where it is stated that crisis management inherent in healthcare means that clinical staff do not have time to consider the advantages of engaging with academia or research, either in terms of developments in nursing practice or improving patient care and outcomes (Redekopp, 1997).

In consideration of these issues, and as acknowledged by my study participants, it is clear that research integrity would be threatened if research specific tasks were delegated solely to the clinical team. Alternative structures – i.e. the deployment of research nurses - are therefore required if research is to be successfully undertaken within the NHS.

9.4 Can The Employment Of Dedicated Research Nurses Within The Clinical Environment Provide An Effective And Workable Means To Close The Gap Between Research And Clinical Practice?

It has been suggested that the gap between research and clinical practice is affected by resources and knowledge, as noted above, and the perceptions and expectations of nurses (Albert and Siedlecki, 2008). Although Albert et al refer to the nurse researcher, rather than the research nurse role (for summary of differences see Gordon, 2008) there are some areas of commonality. For example, in my study, the clinical staff presented and expected a very specific version of the role of the nurse, which was, for the most part, the socially constructed, stereotypical image of the caring professional 'tending the fevered brow'. Simultaneously, and as suggested by other authors, the research nurses were also stereotyped as being detached, objective, analytical, and driven by paperwork and protocols (Chalmers, 1983; Robson, 1993; Hicks, 1996; Roberts et al., 2006).

There has been little empirical examination of the role and experiences of the clinical research nurse (Raja-Jones, 2002; Stephens-Lloyd, 2004; Spilsbury et al., 2008). However, work has been undertaken focussing upon some of the other recently established senior nursing roles such as specialist nurses, advanced nurse practitioner and nurse consultants. Raja-Jones (2002), suggests that there may be some overlap and/or similarities between these roles and that of the clinical research nurse. Therefore, as it has been suggested that specialist nurses can improve patient satisfaction and can provide continuity of care (Hammond et al., 1995), it seems likely that research nurses could demonstrate similar impact. Compared with medical staff who operate a rotational

system, and ward or clinic based nurses who typically see the patient in only one bounded area, it has been noted that dedicated research staff generally have more time to spend with individual patients, and are encouraged to do so (Fisher, 2006a). This allows for discussion of patients' and families' fears and concerns about the research, and for clarification of understanding, by reiterating information given by the physician-investigator or presented in study information documents. They are also able to spend time reviewing this information in the light of the patient's personal circumstances, rather than solely with a view to advancing recruitment targets and meeting sponsor requirements. Also, as discussed in Chapter 7, not only can research nurses spend more time with study participants than would typically be the case in the clinical situation, but they can follow them up as they move between and within clinical areas, and at review appointments. In this respect then, because the research nurses within my study were not ultimately responsible for planning the clinical management of patients and did not (with the exception of assessment for and delivery of certain interventions e.g. thrombolysis) usually deliver clinical care, they were better placed to emphasise the delineation between research and clinical activity, and the voluntary nature of research participation.

Contrary to Hicks'(1996) claim that the care-giving element of nursing has less prominence in the research nurse role, other work has highlighted the contribution that nurses make to trial coordination **because** of their dedication to care work and nursing related knowledge and skill (Mueller, 2001; Mueller and Mamo, 2002) and the fact that utilising the interactive skills of the nurse can benefit, rather than detract from, the research process (Colbourne and Sque, 2004). Although some of these studies report on the role of clinical trial coordinators, this title (and others) is often used interchangeably with that of research nurse (White-Hershey and Nevidjon, 1990; Hill and Schron, 1992), and both are acknowledged to play a vital role in clinical trials (Dennis and Strickland, 1987; McKinney and Vermeulen, 2000). McKinney and Vermeulen noted that since employing research nurses in their Clinical Trials Unit they took on more studies, and increased patient recruitment and retention, whilst others have reported that the involvement of research nurses has also enhanced communication with clinical staff and participants, and has thus improved recruitment and patient compliance (Spilsbury *et al.*, 2008).

Despite these potential advantages associated with the research nurse role, there was evidence (Chapters 6 and 7) that the research nurses in this study were perceived, or

perceived themselves as occupying a liminal position - lying outwith the perceived boundaries of the taken-for-granted nursing role - and were therefore, viewed with apprehension and were more or less socially excluded by others in the ASU (Chapter 6.3.2). We define ourselves in contrast and in relation to 'the other'; therefore if we cannot recognise and define 'the other', this raises questions about our own identity. Those who occupy a liminal status, such as the research nurses in this study, are often perceived as threats to the social order and as a result become further marginalised (Bauman, 1991). Not only were the research nurses in this study perceived as functioning outside the traditional boundaries of nursing, but also they were seen as transgressing those of other disciplines, such as medicine and management. Consequently they were rendered hybrids (Bhabha, 1994), not easily recognised and not easily identified and thus viewed with an air of suspicion. It is possible that the clinical staff's perception of the extended, or otherwise different, role of the research nurse, brought into sharp relief the limitations of their own role, skills, knowledge and attributes, and engendered an uncomfortable sense of ignorance in this regard. Such a realisation may be threatening or destabilising and this, rather than a rejection of, or animosity towards the research role and its incumbents, may account for their reticence to engage with research. Whatever the cause, there is a danger that such perceptions may generate a spiral of exclusion, resulting in the marginalisation of the research nurses, and the entire research endeavour, which in turn may adversely impact upon recruitment and retention of patients to, and in, clinical trials.

The employment of dedicated research nurses may reduce the potential burden of extra work for the clinical staff but may simultaneously minimise the incentive to engage with research and the research team. Thus, although it was noted that integration of research in a clinical context can raise research awareness, there are examples within my study which suggest that integration may have an adverse effect by perpetuating poor research awareness and a sense of lack of involvement in wider decisions (c.f. Spilsbury *et al.*, 2008).

9.4.1 Professionalisation and extension of the nursing role.

As noted above, the research nurses' liminality (Chapter 5) was compounded by their transgression of other professional boundaries, which may be related to the observation that part of the rationale for the uptake of research and research roles by nurses has been the desire to achieve professional status (Mulhall, 2002), which is itself

seen as a desirable and natural occupational goal (Storch and Stinson, 1988) . Attainment of professional status can enhance an occupation's self-esteem and its development of self-regulatory mechanisms and ethical codes, whilst facilitating the abandonment of historically entrenched hierarchies (Meulenbergs *et al.*, 2004) – in this case, for example, the subordination of nursing to the medical profession. However, attempts to professionalise nursing have been criticised for mimicking other professions rather than developing distinct structures, ideologies and codes of practice (Rutty, 1998; Radcliffe, 2000). This has meant that those who choose to engage with what are considered to be the more professional aspects of their role, such as research, may be seen to be aligned to the historically dominant medical profession (Baumann *et al.*, 1998; Bonell, 1999), rather than the neophyte profession emerging from their own discipline.

Moreover, whilst research nurses might often experience a more autonomous role than their clinical colleagues, they do not have the professional freedom of their academic counterparts - nurse researchers - who may either pursue their own academic interests, without medical input, or may collaborate jointly and equally with other disciplines (Gordon, 2008). For the most part, and certainly within my study site, most research nurses are involved in coordinating and managing randomised controlled trials under the (often remote) auspices of a senior medical colleague. Rather than being seen as a positive extension of their role then, this might be viewed as delegation – or cherry picking- on the part of the Principal Investigator so that the research nurses are left with the more technical and potentially less challenging aspects of the role. For example, Research Nurse Higgs (Chapter 7.4) expressed concern that although the research nurses were usually more familiar with study processes and procedures, they must still defer to either the research fellow or a non-research medic (in the absence of the research fellow) in order to obtain informed consent. Although I did not observe the latter practice during my fieldwork, involvement of non-research personnel in recruitment has raised questions about the quality and adequacy of information conveyed to potential study participants (Monico *et al.*, 2008), and also raises questions about the perceived level of confidence and trust in the research nurse role. As described in Chapter 7.4 however, research nurses at the study site frequently guided medical staff, including the research fellow, through study procedures that they were not permitted to complete themselves. This gives mixed messages about the research nurses' status and credibility and it is possible, that rather than enhancing professional

status, this particular manifestation of the research role cements nurses' position as handmaidens and doctors' helpers, thus undermining their skills and knowledge. Further, although remote management of research nurses allows them greater autonomy, lack of contact with nursing peers is likely to contribute to a similar sense of isolation to that reported by nurse researchers (Spilsbury *et al.*, 2008). Thus, research nurses often miss the camaraderie and connections that they enjoyed in the clinical environment (Hill and MacArthur, 2006), as evidenced by the example of the research nurses' exclusion from the Christmas tombola (Chapter 6.3.2).

In addition to their potential isolation, research nurses are frequently treated with disdain by their clinical counterparts and are considered in some way to have turned their backs on the most fundamental principles of their profession (Hill and MacArthur, 2006) (see Chapter 6.3.1, Nurse Cooper's perception of the attractiveness of the research nurse role). It is significant that doctors who undertake research are often lauded, admired and respected, whilst nurses who do so, or who extend their skills across professional boundaries frequently find their clinical skills and motivation brought into question (Rutty, 1998). This may be due to the fact that senior doctors who undertake research usually still undertake some of the same clinical activities as their non-research colleagues. By integrating research with practice in this way, senior research doctors have avoided being seen as a separate group, or as clinically incompetent. Similar models exist for nurses within other units, where they can combine clinical and research roles without the same negative implications I witnessed. For example, diabetes research nursing is considered a specialist role and is usually embedded within that of the diabetes specialist nurse (Chester *et al.*, 2007). However, this career model was not available to senior nurses within my study site, even though the role of 'specialist practitioner', as outlined in the UKCC's Post-registration Education and Professional Practice (PREPP), includes a research element (United Kingdom Central Council for Nursing Midwifery and Health Visiting, 1995).

It has been suggested that clinical research nurses are often perceived as being 'elitist and removed from clinical practice', which may be linked to the fact that many work in academic units removed from the hospital environment, but in in my study it was simply that they were removed from their patient population due to organisational/operational constraints (Raja-Jones, 2002). Raja-Jones' experience also differs from my own, in that she suggests that nurse specialists do not perceive research

to be part of their role, whereas my observations demonstrated a strong affinity between specialist and research staff.

Given this affinity at the study site, it is also possible that there may be other areas of similarity between research and specialist nurse roles. I noted in Chapter 7 that at the study site, even amongst the research nurses themselves there were differing perceptions of their role. Similar findings were noted in a study of the relatively new role of clinical nurse specialist (CNS), and it is suggested that such ambiguity or confusion may lead to frustration when ward staff are perceived to harbour unrealistic expectations and make unreasonable demands of these specialist staff (Redekopp, 1997). I suggest that similar disparities exist between research and clinical staff, and are not necessarily unilateral. Either group may make what are perceived to be unusual or unreasonable demands of the other, either because they do not understand each other's roles, or do not appreciate the impact that requests for assistance/support (in either direction) may have. Examples include the request for research staff to fix a malfunctioning ECG machine (Chapter 6.7), and requests for clinical staff to undertake blood pressure recordings more frequently than would usually be expected for clinical purposes (Chapter 6.6). Redekopp (1997) also states that there may be knock on effects on communication and collaboration which may develop into situations of conflict with other healthcare professionals when the CNS applies specialist knowledge that cuts across professional boundaries, as demonstrated in the interaction between the senior research nurse and senior radiography staff (Chapter 7.8).

But while they may treat their research colleagues with disdain, Mulhall (2002) suggests that generally, nurses perceive the activity of research in a positive light. Similar observations could be made about the current study, which, like Mulhall, revealed that for some, research is perceived as a slightly mysterious and elite activity. Mulhall also observed that researchers are often perceived to be seeking academic rather than practice goals. In contrast, the clinical staff in my study, often seemed to think that individuals take up research roles to **avoid** the unpleasant aspects of clinical work (Chapter 6.3.1), rather than to **achieve** more positive outcomes either in terms of improved healthcare outcomes at a population level or their own personal and professional development.

A criticism of research nurse roles is that although they usually offer the prospect of promotion and enhanced autonomy, this is often unsupported by subsequent career development opportunities (Johnson, 1986). It is argued that research should be

integrated within senior nursing roles as a clinical skill with direct practical relevance (Richardson, 2005b) and steps have been taken to address such issues but were not sufficiently advanced to allow comment in relation to this study (UKCRC Subcommittee for Nurses in Clinical Research (Workforce), 2007)

So far, in this chapter, I have discussed the advantages and disadvantages of integrating research and clinical practice, primarily with regard to the impact upon research itself and upon healthcare professionals involved in these activities. However, the patient-participant is also drawn into the liminal space between experimentation and routine care, and it is this element that I now discuss below.

9.5   Positioning The Patient

As well as the ethical, organisational and professional issues discussed above, a further difficulty associated with the separation of research and clinical practice, relates to the positioning of the patient. Despite the theoretical distinction between research and clinical practice, at a pragmatic level, these activities overlap and become blurred, and are thus conflated by researchers, clinicians and patients alike (Hallowell *et al.*, 2009). Further, as the focus of these activities, the patient cannot be compartmentalised, particularly in an emergency and potentially life threatening situation. Nevertheless, although it is not physically possible to divide an individual into 'the part that is participating in research' and 'the part that is receiving clinical care', in practice such distinctions are made everyday, usually for good reason and to good effect.

As discussed in Chapter 5.6, in different departments and across different disciplines multiple configurations of the patient exist, according to the spaces they occupy and in relation to activities and outcomes. The research team's interactions with patients were conducted in the environments that they shared (albeit as guests) with their clinical counterparts and their activities often relied upon the same props and processes. The similarities were finite however and although they might be expected to orientate towards their patient population in the same way, they did not.

In my study, the clinical nurses judged the research nurses' behaviour in comparison to their own - because this was their closest point of reference – and found them lacking. Similarly patients and families approached by the research fellow seeking consent for study involvement responded to him **as a doctor** (Chapter 8.3 and 8.4), because they were not familiar with the research aspect of his role. Likewise their reaction to 'research' is likely to be based on what, if anything, they already know about

research. As others have similarly noted (Mueller, 1997; Edwards and Chalmers, 2002; Brody and Miller, 2003), the clinician-researcher must negotiate dual roles and their attendant conflicts; it may be less obvious however, that potential study participants are also faced with optional identities.

In the context of a RCT, such as those observed in my study, when approaching a potential study participant the clinician-researcher has a choice of vantage points based on experience; the patient is always known to be a patient, but anticipated to be a research participant. Patients approached to consider research participation do not enter the encounter furnished with the same set of assumptions. Most adults are familiar with at least some of the assumptions about the patient role (Parsons, 1951; Makoul, 1998), (although the traditional, more passive role is gradually being replaced by a more active participatory one), and therefore know what is expected of them as a patient. They are less likely however, to be familiar with research, the role of the clinician-researcher, or their potential role as study participant.

Patients and their proxies have certain expectations about members of the caring professions, as well as a considerable degree of trust concerning medical research (Kass *et al.*, 1996; Sugarman *et al.*, 1998). Based on these factors, and in the absence of any evidence to the contrary, they are generally willing to accept advice (McNeally and Martin, 2000; Bosk, 2002). This is particularly so in what are usually unfamiliar, one-off situations, such as those of an emergency or life threatening nature. In such situations they may struggle with the nature, complexity and volume of information delivered to them when being invited to participate in a clinical trial (Featherstone and Donovan, 1998; Akkad *et al.*, 2006). Thus, whilst policy makers contend that it is important for patients to have the opportunity to make their own healthcare choices, it is also argued that others would perhaps prefer 'to be taken care of, to have experts relieve them of the burden of tragic choices by deciding what is best' (Bosk, 2002 p.V-67).

However, although the question "what would you do?" is a familiar one for doctors and nurses, for the clinician-researcher, it is one that most are reluctant to answer. Even, or perhaps especially, where the patient lacks capacity, the clinician researcher can do no more than present the options and their pros and cons. The professionals involved in my study, whether research or clinically orientated, confirmed that whilst they would, or would expect to be able to, make a recommendation about clinical care, this would not be the case with regard to a decision about research participation. The clinician-researcher's reluctance to make a recommendation may be

perceived by the patient or their family as a lack of engagement and may be both confusing and isolating for the patient, particularly those unfamiliar with the clinician-researcher role and inexperienced in participating in decision making about their own healthcare. For the patient who is used to following the clinician's advice, lack of guidance in such situations, although intended to promote voluntariness and to avoid coercion, may be interpreted as abandonment (Ingelfinger, 1980; Burns and Troug, 1996).

Clearly, an individual cannot make an autonomous choice about participating in a clinical trial if they are not aware of, or do not understand, basic concepts of research methodology and ethical frameworks (Pickersgill, 2011). My research participants broadly echoed Pickersgill's suggestions that work within communities, for example schools and local groups, and within research forums, may usefully promote public understanding of research and associated concepts.

Lack of familiarity with research and the research participant role, procedural and therapeutic misconceptions, and the likelihood of the patient being in a dependent relationship with the clinician-investigator, along with its potential influence on voluntariness, brings us to the final issue that my study set out to address, i.e. whether or not one of the main problems in conducting emergency research was that of obtaining informed consent.

9.6 Obtaining Informed (Or Proxy) Consent For Participation In Randomised Controlled Trials In Acute And Hyperacute Stroke

Whilst I did not see sufficient research consent interactions to draw firm conclusions, it was evident that the issues noted above may undermine efforts to promote and/or maintain patient autonomy during the informed consent process. The impact of procedural or therapeutic misconceptions makes it difficult for the unprepared patient to understand that they are in a different situation and this lack of understanding may impact upon their understanding of, and voluntariness to, consent to study participation. The situation is further complicated when capacity is compromised.

In the clinical situation where an urgent decision is required, but capacity is compromised, the default position, based on the common law doctrine of necessity, is that the clinician will act in the patient's 'best interests', and the requirement for consent is therefore waived (Frazier *et al.*, 1995; Johnston and Liddle, 2007). Nevertheless, consent is often assumed by clinicians, on the grounds that most rational patients would

wish to take the course of action that would save their life and/or avoid any severe or lasting disability (Miller, 1993). For research participation however, it is a requirement that consent is informed, rather than assumed (Declaration of Helsinki, 2000; EU Directive, 2001). Because research participants are being invited to contribute to the evaluation of an intervention of unknown efficacy, involvement can neither be claimed to be in, nor against, their best interests, and therefore, the final decision regarding study participation lies with the patient. The patient may consult others, such as family members to help them in reaching a decision, but when no decision can be reached, either because of time restrictions, lack of understanding or non-availability of next of kin (either to provide support or to act as proxy in the case of the incapacitated patient), the default position (prior to the changes introduced within the Medicines for Human Use (Clinical Trials) Amendment (No. 2) Regulations, 2006) was exclusion. Although these changes came into force during my data collection period, the studies ongoing within the study site had commenced before these changes were introduced and no such changes to the recruitment processes had been made or requested, hence the continued default position of exclusion, as demonstrated in the interactions examined in Chapter 8.3 and 8.4. These contrast sharply with the interactions concerning clinical thrombolysis in Section 8.2, where decision making authority was devolved to, and accepted by, the consultant physician in these examples.

It is argued that the default position of exclusion from research participation in the absence of prospective informed (or proxy) consent, protects vulnerable persons from risks associated with experimental treatment and upholds their autonomy by not including them in a study for which, had they been capable, they may not have given their informed consent (Lazar *et al.*, 1996). However, acceptance of exclusion by default was mixed among my study participants, and it is argued in the literature that a presumption of willingness to participate is no more or less likely to contravene an individual's wishes (Harris, 2005; Rhodes, 2005; Brazier, 2008).

Further, we should not assume that patients or their proxies are always the neutral, rational, decision makers upon which normative ethics grounds the concept of informed consent (Bosk, 2002), or that they make their decisions based only on the information provided to them by the clinician-researcher. It has been suggested that Western thought is stifled by an 'irrational passion for dispassionate rationality' (Williams, 1998; p.747) . There are few situations where this is more obviously apparent than the research consent interaction, and where the tendency to attempt to

hold separate emotion and reason in relation to decision making (Rieff, 1979; Williams, 1998) is pronounced. Conversely, others suggest that we are able to make informed decisions **because** of our emotions rather than in spite of them, and that they are in fact an essential element of rational thought and normal social behaviour (Damasio, 1994). It is a limitation of this thesis that I was not able to demonstrate this more clearly in relation to research consent interactions. However, I believe that I have touched upon this with regard to decision making for clinical thrombolysis, particularly in Mrs Adams' delegation of responsibility to Dr White, based upon her own perception of her husband's beliefs and values and her potential burden of guilt about making the 'wrong' decision (Chapter 8.2). A patient is never **only** a patient; they may be husband/wife, parent, employer, employee and/or any number of other roles, with their attendant life experiences – any or all of which may have a bearing on decisions they make, or those that others make on their behalf (for example Clare's refusal to sanction her grandmother's study participation, Chapter 8.4).

In the previous sections I have discussed my main findings in relation to the advantages and disadvantages of separating or integrating research and clinical activity, including the impact of employing dedicated research personnel. I have considered the different roles available to the patient in the research encounter, and the way in which their understanding of research and the research role may influence decisions regarding study participation. I have demonstrated that issues discussed in the literature are not the only, or necessarily the main, obstacles to research recruitment. I now move to some of the difficulties and limitations in the conduct of this study, before making recommendations for practice and further work.

9.7   Limitations Of The Study

In Chapter 2, I identified a gap in the literature, which consists predominantly of theoretically based work, or empirical studies exploring responses (anticipated or actual) to hypothetical situations. This study, by adopting an ethnographic approach, facilitated the accrual of empirical observational data, regarding the actual day to day conduct of clinical research activity in an acute clinical environment, which are not widely available in the current literature. However there were also problems associated with employing this method in this particular clinical situation.

9.7.1 Unpredictable volume and erratic timing of the presentation of stroke referrals

An ethnographic approach is useful when one wishes to observe all aspects of a situation or regular occurrences/behaviours. However, when the focus of study is less predictable, the cost-benefit trade-off between long hours of observation versus volume and quality of data collected is an important consideration, especially for a single researcher. Predominantly as a result of the emergency nature of the topic of exploration, it was not possible to identify in advance how many patients (and therefore observations of their management) would occur during my periods of observation, or to predict when study eligible patients would be received at the EAS. Thus I could not guarantee to be in 'the right place at the right time' and my periods of observation involved long periods of 'hanging around'. However, maintaining a presence in this way was essential in providing rich contextual data and in ensuring that the clinicians became accustomed to me being there, so that when interactions occurred that I wished to observe more closely, team members were not unduly perturbed or excessively influenced by my presence.

Having become aware of the fact that the unit was receiving fewer stroke referrals than anticipated, I sought and secured the necessary permissions to extend recruitment to a neighbouring hospital and was able to obtain two recordings of research consent interactions from that site. However, because I did not collect observational and contextual data from this second site I decided not to incorporate these data within this thesis. They will however inform other academic work.

9.7.2 Research awareness and participants' unfamiliarity with the research method

Despite my long periods of observation in the ASU, just as clinical research was not a priority for the clinical team, my observational research was not uppermost in the minds of the research team when receiving and assessing potential participants for acute or hyperacute clinical trials. In general, the paucity of consent interactions observed was due to a lack of eligible patients, but on two occasions I missed the opportunity to record consent interactions.

On the first of these occasions I was present in one of the ward bays when the research team assessed a patient in EAS. They later acknowledged that they had not informed me because it was one of the few occasions when I had stayed in the department after 5pm and they had forgotten that I intended to do so. On the other occasion, I was outside the hospital but was able to get there quickly when contacted by

the research nurse. Despite this however, the research fellow forgot about my study and despite the fact that there was plenty of time remaining, had approached the patient for consent before I arrived and therefore it was not possible to record the exchange. Whilst it was frustrating to miss these interactions, these scenarios themselves were useful indicators of the way in which research is perceived, and the way in which the staff engaged with it. The research team's limited engagement with my study, was similar to the way in which clinical staff engaged, or did not, with their own academic or pharmaceutical studies, and reinforced the issue of research awareness, prioritisation, exposure and training requirements.

9.7.3 Scope of the study

The study may be criticised for its single centre focus. However, as a single researcher, and in light of some of the issues noted above pertaining to the unpredictable and erratic nature of the topic under investigation, a multicentre approach was not logistically feasible. It may also be noted that my interactions, particularly the interviews but also the less formal discussions through the fieldwork, focussed primarily upon healthcare professionals rather than patients or their family members. I outlined my rationale in this regard in Chapter 4.4.5, and maintain that greater involvement of patients and their carers would have been more useful and more acceptable had there been a greater number of patients enrolled in or approached for enrolment in the ongoing clinical trials.

9.8   Strengths Of The Study

Despite the difficulties noted above, the observational aspect of this ethnographic study furnished a rich description of ongoing research activity in the ASU, whilst data collected via interviews and less formal discussions, facilitated exploration of participants' perception of their own, and others' roles in relation to research, and the ways in which these roles were fulfilled. I was thus able to compare observed and reported behaviour and rationale, and to explore the reasons why discrepancies may exist. I was also able to explore the extent to which actual practice reflects accounts in the literature. Interviews alone would not have allowed for contextualisation of responses, whilst isolated observations would have relied solely upon my own interpretation of events, rather than co-constructing an understanding in collaboration with study participants.

The ethnographic approach facilitated observation of activity in all of the clinical areas through which the suspected stroke patient was likely to pass, and the opportunity to clarify issues as and when they arose, rather than attempting to anticipate and explore every issue within the context of a single interview. It is unlikely that interviews alone would have highlighted issues beyond the consent interaction which nevertheless have considerable impact upon recruitment and retention of study participants. The study highlighted that such difficulties are not confined solely to process of obtaining informed consent.

Despite the difficulties noted in the previous section, I am confident that this approach provided more comprehensive and robust data than interviews alone. Although limited to one diagnostic area, the study begins to address the absence of empirical work examining the conduct of emergency research within the clinical environment. It provides data that can be used to furnish an understanding of the actual difficulties encountered in the day to day conduct of acute and hyperacute RCTs of stroke treatments in the clinical environment. Its broader focus, extending to include the context in which decisions regarding study participation are made, and not just the decision making process itself, supports a number of recommendations which I outline in the following section. In addition to the provision of empirical data however, the study also adds to the understanding of the practicalities of ethnographic methodology by means of a reflexive approach which allows the reader to apprehend some of the difficulties encountered in conducting ethnographic work in this context.

9.9   Recommendations

The study identified a number of issues that may contribute to the development of research awareness and thus enhance recruitment.

9.9.1 Integration of research within clinical practice

The model of partial integration of clinical and research activity adopted at the study site is a method that ensures research processes and procedures are completed in a timely manner, thus maintaining study integrity and participant safety. However, this study identified a need for closer temporospatial integration of clinical and research staff, from both medical and nursing teams, in order to promote research awareness and a general understanding of each other's roles, responsibilities and restrictions. Dedicated administrative space for the research team within the clinical area would contribute to

the visibility of the team and promote closer working between the two teams. Whilst the cost of providing an 'on-call' research service may be prohibitive, a two shift system with provision of some weekend cover would also raise the profile of the research and the research team within the ASU. The purported ethical benefits of total separation are outweighed by the practical limitations in this particular scenario.

9.9.2 Greater integration of research in professional education and training

Clinical and research staff alike noted deficiencies in their basic/undergraduate training with regard to research concepts and methodologies. Development and inclusion of more applied research modules within educational programmes at undergraduate and/or postgraduate level may demystify research and promote understanding and acceptance of research concepts.

The report of the UK Clinical Research Collaboration Subcommittee for Nurses In Clinical Research (Workforce) made recommendations for the development of clinical academic nursing roles and aimed to address issues of research capacity and capability (UKCRC Subcommittee for Nurses in Clinical Research (Workforce), 2007). My data collection was undertaken prior to the publication of this report and therefore it is not possible to say what effect, if any, this report has had.

Finally, it is a requirement that research personnel undergo training in Good Clinical Practice, with refresher sessions every three years ('The Medicines for Human Use (Clinical Trials) Regulations,'). In terms of patient safety, I suggest that this training should not be restricted solely to research staff, but should also be undertaken by any healthcare professional employed in an environment where clinical trial participants may be cared for.

9.9.3 Raising public awareness

Many of the healthcare professionals participating in this study reported a perception that patients and the public have little knowledge or awareness of healthcare research. Although limited by small numbers, my data suggest that patients are ill prepared for the likelihood of research participation during healthcare encounters and experience difficulty in orienting to a potential participant role. Wider and more easily accessible reporting of research activity may promote understanding and engagement, and could be achieved locally by displaying notification of research activity on hospital noticeboards, within community groups and via presentations to student groups in schools and colleges. Forums such as Café Scientifique would also be appropriate to

disseminate such information and I will consider presenting the findings of this study in this arena.

9.10 Further Work

Study data supported some of the conceptual and theoretical literature but often also provided some contradictory evidence. Having observed fewer research consent interactions than anticipated, it was difficult to support or refute the claims made in the literature and by healthcare participants, regarding the emotional distress, and by implication, impaired decision making capacity, of patients and families approached to consider participation in RCTs in the acute or hyperacute period following the onset of stroke symptoms. Further empirical work is required to explore this issue.

The parallel study, funded by The Stroke Association (noted in Chapter 4), explores patients' and families' views about recruitment to acute and hyperacute stroke studies, and will provide some insight into this question. However, this sister study relies upon accounts of reported behaviour, which may be tainted by hindsight, particularly as the behaviour in question took place at a very emotionally charged time. Joint analysis of the data from both studies is planned and is expected to broaden and strengthen the findings of each.

Further work exploring areas in which research and clinical activity are either wholly integrated or completely separated would provide a more comprehensive picture of the difficulties encountered and alternative management approaches. Logistical issues inherent in the method, may be less pronounced in non-emergency situations, but nevertheless might be better managed by nesting such ethnographic work within the RCT(s) under observation.

9.11 Conclusion

This study has confirmed that recruitment to acute and hyperacute stroke studies is problematic; however, the primary barriers reported and observed within this study were not necessarily those described in the medical and bioethical literature, and reflect more local, policy and organisational issues. This study has also demonstrated, that the differences between the activities we call research and clinical practice may be more apparent than real.

It was observed that absolute separation between research and clinical activities is neither: a) attainable, due to resource issues; b) sustainable, because even though separately 'identified' by research specific personnel, individuals cannot subsequently

be compartmentalised into separate patient/participant roles, nor can research staff withdraw themselves entirely from every aspect of clinical or caring activity as there are inevitable areas of overlap; nor c) desirable, because it potentially alienates professionals within and across disciplinary groups and teams, minimising incentives and opportunities for joint learning and collaboration . Therefore, whilst research and clinical practice may involve different types of activities, and have different aims and objectives, perhaps a more helpful way to look at these concepts is to consider them different, but complementary, aspects of 'treatment' ranging from experimental to routine.

A conundrum exists in that ethical concerns recommend the separation of clinical practice and clinical research so that potential participants can make autonomous choices about research participation, without coercion, and without unrealistic expectation of benefit (Appelbaum *et al.*, 1982; Brody and Miller, 2003; Fisher, 2006b), pragmatic considerations, such as staffing requirements, preclude this total separation however. In order to ensure participants' safety and study integrity, it is essential that potential participants (and non-research healthcare professionals) have at least a basic understanding of research methodologies, processes and practice. In addition, if research and clinical teams cannot demonstrate confidence and trust in each other's capabilities, patients may also struggle to do so; clinical staff's lack of understanding of the research nurse role and the studies which they administer, will fail to engender trust and confidence among patients who may be invited to participate in such studies thus threatening recruitment rates.

Placement of research nurses within the clinical environment may promote transparency and greater understanding of their role and may simultaneously demystify research and its associated concepts; ultimately this may promote closer working relationships and contribute to the enhancement of recruitment, retention and management of research participants. It is both a functional and an ethical requirement that both research input and output should be shared (Mulhall, 1997). Research findings will only be applied and embedded if they are fully understood. An effective way for all parties to achieve this is to promote wider exposure to research in both educational and experiential settings, and to ensure understanding at the earliest stages, not just at the implementation phase. We respond to people and situations on the basis of what we already know and expect (Blumer, 1969b; Rock, 2001) therefore, it can be argued that patients, the public, and healthcare practitioners will not become familiar with research

activities until they become normalised within our everyday lives, and more specifically, our healthcare.

Chapter 10. Appendices

10.1 APPENDIX A.

Sunderland Local Research Ethics Committee
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30 May 2006

Dr Madeleine Murtagh
Lecturer in Social Science and Public Health
University of Newcastle upon Tyne
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NE2 4HH

Dear Dr Murthagh,

Full title of study: **Processes and practices in the enrolment of patients to RCTs of acute and hyperacute stroke treatment: decision making by patients, relatives/carers and healthcare professionals.**
REC reference no: **06/Q0904/19**

Thank you for your letter date 15th May 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by myself as Vice-Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard operating Procedures for Research Ethics Committees in the UK.

06/Q0904/19	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

[**electronic signature deleted**]

Reverend Caroline Worsfold
Vice-Chair

10.2 APPENDIX B.

Semi-Structured Interview Guide

(Healthcare Professionals)

- *Interviewee consent–*
- Review participant information: purpose of the study and aim of the interview
- Consent form
- Check acceptability of audio recording the interview
- Clarify any questions or concerns

- *Purpose of the study*: to examine how medical and nursing staff approach patients or relatives for consent/assent to take part in acute and hyperacute RCTs of treatments for stroke.

1. Could you please tell me a little about your background and how you came to be working at the Acute Stroke Unit?

2. You are involved in the care of patients enrolled in acute and hyperacute RCTs of treatments for stroke. Think about a recent patient*. How was a decision made about study eligibility? Can you describe the consent process (including 'pre-approach')?

Explore:

- * Last interaction, typical interaction, atypical interaction
- Level of involvement
- Involvement of other healthcare professionals
- Issues discussed before and during consent interaction
- Assessment of capacity
- How did the patient/relative respond to the invitation?
- What worked well? Examples that worked better/worse? Why was this so?
- Different approaches
- Factors that facilitate or hinder participation in research
- Key challenges to engaging patients/relatives in research in the acute or hyperacute situation
- Differences/similarities to engagement in clinical situations, or less acute research studies

3. What do you understand by the term informed consent? Are you aware of any alternatives to prospective informed consent? Can you describe them?

Explore:

- Understanding of the legal requirements regarding consent for research purposes.
- Assessment of patients'/relatives' decision making capacity in the acute/hyperacute.
- Own feelings re. consent/assent process for research purposes in the acute or hyperacute situation.

4. Is there anything else you would like to tell us about the consent process, or about acute or hyperacute research in stroke?

Thank you for taking part in this interview. Are there any questions you would like to ask, for example, about the study?

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