An exploration of the process of informed consent for Electroconvulsive therapy (ECT): the nurses' and doctors' role.

A dissertation submitted for the degree of MSc (by Research) at The Robert Gordon University

By

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Declaration

I hereby declare that I conducted all the work represented in this thesis, entitled *An exploration of the process of informed consent for Electroconvulsive therapy (ECT): the nurses' and doctors' role* and composed its presentation. No part of this has been accepted in any previous application for a degree. All quotation marks and their sources are acknowledged.

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Abstract

An exploration of the process of informed consent for Electroconvulsive therapy (ECT): the nurses' and doctors' role.

Experience suggests that there is variability in the knowledge of medical and nursing staff with regard to informed consent. This includes the type of information given to patients to enable them to make an informed decision in the consent process, as suggested by Rose et al (2005).

The purpose of this study is to explore the nature, indication and processes of informed consent in patients receiving ECT.

The study used quantitative and qualitative methods including a questionnaire survey of ECT nurses in Scotland. The sample consisted of ECT consultants and ECT nurses at 24 ECT sites in Scotland and a user representative who also has knowledge of ECT. This ascertained their interpretation of their role in the consent process. The survey findings helped to inform the design of the modified Delphi study phase (Jones and Hunter 1995) of the project. This established the knowledge base required for patients to be considered "fully informed" to consent to ECT.

Questionnaire data were analysed using SPSS (version 15.0 for Windows) and the knowledge base was synthesized utilizing a modified version of the Delphi consensus process.

The benefit of the study is that a tool has been developed which can be administered by staff to confirm that the knowledge required for informed consent has been obtained in patients consenting to ECT. Practice can also be developed through increased awareness of informed consent so that each ECT treatment is administered in the context of fully informed consent.

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CHAPTER 1

Introduction

Electroconvulsive therapy (ECT) is a treatment that is frequently used in Scotland for particular acute mental health disorders (CRAG, 1997) and an estimated 1000 people receive the treatment each year (Scottish ECT Accreditation Network, 2000). Despite this, consumer-led research such as Rose et al (2005) has identified significant concerns about the quality of informed consent stating that practice in this area has not improved over the past twenty years. Rose et al (2005, p.58) concluded that "current legal frameworks fail to ensure that a majority of recipients of ECT, voluntary or involuntary, feel that information and consent procedures are adequate".

1.1 The problem

Chada and Repanos (2004) research also concluded that consent is insufficiently comprehended by the majority of healthcare practitioners although it is exercised in most patient contacts. CRAG (1997) cites the Scottish Association of Mental Health who disputed the type of information being distributed to patients and the patients' capability of providing informed consent. The author also had concerns about the quality of the consent process based on practical experience gained within her role of ECT nurse. Her experience suggests that there is variability in the knowledge of medical and nursing staff with regard to informed consent in

relation to ECT and the type of information being given to patients to enable them to make an informed decision in the consent process. It was this experience that led the author to be interested in the area and to want to ask questions about the related quality of professional practice.

It was noted that there has been little written in the medical or nursing literature reviewed about the ECT Nurses' role in the consent process. The Clinical Resource and Audit Group (CRAG) Working Group on Mental Illness (1997) states only that the ECT Nurse should ensure that the consent form has been signed by the patient. However, Aveyard (2002 a) states that it is essential that nurses comprehend the moral and lawful reasoning behind the requisite to obtain informed consent so that the precept of informed consent is administered suitably and uniformly before the nursing process is carried out. The NMC code of professional conduct (2008) affirms that when the nurse is securing the patient's legitimate consent, he/she should ensure that it is presented by a person who has lawful capacity, is given willingly and the person has been given information. Therefore the ECT Nurse may have a more important role in the consent process than which is currently recognized in practice or in the literature.

1.2 Structure of the thesis

The thesis is divided into seven chapters. Chapter 1 contains an introduction to the research aim. Chapter 2 contains the background to the practice of informed consent in ECT. Chapter 3 contains the literature

review which discusses the concept of informed consent, and healthcare and informed consent, and examines nurses and informed consent and ECT and informed consent. Chapter 4 explains the research design including the methods chosen for data collection and analysis of the data. Chapter 5 presents the findings of the questionnaire and Delphi process data. Chapter 6 contains a discussion of the findings and the strengths and limitations of the study. Chapter 7 offers conclusions and then recommendations are made.

CHAPTER 2

Background to the practice of informed consent in ECT

Scholefield et al (1997), in discussing the process for legal, valid informed consent, refer to the principles outlined by Kennedy and Grubb (1994) as essential requirements for this to be completed. The patient has to have "capacity in law" and be "properly informed", and consent has to be "given voluntarily".

The experience of the author over a number of years has resulted in her questioning whether these principles are actually realized in the informed consent process for ECT. Examples from the author's own practice are as follows.

A voluntary elderly patient had signed a consent form according to the ward based team of doctors and nurses. When attending for treatment the patient who was on foot was pushed forcibly into the treatment room by the staff nurse escorting her when it was clear she did not wish to enter the room of her own accord. This patient did not appear to be giving consent to ECT voluntarily. Nursing and medical staff may have been anxious for the patient to receive treatment urgently due to the severity of her illness.

While the outcome of the patient receiving ECT would have most probably alleviated her symptoms of depression, the course of action that the staff

had taken part in did not allow the patient to retain her autonomy as described by Kashka et al (1995). In this instance the essential requirements for informed consent of decisional capacity and voluntarism were not achieved.

This raises a number of questions:

Do professionals possess the required knowledge of informed consent?

Are they aware of the ethical and legal consequences of their interventions with patients having ECT? Gass (1998) and Byrne et al (2006) both concluded from their research that mental health nurses' knowledge of ECT did require to be improved.

The second incident highlights issues of quality improvement in the informed consent process for a patient who was detained under Section 26 of the Mental Health (Scotland) Act 1984 and had signed a Form 9 - a consent form which indicated that she was giving her permission to have ECT. When the author carried out her duties to prepare the patient for the treatment by providing verbal and written information on ECT and its side effects, the patient became very concerned about the fact that memory loss could occur and stated that she was not aware of this. When information about the patient's concerns regarding memory loss was relayed to one of the doctors in the patient's referring team, the response was that the patient had a degree of cognitive impairment so had probably forgotten the explanation.

The matter of concern here is whether the patient's consent would have been considered legal if she signed the consent form whilst being unable to remember the information. Earlier work by Freeman et al (1980) found that only 15% of the patients they interviewed could state that they had a thorough knowledge of what the information consisted of. The patient also had the right to withdraw her consent as she had signed the form 9 voluntarily.

It was noted by the author that there had been little written in the medical or nursing literature reviewed about the ECT nurse's role in the consent process. The Clinical Resource and Audit Group (CRAG) Working Group on Mental Illness (1997) states only that the nurse should ensure the consent form had been signed by the patient. Cullen (2005) recommends that the ECT nurse should arrange for the patient and their relatives, if feasible, to have access to information. Cullen (2005) also advises that the nurse ensures that the compulsory documentation such as consent forms and The Mental Health (Scotland) (Care and Treatment) Act 2003 forms, as appropriate, accompany the patient to their treatment. The ECT nurse should have a much more important role in the consent process than that which is recognized in practice or in the literature. This role consists of assisting in the assessment of the patient's decisional capacity to provide informed consent and that the patient is giving informed consent on a voluntary basis, ensuring that the patient understands the nature, purpose and side effects of the treatment and has been given sufficient verbal and written information in order to make an informed decision.

In doing this, if the ECT nurse is to ensure that sufficient information is given, what knowledge base should a patient have to be considered "fully informed" to provide informed consent to ECT? In addition, what could the author do to improve the quality of informed consent within practice so that nursing and medical staff also have an increased awareness of informed consent? This would ensure that each treatment is administered in the context of fully informed consent so that the patient's autonomy is protected and promoted. In order to answer these questions the research aims to explore the nature, indication and processes of informed consent in patients receiving ECT.

CHAPTER 3

Literature Review

In this chapter the elements that make up the concept of informed consent in conjunction with the significance and development of informed consent will be considered. The concept of informed consent will be discussed along with the examination of nurses' knowledge of informed consent and the recent events and developments in healthcare and informed consent. The latest changes in the Mental Health (Care and Treatment) (Scotland) Act 2003 which have affected practice surrounding informed consent and ECT will also be reflected upon.

3.1 Search strategy

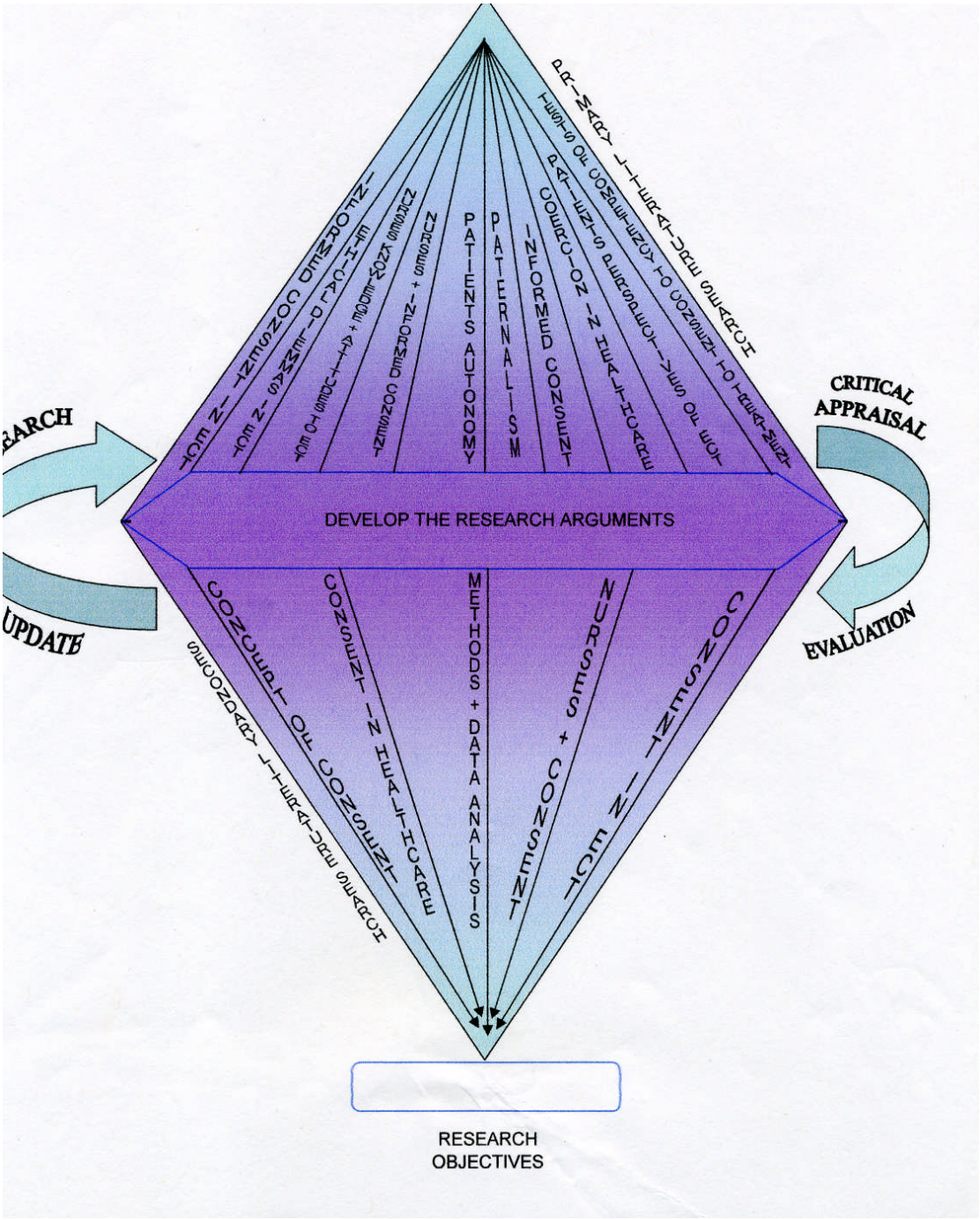
A primary search of the literature was carried out using the keywords "informed consent" "ECT" and "nursing" alone and in combination. The databases which were used included Medline and Cinahl. This provided material relevant to this research in the form of background knowledge and also on previous research surrounding informed consent. The articles which were selected and evaluated also supplied an argument for the study, put the study into the context of what is understood about the subject of informed consent and considered the ideas and the hypothetical basis for this study as described by Parahoo (1997)

3.2 Development of the literature review

The diagram in figure 1 titled 'Development of the literature review' illustrates the stages of the literature review including the primary literature search when the literature was evaluated and critically appraised in order to develop the research arguments. The secondary literature search is also described.

Figure 1

Development of the literature review



3.3 Concept of informed consent

This section of the chapter will examine the concept of informed consent by reviewing its development and nature in conjunction with pertinent philosophical and ethical issues particularly those in relation to healthcare.

3.3.1 *Informed consent*

The Chambers super-mini dictionary (1997, p. 326) defines the word "inform" as to "give knowledge to" and "consent" as "agree (to)" (p.130). Beauchamp and Childress's (1994, p.145) interpretation of informed consent is to identify the two components of which it comprises which are the 'information' element and the 'consent' element. They state that the information component refers to the communication and the understanding of that information. The consent element refers to a judgement that is made on a voluntary basis and the person's compliance with having the prescribed treatment. Freedman (1975) discusses how, in general, medical systems of principles and precepts and doctors concede that the doctor should gain the unimpeded and informed consent of the person prior to endeavouring any treatment whether it is for research or is curative in its essence. Pape (1997) interprets informed consent as the doctor's legal obligation to reveal information to the patient, making it possible for the patient to assess the process prior to providing his/her consent. Sims (2008) describes informed consent as a method of safeguarding the freedom of patients, which encompasses their entitlement to refuse all or any part of their therapy.

3.3.2 *Development of informed consent*

One of the most important philosophical principles in support of informed consent according to Bloch et al (1999) is that of respecting the individual's autonomy. They assert that this is a precept which is constantly acknowledged in mental health ethics. Booth (2002) states that the principle of informed consent consequently values the patient's entitlement to independent self-government. Beauchamp and Childress (1989) idea of autonomy is that of the person being able to determine what happens to him or her without the influence and interventions of others and individual restrictions such as insufficient knowledge which restricts significant decision making. Freedman (1975) asserts that obtaining informed consent is not just a judicial necessity, or something that should just be done, but a solid requisite of ethics.

Dyer and Bloch (1987) describe how there can be occasions when there is difficulty for the psychiatrist in clinical practice between valuing the patient's autonomy and the requirement for some measure of paternalism although Worthington (2002, p.378) considers that enduring paternalism is not an element of acceptable practice, and can't be condoned by being shrouded as a beneficent purpose (or "doctor knows best"). Beauchamp and Childress (2001) state that people who are usually not able to make decisions independently can, on occasion, make independent choices. They give the example of a psychiatric patient who has difficulty self caring and has been certified as lacking in competence can make choices for him or herself such as saying what he or she would like to eat or

rejecting medication. Ottosson and Fink (2004, p.26) also cite Beauchamp and Childress's (2001) concept of "weak paternalism". When patients display a weakened capacity, doctors are invited to act as concerned parents with regard to their offspring. However, Ottosson and Fink (2004) continue to state that this accountability should not last any longer than necessary and paternalism that overrules informed and conscious judgements is not ethical. Dyer and Bloch (1987) consider that The Mental Health Act (1983), which was relevant in England and Wales, is essential to protect the patient's concerns but is not adequate to guarantee the superior moral benchmarks that a psychiatrist should aim for when protecting a patient's concerns. Dyer and Bloch (1987, p.15) suggest that these moral benchmarks consist of three conflicting ideals: "autonomy (freedom), beneficence (paternalism), and fiduciary (partnership)". They describe the conflict that could arise between beneficence, which involves supplying some assistance to the patient, and autonomy when the opinions of the psychiatrist and patient are not the same. Beauchamp and Childress (2001) cite Pellegrino and Thomasma (1993) who argue that the principle pursuits of the patients are closely connected with their choices from which are gained our basic responsibilities toward them. Dyer and Bloch (1987) suggest that the fiduciary precept provides an answer to the dissension between the theories of self-determination and paternalistic beneficence with respect of informed consent. This is because the doctor reaches a decision with the patient which is a procedure determined by the promotion of the patient's faith in the doctor. Dyer and Bloch (1987) continue that this precept is best viewed as a kind of alliance between the doctor and the patient.

The concept of autonomy as it is related to medical ethics dates back to the Hippocratic Oath which presents the ideal of valuing the individual with regard to the serious assurance not to harm the person with whom there is a professional association (Bunch 2000). Meisel (1996), however, states that patient autonomy was left quiescent in the patient-doctor association until more recent times. Beauchamp and Childress (2001) describe how conventionally, doctors were able to depend virtually on their own conclusions about their patients' requirements for therapy, information, and advice. Nevertheless, medicine has in modern times increasingly defied declarations of patients' entitlements to execute autonomous assessments about their treatment. As emphasis of patients' rights of autonomy developed, the question of paternalism has emerged extensively. Corrigan (2003) states that the concept of informed consent is not only difficult inside its own conditions of allusion, but theories of self-determination, liberty and decision-making prove to be false within the dictatorial and paternalistic bounds by which they are restricted and moderated. In Corrigan's (2003) opinion the patient's self-determination is limited by the authoritative dominant practices of doctors. Corrigan (2003) reports that due to the patient frequently being reliant on the doctor, informed consent cannot consistently be achieved entirely. Furthermore, due to the patient's illness and unexpressed reliance on the clinician and medicine, satisfactory comprehension of the information and precise deliberation of the possible advantages and dangers are challenging to accomplish in effect.

Atwell (2006) describes a landmark case in legal history which contributed to the establishment of the doctrine of autonomy in healthcare decisions universally. This was in 1914 when Judge Cardozo in *Schloendorff v. Society of New York Hospital* determined that "every human being of adult years and sound mind has a right to determine what shall be done with his own body…." (Atwell 2006, p.594) This regard for the person's autonomy should also encompass, for those capable of making decisions, a choice to refuse medical treatment even when the effect of that refusal is detrimental to the person or even resulting in the individual's death (GMC, 1998). Mishra et al (2006) describe the judge's statement as a milestone for informed consent in surgical specialties. They state that the essential values have stayed the same and have been reiterated in British formal guidance such as The Medical Defence Union (1992), the General Medical Council (GMC, 1998) and the Department of Health (2001).

Among the gravest breaches of personal autonomy and human rights were the barbaric medical experiments that were carried out in World War Two in Germany. One outcome of the post-war Nuremberg Trials was the Nuremberg Code, which Shuster (1998) states served to combine the Hippocratic Oath and the preservation of human rights into an individual code. Despite this, research continued to be carried out on people without their consent until the National Institutes of Health and then the Federal Drug Administration in the United States of America (USA) issued guidelines which forbade research that was not treatment based, unless the person gave his/her consent (Bunch, 2000). Bunch (2000) continues to state that by 1974, Congress had set up the National Commission for

the Protection of Human Subjects of Biomedical and Behavioral Research in the USA which published the Belmont Report (1979). This clarified that informed consent should consist of three components - information, comprehension and voluntarism which were also to become significant guidelines in clinical care. Corrigan (2003) describes the progress which was selected to govern ethical actions in research by the creation of Local Research Ethics Committees in the early 1970's in the UK and in 1996 the inauguration of the Multi Research Ethics Committees whose major commission is to appraise proposals to perform research within medical settings and ensure that informed consent is gained from patients participating in biomedical research.

3.3.3 *Nature of informed consent*

The components which make up the nature of informed consent - information, comprehension/capacity and voluntarism - will now be discussed.

3.3.4 *Information*

Worthington (2002, p. 378) discusses the importance of the "information exchange" which is pivotal in the decision-making procedure. In order to ensure that consent is legitimate it should be grounded in the patient's understanding of the information, particularly the dangers and advantages of the treatment. This can be achieved by conveyance of information in an outline so that the patient can understand the important points related to

his/her care; without an acceptable degree of understanding the practice of informed consent forfeits its just meaning (Worthington, 2002). Sims (2008) contends that the information that a client receives should be given in a way they can understand in order that the client's autonomy is valued.

Booth (2002) raises the issue of how a practitioner can ascertain when the patient has received adequate information in order to reach an informed decision about their care. The GMC (1998) states that the quantity of information that should be distributed to each patient will change in relation to aspects such as type of illness they are suffering, what is involved in the therapy, the hazards connected with the therapy or process, and the patient's own objectives. Strong (1979, p.196) recommends that patients are given the "reasonable person standard" which would incorporate giving the patient information which is relevant to their decision to give informed consent and this information would be what a rational person in the patient's situation would deem to be worthwhile. Atwell (2006, p.596) describes how some courts in the USA implement a "reasonable physician or professional standard" which requires that the doctor produces similar information that a different credible doctor would supply in a comparable situation.

Strong (1979) also states that people are entitled to select their life objectives independently and rationally and that the main way to hinder someone is to hold back information which is required in order to make a rational choice. Culver et al (1980) describe how on most occasions if a

patient is considered to be competent their requests are considered even when the requests appear irrational to the doctor or others. Meisel (1996) states that if a patient does not wish to accept information then this decision should also be considered in order to respect the patient's autonomy.

What type of information should a patient be provided with in order to have the required knowledge base to give valid informed consent? The Medical and Dental Defence Union of Scotland (2004) reports that there is presently no doctrine of informed consent in UK law, however this does not indicate that the patient should receive anything except for full information on individual therapies, the dangers entailed and the expected result. Meisel et al (1977) state that the general standard is that the patient should be informed of the benefits, risks, side effects and the options that are accessible. Worthington (2002, p.377) asserts that English case law suggests that medical staff should provide their patients with a standard of information that is in line with the "Bolam test". This is when a patient simply has to be informed of what a credible committee of professionals' point of view would judge to be applicable (in terms of information concerning the apparent dangers of receiving a treatment). (Worthington, 2002). Meisel (1996) considers that there is a danger of providing too much information and leading to the dismay of the patient, and that the doctor could be accountable for this.

3.3.5 *Comprehension and capacity*

Patients may not always be in a position to give informed consent due to their illness. So how is their comprehension and capacity to make this decision determined? Roth et al (1977) state that to be deemed capable a person must have the ability to comprehend the essence of the specific item under consideration and to recognize its characteristics and its outcomes. Berger (2003, p.745) describes "disclosure" as the production of appropriate information by the doctor and its understanding by the client. Pape (1997) states that the different components concerned with the patient's comprehension of a process consist of their standard of hearing, reading and writing, lucidity, perceptiveness and communication. Pape (1997) continues that if a patient has been unable to understand the information provided then they can't attain actual self determination in demonstrating their conclusions about the proposed treatment.

Bunch (2000) describes various studies where patients appeared to lack initial understanding of what their surgery would consist of, such as Kekuchi et al (1996) who detailed how a doctor and nurse had described the operation two or three months prior to it taking place. At the time of surgery patients could only respond to 50% of the questions concerning the process therefore Kekuchi et al (1996) emphasized the requirement for improved patient instruction.

Bollschweiler et al's (2008) study examined if conventional means of gaining informed consent could be developed by using a multimedia-based

information programme (MM-IP) which is described as the use of film or animation to illustrate the procedure. Their methods included 76 patients who were going through a laparascopic cholecystectomy operation and had the customary informed consent procedure while one sub-group of 35 patients were also allocated access to a MM-IP. Questionnaires were employed prior to surgery to assess patients' perceived comprehension of essential details of their condition and to determine the outcome of the MM-IP for enhancing the informed consent procedure. The results revealed that 82% of all participants were pleased with the customary informed consent procedure but the perceived comprehension of the information was positively progressed in the MM-IP group. However, Bollschweiler et al (2008) did indicate that the outcome was a subjective assessment as the study evaluated only the patients' perception of their comprehension rather than their definite understanding of the information.

Dyer and Bloch (1987) assert that in psychiatry a patient's autonomy could be restricted due to his/her mental state which might prevent him/her from applying independent reasoning in the informed consent process or might impede the consideration necessary to understand the nature of the recommended therapy. Lavelle-Jones et al (1993) conducted a study which examined factors affecting the quality of informed consent by conducting interviews with 265 patients who were having various surgical procedures. The primary outcome criteria were the patient's recollections of information at different points in the research; this score was matched by age, production of information, cognitive function,

intelligence quotient (IQ), mood state and personality traits, and health locus of control. All patients were provided with identical verbal information during their hospital admission but half were also supplied with operation information cards. Lavelle-Jones et al (1993) concluded that older patients and patients with lower IQs, and an external locus of control, had a lower recollection of the information. They recommended that written information could be increasingly beneficial if it were provided prior to hospital admission and that the information should be systematically phrased in order to increase understanding and recollection.

Roth et al (1977) state that to be deemed to have capacity the person must be able to appreciate the qualities that make up the specific item under discussion and to comprehend its characteristics and its outcomes. The Scottish Executive (2005a) reports that part of having capacity means that the person should be competent enough to comprehend, have faith in and retain information about the treatment that is being recommended.

In Scotland informed consent that is considered legal must be provided by a person who is considered to be capable of giving consent as detailed by The Mental Welfare Commission (MWC) for Scotland (2003). The MWC (2003) for Scotland also states that capacity is determined legally while the assessment of a patient's competence is generally a medical decision. The MWC for Scotland (2003) describes the criteria that a patient must have to be considered to have capacity. The patient should be able to:

- Comprehend the procedure, the qualities that characterise it and the expected outcomes
- Appreciate the main advantages, the dangers and other possibilities and be able to consider the options
- Comprehend the repercussions of refusing the recommended treatment, remember the information for enough time in order to utilize it and evaluate for the purpose of reaching a conclusion
- Have the ability to convey that conclusion.

Booth (2002) states that if a patient is deficient in one or more of the elements required to show they are competent, he or she would be incapable of imparting informed consent. Patients may also have fluctuating capacity due to the nature of their illness, therefore it is important to review their judgement at regular times in order to ensure their perceptions are unchanging and can be depended upon (GMC, 1998).

3.3.6 *Voluntarism*

The Chambers mini dictionary (1997, p.754) definition of voluntary is "done or acting by choice, not under compulsion." In order to have informed consent that is valid the patient is also required to have given his or her consent voluntarily. Ottosson and Fink (2004) state that personal autonomy has a foundation in voluntary decision making and freedom from coerced measures. The GMC (1998) affirms that the practitioner should present an impartial opinion of the possibilities in

order to ensure that the patient has arrived at a voluntary conclusion about their treatment. The MWC for Scotland (2003) states that consent should be given independently, in the absence of pressure or compulsion. The Scottish Executive (2005) reports that practitioners have a responsibility to guarantee that patients have arrived at their own conclusions and appreciate that they can amend their decision as to whether they want to proceed with the process.

3.3.7 Ethical issues surrounding informed consent

The ethical issues that may lead to conflict in relation to informed consent are beneficence and non-maleficence/paternalism and respect for persons/respect for autonomy. These ethical concepts were introduced in the previous sections.

Berglund (2004) states that these precepts have received approval because they afford a rapid method for considering ethical matters. These principles are used as instruments to gather and recapitulate questions communicated by professionals, patients and society as being of relevance. Beauchamp and Childress (2001) report respect for autonomy as an average level of valuing the decision making capabilities of self-governing individuals. They continue to assert that to recognize a self-determining representative is, at the least, to accept that individual's entitlement to retain their own convictions, to make decisions and to carry out endeavours grounded on individual principles and attitudes. Ottosson

and Fink (2004) state that respect for autonomy and the individuals' principles are predominant subjects of codes of ethics.

Beauchamp and Childress (2001) describe beneficent action as combining all types of endeavor designed to assist other people while Berglund (2004) states that beneficence includes the requirement to be benevolent; to take care of people. Ottosson and Fink (2004, p.24) define the principle of non-maleficence as the Hippocratic axiom *primum non nocere* (above all, do no harm) which combines the principles of beneficence and non maleficence "I will use the treatment to help the sick according to my ability and judgement, but I will never use it to injure or wrong them."

Beauchamp and Childress (2001, p.178) outline paternalism as "the intentional overriding of one person's known preferences or actions by another person, where the person who overrides justifies the action by the goal of benefiting or avoiding harm to the person whose preferences or actions are overridden. Ottosson and Fink (2004) state that it is not essential to dismiss paternalism completely because it is occasionally mixed up with authoritarianism. Incapable patients have an entitlement to the most efficient therapy, be it ECT or another treatment.

One of the ethical considerations of seeking a patient's informed consent in this study is whether a severely depressed patient could be considered to have the decisional capacity to give informed consent to ECT. This is questioned by Culver et al (1980) who concluded that most severely depressed patients do provide informed consent to having ECT. Ottosson

and Fink (2004) also state that the autonomous judgements are disrupted in mental health illnesses therefore how far is it conceivable to uphold autonomy when giving treatment to the patient with mental health problems. Medical and nursing staff have separate moral and lawful obligations to protect the informed consent of the patient as described by Barnes et al (2005) but what is their actual knowledge and understanding of the principles of informed consent? What knowledge base should patients possess to give fully informed consent? These issues will be considered in more depth in this research.

3.4 Healthcare and informed consent

The literature reviewed on healthcare and informed consent that appeared pertinent to this study included the change in the way that patients are involved with decisions regarding their own care, as suggested by the GMC (1998). In addition, it will be described how recent events in healthcare within the United Kingdom such as the reports of the Bristol Infirmary (Coulter, 2002) Alder Hey (House of Commons, 2001) Shipman (Richards, 2006) and Allitt (O'Neill, 2000) has led to developments in Government policy surrounding informed consent and relevant policy documents and the further promotion of equality in the doctor/nurse - patient relationship. The concepts of culture, health and illness which have relevance to informed consent will also be considered.

3.4.1 *Patient - centred informed consent procedures*

The rise in importance of patient-centred informed consent procedures in healthcare was a significant theme to emerge in the literature. Worthington (2002) states that the degree to which the government and medical profession presume accountability for formulating the doctrine of consent was not evident and reported that for countless years there had only been small changes made to the English rulings on consent. Worthington (2002) continues to submit that because, according to the law there is no agreed arrangement for informed consent, the law does not provide a distinct direction with regard to determining the boundaries of liability and accountability for informed consent. Despite this, the GMC (1998) prompted doctors to discover the requirements of individual patients when determining what information to make known about treatments. The NHS Executive (2001) recognised the requirement for a transformation in the manner that patients are requested to give their consent to treatment so that the procedure developed in order that it is concentrated on the prerogative of the particular patient and their family. The BMA (2007) announced that the Human Rights Act (1998) had affected how medical staff practise. This was in terms of the significance of a reliable and complete account of the decision-making procedure due to the fact that the Human Rights Act (1998) had been employed to dispute some medical judgements. Consequently the importance of involving patients in this process had gained much more significance. The BMA (2007, p.1) describes how Human Rights are appropriate to some

general medical judgements and demonstrates how a "rights-based approach" could be included in practitioners' decision-making procedure.

In nursing, the NMC (2004) states that the nurse must acknowledge and give consideration to the part patients have as associates in their own care. Fry and Johnstone (2002, p. 208) describe The International Council of Nurses (ICN) Code of Ethics which affirms that the nurse should support a setting in which "the human rights, values, customs and spiritual beliefs of the individual, family and community are respected".

3.4.2 *Recent events in healthcare*

Recent events which also contributed to reforming the rights of patients and patient-centred care have been described by Coulter (2002) who details the recommendations following the report of the Bristol Royal Infirmary (BRI) public inquiry into the breakdown of the professional conduct of the surgeons who were associated with cardiac surgery. The recommendations included that communication with patients should improve and that all actions should proceed securing the informed consent of the patient or his/her parent. Coulter (2002, p.648) also states that the government's target was to update the healthcare system to ensure there was an increased responsiveness to patients who should be considered as "equals with different expertise". Coulter (2002) continues to explain that while doctors are knowledgeable about the clinical aspects of healthcare it is only patients who know about their own understanding of their medical condition and social background, routines, attitudes, principles and

wishes. Coulter (2002) suggests that the doctor and patient should be willing to co-operate with information and make shared conclusions, outlining a coherent foundation of information. Fyle and McGlynn (2002) also specified that developments in the NHS following the report of the BRI inquiry should include taking into account the service user's point of view.

The House of Commons (2001) described the inquiry into another significant event in healthcare which was the removal, retention and disposal of human tissues and organs following coroners' and hospital post mortem examinations. This was following the discovery that pathologists at Alder Hey hospital had collected 3,500 organs without the informed consent of children's parents. Among the inquiry's conclusions were that informed consent can only be obtained if persons receive full information in order to formulate their decision, that they should not be coerced into this and that practitioners should improve upon their communication skills in the informed consent process. Corrigan (2003) also reports the requirement to establish patients' informed consent so that they are comprehensively informed prior to receiving treatment or participating in research which had developed as a moral remedy to neutralise the possible risk of paternalistic and authoritarian practices.

O'Neill (2000) describes how Beverly Allitt, a nurse on a paediatric ward, managed to murder and harm the children in her care and stated that serial killers like Shipman and Allitt spoil the trust that occurs between practitioners and their patients. Richards (2006) cites Dame Janet Smith,

the chairwoman of the inquiry into Dr. Harold Shipman, a GP who had murdered more than two hundred patients in his care, and stated that cases such as Shipman, the Alder Hey Hospital and the Bristol Royal Infirmary had shown patients what could go astray in the health service. Richards (2006) also cites Dame Janet Smith as describing that the Shipman inquiry had uncovered medical inadequacies and that patients' confidence in their doctors should be on an informed basis.

In an editorial, Smith (1998) submits that since the events at Bristol there had been a change in the rapport between doctor and patient. This is characterised by the change from the patient being the submissive receiver of care to sharing a vital collaboration in all healthcare conclusions and becoming evenly matched in the doctor-patient rapport. Recent events such as the Alder Hey affair serve to bring the individual rights and the informed consent of the patient into sharp focus within healthcare in Britain (Messer, 2004)

Despite the focus on these events some healthcare staff continued to show a lack of understanding of the elements of informed consent (Chada et al, 2004). Chada et al (2004) compared health care professionals' understanding of informed consent against agreed standards found in consent guidelines and UK case law. The study involved giving 12 "true or false" questions which tested the knowledge of the consent process, to a sample of 118 health care staff in one healthcare trust. These healthcare staff consisted of 50 doctors, 61 nurses and 7 medical technical officers. Chada et al (2004, p.4/9) summarised that most health care staff did not

have a good knowledge of the informed consent policy. Considerable areas of inadequacy were recognised in the function of the consent form, understanding of Gillick case law and patients with mental health problems. Gillick case law states that if a child has satisfactory insight and discernment to assist him/her to comprehend the treatment and the significance of treatment then he/she is "Gillick competent" and is able to consent to or refuse treatment. Chada et al (2004) reported that the level of success was mainly more effective amongst doctors, those in surgical specialities and junior medical staff. For example the doctors were the only sub-group to gain statistically important superior ratings in total (53.7%) when compared with non-doctors (47.8%) Chada et al (2004) stated that developments in education and practice should be made specifically for staff particularly involved in the consent process.

The BMA (2001, p.1/4) described one of the conclusions of the report of the consent working party "current awareness of the relevant ethical and legal principles relating to consent among the medical profession is largely inadequate". The working party saw its role as reiterating the ethical and legal ideals and discovering methods of making certain that the present principles on obtaining the patient's informed consent were applied in practice. Importantly they did not see the informed consent process as being exclusively the role of the medical officer but as the responsibility of all the multidisciplinary team who are also accountable for making sure that the patient's queries and anxieties surrounding the treatment are satisfactorily taken care of. The BMA (2001, p.1/4) outlined that the working party believed that "health authorities, trusts, employing

authorities, medical schools and individual doctors all have an interest and responsibility in ensuring that the ethical and legal principles relating to consent are adhered to in practice." These points, raised by the BMA (2001), relate strongly to this research which explores the roles and responsibilities of nurses and medical staff in the informed consent process surrounding ECT.

3.4.3 Recent policy documents

Policy documents such as the Millan principles as described by Rae and Boland (2008), the Ten Essential Shared Capabilities (NES, 2007), *Delivering Care Enabling Health* (Scottish Executive, 2006a) and *Delivering for Mental health* (Scottish Executive, 2006b) and the *National Programme for improving Mental Health and wellbeing* (Scottish Government, 2007) also had an impact on patients rights within healthcare and the informed consent process.

Rae and Boland (2008) describe how the Mental Health (Care and Treatment) (Scotland) Act 2003 is supported by the Millan principles of reciprocity, respect for equality and diversity in a non-discriminatory manner. Rae and Boland (2008, p.2) also state how the 10 Essential Shared Capabilities for Mental health (NES, 2007) "promotes working in partnership, challenging inequalities (social inequality and exclusion), promoting recovery, providing service user centred care and making a difference". The Lanarkshire Mental Health (2009) include principles such as informal care, respect for carers, the least restrictive alternative,

benefit of the intervention and child welfare as values that mental health practitioners should be aware of.

The Scottish Executive (2006a) report that practice improvement is the conveyance through which education can be converted into practice to enhance patient outcomes. The Scottish Executive (2006a) also describes a caring base for nursing and midwifery practice which encompasses providing the means for the patient to be autonomous. The Scottish Executive (2006b) describes the *Delivering for Mental Health* delivery plan which includes details of how benchmarks for an integrated care pathway (ICP) for depression were augmented and additional work would be carried out with GPs surrounding the requirement to assess all new patients who may have depression or anxiety by utilising an accepted assessment instrument and then making provisions for a treatment programme which is adapted to their requirements. The Scottish Government's (2007) National Programme for improving Mental Health and Wellbeing study surveyed the connections between non-suicidal self-harm and attempted suicide in young individuals, and in doing so, to recognize the potential method of diminishing the possibility of suicide among young individuals who self-harm. The research comprised of one-to-one interviews with 20 young individuals aged 14-25 from across Scotland who had been involved in both self-harm and attempted suicide. The findings of the research had significance for organizations, policy and public health. Scotland's Mental Health Delivery Plan has made a guarantee to educate 50% of key frontline healthcare experts in administering suicide evaluation tools/suicide prevention plans by 2010.

The research also indicated the importance of developing services that were beneficial to the young person's needs and staff refraining from having attitudes towards the person that were destructive and judgemental which is similar to the findings of this research.

3.4.4 *Promotion of equality in the doctor/nurse-patient relationship*

The balance of the rapport between the practitioner and the patient is an important part of the informed consent process. Habiba (2000) stated that evidence dating back to Hippocrates indicates that treatments were perhaps not considered with patients, particularly if weighing up the pros and cons was believed to be averse to the patient's benefit. Official groups condoned this, arguing that this could possibly safeguard the patient or the doctor-patient relationship. Habiba et al's (2004, p.426) study on the quality of consent consisted of semi-structured interviews which were conducted with 25 women who had consented to surgery. The analysis of the data was based on the constant comparative method and one of the conclusions of the research was that individuals who gave consent often saw it as "ritualistic, bureaucratic, and embedded within a legal rather than an ethical framework". Habiba et al (2004) gave an example of this as how some women in their research wanted to have surgery but perceived signing the consent form as superfluous because it neglected to empower those with doubts or anxieties to speak of their fears. Some of these fears presented in a situation such as when the protection of the woman or baby seemed to be in danger. The consent procedure which

ought to have gained their comprehension and compliance seemed to have been unsuccessful. Habiba et al (2004) state that one of the key messages of this research was that prevailing discussions on informed consent had placed it at the centre of the practitioner-client association and they highlighted the significance of divulging information to the client. Health practitioners should be extremely responsive to the manner in which individuals can experience being made powerless while receiving treatment, specifically in emergency circumstances, and should persuade the individuals to raise their fears and queries rather than saying nothing, and their name on the consent form should be confirmation of their clear approval of the medical outcome.

Usher and Arthur (1998) state that one of the advantages of "process consent" is that the continual method of involving the patient in the consent process would result in reciprocal value and esteem developing between the patient and nurse. The NMC (2004) states, in general, that the nurse should identify and value the contribution a patient has as an associate in his/her own treatment. Forming a therapeutic rapport with the patient and engaging good communication skills is crucial for the nurse's role in the informed consent process (Finch, 2005). However, Doyal (2004) states in a commentary that there could be an improvement in this area with doctors and patients receiving medical and surgical procedures because patients often felt that their time with medical staff prior to signing the consent form had been hurried and meaningless. There had not been enough time to build an understanding rapport between the doctor and patient nor impart the smallest sum of relevant

information. However, Meisel (1996) affirms that the informed consent form actually supplies very little defence for practitioners against her/his legal responsibility for gaining the patient's informed consent. Atwell (2006) points out that the health professional may be more interested in getting an endorsement on the consent form than ensuring that the patient makes sense of the information surrounding their treatment.

3.4.5 Culture, health and illness and informed consent.

NES (2007) state that the values base for mental health nursing should include respect for the varying values of the individual and that this should be the focus of practise. Also, the person should be perceived as an authority in his/her experience and relatives' and carers' input should be respected. Different cultures have contrasting values and principles as illustrated by Bhugra and Bhui (1997) therefore gaining informed consent has different challenges. Bhugra and Bhui (1997) explain how the practitioner must make a sincere aim to appreciate particular patients' and their relatives' ideals of the origin of their health problem and how to deal with it. There are increased difficulties when patients with cultural differences are prescribed ECT as the treatment is regarded with apprehension and shame. Therefore any contact with the patient should be sympathetic and must involve their families in a complete and honest consultation so that they can make an informed choice with regard to the treatment (Bhugra and Bhui, 1997). Bhugra and Bhui (1997) describe how the clinical management of patients across cultures questions the doctor's conventional trialled and evaluated methods. They conclude that the

clinical management of patients from alternative civilised groups relies on the particular practitioner's ability, knowledge and preparation. Bhugra and Bhui (1997) also state that exchanges require to be perfected in agreement to cultural groups in addition to treatment requirements. The practitioner should include the family and society's customs when proposing any therapy so that they can arrange for treatment which is culturally responsive and applicable.

3.5 Nurses and informed consent

In this section of the literature review the nurse's knowledge of informed consent will be examined. The nurse's attitude towards informed consent in ECT and role in the informed consent process will also be discussed.

3.5.1 *Knowledge of informed consent*

What is the state of nurses' current knowledge of the elements of informed consent and their role in the process? Sweeney (1991) states that for numerous nurses the informed consent procedure is filled with bewilderment such as how much information the nurse should provide. Calder (1994) describes how almost all healthcare staff have at some point come across circumstances in which they doubt their own participation and accountability in securing informed consent for therapy. Kashka and Keyser (1995) also question whether the nurse is aware of the moral elements of informed consent. Aveyard (2002b) states that consideration of the implementation of the components of informed

consent prior to using the nursing process has been given insufficient consideration in nursing ethics publications, which suggests that this is an area which could be developed.

Aveyard (2002b) conducted research that included using focus groups and critical incident technique to appraise how nurses obtained informed consent prior to performing nursing techniques. Aveyard (2002b, p.205) concluded that there was a deficiency of understanding in the midst of nurses as to the composition of "implied consent" with the outcome being that informed consent before nursing care procedures being carried out is frequently not attended to. Aveyard (2002b) described implied consent as the patient turning up his/her sleeve to receive an injection rather than by providing verbal or documented confirmation of consent. Aveyard (2002b) recommended that nurses should always make information available and ask for oral confirmation of informed consent before carrying out a nursing procedure.

Cable (2003) reports that the nurse should be familiar with the ethical values on which informed consent is grounded and the law and their vocational accountability for their performance. The NMC (2004) states clearly that the nurse should ensure that informed consent is given prior to any treatment and care being administered. In addition NHS Scotland (2007) affirms that nurses should ensure their knowledge is current and that practice is appraised consistently so that patient care is increasingly effectual.

Calder (1994) states that it should not be the concern regarding legal proceedings that reminds nurses to contribute to the consent process but their duty to their vocation and application of ethics that should guarantee that they include themselves in the informed consent procedure in order to guarantee the highest standards of concern for the patient in their care. Cable (2003) asserts that nurses should be acquainted with the doctrine of informed consent within a healthcare setting in which there has been an increased awareness of law suits and the practitioner's professional accountability for their actions.

3.5.2 *The nurse's knowledge and attitude towards informed consent in ECT*

It could be argued that the nurse should have positive values towards ECT if they are expected to provide information and support to assist the patient in the informed consent process. Byrne et al (2006) describe their concerns that it is crucial that nurses are able to give unbiased, factual information to the patient and that the recommendation of ECT could be influenced by nurses giving patients misleading information about the treatment due to the fact that they have more contact with patients than medical staff. Parsons (2000) also states that nurses have a responsibility to look after patients, to be present throughout their course of ECT and to provide reassurance to the patient and their family.

Research that has been completed on healthcare staff's knowledge and attitudes illuminates that their knowledge does require improvement. A

study by Gass (1998) incorporated evaluating the knowledge and attitudes of mental health nurses to ECT by distributing questionnaires comprising a knowledge and attitude scale which was designed by Janicak et al (1985). The study concluded that mental health nurses' knowledge of ECT did require development at both pre and post registration level.

Byrne et al (2006) also conducted some research on the knowledge and attitudes of various health care professionals and students towards ECT by administering a questionnaire to 593 medical and nursing students, psychiatrists, anaesthetists, theatre and psychiatric nurses. In addition, Byrne et al (2006, p.2/10) challenged the findings of Gass (1998) stating that nursing students had better knowledge than trained nurses and were 5 and 4 times more accurate with their answers to the two questions that they had set on consent which were "ECT is usually given to patients against their will" and "the majority of patients who have ECT will refuse to have the treatment again."

Byrne et al (2006) also found that medical students had better knowledge and a more positive attitude than nursing students and that the most convincing anticipation of improved understanding and increased certainty about ECT was from medical practitioners. Byrne at al (2006) considered that low awareness of ECT in mental health nurses has significance in gaining informed consent from patients. This was due to the requirement for the mental health nurses to be able to give balanced reliable correct information about ECT to the patient. Byrne et al (2006, p.7/10) however, did indicate that the limitations of their study did include

that participants were an "opportunity sample" who were present at psychiatry lectures and anaesthetic seminars so could perhaps not be considered as demonstrative of all nursing and medical groups. Also half of nursing students were recruited by the researcher who was just going to give a talk on ECT therefore the students had possibly given an ideal response.

The requirement to revise the preparation that nursing students receive to equip them for caring for patients having courses of ECT was illustrated by Byrne et al (2006) who asserted that there should be a complete appraisal of the nursing curriculum with respect to ECT due to the demonstration of the deficiency that present training has on nursing students. Gass (1998) also concluded that the training for nurses at both pre and post registration phases should be progressed. In addition to this, Fitzsimons and Mayer (1995) cited Jacobsma (1991) who stated that the time spent teaching nurses at the Northwestern Memorial Hospital; Institute of Psychiatry only amounted to 15 minutes per course. Fitzsimons and Mayer (1995) thought this was indicative of the discernible prejudice in relation to ECT at that time. Culas et al's (2003) study on the knowledge of ECT among staff of a Mental Health Service in a general hospital setting in England consisted of a semi structured questionnaire that incorporated questions about ECT which were applied to all staff in a mental health unit. Their findings concluded that only 36.9% of staff knew of the guidelines with consideration of informed consent and ECT. They also recommended that all staff received regular instruction on ECT. However, the validity and the reliability of the questionnaire were not reported in

the article therefore it is uncertain if the method measured what was intended and whether the method was constant in measuring similar phenomena (Parahoo, 1997).

3.5.3 *The nurse's role in the informed consent process*

What is the nurse's role in the informed consent process? The NMC (2008) asserts that the nurse should gain informed consent from the patient prior to giving any nursing care. In order to do this the NMC (2008) state the patient should be provided with information; their autonomy should be valued; for consent to be valid the nurse must ensure that it is provided by someone who is legally competent and consent is presented voluntarily and that the nurse should be knowledgeable of the mental health act. Fry and Johnstone (2002) describe The International Council of Nurses (ICN) Code of Ethics for Nurses which affirms that the nurse should guarantee that the patient receives enough information to establish informed consent for their treatment. Aveyard (2002b) also states that the nurse should move toward all situations involving nursing care of a patient with the objective of providing information to the standard necessary for the person to arrive at an informed decision.

Sims (2008) asserts that critical care nurses should be familiar with his/her organisation's guidelines relating to informed consent in addition to the legislation that influences informed consent for procedures such as surgery. In addition to this Gass (2006, p.4) states that in their rapport

with patients receiving ECT the roles that nurses cultivate include those of "information-giver, persuader and supporter" which incorporates supplying patients with information about the ECT procedure and acknowledging the patient's queries and fears about the treatment. Gass (2006) confirms the importance of the nurse providing information particularly when patients are apprehensive about receiving the treatment when supplementary facts and reassurance could affect the patient's judgement to receive the treatment. Finch (2005, p.3) states that the nurse should ensure that the patient comprehends the "nature, purpose and implications of the treatment, including the option to withdraw consent at any time". Gass (2006) also describes the ECT nurse's role of confirming that the patient is giving informed consent in order that the treatment can go ahead, while Finch (2005) reports that before treatment commences the nurse should again ensure that the patient comprehends the information that they were given prior to completing the informed consent form. Finch (2005) suggests that this should also be done at repeated times during the course if the patient has reduced cognitive ability which affects their ability to understand and remember additional knowledge. Kashka et al (1995) also describes informed consent as an active technique which does not cease with the endorsement of the consent form.

Finch (2005) affirms the importance of the nurse commencing instruction on ECT with patients and his/her family/carer when feasible and that the information supplied should be specific to each individual patient and his/her family/carer. Cullen (2005) suggests that the nurse could

accompany the patient around the ECT suite if suitable and states that the ECT nurse should verify the patient's legal status and that all the appropriate records and certificates are at hand. Cullen (2005) also recommends that any anxieties or questions resulting from the nurse's assessment of the patient should be presented to the appropriate person in the ECT team.

Aveyard (2002a) reports that nurses ought to undertake all aspects of client care with the aim of informing clients to the standard which is essential so that the individual patient has the information that they require in order to arrive at a worthwhile conclusion. Clarke (1995, p.330) states that the nurse should take "an advocacy/mediation approach" in order to communicate their opinion on the prescription of ECT for a particular patient and also to preserve the patient's autonomy. This could clarify the nurse's duty to assist in determining the depth of informed consent the patient is giving and to act to improve the patient's freedom of choice and to preserve and increase the patient's liberty. Calder (1994) also describes the nurse's accountability for conveying the patient's fears so that the correct individual, ideally the doctor, could correct the position by providing the patient with more information so that he/she has a satisfactory comprehension of the procedure. Sweeney (1991) indicates the importance of the nurse documenting the part that they had performed in the informed consent process such as supplying the appropriate information about the treatment.

Usher and Arthur (1998, p.696) state that the nurse should champion the role of "seeker of informed consent" in the nurse-patient relationship. This could be achieved by the nurse being frequently involved with the patient in order to ensure that informed consent is seen as a system of continued agreement which involves the patient in appraising their own care and is advised of their choices and objectives. Scholefield et al (1997) also describe the Queen's Medical Centre, Nottingham and the Nottingham University School of Nursing's educational package which aimed to provide the practitioner with the principles and understanding so that they could secure informed consent for all forms of treatment. This package was developed as a reaction to the development of the nurse's role in order to develop their abilities and competence in order to accept responsibility for tasks formerly managed by other practitioners. This would incorporate the reorganization of health care requirements so that nurses presented care which was increasingly holistic and patient focused which was outlined in The Scope of Professional Practice (UKCC, 1992a) as described by Scholefield et al (1997)

Good communication skills are necessary in obtaining informed consent (Cable, 2003). Calder (1994) also describes that nurses are familiar with building collaborative associations with patients when pursuing informed consent. This is due to the fact that nurses are often more evident and available than doctors so the patient may perceive that he/she are increasingly relaxed about going to their nurse if they have any queries about the process necessary for informed consent. Finch (2005) also outlines the importance of the nurse who is in contact with the patient

during the informed consent process being one who has demonstrated a dependable and beneficial rapport with them as they would be best equipped to evaluate if the patient grasps the description of the treatment.

While there is a wealth of literature outlining the relationship and communication skills required when explaining treatment little literature could be found about the nurse's role in assisting in gaining the informed consent of patients receiving ECT. Clarke (1995, p.330) as previously described states that the nurse should take an "advocacy/mediation approach" when establishing the standard of informed consent provided by the patient. Halsall et al (1995) only document that the ECT nurse should alert medical staff if patients withdraw his or her consent, whereas the CRAG Working Group on Mental Illness (1997) merely state that the ECT nurse should ensure that the consent form has been signed by the patient. Fitzsimmons (1995) also has a section on informed consent in ECT although she does not appear to clearly define the nurse's role. If the nurse's role has expanded to incorporate carrying out techniques which require the patient to provide oral or documented informed consent as previously described by Scholefield et al (1997) then perhaps the ECT nurse's role in the informed consent process has also developed more than is recognized in practice or in the literature.

3.6 ECT and informed consent

In this section of the literature review, ECT will be defined in conjunction with the advantages and disadvantages of its use. Informed consent in ECT will be considered by discussing the latest developments in the Mental Health (Care and Treatment) (Scotland) Act 2003 which have affected practice surrounding informed consent in ECT. The issue of cognitive impairment and the consequences for informed consent will be considered. Finally, the question about whether valid, informed consent can be obtained under such circumstances will be examined along with the type of information and knowledge that should be anticipated.

3.6.1 Definition of ECT

CRAG (1997) describes ECT as comprising of the passage of a little quantity of electricity from side to side of the head in the time that the patient is under an anaesthetic. The object of the electricity is to produce seizure activity in the brain. This seizure activity is crucial for the curative efficiency of ECT. The outer manifestations of the principal seizure are noticeably decreased or eliminated by the use of a muscle relaxant administered with the anaesthetic (CRAG, 1997). NICE (2003) details how ECT is usually administered as a course of treatments which can be given twice a week for 3 to 6 weeks.

The Mental Health Foundation (2004) describes how ECT is generally administered to patients with severe depression which has not responded

to alternative kinds of therapies. Ottosson and Fink (2004) state that ECT is identified as being specifically useful in treating depression, mania, psychosis, and suicide risk of schizophrenia and manic depressive illness while the Consensus group affiliated to the Special Committee (2005) report that ECT may be advisable if a patient who is suffering from catatonia syndromes treatment has not responded to benzodiazepines. The Mayo clinic (2004) specifies that in particular circumstances, ECT can provide rapid and effective benefits. The Manic Depression Fellowship (1996) report that ECT may be life saving in some instances however, the treatment may have a temporary result only, with other therapies required to sustain the enhancement. Ottosson and Fink (2004) describe how the alleviation of the possibility of the person committing suicide and initiation is quick, often recognized within two weeks.

CRAG (1997) details psychiatric complications such as mania and prolonged seizures as side effects of ECT. SEAN (2000) described a transient loss of memory as the central adverse effect of the treatment. Benbow (2005) lists prolonged seizures, cognitive adverse effects, mortality rate and headaches, muscular aches and nausea as the main adverse effects of ECT.

3.6.2 *Developments in the Mental Health (Care and Treatment) (Scotland) Act 2003*

A number of changes in the Mental Health (Care and Treatment) (Scotland) Act 2003 have implications for the practice surrounding

informed consent in ECT. These include the circumstances when a patient is capable of giving informed consent but is refusing to give consent. In these circumstances ECT can't be administered even in an emergency situation (Lyons, 2005). Barnes et al (2005) state that under the previous Mental Health (Scotland) Act, 1984, it was feasible to administer ECT to a patient sectioned under the Mental Health Act who was capable of giving legitimate consent but declined to give informed consent. However, Barnes et al (2005) affirm that the Royal College of Psychiatrists' Special Committee on ECT would not deem this to be practice that is approved of due to the fact that an adult whose capacity is intact can decide to dismiss the doctor's recommendation and treatment. Lyons (2005) asserted that under the new Mental Health Act there would be more unambiguous assessments for the patient who is having compulsory treatment. Barnes (2005) also cites the Mental Welfare Commission (MWC) for Scotland guidelines on consent for ECT coordinators (Mental Welfare Commission for Scotland, 1999, p.187) which highlights that "no patient should be treated with ECT unless there has been careful consideration of the consent issues and proper and lawful procedures have been followed to obtain consent, or, in the absence of consent, lawful authority to proceed". The Mental Welfare Commission for Scotland (2003) affirms that the practitioner should consider the minimal compulsory constraint of the autonomy of the patient when employing the Mental Health (Care and Treatment) (Scotland) Act 2003. Therefore the patient's self determination would be affected as little as was possible.

Another recent change in the Mental Health laws according to Barnes et al (2005) pertaining to ECT which defined a previously unclear area surrounding informed consent was the introduction of the Adults with Incapacity (Scotland) Act 2000. They discuss how ECT could now be provided to an adult who is deemed incapable of giving informed consent to the treatment but who is not sectioned under the Mental Health (Care and Treatment) (Scotland) Act 2003 and is not refusing or disputing the treatment. Barnes et al (2005) describe this as the doctor having a lawful authority to administer practical therapy to patients who are in agreement with receiving treatment who are not capable of giving informed consent. Nazarko (2004) submits that without such protection to guarantee that capacity is thoroughly evaluated; patients with incapacity would be at risk and could possibly be deemed as though they had fewer privileges than adults with capacity. Anderson (2002) also submitted that it was thought that the previous system did not have adequate support for adults at risk and could result in the view that adults and their relatives and carers were not referred to.

3.6.3 *Cognitive impairment of patients referred for ECT*

Some patients referred for ECT may be suffering from psychosis and due to the nature of their illness their competence and ability to give informed consent voluntarily require to be assessed (Journal of Medical Ethics, 1983). Van Staden and Kruger (2002) state that the presumption that a person who is psychotic is unable to give informed consent is excessive

because it is established on the common clinical characteristics indicated by a medical opinion. It is not established on the evaluation of a specific patient's competence to give informed consent, neither particularly for each intervention nor at the moment when consent has to be provided. Van Staden and Kruger (2002) suggest that this evaluation should be influenced by weighing up particular circumstances for informed consent, specifically those that cannot be achieved because of mental illness. They suggest that the essential circumstances for informed consent are that the mental illness should not impede the patients' comprehension of what they are consenting to, opting for or against the treatment, expressing their informed consent and acknowledging the requirement for treatment. However, Ottosson and Fink (2004) state that there are contrasting views in mental health practice in the USA as how to assess the patient's competency and whether competent patients who arrive at illogical conclusions should be given treatment in opposition to their request. They offer that patients should be given treatment in opposition to their request if the omission to do so jeopardizes their existence. As previously discussed this practice would not be recommended under the Mental Health (Care and Treatment) (Scotland) Act 2003.

Kashka and Keyser (1995) suggest that due to cognitive impairment patients requiring ECT may be unable to understand complicated information. Therefore it is important for the practitioner to ascertain that the information given to patients to inform their decision is comprehended by them. Caird and Worrall (2003) state that the patient should receive information in both verbal and written formats.

Lapid et al's (2004) research set out to calculate the capabilities of severely depressed older patients to provide informed consent to ECT and to examine the effect of teaching sessions on their capacity. The method included using the MacArthur Competence Assessment Tool for Treatment to evaluate the decisional capacities of 40 patients with severe depression who had been referred for ECT. The patient's decisional capacities were assessed at the starting point and then after teaching sessions. Lapid et al (2004) concluded that the elderly patients included in the study who had severe depression did have sufficient reasoning competence in order to provide informed consent to ECT. Their findings also emphasized the significance of arranging comprehensible, organized teaching sessions to older people in order to maximize their capacity to provide informed consent. This could also be integrated into practice in ECT with all patients suffering from cognitive impairment in order to increase their capacity to provide informed consent. Taylor (1983) also outlines the importance of reiterating the information on ECT at frequent times as the patient who is depressed may have a reduced attention span so be less inclined to take account of or remember unfamiliar information. The GMC (1998) also advises that if a patient has problems with comprehending information it could be applicable to supply it in reasonable quantities along with written information which should be given at regular intervals.

3.6.4 *Information provision*

The provision of information is an important part of the informed consent process in ECT. Taylor (1983) asserts the clinical significance of making

sure that patients are provided with sufficient information in order to arrive at an informed judgement. However, there appeared to be evidence that information on ECT was not being adequately provided to patients such as the CRAG Working group on Mental Illness (1997). This good practice statement reported that users and user groups have raised their concerns that patients are not provided with an adequate description of ECT. Rose et al's (2005) research aimed to review patients' views on issues of information, consent and coercion. They identified seventeen papers and reports that had patients' views on information and submitted the papers and reports to a descriptive systematic review. The testimony data was analysed qualitatively. Rose et al (2005) concluded that "current legal frameworks fail to ensure that a majority of recipients of ECT, voluntary or involuntary, feel that information and consent procedures are adequate". However, Rose et al (2005) stated that the questions asked in the seventeen surveys studied were not consistently directly comparable although 9 out of 12 studies gave a reliable outline. Also they state in the declaration of interest that two of the authors had been recipients of ECT which may have caused them to have biases about the treatment.

Pippard and Ellam (1981), some years earlier, documented that patients were not provided with a written description of the treatment in 87% of cases. Earlier research by Freeman et al (1980) included semi-structured interviews on 166 patients who had ECT in 1971 or 1976 and reported on their understanding and opinion of it. They found that only 15% of patients that they interviewed could state that they had a thorough knowledge of what ECT consisted of and it was apparent that patients

desired more information about the treatment. Freeman et al (1980) state that their study was conducted in a mental health hospital by psychiatrists so the findings may be unreliable due to the fact that patients may have felt unable to find fault with the treatment in front of the clinicians who were treating them.

CRAG (1997) describes that due to the severe illness that patients receiving ECT are suffering from or the fact that the treatment itself can cause short term memory loss, the patient may fail to remember the information that they were initially given. The provision of information as a continuous process rather than a one off event may be advisable (Rose, 2005). Kashka and Keyser (1995) also advise that due to the patient's loss of cognitive ability the information should be appraised prior to each treatment and at regular intervals during the treatment episode. Barnes et al (2005) also assert the importance of orally verifying the patient's on-going consent prior to the administration of each treatment.

3.6.5 *The knowledge base that patients should possess to give full informed consent to ECT*

When considering what particular knowledge base a patient should possess in order to give informed consent to ECT, Barnes et al (2005, p.182) announced that the medical practitioner must guarantee that the patient comprehends "what the medical treatment is, its purpose and nature, and why it is being proposed; its principal benefits, risks and alternatives and in broad terms the consequences of not receiving the

proposed treatment" in order to provide informed consent. Caird and Worrall (2003) also report the importance of the patient being provided with information about their rights.

Rose et al (2005) report that patients should be provided with comprehensive information about the possible advantages and side-effects of the treatment, including in particular, memory loss. This is relevant because Rose et al's (2003) descriptive systematic review on patients' perspectives on electroconvulsive therapy extracted data from 26 studies undertaken by clinicians and nine reports conducted by patients or in the partnership of patients and concluded that one third of patients communicate that there was considerable memory loss after ECT.

Ottosson and Fink (2004) state that the information that the patient and his/her relatives receive should include reference to the fact that confusion and disorientation could be expected after ECT and also information on the short and longer term effects of ECT should also be provided. Kashka et al (1995) confirm that the patient should also be advised of the side effects of the anaesthetic and muscle relaxant. Kashka et al (1995) report that the information provided should include that if the patient's consent is voluntary it can be taken back at any juncture.

Culver et al (1980) report that in the first phase of the informed consent process the patient should be made aware that [if they were to refuse ECT] there may be a prolongation of the illness that it is expected that

ECT may diminish. They also suggest that ECT could be described as having an impressive likelihood of allaying depression with the risk of memory problems occurring. CRAG (1997) presents that patients should be made aware of the mortality rates, medical complications and psychiatric complications while Benbow (2005) states that other adverse effects of ECT include muscle aches, headaches and nausea. Benbow (2005) also describes the risk of prolonged seizures and status epilepticus which is increasingly possible in people on medication or who have previously occurring medical states which reduce their seizure threshold.

3.7 Summary

From reviewing the literature it is apparent that there is a substantial amount of information on electroconvulsive therapy and informed consent and some literature on the nurse's role in informed consent such as Usher and Arthur (1998, p.696) who suggest that the nurse should be a supporter of the role of "seeker of informed consent" in the nurse - patient relationship. Clarke (1995, p.696) suggests that the psychiatric nurse should adopt an "advocacy/mediation" approach when trying to establish the standard of informed consent provided by a patient. However, overall, there was sparse literature concerning the nurse's role in the informed consent process in ECT.

Although autonomy is considered one of the most important philosophical principles of informed consent (Bloch et al, 1999), informed consent was left quiescent in the patient-doctor association until more recent times

(Miesel, 1996). Recent events in healthcare such as the BRI report, Alder Hey, Shipman and Allitt (Richards, 2006), Coulter (2002) have also contributed to reforming the rights of patients and developing patient centered care. However, research such as Chada et al (2004) has concluded that healthcare staff included in their study still failed to have a good understanding of the process of informed consent.

Many sources cited gave evidence that patients were not being provided with enough information on ECT (Rose, 2005; CRAG, 1997; Freeman et al, 1980; Pippard and Ellam, 1981) which could have affected the patient's ability to provide informed consent. Sources such as Barnes (2005) and Ottosson and Fink (2004) have suggested some of the information that a patient should be aware of in order to provide informed consent to ECT. However, due to the cognitive impairment that patients receiving ECT can suffer it is recommended that information should be given on a continuous basis (Rose, 2005).

These are areas which could be developed and it is anticipated that the research question that this study examines will add to the body of evidence in this field. The next chapter will describe the research design of the study.

CHAPTER 4

Research design and methods

This section will consider the research aims and objectives and the methods chosen for this study. Data collection methods including the ECT nurse questionnaire used in stage one of the project will be described. The statement of the knowledge base that a patient is required to have to provide full informed consent and the roles and responsibilities of medical and nursing staff in the informed consent process in ECT in the second stage of the research will also be described. The sample population, ethical issues, means by which the data were collected and the validity and reliability of the findings will also be considered.

4.1 Research question

What is the nurses' and doctors' role in obtaining informed consent for ECT, and what knowledge is required to inform this role?

4.2 Aim and objectives

4.2.1 *Aim*

To explore the nature, indication and processes of informed consent in patients receiving ECT.

4.2.2 *Objectives*

1. To explore the ECT nurse's role in the consent process.
2. To evaluate medical and nursing staff's knowledge and understanding of the principles of informed consent.
3. To assess the knowledge base that patients would be required to have in order to provide informed consent.

4.3 Methodology

The design was chosen for the project because it was considered that the use of the quantitative method of the ECT nurse questionnaire and the Delphi process would provide data which would inform the aims and objectives of the research. Other designs such as the semi-structured questionnaire, which was initially considered for the first stage of the research, was rejected because it was thought that the semi-structured questionnaire would be too time consuming to administer within the constraints of the research period. However, the advantage of the questionnaire was that it was an economical method of contacting participants over a wide geographical area (Oppenheim, 1992). The Delphi consensus method was chosen because of its potential to form and arrange group contact and attempt to achieve consistent consensus of viewpoints from a knowledgeable group (Powell, 2003).

4.3.1 *Overall design of the project*

The overall design of the project included the construction of two stages of questionnaires which included a questionnaire which would be sent to ECT nurses in the first stage and questionnaires which would be sent to an ECT 'expert' panel in the second stage.

The methods used in each phase of the study helped to inform other objectives e.g. the data collected from the questionnaire for ECT nurses provided information which informed the development of the statement of the knowledge base that clients require to have to be considered "fully informed". Unfortunately, the second objective which was proposed in order to evaluate medical and nursing staff's knowledge and understanding of informed consent was not carried out. This was due to the length of time it took to receive ethical clearance in each health board which caused a delay which meant it was not possible to carry this out within the time scale set for the MSc by Research.

4.4 Research methods

Research methods included:

1. A self-administered questionnaire was developed and following piloting was sent to all the ECT nurses in the 24 ECT sites in Scotland who were also part of the Scottish ECT Accreditation Network (SEAN) to ascertain their interpretation of their role in the consent process.

2. The data gained from the questionnaire informed the development of an explicit statement of the knowledge base of ECT that clients would be required to have to be considered "fully informed". This was also achieved by reviewing the literature on informed consent and by writing to ECT clinics in Britain and abroad and user groups such as MIND in order to gather the information that was currently available for patients receiving ECT. A statement of the knowledge base required was then devised and disseminated amongst an 'expert panel' - ECT Consultants and ECT nurses in Scotland and a representative from the Depression Alliance (Scotland) who were all members of SEAN. It was considered that this panel would be experts in the field of ECT.

The Delphi process was the consensus method used to combine the information found on informed consent. This method was chosen because, as noted by Jones and Hunter (1995), the advantage of using a Delphi method approach is that it deals with the drawback of a group being influenced by the strongest member. Also, as outlined by Parahoo (1997), it was possible to gather the opinions of the 'expert panel' with little expense as there was no requirement to bring the group together. This method was modified for this research project by reviewing some of the other approaches used in healthcare which included the Delphi process such as Jones and Hunter (1995), Whitehead (2008) and Keeney et al (2006). In particular Jones and Hunter's (1995) description of the sequence of rounds of the Delphi process, Whitehead's (2008) outline of the Likert scale, which was used to score the participants' responses, and Keeney et al's (2006) suggestions on improving the participants' replies to

each round were useful in informing the Delphi process in this research. The 'expert panel' was requested to rate each statement in the information on the required knowledge base. The order of importance was then summed up and combined in a repeat version of the questionnaire. The 'expert panel' was then requested to re-rank each statement, this time having the opportunity to alter their mark considering what the panel's reaction was. The change in consensus was then summed up and the extent of consensus was ascertained.

The development of the questionnaires will be discussed in more detail later in this section.

4.5 Participants

4.5.1 *Population*

The population identified in the study were ECT consultants and ECT nurses in Scotland and a representative from the user group the Depression Alliance (Scotland).

4.5.2 *Sample*

The sample was drawn from healthcare staff working in ECT suites in Scotland and included ECT consultants and ECT nurses from the 24 ECT suites in Scotland and one user representative from the Depression Alliance (Scotland). They were all members of the Scottish ECT

Accreditation Network (SEAN). It was not possible to ascertain the exact number of participants available as there were no data held on this by SEAN and it was considered unethical by the Grampian Local Research Ethics Committee to ask each health board independently. The sample was obtained by sending questionnaires directly to each ECT suite in Scotland.

These participants were decided on because it was thought that by including all the ECT services in Scotland it would produce a sufficient sample to provide adequate data to achieve worthwhile results in order to address the research aims and objectives. A wide geographical coverage was required for the sample because there were only two other ECT nurses apart from the author and one ECT consultant that could be accessed locally. It was proposed that a sample of nurses and doctors would be drawn locally for the second stage of the research but it was not possible to carry out this stage due to the research time constraints. It was considered that the knowledge and experience of the Scottish ECT consultants and ECT nurses would typify that of the staff working in ECT in Britain in general. As described by Parahoo (1997) the sample should be representative of the target population in general.

The rationale for choosing this group for the sample was that it was assumed that the ECT consultants and ECT nurses would be able to give valid and reliable accounts of practice with regard to informed consent in their respective areas due to their expertise in the subject area chosen for this research as described by Keeney (2006). This expertise is due to the

number of patients that they treat with ECT, their professional background and experience within the field of ECT. The user representative who was part of the 'expert panel' in the Delphi process was included because he/she had a good knowledge of ECT and the information that people require pre-treatment which he/she had gained from a user's perspective and his/her work with the Depression Alliance (Scotland). This is an association which offers advice to people who suffer from depression and who may be offered ECT as a treatment option. The representative was also a member of SEAN. It was felt that this would benefit the 'expert panel' by offering an alternative viewpoint from a user's perspective. One user representative was chosen as this person was known to the author via the SEAN network and it was thought that it would be difficult to gain ethical clearance for a group of users due to the fact that they were users and it was not known if they were well enough to participate. In fact a few Research and Development sites did require further information on the user representative chosen for the research prior to giving ethical permission to conduct the research which delayed the research being carried out. However, in retrospect, the fact that the user's views were similar to the professional group and he/she had become an 'expert' patient/user resulted in the fact that her/his views did not add validity to the research.

4.5.3 *Eligibility*

The inclusion criteria for the study were that the participants had to have an extensive knowledge and experience of ECT. The inclusion criteria were

very selective as, particularly in the second stage of the project, an 'expert panel' with an in-depth knowledge of ECT was required. Keeney et al (2006) describe choosing an expert panel that are recognized as having particular skills related to the point in question. The exclusion criteria were: (1) participants without knowledge and experience of ECT - because he/she would not have knowledge of the subject area, (2) ward doctors and nurses involved in the administration of ECT were excluded from the expert panel because of the initial intention to ascertain their knowledge in the proposed second stage.

4.5.4 *Selection of the participants*

The potential participants were initially informed of the research by the author communicating the aims of the study in a presentation given at the Scottish ECT Accreditation Network (SEAN) meeting in November 2005.

Written information regarding the aims of the research and a letter of invitation stating their participation in the research would be purely voluntary, that they would be free to withdraw from the study at any stage and that their responses would be confidential and would remain anonymous was sent to all participants in both stages of the study (Appendix 1 and 2). The participants were identified by information which was requested from the SEAN nurse co-ordinator. This information consisted of the lead ECT nurse for each ECT site in Scotland who were also members of SEAN. The lead nurses were requested to give the

recruitment papers and questionnaires to any other nurse in their department who assisted in ECT as they deemed appropriate.

The participants of the Delphi process were also sent an informed consent form (Appendix 3) which was developed according to Ethics Committee guidelines to complete and return if they were willing to take part in the project. These participants were identified by information received from the SEAN nurse co-ordinator which included the latest names of delegates from SEAN meetings and also an updated lead ECT nurse for ECT from the ECT sites. An e-mail was sent to all the contacts received within the public domain which contained details of the research to ascertain if they would like to take part.

All participants were informed by the letter of information which was attached to the research, as stated above, that the benefits of the research would be that a tool would be developed which could be administered by staff to confirm that the knowledge required for informed consent has been obtained in patients consenting to ECT. In addition, it is anticipated that recommendations for developing practice would be made in order to increase practitioner's awareness of informed consent. This would help to ensure that each treatment is administered in the context of fully informed consent with the intention of improving patient care.

4.6 Ethics

An ethics committee application form was completed and submitted to the Local Research Ethics Committee. Approval was granted subject to a request for further information and clarification on the points raised, minor changes which were to be made to the letters of invitation and that the questionnaire for medical and nursing staff was made available to the Committee once it was available (Appendix 4).

An application form was completed and sent to the local Research and Development Department. An ethics application was sent to the School of Nursing and Midwifery Ethics Review Panel. Approval was received from both of these departments (Appendices 5 and 6).

Authorisation was gained from the local psychiatric hospital service manager so that management approval could be gained in order to have access to staff to request that they complete questionnaires.

A submission was made through the Multicentre Research and Development Review for Scotland (MRAD) who forwarded all details of the project to the research and development departments in Scotland where the research would be carried out (Appendix 6). Approval was gained to conduct the research in each of the eleven healthboards where ECT was administered in 24 ECT sites in Scotland. It was discovered in the Deplhi phase of the research that two of the ECT sites had merged with other

ECT centres so details of this stage of the research were sent to these 22 ECT sites in Scotland.

The author recognized that she may encounter a source of tension between her role as ECT nurse and researcher because present practice was being explored. However, this did not become an issue while the research was being conducted. On a personal level the author was concerned that evaluating present practice might displease the sites where the research was being conducted as described by Cormack (2000). As also indicated by Cormack (2000), unease can be created by this dual role as classified facts could be received within the role of practitioner or researcher. In this research this included the ECT nurses' and ECT Consultants' perceptions of present practice. Assurances were offered that this information would not be revealed either outside of the supervisory team or without the participants' direct approval. However, information would be available stating the benefits of the project to present practice and patient care. It was also made clear to participants when the author was functioning within her role as ECT nurse and researcher. Care was taken to ensure the anonymity of any response given by the participants and to maintain the anonymity of the institutions which participated in the research. This was achieved by the method of the questionnaires being self administered therefore the participants and institutions were anonymised as described by Parahoo (1997). The identity of the participants and institutions would remain anonymous in both the thesis and any subsequent publications and presentation. The results of the research will also be communicated to the participants as recommended

by Parahoo (1997) through conference and journal club presentations, journal articles and recommendations for future practice.

4.7 Questionnaires

4.7.1 *Formulation of the questionnaires for ECT nurses*

The first draft of the questionnaires for ECT nurses was devised by brainstorming elements of the ECT nurse's role in the informed consent process based on reflecting on my own practice. The first stage of the research was originally planned to be a semi-structured interview but this was changed to the method of self administered questionnaires due to the length of time it was thought that semi-structured interviews would take. The first questions included what was the ECT nurse's role in the consent process; whether the nurse provided information on informed consent; had the nurse ever thought that a consented patient was not giving informed consent; were there any written specifications about the role of the ECT nurse and the consent process at the nurse's place of work; what did they consider the ECT nurse's role to be; the review of consent and the assessment of cognitive function of patients receiving ECT.

In order to further develop the original research proposal which was submitted at the beginning of the research period with the questions which had been formulated by reflecting on informed consent, the role of ECT nurse in informed consent, and the literature which informed this, the author gave a presentation to the supervisory team. Following verbal

communication with the supervisory team, the original proposal was eventually divided into two parts. It was decided that it would not be possible to design and test out the tool created in this research project due to the research time limits. The second stage would have to be carried out in a future research project.

The formative stages of the questionnaire included regular supervisory meetings which were very beneficial in considering and developing the drafts.

4.7.2 *Literature informing the design of the ECT nurse questionnaires*

The ECT nurse questionnaires (appendix 7) were formulated by reflecting on present practice and reviewing the literature. Appendix 8a illustrates a research journal entry of how the first draft of the questionnaires was devised and the literature informing this. Appendix 8b contains a mind map in the research journal which describes the objectives of the research and the early concepts of informed consent that were identified in the literature.

The questionnaires included Section A which contained questions about the participants' personal details and Section B contained statements on the ECT nurses' role in the informed consent process, as informed by the literature.

Section C examined the nature of pre-treatment information that should be provided to patients. The tables of evidence this information came from included user groups such as the Manic Depression Fellowship and internet sources such as the American Psychiatric Association. Two patient information sheets currently used in the ECT suites in Scotland which had been requested by the author along with the completed ECT nurse questionnaires were received. One of these was the patient information book from SEAN (2000). This was out of a possible 24 that were requested from each ECT suite. Two other information sheets were received from ECT sites in England. Two information sheets were received from local practice. Appendix 8c contains a research journal entry on the patient information that was assimilated from the patient information sheets and was also based on the author's practice experience.

Section D examined the provision of informed consent which was developed by reference to the literature on this issue. Section E examined the confirmation of informed consent to ECT and was based on practice experience and reference to the literature. The statements in section F related to the patient's capacity to provide informed consent which was particularly informed by the research of Lapid et al (2003). The final draft of the questionnaire consisted of six sections covering 35 questions.

4.7.3 *Question construction*

The questionnaire was designed utilizing a range of question designs which were informed by Oppenheim's (1992) literature on questionnaire design and attitude measurement. Section A contained choice categories in order to measure nominal data such as the participant's age and gender as described by Parahoo (1997). The category of 'other' was also added to some questions such as which part of the NMC (2008) register the participants were on, in order to capture the uncommon responses as described by Munn and Drever (1996). Some questions in this section also contained open responses. Section B contained questions which involved the participant giving their answer by using a Likert scale ranging from "strongly agree" to "strongly disagree". Oppenheim (1992) describes the use of these attitude scales which were designed to ensure that all the components measure identical items. The participants would be expected to position themselves on the attitude scale for each statement rather than have the requirement for a person to appraise their attitude (Oppenheim, 1992). Robson (1999) states that the benefit of using the Likert scale in questionnaires is that participants often like to fill in this type of rating scale as it can make a questionnaire appear more interesting. This is helpful due to the fact that if the participants are responsive to the questionnaire it is possible that they will bestow responses that they have reflected upon. This approach was used for the majority of the questions in this section. This section also contained questions which required a closed response which was indicated by a 'YES'/ 'NO' answer. Cormack (2000) identifies the benefit of using closed

questions as being that they decrease the amount of time the questionnaire will take to finish. An open response category was included so that the participants were free to respond as they wished as described by Oppenheim (1992). This would be beneficial to gain more information from the participants' perspective on the subject matter of informed consent. Parahoo (1997) discussed the importance of open ended questions being well defined so that all the participants can construe them in the same way. Section C contained questions which required the participants to rank order their responses. Oppenheim (1992) describes rank ordering as ordinal scales which will record how the participants choose to order items. In this section the participants were requested to rank the importance of the items of information and side effects that a patient should be provided prior to consenting to ECT. Section D included questions which required 'YES' / 'NO' answers, open ended questions and the judgement scale. Section E contained questions using the judgement scale tick boxes ranging from "after every treatment" to "never" and also open ended responses. Section F contained questions ranging from "always" to "never", open ended questions and rank ordering questions. It was anticipated that the range of types of questions would provide a mixture of quantitative and qualitative data which would inform the research. Participants also had the opportunity to add information that they would like to have included in the questionnaire.

The questions were ordered in a way that the simpler and less demanding questions to answer were at the beginning such as the participant's personal information as described by Munn and Drever (1996). As

outlined by Oppenheim (1992), the questionnaire was then built up using individual modules which contained different variables on the elements of informed consent. The questionnaire was also designed to contain a range of question types so that the participant would not find it too time consuming or laborious to complete as described by Oppenheim (1992). The overall design and arrangement of the questionnaire was planned to be agreeable and tidy in order to encourage the participants to complete it as described by Munn and Drever (1996). The instructions on the questionnaire and on the letter accompanying it were planned to be as comprehensible as possible as detailed by Cormack (2000). The questionnaire design had many drafts completed in order to ensure that the wording was clear and unambiguous to prevent the participants misconstruing the meaning of the question which would result in the answers being biased as described by Oppenheim (1992). Parahoo (1997) also outlines how the reliability and validity of the questionnaires can be significantly enhanced by diligent organization and structuring. It was also important to place a thank you message at the end of the questionnaire so that the participants knew their participation had been greatly appreciated as outlined by Cormack (2000).

4.8 Piloting the tool

4.8.1 *ECT nurse questionnaires*

Oppenheim (1992) describes the importance of pilot work as testing out the method to ensure that it functions in the way which was intended.

Cormack (2000) also identifies that the benefits of the pilot are that it will assist the investigator in determining if there are any problems apparent with the method and that it gives the researcher practice in utilizing the research tools with participants.

A draft of the questionnaire was given to an experienced colleague, who had considerable experience in questionnaire design, to consider. This colleague offered constructive comments on the further development of the questionnaire in terms of structuring the content, avoiding repetition and ensuring clarity of the statements. This was very beneficial in ascertaining the face validity of the questionnaire as outlined by Oppenheim (1992). This is whether the questionnaire would measure what it was intended to by reviewing the balance of its contents so that, in this research, all the elements of informed consent were being considered.

The next stage of the pilot study incorporated sending the questionnaires to two ECT nurses in England who were willing to take part in the pilot and would not be participating in the main part of the study. This group had attributes resembling the participants that were proposed for the main part of the study, as outlined by Parahoo (1997), as they were also ECT nurses. This stage of the piloting process was very useful as it showed that the nurses were able to understand and complete the questionnaires without any apparent problem which suggested a degree of validity and reliability of the method. This is described by Cormack (2000) as illustrating that the tool was able to gather the information that was required to inform the research.

4.9 Mode of data analysis

The data from the questionnaires were entered into a Statistical Package for the Social Sciences (SPSS database), version no. 15, in order to be analysed. As detailed by Cormack (2000), the SPSS offered a large variety of statistical processes which were useful in analyzing the nominal and ordinal data that the questionnaire presented. The nominal data in the questionnaires included questions such as the participants' personal details and the ordinal data included the response to questions such as the ones which used the Likert rating scales. A template was devised which contained abbreviations of each question in order to devise a coding frame on the questionnaire that could be measured and entered into the database. As described by Oppenheim (1992), each response group was given a numerical value. Great care was taken in order to check the template so that the information on it did not contain any errors as also outlined by Oppenheim (1992). Robson (1999) states that the benefits of using this method is that the regulations for systematically coding the content have to be made comprehensively clear or the computer programme will be unable to perform the activity or will come up with false results. The data were entered into the SPSS database and tables of results were created. The data set was then 'cleaned' by going through it all again and checking it. This was carried out in order to ensure that the data had been entered correctly and an internal consistency check as described by Oppenheim (1992) was performed to ensure there were no unreliable data. Missing data were recorded by a specific code and common themes considered, such as a question that a high percentage of

participants had failed to answer, as indicated by Cormack (2000), which could indicate the poor structuring of a question.

The qualitative data that were present in the open-ended questions were then formulated into a 'string' word document and the common themes of its content were examined as outlined by Cormack (2000). The string variables from the ECT Nurse questionnaire were categorized by putting all the participants' responses together by question and checking for any collective themes.

4.10 Delphi study

4.10.1 *Statement design*

The questionnaires for the statement of knowledge a patient would be required to have to give informed consent and the roles and responsibilities of medical and nursing staff in the informed consent process in ECT were developed by reviewing the information given to patients on ECT in Britain and abroad. This also involved reviewing the literature on informed consent. Further work was completed by analysing and using the findings from the ECT nurse questionnaires. Finally, the experience of the author in practice helped to bring all the information together into the statements.

Common themes of information that a patient should be provided became apparent and these were grouped inductively along with the themes set

out in ECT good practice text books such as the CRAG Working Group on Mental Illness (1997), Caird and Worrall (2003) and Scott (2005) and also recent recommendations such as those from NICE (2003) and the Mental Welfare Commission (2003). The themes that emerged from this literature were information such as: ECT is given under a full anaesthetic and muscle relaxant; the side effects and benefits of ECT. This literature was compared to the author's practice experience which gave an indication of what the patient required to know before, during and after the course of treatment. Patients tended to ask the author questions such as what was the method of ECT, how effective was the treatment, what were the side effects and how many treatments would they be required to have? This was similar to the documentary evidence which was contained in patient information on ECT such as that provided by The Royal College of Psychiatrists (1993), Manic Depression Fellowship Scotland (1996). American Psychiatric Association (2004). It was considered that enough information had been gained when the same information themes were found repeatedly.

The statements were then condensed by mapping out the sources of information and then rating them depending on the reliability of the source such as good practice guides on ECT or associations which were recommended in practice such as Manic Depression Fellowship (1996), SEAN (2000) or NICE (2003). The reliability of the source of information was based on the author's practice experience and knowledge of the literature which was used to inform good practice in ECT. The statements were also divided into sections concerned with information required by a

patient in order to give informed consent to ECT and the process involved in gaining the informed consent of a patient. The first questionnaire was named the "Statement of the knowledge base that a patient is required to have to give full, informed consent in ECT" (appendix 9). The process involved with gaining the informed consent of patients went on to be the second part of the Delphi questionnaires - "The roles and responsibilities of medical and nursing staff in the informed consent process in ECT" (appendix 10).

The roles and responsibilities were devised by the author reflecting on her own practice experience, by adapting the categories that were used in the ECT nurse questionnaires and by reviewing the literature on informed consent and informed consent in ECT. For example the medical role section included in the statement:

The psychiatrist obtaining informed consent from the patient has sufficient knowledge of the nature, purpose and effects of ECT.

This statement was informed by data received in the ECT nurse questionnaire question on the knowledge of medical staff on the elements of informed consent and literature such as the GMC (1998), The Medical and Defence Union of Scotland (2004) and Barnes (2005).

The nurse's role section included the statement:

The nurse assists the referring psychiatrist in assessing the patient's decisional capacity to ensure that informed consent is valid.

This statement was developed from the author's practice experience, the ECT nurse questionnaire and literature such as Cable (2003), NMC (2004), Scholefield, et al (1997) and Usher and Arthur (1998).

Questionnaires containing the references which had informed the statement of knowledge and the roles and responsibilities of medical and nursing staff were included in the information which was sent to the participants in the second round of the Delphi process.

4.10.2 *Statement construction*

The statements required to be explicit, concise and clear and were constructed carefully so as to try and avoid any bias that may occur if the participants found them difficult to comprehend, an issue recognised by Oppenheim (1992).

There were ten sections included in the statement of knowledge which contained 26 statements overall in the first round. The sequence of statements were taken from the findings of the ECT Nurse questionnaire. The statements were ordered in the importance that the ECT nurses placed the information that should be provided to patients. The exception to this was the statement on ECT and consent. This was placed third in the statement of knowledge although the ECT nurses had rated it sixth in

importance of the information that patients should be provided. The rationale for this was that consent in ECT was an important element in the informed consent process and because it appeared an important part of ECT good practice literature such as CRAG (1997) and Barnes (2005). It was decided to split 'the nature of ECT' and 'why it is prescribed' which was one statement in the information provided to patients in the ECT nurse questionnaire into two separate statements as it was reflected upon that these were two different elements of informed consent. For 'reported risks', the position of the side effects of memory loss and confusion were changed around in the statement of knowledge. The ECT nurses had placed memory loss as second in order of importance that a patient should be aware of and confusion as first in order of importance. However, it was considered that memory loss had been given slightly more importance as a side effect in ECT literature such as Caird and Worrall (2003) and Benbow (2005).

The "Roles and responsibilities" questionnaire was divided into two sections consisting of medical role and nursing role. The medical staff section contained 32 statements and the nursing staff section contained 31 statements in the first round.

The statement of knowledge required to be rated by the participants by ticking the boxes: 'very appropriate', 'appropriate' and 'not applicable' and the roles and responsibilities: ' desirable', 'essential' and 'not applicable'. These terms were chosen in particular to ascertain what the participants perceived was very appropriate and essential in the questionnaires. These

Likert scales, as described by Parahoo (1997) were chosen in order to measure the participants' attitudes to the statements. At the end of the statement of knowledge, participants were given the opportunity to place the statements in a different sequence or add any other information that they considered should be contained in the statements or qualify their response. In the roles and responsibilities questionnaire, participants were asked to add any other information that they would like to be included in the statements. The instructions on how to complete the questionnaires required to be very clear and were included at the beginning of the questionnaires and in an information letter which would be sent with the questionnaires.

4.10. 3 *Mode of data analysis*

The responses to each round of the questionnaire in the two rounds of the Delphi process were calculated as a percentage by dividing the total number of responses by the number of participants and multiplying this number by 100 in order to establish the median response. This mode of data analysis was informed in part by the methods to analyse the data which were described by Jones and Hunter (1995). After the first round the responses were assimilated and included in the information sent to the participants. They were requested to give their response to the second round of questionnaires taking into account the group response.

4.10.4 *Level of consensus*

The level of consensus for the project was decided by reviewing what other Delphi studies had done in this area. Bowles (1999) stated that few investigators had clarified consensus in definite statistical terms. However, Keeney et al (2006) stated that there is no identifiable guidance on an applicable degree of consensus but suggested that 75% was the lowest level although they state that there is no clear systematic reason for this. Whitehead (2008) accepted a consensus level of 81.3% in his study which examined health promotion and health education in nursing practice, education and policy while Witt (2008) decided on a consensus measure of 75%. It was decided that the level of consensus for this study would be 75% because as Whitehead (2008) stated, further rounds may have achieved additional consensus but there was also a risk of the participants becoming tired and no longer willing to participate in the study. This was anticipated for this research and illustrated by a response in the second round of the Delphi process that was poorer and it also took longer to receive the questionnaires back.

4.10.5 *Piloting of the tool*

A pilot of the questionnaires was also carried out by sending them to an ECT nurse in England who passed copies onto the ECT consultant and another ECT nursing colleague who would not be participating in the rounds of the Delphi. Their responses indicated that they were able to follow the instructions as set out and fill in the questionnaires response

categories accordingly. Their response was also quick which may have indicated that the questionnaires were self explanatory and did not take too long to fill in. The ECT consultant made some suggestions on the questionnaires which were taken into account when making alterations to the final draft. The ECT consultant's suggestions on the "Statement of Knowledge" included questioning the suitability of the use of light therapy as an alternative treatment to ECT and suggesting that the section on memory loss underplayed the risks involved. Therefore light therapy was omitted and the section on memory loss was extended to include more detail on the long term effects.

4.10.6 *Communication of the Delphi process*

In part due to the disappointing response to the first round of questionnaires through blanket mailing it was deemed important to check that the details for the ECT nurses were correct and it was also necessary to gather contact details for the ECT consultants. This information which was in the public domain was received from the SEAN co-ordinator. The ECT sites mentioned on the delegates list were contacted directly for confirmation of e-mail addresses for some of the staff so that the research could be sent out more promptly. It was established that two of the original ECT sites had merged so there were now 22 sites where ECT was administered.

The local R&D and GREC were also sent details of this stage of the project as requested by them on the original ethics approval form in order to keep

them updated and so that the questionnaires for the Delphi phase could have ethical approval and receive a favourable response to continue with the second stage of the project.

An informed consent form, information about the study and the two questionnaires on the knowledge statements and roles and responsibilities of nursing and medical staff were sent out by e-mail to the user representative from the Depression Alliance (Scotland), ECT consultants and ECT nurses at the 22 ECT sites. A covering e-mail asked the ECT nurses to distribute the information on the project, as they thought appropriate, to other ECT nurses if there was more than one nurse working within the ECT suite. It was requested that the staff and the user representative sent back an electronic version of the informed consent form if they wished to take part and follow this up by post with a signed hard copy which was then countersigned and sent back to them.

One participant had sent his/her responses with an uncompleted informed consent form. On questioning the participant communicated that he/she thought signing the consent form was optional. He/she was advised that to be included in further rounds his/her identity would need to be known to the researcher. Reassurance was given that his/her identity would remain anonymous in both the thesis and any subsequent publications or presentations therefore the participant agreed to sign the consent form.

Five participants had difficulty downloading the questionnaire on the statement of knowledge properly and had only answered the

questionnaire partially. Three of these were picked up at the time therefore the questionnaire was sent back to them and these were completed successfully. Unfortunately in two of the questionnaires it was not noted until it was too late to send the questionnaires back for completion however, the responses that were given were included. Another participant only completed the roles and responsibilities questionnaire so he/she were requested to complete the questionnaire on the statement of knowledge and this was completed and received back. Another participant had just completed the medical role in the roles and responsibilities questionnaire and not the nursing role. For the second round it would be important to ensure there were clear instructions to complete both of the questionnaires as fully as possible and to ensure that all questionnaires were completed when they arrived.

4.11 Validity and reliability

4.11.1 *ECT nurse questionnaires*

Measures to ensure the validity and reliability of the ECT nurse questionnaires included careful design of the questionnaire by reviewing the literature on informed consent and informed consent in ECT. The statements in each section of the ECT nurses' questionnaires were carefully worded and structured in order to avoid inadvertent bias as described by Oppenheim (1992) and contained closed, pre-coded questions and also open questions. The questionnaires were chosen as a methodology because it was thought to be an effective and efficient way

of collecting data in an anonymous way as outlined by Cormack (2000) because they can be delivered in considerable amounts with minimal cost to many participants, involve minimal administration tasks and do not require previous experience to carry them out. The advantage in this research is that the questionnaires were sent out to ECT nurses in a wide geographical area in Scotland with minimal cost in terms of collecting the data as also described by Oppenheim (1992). Parahoo (1997) also states that an advantage of using questionnaires is that they are designed and arranged beforehand and cannot in principle be changed in their phrasing or in the sequence in which they are responded to. As a result they have an acceptable level of reliability.

The disadvantage of using the questionnaires was that there was not an opportunity to ask the participants to explain or develop their responses as demonstrated by Parahoo (1997). This was a disadvantage in this research as there was no opportunity to ask participants to clarify or complete their responses. As also stated by Parahoo (1997) the participants may have discussed the questionnaires together due to the fact that in some ECT suites there was more than one nurse answering the questionnaire. Oppenheim (1992) details the low response rate and the consequent bias in the method as being a disadvantage of the postal questionnaire. The author tried to increase the participants' response rate by announcing the research at a SEAN conference which increased the contact between the participants and the researcher and by ensuring the information included with the questionnaires contained details of how the research would benefit the participants. The methods used in both stages

of the research were also designed to provide more validity to the findings as the phenomenon would be examined by different processes included in the methods of the questionnaire and Delphi process. Cormack (2000) describes another disadvantage of questionnaires is that a pressured selection in responses which do not reveal the participants knowledge and therefore lower their desire to reply. However, the questionnaires contained a mixture of open and closed questions which may encourage the participants to take part and offer their opinion on the practice of informed consent in ECT.

4.11.2 *Delphi technique*

The validity of the Delphi technique is often disputed. Whitehead (2008) cites Powell (2003) who argues that the outcome of the Delphi project illustrated the expert point of view but not essentially clear certainty about a subject. However, Whitehead (2008) states that in the absence of clear certainty the expert agreement that the Delphi process produces is more powerful than alternative sources as consensus processes such as focus groups. Jones and Hunter (1995) also describe the Delphi method as a valuable means of organizing a collective opinion.

In this research there was just one perspective from a user point of view which may have indicated that his/her views were in the minority. The user was part of the SEAN network therefore her views were actually very similar to the doctors and nurses and may not be considered to be genuinely representative of a user which did not enhance the validity of

the research findings. However, Powell (2003) cites Rowe (1994) who proposes that experts should be selected from different backgrounds so that there can be an assurance that there is a large foundation of knowledge would have been the initial thinking around including this user representative.

Bowles (1999) describes how the optimum panel size of the Delphi method has not been recognized but he cites Linstone and Turoff (1972) who recommend between 10 and 50 participants. Bowles (1999) states that the Delphi method makes it possible to confer with more personnel than could be brought together in another method which gained their views and opinions on a subject which improves upon the reliability of the method.

Parahoo (1997) discusses the difficulty of inadequate response rates, particularly in the latter stages of the process which sheds uncertainty on the agreement that is arrived at. In order to attempt to decrease this, the letter of information included the information that the results of the study would benefit the participants in their practice. Appreciation of the panel's participation was also given at every stage of the process. The level of drop out from the panel would also be continually observed and assessed if required in order to ascertain if it will affect the results of this stage of the research.

Huang et al (2008) concluded that their research which developed a fall - risk checklist using the Delphi technique had created a tool which was

valid as it had been formulated by reviewing literature and employing three rounds of the Delphi process with their panel. Therefore it was anticipated that the questionnaires developed by reviewing the literature surrounding informed consent and employing the expert panel in consecutive rounds of the Delphi process would create questionnaires on the statement of knowledge and roles and responsibilities that were valid.

Bowles (1999) suggests that Delphi studies should be followed up to ensure the validity and reliability of the method. It would be important to test the statement of knowledge and roles and responsibilities questionnaires created in this project in practice to ensure the validity and reliability of the method which would entail a further research project. This will be described at a later stage in this thesis.

In conclusion, this chapter has discussed the research design and the two stages of the research where the data will be gathered and then analysed in order to consider the aim and objectives of this research. A description of the data that were collected and analysed will be given next in chapter 5.

CHAPTER 5

Findings

This chapter will describe the findings from analyzing the data received in the first stage of the research which consisted of the ECT nurse questionnaire and the two rounds of the Delphi process. The Delphi process consisted of the Statement of knowledge that a patient is required to have to give full informed consent and the roles and responsibilities of medical and nursing staff in the informed consent process.

5.1 ECT Questionnaire Data

A total of 144 questionnaires were sent out to the ECT nurses in Scotland. This consisted of blanket mailing 6 questionnaires to the nurse in charge of each ECT department as the Ethical Committee did not think it was appropriate for hospitals to supply information relating to the staff employed there. 11 ECT nurse questionnaires were received back. Further letters and questionnaires were sent out to the sites that had not responded and one more questionnaire was received back which was a total response rate of 8%. Parahoo (1997) states that the difficulty with questionnaires is the unsatisfactory response rates. As also described by Parahoo (1997) perhaps the ECT nurses felt that they already had too much written work to do without filling in the questionnaire although the benefits of the project to their practice had been elaborated upon in the accompanying letter.

However a total of 9 out of 24 ECT sites responded to the questionnaire which is a percentage of 37.5 % of the total sites. This suggests a wider geographical coverage was actually obtained. However the actual figure of ECT nurses that were employed in Scotland was not available so it was impossible to calculate the actual sample size.

5.1.1 *Personal details*

In summary 50% of the participants were aged between 41 - 50 years old; 50% were RMN (Pre 1992); 41.7% had 0 - 5 years and 6 - 10 years experience as ECT Nurses respectively. 66.7% of the clinics treated between 0 - 5 patients on average in a week. Responses were received back from 7 NHS Trusts from the West, East and North of Scotland. A full description of the personal details of the ECT Nurses can be seen in table 1 (Characteristics of sample).

Table 1 Characteristics of sample

	Frequency	**Percent**
Age		
Valid 31 - 40 years	4	33.3
41 - 50 years	6	50
51 - 60 years	1	8.3
Total	11	91.7
Missing 999	1	8.3
Total	12	100
NMC Registration		
Valid RMN (Pre - 1992)	6	50
RMN (Project 20000	1	8.3
RMN + RGN	3	25
RMN + EN	1	8.3
Other	1	8.3
Total	12	100
Length of experience		
Valid 0 - 5 years	5	41.7
6 - 10 years	5	41.7
11 - 20 years	1	8.3
Total	11	91.7
Missing 999	1	8.3
Total	12	100

5.1.2 *Role of the nurse in the consent process*

The statements in this section considered the role of the nurse in the consent process.

66.7% (8) of the participants 'always' ensured that patients had been given sufficient verbal and written information to assist them in making an informed decision about receiving ECT while 25% (3) 'usually' did. 8.3% (1) 'sometimes' did.

66.7% (8) 'always' assisted in ensuring that the patient understands the nature, purpose and side effects of the treatment, while 16.7% (2) 'usually' did. 16.7% (2) 'sometimes' did.

Half of the participants appeared to consider that assisting in the assessment of the patient's decisional capacity and voluntarism was a main part of their role: (50% 'always' assisted in the assessment of the patient's decisional capacity to provide informed consent while 8.3% (1) 'usually' and 'sometimes' did.) Interestingly 16.7% (2) stated that they 'seldom' did and 8.3% (1) stated that they never did. 8.3% of the response was missing. The responses can be seen in table 2.

Table 2. Assessing patient's decisional capacity

		Frequency	Percent
Valid	Always	6	50
	Usually	1	8.3
	Sometimes	1	8.3
	Seldom	2	16.7
	Never	1	8.3
	Total	11	91.7
Missing	999	1	8.3
Total		12	100

This pattern was repeated when considering voluntarism; 50% 'always' assisted in assessing the patient's voluntarism to provide informed consent while 16.7% (2) 'usually' assisted. 16.7% (2) 'sometimes' did while 16.7% (2) of participants reported that they 'seldom' did. This can be seen in table 3.

Table 3. Assessing voluntarism

		Frequency	Percent
Valid	Always	6	50
	Usually	2	16.7
	Sometimes	2	16.7
	Never	2	16.7
	Total	12	100

A unanimous 100% of participants reported that they ensured that the patient giving informed consent had signed and dated the consent form. 91.7% (11) 'always' informed medical staff if a patient refused to go ahead with receiving ECT while 8.3 % (1) 'usually' did. 91.7 % (11) 'always' informed medical staff if a patient is unsure about receiving ECT while 8.3% (1) 'usually' did.

75% (9) 'always' assessed that the patients continued to consent to treatment on the basis of the information that was originally provided when the patient initially agreed to ECT while 16.7% (2) 'usually' did and 8.3% (1) 'sometimes' did. Judging by the percentage of positive responses there appeared to be quite a high standard of practice among the participants in this area of ensuring the continuity of the patient's consent.

75% (9) of the participants had written specifications about the role of the ECT nurse in the consent process in their workplaces while 16.7% (2) said that they did not. 8.3% (1) stated that they did not know if their work area had written specifications.

Included in the ECT nurse's response to what they considered their role in the consent process were the following comments:

> *"The ECT nurses have an important role with regard to consent as they will normally be the last person with whom the patient spends time prior to delivery of treatment".*

> *"I consider that the ECT nurse has a very important role to play as generally speaking she is the last person to have a dialogue with the patient before delivery of ECT. Also he/she has a full understanding of the process of assessing validity of consent and is competent to make firm decisions regarding the outcome of her assessments".*

These participants indicate that the ECT nurse is often the last person to spend time with the patient prior to ECT treatment taking place.

Some participants documented that the importance of their role in the informed consent process was ensuring the patient had access to written and verbal information.

> *"That the patient is aware of what they are consenting to."*

> *"Ensures that the patient is given both written and verbal information. Ensure patient understands the purpose/side effects of treatment. Assist in assessing the client's capacity to make an informed decision. Ensure consent is signed/dated. Liaise fully with the medical staff re. treatment/progress/problems".*

> *"We are here to protect the patient".*

> *"ECT nurse should be involved in checking ongoing consent process throughout treatment. I sometimes found that during early treatment sessions, although patient is consenting, they do not fully understand the process - due to current mental state".*

The evidence provided indicates that ECT nurses were aware of the importance of continuously ensuring that the patient is consenting to the treatment and also assessing their information requirements throughout the course of ECT, particularly due to the severity of the patient's illness.

The participants were asked to describe the nursing values that influenced a Mental Health nurse's ability to provide care for patients. It was noted that 33% (4) of the participants had left this whole question blank and 17% (2) of the participants had only answered the positive part of the question. However, 50% (6) of the participants had provided a response to both parts of the question.

The responses to the question which requested information on the nursing values which influenced the Mental Health nurse's ability to provide care in a positive and negative way included:

In a positive way

Building a good relationship with the patient in which the patient felt valued appeared to be important to one of the participants while another participant stated that valuing a patient as a unique person included procuring their informed consent prior to treatment.

> *"I believe the rapport developed with the patient provides a more in depth knowledge of mental state. Also builds trust with the patient".*

> *"Respect as individuals; obtain consent before treatment".*

Other responses to this question on positive nursing values included:-

> *"Good up to date knowledge; constructive feedback; team working; non-judgemental; patience and consideration; excellent communications".*

Judging from this type of response which appeared to be describing some of the skills a nurse should possess, rather than their values, approximately six of the participants had not appeared to completely understand the meaning of the question. However, five out of the eight nurses (63%) that responded to this question included the use of good communication skills and three out of the eight nurses also referred to

good listening skills which is considered to be part of the values base for mental health nursing which is included in the NES (2007) 10 essential shared capabilities which will be discussed at a later stage.

In a negative way

It appeared that the diagnosis of some patients influenced the Mental Health nurse's ability in a negative way in relation to providing care for them judging by this response from one ECT nurse:

> *"Thoughts re. certain 'illnesses' such as personality disorders, revolving door syndrome i.e. repeat of admissions for some patients".*

One participant also stated that the nurse's own beliefs about ECT could affect how the treatment is related to the patient which could affect their judgment on accepting the treatment or not.

> *"Nurses' personal opinion can depend how the treatment is described to patient thereby influencing decision".*

One participant replied that an attitude which is unjust and insensitive towards a patient affects the nurse's ability to provide care for patients in a positive way:

> *"Opposite to positive; unfair approaches (unequitable service); uncaring - lack of conscience".*

Finch (2005) outlines the importance in the nursing procedure surrounding ECT of the nurse forming a beneficial rapport with the patient with is focused on trust. The NMC (2004) Code of Conduct also states that

the nurse has a responsibility to look after and tend to the requirements of the patients in his/her care. Therefore the nurse should form a therapeutic rapport with all the patients in his or her care which is based on care and trust.

5.1.3 *Information that should be provided to patients pre ECT*

Participants were asked to rank in order of importance information that should be provided to patients who are considering the treatment of ECT. The order of importance the participants gave to each element of information can be seen in Table 4.

Table 4. Information on ECT

Information items	**Number of participants ranking an item**							
	1st	**2nd**	**3rd**	**4th**	**5th**	**6th**	**7th**	**8th**
The nature or ECT and why it has been prescribed	10							
Alternative treatments to ECT		6						
The reported benefits of ECT including short and long term side effects			5					
ECT requires the administration of a general anaesthetic and muscle relaxant				4				
Patient is aware they can withdraw their consent at any time					4			

The reported risks of ECT including short and long term side effects						4		
Treatment requires fasting prior to administering the anaesthetic							2	
The duration of an average course of treatment with ECT								1

The percentages were calculated cumulatively by adding together the first, second and third percentages which were given to each element by the participants. This was the importance that the participants gave to each element of information in ECT.

The elements of information including that the patient is aware they can withdraw consent at any time and the reported risks of ECT both gained the same percentage so their position was calculated on the 4th and 5th percentages gained therefore the patient is aware of the withdrawal gained a higher percentage based on this calculation.

It was surprising that the information concerning the patient being aware that he/she can withdraw their consent at any time was in fifth position as information regarding the informal patient's right to withdraw their consent was apparent in patient information guides such as those from The Royal College of Psychiatrists (1993) and SEAN (2000). Also the

reported risks of ECT came sixth in order of importance although the risks included in receiving ECT were documented in patient information from, for example, the Manic Depression Fellowship (1996) and the American Psychiatric Association (2004).

There was quite a marked difference in the percentages given to the information with the first statement on the nature of ECT receiving 83.3% (10) and the item rated eighth in importance, the element on the duration of a course of ECT, receiving just 8.3% (1) which would indicate a consensus of opinion on what elements the participants thought were important. However, a couple of the participants also replied that they had found the rating hard to do as they thought the information was equally important. This meant that only 10 participants had ranked the importance of the items of information overall which was quite a small sample.

The participants were asked if there was any other information that a patient should be aware of and one participant thought that other information that should be included consisted of information on the relapse rates and potential for further treatments. This is perhaps information that could be included at a further stage in the consent process.

The order of importance that the participants ranked the side effects that a patient should be aware of is included in Table 5.

Table 5. Side effects of ECT

Side effects	Number and percentage of participants ranking the item						
	1st	2nd	3rd	4th	5th	6th	7th
Confusion	9						
Memory loss		9					
Headaches			6				
Psychiatric complications				2			
Nausea					2		
Muscular stiffness						1	
Loss of appetite							1

The order of importance for the side effects was based on a combination of the participants first, second and third scores which were given to each item. This was converted into a percentage by the SPSS database. Both confusion and memory loss scored 75% (9) so the fourth score given by the participants was added resulting in confusion coming first with a combined score of 83.3% (10). Memory loss and confusion were side effects which were included in most of the patient information such as Central and North West London Mental Health NHS Trust (2003) Mayo Clinic (2004) and the American Psychiatric Association (2004) therefore it is understandable that the participants placed these side effects as first in importance. Headaches, which was placed third in importance by the participants, was also detailed in the patient information as mentioned above. Psychiatric complaints was rated as fourth in importance but was not a side effect described in the patient information sourced although it was detailed in the ECT good practice guide (CRAG, 1997). Physical complaints such as nausea and muscular stiffness were rated fifth and

sixth importance and was described in some of the patient information such as from the Mayo Clinic (2004) and the American Psychiatric Association (2004). Muscular stiffness and loss of appetite both received 8.3% (1) so the participants' fourth score was added which resulted in muscular stiffness being placed as sixth in importance and loss of appetite as seventh. However, loss of appetite had been added as a 'red herring' in the list of side effects.

The participants were given the opportunity to add any other side effect that they would like included but the only response gained was: *Loosen crowns/bridges, teeth*. It was not considered that this would be included as a side effect of ECT.

There was also a variation in the order of importance that the participants had given the side effects. Confusion and memory loss had received 75% while muscular stiffness and loss of appetite had received 8.3%. This provided evidence that the participants that did rate the side effects had clear ideas on the importance they placed on each side effect. Again, two of the participants had commented that they thought all the side effects should have equal importance therefore just ten of the participants had rated the importance of the side effects which was not a large sample as described before. However, the development of the statement of knowledge in the second stage of the research would provide further evidence of how the participants further rated the information and side effects that a patient should be provided in order to provide informed consent.

5.1.4 *Provision of consent*

The first question in the section examining the provision of consent asked the participants to consider how many patients in the participants' recent practice had not provided informed consent to ECT.

Table 6 illustrates the percentage of patients the participants perceived as not providing informed consent. Overall a total of 66.7% (8) of the participants thought that 1-25% and above patients had not given informed consent to the treatment.

Table 6. Percentage of patients perceived as not providing informed consent

		Frequency	**Percentage of patients perceived as not providing informed consent**
Valid	0%	4	33.3
	1 - 25%	5	41.7
	26 - 50%	2	16.7
	51 - 75%	1	8.3
	Total	12	100

Included in the participants main reasons for the patient not providing informed consent were the following comments:

> *"Lapse of time from having been seen by medical staff to having first ECT and obvious deterioration in mental state having occurred".*

This indicates the importance of informed consent being gained just prior to the treatment taking place as described by Caird and Worrall (2003)

Some participants indicated that the severity of patient's condition made them unable to give informed consent and this had also affected some patient's capacity to provide informed consent:

> *"The severity of the illness caused them to be unable to give informed consent."*
>
> *"Incapacity Act - confusion and disorientation - mood too low to take in information and make an informed choice".*
>
> *"Poor information provision to allow this. On some occasions, due to the patient's mental condition and capacity".*
>
> *"Elderly unable to consent".*

This participant's comment that the patient was "*Elderly unable to consent*" is different from the findings of Lapid et al's (2004) research. Lapid et al (2004) concluded that the elderly patients with severe depression in their study did have sufficient decisional capability to consent to ECT following the provision of further training.

When asked if they had reported a patient's lack of consent to ECT, 50% (6) said 'YES' and 8.3% (1) said 'NO'. 8.3% of the response was missing and 33.3% of the response was not applicable because four of the participants had stated their recollection that no patients had failed to give informed consent. The descriptions of what happened when it was thought that patients were not giving informed consent included the treatment being delayed until the patient was re-assessed and the implementation of the Mental Health (Care and Treatment) (Scotland) Act 2003:

"Patients given treatment under MHA after discussion with medical staff apart from on one occasion when whether the patient was able to consent was an issue".

"All patients were not given ECT on that day. Reassessed and ECT went ahead using M.H.A".

"The ECT Consultant was informed of poor information on occasions and misuse of detention (in my opinion) was highlighted".

When asked if they thought they had sufficient knowledge on elements of informed consent, 66.7% (8) of the participants 'strongly agreed' that they had sufficient knowledge on elements of informed consent such as the ongoing process, purpose and equitable nurse/patient relationship and 58.3% (7) 'strongly agreed' that they had sufficient knowledge, decisional capacity, patient's autonomy, providing sufficient information and ethics. One participant had replied that they were unsure of their knowledge of the elements of informed consent and added the statement "*Needs to be a better training process for ECT nurse".*

Participants did not disagree or strongly disagree with any of the statements that they had sufficient knowledge on any of the elements of informed consent. This is further illustrated in Table 7.

Table 7. ECT Nurses' perception of their knowledge of the elements of informed consent

	Strongly agree	**Agree**	**Unsure**
Ongoing process	66.7% (8)	25% (3)	8.3% (1)
Mental Health Act	50% (6)	41.7% (5)	8.3% (1)
Knowledge	58.3% (7)	25% (3)	16.7% (2)
Human rights	50% (6)	41.7% (5)	8.3% (1)
Decisional capacity	58.3% (7)	25% (3)	16.7% (2)
Patient's autonomy	58.3% (7)	33.3% (4)	8.3% (1)
Providing sufficient information	58.3% (7)	25% (3)	16.7% (2)
Purpose	66.7% (8)	16.7% (2)	16.7% (2)
Ethics	58.3% (7)	33.3% (4)	8.3% (1)
Equitable nurse/patient relationship	66.7% (8)	25% (3)	8.3% (1)

The participants were then asked to rate their perspective of the knowledge of student nurses (Table 8). The participants appeared more unsure of the knowledge that nursing students had as indicated in the differences between Table 7 and Table 8. For example 66.7% (8) were unsure if student nurses had knowledge of the ongoing process, human rights, providing sufficient information and purpose. 16.7% (2) of the participants also disagreed that the student nurses had knowledge of the ongoing process, Mental Health Act and providing sufficient information.

Table 8. ECT Nurses' perception of student nurses' knowledge of the elements of informed consent

	Strongly agree	Agree	Unsure	Disagree
Ongoing process	8.3% (1)	8.3% (1)	66.7% (8)	16.7% (2)
Mental Health Act	16.7% (2)	8.3% (1)	58.3% (7)	16.7% (2)
Knowledge	25% (3)	50% (6)	25% (3)	0
Human rights	16.7% (2)	16.7% (2)	66.7% (8)	0
Decisional capacity	8.3% (1)	33.3% (4)	50% (6)	8.3% (1)
Patient's autonomy	8.3% (1)	25% (3)	58.3% (7)	8.3% (1)
Providing sufficient information	8.3% (1)	8.3% (1)	66.7% (8)	16.7% (2)
Purpose	8.3% (1)	8.3% (1)	66.7% (8)	8.3% (1)
Ethics	16.7% (2)	16.7% (2)	58.3% (7)	8.3% (1)
Equitable nurse/patient relationship	16.7% (2)	16.7% (2)	50% (6)	8.3% (1)

The participants were then asked to rate their perception of the knowledge of medical staff in general. A slightly larger percentage of participants 'strongly agreed' that medical staff possessed sufficient knowledge compared with the knowledge of student nurses. Only 25% (3) 'strongly agreed' that they had sufficient knowledge of the Mental Health Act. Surprisingly 41.7% (5) were unsure and 16.7% (2) disagreed that medical staff had sufficient knowledge of providing sufficient information. 33.3% (4) were 'unsure' if medical staff had sufficient knowledge of the ongoing process, human rights, decisional capacity, patient's autonomy and an equitable doctor/ patient relationship.

One participant had replied that they were unsure of the knowledge of medical staff on each of the elements of informed consent. The

participants did not strongly disagree that the medical staff had sufficient knowledge of any of the elements of informed consent. This is further displayed in Table 9.

Table 9. ECT Nurses' perception of medical staffs' knowledge of the elements of informed consent

	Strongly agree	**Agree**	**Unsure**	**Disagree**
Ongoing process	16.7% (2)	41.7% (5)	33.3% (4)	8.3% (1)
Mental Health Act	25% (3)	58.3% (7)	16.7% (2)	0
Knowledge	25% (3)	41.7% (5)	25% (3)	8.3% (1)
Human rights	8.3% (1)	50% (6)	33.3% (4)	8.3% (1)
Decisional capacity	16.7% (2)	41.7% (5)	33.3% (4)	8.3% (1)
Patient's autonomy	8.3% (1)	50% (6)	33.3% (4)	0
Providing sufficient information	16.7% (2)	25% (3)	41.7% (5)	16.7% (2)
Purpose	33.3% (4)	33.3% (4)	25% (3)	8.3% (1)
Ethics	16.7% (2)	50% (6)	25% (3)	8.3% (1)
Equitable doctor/patient relationship	16.7% (2)	41.7% (5)	33.3% (4)	8.3% (1)

Although no direct comparison was made between the three groups of staff, overall the participants had rated their knowledge of the elements of informed consent more highly overall in the 'strongly agree', followed by the knowledge of medical staff and then nursing students. It was also noted that the ECT nurses did not report that they disagreed or strongly disagreed that they had sufficient knowledge of any of the elements of informed consent. However, they rated that they disagreed that nursing students and medical staff had sufficient knowledge of certain elements of

informed consent. The participants did not identify any other elements of informed consent that they would like included in the list.

The participants were asked if they had ever challenged medical staff prescribing treatment when they thought that a patient was not giving informed consent. 75% (9) of participant said that they had while 16.7% (2) said that they had not. 8.3% (1) of the response was missing. Included in the descriptions of this were:

> *"After discussion with nursing colleagues, Mental Welfare Commission and junior medical staff, the locum Consultant decided that the patient was able to give valid consent and I was told to document that I had expressed my concerns with regard to this person's ability to consent, but that the Consultant had made his decision".*

One participant documented the friction that occurred between the referring consultant psychiatrist and the ECT nurse when the nurse reinforced the patient's consent status to them:

> *"Prescribing consultant said I had: "talked patient out of having ECT." I had only pointed out that she did not (have to) have it if she didn't want, as she was informal and consenting. Patient had no further ECT, consultant still hates me".*

These responses would indicate that some of the participants do speak up for the patient and represented them when they considered that they were not providing informed consent. Another participant describes how she discovered that a patient was not giving informed consent and appeared to have been coerced into having the treatment. However, CRAG (1997) states that no type of coercion should be employed to influence patients to receive ECT treatment at any time.

"Patient had consented and then implied to me that she would be taken under duress".

On occasion providing further information and clarification may be sufficient for a patient to provide informed consent:

"Medical staff further explored the matter and patient did give informed consent".

"More information was provided".

The participants were asked to consider if medical staff had ever appeared to be coercing patients into having ECT. 41.7% (5) of participants considered that medical staff at times appeared to be coercing a patient into having ECT while 41.7% (5) said that they had not seen this. 16.7% (2) said that they didn't know. If the participant had considered that he/she had seen a member of medical staff coerce a patient into having ECT, the descriptions given for this included:

"Again referred my concerns to ECT consultant [psychiatrist] where he then would discuss case with referring medical team."

"Patient was refused at clinic".

One participant described how coercion may have been used to try and persuade the following patient to give his/her consent to treatment:

"The information provided was: "It will make you better".

However, using persuasive techniques to try to get a patient to accept treatment could also be interpreted by the patient as being coercive as described by the Mental Welfare Commission (2003).

In contrast to this only 8.3% (1) of participants considered that nursing staff had coerced a patient into having ECT while 58.3% (7) said that they had not. This indicates a marked difference in the nurses' perception of nurses and medical staff with regards to coercion. There was a meaningful response of 33.3% (4) of the nurses who answered that they did not know. One participant described what had happened which could also be viewed as a coercive action:

> *"By pointing out eventual benefits thereby persuading patient this was the best course of action".*

Practitioners may think that persuading a patient to accept ECT is appropriate but the patient may see this as coercion.

One participant who had replied 'Don't know' replied:

> *"Unsure as staff I have personally observed have referred the patient to myself".*

This participant was unsure if nursing staff had coerced a patient into having ECT as it appears that the staff had referred the patient to her for further assessment.

5.1.5 *Confirmation of consent*

In this section when examining consent, the first question asked the participant to confirm when the patient's consent to ECT was confirmed. 83.3% (10) of participants considered that a patient's consent was confirmed after every treatment. 16.7% (2) of the participants responded with comments that emphasized that consent should be confirmed prior to ECT:

"Surely before each treatment".

Another participant had stroked out 'after' each treatment and written in 'before'. One participant had ticked 'after every treatment' and added in 'before treatment' also. Having noted these comments, the wording of this statement may have caused some of the participants difficulty and the participants' comments were very useful. The piloting process of this research, as described by Oppenheim (1992), had not picked up on how this statement could have been worded more clearly.
Another participant had added in:

"Ensuring that they are 'happy' to continue with treatment".

The participants were then asked to consider how often a patient's consent was reviewed. This is different to the previous question of confirming consent as this statement seeks to ascertain how often that medical staff review the patient's consent status whereas the confirmation

of consent is an action that could be performed by practitioners prior to the treatment proceeding. 25% (3) of participants considered that a patient's consent to ECT is reviewed after every treatment while 41.7% (5) considered that it was reviewed after each second treatment. 25% (3) had responded 'other' and included comments such as:

"Surely before each treatment".

"I'm not sure as this is done by prescribing doctor".

Another participant had replied that the patient's consent is reviewed 'after every treatment' by staff and 'after each second treatment' by medical staff. This is further described in table 10.

Table 10. Review of patients' consent

	Frequency	**Percentage**
After every treatment	3	25 (3)
After each second treatment	5	41.7(5)
Other	3	25 (3)
Total	11	91.7(11)
Missing	1	8.3 (1)
Total	12	100 (12)

The participants were asked to consider when a detained patient's consent to ECT was reviewed. A table of the responses can be seen in table 11. 41.7% (5) of participants considered that when a detained patient doesn't consent to ECT for whatever reason the patient's consent is reviewed after every treatment while 33.3% (4) considered that their consent status is

reviewed after each second treatment. 16.7% (2) replied 'other' and included comments such as:

"Surely after each treatment".

"Immediately".

Table 11 Review of detained patients' consent

	Frequency	**Percentage**
After every treatment	5	41.7(5)
After each second treatment	4	33.3 (4)
Other	2	16.7 (2)
Total	11	91.7(11)
Missing	1	8.3 (1)
Total	12	100 (12)

5.1.6 *Patient's capacity to provide consent*

Participants were asked to consider the assessment of the cognitive function of the patient receiving ECT by the referring team. 66.7% (8) of the participants replied that the cognitive assessment of patients receiving ECT is 'always' assessed by the prescribing team while 8.3% (1) replied that it is 'usually' assessed. 16.7% (2) replied that it is 'sometimes' assessed by the prescribing team. 8.3% (1) replied that they didn't know. A table describing the responses can be seen in table 12. Participants described the method of assessment that took place in their area as including the Mini Mental State Examination and Questionnaire test. Other participants replied:

"Multi-disciplinary - liaison with ECT team."

"I presume it's feedback from nurses, a multidisciplinary team approach and review of orientation, time and date during interviews etc".

"Assessment of cognitive function - by prescribing team - a brief questionnaire on problems with memory, concentration, confusion, psychosis, anxiety, performed day before and day after treatment".

Table 12 Assessment of cognitive function of patient by referring team

	Frequency	**Percent**
Always	8	66.7 (8)
Usually	1	8.3 (1)
Sometimes	2	16.7 (2)
Other	1	8.3 (1)
Total	12	100 (12)

The participants were asked to confirm if the cognitive assessment of patients was assessed in the treatment centre by the ECT team as indicated in table 13. Participants replied that the cognitive assessment of patients is 'always' assessed in the treatment centre by the ECT team 50% (6) of the time, 'sometimes' 8.3% (1) of the time, 'seldom' 8.3% (1) of the time and 'never' 25% (3) of the time. 8.3% of the response was missing. The description of this included:

"Short ten question memory test done by nursing staff prior to ECT and after".

"Small memory testing before and after each treatment for every patient".

"Following treatment, question on time, date, place, orientation etc".

"Assessment of cognitive function - by ECT team - completed by ward staff but paperwork checked by ECT nurse prior to session. Any noted deviation from documentation pointed out to medical staff".

Four participants replied that the cognitive function assessment of the patients was completed both at ward level and at the ECT clinic.

Table 13 Assessment of cognitive function by ECT team

	Frequency	**Percent**
Always	6	50 (6)
Sometimes	1	8.3 (1)
Seldom	1	8.3 (1)
Never	3	25 (3)
Total	11	91.7 (11)
Missing	1	8.3 (1)
Total	12	100 (12)

There appeared to be some variation between the cognitive function of patients being assessed between the referring team and the ECT team with 66.7% of the referring team 'always' assessing the cognitive function of the patient while 50% of the ECT team 'always' assessed the cognitive function.

When asked what happens if, at any stage of the patient's treatment, it becomes apparent that giving informed consent cannot be recalled, participants replied:

"Consent would be revisited".

"I'm not aware that this has happened but in this case I would liaise with both medical referring team and ECT consultant to discuss this. If I was unable to discuss this in between, treatment would have to be postponed or ask ECT consultant to review the patient prior to ECT (even if on the morning of treatment). This issue would have to be addressed prior to treatment continuing".

"Dr re-approaches and patient signs consent form to confirm before each treatment".

One participant described how he/she would use their status as the ECT nurse to ensure that the patient was providing informed consent:

"As an ECT nurse I would insist on having consent status reviewed".

The practice of reviewing the patient's capacity to provide informed consent was explored in this section. The ECT nurses provided evidence that most ECT departments used the MMSE to assess cognitive function and there was some variation whether this took place in the referring ward or in the ECT centre or both. Most participants stated that if the patient cannot recall giving informed consent during the treatment course their consent would be reassessed by either the ECT team or the referring team.

5.2 Delphi Questionnaire data

5.2.1 *First round responses*

60 invitations were sent out to ECT staff within the SEAN network and the user representative to participate in the Delphi process. 13 informed consent forms were returned from the original 60 e-mails. A reminder letter was sent out after two weeks to let staff know there was still time to participate in the study and a further four informed consent forms were received. The expert panel consisted of 5 ECT consultant psychiatrists, 11 ECT nurses (nurses that worked in ECT suites) and the participant giving a user perspective from Depression Alliance Scotland. Staff from 9 of the 22 ECT sites in Scotland that were contacted took part which was a total of 41% of the ECT sites.

The panel was made up of 16 members of staff from 6 different health boards in the north, west, east and south of Scotland.

5.2.2 *Statement of Knowledge*

Two participants had just completed the questionnaire up to statement 4 on alternative treatments. A consensus of 75% and over (12 or more panel members) was gained in 10 out of the 26 statements relating to the response 'very applicable' in the first round. This is a total of 38% of the statements in the statement of knowledge. The collation of responses to the statement of knowledge can be seen in Table 14.

Table14. Statement of knowledge - first round results

1. The nature of ECT	Very applicable	Applicable	Not Applicable
• ECT involves the administration of a mild, controlled electric current which is passed across the head via the application of electrodes for a few seconds resulting in a seizure	82% (14)	17% (3)	
• It is the seizure activity that can assist in the correction of the chemical imbalance in the brain that is thought to be the cause of depression	65% (11)	35% (6)	
2. Why ECT is prescribed			
• For severe depressive illness that has not responded to a number of different treatments	94% (16)	5% (1)	
• Antidepressant treatment has had to be discontinued due to side effects	47% (8)	47% (8)	
• For a depressed person who is not eating or drinking adequately or has suicidal feelings	88% (15)	11% (2)	
• A patient has responded well to ECT in the past	70% (12)	29% (5)	
3. ECT and consent			
• An informal patient can withdraw their consent to ECT at any stage during the treatment	94% (16)	5% (1)	
• No type of coercion should be used at any time to coax a patient to have ECT	70% (12)	5% (1)	23% (4)
• The patient remains completely entitled to have alternative treatments if they have refused ECT	82% (14)	17% (3)	
• If someone is unsure about consenting to the treatment they can request independent advice from places such as the Advocacy service or the Mental Welfare Commission	70% (12)	23% (4)	5% (1)

	Very applicable	Applicable	Not Applicable
• The patient's consent should be verified prior to each ECT treatment	94% (16)	5% (1)	
4. Alternative treatments to ECT Consist of treatments such as antidepressant therapy or psychological treatments such as counselling	70% (12)	23% (4)	5% (1)
5. Effectiveness • In Scotland, there was a particular improvement in three - quarters of people treated with ECT for depressive illness. (SEAN, 2000)	58% (10)	29% (5)	
• ECT can be quick acting with benefits being recognized after 2 - 3 treatments	41% (7)	47% (8)	
• In some instances, such as when a patient is acutely suicidal or is refusing to eat or drink, ECT can be life saving	64% (11)	23% (4)	
6. Anaesthetic and muscle relaxant Prior to receiving ECT the patient will receive a short acting general anaesthetic and muscle relaxant via an intravenous injection	76% (13)	11% (2)	
7. Reported risks **Short term** Side effects that can occur include short term memory loss and confusion; headaches; nausea and muscular stiffness and psychiatric complications. **Long term**	76% (13)	11% (2)	
• A small number of patients have complained of longer term memory loss for events that have occurred before, during and after	64% (11)	23% (4)	

	Very applicable	Applicable	Not applicable
the treatment • It is difficult to comprehend how much of the memory loss is the result of severe depression or ECT	58% (10)	29% (5)	
Medical complications Patients with ongoing health problems have an increased possibility of cardiac or respiratory difficulties occurring proceeding the treatment	29% (5)	41% (7)	11% (2)
Mortality rate The practice of ECT comprises a low risk with an associated mortality rate reported to be comparable with anaesthesia administered in minor surgery	58% (10)	29% (5)	
8. Fasting requirements ECT is given under a general anaesthetic so the patient should not eat six hours prior to or drink fluids four hours prior to the treatment	70% (12)	17% (3)	
9. Duration of an average course • The average course of ECT consists of around six treatments up to approximately twelve treatments.	70% (12)	17% (3)	
• ECT is usually administered twice a week.	82% (14)	5% (1)	
10. Physical examination • Each patient receives a physical examination prior to receiving ECT in order to ensure that they are fit enough to receive a general anaesthetic.	76% (13)	5% (1)	5% (1)
• The physical examination includes a blood test, ECG and chest x- ray where indicated.	70% (12)	11% (2)	5% (1)

None of the statements gained 100% consensus in the first round. The participants had achieved a consensus of opinion of 75% or above on the

statements included in the elements of informed consent which included the nature of ECT; why ECT is prescribed; ECT and consent; anaesthetic and muscle relaxant; reported risks; duration of an average course of ECT and physical examination. A consensus was not achieved in the sections on alternative treatments; effectiveness; anaesthetic and muscle relaxant and fasting requirements.

The participants provided very useful qualitative comments on the statements, some of which were collated and added to the statements in the questionnaires for the second round of the Delphi process. These comments and how they were included in the statements used in round two can be seen in appendix 11.

5.2.3 *Roles and responsibilities of medical and nursing staff in the informed consent process in ECT*

The second questionnaire in this phase of the research contained statements on the roles and responsibilities of medical and nursing staff in the informed consent process in ECT. The participants were requested to give their response to the statements whether they regarded the statement as desirable, essential or not applicable.

In the medical role a consensus of 75% and over was gained in 23 out of 32 of the statements relating to the response 'essential' which is a total of 72% of the statements. 100% consensus was gained in 11 out of the 32

statements at this stage. 9% of the responses were missing in the following two statements in the medical role:

> *The patient's voluntary informed consent is confirmed by the referring psychiatrist.*

> *The psychiatrist obtaining informed consent from the patient has sufficient knowledge of the nature, purpose and effects of ECT.*

A collation of the results of the roles and responsibilities of medical staff can be seen in Table 15.

Table 15. Roles and responsibilities of medical staff - first round results

The patient's decisional capacity is assessed by the referring psychiatrist to ensure informed consent is valid.	**Desirable**	**Essential** 100%	**Not Applicable**
The patient's voluntary informed consent is confirmed by the referring psychiatrist		100%	
To ensure that the patient understands the nature, purpose and consequences of receiving the treatment and therefore what the patient is consenting to.		100%	
When ECT is considered the best treatment option for a patient but due to their mental state they are unable or unwilling to give consent then action under the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2002 is employed and a doctor from the Mental Welfare Commission provides a second opinion		100%	
Ensuring that the relevant documentation regarding the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2002 has been completed and is available for inspection		100%	
An equitable relationship is formed with the informal patient so that the decision to receive ECT is made jointly between the patient and the treating psychiatrist	53% (9)	41% (7)	6% (1)
The patient is aware of alternative treatments and that these would be available if they decide to refuse ECT	11% (12)	88% (15)	
The informal patient is made aware that he or she can withdraw their consent to ECT at any time		100%	

Ensuring that the patient is aware that a consequence of not receiving the treatment may be a prolonged and increasingly severe phase of the illness	**Desirable** 35% (6)	**Essential** 59% (10)	**Not Applicable**
The patient and the treating psychiatrist sign the informed consent form just prior to the ECT course commencing in order to record the consultation and decision which has taken place recently	41% (7)	53% (9)	6% (1)
All discussions and decisions taken relating to obtaining informed consent are documented in the patient's case notes	17% (3)	82% (14)	
A patient who is unsure about consenting to ECT will be aware that they can have access to independent advice or a second opinion from advocacy service or the Mental Welfare Commission	23% (4)	70% (12)	6% (1)
The psychiatrist obtaining informed consent from the patient has sufficient knowledge of the nature, purpose and effects of ECT	6% (1)	94% (16)	
Ensuring that coercion is not employed at any time in order to persuade the patient to have ECT	12% (2)	82% (14)	6% (1)
Relatives/carers should be involved in discussions regarding the treatment unless issues of patient confidentiality prevents this.	82% (14)	17% (3)	
When a patient has lost the capacity to provide informed consent to ECT or refuse the treatment any advance statements regarding treatment choices should be taken into account	47% (8)	53% (9)	
In an emergency situation, where a patient's life is at risk, ECT can be given as soon as it can be organised, preferably with a second opinion given by a local Consultant Psychiatrist	12% (2)	82% (14)	6% (1)

Each individual patient is provided with sufficient verbal, written and/or audio information in order to enable her or him to make the decision whether to give informed consent to ECT or not	**Desirable** 6% (1)	**Essential** 94% (16)	**Not Applicable**
Information previously given about ECT is brought to the patient's attention at different intervals during the course of treatment	53% (9)	41% (7)	6% (1)
Information necessary for the decision making process should not be withheld from the patient unless in exceptional circumstances when the practitioner can justify that disclosing the information would have a detrimental effect on the patient	23% (4)	65% (11)	6% (1)
If information has been withheld from the patient this requires to be documented in the patient's case notes as there may be a necessity to justify this decision at a later date	17% (3)	82% (14)	
The patient should have sufficient time, as far as possible, without being subject to pressure to reflect on the information prior to making a decision about consenting to ECT	17% (3)	82% (14)	
Patients' questions about ECT should be answered as truthfully and fully as possible		100%	
The patient's understanding of the information provided to him or her about ECT should be confirmed prior to the signing of the informed consent document		100%	
In consenting to ECT the patient's understanding of the side effects and risks of receiving ECT should be confirmed		100%	
The patient is aware of the purpose and intended benefits of ECT including the probability of success	6% (1)	94% (16)	

The patient is made aware that the treatment includes receiving an anaesthetic and muscle relaxant	**Desirable**	**Essential** 100%	**Not Applicable**
The patient's relatives/carers are provided with information about ECT in order to facilitate informed discussion in the decision making process	70% (12)	29% (5)	
When information is refused by a patient this should be documented in the patient's case file/care plan.	17% (3)	82% (14)	
The patient's informed consent is verified prior to each ECT treatment.	6% (1)	94% (16)	
The detained patient's competence to give informed consent is continuously assessed throughout the course in order to determine if they have the capacity to give informed consent	6% (1)	94% (16)	
The validity of the consent form and other relevant Mental Health legislation documentation is continuously reviewed throughout the course in case the patient's consent status has changed and the documentation requires to be amended		100%	

The participants' qualitative comments to the roles and responsibilities questionnaire were reviewed and incorporated into the second round of questionnaire as detailed in appendix 12.

5.2.4 *Nursing role*

The participants were also requested to give their responses to the statements in the nurse's role in the informed consent process by considering if each statement was desirable, essential and not applicable.

In the nursing role consensus was gained in 14 out of 31 statements relating to 'essential' which is a total of 45% of the statements. One participant had not completed the nursing role part of the questionnaire and another participant's response was not complete. The participants' responses to the nurse's role and responsibilities can be seen in Table 16.

Table 16. Nurse's role and responsibilities - first round results

	Desirable	**Essential**	**Not Applicable**
The nurse assists the referring psychiatrist in assessing the patient's decisional capacity to ensure that informed consent is valid	17% (3)	76% (13)	
The nurse assists the referring psychiatrist in confirming that the patient is giving voluntary informed consent	35% (6)	59% (10)	
The nurse assists the referring psychiatrist in ensuring that the patient understands the nature, purpose and consequences of receiving the treatment and therefore what the patient is consenting to	29% (5)	65% (11)	
To understand the application of the Mental Health Act in relation to ECT and the provision of nursing care in ECT when it is administered without the patient's consent.	12% (2)	82% (14)	
Ensuring that the relevant Mental Health legislation documentation regarding the Mental Health (Care and Treatment) (Scotland) Act 2003 or Adults with Incapacity (Scotland) Act 2002 has been completed and is available	17% (3)	76% (13)	
An equitable relationship is formed with patients in order to enable them to be part of the decision making process leading to their making an informed decision about accepting ECT or not	29% (5)	65% (11)	
The patient is aware of alternative treatments and that these would be available in the event that he or she chooses not to accept ECT	23% (4)	70% (12)	
The informal patient is made aware that they can withdraw their consent to ECT at any time	6% (1)	88% (15)	

The nurse should act as an advocate for the patient considering ECT, evaluating any concerns and referring them to the relevant member of the multidisciplinary team	**Desirable** 29% (5)	**Essential** 59% (10)	**Not Applicable** 6% (1)
Ensuring that the patient is aware of the possible risks involved of choosing not to receive treatment is that this may lead to a prolonged and increasingly severe phase of illness although their informed choice should be respected	41% (7)	35% (6)	12% (2)
The nurse ensures that the informed consent form has been signed by the RMO and patient prior to the ECT course commencing in order to record the consultation and decision which has recently taken place	12% (2)	76% (13)	6% (1)
Any discussions and decisions relating to informed consent are documented in the patient's case notes/care plan	12% (2)	82% (14)	
The nurse understands the nature, purpose and effects of ECT	6% (1)	88% (15)	
Ensuring that coercion is not employed at any time in order to persuade the patient to have ECT	17% (3)	70% (12)	6% (1)
A patient who is unsure about consenting to ECT will be aware that they can have access to independent advice or a second opinion from an advocacy service or the Mental Welfare Commission.	23% (4)	70% (12)	
In an emergency situation when a patient's life is at risk the nurse assists in the administration of ECT to the patient as directed by Medical staff	12% (2)	76% (13)	6% (1)
Each individual patient is provided with sufficient verbal, written and/or audio information in order to enable them to make an informed decision about whether or not to accept ECT.	17% (3)	76% (13)	

The nurse arranges for the patient to visit the ECT suite if he or she would like to	**Desirable** 59% (10)	**Essential** 35% (6)	**Not Applicable**
Information previously given about ECT is brought to the patient's attention at different intervals during the course of treatment	23% (4)	65% (11)	6% (1)
The patient should have sufficient time without being subject to pressure to reflect on the information prior to making a decision about consenting to ECT	17% (3)	76% (13)	
Patient's questions should be answered truthfully and fully and where the nurse is unable to answer a question this should be referred to the treating psychiatrist	17% (3)	70% (12)	
The patient's understanding of the information provided to him or her about ECT should be confirmed prior to the completion of the informed consent document	17% (3)	70% (12)	
In consenting to ECT the patient's understanding of the side effects and risks of receiving ECT should be confirmed	12% (2)	76% (13)	
The patient is aware of the purpose and intended benefits of ECT including the probability of success	17% (3)	70% (12)	
The patient is made aware that the treatment includes receiving an anaesthetic and muscle relaxant	17% (3)	70% (12)	
The patient's relatives/carers are provided with information about ECT in order to facilitate informed discussion in the decision making process when possible	65% (11)	23% (4)	
When information is refused by a patient this should be documented in the patient's case file/care plan.	23% (4)	65% (11)	
The patient's informed consent is verified prior to each ECT treatment	6% (1)	82% (14)	

If the patient is unsure or refuses to give consent to ECT this is accepted and the treating psychiatrist is informed of this decision so that the patient's consent status and the continuation of the treatment can be reviewed.	**Desirable** 6% (1)	**Essential** 76% (13)	**Not Applicable** 6% (1)
The nurse assists in the assessment of the detained patient's competence to give informed consent continuously throughout the course in order to determine if they have regained capacity to give informed consent	29% (5)	59% (10)	
The validity of the consent form and other relevant Mental Health legislation documentation is continuously reviewed throughout the course in case the patient's consent status has changed and the documentation requires to be amended	12% (2)	76% (13)	

The participants had no additional comments to add to the nurse's role in informed consent in the questionnaire. The second round would show if the participants would change their views that only 45% of the statements were viewed as 'essential'.

5.2.5 *Second round of Delphi process*

The comments from the first round were incorporated into the questionnaires for the second round of the Delphi process. The statement of knowledge questionnaire can be seen in appendix 13 and roles and responsibilities questionnaires can be seen in appendix 14. These questionnaires, a letter of explanation (appendix 15), results of the first round (Tables 14, 15, 16) and the references that informed the development of the questionnaire were e-mailed to the 17 participants. A reminder e-mail was also sent out after two weeks. 11 participants sent back questionnaires giving a response rate of 65% of the original panel.

This consisted of a mixed group of 4 ECT consultants, 6 ECT nurses and the participant giving a user perspective from Depression Alliance (Scotland).

In the second round the responses were received from panel members from 5 different health boards in the north, west, south and east of Scotland and from the member of the panel who was from the Depression Alliance (Scotland).

Four responses were received two months after the data had been analyzed and due to time constraints could not be followed up and included in the study. There was no communication gained from the other two participants who did not participate in the second round. Two of the other participants in the panel in the second round had not completed the statement of knowledge so another copy of the questionnaire was sent to them. One questionnaire was received back.

It was decided that two rounds of the Delphi process was adequate as consensus of 75% and over had appeared to have been gained in a satisfactory number of the statements. 72% of the statements in the statement of knowledge, 75% in the medical role and 56% in the nursing role. Also, a third round would have been difficult to facilitate due to the time constraints of the study. There had been a large decrease in qualitative comments which could be construed as the panel agreeing with the wording of the statements. There were nine qualitative comments received back in connection with the roles and responsibilities from two

participants and three were received back about the statement of knowledge from three participants. There was also the anxiety that participants may no longer participate in the Delphi process if another round was proposed (Whitehead, 2008), judging by the 4 participants that had not responded in time and the 2 participants from the panel that had not responded to the second round.

5.2.6 *Statement of knowledge*

The participants were asked to rate the revised statement of knowledge in the second round. One participant did not complete the questionnaire and a response was left blank to the section on alternative treatments concerning psychological treatments. A consensus of 75% and above was gained in 21 out of 29 of the statements in the second round relating to the response of 'very applicable' This was a total consensus of 72% of the statements compared to the 38% consensus gained in the first round. 8 out of the 29 statements had a 100% consensus to the response of 'very applicable'. This can be seen in Table 17.

Table 17. Statements gaining consensus in Statement of Knowledge

Rounds	**Consensus ≥75%**	**Consensus 100%**
First round responses	38%	0
Second round responses	72%	27.5%

Table 18 indicates the scores given to the statements by the participants in the second round.

Table 18. Statement of knowledge - second round results

1. The nature of ECT	**Very applicable**	**Applicable**	**Not Applicable**
• ECT involves the administration of a mild, controlled electric current which is passed across the head via the application of electrodes for a few seconds resulting in a seizure	90% (9)	10% (1)	
• It is the seizure activity that can assist in the correction of the chemical imbalance in the brain that is thought to be the cause of depression	50% (5)	50% (5)	
2. Why ECT is prescribed			
• For severe depressive illness that has not responded to a number of different treatments	90% (9)	10% (1)	
• Antidepressant treatment has had to be discontinued due to side effects	40% (4)	60% (6)	
• For a depressed person who is not eating or drinking adequately or has suicidal feelings	100%		
• A patient has responded well to ECT in the past	80% (8)	20% (2)	
3. ECT and consent			
• An informal patient can withdraw their consent to ECT at any stage during the treatment	100%		
• No type of coercion should be used at any time to coax a patient to have ECT	80% (8)	10% (1)	10% (1)
• The patient remains completely entitled to have alternative treatments if they have refused ECT	100%		
• All patients, particularly those unsure about consenting to ECT will be aware that they can have	90% (9)	10% (1)	

access to independent advice from an advocacy service or additional information from organizations such as Depression Alliance (Scotland) • The patient's consent should be verified prior to each ECT treatment	**Very applicable** 100%	**Applicable**	**Not applicable**
4. Alternative treatments to ECT Consist of treatments such as:- • antidepressant drug therapy • Psychological treatments such as counselling, psychotherapy or Cognitive Behavioural Therapy in a person who is able to tolerate these approaches	80% (8) 60% (6)	20% (2) 30% (3)	
5. Effectiveness • In Scotland, there was a particular improvement in three - quarters of people treated with ECT for depressive illness. (SEAN, 2000) • ECT can be quick acting with benefits being recognized after 2 - 3 treatments • In some instances, such as when a patient is acutely suicidal or is refusing to eat or drink, ECT can be life saving	60% (6) 60% (6) 80% (8)	40% (4) 40% (4) 20% (2)	
6. Anaesthetic and muscle relaxant Prior to receiving ECT the patient will receive a short acting general anaesthetic and muscle relaxant via an intravenous injection	100%		
7. Reported risks **Short term** Side effects that can occur include:- • short term memory loss and confusion; headaches; nausea and muscular stiffness	100%		

	Very applicable	Applicable	Not applicable
• psychiatric complications such as manic illness	70% (7)	30% (3)	
• prolonged seizures	60% (6)	40% (4)	
Long term			
• A small number of patients have complained of longer term memory loss for events that have occurred before, during and after the treatment	80% (8)	20% (2)	
• It is difficult to comprehend how much of the memory loss is the result of severe depression or ECT	80% (8)	20% (2)	
Medical complications			
Patients with ongoing health problems have an increased possibility of cardiac or respiratory difficulties occurring following the treatment	40% (4)	60% (6)	
Mortality rate			
The practice of ECT comprises a low risk with an associated mortality rate reported to be comparable with anaesthesia administered in minor surgery - 2 per 100,000 treatments (CRAG, 1997)	80% (8)	20% (2)	
8. Fasting requirements			
ECT is given under a general anaesthetic so the patient should not eat six hours prior to or drink fluids four hours prior to the treatment	90% (9)	10% (1)	
9. Duration of an average course			
• The average course of ECT consists of around six treatments up to approximately twelve treatments.	80% (8)	20% (2)	
• ECT is usually administered twice a week.	100%		

10. Physical examination	**Very applicable**	**Applicable**	**Not applicable**
• Each patient receives a physical examination prior to receiving ECT in order to ensure that they are fit enough to receive a general anaesthetic.	100%		
• The physical examination includes a blood test, ECG and chest x- ray where indicated.	90% (9)	10% (1)	

Statements that did not achieve the 75% consensus in the response of 'very applicable' included:

The nature of ECT

50% (5) of the panel responded that it was very applicable that it is the seizure activity that can assist in the correction of the chemical imbalance in the brain that is thought to be the cause of depression'.

Why is ECT prescribed?

40% (4) of the panel thought that it was very applicable that 'antidepressant treatment has had to be discontinued due to side effects'.

Alternative treatments to ECT

60% (6) of the panel thought that psychological treatments were very applicable. The wording in this statement had changed in round two as a response to the participants' comments.

Effectiveness

60% (6) of the panel thought that it was very applicable that there was a particular improvement in three quarters of people treated with ECT for a depressive illness and ECT can be quick acting with benefits being recognized after 2 - 3 treatments.

Reported risks

Short term

The following statements on short term risks had been included in the second round following the suggestion of a participant in the first round but had not received a consensus from the panel:

70% (7) of the panel thought that it was very applicable that a psychiatric complication such as manic illness was included.

60% (6) of the panel thought that it was very applicable that prolonged seizures were included.

The wording in the statement on medical complications had been changed following participants suggestions in the first round but did not receive consensus from the panel in the second round. However, the response did increase from 29% in the first round to 40% in the second round.

The wording in the following statements had also been changed following participants comments in round one and the statements had then achieved a consensus in round two.

Alternative treatments to ECT

The consensus for antidepressant therapy had increased from 70% in the first round to 80% consensus in the second round.

Reported risks

Mortality rate

The consensus had increased from 58% in the first round to 80% in the second round.

Included in the participants qualitative responses in the second round were:

ECT and consent

No type of coercion should be used at any time to coax a patient to have ECT

One participant had answered 'not applicable' to this statement but had unfortunately not qualified his/her response.

Other information that participants had included in their qualitative response that they would like added to the statement of knowledge in the second round included adding a statement regarding the affects of unilateral and bipolar ECT and also the observation of the patient for 18 hours after treatment as this may restrict their activities. It was decided that this could be information that could be related to patients at a later stage rather than information that should be included in the ten statements.

The statements that did receive consensus in the second round included:-

1. The nature of ECT ECT involves the administration of a mild, controlled electric current which is passed across the head via the application of electrodes for a few seconds resulting in a seizure
2. Why is ECT prescribed • For severe depressive illness that has not responded to a number of different treatments • For a depressed person who is not eating or drinking adequately or has suicidal feelings • A patient has responded well to ECT in the past
3. ECT and consent • An informal patient can withdraw their consent to ECT at any stage during the treatment • No type of coercion should be used at any time to coax a patient to have ECT • The patient remains completely entitled to have alternative treatments if they have refused ECT • The patient remains completely entitled to have alternative treatments if they have refused ECT • All patients, particularly those unsure about consenting to ECT will be aware that they can have access to independent advice from an advocacy service or additional information from organizations such as Depression

Alliance Scotland

- The patient's consent should be verified prior to each ECT treatment

4. Alternative treatments to ECT

Consist of treatments such as:-

Antidepressant drug therapy

5. Effectiveness

In some instances, such as when a patient is acutely suicidal or is refusing to eat or drink, ECT can be life saving

6. Anaesthetic and muscle relaxant

Prior to receiving ECT the patient will receive a short acting general anaesthetic and muscle relaxant via an intravenous injection

7. Reported risks

Short term

Side effects that can occur include:-
Short term memory loss and confusion; headaches; nausea and muscular stiffness

Long term

- A small number of patients have complained of a longer term memory loss for events that have occurred before, during and after the treatment

- It is difficult to comprehend how much of he memory loss is the result of severe depression or ECT

Mortality rate

The practice of ECT comprises a low risk with an associated mortality rate reported to be comparable with an anaesthesia administered in minor surgery - 2 per 100,000 treatments (CRAG, 1997)

8. Fasting requirements ECT is given under a general anaesthetic so the patient should not eat six hours prior to or drink fluids four hours prior to the treatment
9. Duration of an average course • The average course of ECT consists of around six treatments up to approximately twelve treatments. • ECT is usually administered twice a week
10. Physical examination • Each patient receives a physical examination prior to receiving ECT in order to ensure that they are fit enough to receive a general anaesthetic. • The physical examination includes a blood test, ECG and chest x-ray where indicated

5.2.7 *Roles and responsibilities of medical and nursing staff*

A consensus of 75% and above was gained in 27 out of 36 of the statements in the medical role as to what is 'essential' which is a total of 75% consensus compared to 72% in the first round. 7 statements had 100% consensus to the response of 'essential', 19% in total in the second round which is compared with 11 statements, 34% in the first round.

In the nursing role a consensus of 75% and above was gained in 19 out of the 34 statements as to what was considered 'essential' which is a total of 56% consensus compared to 45% in the first round. 6 statements had 100% consensus to the response of 'essential' which is 18% in total in the second round compared to none of the statements having 100% consensus in the first round.

Table 19 describes the consensus achieved in the statements in the roles and responsibilities questionnaire.

Table 19 Statements gaining consensus in roles and responsibilities questionnaire

Rounds	**Consensus ≥75%**	**Consensus 100%**
First round - medical role responses	72%	34%
Second round - medical role responses	75%	19%
First round - nursing role responses	45%	0
Second round - nursing role responses	56%	18%

The total number of statements that reached consensus in the medical and nursing role combined was 46 out of a possible number of 70 statements achieved consensus which is a total of 66% of the statement in the second round.

In the "questionnaire" about medical roles and responsibilities, responses were missing from the statements - "the patient's voluntary informed consent is confirmed by the referring psychiatrist" and "the psychiatrist obtaining informed consent from the patient has sufficient knowledge of the nature, purpose and effects of ECT". A collation of the responses can be seen in Table 20.

Table 20. Medical role - responses to second round

The patient's decisional capacity is assessed by the referring psychiatrist to ensure informed consent is valid	**Desirable**	**Essential** 100%	**Not Applicable**
The patient's voluntary informed consent is confirmed by the referring psychiatrist		91% (10)	
The psychiatrist administering ECT confirms that the patient is giving voluntary consent prior to each treatment proceeding	27% (3)	73% (8)	
To ensure that the patient understands the nature, purpose and consequences of receiving the treatment and therefore what he or she is consenting to.		100%	
When ECT is considered the best treatment option for a patient but due to their mental state they are unable or unwilling to give consent then action under the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2002 is employed and a doctor from the Mental Welfare Commission provides a second opinion		100%	
Ensuring that the relevant documentation regarding the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2002 has been completed and is available for inspection		100%	

An equitable relationship is formed with the informal patient so that the decision to receive ECT is made jointly between the patient and the Responsible Medical Officer (RMO).	**Desirable** 36% (4)	**Essential** 64% (7)	**Not Applicable**
An equitable relationship is formed with the patient detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 so that the decision to receive ECT is made jointly between the patient and RMO	64% (7)	27% (3)	9% (1)
The patient is aware of alternative treatments and that these would be available if he or she decided to refuse ECT	9% (1)	91% (10)	
The informal patient is made aware that he or she can withdraw their consent to ECT at any time		100%	
The patient detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 who is assessed to have the capacity to give informed consent is made aware that they can withdraw their consent to ECT at any time	9% (1)	91% (10)	
Ensuring that the patient is aware of the possible risks involved in choosing not to receive the treatment; that this may lead to a prolonged and increasingly severe phase of illness, although their informed choice should be respected	27% (3)	73% (8)	
The patient and the RMO sign the informed consent form prior to the ECT course commencing in order to record the consultation and decision which has recently taken place		91% (10)	9% (1)

All discussions and decisions taken relating to obtaining informed consent are documented in the patient's case notes	**Desirable** 9% (1)	**Essential** 91% (10)	**Not Applicable**
All patients will be aware that they can have access to independent advice from an advocacy service or additional information from organisations such as Depression Alliance Scotland	18% (2)	82% (9)	
If a patient appears unsure about receiving ECT they should be given the opportunity to address their concerns and the possible benefits of the treatment should be reiterated in order to ensure that the patient has the information necessary to inform their decision	9% (1)	91% (10)	
The psychiatrist obtaining informed consent from the patient has sufficient knowledge of the nature, purpose and effects of ECT		91% (10)	
Ensuring that coercion is not employed at any time in order to persuade the patient to have ECT	18% (2)	82% (9)	
When possible the patient's relatives/carers are provided with information about ECT in order to facilitate informed discussion in the decision making process when the patient has given their consent to their involvement in their treatment	64% (7)	36% (4)	
When a patient has lost the capacity to provide informed consent to ECT or refuse the treatment any advance statements regarding treatment choices should be taken into account	27% (3)	73% (8)	

In an emergency situation, where a patient's life is at risk, ECT can be given as soon as it can be organised with a second opinion given by a local Consultant Psychiatrist	**Desirable** 9% (1)	**Essential** 73% (8)	**Not Applicable** 9% (1)
Each individual patient is provided with sufficient verbal, written and/or audio information in order to enable her or him to make the decision whether to give informed consent to ECT or not	9% (1)	91% (10)	
Information previously given about ECT is brought to the patient's attention at different intervals during the course of treatment	82% (9)	18% (2)	
Information necessary for the decision making process should not be withheld from the patient unless in exceptional circumstances when the practitioner can justify that disclosing the information would have a detrimental effect on the patient	18% (2)	82% (9)	
If information has been withheld from the patient this requires to be documented in the patient's case notes as there may be a necessity to justify this decision at a later date	18% (2)	82% (9)	
The patient should have sufficient time, as far as possible, without being subject to pressure to reflect on the information prior to making a decision about consenting to ECT	9% (1)	91% (10)	
Patients' questions about ECT should be answered as truthfully and fully as possible		100%	

The patient's understanding of the information provided to him or her about ECT should be confirmed prior to the signing of the informed consent document	**Desirable** 9% (1)	**Essential** 91% (10)	**Not Applicable**
In consenting to ECT the patient's understanding of the side effects and risks of receiving ECT should be confirmed	9% (1)	91% (10)	
The patient is aware of the purpose and intended benefits of ECT including the probability of success	9% (1)	91% (10)	
As far as possible the patient should be advised of bilateral or unilateral electrode placement and the final choice of electrode placement should be the outcome of a proportionate appraisal of the risks and benefits between the patient and medical practitioner	45% (5)	55% (6)	
The patient is made aware that the treatment includes receiving an anaesthetic and muscle relaxant	9% (1)	91% (10)	
When information is refused by a patient this should be documented in the patient's case file/care plan.	9% (1)	91% (10)	
The patient's informed consent is verified prior to each ECT treatment by the referring team	18% (2)	82% (9)	

The detained patient's competence to give informed consent is continuously assessed by the referring team throughout the course in order to determine if he or she has the capacity to give informed consent	**Desirable** 18% (2)	**Essential** 82% (9)	**Not Applicable**
The validity of the consent form and other relevant Mental Health legislation documentation is continuously reviewed throughout the course in case the patient's consent status has changed and the documentation requires to be amended		100%	

There will be further discussion on those statements which did or did not reach consensus in the next chapter.

The responses given to the new statements in the questionnaire that were added in the second round of the Delphi process as a result of the participants' comments; the effect of the change in wording of the statements to the response and the statements that received a non applicable response are included in appendix 16.

The table of the collated responses to items about the nurse's role in the "roles and responsibilities in informed consent" section is as follows in Table 21.

Table 21. Nurse's role - responses to second round

The nurse assists the referring psychiatrist in assessing the patient's decisional capacity to ensure that informed consent is valid	**Desirable** 36% (4)	**Essential** 55% (6)	**Not Applicable** 9% (1)
The nurse assists the referring psychiatrist in confirming that the patient is giving voluntary informed consent	45% (5)	55% (6)	
The nurse assists the referring psychiatrist in ensuring that the patient understands the nature, purpose and consequences of receiving the treatment and therefore what the patient is consenting to	45% (5)	55% (6)	
To understand the application of the Mental Health Act in relation to ECT and the provision of nursing care in ECT when it is administered without the patient's consent.		100%	
Ensuring that the relevant Mental Health legislation documentation regarding the Mental Health (Care and Treatment) (Scotland) Act 2003 or Adults with Incapacity (Scotland) Act 2002 has been completed and is available		100%	
An equitable relationship is formed with the informal patient in order to enable him or her to be part of the decision making process leading to their making an informed decision about accepting ECT or not	27% (3)	73% (8)	
An equitable relationship is formed with the patient detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 in order to enable them to be part of the decision making process where possible, leading to their making an informed decision about accepting ECT or not	36% (4)	55% (6)	9% (1)

The patient is aware of alternative treatments and that these would be available in the event that he or she chooses not to accept ECT	**Desirable** 18% (2)	**Essential** 82% (9)	**Not Applicable**
The informal patient is made aware that they can withdraw their consent to ECT at any time	18% (2)	82% (9)	
The patient detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 who is assessed to have the capacity to give informed consent is made aware that his or her consent to ECT may be withdrawn at any time	18% (2)	82% (9)	
The nurse should act as an advocate for the patient considering ECT, evaluating any concerns and referring these to the relevant member of the multidisciplinary team	18% (2)	82% (9)	
Ensuring that the patient is aware of the possible risks involved of choosing not to receive treatment is that this may lead to a prolonged and increasingly severe phase of illness although their informed choice should be respected	55% (6)	45% (5)	
The nurse ensures that the informed consent form has been signed by the RMO and patient prior to the ECT course commencing in order to record the consultation and decision which has recently taken place	9% (1)	82% (9)	9% (1)
Any discussions and decisions relating to informed consent are documented in the patient's case notes/care plan	18% (2)	82% (9)	

The nurse understands the nature, purpose and effects of ECT	**Desirable**	**Essential** 100%	**Not Applicable**
Ensuring that coercion is not employed at any time in order to persuade the patient to have ECT	27% (3)	73% (8)	
All patients will be aware that they can have access to independent advice from an advocacy service or additional information from organisations such as Depression Alliance Scotland.	27% (3)	73% (8)	
If a patient appears unsure about receiving ECT an opportunity to address their concerns should be given and the possible benefits of the treatment should be reiterated in order to ensure that the patient has the information necessary to inform their decision	27% (3)	73% (8)	
In an emergency situation when a patient's life is at risk the nurse assists in the administration of ECT to the patient as directed by Medical staff		100%	
Each individual patient is provided with sufficient verbal, written and/or audio information in order to enable him or her to make an informed decision about whether or not to accept ECT.	18% (2)	82% (9)	
The nurse arranges for the patient to visit the ECT suite if he or she would like to	91% (10)	9% (1)	

Information previously given about ECT is brought to the patient's attention at different intervals during the course of treatment	**Desirable** 36% (4)	**Essential** 64% (7)	**Not Applicable**
The patient should have sufficient time without being subject to pressure to reflect on the information prior to making a decision about consenting to ECT	9% (1)	91% (10)	
Patient's questions should be answered truthfully and fully and where the nurse is unable to answer a question this should be referred to the treating psychiatrist	9% (1)	91% (10)	
The patient's understanding of the information provided to him or her about ECT should be confirmed prior to the completion of the informed consent document	27% (3)	73% (8)	
In consenting to ECT the patient's understanding of the side effects and risks of receiving ECT should be confirmed	27% (3)	73% (8)	
The patient is aware of the purpose and intended benefits of ECT including the probability of success	18% (2)	82% (9)	
The patient is made aware that the treatment includes receiving an anaesthetic and muscle relaxant	18% (2)	82% (9)	

When possible the patient's relatives/carers are provided with information about ECT in order to facilitate informed discussion in the decision making process when the patient has given their consent to their involvement in their treatment	**Desirable** 73% (8)	**Essential** 27% (3)	**Not Applicable**
When information is refused by a patient this should be documented in the patient's case file/care plan.		100%	
The patient's informed consent is verified prior to each ECT treatment		100%	
If the patient is unsure or refuses to give consent to ECT this is accepted and the treating psychiatrist is informed of this decision so that the patient's consent status and the continuation of the treatment can be reviewed.	9% (1)	91% (10)	
The nurse assists in the assessment of the detained patient's competence to give informed consent continuously throughout the course in order to determine if they have regained capacity to give informed consent	27% (3)	73% (8)	
The validity of the consent form and other relevant Mental Health legislation documentation is continuously reviewed throughout the course of treatment in case the patient's consent status has changed and the documentation requires to be amended	9% (1)	91% (10)	

19 of the nurse's role statements received consensus as 'essential' in the second round. The statements receiving consensus and not receiving a consensus will be discussed in the next chapter.

This chapter has described the analysis of the data and findings which were received from the questionnaires in the two stages of the research. The findings will now be discussed in Chapter six.

CHAPTER 6

Discussion of findings

6.1 Introduction

This chapter discusses the findings of the ECT nurse's questionnaire which examined their perception of their role in the consent process and the development of the statement of knowledge base that a patient is required to have to give full, informed consent and the roles and responsibilities of medical and nursing staff in the informed consent procedure. The strengths and weaknesses of the study and conclusions will also be discussed along with a summary of recommendations.

6.2 Research question

The findings of the study provided information which addressed the research question which inquired what knowledge base are patients required to have in order to provide full informed consent to ECT? Information received from the ECT nurse questionnaire informed the development of the "Statement of knowledge" which was used in the Delphi process. The "Statement of knowledge" is a tool that, with further development could be used in practice to ensure that the patient is providing informed consent to each ECT treatment.

6.3 Aim and objectives

The literature review and methods applied provided information which informed the research aim that set out to explore the nature, indication and processes of informed consent in patients receiving ECT. This was achieved by reviewing the literature on informed consent which included the concept of consent, healthcare and consent, nurses and consent and ECT and consent. Data was also gathered by performing the objectives which explored the ECT nurse's role in the consent process and assessed the knowledge base that patients required to have in order to provide informed consent.

6.4 The ECT nurse's role in the consent process

6.4.1 *Personal details*

There appeared to be a good level of practice experience from the nurses who participated in the study. 33% of the nurses were 'E' grades and 41.7 % were 'F' grades. 42% of the nurses had worked 0-5 years as an ECT nurse and 41.7 % had worked 6-10 years. 66.7% of the nurses stated that 0 - 5 patients on average were treated in a week in their ECT suite. Gass (1998) concluded from his research that a higher standard of knowledge seemed to be connected with the duration of practice of the nurse so perhaps this level of practice experience contributed to the rich data that were received back from the ECT nurses which was very useful in informing the study.

6.4.2 *Role of the nurse in the consent process*

There were a high percentage of positive responses to the nurse's role in the consent process, some of which are described in ECT good practice statements such as CRAG (1997) and Finch (2005). These aspects of the role include 100% of the nurse participants who reported that they ensured the consent form is signed and 91.7% who reported that they informed medical staff if a patient refused or was unsure about receiving the treatment. This would appear to indicate that the participants had a very good understanding of the ECT good practice literature as described previously with regards to these aspects of their role.

The part of the role which appeared next in importance in terms of the percentages of responses from the ECT nurses was ensuring that the patient continued to consent to treatment on the basis of the information that was originally provided which gained 75% of the response. Caird and Worrall (2003) stated that ECT clinic staff should ensure that the patient continues to give their authorized consent prior to each treatment while Usher and Arthur (1998) also present that the nurse should frequently include and discuss the procedure with their patients.

Only 66.7% of the nurses reported that they 'always' ensured that the patient had received sufficient verbal and written information to assist them in making an informed decision about receiving ECT although Finch (2005), Flint (2005) and Culas et al (2003) all illustrate the importance of the nurse's role in this area. It is also essential that practitioners such as

nurses are providing information to patients when earlier studies such as Pippard and Ellam (1981) state that 87% of patients received no written description of ECT in the hospitals in Britain that they surveyed the practice of ECT in.

Freeman and Kendall (1980) describe how patients in an earlier project (Freeman et al, 1978) had been given complete information but had appeared to forget this. In addition, CRAG (1997) described how service user groups felt that patients did not receive enough information about the treatment. Therefore, repeating the information before, during and after the treatment would be beneficial to the patient's comprehension. The Manic Depression Fellowship Scotland (1996) patient information leaflet also describes how the patient due to have treatment may be too ill to be able to take in much information and encourages relatives, carers or trained staff to help the patient understand the contents as much as is possible. They include that the individual may want to read the information on ECT when they have recovered sufficiently. Therefore the nurse should ensure the patient has access to information at all stages of their treatment.

CRAG (1997) included information from service user groups such as the Scottish Association of Mental Health (SAMH) which stated that SAMH disputed the quality of the information that was being offered to patients and therefore the patients' capability of providing informed consent. They suggested a second opinion and advocacy for all patients receiving ECT.

Only 66.6% of the nurses 'always' assisted in ensuring that the patient understood the nature, purpose and side effects of the treatment. Scholefield (1997) states that if the practitioner is involved in the consent process, they must ensure the patient understands this information. Finch (2005) also describes how the nurse should ensure that this information has been understood. Therefore more training and education should occur so that the nurses had a better awareness of their role in assisting in this aspect of the consent procedure.

Only 50% of the participants 'always' assisted in assessing the patient's decisional capacity to provide informed consent. The NMC (2004) and Cable (2003) both specify that the nurse should ensure that in gaining consent to give any treatment the nurse must ensure the patient is capable of giving consent under the law. An example of this could be how the ECT nurse informally ensures the patient is giving consent to the treatment by making sure the patient is willing to be escorted to the treatment room. Cable (2003) states that it is important that the nurse confirms that the patient understands what he/she has provided consent to therefore it is essential that the nurse ensures the patient has the decisional capacity to provide informed consent to any procedure that he/she is assisting with.

Just 50% of the participants 'always' assisted in assessing the patient's provide informed consent voluntarily. The NMC (2006) describes how the nurse should ensure that consent is provided voluntarily in order for it to

be considered legitimate. Cable (2003) also points out that consent should be given voluntarily, without coercion.

33% of the participants did not answer the question on the nursing values that influence a Mental Health nurse's ability to provide care. 17% of the participants had left the part of the question which asked the participants to consider the nursing values that influenced a Mental Health Nurse's ability to provide care for patients in a negative way blank. It was also noted that in the pilot of the questionnaire one of the participants had left the whole question blank and one had left the question on the negative values blank but it was considered at this time that a larger sample would provide more response. Perhaps it was the wording in the question which caused some confusion. Oppenheim (1992) submits that the researcher should remember the problem the participants could experience in comprehending the question. However, 50% of the participants in the main part of the research gave complete responses to the question although approximately 50% of all responses also included nursing skills rather than values although some responses included both skills and values.

NHS Education for Scotland (NES) (2007) states that the theory supporting the Mental Health (Care and Treatment) (Scotland) Act 2003 could be viewed as clarifying in legal terms some of the principles that should support the practitioner's performance in mental health. NES (2007) also describes the values declaration developed by the expert committee included in the Rights, Relationships and Recovery: the report

of the national review of mental health nursing in Scotland (SEHD, 2006). This statement included reference to professional relationships such as the importance of ensuring that constructive practicing associations maintained by an excellent communication technique are at the centre of the practitioner's performance. One of the participants supplied the following comment regarding the nursing values that she considered influenced a Mental Health nurse's ability to provide care for patients in a positive way:

> *"I believe the rapport developed with the patient provides a more in depth knowledge of mental state. Also builds trust with the patient".*

Another participant replied:

> *"Respect as individuals; obtain consent before treatment".*

The SEHD's (2006) declaration of principles that underpin mental health nursing includes 'respect' as one of the variety of principles that individuals should have and included the importance of positioning the principles of the specific person at the heart of practice (NES, 2007). NES (2007) also describes how the practitioner should practice in alliance with the client and place importance on the client being their equivalent with regards to their treatment.

One participant had identified this negative value which could affect the nurse's ability to provide care for the patient:

> *"Nurses' personal opinion can depend* [affect] *how the treatment is described to patient thereby influencing decision".*

This was an important point as the nurse's part in the information provision is an important role as described by Finch (2005) who states that the nurse should ensure that the patient understands the information about the treatment. The NMC (2004) and ICN Code of Ethics as described by Fry and Johnstone (2002) also recommend that the nurse should ensure the patient receives sufficient information to confirm their informed consent to treatment. Gass (2006) describes the importance of the nurse providing information particularly when the patient is apprehensive about receiving the treatment and further information and reassurance could effect the patient's conclusion to receive treatment. However, Byrne et al (2006) concluded that some mental health nurses had shortfalls in their lack of awareness of ECT which could affect the referring team's recommendation of the treatment. The Nursing Times News (1983) reported how student nurse Dee Kraaij was dismissed and two other students resigned in a hospital in Hertfordshire because they refused to accompany patients to ECT. Dee Kraaij stated in the interview that she did not think ECT was ethically justified and she did not want to participate in the treatment. Keen (2000, p.18) also argued that nurses should not be forced to engage in "this controversial treatment". However, Parsons (2000) countered that nurses should not be entitled to decline to participate in ECT because ECT is an accepted therapy which can be very efficient in the treatment of severe depression and that a nurse's denial to take part would mean that the nurse was discarding her duty to care. Therefore, the nurse's values with respect to ECT as a

treatment and the information they impart to patients should be informed by their knowledge on the subject. An appraisal of the current provision of instruction surrounding ECT is justified as recommended by Byrne et al (2006) to ensure that nurses have the necessary knowledge and skills to provide information to patients in the informed consent process surrounding ECT.

Additional training on the 10 essential shared capabilities as set out by NES (2007) should also be incorporated into the ECT nurses continuing professional development (CPD) programme in order to build on the values that they already hold so that they are practising in accordance with the theories and principles that support the Mental Health (Care and Treatment) (Scotland) Act 2003. This training would also be useful to add to the ECT consultants' CPD programme.

The evidence from this study shows that the participants perceived that the most important part of their role in the consent process was that of an administrative checking role. Other participants added that they perceived their role as protecting the patient, therefore ensuring the patient's autonomy and enabling informed consent. Also, a participant perceived that, as often being the last person to spend time with the patient, the nurse may identify last minute issues involved with the consent process. Another participant stated that part of the role is that of verifying that consent is ongoing throughout the treatment course (Finch, 2005).

6.4.3 *Information that should be provided to patients*

There was a clear difference between the weighting given to the statements by participants concerning the information that should be provided to patients. The first most important according to participants - 'the nature of ECT and why it has been prescribed', received 83.3% and the statement that participants thought was least important- 'the duration of an average course of ECT', received 8.3%. This would indicate that there was a consensus from the participants as to the level of importance they would place on the items of information they would provide to patients. However, a couple of participants stated that they found it difficult to rank the information as they thought it was all equally important. Therefore, strong conclusions can not be drawn from this part of the research due to the size of the sample and also the nature of ranking-type questions, which force ordering which may be false because it may not reflect the participants' actual views. However, this could be ascertained in future research.

The important principles in providing information to patients who are going to receive ECT include assessing the patient's information requirements on an individual level as described by the GMC (1998) and information being given as an ongoing process before, during and after treatment in the author's opinion, so that all aspects of the information can be offered. Rose et al (2005) also state that information on ECT should be reiterated until the patient has understood it appear to be the important principles in providing information to patients. It appears that

individual patients may require different aspects of the information in the statement at different times in their course of treatment. For example the nature of ECT and why it has been prescribed may be an important element of information to ensure the patient is aware of at the beginning of their treatment whereas the duration of the average course of treatment with ECT may be information a patient would like to know further on in the course.

The order of importance that the participants gave to the side effects that the patient should be aware of in order to provide informed consent placed the main cognitive side effects of confusion and memory loss as most important. The physical side effects were rated next in importance with the exception of psychiatric complaints which was rated fourth in importance. There was a marked difference in the percentage that participants had given the side effects with confusion and memory loss both scoring 75% in the first instance and the 'red herring', loss of appetite scoring 8.3%. As with the elements of information, this would appear to indicate that participants were quite clear of what side effects they thought were most important although two participants (17% of the sample) stated that it was difficult to rate them as they felt they had the same importance and left the question blank.

The data gained in this section on information that should be provided to patients considering having treatment with ECT were very useful in informing the statement of the knowledge base that a patient is required to have to give full, informed consent in the Delphi phase of this research.

It was interesting to note that most of the statements from the information that could be provided to patients and also the side effects that could occur which were adapted from the ECT nurse questionnaire and included in the statement of knowledge reached a consensus. The only original statement from the ECT questionnaire that did not receive consensus in the second round of the project was psychiatric complaints.

6.4.4 *Provision of consent*

In total 67% of the participants considered that patients in their practice were not giving informed consent to receive ECT while 33% stated that none of their patients were providing informed consent. Therefore, according to the assessment of participants, it would appear that quite a high percentage of patients were not providing informed consent. Rose et al (2005) concluded from their research on patient's perspectives on the information provision and consent procedures surrounding ECT that the patients who received it found that the information and consent process were unsatisfactory.

As noted earlier, some patients referred for ECT could be suffering from cognitive impairment due to the severity of their illness and may have difficulty comprehending the information provided to them (Kashka and Keyser 1995). There is also evidence in the past that patients were not being provided with sufficient information from research, such as in studies by Freeman et al (1980), Pippard and Ellam (1981) and more recently Rose et al (2005) as above. The participants in this research

indicated that this is still occurring. Lapid et al's (2004) conclusions from their study, which included the significance of organizing teaching sessions for elderly patients who did have restricted comprehension of the treatment, could be integrated into practice in ECT with all patients suffering from cognitive impairment in order to increase their capacity to provide informed consent. It is also essential that the practitioner (this could be the nurse or doctor) ascertains that the information that is provided to patients to inform their decision is comprehended by them on an ongoing basis (Rose et al, 2005). Therefore the patient receiving ECT should be assessed before, during and after ECT treatment during the course to ensure that they have understood and retained the information regarding ECT to ensure they are giving full, informed consent to each ECT treatment. NHS Education for Scotland (NES) (2007) describes the ten fundamental collective skills for mental health practice which include performing in alliance with the patient. They continue that in order to do this, practitioners should employ individuals as associates in their own therapy in an approach which increases their part in determining the outcomes and executing their preferences.

The participants fed back their accounts of the practice which had occurred when they considered that patients were not giving informed consent. This practice included postponing treatment until the patient was reassessed by the multidisciplinary team and the utilization of the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2000 as described by Barnes et al (2005) which would appear to follow good practice guidelines.

According to the ECT nurses' responses to the question on the elements of informed consent, the ECT nurses had the largest percentage of responses in the 'strongly agree' category with one element receiving 50%, five elements receiving 58.3% and three elements receiving 66.7%. The ECT nurses' perception of the nursing student's knowledge contained five elements receiving 8.3% in the 'strongly agree' category, 4 elements gaining 16.7% and one element gaining 25%. The ECT nurses' perception of the medical staff's knowledge was that two elements received 8.3%, five elements gained 16.7% and two elements gained 25%. According to these percentages it would appear that the ECT nurses perceived that their overall knowledge of the elements of informed consent was best followed by the knowledge of medical staff and then nursing students. However, Chada et al's (2004) research concluded that although all healthcare staff in their study required to enhance their understanding and skills in the consent procedure, doctors' knowledge was predominantly more advanced to that of the nurses and ODPs that took part in the project. Byrne et al (2006) also determined that the nursing group in their research had a less satisfactory knowledge of ECT in general than the psychiatrists, anaesthetists and medical students who completed their questionnaire. They also concluded that nursing students had a better knowledge than qualified nurses.

On reflection, the research question did not differentiate between the knowledge of medical staff in the multidisciplinary teams or ECT clinic although the original purpose of this part of the research was to ascertain the ECT nurses' opinions of the knowledge of the medical staff in the

multidisciplinary teams. It had been expected that this objective would be achieved in the second stage of the project which proposed to evaluate medical and nursing staff's knowledge and understanding of the principles of informed consent, but that stage did not occur.

The results indicated in particular that the ECT nurses were largely 'unsure' whether medical staff had sufficient knowledge of providing sufficient information to patients in the informed consent process and a few participants 'disagreed' that medical staff provided sufficient information. However, as previously discussed, the GMC (1998) stated that doctors must ensure that patients have been provided with enough information, in a manner that they can comprehend, in order to make it possible for them to execute their entitlement to arrive at informed judgements regarding their treatment. Coulter et al's (1999) study evaluated the patient information available for ten common conditions and treatments. They organised reviews of 54 of the materials provided by organisations such as self help groups, NHS trusts and professional bodies. The reviews were carried out by 62 patients with their own knowledge of the particular conditions and 28 medical or academic professionals who were accustomed with the accessible study information. Coulter et al (1999) concluded that doctors may at times be deficient in their knowledge of treatment options and their outcomes. This may therefore affect the patient's ability to give informed choices due to the lack of quality information given. Coulter et al (1999) state that patients in their study had required much more information than they were actually given. Included in the recommendations that they made to the

NHS Executive were that all doctors were to be given instruction in communication techniques and procedures to support joint decision making.

Sharma et al (2003) conducted a prospective audit of patients who were having elective orthopaedic surgery in order to determine how meaningfully patients were consented at a busy teaching hospital. A questionnaire evaluating the standard of information provided to patients and their general contentment with the method of informed consent was distributed to 76 patients directly after they had given informed consent to go through an operation. The results illustrated that although patients were regularly given insufficient information about the procedure such as how alternative treatment choices were only considered with 42% of patients (Sharma et al, 2003), 99% of patients felt that the amount of information provided was about right and enabled them to reach an informed decision. Sharma et al (2003) suggested that there needs to be a means of enabling patients to have as much information as they want on an individual basis and this could be achieved by providing a sequence of written information sheets comprising of an increasing standard of detail. Primarily patients could be given the basic information and if additional information was requested then it could be given. Coulter et al (1999) also assert that information should be pertinent and evidence based in a design that is suitable and beneficial to patients.

Research such as studies by Gass (1998) and Culas et al (2003) also concluded that healthcare staff's knowledge of ECT in general did require

improving. Pippard (1992) concluded that most nurses gained their expertise by practising with knowledgeable staff and this would appear to be mostly relevant to the present training of ECT nurses. One participant replied to the question asking if they thought that they had sufficient knowledge on the elements of ECT that there *"needs to be better training process for ECT nurses*". The participant also stated the same about nursing students and that she did not know what college provided for students. It would appear from this research that ECT nurses, nursing students and medical staff all require more training surrounding the elements of informed consent although further research would be useful to further ascertain the knowledge of medical and nursing staff in this area.

It is evident from the ECT nurses' replies that a large percentage of them had challenged medical staff prescribing the treatment when they thought that the patient was not giving informed consent. This is similar to Clarke's (1995) description, that the nurse should have an attitude of supporting the patient and acting as an intermediate between the patient and medical staff in the consent process. Judging from the participants' qualitative comments, as previously described, of how they had defended their patients when they did not perceive that they were providing consent that was informed, then this would appear to be the role that is taking place in practice.

The participants perceived marked differences between the occasions when they thought medical staff and nursing staff appeared to be coercing

patients into having ECT. More research would need to be carried out in order to establish if a wider range of participants had the same perceptions of the difference between nursing and medical staff with regard to the possible coercion of patients. It should be noted that participants in this study had not offered many descriptions of what had happened when they thought a patient had been coerced into treatment.

One participant described what had happened when she had considered that a doctor had been coercing a patient into having ECT and had told the patient that "*It will make you better*". This is similar to Kashka and Keyser's (1995) description of how a nurse's words, which had probably been said in order to comfort the patient, could be understood to be coercive. It would appear that both doctors and nurses have been noted to have employed coercion in order to persuade the patients in their care to accept ECT. However, O'Brien and Golding (2003) assert that practitioners do not use coercive actions due to the fact that they choose to operate in this way. Nevertheless, O'Brien and Golding (2003) submit that coercion takes place more than it should. Lutzen's (1998) qualitative study examined subtle coercion in mental health practice. This was done by collecting data from unstructured interviews which were held with ten British nurses who had extensive practise in mental health nursing. Lutzen (1998) submits that in circumstances where nurses perceive that coercive measures are essential, they state that these measures are morally difficult. Lutzen (1998, p.104) gives an example of this by describing an interview with a nurse who was using the gentle method of "persuading" a patient. This was described as attempting to bring about the client's

comprehension, but this action was not successful and the team required to employ substantial pressure to ensure he did not run away from the ward. The nurse described this as very onerous. Rose et al (2005) also described how a third of the patients in their study felt that they had been coerced into having the treatment and patients had included reasons such as lack of information about the treatment or having felt pressed into it by medical staff. O'Brien and Golding (2003) outline how coercive actions are comparatively frequent in psychiatry. They also state that in psychiatric practice it is often considered that the expectation to respect the patient's autonomy is not exercised due to the belief that the ideal of valuing self-determining judgements is only relevant to capable judgements. Therefore, because they are psychiatric patients, they have an absence of capacity so staff are at liberty to coerce them for their own benefit.

It was also interesting to note that many of the ECT nurses didn't know if nursing staff had coerced patients into having the treatment. The only reason given for this was by one participant who stated *"Unsure as staff I have personally observed have referred the patient to myself."* Perhaps this was so that, as ECT nurse, she could assist in the assessment of the patient's consent status.

It would appear from the responses to this part of the study that both medical and nursing staff's awareness of the ethical consequences of their interactions with patients should be increased so that the patient always signs the consent form on an informed and voluntary basis. Therefore more training should be available for practitioners on this aspect of the

informed consent process. This is an area which would benefit from additional research to further ascertain practitioner's perceptions of the coercion of patients in the informed consent process in their practice.

6.4.5 *Confirmation of consent*

83.3% of the participants replied that the patient's consent was confirmed after every treatment during the course of ECT. This means that the patient's consent was confirmed prior to the next ECT treatment being administered. This would have indicated that good practice was taking place at the ECT centres where the participants worked. However, 41.7% of the participants replied that most informal patient's consent is reviewed after every second treatment. The Scottish ECT Accreditation Network (SEAN) have created an ECT database for ECT centres in Scotland which requires medical staff to enter on the programme that they have reviewed the patient's consent after every second treatment which may account for this response from participants. As described by Barnes et al (2005) some patients receiving ECT may be cognitively impaired due to the acute depressive disorder from which they are suffering. This may result in patients being unable to remember precisely what they have consented to with regard to subsequent treatments therefore consent must be sought prior to each ECT treatment. Caird and Worrall (2003) also assert that the patient's initial and continued consent should be verified before each treatment is given.

41.7% of the participants replied that the detained patient's consent to ECT is reviewed after every treatment or after every second treatment which again would indicate that good practice is taking place in the ECT centres where the participants practice. This was important due to the fact that the detained patient's consent status could change during the course of the treatment, for example, if their mental state improved they could be capable of providing informed consent. The GMC (1998) also states that the patient's consent should be reviewed if there have been any significant variations in the patient's physical/mental status.

6.4.6 *Patient's capacity to provide consent*

66.7% of the participants replied that the cognitive function of patients receiving ECT was assessed by the prescribing team using the mini mental state examination (MMSE) most commonly. This was encouraging due to the fact as described by CRAG (1997) that the illness and treatment itself can cause memory impairment. Some of the participants had replied that the patient's cognitive function was assessed prior to and after ECT. However, there was a variation in the amount of participants who stated that the cognitive assessment of patients was assessed at the ECT suite. 50% of the participants said that it was always done although 25% of the participants stated that this was never done. CRAG (1997) outlines that the nurse should re-orientate the patient following treatment. This is an area that could be improved upon in order to ensure that patient has been re orientated to time, place and person as much as is possible following the treatment and that discussion takes place between the referring team

and the ECT suite regarding the patient's cognitive function during the treatment course as also described by CRAG (1997). This is an area where staff could benefit from further training on.

If at any stage of the patient's treatment it became apparent that the patient could not recall giving informed consent the ECT nurses replied that they liaised with the ECT consultant psychiatrist and referring team so that the patient's consent status was reviewed and the treatment was postponed until this was done. One participant stated that the doctor would ensure that the patient signed another consent form prior to each treatment. Another participant replied that they would "insist" that the patient's consent status was reviewed which would appear to indicate that the ECT nurse does have a more important role in the consent process than that, which is recognized in practice or the literature. There is evidence from the qualitative comments that some of the participants do assist in assessing the patient's decisional capacity and ability to make a voluntary choice to provide informed consent, such as the ECT nurse who described part of the ECT nurse's role in the informed consent process in this way:

> "*I consider that the ECT nurse has a very important role to play as generally speaking she is the last person to have a dialogue with the patient before delivery of ECT. Also he/she has a full understanding of the process of assessing [the] validity of consent and is competent to form decisions regarding the outcome of her assessments*".

However, only 50% of the participants had replied that they considered that assisting in assessing both these elements of informed consent was partly their responsibility. Perhaps this is dependent on the length of

experience the ECT nurse had, how many patients were treated or if the role of ECT was the nurse's main responsibility as opposed to some ECT centres where there is a pool of nurses based on a ward who perform the ECT nurse's role. This part of the nurse's role is described in general literature on the nurse's role in informed consent such as in work by Scholefield et al (1997), Cable (2003), Usher and Arthur (1998) and the NMC (2004) but not in good practice guides on ECT such as those provided by CRAG (1997) and Cullen (2005).

Some of the main points that can be taken from the discussion on the ECT nurses' interpretation of their role in the consent process are that the nurses did not always ensure that patients received enough verbal and written information about the treatment; there was a variation between the participants' response to the question on their role in assisting in the assessment of the patient's decisional capacity and voluntarism and ability to consent voluntarily qualitative comments of their role in this element of informed consent. The nurses perceived a large part of their role to be administrative and monitoring that patients continue to consent to the treatment as well as informing medical staff if a patient were unsure or refused the treatment.

There was a variation in the importance that the ECT nurses gave to the information that should be provided to the patients including information on side effects. A high percentage of the participants perceived that some patients in their practice had not given informed consent and that ECT nurses, medical staff and students' knowledge of the elements of informed

consent should be improved. A high percentage of the participants stated that they had challenged medical staff when they had perceived that they were prescribing ECT when a patient was not giving informed consent. Most of the participants stated that the patient's consent to ECT was confirmed after every treatment and the patient's consent was reviewed after every second treatment. The detained patient's consent was reviewed most commonly after every treatment or after every second treatment. The assessment of the patient's cognitive function was usually assessed by the prescribing team using the MMSE but a proportion of the participants stated that this was not done by the ECT team.

6.5 Knowledge base that patients require to have in order to provide informed consent

6.5.1 *Delphi questionnaires*

The Delphi process was a useful method to use in this project because, as described by Whitehead (2008), a consensus of opinion was achieved in most of the statements in the questionnaires which could be presented as a foundation to further inform present practice.

The information that the participants sent back, particularly in the first round of questionnaires, was full of useful suggestions on what they would like included in the statements, and they also offered insights which were useful to amending the statements in the second round.

6.5.2 *Statement of knowledge*

A consensus of 75% and above was gained in 72% of statements of knowledge in the second round of the Delphi process relating to the response of 'very applicable' which was considered to be a satisfactory level of consensus. The consensus of opinion had increased compared to the consensus received in the first round which was 38%. Included in the 8 statements that received a 100% consensus from the participants were elements on ECT and consent; anaesthetic and muscle relaxant; fasting requirements; duration of an average course and the physical examination. It was interesting to note that these elements received a different rating in the ECT nurse questionnaire with ECT and consent being rated as the 5th most important item of information that a patient should be provided with; anaesthetic and muscle relaxant being rated 4th most important and the duration of a course of ECT as 8th most important. The physical examination statement was added in at the second stage of the project.

13 of the other statements achieved a consensus of 75% or above. These included statements on the nature of ECT, why is ECT prescribed, ECT and consent, alternative treatments to ECT, effectiveness, long term reported risks and mortality rate, fasting requirements, duration of an average course and physical examination. Therefore these components of the informed consent procedure which the participants reached a consensus on were perceived by them as being important statements to include in the statement of knowledge.

The elements of the statement of knowledge that did not receive a consensus from the participants included the nature of ECT, why is ECT prescribed, alternative treatments, effectiveness and reported risks, although some of the statements in each of these elements did receive a consensus. The statements that did not achieve a consensus from the participants were based on literature from ECT good practice guides and information on ECT are further described in appendix 17.

While the expert panel's collective opinion on what the statement of knowledge should consist of is valued due to their knowledge of present practice; perhaps the lack of consensus in some statements represents a training issue for ECT consultants and ECT nurses. In particular the elements of informed consent that the practitioners could benefit from further training on include the nature of ECT, why ECT is prescribed, alternative treatments, effectiveness and reported risks, although some of the statements in each of these elements did receive a consensus. Alternatively, statements that did not receive consensus, such as prolonged seizures, could be included in the information giving process at a further stage through the patient's course of treatment or at the patient's request. Also, the information on prolonged seizures was in ECT good practice literature such as CRAG (1997) but was not contained in patient information such as Mayo clinic (2004) or American Psychiatric Association (2004). Therefore, it could be perceived that informing patients about the risks of prolonged seizure is not what is required in the statement of knowledge that patients should be aware of prior to providing informed consent to ECT. The GMC (1998) describes that the

quantity of information that the practitioner gives the patient will also depend on the patient's individual request which practitioners should bear in mind when providing information to the patient receiving ECT. The main issue would be that the patient is aware of the nature, purpose and likely effects of the procedure as described by Mental Welfare Commission (2005) in order to give valid informed consent to the treatment.

In order to ascertain the patient's standard of knowledge throughout a course of ECT the statement of knowledge would require to be tested on patients in a routine care setting in a further research project. A self report "test" would also be developed and would measure the quality and retention of the information on the statement of knowledge by a patient throughout a course of ECT. The statement of knowledge and self report "test" would require to be validated and then it would need to be determined in routine care how the quality of consent may vary during a course of treatment. This proposed research would seek to determine the impact of structured information delivery and consent evaluation on quality of consent compared to standards achieved in routine care.

6.5.3 *Roles and responsibilities of medical and nursing staff*

There was a total of 66% consensus for the statements in both sections as to what the participants considered to be essential in the roles and responsibilities of medical and nursing staff. There was a difference in consensus between the roles and responsibilities of medical staff and nursing staff with the statements concerning the medical staff role gaining

a consensus of 75% and nursing staff just 56%. This may suggest that medical staff and nursing staff are more aware of the medical staff's role than the nurse's role and responsibilities with regards to the informed consent process. The results may have also been affected by the four nursing staff whose questionnaires were received too late to be included or the one nurse who did not participate in the second round. Perhaps the difference in consensus between the roles is also due to the fact that there appears to be more literature concerning the medical role than the nursing role with regards to informed consent and in particular, informed consent in ECT therefore, in the author's opinion, the medical role is less ambiguous than the nursing role.

There was also a decrease in the statements that received a 100% consensus in the medical role which decreased from 34% in the first round to 19% in the second round. However, the amount of statements receiving 100% consensus in the nursing role increased from none in the first round to 18% in the second round.

A total of 34% of the statements did not receive consensus in the second round of the Delphi process. A description of the literature on which some of the statements were based is detailed as follows:

The psychiatrist administering ECT confirms that the patient is giving voluntary consent prior to each treatment proceeding.

Although this statement received a response that was just under the 75% required for consensus in this study, professional guidance such as the

GMC (1998) described how it is the doctor who is performing the treatment who should be certain that consent is gained. CRAG (1997) also state that the psychiatrist should verify that consent is legitimate in advance to the ECT treatment taking place. Therefore this is a part of practice in informed consent that the participants may require further training on.

An equitable relationship is formed with the informal patient so that the decision to receive ECT is made jointly between the patient and the RMO.

Although a consensus was not gained, this statement received a response of 73% from the participants who considered it to be essential in the roles and responsibilities of the nurse while it gained 64% from the participants who considered it to be essential in the roles and responsibilities of medical staff. The balance of the rapport between the practitioner and the patient is a significant part of the informed consent procedure but the evidence gained in this research indicates that the participants' perceive the importance of an equal relationship with the patient as being more important in the nurse's role in the consent process than the medical role. Doyal (2004) stated that patients felt that their exchanges with doctors could be hurried and could comprise of an absence of purpose. This is an area that practitioners could receive further training on so that patients receiving ECT's contribution to their own care is acknowledged and they are perceived as being associates in their own treatment as outlined by the NMC (2004).

The nurse assists the referring psychiatrist in assessing the patient's decisional capacity to ensure that informed consent is valid.

The nurse assists the referring psychiatrist in confirming that the patient is giving voluntary informed consent

Both these statements did not receive a consensus of opinion but the ECT nurses' qualitative comments in the ECT nurse questionnaires supplied evidence that they did assist in these elements of informed consent in practice. As described by Sims (2008) nurses may be the initial person to recognize any possible complications in the informed consent procedure due to the fact that they often have the most contact with patients and their relatives. They may comprehend that the patient and/or their family may not completely appreciate the procedure. Therefore the ECT nurse or the ward based nurse may be first to ascertain that the patient does not have the decisional capacity to give informed consent or may not be giving voluntary consent to the treatment.

Ensuring that coercion is not employed at any time in order to persuade the patient to have ECT.

Beauchamp and Childress (2001) state that coercion exists if one individual deliberately uses a conceivable and harsh risk of pressure to dominate another. The statement above from the Roles and responsibilities questionnaire regarding ensuring coercion is not employed received a response just under the consensus level in the nursing role section. However, CRAG (1997) recommends that no type of coercion should be used at any point to influence a patient to receive ECT. This is especially important as it is extensively described in healthcare and consumer literature that although patients were not detained under a mental health act to receive ECT, they frequently perceived that they had not supplied their consent voluntarily (Rose et al, 2005).Therefore, nurses

should be aware of the moral/legal consequences of their interventions with patients as described by Kashka and Keyser (1995). The same statement received a consensus of 82% as essential in both the first and the second round of questionnaires in the medical role; however one participant added this interesting comment in the first round of the Delphi process:

> *"Whilst I agree that coercion would always be inappropriate, persuasion may be the most pragmatic option when you have a patient who is suffering greatly or at heightened risk and you believe that ECT will be the most appropriate treatment – however this would be true for any significant medical procedure".*

The participant's comment is understandable when the practitioner is dealing with a patient whose illness is severe; nevertheless, what is the difference between persuasion and coercion? The Mental Welfare Commission (2003) describes how the practitioner who is trying to bypass using the Mental Health (Care and Treatment) (Scotland) Act 2003 might use what they consider to be reasoning skills in order to persuade the patient to receive treatment willingly. However, this could still be perceived by the patient as coercion and may in fact be coercion. Kashka and Keyser (1995) also state that indirectly influencing the patient can affect their consent status because unimpeded consent is debatable whenever any form of coercion or "persuasion" is demonstrated.

A more detailed description of the statements that did not receive consensus is detailed in appendix 18.

The statements that received 100% consensus in the medical role are featured in Table 22.

Table 22. Medical role - 100% consensus

The patient's decisional capacity is assessed by the referring psychiatrist to ensure that informed consent is valid	**Desirable**	**Essential** 100%	**Not applicable**
To ensure that the patient understands the nature, purpose and consequences of receiving the treatment and therefore what he or she is consenting to		100%	
When ECT is considered the best treatment option for a patient but due to their mental state they are unable or unwilling to give consent then action under the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2002 is employed and a doctor from the Mental Welfare Commission provides a second opinion		100%	
Ensuring that the relevant documentation regarding the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2002 has been completed and is available for inspection		100%	
The informal patient is made aware that he or she can withdraw their consent to ECT at any time		100%	
Patients' questions about ECT should be answered as truthfully as possible		100%	

The validity of the consent form and other relevant Mental Health legislation documentation is continuously reviewed throughout the course in case the patient's consent status has changed and the documentation requires to be amended		100%	

The statements including the employment of the Mental Health (Care and Treatment) (Scotland) Act 2003 and the Adults with Incapacity (Scotland) Act 2002 and ensuring the relevant documentation regarding the Mental Health Act had been completed and were available were elements receiving 100% consensus as essential in both the medical and nursing sections. This issue has been documented in ECT good practice guides such as Barnes et al (2005), CRAG Working group on Mental Illness (1997) and Caird and Worrall (2003). Reviewing the validity of the consent form and other relevant Mental Health legislation documentation continuously throughout the course also gained 100% consensus as essential in the medical role as documented in sources such as Ritter (1989) and the Mental Welfare Commission (2003).

Other statements which received 100% consensus as being essential in the medical role was the referring psychiatrist assessing the patient's decisional capacity to ensure informed consent is valid as documented by research based literature such as Lapid et al (2004) and good practice based literature such as Barnes (2005), the Mental Welfare Commission (MWC) (2003). Ensuring the patient understood the nature, purpose and consequences of receiving the treatment and therefore what he or she is consenting to is documented in good practice guides such as Grampian

University Hospitals NHS Trust (2002), Caird and Worrall (2003) and the Medical and Defence Union of Scotland (2004).

Ensuring the patient is made aware that he or she can withdraw their consent to ECT at any time achieved a 100% consensus as essential in the medical role as described in good practice guides such as BMA (2003), NHS Scotland (2006) and National Institute for Clinical Excellence (2003). The final statement to receive 100% consensus in this section was the patients' questions about ECT should be answered as truthfully and fully as possible as documented in good practice guides such as the GMC (1998), Department of Health (2001) and BMA (2003).

Included in the other statements which received a consensus from the participants in the medical role were elements of informed consent such as the provision of sufficient information as described by the Mental Welfare Commission for Scotland (2003) and Rose et al (2005). This differed from the ECT nurses' perception that 41.7% were unsure if medical staff provided sufficient information. The mix of participants in the second stage of this research of ECT consultants, ECT nurses and a representative from a user group provided further data on the perception of the medical staff's role in this element of informed consent. Ensuring the patient understood the information on side effects and risks of receiving ECT as described by NICE (2003) and NHS Scotland (2006) and that the patient is aware of the purpose and intended benefits of ECT including probability of success as documented by GMC (1998) and the BMA (2003) also received 91% of the participants' consensus. The provision and understanding of the information given appeared to be an

important part of the participants' perception of the medical role in the informed consent process.

Only a small number of the statements (7) achieved a 100% consensus but nevertheless these items give a clear indication of what the panel considered to be important in the medical role in informed consent.

The statements receiving 100% consensus in the nursing role are featured in Table 23.

Table 23. Nurses role - 100% consensus

To understand the application of the Mental Health Act in relation to ECT and the provision of nursing care in ECT when it is administered without the patient's consent	**Desirable**	**Essential** 100%	**Not Applicable**
Ensuring that the relevant Mental Health legislation documentation regarding the Mental Health (Care and Treatment) (Scotland) Act 2003 or Adults with Incapacity (Scotland) Act 2002 has been completed and is available		100%	
The nurse understands the nature, purpose and effects of ECT		100%	
In an emergency situation when a patient's life is at risk the nurse assists in the administration of ECT to the patient as directed by Medical staff		100%	
When information is refused by a patient this should be documented in the patient's case file/care plan		100%	
The patient's informed consent is verified prior to each ECT treatment		100%	

The statements achieving consensus (100%) in the nursing role were understanding the application of the Mental Health Act in relation to ECT and the provision of nursing care in ECT when it is administered without the patient's consent as documented by good practice guides such as Cullen (2005), Ritter (1989), NMC (2004). The statement *the nurse understands the nature, purpose and effects of ECT* was supported in literature on informed consent in nursing such as Scholefield et al (1997) and Sweeney (1991). Other statements reaching consensus in the nurses role were: *In an emergency situation when a patient's life is at risk the nurse assists in the administration of ECT to the patient as directed by Medical staff* which was based on literature in good practice guides such as the NMC (2004), the Scottish Executive Health Department (2005) and Grampian University Hospitals NHS Trust (2002). When information is refused by a patient this should be documented in the patient's case file/care plan as recorded in literature on informed consent such as Kirby (1983) and Meisel and Kuczewski (1996). The final statement to receive 100 % consensus in this section was: *The patient's informed consent is verified prior to each ECT treatment* as documented by the MWC (2003), Caird and Worrall (2003) and the Scottish Executive Health Department (2005). These six statements also give a clear indication of what the panel believed to be essential in the nurse's role in informed consent.

Included in the other statements that received a consensus of 75% or above in the nursing role are: *If the patient is unsure or refuses to give consent to ECT this is accepted and the treating psychiatrist is informed of this decision so that the patients' consent status and the continuation of*

the treatment can be reviewed, as documented by Kashka and Keyser (1995) and Ritter (1989). Continuously assessing the validity of the consent form and other Mental Health documentation as described by Barnes et al (2005) and the Mental Welfare Commission (2003) also received a consensus. These were also elements that received a high percentage of the response from the ECT nurses in stage one of this research. Ensuring the patient's questions are answered as truthfully and fully as possible as documented by the Department of Health (2001) and Scholefield et al (1997) and ensuring the patient has sufficient time without being subject to pressure to reflect on the information prior to consenting to ECT as documented by Meisel and Kuczewski (1996) and the Scottish Executive Health Department (2005) also appeared to be important elements of informed consent in the nursing role from the participants' perspective.

The statements in the second stage of this research were informed by the data gained from the participants in the first stage of the study, the ECT nurse questionnaire and information from good practice guides on informed consent. The panel's opinion is respected due to their level of expertise in ECT; however, the participants' lack of consensus in many of the statements appears to indicate the requirement for further training on the elements of informed consent for both medical and nursing staff in order to enhance their awareness of consent. In particular, in the medical role the elements of informed consent that practitioners would benefit from further education and training on include that the psychiatrist administering ECT should confirm that the patient is giving voluntary

consent. Also the importance of forming an equitable relationship with the informal patient so the decision to receive ECT is made jointly between the patient and Responsible Medical Officer and ensuring the patient detained under The Mental Health (Care and Treatment) (Scotland) Act 2003 is aware of advocacy and the importance of maintaining a therapeutic relationship with the detained patient are elements that the panel may require additional training on. Ensuring the patient is aware of the possible risks involved in choosing not to receive treatment; providing relatives and carers with information about ECT; when the patient has lost capacity to provide informed consent any advanced directives should be taken into account. Information previously given should be repeated during the course of ECT and patients should be advised whether the treatment is to be bilateral or unilateral and their views on this taken into account when possible.

In the nursing role the elements of informed consent that practitioners could benefit from further education and training on include the importance of the nurse assisting the referring psychiatrist in assessing the patient's decisional capacity and voluntarism to provide informed consent and ensuring that the patient understands the nature, purpose and consequences of receiving treatment; ensuring coercion is not employed at any time to persuade a patient to have ECT. The patient should have access to independent advice; if the patient appears unsure about receiving ECT they should be given the opportunity to address concerns and the possible benefits of treatment should be re - iterated to ensure they have the information to inform their decision. Patients

understanding of the information provided and the side effects and risks of ECT should be confirmed prior to the completion of the informed consent document. Finally, the nurse should assist in the assessment of detained patient's competence to give informed consent continuously throughout the course in order to determine if they have regained the capacity to give informed consent.

Further education and training on these aspects of informed consent would further benefit the practice of ECT consultants and ECT nurses and the service delivery of ECT so that each treatment the patient receives is administered in the context of fully informed consent. However, a further round of the Delphi may have provided additional consensus as the percentages gained for many statements was just 2% under the 75% required to achieve consensus although this was not possible due to the time restrictions of the study.

Perhaps a method such as a focus group as described by Keeney (2006) could also be facilitated in order to draw parallels between the results gained which would further increase the reliability of the data gained in this project. A group of ECT consultants, ECT nurses and representatives from user groups could be gathered together and their views and insight on the statements in the questionnaires could be collected in order to further validate the findings in this study as also described by Parahoo (1997).

The roles and responsibilities of medical and nursing staff in the informed consent process in ECT document could be further developed and used to inform the routine practice of all medical staff and nursing staff involved in the administration of ECT. This would include both the staff involved in the administration of ECT and ward based staff on the wards referring patients for ECT. The development of present practice surrounding the informed consent of patients would benefit the service delivery of ECT in Scotland. This may be as part of the SEAN network where the findings of this research will be disseminated and also nationally if other ECT services in Britain decided to adopt the findings of this research and integrate it into their practice and service delivery. The findings will also be discussed with the ECT consultant and managers of local services so that they can be applied to present practice in ECT.

6.6 Strengths and limitations of the study

As associated with most research projects, this study had strengths and limitations. The most important strength is that the project investigates an area that has not been previously researched which could be the foundation for further research. Therefore, this could be carried out on a larger scale beyond the confines of Scotland, in the future. The questionnaires created in this research - the statement of the knowledge base that a patient is required to have to give full informed consent and the roles and responsibilities of medical and nursing staff in the informed consent process - could formulate a baseline to inform practice in informed consent in ECT. A tool has been created in the formation of 'the

statement of knowledge base that a patient is required to have to give full informed consent' (Appendix 13) which can be used in practice to assist in ensuring that patients are giving informed consent to ECT. This will assist in improving the quality of consent and a consensus of opinion on the roles and responsibilities of medical and nursing staff in the informed consent process and could further inform practice in this area which will enhance the service delivery in ECT.

In the study the use of qualitative and quantitative methods meant that the quantitative method used in the ECT nurse questionnaire informed the development of the Delphi questionnaires. The ECT questionnaires also resulted in qualitative data being gained from the open questions which was also very useful in informing the aims and objectives of this research. The drawback of using different methods was as the length of time it took to collect and analyse the different types of data within the time limits of the research period particularly with being a first time researcher and balancing the demands of the research with a demanding full time post. However, the data were gathered and analysed within the time frame of the research period.

The questionnaires were a valid method as described by Parahoo (1997) as the questions used within the questionnaires in both sections combined appeared to answer the research's aims and objectives and sufficiently typify the variety of theories of informed consent which were being examined in this research. The time taken in the pilot phase of the research which included the careful design, creation, piloting and

modification of the questionnaires in both stages was beneficial in increasing the validity and reliability of the findings. As described by Oppenheim (1992), the pilot phase increased the content and face validity of the questionnaires by receiving valuable feedback which assisted in the formation of the final draft. If the questionnaires were to be replicated in another study the instructions and statements are comprehensible enough for participants to understand and answer (Parahoo, 1997). However, the reliability of the questionnaire has not been established due to the size of the study.

The advantage of using the questionnaires as a method at both stages of the research is that the participants' answers were anonymous so they could offer their opinions on the practice of informed consent without being recognized as described by Parahoo (1997). The content validity of the questionnaires was also appraised during the process in both stages as the participants were invited to submit any element which they would like included. Their suggestions were evaluated and included in the second stage of the Delphi process questionnaires. The author tried not to allow her own biases on the subject of informed consent, which were gained after seven years practice experience, affect the results of the research as described by Parahoo (1997). The steps taken were to describe any thoughts and feelings throughout the process in a research journal which were discussed in supervisory meetings; the questionnaires were also based on the literature reviewed. The data that did not correspond with the author's beliefs were equally reported such as the ECT nurses response in the ECT nurse questionnaire that only 50% of them assessed

the patient's decisional capacity and voluntarism to provide informed consent. The participants' suggestions and opinions were appreciated and included in the formation of the Delphi questionnaires.

The study was small therefore its findings cannot be generalized. It was not possible to know how many of the 144 questionnaires were actually distributed to practitioners but the response rate was poor. The low response rate to the ECT nurse questionnaire was likely to have caused a consequent bias in the results as described by Oppenheim (1992) as the participants could have been considered to be less representative of the sample that was aimed at. However the participants that did take part provided data which were very beneficial in informing the research on the present practices of the professionals involved in the informed consent of patients receiving ECT which assisted in the development of the Delphi questionnaire in the second stage. There could be many reasons for this low response rate but the initial pilot work that was completed indicated that the questionnaire's content appeared to be understandable as the participants at this stage were able to give prompt and comprehensive answers to the questionnaire. Munn and Drever (1996) describe a restriction of using questionnaires is that the results gained can be information that is quite shallow and there is not the opportunity to translate the point of the questions. However, the qualitative data in the questionnaires that were received from the participants gave a good insight into the ECT nurses' perception of their role in the informed consent process. Another limitation of using the questionnaires as a method is the fact that the data collection depended on the participants

reporting on their own practice therefore the data is dependent on what the participants said occurred in their practice rather than what actually happened. Additional research covering a wider demographic area outside Scotland and a therefore a larger sample would further add to the reliability and validity of the results of the ECT nurse questionnaires.

The strengths of using the Delphi approach to gain a consensus on the statement of knowledge and roles and responsibilities of medical and nursing staff is that a panel who were expert in ECT's opinion was gained on these elements of informed consent. Huang et al (2008) describe the Delphi process as an effective method for organizing a panel's correspondence and establishing a structured opinion in the process of reaching a conclusion which, in this research culminated in devising the two questionnaires. However, in retrospect, the limitations of using this panel is that there was an imbalance of using one user and 16 professionals and representatives from an ethical expert would have been very useful since informed consent is an ethical matter. Also, the fact that the user representative's views were similar to the professionals indicates that he/she had become an 'expert' patient/user and does not represent the typical user.

Powell (2003, p.7) refers to the personal communication received that offers criticism of the Delphi process stating that the Delphi was 'opinion based' rather than 'evidence based'. (Silbert, 2000). However, Powell (2003) concluded that the results of a Delphi illustrate a professional viewpoint rather than the proven truth. There was also the concern of the

drawback of the bias of choosing an expert panel that was already involved in ECT therefore would have developed opinions and attitudes on the subject. The advantage of having a panel that was expert in ECT for this research was that the range of disciplines within the group and the representative from a service user perspective provided constructive suggestions and interesting feedback on the practice of informed consent in ECT within the qualitative data that was received with the questionnaires which greatly assisted in the development of the final questionnaires.

However, Keeney et al (2006) report that there is a possibility of bias in the 'experts' selected for the panel as they are particularly interested in the theme which would be the case in this research as it is perceived that the ECT consultants and ECT nurses would have a special interest in the subject of ECT. In this study the experts chosen were from different professional groups of doctors and nurses and also it was thought that the user representative would offer another independent point of view. Nevertheless, Keeney (2006) also describes the importance of the expert panel requiring to be informed on the theme under investigation therefore participants cannot be chosen by chance.

As suggested by Crotty (1993) this information would have been more complicated to acquire by an alternative method such as a group or committee. Whitehead (2008) also states that the Delphi process is more resilient than other consensus methods such as focus groups. Another difficulty was the loss of two participants and the late responses from four

participants in the second round of the Delphi process which meant the loss in the panel of five nurses and one ECT consultant. However, this left a balance of disciplines in the expert group of 4 ECT consultants, 6 nurses and the representative giving a user perspective. Parahoo (1997) states that poorer response rates in subsequent rounds of the process can call into question that a consensus of opinion was achieved. Nevertheless, the reasons that the participants dropped out is not known so it is not discernable how their absence may have distorted the findings of this research. The final round of questionnaires contained a marked decrease of qualitative comments and the majority of the statements had achieved a consensus which appeared to indicate that the participants were agreeing with most of the content of the two questionnaires.

6.7 Reflection

If I was to conduct the research again I would attempt to undertake a design which was much less complex and time consuming as it was difficult to complete this research within the time scale given. This could be achieved by studying one element of the research at a time such as the ECT nurse questionnaire and then the questionnaires in the Delphi process. However, there was a conflict in the first stages of developing a research proposal which was between the research I had been requested to carry out for my workplace and the research I required to complete to receive a higher degree in nursing.

However, the research process has led to my development as a research practitioner and the experience will be useful if I receive the opportunity to conduct research in the future. The skills and knowledge I have gained include developing literature review skills, designing questionnaires, implementing and evaluating a research project, analyzing data, and using the Delphi process. I have a greater understanding of the strengths and limitations of using questionnaires as a research method. It has also been a great opportunity to develop my computer skills and skills in giving presentations which has been beneficial to my every day practice as a health professional. I also feel that laterally I was able to direct my own studies with some autonomy and have been able to critically reflect on my own research in addition to the research of others. I have also learned to question routine practice and understand the benefits of research based practice to the improvement of patient care. I have developed skills in articulating, defending and presenting my research and have also learned to develop my knowledge and deepen my understanding of the theories, principles and concepts which constitute informed consent and test the effectiveness of the care which is presently provided as described by Parahoo (1997).

CHAPTER 7

Conclusions and recommendations

7.1 ECT nurses' perception of their role in the consent process

The ECT nurses' perception of their role in the consent process was largely administrative - that of ensuring that the consent form is signed and monitoring that patients continue to consent to treatment as well as informing medical staff if the patient is unsure or refuses treatment. The nurses also commented that their role was one of "protecting the patient" which provides evidence that they perceive their role as evaluating any concerns the patient had and passing them on to medical staff as appropriate. The ECT nurses also indicated that they were often the last person to spend time with the patient so could often identify and address any last minute issues in the consent process.

Training issues were highlighted in the evidence provided by nurses. The current training for student nurses and registered nurses should be appraised to ensure that nurses have the necessary skills and knowledge to provide information to patients in the informed consent process. Particular issues related to assisting in ensuring that the patient understands the nature, purpose and side effects of the treatment. There was also a variation in the response to the questionnaire questions and qualitative comments in the nurse's role in assisting in assessing the patient's decisional capacity and voluntarism. The participants' qualitative comments suggested that they perceived that they had a good

understanding of assessing the validity of the patients' consent and felt capable of making decisions based on their assessments.

There was a variation to the nurses' response to their role in providing sufficient verbal and written information in the two stages of research; however, the nurses considered it important to assess that patients continued to consent to treatment on the basis of the information that was originally provided.

Values that the ECT nurses considered were important in influencing the Mental Health nurse's ability to provide care for patients included possessing good communication skills in order to build an effective rapport with the patient, respecting the patients as individuals and obtaining consent before treatment. NES (2007) cites the SEHD (2006) document which included reference to the importance of the practitioner possessing an excellent communication technique, adhering to the principle of respect and the importance of positioning the principles of the specific person at the heart of practice. Therefore the NES (2007) 10 essential shared capabilities could be incorporated into the ECT nurses' and ECT consultants' CPD programmes in order to build on the values that they already possess so that they are practising in accordance with the theories and principles that support the Mental Health (Care and Treatment) (Scotland) Act 2003.

There was a clear difference between the percentages the participants gave to the elements of information and the side effects which indicated

that they were sure of what information should be given to patients. However, additional research would ascertain practitioners' views of information that patients should be provided with.

A high percentage of the ECT nurses considered that they had recently had patients who had not provided informed consent. The main reasons given for this included that the severity of the patient's illness made it difficult for them to provide informed consent due to confusion, disorientation and lack of capacity to make an informed decision. Poor information provision was also given as a reason. Kashka and Keyser (1995) also suggest that patients referred for ECT could be suffering from cognitive impairment due to the severity of their illness. Therefore Lapid et al's (2004) approach could be adapted in order to organize structured teaching sessions for patients suffering from cognitive impairment who are going to receive ECT in order to increase their capacity to provide informed consent. The practitioner should also ascertain that the information provided to patients to inform their decision is comprehended by them on an ongoing basis as described by Rose et al (2005).

The ECT nurses' responses to the question on the elements of informed consent provided evidence that they rated their knowledge of the elements of informed consent as having the largest percentage of responses in the 'strongly agree' category. This was followed by the overall knowledge of medical staff and then the knowledge of nursing students, although a direct comparison was not made. However, it would appear from this research that ECT nurses, nursing students and medical

staff all require additional training and education on the elements of informed consent although additional future research would be useful to further ascertain the knowledge of medical and nursing staff on the principles of informed consent.

A large percentage of the participants said that they had challenged medical staff who had prescribed the treatment when they thought the patient was not giving informed consent. This provides evidence to support Clarke's (1995) suggestion that the nurse could undertake to champion the patient and act as an intermediary between the patient and doctor in the consent procedure. It appears that many of the ECT nurses are presently executing this role judging by their responses.

Just under half of the ECT nurses considered that medical staff appeared to have coerced a patient into having ECT whereas just over half did not consider that they had seen nursing staff coercing a patient into having ECT while a third did not know if they had seen nursing staff doing this. Further research would indicate if a larger sample of participants had similar perceptions that staff may have been coercing patients into receiving ECT. Medical and nursing staff's familiarity of the ethical repercussions of their interactions with patient should be increased by further education so that the patient consistently signs the consent form on an informed and voluntary basis.

The ECT nurses fed back that good practice in the confirmation of informed consent was taking place in the ECT centres according to recent

practice guidelines such as Caird and Worrall (2003). However, the largest proportion of participants confirmed that the patient's consent was reviewed after every second treatment in line with the programme which is included in the SEAN ECT database, as previously discussed. Nevertheless, due to the cognitive impairment of patients, as described by Barnes et al (2004), consent should ideally be sought prior to each ECT treatment so that each and every treatment is administered in the context of fully informed consent.

The majority of participants replied that the informal patient's consent was confirmed after every treatment and the detained patient's consent was reviewed after every treatment or after every second treatment. Recommendations should be made so that each patient's informed consent is reviewed after every treatment and confirmed prior to each ECT treatment commencing.

Most participants replied that the patient's capacity to provide consent was reviewed by the referring team by assessing the patient using the Mini mental state examination. However, a quarter of the participants stated that the cognitive assessment of the patient was never assessed at the ECT suite by the ECT team. This is practice that could be improved upon in some ECT centres so that the patient is re-orientated as much as is possible prior to leaving the ECT suite.

There was evidence gained from the qualitative comments that some of the participants did assist in assessing the patient's decisional capacity

and voluntarism to provide informed consent even though their response to the questionnaire question did not fully suggest this. This indicates that the ECT nurse does have a key role in assisting in the informed consent process which is perhaps not presently recognised in practice or the ECT good practice literature. It is recommended that this practice should be included in the ECT good practice guides.

7.2 Knowledge base that patients require to have in order to provide informed consent

A consensus of opinion of 75% or above was achieved in 72% of the statements in the statement of knowledge and eight statements received 100% consensus from the participants.

The important issue is that the patient is aware of the nature, purpose and likely affects of receiving ECT in order to give valid informed consent to the treatment. A tool has been developed in the 'Statement of the knowledge base that a patient is required to have to give full, informed consent questionnaire' (appendix 13) which practitioners can administer to confirm that the knowledge required for informed consent has been obtained from patients consenting to ECT. A further research project would require to be undertaken in order to ascertain the patient's standard of knowledge throughout the course of ECT in order to validate the tool.

The lack of consensus in some statements could present as a training issue on some of the elements of informed consent for ECT Consultants

and ECT nurses. Another option is that these elements of the statements could be incorporated in the information that is given at an additional phase of the patient's treatment course depending on the patient's individual information requirements.

7.3 Roles and responsibilities of medical and nursing staff

There was a total of 66% of consensus in both sections of the questionnaire with consideration to what the participants considered to be essential in the roles and responsibilities of medical and nursing staff.

There was a difference in consensus between the roles and responsibilities of medical staff and nursing staff with the statements concerning the medical staff role gaining a consensus of 75% and nursing staff just 56%. This appears to indicate that the participants had more awareness of the medical staff's role than the nursing staff's role which coincides with the fact that there was more literature sourced on the role of medical staff in the informed consent process in ECT than the role of nursing staff. Therefore, more literature should be included on the ECT nurses' role in informed consent in the good practice literature on ECT.

Seven statements received 100% consensus from the participants in the medical role and six statements received 100% consensus in the nursing role. In particular, some of the statements that concerned the Mental Health (Care and Treatment) (Scotland) Act received 100% consensus from the medical and nursing staff.

The participants' lack of consensus in some of the statements indicates the requirement for further education and training on some of the elements of informed consent for both medical and nursing staff. This would further benefit practice and the delivery of ECT so that each treatment is administered in the context of fully informed consent. A further round of the Delphi may have provided additional consensus as many of the statements received a consensus of just under the 75% consensus required in this research to achieve consensus but this was not possible due to the time restrictions of the study. A focus group made up of ECT consultants, ECT nurses and representatives from a user's perspective could be facilitated in order to draw parallels between the results gained which could possibly increase the reliability of the data gained in this research.

The roles and responsibilities of medical and nursing staff in the informed consent process document could be further developed and used to inform the routine practice of all medical and nursing staff involved in the administration of ECT. This would further ensure the quality of the consent process so that each and every treatment is administered in the context of fully informed consent. Practice can now be developed through increased awareness of the principles of informed consent. This would improve upon the present service delivery of ECT in Scotland as part of the SEAN network and nationally if the results of this research are more widely adopted.

7.4 Recommendations: summary

7.4.1 Outcome of the literature review

1) ECT services in Scotland should incorporate the NES (2007) 10 essential shared capabilities to the ECT nurse and ECT consultant Continuing Practice Development programme in order to build on values they already possess so that they are practicing in accordance with the theories and principles that support the Mental Health (Care and Treatment) (Scotland) Act 2003.

2) Services should organize structured teaching sessions on the lines of Lapid et al's (2004) approach in order to organize structured teaching sessions for patients suffering from cognitive impairment who are going to receive ECT in order to increase their capacity to provide informed consent.

3) The ECT nurse's key role in assisting in the informed consent process should be included in the ECT good practice literature such as assisting in the assessment of the patient's decisional capacity and voluntarism to provide informed consent.

7.4.2 Findings of this research

1) Schools of Nursing and Midwifery and NHS Trusts should appraise the current pre and post registration training for nurses so that there is more emphasis on the elements of informed consent and the ethical repercussions of their interactions with patients receiving ECT in the education and further training of nursing students, ECT nurses, ward based nurses. An appraisal should also include the current training available for medical students and medical staff.

2) It is recommended that each patient's informed consent is reviewed after every ECT treatment during the course and confirmed prior to each treatment commencing.

3) It is recommended that a cognitive assessment of the patient using tools such as the Mini mental state examination should be performed by the referring team and the ECT team should ensure that the patient is re - orientated as much as is possible prior to leaving the ECT suite.

4) Integrate the roles and responsibilities document into present practice in ECT in Scotland via the SEAN association and also into local practice.

5) Further research should be conducted in order to further ascertain the knowledge of medical and nursing staff on the principles of informed consent.

6) Additional research to determine the perceptions of medical and nursing staff on the use of coercion in the informed consent process in ECT in their practice.

7) Further research should be completed to ascertain staff's and patients' opinion of information on ECT that patients should be provided with.

8) Further research should be completed to ascertain the patient's standard of knowledge throughout the course of ECT. This includes developing a self report "test" to administer in practice in order to measure whether the patient has been able to retain the information contained in the statement of knowledge during the course of ECT. Also to determine the impact of structured information delivery and consent evaluation on the quality of consent compared to standards achieved in routine care.

9) Facilitate a focus group of ECT consultants, ECT nurses and representatives from a user group perspective in order to further validate the statements contained in the roles and responsibilities of medical and nursing staff.

10) Further administer the roles and responsibilities questionnaire through ECT services in Scotland, England and Wales bearing in mind that the legal context in England and Wales is different from Scotland.

References

ANDERSON, A., ed. 2002. *Adults with Incapacity Act 2000*. Aberdeen: Grampian Primary Care NHS Trust.

AMERICAN PSYCHIATRIC ASSOCIATION., 2004. *Electroconvulsive therapy (ECT).* [online] Arlington, Va.: American Psychiatric Association. Available from: www.psych.org/research/apire/training_fund/clin_res/index.cfm. [Accessed 20/06/2005]

ATWELL, B.L., 2006. The Modern Age of Informed Consent. *University of Richmond Law Review*, 40, pp. 591 - 611.

AVEYARD, H., 2002 (a). The requirement for informed consent prior to nursing care procedures. *Journal of Advanced Nursing*, 37(3), pp. 243 - 249.

AVEYARD, H., 2002 (b). Implied consent prior to nursing care procedures. *Journal of Advanced Nursing*, 39 (2), pp. 201 - 207.

BARNES, R., DYER, J.A.T., McCELLAND, R.J., SCOTT, A.I.F., 2005. The law and consent to treatment. In. A.I.F. SCOTT, ed. *The ECT Handbook.* Second ed. London: Royal College of Psychiatrists. pp. 181 - 198.

BEAUCHAMP, T.L., CHILDRESS, J.F., 1989. *Principles of Biomedical Ethics.* 3rd Ed. Oxford: Oxford University Press

BEAUCHAMP, T.L., CHILDRESS, J.F., 2001. *Principles of Biomedical Ethics.* Fifth Ed. Oxford: Oxford University Press

BENBOW, S., 2005. Adverse effects of ECT. In: A.I.F. SCOTT, ed. *The ECT Handbook.* Second ed. London: The Royal College of Psychiatrists. pp. 170 - 174.

BERGER, K., 2003. *Informed consent: information or knowledge?* 22, pp. 743 - 750.

BERGLUND, C.A., 2007. *Ethics for health care.* Oxford: Oxford University Press

BIGWOOD, S., CROWE, M., 2008. 'It's part of the job but it spoils the job': A phenomenological study of physical restraint'. *International Journal of Mental Health*. [online] 17 (3). Available from: http://ovidsp.uk.ovid.com/spa/ovidweb.cgi [Accessed 2 April 2009]

BLOCH, S., CHODOFF, P., GREEN, P., 1999. *Psychiatric Ethics.* 3rd ed. Oxford: Oxford University Press

BOLLSCHWEILER, E., APITZSCH, J., OBLIERS, R., KOERFER, A., MONIG, S.P., METZGER, R., HOLSCHER, A.H., 2008. Improving informed consent of surgical patients using a multimedia - based program? Results of a

prospective randomized multicenter study of patients before cholecystectomy. *Annals of surgery [online]*, 248 (1), pp. 205 - 211. Available from: ovidsp.uk.ovid.com/spa/ovidweb.cgi? [Accessed 07/10/2008]

BOLTON, SALFORD AND TRAFFORD MENTAL HEALTH NHS Trust, 2003. *Understanding Electroconvulsive therapy (ECT).* England: Bolton, Salford and Trafford Mental Health NHS Trust

BOOTH, S., 2002. A philosophical analysis of informed consent. *Nursing Standard.* [online] 16 (39), pp. 43 - 46. Available from: http;//ovidsp.uk.ovid.com/spb/ovidweb.cgi. [Accessed 11/02/2008]

BOWLES, N., 1999. The Delphi Technique. *Nursing Standard*, 13 (45), pp. 32 - 36.

BRITISH MEDICAL ASSOCIATION (BMA), 2001. *Report of the consent working party*. [online] London: BMA. Available from: *http:www.bma.org.uk/ap.nsf/Content/Reportoftheconsentworkingparty* [Accessed 17/10/2007]

BRITISH MEDICAL ASSOCIATION (BMA), 2003. *Consent tool kit.* [online] London: British Medical Association. Available from: http://www.bma.org.uk/asp.nsf/Content/consenttk2. [Accessed 17/10/2007]

BRITISH MEDICAL ASSOCIATION (BMA), 2007. *The impact of the Human Rights Act 1998 on medical decision making.*[online] London: BMA. Available from: http://www.bma.org.uk/ap.nsf/Content/HumanRightsAct. [Accessed 17/10/2007]

BUNCH, W.H., 2000. Informed consent. *Clinical Orthopaedics and Related Research,* 1 (378), pp.71 - 78.

BHUGRA, D., BHUI, K. (1997) Clinical management of patients across cultures. *Advances in Psychiatric Treatment*, 3, pp 233 - 239

BYRNE, P., CASSIDY, B., HIGGINS, P., 2006. Knowledge and attitudes toward Electroconvulsive Therapy among health care professionals and students. *Journal of ECT*, 22 (2), pp. 133 - 138.

CABLE, S., LUMSDAINE, J., SEMPLE, M., 2003. Informed Consent. *Nursing Standard*, 18 (12), pp. 47 – 53.

CAIRD, H., WORRALL, A. ed., 2003. *Electroconvulsive Therapy Accreditation Service (ECTAS). Standards for the administration of ECT 2003 - 2004.* London: The Royal College of Psychiatrists

CALDER, K., 1994. Beyond Informed Consent. *Canadian Nurse,* December, pp. 23 - 26.

CENTRAL AND NORTH WEST LONDON MENTAL HEALTH NHS TRUST, 2003. *Finding out more about ECT Electroconvulsive therapy*. London: Central and North West London Mental Health NHS Trust

CHADA, N.K., REPANOS, C., 2004. How much do healthcare professionals know about informed consent? A Bristol experience. *Surgical journal of Royal College Surgeons*. [online] 2, pp. 328 - 333. Available from http://www.rcsed.ac.uk/journal/svol2_6/206004.htm [Accessed 08/02/2008]

CLARK, L., 1995. Psychiatric Nursing and Electroconvulsive Therapy. *Nursing Ethics*, 2 (4), pp. 321 - 331.

COBB, A., 1993. *Safe and effective. MIND's views on psychiatric drugs, ECT and psychosurgery*. London: MIND publications

CORMACK, D., ed. (2000) *The research process in nursing.* Oxford: Blackwell Science Ltd.

CORRIGAN, O., 2003. Empty Ethics: the problem with informed consent. *Sociology of Health and Illness*, 25 (3), pp. 768 - 792.

COULTER, A., ENTWISTLE, V., GILBERT, D., 1999. Sharing decisions with patients: is the information good enough? *British Medical Journal*. [online] 318, pp. 318 - 322. Available from: http://www.bmj.com/cgi/content/full/318/7179/318 [Accessed 02/10/2007]

COULTER, A., 2002. After Bristol: putting patients at the centre. *British Medical Journal*, 16, pp. 648 - 651.

COWIE, C., BURKE, S., 2005. *Patients' information sheet. ECT treatment.* 2nd ed. Royal Cornhill Hospital, Aberdeen: NHS Grampian

CRAG WORKING GROUP ON MENTAL ILLNESS, 1997. *Electroconvulsive Therapy (E.C.T). A Good Practice Statement.* Scotland: The Scottish Office

CROTTY, M., 1993. The emerging role of the British nurse teacher in Project 2000 programmes: a Delphi survey. *Journal of Advanced Nursing*, 18, pp. 150 - 157.

CORMACK, D., ed., 2000. *The research process in nursing.* 4th ed. London: Blackwell Science

CULAS, R., PORT, M., ASHAYE, K., 2003. Knowledge of E.C.T. among staff of a Mental Health Service. *The Journal of E.C.T.,* 19 (40) pp. 245 - 246.

CULLEN, L., 2005. Nursing guidelines for ECT. In: A.I.F. SCOTT ed. *The ECT handbook*. Second ed. London: The Royal College of Psychiatrists, pp. 214 - 223.

CULVER, C.M., FERRELL, R.B., GREEN, R., 1980. ECT and special problems of informed consent. *American Journal of Psychiatry*, 137 (5), pp. 586 - 591.

DENZIN , N., 1970. *Strategies of multiple triangulation in the research act.* McGraw Hill: New York, pp. 297 - 331.

DEPARTMENT OF HEALTH, 2001. Consent – what you have the right to expect [online] Available from: http: //www.dh.gov/PolicyAndGuidance/ HealthAndSocialCareTopics/Consent/Con [Accessed 08/12/04]

DEPRESSION ALLIANCE, 2004. *Everything you need to know about depression.* London: Depression Alliance

DOYAL, L., 2004. Informed consent: don't throw out the moral baby with the critical bath water. *Quality Safety Health Care.* 13 (4), pp. 414 - 415.

DYER, A.R., BLOCH, S., 1987. Informed consent and the psychiatric patient. *Journal of medical ethics*, 13, pp. 12 - 16

ELAMENT- E LANARKSIRE MENTAL HEALTH RESOURCES, 2009. *Principles of the New Act*. [online] England: Elament. Available from: http://www.lanarkshirementalhealth.org.uk/Mental -Health-Act/Principles.aspx [Accessed 12/11/2009]

FINCH, S., 2005. Nurse Guidance for ECT. London: Royal College of Nursing

FITZIMONS, L., 1995. Electroconvulsive Therapy: What nurses need to know. *Journal of Psychosocial Nursing*, 33 (12), pp.14 - 17.

FITZIMONS, L.M., MAYER, R.L., 1995. Soaring beyond the cuckoo's nest. Health care reform and ECT. *Journal of Psychosocial Nursing,* 33 (12), pp. 10 - 13.

FLINT, V., 2005. The place of ECT in mental health care. *Nursing New Zealand, 11 (9), pp. 18 - 19*

FREEDMAN, B., 1975. A moral theory of informed consent. *Hastings Center Report,* August. pp. 32 - 39.

FREEMAN, C.P.L., WEEKS, D., KENDELL, R.E., 1980. E.C.T: Patients who complain. *British Journal of Psychiatry*, 137, pp. 17 – 25.

FYLE, J., McGLYNN, A. G., 2002. Bristol: still posing questions. *RCN Midwives Journal*, 5 (7), pp. 212 - 213.

FRY, S., JOHNSTONE, M., 2002. *Ethics in nursing practice.* Second ed. Oxford: Blackwell Science Ltd.

GASS, J.P., 1998. The knowledge and attitudes of mental health nurses to Electroconvulsive therapy*. Journal of Advanced Nursing,* 27, pp. 83 – 90.

GASS, J., 2006. Electroconvulsive therapy and the work of mental health nurses: A grounded study. *International Journal of Nursing Studies* [online] 45 (2), pp. 191 - 202. Available from: www.sciencedirect.com. [Accessed: 02/02/2008]

GENERAL MEDICAL COUNCIL, 1998. Seeking patients' consent: the ethical considerations [online] London: General Medical Council. Available from: *http://www.gmc -uk.org/standards/consent.htm* [Accessed 17th February 2005]

GRAMPIAN UNIVERSITY HOSPITAL NHS TRUST, 2002. *Informed consent policy.* Aberdeen: NHS Grampian

GRIESBACH, D., 2007. *National programme for improving mental health and wellbeing: small research projects initiative 2006-07: A qualitative exploration of the links between self-harm and attempted suicide in young people.* [online] Crieff: Griesbach & Associates. Available from: http://www.scotland.gov.uk/Publications/2007/09/13094713/1. [Accessed: 02/04/2010]

HABIBA, M.A., 2000. Examining consent within the patient-doctor relationship. *Journal of Medical Ethics,* 26, pp. 183 - 187.

HABIBA, M., JACKSON, C., AKKAD, A., KENYON, S., DIXON - WOODS, M., 2004. Women's accounts of consenting to surgery: is consent a quality problem? *Quality Safety Health Care.* [online]13, pp. 422 - 427. Available from: qshc.bmj.com [Accessed: 26/09/07]

HALSALL, S.M., LOCK, T., ATKINSON, A., 1995. Nursing guidelines for ECT. In: C.P. FREEMAN, ed. *The E.C.T. Handbook*. London: Royal College of Psychiatrists. pp. 114 -121.

HOUSE OF COMMONS, 2001. *The Royal Liverpool Children's Inquiry. Summary & Recommendations.* London: House of Commons

HUANG, H. C., LIN, W.C., LIN, J.D., 2008. Development of a fall - risk checklist using the Delphi technique. *Journal of Clinical Nursing*, 17 (17), pp. 2275 - 2283.

JANICAK, P.G., MASK, J., TRIMAKAS, K.A., GIBBONS, R., 1985. ECT: An assessment of Mental Health professionals' knowledge and attitudes. *Journal Clinical Psychiatry,* 46 (7), pp. 262 - 266.

JOURNAL OF MEDICAL ETHICS. 1983. Editorial. Impaired autonomy and rejection of treatment. *Journal of medical ethics,* 9, pp. 131 - 132.

JONES, J., HUNTER, D., 1995. Qualitative research: Consensus methods for medical and health services research. *British Medical Journal,* 5th August, pp. 311 – 380.

KASHKA, M.S., KEYSER, P.K., 1995. Ethical issues in informed consent and ECT. *Perspectives in Psychiatric Care*, 31 (2), pp.15 - 21.

KEEN, T, 2000. Should nurses have the right to opt out of ECT treatment? *Nursing Times,* 96 (9), p.18.

KEENEY, S., HASSON, F., 2006. Consulting the oracle: ten lessons from using the Delphi technique in nursing research. *Journal of Advanced Nursing*, 53 (2), pp. 205 - 212.

KIRBY, M.D., 1983. Informed consent: what does it mean? *Journal of Medical Ethics,* 9, pp. 69 – 75.

LAPID, M.I., RUMMANS, T. A., PANKRATZ. S., APPLEBAUM, P.S., 2004. Decisional capacity of depressed elderly to consent to Electroconvulsive Therapy. *Journal of Geriatric Psychiatry and Neurology,* 17(1), pp. 42 - 46.

LAVELLE-JONES, C., BYRNE, D.J., RICE, P., CUSCHIERI, A., 1993. Factors affecting quality of informed consent. *British Medical Journal*, 306 (6882), pp. 885 - 890.

LUTZEN, K., 1998. Subtle coercion in psychiatric practice. *Journal of Psychiatric and Mental Health Nursing,* 5, pp. 101 - 107.

LAMPECHT, H.C., FERRIER, N., SWANN, A.G., 2005. The use of ECT in depressive illness. In: A.I.F. Scott, ed. *The ECT handbook*. Second edition. London: Royal College of Psychiatrists. pp. 9 - 24.

LYONS, D., ed., 2003. *Mental Health (Care and Treatment) (Scotland) Act 2003. Implications for ECT.* Proceedings of the Scottish ECT Audit Network meeting. 23/11/2005. Edinburgh: Mental Welfare Commission for Scotland. pp. 1 - 8.

MANIC DEPRESSION FELLOWSHIP SCOTLAND, 1996. *ECT. Your questions answered*. Glasgow: Manic Depression Fellowship Scotland and Scottish Association for Mental Health

MAYO CLINIC, 2004. *Electroconvulsive Therapy: Dramatic relief for severe mental illness.* [online] America:Mayo Foundation for Medical Education and Research. Available from: www.mayoclinic.com/invoke.cfm? [Accessed: 20/06/05]

MEISEL, A., ROTH, L.H., LIDZ, C.W., 1977. Toward a model of the legal doctrine of informed consent. *American Journal of Psychiatry. 134 (3), pp. 285 - 288*

MEISEL, A.J.D.., KUCZEWSKI, M., 1996. Legal and ethical myths about informed consent. *Archives of Internal Medicine.* 156 (22), pp. 2521 – 2526.

MENTAL WELFARE COMMISSION FOR SCOTLAND, 2003. Consent to treatment: Mental Health and the law. A guide for Mental Health practitioners. Edinburgh: The Mental Welfare Commission for Scotland

MESSER, N.G., 2004. Professional - patient relationships and informed consent. *Postgraduate Medical Journal.* [online] 80, pp. 277 - 283. Available from: http://journals.bmj.com/cgi/reprintform. [Accessed 11/02/08]

MISHRA, P. K., OZALP, F., GARDNER, R, S., ARANGANNAL, A., MURDAY, A., 2006. Informed consent in cardiac surgery: is it truly informed? *Journal of Cardiovascular Medicine*, 7(9), pp. 675 - 681

MUNN, P., DREVER, E., 1990. *Using questionnaires in small - scale research*. Edinburgh: The Scottish Council for Research in Education
NHS BORDERS, 2007. *Patient information on ECT*. Huntlyburn House, Melrose: NHS Borders

NHS SCOTLAND, 2006. *Consent it's your decision*. Scotland: Health Rights Information

NHS SCOTLAND, 2007. Educational resources. *Clinical Governance.* [online] Scotland: NHS Scotland. Available from: http://www.clinicalgovernance.scot.nhs.uk/section6/introduction.asp [Accessed 02/03/2008]

NHS Education for Scotland, 2007. *The 10 essential shared capabilities for Mental Health practice: learning materials (Scotland).*Edinburgh: NHS Education for Scotland

NHS EXECUTIVE HEALTH SERVICE CIRCULAR, 2001. Good practice in consent [online] London: Crown. Available from: http: //www.doh.gov.uk/ publications/ coinh.html [Accessed 04/02/2005]

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE (NICE), 2003. *The use of electroconvulsive therapy.* London: NICE

NAZARKO, N., 2004. Making decisions. *Nursing Management*, 10 (10), pp. 18 - 22.

NURSING & MIDWIFERY COUNCIL, 2004. *The NMC code of conduct: standards for conduct, performance and ethics*. London: NMC

NURSING AND MIDWIFERY COUNCIL, 2006. A - Z advice sheet. Consent. [online] London: NMC. Available from: www. nmc - uk.org [Accessed 30 March 2009]

NURSING AND MIDWIFERY COUNCIL, 2008. *The NMC code of conduct: standards for conduct, performance and ethics*. London: NMC

NURSING TIMES NEWS (1983) Student sacked and two resign in ECT row. *Nursing Times.* January, 19, p.4

O' BRIEN, A.J., GOLDING, C.G., 2003. Coercion in mental healthcare: the principle of least coercive care. *Journal of Psychiatric and Mental Health Nursing,* 10, pp. 167 - 173.

O'NEILL, B., 2000. Death certification needs tightening up, but it still might not have stopped Shipman. *British Medical Journal*. [online] 320 (7231):329. Available from http://www.bmj.com/cgi/content/full/320/7231/329. [Accessed 02/10/2007]

OPPENHEIM, A.N.1992. *Questionnaire design, interviewing and attitude Measurement.* London: Pinter Publishing Ltd.

OTTOSSON, J., FINK, M., 2004. *Ethics in Electroconvulsive Therapy.* New York: Brunner- Routledge

OVERTON, W.E., 1999. *E.C.T. Your questions answered*. Dr. Gray's Hospital, Elgin: NHS Grampian

PAPE, T., 1997. Legal and ethical considerations of informed consent. *Aorn.* [online] 65 (6), pp. 1122 - 1127. Available from: http://ovidsp.uk.ovid.com/spb/ovidweb.cgi [Accessed 11/02/2008]

PARAHOO, K., 1997. *Nursing research. Principles, process and issues*. Hampshire: Palgrave Macmillan

PARSONS, S., 2000. Should nurses have the right to opt out of ECT treatment. 96 (9), p. 18.

PIPPARD, J., ELLAM, L., 1981. Electroconvulsive treatment in Great Britain. *British Journal of Psychiatry*, 139, pp. 563 - 568.

PIPPARD, J., 1992. Audit of Electroconvulsive treatment in two National Health Service regions. *British Journal of Psychiatry*, 160, pp. 621 - 637

POWELL, C., 2003. The Delphi technique: myths and realities. *Journal of Advanced Nursing,* 41, pp. 376 - 382.

RAE, P., BOLAND, L., 2008. *The value of the Scottish recovery indicator*. [online] Scotland: NHS Quality Improvement Scotland. Available from: http://www.piramhids.com/case-studies. [Accessed 01/04/2010]

RENNIE, S., ed., 1997. *Chambers Super - mini dictionary*. St. Ives: Chambers Harrap Publishing Ltd.

RICHARDS, T., 2006. Chairwoman of Shipman inquiry protests at lack of action. *British Medical Journal* [online] 332 (7550). Available from: *http://www.bmj.com/cgi/conent/full/332/7550/1111* [Accessed 02/10/2007]

RITTER, S., 1989, *Manual of clinical psychiatric nursing principles.* London: NMC

ROBSON, C., 1999. *Real world research*. Oxford: Blackwell

ROSE, R., WYKES, T., LEESE, M., BINDMAN, J., FLEISCHMANN, P. (2003) Patients' perspectives on electroconvulsive therapy: systematic review. *British Medical Journal,* 326, pp. 1363 - 1365.

ROSE, R., WYKES, T.H., BINDMAN, J.P., FLEISCHMANN ,P.S., 2005. Information, consent and perceived coercion. *British Journal of Psychiatry,* 186, pp. 54 - 59.

ROTH, L.R.., MEISEL, A., LIDZ, C.W., 1977. Tests of competency to consent to treatment. *American Journal of Psychiatry*, 134 (3), pp. 279 - 284.

SCHOLEFIELD, H.A., VINEY, C., EVANS, J., 1997. Expanding Practice and obtaining consent. *Professional Nurse.* 13 (1), pp. 12 – 16.

SCOTT, A.I.F, 2005. Prescribing. In: A.I.F., ed. *The ECT handbook.* Second ed. London: Royal College of Psychiatrists. pp. 136 - 143

SCOTTISH EXECUTIVE HEALTH DEPARTMENT, 2005. A good practice guide on consent for Health Professionals in NHS Scotland [online]. Available from: www.show.scot.nhs.uk/sehd/cmo letters.htm [Accessed December 2005]

SCOTTISH EXECUTIVE, 2006 (a). *Delivering care, enabling health.* Edinburgh: Scottish Executive.

SCOTTISH EXECUTIVE, 2006 (b) Delivering for health: Delivering for mental health using self-help in primary care and community based services. Edinburgh: Scottish Executive.

SHARMA, P., ANAND, A, SINGH, S., 2003. Informed consent for orthopaedic surgery: a prospective audit. *Clinical Governance: an international journal*. 8 (3), pp. 236 - 241.

SHUSTER, E., 1998. The Nuremberg Code: Hippocratic ethics and human rights. *Department of ethics.* 351, pp. 974 - 977.

SIMS, J.M., 2008. Your role in informed consent. *Dimensions of Critical Care Nursing.* [online] 27 (2), pp. 70 - 73. Available from: http://ovidsp.uk.ovid.com/spb/ovidweb.cgi? [Accessed 31/07/2008]

SMITH, R. ed., 1998. British medicine will be transformed by the Bristol case. *British Medical Journal,* 316, pp. 1917 - 1918. Available from: http://www.bmj.com/cgi/content/full/316/7149/1917 [Accessed 27/09/2007]

SOMATICS, LLC., 2004. *Frequently asked questions.* [online] Somatics, LLC. Available from: http://thymatron.com/main faq.asp. [Accessed 27/09/2005]

STRONG, C., 1979. Informed consent: theory and policy. *Journal of medical ethics,* 5, pp. 196 - 199.

SWEENEY, M.L., 1991. Legally speaking. *RN,* August, pp. 55 - 60.

TAYLOR, P.J., 1983. Consent, competency and ECT: a psychiatrist's view. *Journal of Psychiatry*, 9, pp. 146 - 151.

THE CONSENSUS GROUP AFFILIATED TO THE SPECIAL COMMITTEE. (2005) The place of ECT in contemporary psychiatric practice. In: A.I.F. SCOTT, ed. The ECT Handbook. 2nd ed. London: Royal College of Psychiatrists. pp. 3 - 8.

THE MEDICAL DEFENCE UNION, 1992. *Consent to treatment*. London: The Medical Defence Union

THE MENTAL HEALTH FOUNDATION, 2004. *Electroconvulsive Therapy (ECT), a factsheet from the Mental Health Foundation*. [online] The Mental Health Foundation. Available from: http://www. mentalhealth.org.uk [Accessed 14/06/2005]

THE ROYAL COLLEGE OF PSYCHIATRISTS, 1993. *Patient Factsheet on ECT (Electroconvulsive Therapy)* London: The Royal College of Psychiatrists. [online] London: The Royal College of Psychiatrists. Available from: *http://sean.org.uk/Main/RoyalCollegeOfPsychiatristsPatientFactsheetECTElecrocon*… [Accessed: 25/06/2007]

THE SCOTTISH E.C.T. AUDIT NETWORK (SEAN), 2000. *E.C.T. in Scotland. A guide to Electroconvulsive Therapy. The latest evidence.* Glasgow: Mackay and Inglis

USHER, K., ARTHUR, D., 1998. Process consent; a model for enhancing informed consent in mental health nursing. *Journal of Advanced Nursing*, 27, pp. 692 - 697.

VAN STADEN, C.W., KRUGER, C., 2003. Incapacity to give informed consent owing to mental disorder. *Journal of Medical Ethics,* 29, pp. 41 - 43.

WHITEHEAD, D., 2008. An international study examining health promotion and health education in nursing practice, education and policy. *Journal of Clinical Nursing.* [online]17 (7), pp. 891 - 900. Available from: *http: ovidsp.uk.ovid.com/spb/ovidweb.cgi?* [Accessed 3 September 2008]

WITT, R.R., ALMEIDA, M.C.P. de, 2008. Identification of nurses' competencies in primary health care through a Delphi study in southern Brazil. *Public Health Nursing.* [online] 25 (4), pp. 336 - 343. Available from: *http: ovidsp.uk.ovid.com/spb/ovidweb.cgi?* [Accessed 3 September 2008]

WORTHINGTON, R., 2002. Clinical issues on consent: some philosophical concerns. *Journal of Medical Ethics,* 28, pp. 377 – 380.

APPENDICES

Appendix 1

ECT Nurses - Letter of information

ECT Dept.,
Mearns Suite,
Royal Cornhill Hsp.,
Cornhill Rd.,
Aberdeen,
AB25 2ZH
Tel: (01224)557615
E - Mail: shona.burke@gpct.grampian.scot.nhs.uk

Dear Colleague,

Research Project Title - Informing consent for ECT

I am an MSc student at Robert Gordon University and am currently conducting a research project in order to explore the nature, indications and processes of informed consent in patients receiving ECT. As part of this project I would like to explore the ECT nurse's role in the consent process. In order to do this I would like to invite you to complete the enclosed questionnaire. Your participation is purely voluntary and your response will remain confidential and anonymous. The data will be stored so that no one is able to access it.

Benefits of the study

The perceived benefits of the study is that a tool will be developed which can be administered by staff to confirm that the knowledge required for informed consent has been obtained in patients consenting to ECT.

Collation of patient information

As another part of this project I am collating the information that is currently available for patients receiving ECT in order to formulate a knowledge base that clients are required to have to be considered “fully informed”. I would be grateful if you could provide me with a copy of the information that you currently provide for patients receiving ECT.

Please return the questionnaires and information separately in the two envelopes provided.

Please contact me if you have any questions that you would like to ask about this research,

Yours Sincerely,

Shona Burke,
Mearns Suite Co - ordinator

Appendix 2

Delphi process – letter of information

Adult Mental Health Directorate
C/o Block A,
Royal Cornhill Hsp.,
Cornhill Rd.,
Aberdeen
AB25 2ZH
Tel: (01224) 557471
E - Mail: shona.burke@gpct.
grampian.scot.nhs.uk

Dear Colleague,

Project title - Informing consent for ECT

I am an MSc student at Robert Gordon University and am currently conducting a research project in order to explore the nature, indications and processes of informed consent in patients receiving ECT. As part of this project I would like to assess the knowledge base that patients would be required to have in order to provide informed consent.

Delphi process

In order to do this I would like to invite you to participate in a consensus method named the Delphi process. This method will involve asking members of the 'expert panel', which will consist of ECT Consultants and ECT nurses in Scotland and a representative from a user group, for expert consensus on an explicit statement of the knowledge base that clients would be required to have to be considered " fully informed". As a member of the 'expert panel' you will be requested to rate each statement on the information sheet. The order of importance will then be summed up and combined in a duplication of the questionnaire. Members of the 'expert panel' will then be requested to re - rank each statement, this time having the opportunity to alter their mark considering what the panel's reaction was. The change in consensus will then be summed up and the extent ascertained. If there is a satisfactory agreement the method will be discontinued and if not the last step will be repeated. If you consider that the statements should appear in a different sequence or if there is any information that you consider should be added to the statement of knowledge please state this at the end of the questionnaire.

Roles and responsibilities of medical and nursing staff in the informed consent process

The second part of this stage of the project contains a questionnaire on the roles and responsibilities of medical and nursing staff in the informed consent process. Please consider the statements and tick the column that you consider is appropriate. If there is anything that you consider should be included in the statements then this can be added at the end of the questionnaire.

Both questionnaires were compiled by reviewing the literature on informed consent and writing to ECT clinics in Britain and abroad and user groups to gather the information that is currently available for patients receiving ECT. Data was also gathered from questionnaires which were sent to all ECT nurses in the 24 ECT sites in Scotland to ascertain their interpretation of their role in the consent process

The length of time the process will take is approximately 30 minutes for both questionnaires.

Your participation is purely voluntary and your response will remain confidential and anonymous. The data will be stored so that no one is able to access it.

Benefits of the study

The perceived benefits of the study are that a tool will be developed which can be administered by staff to confirm that the knowledge required for informed consent has been obtained in patients consenting to ECT.

Please contact me if you have any questions that you would like to ask about this research.

Informed consent forms

If you are willing to participate in this research please sign the enclosed informed consent forms and return them to me by 16/06/08. I will then countersign the forms and return a copy to you.

Yours Sincerely,

Shona Burke

Appendix 3

Delphi process - informed consent form

Informed Consent Form

Project Title: To explore the nature, indication and processes of informed consent in patients receiving ECT

Name of Researcher: Shona Burke, Adult Mental Health Directorate, C/o Block A, Royal Cornhill Hospital, Cornhill Rd., Aberdeen, AB25 2ZH. Telephone: (01224) 557421
E - Mail: shona.burke@gpct.grampian.scot.nhs.uk

Please initial box

1. I confirm that I have read and understood the covering letter dated: 22/02/08…….. ☐
(version 4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw my consent at any time. ☐

3. I agree to take part in the above study

Name of Participant : …….
Signature of Participant: ……
Date:……..

Name of Researcher: ……..
Signature of Researcher: ……..
Date: ……...

Appendix 4

Letter from Grampian Local Research Ethics Committee

06/S0802/116

NHS
Grampian

Grampian Local Research Ethics Committee (2)
Summerfield House
2 Eday Road
Aberdeen
AB15 6RE

Telephone: 01224 558474
Facsimile: 01224 558629

26 October 2006

Miss Shona M. Burke
Mearns Suite Co-ordinator
Grampian NHS Board
Royal Cornhill Hospital
Cornhill Road
Aberdeen
AB25 2ZH

Dear Miss Burke

Full title of study: **To explore the nature, indication and processes of informed consent in patients receiving ECT.**
REC reference number: **06/S0802/116**

Thank you for your letter of 6th October 2006 and email dated 25th October 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

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.

Condition 1: Annual Progress Report

Under the Central Office of Research Ethics Committees (COREC) regulations NHS Research Ethics Committees are required to monitor research with a favourable opinion. This is to take the form of an annual progress report which should be submitted to the Grampian Research Ethics Committee 12 months after the date on which the favourable opinion was given. Annual reports should be submitted thereafter until the end of the study.

Points to note:

- The first annual progress report should give the commencement date for the study. This is normally assumed to be the date on which any of the procedures in the protocol are initiated. Should the study not commence within 12 months of approval a written explanation must be provided in the 1st annual progress report.
- Progress reports should be in the format prescribed on the COREC website (www.corec.org.uk/applicants/apply/progress.htm).
- Progress reports must be signed by the Principal Investigator/Chief Investigator.

- Failure to submit a progress report could lead to a suspension of the favourable ethical opinion for the study.

- Please note the Annual Progress Report is a short 3 page form which is extremely easy to complete.

Condition 2: Notification of Study Completion/Termination

Under the Central Office of Research Ethics Committees (COREC) regulations researchers are required to notify the Ethics Committee from which they obtained approval of the conclusion or early termination of a project and to submit a Completion/Termination of Study Report. Researchers should follow the instructions on the COREC website (www.corec.org.uk/applicants/apply/endofproject.htm).

Points to note:

- For most studies the end of a project will be the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection described in the protocol.

- Final analysis of the data and report writing is normally considered to occur after formal declaration of the end of the project.

- A Final Report should be sent to the GREC within 12 months of the end of the project.

- The summary of the final report may be enclosed with the end of study declaration, or sent to the REC subsequently.

- There is no standard format for final reports. As a minimum we should receive details of the end date and information on whether the project achieved its objectives, the main findings and arrangements for publication or dissemination of research, including any feedback to participants.

- Please note the Completion/Termination of Study Report need only be a summary document and should, therefore, be easy to prepare.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application		30 August 2006
Application		09 October 2006
Investigator CV		
Protocol	1	30 August 2006
Covering Letter		06 October 2006
Questionnaire	1	30 August 2006
Letter of invitation to participant	1	30 August 2006
Letter of invitation to participant	2 - Delphi process	07 October 2006
Letter of invitation to participant	2 - ECT Nurses	07 October 2006
Participant Consent Form	1	30 August 2006
Response to Request for Further Information		
Letter of Invitation: Delphi Process	1	30 August 2006
Supervisor's CV		
email response to queries		25 October 2006

Research governance approval

You should arrange for the R&D department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain final research governance approval before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

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/S0802/116	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Irene Allan

Dr Sheila Simpson
Chair

Enclosures: *Standard approval conditions*

Copy to: R&D Department for NHS Grampian

Appendix 5

Letters from Local Research and Development department and Scottish Multicentre Research and Development Management review

Research and Development Foresterhill House Annexe
Foresterhill
Aberdeen
AB25 2ZB

NHS Grampian

Date 14/12/06
Ethics 06/S0802/116
R&D Ref: 2006MH011

Ms Shona Burke
Meams Suite
Royal Cornhill Hospital
Cornhill Road
Aberdeen
AB25 2ZH

Enquiries to Katy Booth
Extension 54656
Direct Line 01224 554656
Email k.booth2@nhs.net

Dear Ms Burke,

Project title: To explore the nature, indication and processes of informed consent in patients receiving ECT.

Thank you very much for sending all relevant documentation. I am pleased to confirm that the project is now registered with the NHS Grampian Research & Development Office. The project has R & D Management Approval to proceed locally.

Please note that if there are any other researchers taking part in the project that are not named on the original Ethics application, please advise the Ethics Committee in writing and copy the letter to us so that we may amend our records and assess any additional costs.

Wishing you every success with your research

Yours sincerely

Katy Booth
Data Co-ordinator

Scottish Multicentre Research & Development Management Review

MRAD Head Office: Research & Development
5th Floor, Neurological Sciences
Southern General Hospital
NHS Greater Glasgow & Clyde
Glasgow
G3 8SJ

Telephone: 0141 201 1889
E-mail: rachel.robertson@yorkhill.scot.nhs.uk

1st March 2007

Ms Shona Burke
Mearns Suite
Royal Cornhill Hospital
Cornhill Road
Aberdeen
AB25 2ZH

Dear Ms Burke,

Full title of study: To explore the nature, indication & processes of informed consent in patients receiving ECT

MRAD reference: MRAD07/DI/MH02

REC reference number: 06/S0802/116

REC Status: Approved 26th October 2007

The Multi-Centre Research and Development Consortium (MRAD) Consortium would like to thank you for submitting documents for the above study and for responding to enquiries from the administrator and lead reviewer. MRAD have reviewed the documents associated with the above application at the meeting held on **21st February 2007**

MRAD opinion

Result: - Favourable Opinion

The MRAD Consortium are satisfied with the documents submitted. The complete document set has been sent electronically to each participating site.

Please note that your study cannot begin at a participating site until R&D Management Approval is obtained following locality review from that site.

Locality Review

Locality review has still to be undertaken at participating sites. Each site will be requested to inform MRAD of the outcome of the local review and provide written confirmation of local approval for the study. MRAD shall inform the Chief Investigator and the Research Sponsor of the review decision from each site as soon as it is available and provide a copy of the site approval letter.

Sites Informed

NHS Ayrshire & Arran, NHS Borders, NHS Dumfries & Galloway, NHS Fife, NHS Forth Valley, NHS Grampian, NHS Greater Glasgow & Clyde, NHS Highland, NHS Lanarkshire, NHS Lothian, NHS Tayside.

If you would like to add any additional sites then please inform the MRAD Administrator.

Documents Reviewed

Document	Yes/No/ Not Applicable	File Name	Version
A& B of Ethics	Yes	NHS REC APPn	5-3
Signed back sheet (A & B)	Yes	Signature, Sponsor, REC.pdf	
R & D Form	Yes	NHS R & D Form	1-0
Signed back sheet (R & D)	Yes	Signature, Sponsor, REC.pdf	
Protocol	Yes	ADR 4 proposed plan of work	09/01/07
PIS	Yes	Letter to ECT nurses	8/01/07
		Letter to participants of the Delphi process	7/10/07
Consent	Yes	Informed consent form for COREC (for Delphi process)	7/10/06
Questionnaire	Yes	Shona ECT Questionaire	23/08/06
Sponsors Letter	Yes	Signature, Sponsor, REC.pdf	
List of sites	Yes	List of Sites	10/01/07
Peer Review	Yes MSc Study		
MREC favourable opinion letter	Yes	Signature, Sponsor, REC.pdf	

I would like to thank you for using the MRAD process and confirm that MRAD will notify you of local NHS Management approval as it becomes available.

Yours sincerely,

MRAD Lead
(on behalf of MRAD)
cc. Professor Peter Robertson, The Robert Gordon University

2

Appendix 6

Letter from Robert Gordon University, School of Nursing and Midwifery Ethics Review Panel

THE ROBERT GORDON UNIVERSITY ABERDEEN

SCHOOL OF NURSING AND MIDWIFERY
Faculty of Health and Social Care
The Robert Gordon University
Garthdee Road
Aberdeen
AB10 7QG
United Kingdom
Tel: 01224 262000 Ext:
Fax: 01224 262630
www.rgu.ac.uk

27th September 2006

Research proposal number: 06/09

Research proposal title: The nature, indication and processes of informed consent in patients receiving ECT

Dear Shona

The School of Nursing and Midwifery Ethics Review Panel has now reviewed the above research proposal. Please find details of the outcome and recommended actions below.

☑	Proposal approved	We will forward a copy of the relevant documents to CREDO, RGU. You may go ahead with your research, providing approval from any relevant external committee/s has been obtained.*
☐	Proposal approved subject to amendments.	Please review and amend all relevant documents in the light of the comments given, then forward them to the Convenor who will give final approval.
☐	Proposal not approved: significant ethical issues as yet inadequately addressed.	Please review your proposal in light of the issues identified. If you require further clarification or discussion please contact the Convenor. You are welcome to re-submit your proposal when the issues of concern have all been addressed.
☐	Proposal referred to CREDO and/or the University Ethics sub committee.	Some proposals require consideration and input from colleagues outwith the School of Nursing and Midwifery. We will keep you informed of progress in this regard, and involved in the process as appropriate.

* Where research involves NHS staff or patients, approval through the NHSREC system must be obtained (see www.corec.org.uk). Members of the School Panel can advise on this process if necessary.

Comments

Approved, following satisfactory clarification on a number of points.

Signature of Panel member

Position held:

If you require further information please contact the Panel Convenor, Colin Macduff or Fiona Ramage, Committee Secretary, on 01224 262647.

Appendix 7

ECT Nurse Questionnaires

Questionnaire for ECT Nurses on their interpretation of their role in the consent process

SECTION A: Personal details

1. Please indicate your age ……

2. Please identify your gender Male [ ] Female [ ]

3. Please tick which part or parts of the NMC register you are entered on?

1.	RMN (Pre 1992)	[ ]
2.	RGN (Pre 1992)	[ ]
3.	EN	[ ]
4.	RMHN (Pre 1992)	[ ]
5.	RMN (Project 2000)	[ ]
6.	RGN (Project 2000)	[ ]
7.	RNMH (Project 2000)	[ ]

Other, specify ……

4. Please indicate how long you have worked as an ECT Nurse ……

5. What grade is your post?

D	[ ]
E	[ ]
F	[ ]
G	[ ]
H	[ ]
I	[ ]

Other, specify……

6. Do you work Full time? [ ]

Part time? [ ]

7. In which region in Scotland are you based? .....

8. How many patients are treated on average per week in your ECT Suite? .....

SECTION B: Statements 9 – 19 refer to the role of the nurse in the consent process. Please indicate your response to each of the following by ticking ONE box only.

9. I ensure that patients have been given sufficient verbal and written information to assist them in making an informed decision about receiving ECT

Always	*Usually*	*Sometimes*	*Seldom*	*Never*

10. I assist in ensuring that the patient understands the nature, purpose and side effects of the treatment

Always	*Usually*	*Sometimes*	*Seldom*	*Never*

11. I assist in the assessment of the patient's decisional capacity to provide informed consent

Always	*Usually*	*Sometimes*	*Seldom*	*Never*

12. I assist in the assessment of the patient's voluntarism to provide informed consent

Always	*Usually*	*Sometimes*	*Seldom*	*Never*

13. I ensure that the patient giving informed consent has signed and dated the consent form

Always	*Usually*	*Sometimes*	*Seldom*	*Never*

14. I inform medical staff if a patient refuses to go ahead with receiving ECT

Always	*Usually*	*Sometimes*	*Seldom*	*Never*

15. I inform medical staff if a patient is unsure about receiving ECT

Always	*Usually*	*Sometimes*	*Seldom*	*Never*

16. Prior to each treatment I assess that patients continue to consent to treatment on the basis of the information that was originally provided when they initially agreed to ECT

Always	*Usually*	*Sometimes*	*Seldom*	*Never*

17. Are there any written specifications about the role of the ECT Nurse in the consent process in your workplace?

Don't know	[ ]
Yes	[ ]
No	[ ]

18. What do you consider the ECT nurse's role should be in the consent process?

Please give your comments below

.....

.....

.....

.....

3

19. What nursing values do you think influence a Mental Health Nurse's ability to provide care for patients?

In a positive way	*In a negative way*
Please describe briefly	Please describe briefly
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....

SECTION C: Statements 20 - 21 list items of information that should be provided to patients who are considering having treatment with ECT.

20. Please rank in order of importance (1st to 8th) the information you provide to patients about ECT

	Order of importance
Alternative treatments to ECT	
Patient is aware they can withdraw their consent at any time	
The reported risks of ECT including short and long term side effects	
ECT requires the administration of a general anaesthetic and muscle relaxant	
Treatment requires fasting prior to administering the anaesthetic	
The duration of an average course of treatment with ECT	
The nature of ECT and why it has been prescribed	
The reported benefits of ECT including short and long term effects	

If there is any other information that you think a patient should be aware of other than above please specify

.....

21. Please rank in order of importance the side effects the patient should be aware of in order to provide informed consent

	Order of importance
Nausea	
Confusion	
Psychiatric complaints	
Headaches	
Memory loss	
Muscular stiffness	
Loss of appetite	

If there are other side-effects please specify.....

SECTION D: Items 22 – 29 examine the provision of consent

22. Please consider recent patients in your practice who have consented to ECT. In your opinion how many of these have not provided informed consent?

Please indicate your response by ticking ONE box only

0%	1 - 25%	26 - 50%	51 - 75%	*Over 75%*

What were the main reasons for this? .....

.....

.....

23. Did you draw this to anyone's attention?

Don't know [ ]
Yes [ ]
No [ ]
If yes, please describe what happened
.....

.....

5

24. Do you think that you have sufficient knowledge on each of the following elements of informed consent?

	Strongly Agree	***Agree***	***Unsure***	***Disagree***	***Strongly Disagree***
Ongoing process					
Mental Health Act					
Knowledge					
Human rights					
Decisional capacity					
Patient's autonomy					
Providing sufficient information					
Purpose					
Ethics					
Equitable nurse/ patient relationship					

25. Do you consider that nursing students have sufficient knowledge on each of the following elements of informed consent?

	Strongly Agree	***Agree***	***Unsure***	***Disagree***	***Strongly Disagree***
Ongoing process					
Mental Health Act					
Knowledge					
Human rights					
Decisional capacity					
Patient's autonomy					
Providing sufficient information					
Purpose					
Ethics					
Equitable nurse/ patient relationship					

26. Do you consider that medical staff possess sufficient knowledge on each of the following elements of informed consent?

	Strongly Agree	*Agree*	*Unsure*	*Disagree*	*Strongly Disagree*
Ongoing process					
Mental Health Act					
Knowledge					
Human rights					
Decisional capacity					
Patient's autonomy					
Providing sufficient information					
Purpose					
Ethics					
Equitable Doctor / patient relationship					

If there are any other elements of informed consent that you can identify, please specify

.....

.....

.....

27. Have you ever challenged the medical staff prescribing the treatment when you thought that a patient was not giving informed consent?

Don't know [ ]
Yes [ ]
No [ ]

If yes, please describe what happened

.....

.....

28. Have you ever considered that medical staff appeared to be coercing a patient into having ECT?

Don't know [ ]
Yes [ ]
No [ ]

If yes, please describe what happened

.....
.....

29. Have you ever considered that nursing staff appeared to be coercing a patient into having ECT?

Don't know [ ]
Yes [ ]
No [ ]

If yes, please describe what happened

.....
.....

SECTION E: in this section items 30 - 32 examine the confirmation of consent to ECT

30. A patient's consent to ECT is confirmed (*Please tick one box only*)

After every treatment	*After each second treatment*	*After every third treatment*	*Occasionally*	*Never*

31. A patient's consent to ECT is reviewed (*Please tick one box only*)

After every treatment	*After each second treatment*	*After every third treatment*	*Occasionally*	*Never*

Other, please specify .....

8

32. When a detained patient doesn't consent to ECT for whatever reason the patient's consent status is reviewed (***Please tick one box only***)

After every treatment	*After each second treatment*	*After every third treatment*	*Occasionally*	*Never*

SECTION F: In this section items 33 - 35 relate to the patient's capacity to provide consent

33. The cognitive function of patients receiving ECT is assessed by the prescribing team (***Please tick one box only***)

Always	**Usually**	**Sometimes**	**Seldom**	**Never**

If assessment of cognitive function takes place, please describe how this is completed in your area

.....

.....

34. The cognitive function of patients is assessed in the treatment centre by the ECT team (***Please tick one box only***)

Always	*Usually*	*Sometimes*	*Seldom*	*Never*

If assessment of cognitive function by the ECT team takes place, please describe how this is completed in your area

.....

.....

35. What happens if at any stage of the patient's treatment it becomes apparent that they cannot recall giving informed consent?

.....

.....

Thank you very much for taking the time to complete this questionnaire.
Your time and effort are greatly appreciated.

28 August 2006

Appendix 8

Research journal

8a - Formulation of ECT Nurse questionnaires

①

17/3/06 Research Journal - Devising Questionnaire for ECT nurses

I will try to chart how I went about devising the questionnaire for ECT Nurses

My first draft was basically a brainstorming of what I wanted to ask ECT nurses about their interpretation of consent based on my own experience in practice & literature read initially for the Mod. one assessment on writing a proposal.

In my own practice because I am 5 years into the job I have found that there have been across patients who are not giving informed consent (usually due to their lack of capacity due to the severity of their illness) or that their consent is fluctuating. I can appreciate that this is probably because of the length of time I've been in post & the amount of patients I have seen.

In the literature John Gass (1998) research also relates to this as does the audit done by Pippard (1992) ? SECTION A - Personal details

I thought it would be interesting to see if the ECT nurses interpretation of their role would be influenced by the amount of patients they saw or how long they had been working as an ECT nurse. I also wanted to see if there were any regional variations.

For Section B - Role in the consent process, I made up the statements based on practice experience / literature such as ECT Handbook (2005), CRIG working group on Mental Illness (1997).

Section C - Pre-treatment information - I devised this by looking at the patient information I had received from other centres & the information I thought patient wanted to know & from our own ECT suite.

Section D - Nature of Consent - Q8 - from speaking to Senior, Supervisory session, my own practice, still to define literature source. Q.9 + 10 - From my own experience / conversations with Ian Reid (Keshavan & Kaplan (1998)) at voicing that a patient is not giving informed consent & letting the team know. Luckily my challenges have always been upheld!

Q11 - Don't expect there to be any written specifications as we don't have any but I may be surprised

Q12 - Not much at all on the nurses role in the ECT consent process. Fitzsimmons has a section on consent but not specifying what the nurses role is. CRAG (1997) - just ensuring that the consent form has been signed

Section E:- Continuing Consent to ECT

+ 14, 15

Q13. Literature ? - Through local discussion, new SEAN guidelines to review patients after every second treatment on the data base. My own experience, especially in geriatrics where it is sometimes set out at the beginning of a patients course as documented by medical staff in the notes that ie. a patient will have 8 ECT treatments

Section F:- Cognitive Function - I am wished this to be explored. (see ECT Handbook

Literature - ? Lepid (2003) (includes McArthur competence assessment tool), Pippard (1992)

Through supervision it was ascertained that in the ECT suite we do actually informally assess the cognitive function of patients to see how they are responding to the treatment & in order for the psychiatrist to change the stimulus dosing if required. [Culver, Ferrell & Green (1980) Dunn (1998) - psychotic patients - benefits of educational material Seligmann (1977)

Q. on what would happen if a patient couldn't recall giving consent - John's suggestion. Through practice - patient didn't want to have ECT - severe depression, psychosis.

Q19. Literature - from Roth, Meisel & Lidz (1997) - Tests of competency to consent to treatment, Pippard - ECT Handbook, Crag (1997)

+ 21 - Dunn (1998) - as above; my own experience

References

• CRAG WORKING GROUP ON MENTAL ILLNESS (1997) Electroconvulsive Therapy (ECT) A good practice statement. Scotland: The Scottish Office

• CULVER, C.M., FERRELL, R.B., GREEN, R. (1980) ECT and special problems of informed consent. American Journal of Psychiatry, 137(5) pp. 586-591

• DUNN, C.J. (1998) Ethical Issues in Mental Illness. England: Ashgate Publishing Ltd.

• FITZSIMONS, L.M. + MAYER, R.L. (1995) Soaring beyond the cuckoo's nest: Healthcare reform and ECT. Journal of Psychosocial Nursing, 33(12), pp. 10-17

• GASS, J.P. (1998) The knowledge and attitudes of mental health nurses to Electroconvulsive therapy. Journal of Advanced Nursing, 27, pp. 83-90

• KASHKA, M.S., KEYSER, P.K. (1995) Ethical issues in informed consent and ECT. Perspectives in Psychiatric Care, 31(2), pp. 15-21

(2)

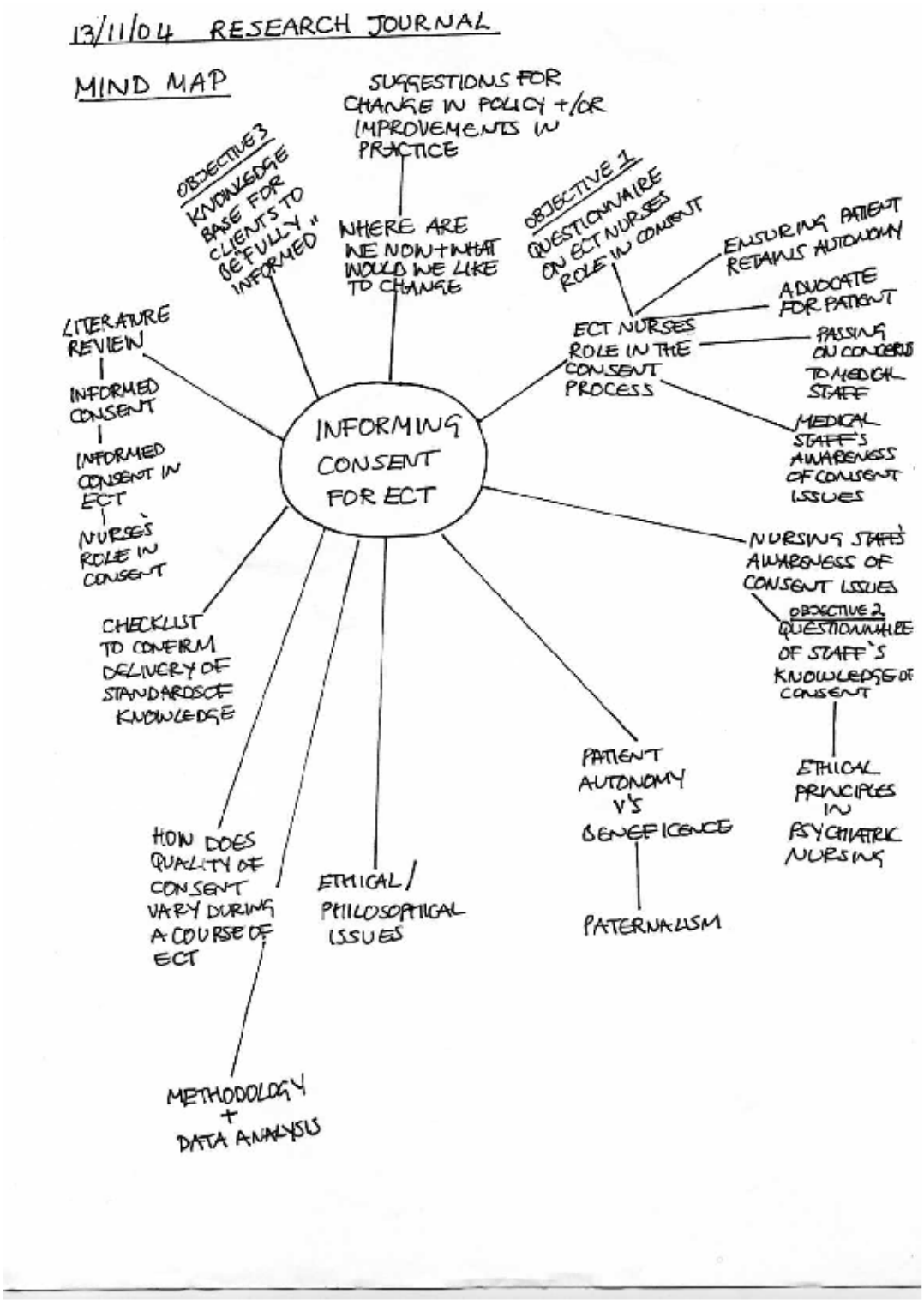
(cont.) ; 17/3/08 Research journal - Devising questionnaire for ECT nurses

Research

- LAPID, M. L., RUMMANS, T. A., POOLE, K. L., PANKRATZ, S., MAURER, M. S., RASMUSSEN, K. G., PHELPHICK, K. L., APPELBAUM, P. S. (2008) Decisional capacity of severely depressed patients requiring ECT. The Journal of ECT, (1912, pp. 67-72
- PUPPARO, J (1992) Audit of Electroconvulsive treatment in two National Health service regions British Journal of Psychiatry, 160, pp. 821-827
- ROTH, L. H., MEISEL, A., LIDZ, C. W. (1977) Tests of competency to consent to treatment. American Journal of Psychiatry; 134 (3), pp. 279-284
- SCOTT, A. I. F. (ed) (2008) The ECT handbook. Second ed. London: The Royal College of Psychiatrists.
- SALZMAN, C (1977) ECT and ethical psychiatry. American Journal of Psychiatry, 134 (9), pp. 1006-1009

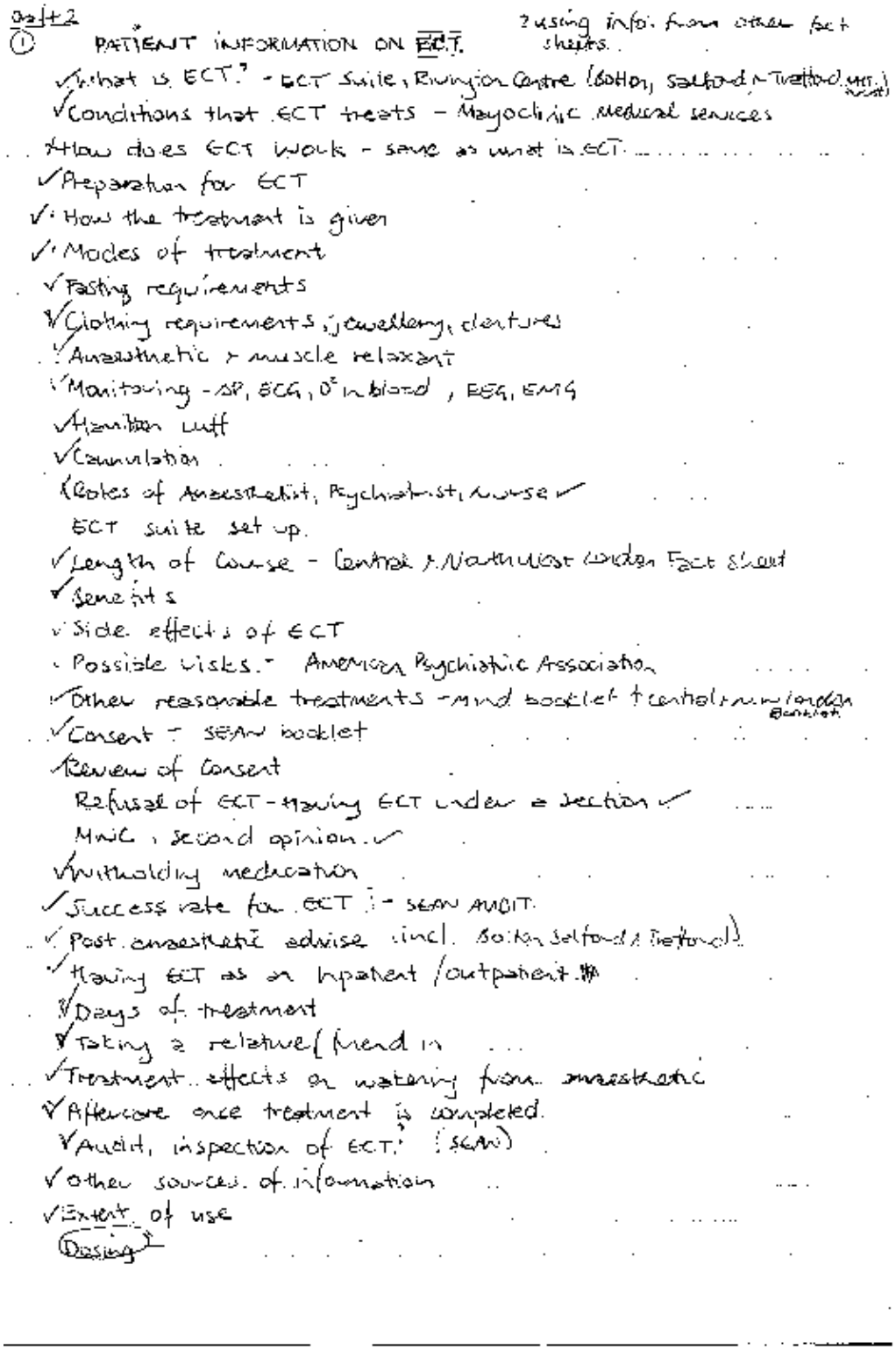
Appendix 8b

Mind map



Appendix 8c

Assimilation of patient information on ECT



Statistics of how well ECT works. ✓
Long term effects.
Historical Background.
✓ Length of treatment - Salford/Salford
✓ Administration of ECT

Appendix 9

Statement of knowledge questionnaire - first round

Statement of the knowledge base that a patient is required to have to give full, informed consent

Please rate the statements by ticking the column that you consider appropriate

1. The nature of ECT • *ECT involves the administration of a mild, controlled electric current which is passed across the head via the application of electrodes for a few seconds resulting in a seizure.* • *It is the seizure activity that can assist in the correction of the chemical imbalance in the brain that is thought to be the cause of depression.*	***Very applicable***	***Applicable***	***Not applicable***
2. Why ECT is prescribed • *For severe depressive illness that has not responded to a number of different treatments* • *Antidepressant treatment has had to be discontinued due to side effects* • *For a depressed person who is not eating or drinking adequately or has suicidal feelings* • *A patient has responded well to ECT in the past*			

3. ECT and consent	***Very applicable***	***Applicable***	***Not applicable***
• *An informal patient can withdraw their consent to ECT at any stage during the treatment* • *No type of coercion should be used at any time to coax a patient to have ECT* • *The patient remains completely entitled to have alternative treatments if they have refused ECT* • *If someone is unsure about consenting to the treatment they can request independent advice from places such as the Advocacy service or the Mental Welfare Commission* • *The patient's consent should be verified prior to each ECT treatment*			
4. Alternative treatments to ECT *Consist of treatments such as antidepressant therapy or psychological treatments such as counselling*			
5. Effectiveness • *In Scotland, there was a particular improvement in three - quarters of people treated with ECT for depressive illness. (SEAN, 2000)* • *ECT can be quick acting with benefits being recognized after 2 - 3 treatments* • *In some instances, such as when a patient is acutely suicidal or is refusing to eat or drink, ECT can be life saving*			

6. Anaesthetic and muscle relaxant *Prior to receiving ECT the patient will receive a short acting general anaesthetic and muscle relaxant via an intravenous injection*	***Very applicable***	***Applicable***	***Not applicable***
7. Reported risks ***Short term*** *Side effects that can occur include short term memory loss and confusion; headaches; nausea and muscular stiffness and psychiatric complications.* ***Long term*** • *A small number of patients have complained of longer term memory loss for events that have occurred before, during and after the treatment* • *It is difficult to comprehend how much of the memory loss is the result of severe depression or ECT* ***Medical complications*** *Patients with ongoing health problems have an increased possibility of cardiac or respiratory difficulties occurring proceeding the treatment* ***Mortality rate*** *The practice of ECT comprises a low risk with an associated mortality rate reported to be comparable with anaesthesia administered in minor surgery*			

8. Fasting requirements *ECT is given under a general anaesthetic so the patient should not eat six hours prior to or drink fluids four hours prior to the treatment*	***Very applicable***	***Applicable***	***Not applicable***
9. Duration of an average course • *The average course of ECT consists of around six treatments up to approximately twelve treatments.* • *ECT is usually administered twice a week.*			
10. Physical examination • *Each patient receives a physical examination prior to receiving ECT in order to ensure that they are fit enough to receive a general anaesthetic.* • *The physical examination includes a blood test, ECG and chest x- ray where indicated.*			

If you consider that the statements should appear in a different sequence please state your preferred sequence below:

……
……
……
……

If there is any other information that you consider should be added to the statement of knowledge please specify below:

……
……
……
……
……
……

Thank you very much for taking the time to complete this questionnaire. Your time and effort are greatly appreciated.

Appendix 10
The roles and responsibilities of medical and nursing staff questionnaire - first round

Roles and responsibilities of medical and nursing staff in the informed consent process in ECT

This questionnaire contains statements regarding the roles and responsibilities of medical and nursing staff in the informed consent process in ECT.

Please tick the box that you consider is relevant to each statement - desirable, essential or not applicable.

1. Medical role

The patient's decisional capacity is assessed by the referring psychiatrist to ensure informed consent is valid	**Desirable**	**Essential**	**Not Applicable**
The patient's voluntary informed consent is confirmed by the referring psychiatrist			
To ensure that the patient understands the nature, purpose and consequences of receiving the treatment and therefore what they are consenting to			
When ECT is considered the best treatment option for a patient but due to their mental state they are unable or unwilling to give consent then the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2002 is employed and a Doctor from the Mental Welfare Commission provides a second opinion			

Ensuring that the relevant documentation regarding the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2002 has been completed and is available	**Desirable**	**Essential**	**Not Applicable**
An equitable relationship is formed with the patient so that the decision to receive ECT is made jointly between the patient and treating psychiatrist.			
The patient is aware of alternative treatments and that these would be available if they decide to refuse ECT			
The informal patient is made aware that they can withdraw their consent to ECT at any time			
Ensuring that the patient is aware that the consequences of not receiving the treatment could result in a prolonged and increasingly severe phase of illness			
The patient and the treating psychiatrist sign the informed consent form just prior to the ECT course commencing in order to record the consultation and decision which has taken place recently			
All discussions and decisions taken relating to obtaining informed consent are documented in the patient's case notes			

A patient who is unsure about consenting to ECT will be aware that they can have access to independent advice or a second opinion from an advocacy service or the Mental Welfare Commission	**Desirable**	**Essential**	**Not Applicable**
The psychiatrist obtaining informed consent from the patient has sufficient knowledge of the nature, purpose and effects of ECT			
Ensuring that coercion is not employed at any time in order to persuade the patient to have ECT			
Relatives/ carers should be involved in discussions regarding the treatment unless issues of patient confidentiality prevents this			
When a patient has lost the capacity to provide informed consent to ECT or refuse the treatment any advance statements regarding treatment choices should be taken into account			
In an emergency situation such as the patient's life being at risk ECT can be given as soon as it can be organised, preferably with a second opinion given by a local psychiatrist			
Each individual patient is provided with sufficient verbal, written and/or audio information in order to enable her or him to make the decision whether to give informed consent to ECT or not			

Information previously given about ECT is brought to the patient's attention at different intervals during the course of treatment	**Desirable**	**Essential**	**Not Applicable**
Information necessary for decision making should not be withheld from the patient unless the practitioner can justify that disclosing the information would have a detrimental effect on the patient			
If information has been withheld from the patient this requires to be documented in the patient's case notes as there may be a necessity to justify this decision at a later date			
The patient should have sufficient time without being subject to pressure to reflect on the information prior to making a decision about consenting to ECT			
Patients' questions about ECT should be answered as truthfully and fully as possible			
The patient's understanding of the information provided to him or her about ECT should be confirmed prior to the signing of the informed consent document			
In consenting to ECT the patient's understanding of the side effects and risks of receiving ECT should be confirmed			

The patient is aware of the purpose and intended benefits of ECT including the probability of success	**Desirable**	**Essential**	**Not Applicable**
The patient is made aware that the treatment includes receiving an anaesthetic and muscle relaxant			
The patient's relatives/carers are provided with information about ECT in order to facilitate informed discussion in the decision making process when possible			
When information is refused by a patient this should be documented in the patient's case file/care plan.			
The patient's informed consent is verified prior to each ECT treatment.			
The detained patient's competence to give informed consent is continuously assessed throughout the course in order to determine if they have regained the capacity to give informed consent			
The validity of the consent form and other relevant Mental Health legislation documentation is continuously assessed throughout the course in case the patient's consent status has changed and the documentation requires to be amended			

If there is any other information that you consider should be added to the statements on the roles and responsibilities of medical staff please specify below:

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Please tick the box that you consider is relevant to each statement - desirable, essential or not applicable

2. Nurses role

	Desirable	**Essential**	**Not Applicable**
The nurse assists the referring psychiatrist in assessing the patient's decisional capacity to ensure that informed consent is valid			
The nurse assists the referring psychiatrist in confirming that the patient is giving voluntary informed consent			
The nurse assists the referring psychiatrist in ensuring that the patient understands the nature, purpose and consequences of receiving the treatment and therefore what they are consenting to			
To understand the application of the Mental Health Act in relation to ECT and the provision of nursing care in ECT when it is administered without the patient's consent.			
Ensuring that the relevant Mental Health legislation documentation regarding the Mental Health (Care and Treatment) (Scotland) Act 2003 or Adults with Incapacity (Scotland) Act 2002 has been completed and is available			
An equitable relationship is formed with the patient in order to enable them to be part of the decision making process leading to their making an informed decision about accepting ECT or not			

The patient is aware of alternative treatments and that these would be available in the event that he or she chooses not to accept ECT	**Desirable**	**Essential**	**Not Applicable**
The informal patient is made aware that they can withdraw their consent to ECT at any time			
The nurse should act as an advocate for the patient considering ECT, evaluating any concerns and referring them to the relevant member of the multidisciplinary team			
Ensuring that the patient is aware that the consequences of not receiving the treatment could result in a prolonged and increasingly severe phase of illness			
The nurse ensures that the informed consent form has been signed by the treating psychiatrist and patient just prior to the ECT course commencing in order to record the consultation and decision which has recently taken place			
Any discussions and decisions relating to informed consent are documented in the patient's case notes/care plan			
The nurse understands the nature, purpose and effects of ECT			

Ensuring that coercion is not employed at any time in order to persuade the patient to have ECT	**Desirable**	**Essential**	**Not Applicable**
A patient who is unsure about consenting to ECT will be aware that they can have access to independent advice or a second opinion from an advocacy service or the Mental Welfare Commission			
In an emergency situation such as a patient's life being at risk the nurse assists in the administration of ECT to the patient as directed by Medical staff			
Each individual patient is provided with sufficient verbal, written and/or audio information in order to enable them to make an informed decision about whether or not to accept ECT.			
The nurse arranges for the patient to visit the ECT suite if he or she would like to			
Information previously given about ECT is brought to the patient's attention at different intervals during the course of treatment			
The patient should have sufficient time without being subject to pressure to reflect on the information prior to making a decision about consenting to ECT			

Patient's questions should be answered truthfully and fully and where the nurse is unable to answer a question this should be referred to the treating psychiatrist	**Desirable**	**Essential**	**Not Applicable**
The patient's understanding of the information provided to him or her about ECT should be confirmed prior to the completion of the informed consent document			
In consenting to ECT the patient's understanding of the side effects and risks of receiving ECT should be confirmed			
The patient is aware of the purpose and intended benefits of ECT including the probability of success			
The patient is made aware that the treatment includes receiving an anaesthetic and muscle relaxant			
The patient's relatives/carers are provided with information about ECT in order to facilitate informed discussion in the decision making process when possible			
When information is refused by a patient this should be documented in the patient's case file/care plan.			

The patient's informed consent is verified prior to each ECT treatment	**Desirable**	**Essential**	**Not Applicable**
If the patient is unsure or refuses to give consent to the treatment this is accepted and the treating psychiatrist is informed of this decision			
The nurse assists in the assessment of the detained patient's competence to give informed consent continuously throughout the course in order to determine if they have regained capacity to give informed consent			
The validity of the consent form and other relevant Mental Health legislation documentation is continuously assessed throughout the course in case the patient's consent status has changed and the documentation requires to be amended			

If there is any other information that you consider should be added to the statements on the roles and responsibilities of nursing staff please specify below:

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Thank you very much for taking the time to complete this questionnaire. Your time and effort are greatly appreciated.

Appendix 11

Delphi process

Qualitative comments made by participants in round one of the Statement of knowledge

3. ECT and consent

"If someone is unsure about consenting to the treatment they can request independent advice from places such as the Advocacy service or the Mental Welfare Commission."

"Not MWC (if patient is unsure re. consenting to treatment)"

This comment was considered and the statement was altered so that the Mental Welfare Commission was omitted and a statement that additional information could be obtained from organizations such as Depression Alliance Scotland was included.

4. Alternative treatments to ECT

"Avoid counselling if v. severely unwell - unable to take in info."

"Suggest that CBT type therapies be added to this statement as patients may want/need knowledge of this alternative with slightly different meaning than 'counselling'."

The statement was altered to include psychological treatments such as counselling, psychotherapy or Cognitive behavioural therapy in a person who is able to tolerate these approaches as described by Somatics LLC (2004), Cobb (1993) and Manic Depression Fellowship (1996).

7. Reported risks

Short term

"As a patient, I'd want more details on 'psychiatric complications'."

The risk of developing psychiatric complications following ECT was not documented in the patient information sourced although it was documented in the good practice guide on ECT, CRAG (1997). It was decided to include this risk in the second round to see what response the panel would give it.

Medical complications

"'Proceeding' - 'should be after treatment'."

A couple of the participants picked up on an error that had been made in the grammar so this was altered accordingly.

"Mortality rate."

"As a patient, I'd wish to know mortality rates of anaesthesia administered in minor surgery."

The mortality rate of ECT is included in CRAG (1997) so it was decided to add this risk as suggested by the participants to see what response that it received in the second round.

Appendix 12

Delphi process

Participants' qualitative comments on round one of the roles and responsibilities

Medical role

"The patient should be advised of unilateral and bilateral ECT and following their weighing up of facts, their choices respected. This should be documented in case notes by referring psychiatrists."

Caird and Worrall (2003) indicate that the patient should be aware that the course is going to consist of bilateral or unilateral treatment and Scott (2005) includes that the patient may be able to indicate their choice about bilateral or unilateral treatment. Therefore, it was decided to include a statement about the mode of treatment in the second round.

The patient and the treating psychiatrist sign the informed consent form just prior to the ECT course commencing in order to record the consultation and decision which has taken place recently.

"Is this about continuing consent? N/A - the clinical team get consent."
"I would hope that informed consent form is signed a few days before treatment and not just prior to treatment"

This statement regarding the signing of the consent form was changed to indicate that the RMO and the patient sign the consent form prior to the consultation and decision which has recently taken place. The term 'treating psychiatrist' was changed to 'RMO' to avoid confusion in the second round

An equitable relationship is formed with the patients so that the decision to receive ECT is made jointly between the patient and the treating psychiatrist

"- desirable - if detained, essential if informal".

A statement was added following this comment that was included by a participant to ask the panel's opinion about forming an equitable relationship with a patient that is detained. The importance of forming a therapeutic rapport with the patient is described by Habiba (2000) and Worthington (2002).

The informal patient is made aware they can withdraw their consent to ECT at any time

"Formal patients who have capacity as well, of course".

A statement was included in the second round to ascertain the participants perceptions on the patient who is detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 who is assessed to have capacity to give informed consent is made aware they can withdraw their consent to ECT at any time. Barnes et al (2005), The Mental Welfare Commission (2003) and Lyons (2003).

Ensuring that the patient is aware that a consequence of not receiving the treatment may be a prolonged and increasingly severe phase of illness

"Consequence is a very strong word to use".

"This will help to make informed decisions and information should be given to patient but not in the form of coercion".

This statement was re phrased following the participants comments to omit the word consequence and add their views as follows:

Ensuring that the patient is aware of the possible risks involved in choosing not to receive the treatment; that this may lead to a prolonged and increasingly severe phase of illness, although their informed choice should be respected.

This was informed by literature such as the GMC (1998) and The Royal College of Psychiatrists (2003).

A patient who is unsure about consenting to ECT will be aware that they can have access to independent advice or a second opinion from an advocacy service or the Mental Welfare Commission.

One participant gave the following answer that independent advice and a second opinion was essential but that the Mental Welfare Commission would not provide a second opinion.

1) independent advice "(essential)", 2) a second opinion from advocacy services "(essential)" or 3) "the MWC wont provide this".

"Independent advocacy advice should be offered to all (patients may not be aware of it or frightened to ask)".

This statement was altered to include the participants' views that the Mental Welfare Commission would not provide a second opinion. It was also important to ensure that all patients should have an awareness of independent advice as described by Manic Depression Fellowship (1996) and Lyons (2003).

In an emergency situation, where a patient's life is at risk, ECT can be given as soon as it can be organized, preferably with a second opinion given by a local psychiatrist - "always".

The word 'preferably' was underlined in this statement by a participant. Therefore the statement was altered to omit the word preferably. This was informed by literature such as Barnes et al (2005), CRAG (1997) and Lyons, ed. (2003).

The patient's relatives are provided with information about ECT in order to facilitate informed discussion in the decision making process when possible.

"If patient consenting to family involvement in care".

"Again, much better to have the relatives involved but not always possible".

"Obviously not involved in the consent process".

This statement was altered to include the participants' views that the patients relatives would be provided with information when possible and with the patient's consent. Lyons (2003) and NICE (2003).

These amendments to the statements were also added to the nursing role part of the questionnaire where applicable.

Appendix 13

Statement of knowledge questionnaire - second round

Statement of the knowledge base that a patient is required to have to give full, informed consent

Please rate the statements by ticking the column that you consider appropriate

1. The nature of ECT • *ECT involves the administration of a mild, controlled electric current which is passed across the head via the application of electrodes for a few seconds resulting in a seizure.* • *It is the seizure activity that can assist in the correction of the chemical imbalance in the brain that is thought to be the cause of depression.*	***Very applicable***	***Applicable***	***Not applicable***
2. Why ECT is prescribed • *For severe depressive illness that has not responded to a number of different treatments* • *Antidepressant treatment has had to be discontinued due to side effects* • *For a depressed person who is not eating or drinking adequately or has suicidal feelings* • *A patient has responded well to ECT in the past*			
3. ECT and consent • *An informal patient can withdraw their consent to ECT at any stage during the treatment* • *No type of coercion should be used at any time to coax a patient to have ECT* • *The patient remains completely entitled to have alternative treatments if they have refused ECT* • *All patients, particularly those unsure about consenting to ECT will be aware that they can have access to independent advice from an advocacy*			

service or additional information from organizations such as Depression Alliance Scotland • *The patient's consent should be verified prior to each ECT treatment*			
4. Alternative treatments to ECT *Consist of treatments such as:-* • *Antidepressant drug therapy* • *Psychological treatments such as counselling, psychotherapy or Cognitive Behavioural Therapy in a person who is able to tolerate these approaches*			
5. Effectiveness • *In Scotland, there was a particular improvement in three - quarters of people treated with ECT for depressive illness. (SEAN, 2000)* • *ECT can be quick acting with benefits being recognized after 2 - 3 treatments* • *In some instances, such as when a patient is acutely suicidal or is refusing to eat or drink, ECT can be life saving*			
6. Anaesthetic and muscle relaxant *Prior to receiving ECT the patient will receive a short acting general anaesthetic and muscle relaxant via an intravenous injection*			
7. Reported risks ***Short term*** *Side effects that can occur include short term memory loss and confusion; headaches; nausea and muscular stiffness and psychiatric complications.* ***Long term*** • *A small number of patients have complained of longer term memory loss for events that have occurred before, during and after the treatment* • *It is difficult to comprehend how much of the memory loss is the result of severe depression or ECT*			

Medical complications *Patients with ongoing health problems have an increased possibility of cardiac or respiratory difficulties occurring proceeding the treatment* ***Mortality rate*** *The practice of ECT comprises a low risk with an associated mortality rate reported to be comparable with anaesthesia administered in minor surgery*			
8. Fasting requirements *ECT is given under a general anaesthetic so the patient should not eat six hours prior to or drink fluids four hours prior to the treatment*			
9. Duration of an average course • *The average course of ECT consists of around six treatments up to approximately twelve treatments.* • *ECT is usually administered twice a week.*			
10. Physical examination • *Each patient receives a physical examination prior to receiving ECT in order to ensure that they are fit enough to receive a general anaesthetic.* • *The physical examination includes a blood test, ECG and chest x- ray where indicated.*			

If you consider that the statements should appear in a different sequence please state your preferred sequence below:

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If there is any other information that you consider should be added to the statement of knowledge please specify below:

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Thank you very much for taking the time to complete this questionnaire. Your time and effort are greatly appreciated.

Appendix 14

Roles and responsibilities questionnaire - second round

Roles and responsibilities of medical and nursing staff in the informed consent process in ECT

This questionnaire contains statements regarding the roles and responsibilities of medical and nursing staff in the informed consent process in ECT.

Please complete both sections of the questionnaire as completely as possible.

Please tick the box that you consider is relevant to each statement in both sections - desirable, essential or not applicable.

1. Medical role

	Desirable	**Essential**	**Not Applicable**
The patient's decisional capacity is assessed by the referring psychiatrist to ensure informed consent is valid			
The patient's voluntary informed consent is confirmed by the referring psychiatrist			
The psychiatrist administering ECT confirms that the patient is giving voluntary consent prior to each treatment proceeding			
To ensure that the patient understands the nature, purpose and consequences of receiving the treatment and therefore what he or she is consenting to.			

When ECT is considered the best treatment option for a patient but due to their mental state they are unable or unwilling to give consent then action under the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2002 is employed and a doctor from the Mental Welfare Commission provides a second opinion	**Desirable**	**Essential**	**Not Applicable**
Ensuring that the relevant documentation regarding the Mental Health (Care and Treatment) (Scotland) Act 2003 or the Adults with Incapacity (Scotland) Act 2002 has been completed and is available for inspection			
An equitable relationship is formed with the informal patient so that the decision to receive ECT is made jointly between the patient and the Responsible Medical Officer (RMO).			
An equitable relationship is formed with the patient detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 so that the decision to receive ECT is made jointly between the patient and RMO			
The patient is aware of alternative treatments and that these would be available if he or she decided to refuse ECT			
The informal patient is made aware that he or she can withdraw their consent to ECT at any time			

The patient detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 who is assessed to have the capacity to give informed consent is made aware that they can withdraw their consent to ECT at any time	**Desirable**	**Essential**	**Not Applicable**
Ensuring that the patient is aware of the possible risks involved in choosing not to receive the treatment; that this may lead to a prolonged and increasingly severe phase of illness, although their informed choice should be respected			
The patient and the RMO sign the informed consent form prior to the ECT course commencing in order to record the consultation and decision which has recently taken place			
All discussions and decisions taken relating to obtaining informed consent are documented in the patient's case notes			
All patients will be aware that they can have access to independent advice from an advocacy service or additional information from organisations such as Depression Alliance Scotland			
If a patient appears unsure about receiving ECT they should be given the opportunity to address their concerns and the possible benefits of the treatment should be reiterated in order to ensure that the patient has the information necessary to inform their decision			

The psychiatrist obtaining informed consent from the patient has sufficient knowledge of the nature, purpose and effects of ECT	**Desirable**	**Essential**	**Not Applicable**
Ensuring that coercion is not employed at any time in order to persuade the patient to have ECT			
When possible the patient's relatives/carers are provided with information about ECT in order to facilitate informed discussion in the decision making process when the patient has given their consent to their involvement in their treatment			
When a patient has lost the capacity to provide informed consent to ECT or refuse the treatment any advance statements regarding treatment choices should be taken into account			
In an emergency situation, where a patient's life is at risk, ECT can be given as soon as it can be organised with a second opinion given by a local Consultant Psychiatrist			
Each individual patient is provided with sufficient verbal, written and/or audio information in order to enable her or him to make the decision whether to give informed consent to ECT or not			
Information previously given about ECT is brought to the patient’s attention at different intervals during the course of treatment			

Information necessary for the decision making process should not be withheld from the patient unless in exceptional circumstances when the practitioner can justify that disclosing the information would have a detrimental effect on the patient	**Desirable**	**Essential**	**Not Applicable**
If information has been withheld from the patient this requires to be documented in the patient's case notes as there may be a necessity to justify this decision at a later date			
The patient should have sufficient time, as far as possible, without being subject to pressure to reflect on the information prior to making a decision about consenting to ECT			
Patients' questions about ECT should be answered as truthfully and fully as possible			
The patient's understanding of the information provided to him or her about ECT should be confirmed prior to the signing of the informed consent document			
In consenting to ECT the patient's understanding of the side effects and risks of receiving ECT should be confirmed			
The patient is aware of the purpose and intended benefits of ECT including the probability of success			

As far as possible the patient should be advised of bilateral or unilateral electrode placement and the final choice of electrode placement should be the outcome of a proportionate appraisal of the risks and benefits between the patient and medical practitioner	**Desirable**	**Essential**	**Not Applicable**
The patient is made aware that the treatment includes receiving an anaesthetic and muscle relaxant			
When information is refused by a patient this should be documented in the patient's case file/care plan.			
The patient's informed consent is verified prior to each ECT treatment by the referring team			
The detained patient's competence to give informed consent is continuously assessed by the referring team throughout the course in order to determine if he or she has the capacity to give informed consent			
The validity of the consent form and other relevant Mental Health legislation documentation is continuously reviewed throughout the course in case the patient's consent status has changed and the documentation requires to be amended			

If there is any other information that you consider should be added to the statements on the roles and responsibilities of medical staff please specify below:

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Please tick the box that you consider is relevant to each statement - desirable, essential or not applicable.

2. Nurses role

The nurse assists the referring psychiatrist in assessing the patient's decisional capacity to ensure that informed consent is valid	**Desirable**	**Essential**	**Not Applicable**
The nurse assists the referring psychiatrist in confirming that the patient is giving voluntary informed consent			
The nurse assists the referring psychiatrist in ensuring that the patient understands the nature, purpose and consequences of receiving the treatment and therefore what the patient is consenting to			
To understand the application of the Mental Health Act in relation to ECT and the provision of nursing care in ECT when it is administered without the patient's consent.			
Ensuring that the relevant Mental Health legislation documentation regarding the Mental Health (Care and Treatment) (Scotland) Act 2003 or Adults with Incapacity (Scotland) Act 2002 has been completed and is available			
An equitable relationship is formed with the informal patient in order to enable him or her to be part of the decision making process leading to their making an informed decision about accepting ECT or not			

An equitable relationship is formed with the patient detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 in order to enable them to be part of the decision making process where possible, leading to their making an informed decision about accepting ECT or not	**Desirable**	**Essential**	**Not Applicable**
The patient is aware of alternative treatments and that these would be available in the event that he or she chooses not to accept ECT			
The informal patient is made aware that they can withdraw their consent to ECT at any time			
The patient detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 who is assessed to have the capacity to give informed consent is made aware that his or her consent to ECT may be withdrawn at any time			
The nurse should act as an advocate for the patient considering ECT, evaluating any concerns and referring these to the relevant member of the multidisciplinary team			
Ensuring that the patient is aware of the possible risks involved of choosing not to receive treatment is that this may lead to a prolonged and increasingly severe phase of illness although their informed choice should be respected			
The nurse ensures that the informed consent form has been signed by the RMO and patient prior to the ECT course commencing in order to record the consultation and decision which has recently taken place			

Any discussions and decisions relating to informed consent are documented in the patient's case notes/care plan	**Desirable**	**Essential**	**Not Applicable**
The nurse understands the nature, purpose and effects of ECT			
Ensuring that coercion is not employed at any time in order to persuade the patient to have ECT			
All patients will be aware that they can have access to independent advice from an advocacy service or additional information from organisations such as Depression Alliance Scotland.			
If a patient appears unsure about receiving ECT an opportunity to address their concerns should be given and the possible benefits of the treatment should be reiterated in order to ensure that the patient has the information necessary to inform their decision			
In an emergency situation when a patient's life is at risk the nurse assists in the administration of ECT to the patient as directed by Medical staff			
Each individual patient is provided with sufficient verbal, written and/or audio information in order to enable him or her to make an informed decision about whether or not to accept ECT.			

The nurse arranges for the patient to visit the ECT suite if he or she would like to	**Desirable**	**Essential**	**Not Applicable**
Information previously given about ECT is brought to the patient's attention at different intervals during the course of treatment			
The patient should have sufficient time without being subject to pressure to reflect on the information prior to making a decision about consenting to ECT			
Patient's questions should be answered truthfully and fully and where the nurse is unable to answer a question this should be referred to the treating psychiatrist			
The patient's understanding of the information provided to him or her about ECT should be confirmed prior to the completion of the informed consent document			
In consenting to ECT the patient's understanding of the side effects and risks of receiving ECT should be confirmed			
The patient is aware of the purpose and intended benefits of ECT including the probability of success			

The patient is made aware that the treatment includes receiving an anaesthetic and muscle relaxant	**Desirable**	**Essential**	**Not Applicable**
When possible the patient's relatives/carers are provided with information about ECT in order to facilitate informed discussion in the decision making process when the patient has given their consent to their involvement in their treatment			
When information is refused by a patient this should be documented in the patient's case file/care plan.			
The patient's informed consent is verified prior to each ECT treatment			
If the patient is unsure or refuses to give consent to ECT this is accepted and the treating psychiatrist is informed of this decision so that the patient's consent status and the continuation of the treatment can be reviewed.			
The nurse assists in the assessment of the detained patient's competence to give informed consent continuously throughout the course in order to determine if they have regained capacity to give informed consent			

The validity of the consent form and other relevant Mental Health legislation documentation is continuously reviewed throughout the course of treatment in case the patient's consent status has changed and the documentation requires to be amended	**Desirable**	**Essential**	**Not Applicable**

If there is any other information that you consider should be added to the statements on the roles and responsibilities of nursing staff please specify below:

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Thank you very much for taking the time to complete this questionnaire. Your time and effort are greatly appreciated.

Appendix 15

Delphi letter of explanation - second round

C/o Lochhead Day Hspl.,
Royal Cornhill Hsp.,
Aberdeen,
AB25 2ZH
Tel: (01224 557447)
E - Mail: shonaburke@nhs.net

Dear Colleague,

Project title - Informing consent for ECT

Here is the second round of questionnaires involved in the Delphi process which is being utilized in order to gain an expert consensus on an explicit statement of the knowledge base that clients would be required to have to be considered "fully informed" and the roles and responsibilities of medical and nursing staff in the informed consent process in ECT.

The expert panel's responses in the first round of questionnaires has been collated into percentages as indicated in the questionnaire attached illustrating the collation of responses and I have also given as much consideration as possible to the participants comments on what information they considered should be altered or added to the statements.

Also attached for your information are the references on which the statements were based.

I would like to invite you to re - rank each statement in the two blank questionnaires that are attached on the statement of the knowledge base that clients would be required to have to be considered "fully informed" and the roles and responsibilities of medical and nursing staff in the informed consent process in ECT. This time you have the opportunity to alter your mark considering what the panel's reaction was.

Do not hesitate to contact me if you have any questions about this research.

Thank - you for participating in this project. Your time and effort is much appreciated.

Please complete and return the questionnaires to me by 16/06/08

Yours Sincerely,

Shona Burke

Appendix 16

Delphi process - second round

New statements, statements with a change in wording and statements receiving a non applicable response

New Statements

The new statements that were added in the second round as a result of the participant's comments received a varying degree of consensus around 'essential' as described:

The psychiatrist administering ECT confirms that the patient is giving voluntary consent prior to each treatment proceeding.

This statement gained 73% of the response in the medical role.

An equitable relationship is formed with the patient detained under the Mental Health (Care and Treatment) (Scotland) Act, 2003 so that the decision to receive ECT is made jointly between the patient and RMO.

This statement gained 27% of the response in the medical role. The similar statement in the nursing role gained 55% of the response in the nursing role.

The patient detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 who is assessed to have capacity to give informed consent is made aware that they can withdraw their consent is made aware that they can withdraw their consent to ECT at any time.

This statement gained 91% consensus in the medical role and 82% consensus in the nursing role.

> *"If a patient appears unsure about receiving ECT they should be given the opportunity to address their concerns and the possible benefits of the treatment should be reiterated in order to ensure that the patient has the information necessary to inform their decision."*

This statement received 91% consensus in the medical role and 73% of the response in the nursing role.

> *"As far as possible the patient should be advised of bilateral or unilateral electrode placement and the final choice of electrode placement should be the outcome of a proportionate appraisal of the risks and benefits between the patient and medical practitioner."*

This statement gained 55% of the response in the medical role.

Change in wording of statements

Changing the wording in the statement between rounds as a result of the participants' comments resulted in an increase of consensus in the 'essential' category. Some of the statements are described:

An equitable relationship is formed with the informal patient so that the decision to receive ECT is made jointly between the patients and the RMO.

The response to this statement increased from 41% to 64% in the medical role. The statement which is similar to this in the nursing role increased from 64% of the response to 73%.

The patient and the RMO sign the informed consent form prior to the ECT course commencing in order to record the consultation and decision which has recently taken place.

The consensus in this statement increased from 52% to 91% in the medical role. One participant had ticked 'not applicable' and had qualified this by adding "*Often junior doctor signs, but RMO prescribes."*

Another participant had also added "*Not necessarily RMO".*

The statement which is similar to this in the nursing role increased from 76% to 82% consensus.

All patients will be aware they can have access to independent advice from an advocacy service or additional information from organizations such as Depression Alliance (Scotland).

The consensus in this statement increased from 70% to 82% in the medical role and the response in the nursing role increased from 70% to 73%.

Ensuring the patient is aware of the possible risks involved in choosing not to receive the treatment: this may lead to a prolonged and increasingly severe phase of illness, although their informed choice should be respected.

The response in this statement increased from 58% to 73% in the medical role and from 35% to 45% in the nursing role which is an obvious difference.

When possible the patient's relatives/carers are provided with information about ECT in order to facilitate informed discussion in the decision making process when the patient has given their consent to their involvement in their treatment.

The response in this statement increased from 17% to 36% in the medical role. However, the same statement decreased from 29% to 27% in response in the nursing role.

In an emergency situation, where a patient's life is at risk, ECT can be given as soon as it can be organized with a second opinion given by a local Consultant Psychiatrist.

The response in this statement decreased from 82% to 73% in the medical role as one participant's had replied that this was not applicable. The qualitative comment the participant had made was: Second opinion not required by law and often impractical if urgent.

This was a good point but CRAG (1997) states that it is firmly advisable to gain another opinion of a resident psychiatrist when such procedures take place.

'Not applicable' responses

The responses to the questionnaire that the participants had marked in the 'not applicable' category included the following:

One participant had replied 'not applicable' to the statement in the nursing role:

The nurse assists the referring psychiatrist in assessing the patient's decisional capacity to ensure that informed consent is valid.

The participant did not qualify this response. This statement received a response of 55% 'essential', 36% 'desirable' and 9% 'not applicable' therefore a consensus of 75% or over was not achieved in general.

Another participant had replied 'not applicable' to the statement:

An equitable relationship is formed with the patient detained under the Mental Health (Care and Treatment) (Scotland) Act 2003 so the decision to receive ECT is made jointly between the patient and RMO.

This statement received a response of 27% 'essential', 64% 'desirable' and 9% not applicable.

The participant had also marked the similar statement in the nursing section, 'not applicable'. This statement received a response of 55% 'essential', 36% 'desirable' and 9% 'not applicable'.

Unfortunately the participant did not qualify these responses.

The participant had also added a qualitative comment to the statement:

The psychiatrist administering ECT confirms that the patient is giving voluntary consent prior to each treatment proceeding:-

"Not essential if nursing staff in clinic have already confirmed this."

This new statement received a response of 73% 'essential' and 27% 'desirable'.

Appendix 17

Statement of knowledge questionnaire - second round

Statements that did not achieve a consensus

The nature of ECT

It is the seizure activity that can assist in the correction of the chemical imbalance in the brain that is thought to be the cause of depression.

This statement is described in various sources such as CRAG (1997); The Royal College of Psychiatrists (1993) and American Psychiatric Association (2004) and is part of the description of ECT that is offered to patients in the information sheets sourced therefore would appear to be an important part of the description of ECT to give to patients.

Why ECT is prescribed

Antidepressant treatment has had to be discontinued due to side effects.

This information is included in Royal College of Psychiatrists; SEAN (2000) and Mayo Clinic (2004). The Consensus Group affiliated to the Special Committee (2005) also describes the use of ECT when the patient's illness has not satisfactorily responded to treatment with antidepressant therapy. Therefore this appears to be useful information to include in the statement of knowledge.

Alternative treatments to ECT

Psychological treatments such as counselling, psychotherapy or Cognitive Behavioural Therapy in a person who is able to tolerate these approaches.

Perhaps consensus was not achieved in this statement because the participants thought that psychological treatments were less important due to their grounding in the physical treatment of ECT although this information was included in patient information guides such as Manic Depression Fellowship (1996) and NICE (2003).

Effectiveness

In Scotland, there was a particular improvement in three - quarters of people treated with ECT for depressive illness.

This information was included in SEAN (2000). This statistic was gained as a result of the National Audit that SEAN carried out in all ECT centres in Scotland between the years of 1996 to 1999. Both the Mayo Clinic (2004) and the American Psychiatric Association (2004) also document that

approximately 80% of people who receive a course of ECT find it to be beneficial. Including this information could assist the patient in making an informed choice about the treatment based on the statistics available on the effectiveness of ECT.

ECT can be quick acting with benefits being recognized after 2-3 treatments.

This information was included in CRAG (1997) who state that ECT continues to be the fastest operating treatment that is accessible. Bolton, Salford and Trafford Mental Health NHS Trust (2003) and Mayo Clinic (2004) also include this in their description of ECT. Lamprecht et al (2005) recommends that the quickness and the efficacy of ECT should guide the judgement to prescribe ECT as a treatment for depression. Therefore this would also be an important element of information to provide to the patient to assist them in coming to an informed decision about ECT.

Reported risks

Psychiatric complications such as manic illness.

This information was included in CRAG (1997) and SEAN (2000). It was also noted that this risk came fourth in importance in the ECT nurse questionnaire therefore was considered to be midpoint in importance at this stage of the research also. Therefore it appears to be information that the patient may find useful.

Prolonged seizures

This adverse effect of ECT causing prolonged seizures was included in good practice guides such as CRAG (1997) and Benbow (2005) although it was not included in patient information on ECT such as the Bolton, Salford and Trafford Mental Health NHS Trust (2003) or user groups such as the Manic Depression Fellowship (1996). This statement was included due to the comments of participants during the first round of the Delphi but could perhaps be included at a further stage of the information giving process rather than in the statement of knowledge.

Medical complications

Patients with ongoing health problems have an increased possibility of cardiac or respiratory difficulties occurring following the treatment.

This was included in SEAN (2000); Royal College of Psychiatrists (1993) and the American Psychiatric Association (2004) so it would be preferable that the patient was aware of the medical complications that could occur if they gave their informed consent to the treatment.

Appendix 18

Roles and responsibilities questionnaire - second round

Statements not receiving a consensus in the second round

A total of 34% of the statements did not receive consensus in the second round of the Delphi process. A description of the literature on which the statements were based is detailed as follows:

The psychiatrist administering ECT confirms that the patient is giving voluntary consent prior to each treatment proceeding.

Although this statement received a response that was just under the 75% required for consensus in this study, professional guidance such as the GMC (1998) described how it is the doctor who is performing the treatment who should be certain that consent is gained. CRAG (1997) also state that the psychiatrist should verify that consent is legitimate in advance to the ECT treatment taking place. Therefore this is a part of practice in informed consent that the participants may require further training on.

An equitable relationship is formed with the informal patient so that the decision to receive ECT is made jointly between the patient and the RMO.

Although a consensus was not gained, this statement received a response of 73% from the participants who considered it to be essential in the roles and responsibilities of the nurse while it gained 64% from the participants who considered it to be essential in the roles and responsibilities of medical staff. The balance of the rapport between the practitioner and the patient is a significant part of the informed consent procedure but the evidence gained in this research indicates that the participants' perceive the importance of an equal relationship with the patient as being more important in the nurse's role in the consent process than the medical role. Doyal (2004) stated that patients felt that their exchanges with doctors could be hurried and could comprise of an absence of purpose. Further research with a larger sample could provide additional evidence to indicate if there is a difference between nursing and medical staff's perception of the importance of there being an equitable relationship with the patient receiving ECT. This is an area that practitioners could receive further training on so that patient receiving ECT's contribution to their own care is acknowledged and they are perceived as being associates in their own treatment as outlined by the NMC (2004). The NMC (2004) describes this as including the patient's wishes with regard to their treatment and valuing these within the boundaries of professional practice, current codes of practice, available funding and the aims of the therapeutic rapport.

An equitable relationship is formed with the patient detained under the Mental Health (Care and Treatment) (Scotland) Act, 2003 so that the decision to receive ECT is made jointly between the patient and RMO.

This statement did not reach a consensus of opinion from medical participants of whom 27% considered this was essential while 55% of nursing staff considered this essential. This could be due to the fact that some patients may result in being detained to receive treatment. CRAG (1997) states that due to the fact that their mental health is such that they not able to comprehend the description of ECT and are unable or not willing to give consent. In these circumstances the relationship between staff and the patient may become more difficult if the patient is unwilling to have the treatment. Therefore the practitioner's views that it may not always be possible to form an equitable relationship with the detained patient so that the decision to receive ECT can be made jointly between the patient and RMO can be understood. Caird and Worrall (2003) also submit that the patient should be aware of how to contact the advocacy services while CRAG (1997) describe how the patient advocacy services could supply a different possibility for confirming that the patient is as completely informed about ECT as is feasible. The Scottish Independent Advocacy Alliance information leaflet states that advocacy involves giving someone the means to receive information, examine and comprehend their possibilities and the opportunity to express their opinions and desires.

Bigwood and Crowe's (2008) research examined mental health nurses' experiences of physical restraint in an acute inpatient psychiatric setting. Their method included using Van Manen's (1990) descriptive phenomenological methodology in order to comprehend the knowledge and involvement of physical restraint in the seven nurses that were recruited. The data was collected by audiotaped interviews and then analysed by transcribing the interviews word for word. Bigwood and Crowe (2008, p.6) summarized the participants' view of restraint by citing one of their responses: "Its part of the job, but it spoils the job." The nurses reported that physical restraint frequently caused them to experience discord in relation to their therapeutic duty and the custom of the nurses being in charge and maintaining power in their workplace. The nurses in Bigwood and Crowe's (2008) research also stated that the nurses' experience of their dissention with physical restraint could be brought to an end if the nurse was able to retain a therapeutic rapport with the patient. The nurses also described how their rapport with patients was strengthened by sharing the incident with them afterwards. Given this medical and nursing staff involved in ECT should always endeavor to maintain a therapeutic relationship with the patient detained under the Mental Health (Care and Treatment) (Scotland) Act, 2003 to receive ECT. This may alleviate the practitioner's experience of discord at treating a patient against their wishes and also sharing and going over the reasons for the requirement to give the patient ECT may assist in the maintenance of an equitable rapport with the patient.

Ensuring the patient is aware of the possible risks involved in choosing not to receive the treatment: this may lead to a prolonged and increasingly severe phase of illness, although their informed choice should be respected.

Although the percentages the participants gave to this statement rose in the second round after the wording was changed due to participants stating that the wording in the original statement was too strong, the statement did not reach a consensus. However, Caird and Worrall (2003), The GMC (1998) and the Royal College of Psychiatrists (1993) all state that the patient should be aware of the dangers involved in not receiving the treatment as prescribed.

When possible the patient's relatives/carers are provided with information about ECT in order to facilitate informed discussion in the decision making process when the patient has given their consent to their involvement in their treatment.

This statement did not reach a consensus level. Nevertheless, Lyons, ed. (2003) states that the patient's carer should be provided with information while NICE (2003) suggests that doctors should invite the participation of the patient's advocate or carer in the consent process. Sims (2008) also recommends that the patient and their family should be encompassed in the decision making and the informed consent procedure.

When a patient has lost capacity to provide informed consent to ECT or refuse the treatment any advance statements regarding treatment choices should be taken into account.

This statement did not receive a consensus although Lyons (2003), NICE (2003) and the Mental Welfare Commission for Scotland (2003) all recommend that any advance directive the patient had made should be taken into account.

Information previously given about ECT is brought to the patient's attention at different intervals during the course of treatment.

This statement did not receive consensus although there was a much smaller amount of the participants that thought this was essential within the medical role than the nursing role. Rose et al (2005) and the GMC (1998) recommend that the practitioner should repeat the information until sufficient understanding has been gained.

As far as possible the patient should be advised of bilateral or unilateral electrode placement and the final choice of electrode placement should be the outcome of proportionate appraisal of the risks and benefits between the patient and practitioner.

This statement was added in on the suggestion of one participant but did not receive consensus. However, Caird and Worrall (2003) state that the patient should be aware whether the treatment is to be bilateral or unilateral. Scott (2005) describes the NICE guidance on ECT which included the recommendation that unilateral ECT should be used in order to lower the cognitive unfavourable outcome of the treatment particularly in patients whose illness was considered not to be critical. Therefore, perhaps the patient should be informed of the hazards and advantages of bilateral and unilateral treatment when possible so that the decision could be made by the doctor in conjunction with the patient.

The nurse assists the referring psychiatrist in assessing the patient's decisional capacity to ensure that informed consent is valid.

The nurse assists the referring psychiatrist in confirming that the patient is giving voluntary informed consent.

Both these statements did not receive a consensus of opinion but as stated previously in the discussion of the ECT nurse questionnaires, the ECT nurses' qualitative comments supplied evidence that they did assist in these elements of informed consent in practice. As described by Sims (2008) nurses may be the initial person to recognize any possible complications in the informed consent procedure due to the fact that they often have the most contact with patients and their relatives. They may comprehend that the patient and/or their family may not completely appreciate the procedure. Therefore the ECT nurse or the ward based nurse may be first to ascertain that the patient does not have the decisional capacity to give informed consent or may not be giving voluntary consent to the treatment.

The nurse assists the referring psychiatrist in ensuring that the patient understands the nature, purpose and consequences of receiving the treatment and therefore what the patient is consenting to.

This statement did not receive a consensus of opinion although Finch (2005) suggests that the nurse should ensure that the patient has been afforded a detailed description; comprehends what the treatment comprises of; the aim of the treatment and its significance prior to completing the consent form. Scholefield et al (1997) also state that the practitioner is accountable for guaranteeing that the patient comprehends the dangers associated with receiving the treatment and what the treatment consists of.

Ensuring that coercion is not employed at any time in order to persuade the patient to have ECT.

This statement received a response just under the consensus level in the nursing role. However, CRAG (1997) recommends that no type of coercion should be used at any point to influence a patient to receive ECT. This is especially important as it is extensively described in healthcare and consumer literature that although patients were not detained under a mental health act to receive ECT, they frequently perceived that they had not supplied their consent voluntarily (Rose et al, 2005).Therefore, nurses should be aware of the moral/lawful consequences of their interventions with patients as described by Kashka and Keyser (1995). The same statement received a consensus of 82% as essential in both the first and the second round of questionnaires in the medical role; however one participant added this interesting comment in the first round of the Delphi process:

> *"Whilst I agree that coercion would always be inappropriate, persuasion may be the most pragmatic option when you have a patient who is suffering greatly or at heightened risk and you believe that ECT will be the most appropriate treatment – however this would be true for any significant medical procedure."*

The participants comment is understandable when the practitioner is dealing with a patient whose illness is severe; nevertheless, what is the difference between persuasion and coercion? The Mental Welfare Commission (2003) describes how the practitioner who is trying to bypass using the Mental Health (Care and Treatment) (Scotland) Act 2003 might use what they consider to be reasoning skills in order to persuade the patient to receive treatment willingly. However, this could still be perceived by the patient as coercion. Kashka and Keyser (1995) also state that indirectly influencing the patient can affect their consent status because unimpeded consent is debatable whenever any form of coercion is demonstrated.

All patients will be aware they can have access to independent advice from an advocacy service or additional information from organizations such as Depression Alliance (Scotland).

This statement received just under the level of response required to reach a consensus in the nursing role although Lyons, ed. (2003) reports that patients should be entitled to advocacy that is readily available. Finch (2005) also submits that nursing staff should advise the patient about how to access supplementary information and means of getting in touch with a neutral advocate.

If a patient appears unsure about receiving ECT they should be given the opportunity to address their concerns and the possible benefits of the treatment should be reiterated in order to ensure that the patient has the information necessary to inform their decision.

This statement did not quite reach the 75% required to reach a consensus in the nursing role. Kashka and Keyser (1995) illustrated an occasion

when a patient did not wish to receive ECT but the nurse's actions in encouraging the patient to receive the treatment appeared to be coercive. Therefore it is important that the nurse is able to listen to the patient's concerns regarding the treatment, provide information and pass the patient's issues with the treatment to medical staff when appropriate as described by CRAG (1997).

The nurse arranges for the patient to visit the ECT suite if he or she would like to.

Patient information sheets such as Overton (1999) and NHS Grampian (2005) suggest that the patient can see the ECT suite preceding treatment in order to help familiarize them with the department and the ECT nurse which may assist in easing their anxieties concerning the treatment. However the panel considered that this was much more a desirable responsibility than an essential one.

The patient's understanding of the information provided to him or her about ECT should be confirmed prior to the completion of the informed consent document.

This statement received just under the percentage required to reach a consensus in the nurse's roles and responsibilities. Cable (2003), however, describes that the nurse must confirm that the consent a patient has provided is established on a comprehensible perception of the treatment they will be given.

In consenting to ECT the patient's understanding of the side effects and risks of receiving ECT should be confirmed.

Again, this statement received just under the percentage required to reach a consensus in the nurse's roles and responsibilities. However, Caird and Worrall (2003) and NHS Scotland (2006) state that the practitioner should verify that they have described the process to the patient, including the proposed advantages, hazards and temporary side effects. As described by Finch (2005) the nurse's proximity when information on the treatment is being given to the patient may help the patient to feel able to enquire about the treatment and the nurse may have the means to clarify the explanation if required.

The nurse assists in the assessment of the detained patient's competence to give informed consent continuously throughout the course in order to determine if they have regained capacity to give informed consent.

This is the final statement which just failed to gain a percentage in order to achieve consensus in the nurse's role. However, Scholefield et al

(1997) cite Gillick v. West Norfolk and Wisbech AHA, 1986, which described the significance of the nurse being able to review if the patient is competent of comprehending the information supplied about the treatment therefore it is important that the nurse is able to assist in this aspect of informed consent.